Influenza
and
Adult Immunization Guide

PharMerica®

2024 - 2025
Updated November 2024
(Post October 23, 2024 Meeting by the ACIP)

CONTENTS

GENERAL

ESSENTIAL RESOURCES

SEASONAL INFLUENZA

PNEUMOCOCCAL DISEASE

CONTENTS

SHINGLES (HERPES ZOSTER)

RESPIRATORY SYNCYTIAL VIRUS (RSV)

COVID-19

APPENDIX

GENERAL

Purpose & Scope

This guide is designed to consolidate key vaccine information into a single resource for long-term care (LTC) providers. Herein, you will find information on select vaccines considered of great consequent to the LTC industry, especially those with regulatory requirements. This guide is for general informational purposes only and is not intended to comment on all potential vaccines for which an individual is eligible. Essential documents to support LTC staff in providing vaccinations are included, such as **Vaccine Information Statements (VIS), Consent Forms** and **Declination Forms**, and **Recommended Vaccine Schedules.**

As vaccine information, like all medical content, is subject to change, links to primary resources are provided throughout the guide. Users are encouraged to access these source materials between annual publications of this guide, to ensure practices align with current recommendations and regulations.

Prior to administering any vaccine or pharmaceutical product, an individual patient's condition should be discussed with the respective medical provider(s) directly involved in their care. Refer to products' package inserts 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 Advisory Committee on Immunization Practices **(ACIP)**, the Department of the U.S. Health and Human Service Department **(HHS)**, the Immunization Action Coalition, and the Centers for Medicare and Medicaid Services **(CMS)** were instrumental in our information gathering.

The nature of drug information is that it is constantly evolving due to 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, current drug information (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 implied.

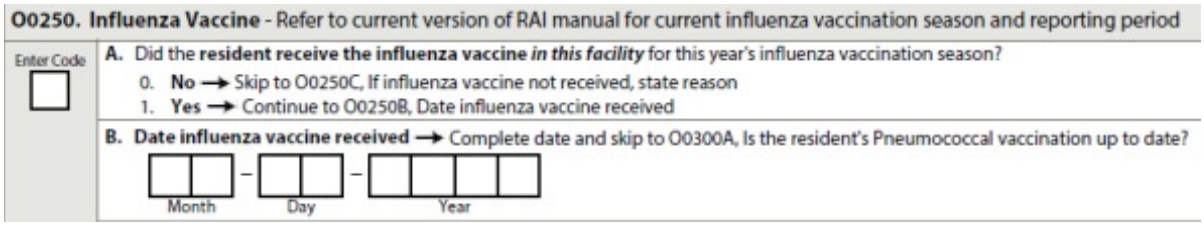
GENERAL

CMS Requires INFLUENZA, PNEUMOCOCCAL, and COVID-19 Vaccinations to be Offered in Nursing Homes

The Centers for Medicare and Medicaid Services (CMS) historically **requires** long-term care facilities (LTCFs) participating in the Medicare and Medicaid programs to ***offer*** all residents **influenza and pneumococcal** vaccines, and to ***document*** the results.

These requirements continue for this 2024-25 season. According to the mandates, each resident is to be vaccinated unless medically contraindicated, the resident or a legal representative refuses vaccination, or the vaccine is not available because of shortage (to be supported with documentation).

This information is to be reported in Section O of the CMS Minimum Data Set (MDS 3.0), which tracks nursing home health parameters. Specifically, MDS Items O0250 and O0300 of the RAI Version 3.0 Manual refer to the influenza and pneumococcal vaccines, respectively.



O0250. Influenza Vaccine - Refer to current version of RAI manual for current influenza vaccination season and reporting period

Enter Code ☐

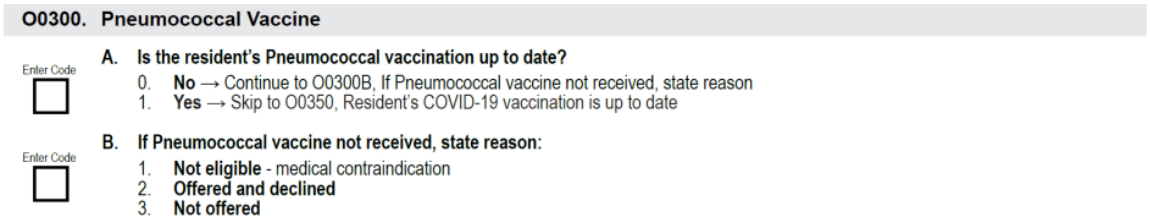
A. Did the **resident receive the influenza vaccine *in this facility*** for this year's influenza vaccination season?

0. **No** → Skip to O0250C, If influenza vaccine not received, state reason
1. **Yes** → Continue to O0250B, Date influenza vaccine received

B. Date influenza vaccine received → Complete date and skip to O0300A, Is the resident's Pneumococcal vaccination up to date?

☐☐ – ☐☐ – ☐☐☐☐
Month Day Year

O0300: Pneumococcal Vaccine



O0300. Pneumococcal Vaccine

Enter Code ☐

A. Is the resident's Pneumococcal vaccination up to date?

0. **No** → Continue to O0300B, If Pneumococcal vaccine not received, state reason
1. **Yes** → Skip to O0350, Resident's COVID-19 vaccination is up to date

Enter Code ☐

B. If Pneumococcal vaccine not received, state reason:

1. **Not eligible** - medical contraindication
2. **Offered and declined**
3. **Not offered**

LTCFs are required to offer the updated seasonal influenza vaccine to residents annually and to offer pneumococcal vaccines to residents in accordance with the contemporary Advisory Committee on Immunization Practices (ACIP) guidelines.

Noncompliance may be cited at F-tag 883, which stipulates that facilities develop policies and procedures to ensure residents are offered these vaccines and that documentation of the vaccine offer, administration, and any refusals must be maintained in the resident's medical record.

- The facility must inform residents or their representatives about the benefits and potential side effects of the vaccines and obtain consent prior to administration.

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.

CMS Issues Final Rule Lifting Mandatory COVID -19 Vaccination for Staff; Requirement to Educate on and Offer COVID-19 Vaccinations to Residents and Staff Continues

On May 11, 2021 CMS published an interim final rule with comment period (IFC), CMS-3414-IFC , titled "Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for LTC Facilities and ICFs-IID Residents, Clients, and Staff." This IFC called for the novel COVID-19 vaccines to be treated in similar manner to influenza vaccines, with LTCFs bearing additional responsibility for ensuring all residents and staff receive **appropriate education** and the **opportunity to be vaccinated**.

In response to the expiration of the Public Health Emergency (PHE) on 5-11-23, CMS published a 6-5-23 final rule on this subject.

Notably, CMS provides guidance around the temporary regulations imposed during the PHE, stating that the final rule:

- **Removes** expired COVID-19 testing requirements, which were first implemented on September 2, 2020.
- **Withdraws** the interim rule's **requirement that all healthcare workers regulated by CMS be fully vaccinated.**

GENERAL

- **Permanently adopts policies requiring covered healthcare providers to continue to educate and offer COVID-19 vaccinations to staff and residents, essentially aligning the CMS approach for COVID-19 with that for other infectious diseases, specifically influenza.**

Coding for resident COVID-19 vaccine status will be officially incorporated into the MDS 3.0 Version 1.19.1, Effective 10/1/2024.

O0350: Resident's COVID-19 vaccination is up to date

O0350. Resident's COVID-19 vaccination is up to date

Enter Code ☐

0. **No**, resident is not up to date
1. **Yes**, resident is up to date

Source: https://www.cms.gov/files/document/draftmds-30-rai-manual-v1191october2024.pdf (page 519)

Noncompliance related to the permanent requirements fo**r educating on** and **offering COVID-19 vaccination** will be cited at **F-tag 887.** Note, this tag does not appear in the current SOM Appendix PP. The tag is only viewable in the LTCSP software. Questions can be addressed to the CMS Nursing Home Survey team via email at NHSurveyDevelopment@cms.hhs.gov.

GENERAL

Medicare Coverage of Vaccinations

	Vaccine Preventable Disease	Examples of Products Covered
Part B	Influenza	Standard, Recombinant, High-Dose, Adjuvanted
	Pneumococcal	Vaxneuvance, Prevnar 20, Pneumovax 23, CAPVAXIVE
	Hepatitis B[1]	Energix-B, Recombivax HB, Heplisav-B, Recombivax, PreHevbrio
	COVID-19[2]	Comirnaty (Pfizer), Spikevax (Moderna), Novavax (and other COVID-19 vaccines under EUA/BLA-approval)
	[1] Patients at Medium to High Risk for infection as designated by Medicare [2] Medicare Part B covers COVID-19 vaccines/boosters, whether you have Original Medicare or a Medicare Advantage Plan.	

Part D[3]	Hep A / Hep B	Twinrix
	Herpes Zoster	Shingrix
	Human Papillomavirus	Gardasil
	Diphtheria/Tetanus/Acellular Pertussis	Adacel, Boostrix, Daptacel
	Meningococcal	Menactra, Menveo
	Measles, Mumps, Rubella	MMR II, Priorix
	Respiratory Syncytial Virus	Arexvy, Abrysvo, mRESVIA
	Others	All commercially available vaccines (not otherwise covered by Part B) when they are reasonable and necessary to prevent illness
	[3] As of January 2023, all Medicare-covered vaccines should be free to beneficiaries (No cost-sharing through copayment, coinsurance, or deductible for covered vaccines)	

Part B with Clinical Review[4]	Anthrax	BioThrax
	Diptheria/Tetanus	DT, Td, TDVAX
	Hep A	Havrix, VAQTA
	Rabies	Imovax, RabAvert
	Tetanus Toxoid	Tetanus Toxoid
	[4] Vaccines directly related to the treatment of an injury or a direct exposure to a disease or condition, such as rabies and tetanus	

GENERAL

What's New in Vaccines?

Adapted from the Creighton University Center for Drug Information & Evidence-Based Practice Drug Information Consultation Service

Introduction

Vaccines remain an important tool for training the body to resist infection. The World Health Organization (WHO) estimated in 2019 that vaccinations prevent 2-3 million deaths each year and that an additional 1.5 million deaths could be prevented with expanded vaccine coverage worldwide.[1] Currently, vaccines can be used preventatively against more than 20 life-threatening diseases.[2] Innovation in the field of immunization is crucial to slowing the spread of illness and reducing mortality associated with vaccine-preventable diseases.

Respiratory Syncytial Virus

Respiratory syncytial virus (RSV) is a virus that typically causes mild, self-limiting upper respiratory symptoms; however, some patient populations are at risk for more severe presentation. Older adults and children under the age of 1 year can develop pneumonia or other respiratory complications that could potentially lead to hospitalization. The virus spreads through droplet contact, often due to sneezing, coughing, or touching contaminated surfaces. Precautions to avoid such contact are especially important during the peak season for viral transmission, occurring between during the fall and winter in the United States.[3] Table 1 on the next page provides a comparison of the products currently on the market for RSV vaccination.

Clinical Data Review

Wilson and colleagues at Moderna are evaluating the safety and efficacy of their new mRNA-based RSV vaccine (mRNA-1345, or "mResvia") in adults ≥ 60 years of age. This ongoing, randomized, double-blind, placebo-controlled trial enlisted 35,541 patients to either receive the new vaccine (n=17,793) or placebo (n=12,748). Primary efficacy endpoints included prevention of LRTD with two signs or symptoms, as well as with three signs or symptoms. A key secondary efficacy endpoint was prevention of RSV-associated acute respiratory disease. Follow-up occurred when approximately half of the anticipated cases of LRTD had occurred, and median time to follow-up was 112 days. Overall, researchers found that the efficacy of mResvia for prevention of RSV-associated LRTD was 83.7% (95.88% CI: 66.0, 92.2) with at least two signs or symptoms and 82.4% (96.36% CI: 34.8, 95.3) with at least three signs or symptoms. Efficacy for the secondary endpoint of RSV-associated acute respiratory disease was found to be 68.4% (95% CI 50.9, 79.7). Most adverse events were mild to moderate and self-limiting. In the treatment group, 58.7% of patients developed local adverse reactions, compared with 16.2% in the placebo group. Systemic reactions occurred in 47.7% of patients treated with mResvia versus 32.9% of those who received placebo.[7]

Continued on next page

GENERAL

Table 1. Comparison of RSV Vaccines[4-6]

	Arexvy	Abrysvo	mResvia
Product	Respiratory Syncytial Virus Vaccine, Adjuvated Suspension for IM Injection	Respiratory Syncytial Virus Vaccine, Solution for IM Injection	Respiratory Syncytial Virus Vaccine, Suspension for IM Injection
Manufacturer	GlaxoSmithKline	Pfizer, Inc.	ModernaTX, Inc.
Pharmacologic category	Inactivated (Viral); Vaccine, Recombinant		mRNA Vaccine
Indication	Prevention of LRTD caused by RSV in people 60 years of age and older. Prevention of LRTD caused by RSV in people 50-59 years of age at increased risk of RSV (note: use in this age range is not currently recommended by the CDC).	Prevention of LRTD caused by RSV in people 60 years of age and older. Immunization of pregnant individuals at 32 through 36 weeks gestational age for prevention of LRTD in infants from birth to 6 months of age. Prevention of LRTD caused by RSV in people 18-59 years of age at increased risk of RSV (note: use in this age range is not currently recommended by the CDC).	Prevention of LRTD caused by RSV in people 60 years of age and older.
Dosage	0.5 mL IM as a single dose		
Preparation for administration	Prior to use, powder (lyophilized antigen vial) must be reconstituted with the liquid (adjuvant vial).	Reconstitute with provided syringe of sterile water diluent component. Act-O-Vial®: Required liquid for reconstitution is housed within the upper chamber of the Act-O-Vial®. Firmly press on the activator cap to release the reconstitution liquid into the lower chamber and gently swirl the vial to mix.	Thaw pre-filled syringes to room temperature [15 to 25°C (59 to 77°F)] before administering.
Storage requirements after preparation	Administer immediately or store in the refrigerator between 2°C (35.6°F) and 8°C (46.4°F) or at room temperature [up to 25°C (77°F)] for up to 4 hours. Protect vials from light. Do not freeze.	Administer immediately or store at room temperature [15 to 30°C (59 to 86°F)] and use within 4 hours. Do not store in refrigerated conditions. Do not freeze.	Administer immediately or store at 8 to 25°C (46 to 77°F) for up to 24 hours after removal from refrigerated conditions. Do not refreeze or return to refrigerator. Do not shake.
Adverse reactions	Most commonly reported (≥ 10%) were injection site pain, fatigue, myalgia, headache, and arthralgia	Most commonly reported (≥ 10%) were fatigue, headache, injection site pain, and muscle pain (patients ≥ 60 years), and nausea (pregnant individuals)	Most commonly reported (≥ 10%) were injection site pain, fatigue, headache, myalgia, arthralgia, axillary swelling or tenderness, and chills
Availability	FDA approved May 2023; available now	FDA approved May 2023; available now	FDA approved May 2024; available now

IM: intramuscular, LRTD: lower respiratory tract disease, FDA: Food and Drug Administration

Recommendations

The most notable change from the previous year is the addition of Moderna's new mRNA vaccine to prevent RSV in patients ≥ 60 years: mResvia. A useful attribute of this vaccine is the fact that it is available in pre-filled syringes and does not require reconstitution like the other two formulations on the market.[6] Furthermore, Pfizer's vaccine Abrysvo has received two additional indications: (1) use in pregnant individuals between 32 and 36 week's gestation for the prevention of RSV in the infant, and (2) use in individuals 18-59 years of age at increased risk of LRTD caused by RSV. As seen in Table 1, Abrysvo is currently the only RSV vaccine with FDA approval for use in these populations..[5] Following approval in pregnant individuals, in September 2023 the Center for Disease Control (CDC) Advisory Committee on Immunization Practices

GENERAL

(ACIP) officially recommended that pregnant patients in this population should receive one dose of the RSV vaccine using seasonal administration in September through January.[8] Recent changes to RSV immunization guidelines provided by ACIP could impact who receives RSV vaccination. In late June 2024, ACIP amended their recommendations for vaccination to state that adults ≥ 75 years of age should receive this immunization, and that adults 60-74 years of age should receive an RSV vaccine if they are at increased risk for severe RSV disease. Previously, the language approved by ACIP was that adults ≥ 60 years of age should receive an RSV vaccination following shared decision-making. Both the former and current guidelines recommend receiving only a single lifetime dose of RSV vaccine.[9] Box 1 below lists factors that place a patient at increased risk for severe RSV disease for the purpose of determining vaccine eligibility in patients 60-74 years of age.

Box 1. Risk factors for severe RSV disease[10]

Risk Factor
• Chronic lung disease (chronic obstructive pulmonary disease, asthma, etc.)
• Cardiovascular disease [congestive heart failure, coronary artery disease, etc.(excluding isolated hypertension)]
• Moderate or severe immune compromise
• Diabetes mellitus with end organ damage
• Severe obesity (body mass index ≥ 40 kg/m2)
• Neurologic or neuromuscular conditions
• Advanced chronic kidney disease
• Liver disorders
• Hematologic disorders
• Residence at a long-term care facility
• Frailty

Note: List is not all-inclusive. Shared decision making should be used to determine if a patient has any additional factors that may put them at risk for severe respiratory infection.

Pneumococcal Disease

Streptococcus pneumoniae is a gram-positive bacterium found in the respiratory tract of 5-90% of healthy individuals. There are over 100 known serotypes of this organism, but not all cause the clinical presentation associated with pneumococcal disease. Up to 5-10% of adults without children and 20-60% of school-aged children may be carriers without actually contracting the disease. Transmission, as with RSV, occurs through contact with respiratory droplets. Symptoms are often upper respiratory in nature and can include sinusitis and otitis media, but if left untreated, the disease could progress to pneumonia, bacteremia, or meningitis. Vaccination is necessary for preventing these escalations.[1]

Most recently, there were three pneumococcal vaccines available on the market, one polysaccharide vaccine (PPSV23) and two conjugate vaccines (PCV15 and PCV20).[12] However, in June of 2024 the FDA approved a new 21-valent conjugate vaccine from Merck, called Capvaxive.[13] Shortly after, on June 27, 2024, ACIP voted to officially add Capvaxive to their recommendations for the treatment of pneumococcal disease.[14]

At the conclusion of the October 2024 meeting, ACIP voted in favor to change the age-related eligibility criteria for routine pneumococcal vaccination from 65 to 50 years of age. The change in the vaccination age cut off is a part of ACIP's goal of increasing availability of the vaccine to populations most at risk for severe pneumococcal disease.

Clinical Data Review

Several phase 3 trials have been conducted or are ongoing to evaluate the safety and efficacy of Capvaxive (termed V116) in different populations. Platt and colleagues at Merck conducted a randomized, double-blind, active comparator-controlled, phase 3 trial to evaluate the safety and efficacy of Capvaxive in adults ≥ 18 years of age who were naïve to pneumococcal vaccination. Patients were split into two cohorts; adults in cohort 1 were ≥ 50 years of age and randomized 1:1 to receive either Capvaxive or PCV20 (n=2,362), while adults in cohort 2 were 18-49 years and randomized 2:1 to receive either Capvaxive or PCV20 (n=301). Randomization in cohort 1 was further stratified by age. Key primary outcomes were non-inferiority of Capvaxive to PCV20 in cohort 1 for serotypes covered by both vaccines, superiority of Capvaxive to PCV20 in cohort 1 for its unique serotypes, and non-inferiority of Capvaxive to PCV20 in cohort 2, compared with cohort 1. Non-inferiority was determined based on serotype-specific opsonophagocytic activity (OPA) geometric mean titers (GMT) ratios for serotypes common to both vaccines. Superiority was determined by a four-fold or greater rise in OPA response at day 30. Researchers evaluated safety based on proportions of adverse effects. Capvaxive met non-inferiority criteria for all serotypes covered by both Capvaxive and PCV20 ($p<0.0001$ for all), and it also met superiority for 10 of the 11 serotypes specific to Capvaxive ($p<0.0001$).

GENERAL

The most common adverse effects were injection site pain, fatigue, and headache. Proportions of these events were similar across groups, with the exception that injection site pain was 12.2% higher in the PCV20 group versus the Capvaxive group in cohort 1 (53.6% and 41.4%, respectively). There were no vaccine-related serious adverse events in any group.[15]

Recommendations

During the June 27th ACIP meeting, the CDC approved use of the new PCV21 vaccine in select adults at risk of pneumoccal disease, that also meet specific eligibility criteria. The October 23rd, 2024 ACIP meeting included changes to these eligibility criteria to now recommend routine pneumococcal vaccination in individuals 50 years of age and older. The CDC's website has since been updated to reflect these additons and a summary of the recommendations has been provided below in Table 2.

Table 2. CDC guidelines for pneumococcal vaccination[14,16,17]

Vaccination	PCV15 or PCV20	PPSV23	PCV21 (Capvaxive)
Patient Population	• Children ≤ 5 years • Age 5-49 years with risk conditions* and no previous PCV • Age ≥ 50 years and no previous PCV • PCV20 only: patients who previously received PCV13 and have not yet received all recommended PPSV23 doses	• Ages 2-18 years with risk conditions* who received PCV15 • Age ≥ 19 who received PCV15 • Previously received PCV13 • Patients who previously received PCV13 and have not yet received all recommended PPSV23 doses	• Ages 19-49 years with risk conditions* and no previous PCV • Age ≥ 50 years and no previous PCV • Age ≥ 19 years who previously received PCV13 and have not yet received all recommended PPSV23 doses

*Risk factors include: alcoholism, chronic heart/liver/lung disease, chronic renal failure, cigarette smoking, cochlear implant, congenital or acquired asplenia, cerebrospinal fluid leak, diabetes mellitus, generalized malignancy, human immunodeficiency virus (HIV), Hodgkin disease, immunodeficiency/immunosuppression, leukemia, lymphoma, multiple myeloma, nephrotic syn-drome, solid organ transplant, sickle cell disease, and other hemoglobinopathies.

Capvaxive is administered as a single 0.5mL intramuscular injection via prefilled syringe. As such, there are no requirements for preparation or reconstitution aside from the need to attach a needle to the Luer Lock syringe tip. It should be stored in the refrigerator between 2 and 8°C (36 to 46°F) until use and protected from light. Do not freeze Capvaxive.[13]

COVID-19

COVID-19 guidance is currently undergoing revision as, at the time of this guide's publication, the FDA is actively approving and authorizing for emergency use multiple 2024-25 COVID-19 vaccine options and the CDC is releasing corresponding recommendations.

Consult the COVID-19 section of this Guide for resources and, for curent COVID-19 vaccine guidance and schedules, see the CDC's webpage on Interim Clinical Considerations for Use of COVID-19 Vaccines in the US here: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Influenza

Influenza (flu) is a contagious virus that causes acute respiratory infection of the nose, throat, and lungs. Most individuals experience mild symptoms and will recover quickly without medical intervention; however, influenza can cause severe illness resulting in hospitalization or death, especially among the very young, the elderly, and those with serious health conditions.[24]

Recommendations

On June 27, 2024, ACIP released the CDC's updated recommendations for flu vaccination this 2024-2025 season. They reaffirmed their previous recommendation that everyone ≥ 6 months of age should receive a single dose of the updated vaccine unless contraindicated. They acknowledge that the best time to receive the vaccine would be during September and October, and they do not recommend flu vaccination in late July or August unless it would be impossible for an individual to receive the vaccine later.[23] Formulations this year are trivalent, and according to the CDC, it is "preferred" that patients ≥ 65 years receive either the trivalent high-dose inactivated influenza vaccine, trivalent recombinant influenza vaccine, or trivalent adjuvanted inactivated influenza vaccine.[20] Vaccine formulations for the 2024-2025 season will be active against H1N1, H3N2, and a B/Victoria lineage virus. Notably, the influenza A virus H3N2 will be an updated version as compared to last year's formulation.[23]

Conclusion

Due to evolving diseases and medical advancements, vaccine schedules and recommendations are updated frequently to reflect the most recent and current information. This allows for effective and safe care to reach communities and individuals for protection and prevention from severe disease, hospitalization, or death.[25] It is recommended to routinely check ACIP for updated guidelines because changes can occur throughout the year. Healthcare providers are a valuable resource to patients regarding vaccine information and administration; leaving a lasting impact on the communities served.

References

1. World Health Organization. Ten Threats to Global Health in 2019. 2019. https://www.who.int/vietnam/news/feature-stories/detail/ten-threatsto-global-health-in-2019. Accessed 18 July 2024.
2. World Health Organization. Vaccines and Immunization. 2024. https://www.who.int/health-topics/vaccines-and-immunization#tab=tab_1. Accessed 18 July 2024.
3. U.S. Centers for Disease Control and Prevention (CDC). About RSV. https://www.cdc.gov/rsv/about/index.html. Last reviewed June 5, 2024. Accessed July 25, 2024.
4. Arexvy [package insert]. Durham, North Carolina. GlaxoSmithKline. Last reviewed May 2023.
5. Abrysvo [package insert]. New York, New York. Division of Pfizer Inc. Last reviewed August 2023.
6. mResvia [package insert]. Princeton, New Jersey. ModernaTX, Inc. Last reviewed May 2024.
7. Wilson E, Goswami J, Baqui AH, et al. Efficacy and Safety of an mRNA-Based RSV PreF Vaccine in Older Adults. N Engl J Med. 2023;389(24):2233-2244. doi:10.1056/NEJMoa2307079.
8. Fleming-Dutra KE. Use of the Pfizer respiratory syncytial virus vaccine during pregnancy for the prevention of respiratory syncytial virus–associated lower respiratory tract disease in infants: recommendations of the Advisory Committee on Immunization Practices—United States, 2023. Morbidity and mortality weekly report. 2023;72.
9. Advisory Committee on Immunization Practices (ACIP). Recommendations. U.S. Centers for Disease Control and Prevention (CDC). https://www.cdc.gov/vaccines/acip/recommendations.html. Last Reviewed June 28, 2024. Accessed July 25, 2024.
10. Melgar M, Britton A. Respiratory syncytial virus (RSV) in adults 60 and older. ACIP adult RSV work group clinical considerations. 2024. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/12-RSV-Adult-Melgar-508.pdf. Accessed July 25, 2024.
11. U.S. Centers for Disease Control and Prevention (CDC). Pneumococcal Disease. https://www.cdc.gov/pneumococcal/hcp/clinicaloverview/index.html. Last reviewed February 6, 2024. Accessed July 25, 2024.
12. Pneumococcal Vaccine, Polyvalent. Clinical Pharmacology powered by ClinicalKey. Philadelphia, Pennsylvania: Elsevier. 2024. https://www.clinicalkey.com/pharmacology/monograph/494?n=Pneumococcal%20Vaccine,%20Polyvalent. Accessed July 25, 2024.
13. Capvaxive [package insert]. Rahway, New Jersey. Merck & Co., Inc. Last Reviewed June 2024.
14. U.S. Centers for Disease Control and Prevention (CDC). Pneumococcal vaccination. Vaccines and preventable diseases. https://www.cdc.gov/vaccines/vpd/pneumo/index.html. Accessed July 25, 2024.
15. Platt HL, Bruno C, Buntinx E, et al. Safety, tolerability, and immunogenicity of an adult pneumococcal conjugate vaccine, V116 (STRIDE-3): a randomised, double-blind, active comparator controlled, international phase 3 trial. Lancet Infect Dis. Published online July 1, 2024.doi:10.1016/S1473-3099(24)00344-X.
16. Cunningham J. CDC's ACIP unanimously recommends Merck's CAPVAXIVE (pneumococcal 21-valent conjugate vaccine) for pneumococcal vaccination in appropriate adults. Merck. 2024. https://www.merck.com/news/cdcs-acip-unanimously-recommends-mercks-capvaxivepneumococcal-21-valent-conjugate-vaccine-for-pneumococcal-vaccination-in-appropriate-adults/. Accessed July 25, 2024.
17. U.S. Centers for Disease Control and Prevention (CDC). Pneumococcal vaccination. Recommended adult immunization schedule for ages 19 years or older. 2024. https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf. Accessed 26 July 2024.
18. U.S. Centers for Disease Control and Prevention (CDC). COVID-19. https://www.cdc.gov/covid/?CDC_AAref_Val=https://www.cdc.gov/coronavirus/2019-ncov/yourhealth/about-covid-19.html. Updated June 13, 2023. Accessed July 31, 2023.
19. Watson OJ, Barnsley, G, Toor J, et al. Global impact of the first year of COVID-19 vaccination: a mathematical modelling study. The Lancet Infectious Disease. 2022;22(9):1293-1302.
20. U.S. Centers for Disease Control and Prevention (CDC). Immunization schedules. https://www.cdc.gov/vaccines/schedules/index.html. Updated June 27, 2024. Accessed July 31, 2024.
21. Novavax COVID-19 Vaccine, Adjuvanted [package insert]. Gaithersburg, MD. Novavax, Inc. Last Reviewed July 2024.
22. Panagiotakopoulos L, Godfrey M, Moulia DL, et al. Use of an Additional Updated 2023–2024 COVID-19 Vaccine Dose for Adults Aged ≥65 Years:Recommendations of the Advisory Committee on Immunization Practices — United States, 2024. MMWR Morb Mortal Wkly Rep 2024;73:377–381. DOI: http://dx.doi.org/10.15585/mmwr.mm7316a4.
23. U.S. Centers for Disease Control and Prevention (CDC). CDC recommends updated 2024-2025 COVID-19 and flu vaccines for fall/winter virus season. CDC Newsroom. https://www.cdc.gov/media/releases/2024/s-t0627-vaccine-recommendations.html. Updated June 27, 2024. Accessed July 31, 2024.
24. Centers for Disease Control and Prevention. About Flu. https://www.cdc.gov/flu/about/index.html. Reviewed September 20, 2022. Accessed August 1, 2024.
25. Immunize.org. Adult Immunization: Importance of Staying Up to Date with Vaccines. http://www.immunize.org/catg.d/p4033.pdf. Updated January 15, 2024. Accessed August 1, 2024.
26. 26. U.S. Centers for Disease Control and Prevention (CDC). CDC Recommends Lowering the Age for Pneumococcal Vaccination from 65 to 50 Years Old. Released October 23, 2024. Accessed October 28, 2024. https://www.cdc.gov/media/releases/2024/s1023-pneumococcal-vaccination.html

Essential Resources

ESSENTIAL RESOURCES

Vaccine Information Statements (VISs)

This section contains all current **Vaccine Information Statements** for **Routine Vaccines**, per the CDC, as of this Guide's publication date.

The CDC maintains an active VIS website at https://www.cdc.gov/vaccines/hcp/vis/current-vis.html.

Here users can additionally access VISs for Non-Routine Vaccines (e.g., cholera, monkeypox, rabies, etc.) as well as any VIS that is updated between publications of this guide.

Users are responsible for ensuring they are using the most current version of any recently updated VIS. As a general rule, when changes to a VIS concern the safety of the vaccine (e.g., contraindications or precautions, or adverse events), it is essential that the new edition be used immediately upon publication.

Below are some common questions and answers regarding Vaccine Information Statements from the CDC:

Q: Why are the edition dates on some of the VISs so old? Are they obsolete? Why can't they be updated every year?

A: VISs are updated only when they need to be. For instance, a VIS would be updated if there were a change in ACIP recommendations that affects the vaccine's adverse event profile, indications, or contraindications. Knowing that VISs posted on CDC's VIS website are always current should help alleviate any concern. Annually changing the dates on VISs that haven't changed otherwise could be confusing too, because there could be multiple VISs in circulation that are identical but have different dates. Providers using paper VISs shouldn't be required to renew their stocks each year because the date changed.

Q: Some VISs contain recommendations that are at odds with the manufacturer's package insert. Why?

A: VISs are based on the ACIP's recommendations, which occasionally differ from those made by the manufacturer. These differences may involve adverse events. Package inserts generally tend to include all adverse events that were temporally associated with a vaccine during clinical trials, whereas ACIP tends to recognize only those believed to be causally linked to the vaccine.

Q: How early can VISs be provided to parents/legal representatives prior to vaccination?

A: The National Childhood Vaccine Injury Act requires that a current VIS be provided to parents/legal representatives prior to vaccination. Although the Act does not specify the amount of time allowed between VIS provision and vaccination, they must be provided as close to the time of vaccination as is programmatically feasible and reasonable, keeping in mind that VISs are designed to inform vaccine recipients (or their parents/legal representatives) about the risks and benefits of specific vaccines, as well as medical eligibility, prior to vaccine receipt.

Users may be also have need for Vaccine Information Statements in non-English languages.

Immunize.org (non-profit organization) maintains a library of VIS translations in multiple languages: https://www.immunize.org/translations/

VACCINE INFORMATION STATEMENT

COVID-19 Vaccine:

What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

COVID-19 vaccine can prevent **COVID-19** disease. Vaccination can help reduce the severity of COVID-19 disease if you get sick.

COVID-19 is caused by a coronavirus called SARS-CoV-2 that spreads easily from person to person. COVID-19 can cause mild to moderate illness lasting only a few days, or severe illness requiring hospitalization, intensive care, or a ventilator to help with breathing. COVID-19 can result in death.

If an infected person has symptoms, they may appear 2 to 14 days after exposure to the virus. Anyone can have mild to severe symptoms.

- Possible symptoms include fever or chills, cough, shortness of breath or difficulty breathing, fatigue (tiredness), muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, or diarrhea.
- More serious symptoms can include trouble breathing, persistent pain or pressure in the chest, new confusion, inability to wake or stay awake, or pale, gray, or blue-colored skin, lips, or nail beds, depending on skin tone.

Older adults and people with certain underlying medical conditions (like heart or lung disease or diabetes) are more likely to get very sick from COVID-19.

2. COVID-19 vaccine

Updated (2023–2024 Formula) COVID-19 vaccine is recommended for everyone 6 months of age and older.

COVID-19 vaccines for infants and children 6 months through 11 years of age are available under Emergency Use Authorization from the U. S. Food and Drug Administration (FDA). Please refer to the Fact Sheets for Recipients and Caregivers for more information.

For people 12 years of age and older, updated COVID-19 vaccines, manufactured by ModernaTX, Inc. or Pfizer, Inc., are approved by FDA.

- **Everyone 12 years and older** should get 1 dose of an FDA-approved, updated 2023–2024 COVID-19 vaccine. If you have received a COVID-19 vaccine recently, you should wait at least 8 weeks after your most recent dose to get the updated 2023–2024 COVID-19 vaccine.
- **Certain people who have medical conditions or are taking medications that affect the immune system** may get additional doses of COVID-19 vaccine. Your health care provider can advise you.

Some people 12 years of age and older might get a different COVID-19 vaccine called Novavax COVID-19 Vaccine, Adjuvanted (2023–2024 Formula) instead. This vaccine is available under Emergency Use Authorization from FDA. Please refer to the Fact Sheet for Recipients and Caregivers for more information.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of COVID-19 vaccine** or an ingredient in the COVID-19 vaccine, or has any **severe, life-threatening allergies**
- Has had **myocarditis** (inflammation of the heart muscle) or **pericarditis** (inflammation of the lining outside of the heart)
- Has had **multisystem inflammatory syndrome** (called MIS-C in children and MIS-A in adults)
- Has a **weakened immune system**

In some cases, your health care provider may decide to postpone COVID-19 vaccination until a future visit.

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

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover. People with current COVID-19 infection should wait to get vaccinated until they have recovered from their illness and discontinued isolation.

Pregnant people with COVID-19 are at increased risk for severe illness. COVID-19 vaccination is recommended for people who are pregnant, breastfeeding, or trying to get pregnant now, or who might become pregnant in the future.

COVID-19 vaccine may be given at the same time as other vaccines.

4. Risks of a vaccine reaction

- Pain, swelling, or redness where the shot is given, fever, tiredness (fatigue), headache, chills, muscle pain, joint pain, nausea, vomiting, and swollen lymph nodes can happen after COVID-19 vaccination.
- Myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart) have been seen rarely after COVID-19 vaccination. This risk has been observed most commonly in males 12 through 39 years of age. The chance of this occurring is low.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

Seek medical attention right away if the vaccinated person experiences chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heart after COVID-19 vaccination. These could be symptoms of myocarditis or pericarditis.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. Countermeasures Injury Compensation Program

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit the program's website at **www.hrsa.gov/cicp**, or call **1-855-266-2427**.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for COVID-19 Fact Sheets, package inserts, and additional information at **www.fda.gov/vaccines-blood-biologics/industry-biologics/coronavirus-covid-19-cber-regulated-biologics**.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's COVID-19 vaccines website at **www.cdc.gov/coronavirus**.

Dengue Vaccine:
What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Dengue vaccine can help protect against dengue in people who have had dengue in the past.

Dengue is caused by one of four viruses spread through the bite of an infected mosquito. A person can get infected by any of the four dengue viruses. Infection with one dengue virus does not protect against infection with the other three viruses. Each year, up to 400 million people are infected with dengue. Almost half of the world's population lives in areas with a risk of dengue.

Most people infected with dengue have no symptoms or experience mild disease.

Some people who get sick with dengue have sudden onset of fever with nausea, vomiting, a rash, and eye, muscle, joint, or bone aches and pains.

A smaller number of people with dengue will have severe disease. Severe dengue is a medical emergency, requiring immediate medical attention at a hospital. Hospitalization with dengue is most common in older children and adolescents. Warning signs of severe dengue begin 12 to 24 hours after fever goes away and include stomach pain and tenderness, vomiting, bleeding from the nose or gums, blood in vomit or stool, and extreme tiredness or restlessness.

Rarely, dengue can have serious effects on the liver, heart, central nervous system, kidneys, eyes, muscles, or bone marrow. Severe dengue can also lead to death.

2. Dengue vaccine

Dengue vaccine is recommended for **children 9 through 16 years** old who

- Have a history of dengue infection in the past confirmed by a laboratory test
- Live in an area where dengue is common, including the U.S. territories of Puerto Rico, American Samoa, and the U.S. Virgin Islands, and freely associated states including the Federated States of Micronesia, the Republic of Marshall Islands, and the Republic of Palau

Dengue vaccine is **NOT** recommended for travelers.

To receive the vaccine, your child must have had dengue in the past, confirmed by blood testing. The vaccine could increase the risk of severe dengue and hospitalization in children who have not had dengue before if they are infected with dengue after vaccination.

Children need 3 doses of the dengue vaccine. The second dose should be given 6 months after the first dose, the third dose 6 months after the second dose.

Dengue vaccine may be given at the same time as other vaccines.

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

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of dengue vaccine**, or has any **severe, life-threatening allergies**
- Has a **weakened immune system**

If the person getting the vaccine is pregnant or breastfeeding, they should discuss benefits and potential risks of dengue vaccination with their health care provider.

In some cases, your health care provider may decide to postpone dengue vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting dengue vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Soreness, redness, or swelling where the shot is given, tiredness or weakness, fever, headache, fatigue, or muscle pain can happen after dengue vaccination.

If a person who has never had dengue in the past gets dengue vaccine, they are at increased risk of severe disease if they become infected with dengue in the future.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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/dengue**.

DTaP (Diphtheria, Tetanus, Pertussis) Vaccine: *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

DTaP vaccine can prevent **diphtheria**, **tetanus**, and **pertussis**.

Diphtheria and pertussis spread from person to person. Tetanus enters the body through cuts or wounds.

- **DIPHTHERIA (D)** can lead to difficulty breathing, heart failure, paralysis, or death.
- **TETANUS (T)** causes painful stiffening of the muscles. Tetanus can lead to serious health problems, including being unable to open the mouth, having trouble swallowing and breathing, or death.
- **PERTUSSIS (aP)**, also known as "whooping cough," can cause uncontrollable, violent coughing that makes it hard to breathe, eat, or drink. Pertussis can be extremely serious especially in babies and young children, causing pneumonia, convulsions, brain damage, or death. In teens and adults, it can cause weight loss, loss of bladder control, passing out, and rib fractures from severe coughing.

2. DTaP vaccine

DTaP is only for children younger than 7 years old. Different vaccines against tetanus, diphtheria, and pertussis (Tdap and Td) are available for older children, adolescents, and adults.

It is recommended that children receive 5 doses of DTaP, usually at the following ages:

- 2 months
- 4 months
- 6 months
- 15–18 months
- 4–6 years

DTaP may be given as a stand-alone vaccine, or as part of a combination vaccine (a type of vaccine that combines more than one vaccine together into one shot).

DTaP may be given at the same time as other vaccines.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of any vaccine that protects against tetanus, diphtheria, or pertussis**, or has any **severe, life-threatening allergies**
- Has had **a coma, decreased level of consciousness, or prolonged seizures within 7 days after a previous dose of any pertussis vaccine (DTP or DTaP)**
- Has **seizures or another nervous system problem**
- Has ever had **Guillain-Barré Syndrome** (also called "GBS")
- Has had **severe pain or swelling after a previous dose of any vaccine that protects against tetanus or diphtheria**

In some cases, your child's health care provider may decide to postpone DTaP vaccination until a future visit.

Children with minor illnesses, such as a cold, may be vaccinated. Children who are moderately or severely ill should usually wait until they recover before getting DTaP vaccine.

Your child's health care provider can give you more information.

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

4. Risks of a vaccine reaction

- Soreness or swelling where the shot was given, fever, fussiness, feeling tired, loss of appetite, and vomiting sometimes happen after DTaP vaccination.
- More serious reactions, such as seizures, non-stop crying for 3 hours or more, or high fever (over 105°F) after DTaP vaccination happen much less often. Rarely, vaccination is followed by swelling of the entire arm or leg, especially in older children when they receive their fourth or fifth dose.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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**.

Influenza (Flu) Vaccine (Inactivated or Recombinant): *What you need to know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Influenza vaccine can prevent **influenza (flu)**.

Flu is a contagious disease that spreads around the United States every year, usually between October and May. Anyone can get the flu, but it is more dangerous for some people. Infants and young children, people 65 years and older, pregnant people, and people with certain health conditions or a weakened immune system are at greatest risk of flu complications.

Pneumonia, bronchitis, sinus infections, and ear infections are examples of flu-related complications. If you have a medical condition, such as heart disease, cancer, or diabetes, flu can make it worse.

Flu can cause fever and chills, sore throat, muscle aches, fatigue, cough, headache, and runny or stuffy nose. Some people may have vomiting and diarrhea, though this is more common in children than adults.

In an average year, **thousands of people in the United States die from flu**, and many more are hospitalized. Flu vaccine prevents millions of illnesses and flu-related visits to the doctor each year.

2. Influenza vaccines

CDC recommends everyone 6 months and older get vaccinated every flu season. **Children 6 months through 8 years of age** may need 2 doses during a single flu season. **Everyone else** needs only 1 dose each flu season.

It takes about 2 weeks for protection to develop after vaccination.

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against the influenza viruses believed to be likely to cause disease in the upcoming flu season.

Even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Influenza vaccine **does not cause flu**.

Influenza vaccine may be given at the same time as other vaccines.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of influenza vaccine**, or has any **severe, life-threatening allergies**
- Has ever had **Guillain-Barré Syndrome** (also called "GBS")

In some cases, your health care provider may decide to postpone influenza vaccination until a future visit.

Influenza vaccine can be administered at any time during pregnancy. People who are or will be pregnant during influenza season should receive inactivated influenza vaccine.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting influenza vaccine.

Your health care provider can give you more information.

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

4. Risks of a vaccine reaction

- Soreness, redness, and swelling where the shot is given, fever, muscle aches, and headache can happen after influenza vaccination.
- There may be a very small increased risk of Guillain-Barré Syndrome (GBS) after inactivated influenza vaccine (the flu shot).

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. Tell your health care provider if a child who is getting flu vaccine has ever had a seizure.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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**.

Influenza (Flu) Vaccine (Live, Intranasal): *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Influenza vaccine can prevent **influenza (flu)**.

Flu is a contagious disease that spreads around the United States every year, usually between October and May. Anyone can get the flu, but it is more dangerous for some people. Infants and young children, people 65 years of age and older, pregnant people, and people with certain health conditions or a weakened immune system are at greatest risk of flu complications.

Pneumonia, bronchitis, sinus infections, and ear infections are examples of flu-related complications. If you have a medical condition, such as heart disease, cancer, or diabetes, flu can make it worse.

Flu can cause fever and chills, sore throat, muscle aches, fatigue, cough, headache, and runny or stuffy nose. Some people may have vomiting and diarrhea, though this is more common in children than adults.

In an average year, **thousands of people in the United States die from flu**, and many more are hospitalized. Flu vaccine prevents millions of illnesses and flu-related visits to the doctor each year.

2. Live, attenuated influenza vaccine

CDC recommends everyone 6 months and older get vaccinated every flu season. **Children 6 months through 8 years of age** may need 2 doses during a single flu season. **Everyone else** needs only 1 dose each flu season.

Live, attenuated influenza vaccine (called "LAIV") is a nasal spray vaccine that may be given to non-pregnant people 2 **through 49 years of age**.

It takes about 2 weeks for protection to develop after vaccination.

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against the influenza viruses believed to be likely to cause disease in the upcoming flu season. Even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Influenza vaccine **does not cause flu**.

Influenza vaccine may be given at the same time as other vaccines.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Is **younger than 2 years or older than 49 years** of age
- Is **pregnant**. Live, attenuated influenza vaccine is not recommended for pregnant people
- Has had an **allergic reaction after a previous dose of influenza vaccine**, or has any **severe, life-threatening allergies**
- Is a **child or adolescent 2 through 17 years of age who is receiving aspirin or aspirin- or salicylate-containing products**
- Has a **weakened immune system**
- Is a **child 2 through 4 years old who has asthma or a history of wheezing** in the past 12 months
- Is **5 years or older and has asthma**
- Has **taken influenza antiviral medication** in the last 3 weeks
- **Cares for severely immunocompromised people** who require a protected environment
- Has other **underlying medical conditions** that can put people at higher risk of serious flu complications (such as **lung disease, heart disease, kidney disease**

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

like diabetes, kidney or liver disorders, neurologic or neuromuscular or metabolic disorders)
- Does **not have a spleen**, or has a **non-functioning spleen**
- Has a **cochlear implant**
- Has a **cerebrospinal fluid leak** (a leak of the fluid that surrounds the brain to the nose, throat, ear, or some other location in the head)
- Has had **Guillain-Barré Syndrome** within 6 weeks after a previous dose of influenza vaccine

In some cases, your health care provider may decide to postpone influenza vaccination until a future visit.

For some patients, a different type of influenza vaccine (inactivated or recombinant influenza vaccine) might be more appropriate than live, attenuated influenza vaccine.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting influenza vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Runny nose or nasal congestion, wheezing, and headache can happen after LAIV vaccination.
- Vomiting, muscle aches, fever, sore throat, and cough are other possible side effects.

If these problems occur, they usually begin soon after vaccination and are mild and short-lived.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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**.

Hepatitis A Vaccine:
What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Hepatitis A vaccine can prevent **hepatitis A**.

Hepatitis A is a serious liver disease. It is usually spread through close, personal contact with an infected person or when a person unknowingly ingests the virus from objects, food, or drinks that are contaminated by small amounts of stool (poop) from an infected person.

Most adults with hepatitis A have symptoms, including fatigue, low appetite, stomach pain, nausea, and jaundice (yellow skin or eyes, dark urine, light-colored bowel movements). Most children less than 6 years of age do not have symptoms.

A person infected with hepatitis A can transmit the disease to other people even if he or she does not have any symptoms of the disease.

Most people who get hepatitis A feel sick for several weeks, but they usually recover completely and do not have lasting liver damage. In rare cases, hepatitis A can cause liver failure and death; this is more common in people older than 50 years and in people with other liver diseases.

Hepatitis A vaccine has made this disease much less common in the United States. However, outbreaks of hepatitis A among unvaccinated people still happen.

2. Hepatitis A vaccine

Children need 2 doses of hepatitis A vaccine:
- First dose: 12 through 23 months of age
- Second dose: at least 6 months after the first dose

Infants 6 through 11 months old traveling outside the United States when protection against hepatitis A is recommended should receive 1 dose of hepatitis A vaccine. These children should still get 2 additional doses at the recommended ages for long-lasting protection.

Older children and adolescents 2 through 18 years of age who were not vaccinated previously should be vaccinated.

Adults who were not vaccinated previously and want to be protected against hepatitis A can also get the vaccine.

Hepatitis A vaccine is also recommended for the following people:
- International travelers
- Men who have sexual contact with other men
- People who use injection or non-injection drugs
- People who have occupational risk for infection
- People who anticipate close contact with an international adoptee
- People experiencing homelessness
- People with HIV
- People with chronic liver disease

In addition, a person who has not previously received hepatitis A vaccine and who has direct contact with someone with hepatitis A should get hepatitis A vaccine as soon as possible and within 2 weeks after exposure.

Hepatitis A vaccine may be given at the same time as other vaccines.

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

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of hepatitis A vaccine**, or has any **severe, life-threatening allergies**

In some cases, your health care provider may decide to postpone hepatitis A vaccination until a future visit.

Pregnant or breastfeeding people should be vaccinated if they are at risk for getting hepatitis A. Pregnancy or breastfeeding are not reasons to avoid hepatitis A vaccination.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting hepatitis A vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Soreness or redness where the shot is given, fever, headache, tiredness, or loss of appetite can happen after hepatitis A vaccination.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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**.

Hepatitis B Vaccine:
What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Hepatitis B vaccine can prevent **hepatitis B**. Hepatitis B is a liver disease that can cause mild illness lasting a few weeks, or it can lead to a serious, lifelong illness.

- **Acute hepatitis B** is a short-term illness that can lead to fever, fatigue, loss of appetite, nausea, vomiting, jaundice (yellow skin or eyes, dark urine, clay-colored bowel movements), and pain in the muscles, joints, and stomach.
- **Chronic hepatitis B** is a long-term illness that occurs when the hepatitis B virus remains in a person's body. Most people who go on to develop chronic hepatitis B do not have symptoms, but it is still very serious and can lead to liver damage (cirrhosis), liver cancer, and death. Chronically infected people can spread hepatitis B virus to others, even if they do not feel or look sick themselves.

Hepatitis B is spread when blood, semen, or other body fluid infected with the hepatitis B virus enters the body of a person who is not infected. People can become infected through:

- Birth (if a pregnant person has hepatitis B, their baby can become infected)
- Sharing items such as razors or toothbrushes with an infected person
- Contact with the blood or open sores of an infected person
- Sex with an infected partner
- Sharing needles, syringes, or other drug-injection equipment
- Exposure to blood from needlesticks or other sharp instruments

Most people who are vaccinated with hepatitis B vaccine are immune for life.

2. Hepatitis B vaccine

Hepatitis B vaccine is usually given as 2, 3, or 4 shots.

Infants should get their first dose of hepatitis B vaccine at birth and will usually complete the series at 6–18 months of age. **The birth dose of hepatitis B vaccine is an important part of preventing long-term illness in infants and the spread of hepatitis B in the United States.**

Anyone **59 years of age or younger** who has not yet gotten the vaccine should be vaccinated.

Hepatitis B vaccination is recommended for **adults 60 years or older** at increased risk of exposure to hepatitis B who were not vaccinated previously. **Adults 60 years or older** who are not at increased risk and were not vaccinated in the past may also be vaccinated.

Hepatitis B vaccine may be given as a stand-alone vaccine, or as part of a combination vaccine (a type of vaccine that combines more than one vaccine together into one shot).

Hepatitis B vaccine may be given at the same time as other vaccines.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of hepatitis B vaccine**, or has any **severe, life-threatening allergies**

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

In some cases, your health care provider may decide to postpone hepatitis B vaccination until a future visit.

Pregnant or breastfeeding people who were not vaccinated previously should be vaccinated. Pregnancy or breastfeeding are not reasons to avoid hepatitis B vaccination.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting hepatitis B vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Soreness where the shot is given, fever, headache, and fatigue (feeling tired) can happen after hepatitis B vaccination.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**
- 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**.

Haemophilus influenzae type b (Hib) Vaccine: *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Hib vaccine can prevent ***Haemophilus influenzae* type b (Hib) disease**.

Haemophilus influenzae type b can cause many different kinds of infections. These infections usually affect children under 5 years of age but can also affect adults with certain medical conditions. Hib bacteria can cause mild illness, such as ear infections or bronchitis, or they can cause severe illness, such as infections of the blood. Severe Hib infection, also called "invasive Hib disease," requires treatment in a hospital and can sometimes result in death.

Before Hib vaccine, Hib disease was the leading cause of bacterial meningitis among children under 5 years old in the United States. Meningitis is an infection of the lining of the brain and spinal cord. It can lead to brain damage and deafness.

Hib infection can also cause:
- Pneumonia
- Severe swelling in the throat, making it hard to breathe
- Infections of the blood, joints, bones, and covering of the heart
- Death

2. Hib vaccine

Hib vaccine is usually given in 3 or 4 doses (depending on brand).

Infants will usually get their first dose of Hib vaccine at 2 months of age and will usually complete the series at 12–15 months of age.

Children between 12 months and 5 years of age who have not previously been completely vaccinated against Hib may need 1 or more doses of Hib vaccine.

Children over 5 years old and adults usually do not receive Hib vaccine, but it might be recommended for older children or adults whose spleen is damaged or has been removed, including people with sickle cell disease, before surgery to remove the spleen, or following a bone marrow transplant. Hib vaccine may also be recommended for people 5 through 18 years old with HIV.

Hib vaccine may be given as a stand-alone vaccine, or as part of a combination vaccine (a type of vaccine that combines more than one vaccine together into one shot).

Hib vaccine may be given at the same time as other vaccines.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:
- Has had an **allergic reaction after a previous dose of Hib vaccine**, or has any **severe, life-threatening allergies**

In some cases, your health care provider may decide to postpone Hib vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting Hib vaccine.

Your health care provider can give you more information.

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

4. Risks of a vaccine reaction

- Redness, warmth, and swelling where the shot is given and fever can happen after Hib vaccination.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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**.

HPV (Human Papillomavirus) Vaccine: *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

HPV (human papillomavirus) vaccine can prevent infection with some types of human papillomavirus.

HPV infections can cause certain types of cancers, including:

- cervical, vaginal, and vulvar cancers in women
- penile cancer in men
- anal cancers in both men and women
- cancers of tonsils, base of tongue, and back of throat (oropharyngeal cancer) in both men and women

HPV infections can also cause anogenital warts.

HPV vaccine can prevent over 90% of cancers caused by HPV.

HPV is spread through intimate skin-to-skin or sexual contact. HPV infections are so common that nearly all people will get at least one type of HPV at some time in their lives. Most HPV infections go away on their own within 2 years. But sometimes HPV infections will last longer and can cause cancers later in life.

2. HPV vaccine

HPV vaccine is routinely recommended for adolescents at 11 or 12 years of age to ensure they are protected before they are exposed to the virus. HPV vaccine may be given beginning at age 9 years and vaccination is recommended for everyone through 26 years of age.

HPV vaccine may be given to adults 27 through 45 years of age, based on discussions between the patient and health care provider.

Most children who get the first dose before 15 years of age need 2 doses of HPV vaccine. People who get the first dose at or after 15 years of age and younger people with certain immunocompromising conditions need 3 doses. Your health care provider can give you more information.

HPV vaccine may be given at the same time as other vaccines.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of HPV vaccine**, or has any **severe, life-threatening allergies**
- Is **pregnant**—HPV vaccine is not recommended until after pregnancy

In some cases, your health care provider may decide to postpone HPV vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting HPV vaccine.

Your health care provider can give you more information.

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

4. Risks of a vaccine reaction

- Soreness, redness, or swelling where the shot is given can happen after HPV vaccination.
- Fever or headache can happen after HPV vaccination.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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

Polio Vaccine:
What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Polio vaccine can prevent **polio**.

Polio (or poliomyelitis) is a disabling and life-threatening disease caused by poliovirus, which can infect a person's spinal cord, leading to paralysis.

Most people infected with poliovirus have no symptoms, and many recover without complications. Some people will experience sore throat, fever, tiredness, nausea, headache, or stomach pain.

A smaller group of people will develop more serious symptoms that affect the brain and spinal cord:
- Paresthesia (feeling of pins and needles in the legs),
- Meningitis (infection of the covering of the spinal cord and/or brain), or
- Paralysis (can't move parts of the body) or weakness in the arms, legs, or both.

Paralysis is the most severe symptom associated with polio because it can lead to permanent disability and death.

Improvements in limb paralysis can occur, but in some people new muscle pain and weakness may develop 15 to 40 years later. This is called "post-polio syndrome."

Polio has been eliminated from the United States, but it still occurs in other parts of the world. The best way to protect yourself and keep the United States polio-free is to maintain high immunity (protection) in the population against polio through vaccination.

2. Polio vaccine

Children should usually get 4 doses of polio vaccine at ages 2 months, 4 months, 6–18 months, and 4–6 years.

Most **adults** do not need polio vaccine because they were already vaccinated against polio as children. Some adults are at higher risk and should consider polio vaccination, including:
- People traveling to certain parts of the world
- Laboratory workers who might handle poliovirus
- Health care workers treating patients who could have polio
- Unvaccinated people whose children will be receiving oral poliovirus vaccine (for example, international adoptees or refugees)

Polio vaccine may be given as a stand-alone vaccine, or as part of a combination vaccine (a type of vaccine that combines more than one vaccine together into one shot).

Polio vaccine may be given at the same time as other vaccines.

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

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of polio vaccine**, or has any **severe, life-threatening allergies**

In some cases, your health care provider may decide to postpone polio vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting polio vaccine.

Not much is known about the risks of this vaccine for pregnant or breastfeeding people. However, polio vaccine can be given if a pregnant person is at increased risk for infection and requires immediate protection.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- A sore spot with redness, swelling, or pain where the shot is given can happen after polio vaccination.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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 Vaccine:
What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

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

Meningococcal disease can cause meningitis (infection of the lining of the brain and spinal cord) and infections of the blood. 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, loss of limbs, nervous system problems, or severe scars from skin grafts.

Meningococcal disease is rare and has declined in the United States since the 1990s. However, it is a severe disease with a significant risk of death or lasting disabilities in people who get it.

Anyone can get meningococcal disease. 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*, the bacteria that cause meningococcal disease
- People at risk because of an outbreak in their community

2. Meningococcal ACWY vaccine

Adolescents need 2 doses of a meningococcal ACWY vaccine:

- First dose: 11 or 12 year of age
- Second (booster) dose: 16 years of age

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

- People at risk because of a serogroup A, C, W, or Y meningococcal disease outbreak
- People with HIV
- Anyone whose spleen is damaged or has been removed, including people with sickle cell disease
- Anyone with a rare immune system condition called "complement component deficiency"
- Anyone taking a type of drug called a "complement inhibitor," such as eculizumab (also called "Soliris"®) or ravulizumab (also called "Ultomiris"®)
- 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 residence halls who have not been completely vaccinated with meningococcal ACWY vaccine
- U.S. military recruits

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

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of meningococcal ACWY vaccine**, or has any **severe, life-threatening allergies**

In some cases, your health care provider may decide to postpone meningococcal ACWY vaccination until a future visit.

There is limited information on the risks of this vaccine for pregnant or breastfeeding people, but no safety concerns have been identified. A pregnant or breastfeeding person should be vaccinated if indicated.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting meningococcal ACWY vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Redness or soreness where the shot is given can happen after meningococcal ACWY vaccination.
- A small percentage of people who receive meningococcal ACWY vaccine experience muscle pain, headache, or tiredness.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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**.

Meningococcal B Vaccine:

What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

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

Meningococcal disease can cause meningitis (infection of the lining of the brain and spinal cord) and infections of the blood. 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, loss of limbs, nervous system problems, or severe scars from skin grafts.

Meningococcal disease is rare and has declined in the United States since the 1990s. However, it is a severe disease with a significant risk of death or lasting disabilities in people who get it.

Anyone can get meningococcal disease. 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*, the bacteria that cause meningococcal disease
- People at risk because of an outbreak in their community

2. Meningococcal B vaccine

For best protection, more than 1 dose of a meningococcal B vaccine is needed. There are two meningococcal B vaccines available. The same vaccine must be used for all doses.

Meningococcal B vaccines are recommended for people 10 years or older who are at increased risk for serogroup B meningococcal disease, including:

- People at risk because of a serogroup B meningococcal disease outbreak
- Anyone whose spleen is damaged or has been removed, including people with sickle cell disease
- Anyone with a rare immune system condition called "complement component deficiency"
- Anyone taking a type of drug called a "complement inhibitor," such as eculizumab (also called "Soliris"®) or ravulizumab (also called "Ultomiris"®)
- 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, based on discussions between the patient and health care provider. The preferred age for vaccination is 16 through 18 years.

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

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of meningococcal B vaccine**, or has any **severe, life-threatening allergies**
- Is **pregnant or breastfeeding**

In some cases, your health care provider may decide to postpone meningococcal B vaccination until a future visit.

Meningococcal B vaccination should be postponed for pregnant people unless the person is at increased risk and, after consultation with their health care provider, the benefits of vaccination are considered to outweigh the potential risks.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting meningococcal B vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Soreness, redness, or swelling where the shot is given, tiredness, headache, muscle or joint pain, fever, or nausea can happen after meningococcal B vaccination. Some of these reactions occur in more than half of the people who receive the vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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**.

MMR Vaccine (Measles, Mumps, and Rubella): *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

MMR vaccine can prevent **measles, mumps**, and **rubella**.

- **MEASLES (M)** causes fever, cough, runny nose, and red, watery eyes, commonly followed by a rash that covers the whole body. It can lead to seizures (often associated with fever), ear infections, diarrhea, and pneumonia. Rarely, measles can cause brain damage or death.
- **MUMPS (M)** causes fever, headache, muscle aches, tiredness, loss of appetite, and swollen and tender salivary glands under the ears. It can lead to deafness, swelling of the brain and/or spinal cord covering, painful swelling of the testicles or ovaries, and, very rarely, death.
- **RUBELLA (R)** causes fever, sore throat, rash, headache, and eye irritation. It can cause arthritis in up to half of teenage and adult women. If a person gets rubella while they are pregnant, they could have a miscarriage or the baby could be born with serious birth defects.

Most people who are vaccinated with MMR will be protected for life. Vaccines and high rates of vaccination have made these diseases much less common in the United States.

2. MMR vaccine

Children need 2 doses of MMR vaccine, usually:

- First dose at age 12 through 15 months
- Second dose at age 4 through 6 years

Infants who will be traveling outside the United States when they are between 6 and 11 months of age should get a dose of MMR vaccine before travel. These children should still get 2 additional doses at the recommended ages for long-lasting protection.

Older children, adolescents, and **adults** also need 1 or 2 doses of MMR vaccine if they are not already immune to measles, mumps, and rubella. Your health care provider can help you determine how many doses you need.

A third dose of MMR might be recommended for certain people in mumps outbreak situations.

MMR vaccine may be given at the same time as other vaccines. Children 12 months through 12 years of age might receive MMR vaccine together with varicella vaccine in a single shot, known as MMRV. Your health care provider can give you more information.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of MMR or MMRV vaccine**, or has any **severe, life-threatening allergies**
- Is **pregnant** or thinks they might be pregnant—pregnant people should not get MMR vaccine
- Has a **weakened immune system**, or has a **parent, brother, or sister with a history of hereditary or congenital immune system problems**
- Has ever had a **condition that makes him or her bruise or bleed easily**
- Has recently **had a blood transfusion or received other blood products**
- Has **tuberculosis**
- Has **gotten any other vaccines in the past 4 weeks**

In some cases, your health care provider may decide to postpone MMR vaccination until a future visit.

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

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting MMR vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Sore arm from the injection or redness where the shot is given, fever, and a mild rash can happen after MMR vaccination.
- Swelling of the glands in the cheeks or neck or temporary pain and stiffness in the joints (mostly in teenage or adult women) sometimes occur after MMR vaccination.
- More serious reactions happen rarely. These can include seizures (often associated with fever) or temporary low platelet count that can cause unusual bleeding or bruising.
- In people with serious immune system problems, this vaccine may cause an infection that may be life-threatening. People with serious immune system problems should not get MMR vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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**.

MMRV Vaccine (Measles, Mumps, Rubella, and Varicella): *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

MMRV vaccine can prevent **measles, mumps, rubella**, and **varicella**.

- **MEASLES (M)** causes fever, cough, runny nose, and red, watery eyes, commonly followed by a rash that covers the whole body. It can lead to seizures (often associated with fever), ear infections, diarrhea, and pneumonia. Rarely, measles can cause brain damage or death.
- **MUMPS (M)** causes fever, headache, muscle aches, tiredness, loss of appetite, and swollen and tender salivary glands under the ears. It can lead to deafness, swelling of the brain and/or spinal cord covering, painful swelling of the testicles or ovaries, and, very rarely, death.
- **RUBELLA (R)** causes fever, sore throat, rash, headache, and eye irritation. It can cause arthritis in up to half of teenage and adult women. If a person gets rubella while they are pregnant, they could have a miscarriage or the baby could be born with serious birth defects.
- **VARICELLA (V)**, also called "chickenpox," causes an itchy rash, in addition to fever, tiredness, loss of appetite, and headache. It can lead to skin infections, pneumonia, inflammation of the blood vessels, swelling of the brain and/or spinal cord covering, and infection of the blood, bones, or joints. Some people who get chickenpox get a painful rash called "shingles" (also known as herpes zoster) years later.

Most people who are vaccinated with MMRV will be protected for life. Vaccines and high rates of vaccination have made these diseases much less common in the United States.

2. MMRV vaccine

MMRV vaccine may be given to **children 12 months through 12 years of age**, usually:

- First dose at age 12 through 15 months
- Second dose at age 4 through 6 years

MMRV vaccine may be given at the same time as other vaccines. Instead of MMRV, some children might receive separate shots for MMR (measles, mumps, and rubella) and varicella. Your health care provider can give you more information.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of MMRV, MMR, or varicella vaccine**, or has any **severe, life-threatening allergies**
- Is **pregnant** or thinks they might be pregnant—pregnant people should not get MMRV vaccine
- Has a **weakened immune system**, or has a **parent, brother, or sister with a history of hereditary or congenital immune system problems**
- Has ever had a **condition that makes him or her bruise or bleed easily**
- Has a **history of seizures**, or has a **parent, brother, or sister with a history of seizures**
- Is **taking or plans to take salicylates** (such as aspirin)
- Has recently **had a blood transfusion or received other blood products**
- Has **tuberculosis**
- Has **gotten any other vaccines in the past 4 weeks**

In some cases, your health care provider may decide to postpone MMRV vaccination until a future visit or may recommend that the child receive separate MMR and varicella vaccines instead of MMRV.

People with minor illnesses, such as a cold, may be vaccinated. Children who are moderately or severely ill should usually wait until they recover before getting MMRV vaccine.

Your health care provider can give you more information.

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

4. Risks of a vaccine reaction

- Sore arm from the injection, redness where the shot is given, fever, and a mild rash can happen after MMRV vaccination.
- Swelling of the glands in the cheeks or neck or temporary pain and stiffness in the joints sometimes occur after MMRV vaccination.
- Seizures, often associated with fever, can happen after MMRV vaccine. The risk of seizures is higher after MMRV than after separate MMR and varicella vaccines when given as the first dose of the two-dose series in younger children. Your health care provider can advise you about the appropriate vaccines for your child.
- More serious reactions happen rarely, including temporary low platelet count, which can cause unusual bleeding or bruising.
- In people with serious immune system problems, this vaccine may cause an infection that may be life-threatening. People with serious immune system problems should not get MMRV vaccine.

If a person develops a rash after MMRV vaccination, it could be related to either the measles or the varicella component of the vaccine. The varicella vaccine virus could be spread to an unprotected person. Anyone who gets a rash should stay away from infants and people with a weakened immune system until the rash goes away. Talk with your health care provider to learn more.

Some people who are vaccinated against chickenpox get shingles (herpes zoster) years later. This is much less common after vaccination than after chickenpox disease.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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**.

Your Child's First Vaccines:
What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

The vaccines included on this statement are likely to be given at the same time during infancy and early childhood. There are separate *Vaccine Information Statements* for other vaccines that are also routinely recommended for young children (measles, mumps, rubella, varicella, rotavirus, influenza, and hepatitis A)

Your child is getting these vaccines today:

☐ DTaP ☐ Hib ☐ Hepatitis B ☐ PCV ☐ Polio

(Provider: Check appropriate boxes.)

1. Why get vaccinated?

Vaccines can prevent disease. Childhood vaccination is essential because it helps provide immunity before children are exposed to potentially life-threatening diseases.

Diphtheria, tetanus, and pertussis (DTaP)

- **Diphtheria (D)** can lead to difficulty breathing, heart failure, paralysis, or death.
- **Tetanus (T)** causes painful stiffening of the muscles. Tetanus can lead to serious health problems, including being unable to open the mouth, having trouble swallowing and breathing, or death.
- **Pertussis (aP)**, also known as "whooping cough," can cause uncontrollable, violent coughing that makes it hard to breathe, eat, or drink. Pertussis can be extremely serious, especially in babies and young children, causing pneumonia, convulsions, brain damage, or death.

Hib (*Haemophilus influenzae* type b) disease

***Haemophilus influenzae* type b** can cause many different kinds of infections. Hib bacteria can cause mild illness, such as ear infections or bronchitis, or they can cause severe illness, such as infections of the blood. Hib infection can also cause pneumonia; severe swelling in the throat, making it hard to breathe; and infections of the blood, joints, bones, and covering of the heart. Severe Hib infection, also called "invasive Hib disease," requires treatment in a hospital and can sometimes result in death.

Hepatitis B

Hepatitis B is a liver disease that can cause mild illness lasting a few weeks, or it can lead to a serious, lifelong illness. Acute hepatitis B infection is a short-term illness that can lead to fever, fatigue, loss of appetite, nausea, vomiting, jaundice (yellow skin or eyes, dark urine, clay-colored bowel movements), and pain in the muscles, joints, and stomach. Chronic hepatitis B infection is a long-term illness that occurs when the hepatitis B virus remains in a person's body. Most people who go on to develop chronic hepatitis B do not have symptoms, but it is still very serious and can lead to liver damage (cirrhosis), liver cancer, and death.

Pneumococcal disease (PCV)

Pneumococcal disease refers to any illness caused by pneumococcal bacteria. These bacteria can cause many types of illnesses, including pneumonia, which is an infection of the lungs. Besides pneumonia, pneumococcal bacteria can also cause ear infections, sinus infections, meningitis (infection of the tissue covering the brain and spinal cord), and bacteremia (infection of the blood). Most pneumococcal infections are mild. However, some can result in long-term problems, such as brain damage or hearing loss. Meningitis, bacteremia, and pneumonia caused by pneumococcal disease can be fatal.

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

Polio

Polio (or poliomyelitis) is a disabling and life-threatening disease caused by poliovirus, which can infect a person's spinal cord, leading to paralysis. Most people infected with poliovirus have no symptoms, and many recover without complications. Some people infected with poliovirus will experience sore throat, fever, tiredness, nausea, headache, or stomach pain, and most people with these symptoms will also recover without complications. A smaller group of people will develop more serious symptoms: paresthesia (feeling of pins and needles in the legs), meningitis (infection of the covering of the spinal cord and/or brain), or paralysis (can't move parts of the body) or weakness in the arms, legs, or both. Paralysis can lead to permanent disability and death.

2. DTaP, Hib, hepatitis B, pneumococcal conjugate, and polio vaccines

Infants and children usually need:

- 5 doses of **diphtheria, tetanus, and acellular pertussis vaccine (DTaP)**
- 3 or 4 doses of **Hib vaccine**
- 3 doses of **hepatitis B vaccine**
- 4 doses of **pneumococcal conjugate vaccine (PCV)**
- 4 doses of **polio vaccine**

Some children might need fewer or more than the usual number of doses of some vaccines to have the best protection because of their age at vaccination or other circumstances.

Older children, adolescents, and adults with certain health conditions or other risk factors or who did not get vaccinated earlier might also be recommended to receive 1 or more doses of some of these vaccines.

These vaccines are given as either stand-alone vaccines or as part of a combination vaccine (a type of vaccine that combines more than one vaccine together into one shot).

3. Talk with your health care provider

Tell your vaccination provider if the child getting the vaccine:

For all of these vaccines:

- Has had an **allergic reaction after a previous dose of the vaccine**, or has any **severe, life-threatening allergies**

For DTaP:

- Has had an **allergic reaction after a previous dose of any vaccine that protects against diphtheria, tetanus, or pertussis**
- Has had a **coma, decreased level of consciousness, or prolonged seizures within 7 days after a previous dose of any pertussis vaccine (DTP or DTaP)**
- Has **seizures or another nervous system problem**
- Has ever had **Guillain-Barré syndrome** (also called "GBS")
- Has had **severe pain or swelling after a previous dose of any vaccine that protects against diphtheria or tetanus**

For PCV:

- Has had an **allergic reaction after a previous dose of any type of pneumococcal conjugate vaccine (PCV13, PCV15, PCV20, or an earlier pneumococcal conjugate vaccine known as PCV7), or to any vaccine containing diphtheria toxoid** (for example, DTaP)

In some cases, your child's health care provider may decide to postpone vaccination until a future visit.

Children with minor illnesses, such as a cold, may be vaccinated. Children who are moderately or severely ill should usually wait until they recover before being vaccinated.

Your child's health care provider can give you more information.

4. Risks of a vaccine reaction

For all of these vaccines:

- Soreness, redness, swelling, warmth, pain, or tenderness where the shot is given can happen after vaccination.

For DTaP vaccine, Hib vaccine, hepatitis B vaccine, and PCV:

- Fever can happen after vaccination.

For DTaP vaccine:

- Fussiness, feeling tired, loss of appetite, and vomiting sometimes happen after DTaP vaccination.
- More serious reactions, such as seizures, non-stop crying for 3 hours or more, or high fever (over 105°F) after DTaP vaccination happen much less often. Rarely, vaccination is followed by swelling of the entire arm or leg, especially in older children when they receive their fourth or fifth dose.

For PCV:

- Loss of appetite, fussiness (irritability), feeling tired, headache, and chills can happen after PCV vaccination.
- Young children may be at increased risk for seizures caused by fever after a pneumococcal conjugate vaccine if it is administered at the same time as inactivated influenza vaccine. Ask your health care provider for more information.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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**.

Pneumococcal Conjugate Vaccine: *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Pneumococcal conjugate vaccine can prevent **pneumococcal disease**.

Pneumococcal disease refers to any illness caused by pneumococcal bacteria. These bacteria can cause many types of illnesses, including pneumonia, which is an infection of the lungs. Pneumococcal bacteria are one of the most common causes of pneumonia.

Besides pneumonia, pneumococcal bacteria can also cause:

- Ear infections
- Sinus infections
- Meningitis (infection of the tissue covering the brain and spinal cord)
- Bacteremia (infection of the blood)

Anyone can get pneumococcal disease, but children under 2 years old, people with certain medical conditions or other risk factors, and adults 65 years or older are at the highest risk.

Most pneumococcal infections are mild. However, some can result in long-term problems, such as brain damage or hearing loss. Meningitis, bacteremia, and pneumonia caused by pneumococcal disease can be fatal.

2. Pneumococcal conjugate vaccine

Pneumococcal conjugate vaccine helps protect against bacteria that cause pneumococcal disease. There are three pneumococcal conjugate vaccines (PCV13, PCV15, and PCV20). The different vaccines are recommended for different people based on age and medical status. Your health care provider can help you determine which type of pneumococcal conjugate vaccine, and how many doses, you should receive.

Infants and young children usually need 4 doses of pneumococcal conjugate vaccine. These doses are recommended at 2, 4, 6, and 12–15 months of age.

Older children and adolescents might need pneumococcal conjugate vaccine depending on their age and medical conditions or other risk factors if they did not receive the recommended doses as infants or young children.

Adults 19 through 64 years old with certain medical conditions or other risk factors who have not already received pneumococcal conjugate vaccine should receive pneumococcal conjugate vaccine.

Adults 65 years or older who have not previously received pneumococcal conjugate vaccine should receive pneumococcal conjugate vaccine.

Some people with certain medical conditions are also recommended to receive pneumococcal polysaccharide vaccine (a different type of pneumococcal vaccine, known as PPSV23). Some adults who have previously received a pneumococcal conjugate vaccine may be recommended to receive another pneumococcal conjugate vaccine.

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

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of any type of pneumococcal conjugate vaccine (PCV13, PCV15, PCV20, or an earlier pneumococcal conjugate vaccine known as PCV7), or to any vaccine containing diphtheria toxoid** (for example, DTaP), or has any **severe, life-threatening allergies**

In some cases, your health care provider may decide to postpone pneumococcal conjugate vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Redness, swelling, pain, or tenderness where the shot is given, and fever, loss of appetite, fussiness (irritability), feeling tired, headache, muscle aches, joint pain, and chills can happen after pneumococcal conjugate vaccination.

Young children may be at increased risk for seizures caused by fever after a pneumococcal conjugate vaccine if it is administered at the same time as inactivated influenza vaccine. Ask your health care provider for more information.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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**.

Pneumococcal Polysaccharide Vaccine (PPSV23): *What You Need to Know*

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Pneumococcal polysaccharide vaccine (PPSV23) can prevent **pneumococcal disease**.

Pneumococcal disease refers to any illness caused by pneumococcal bacteria. These bacteria can cause many types of illnesses, including pneumonia, which is an infection of the lungs. Pneumococcal bacteria are one of the most common causes of pneumonia.

Besides pneumonia, pneumococcal bacteria can also cause:
- Ear infections
- Sinus infections
- Meningitis (infection of the tissue covering the brain and spinal cord)
- Bacteremia (bloodstream infection)

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

Most pneumococcal infections are mild. However, some can result in long-term problems, such as brain damage or hearing loss. Meningitis, bacteremia, and pneumonia caused by pneumococcal disease can be fatal.

2 PPSV23

PPSV23 protects against 23 types of bacteria that cause pneumococcal disease.

PPSV23 is recommended for:
- All **adults 65 years or older**,
- Anyone **2 years or older with certain medical conditions that can lead to an increased risk for pneumococcal disease**.

Most people need only one dose of PPSV23. A second dose of PPSV23, and another type of pneumococcal vaccine called PCV13, are recommended for certain high-risk groups. Your health care provider can give you more information.

People 65 years or older should get a dose of PPSV23 even if they have already gotten one or more doses of the vaccine before they turned 65.

3 Talk with your health care provider

Tell your vaccine provider if the person getting the vaccine:
- Has had an **allergic reaction after a previous dose of PPSV23**, or has any **severe, life-threatening allergies**.

In some cases, your health care provider may decide to postpone PPSV23 vaccination to a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting PPSV23.

Your health care provider can give you more information.

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

4 Risks of a vaccine reaction

- Redness or pain where the shot is given, feeling tired, fever, or muscle aches can happen after PPSV23.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5 What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff do not give medical advice.*

6 How can I learn more?

- Ask your health care provider.
- 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**

Rotavirus Vaccine:
What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Rotavirus vaccine can prevent **rotavirus disease**.

Rotavirus commonly causes severe, watery diarrhea, mostly in babies and young children. Vomiting and fever are also common in babies with rotavirus. Children may become dehydrated and need to be hospitalized and can even die.

2. Rotavirus vaccine

Rotavirus vaccine is administered by putting drops in the child's mouth. Babies should get 2 or 3 doses of rotavirus vaccine, depending on the brand of vaccine used.

- The first dose must be administered before 15 weeks of age.
- The last dose must be administered by 8 months of age.

Almost all babies who get rotavirus vaccine will be protected from severe rotavirus diarrhea.

Another virus called "porcine circovirus" can be found in one brand of rotavirus vaccine (Rotarix). This virus does not infect people, and there is no known safety risk.

Rotavirus vaccine may be given at the same time as other vaccines.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of rotavirus vaccine**, or has any **severe, life-threatening allergies**
- Has a **weakened immune system**
- Has **severe combined immunodeficiency** (SCID)
- Has had a type of bowel blockage called "**intussusception**"

In some cases, your child's health care provider may decide to postpone rotavirus vaccination until a future visit.

Infants with minor illnesses, such as a cold, may be vaccinated. Infants who are moderately or severely ill should usually wait until they recover before getting rotavirus vaccine.

Your child's health care provider can give you more information.

4. Risks of a vaccine reaction

- Irritability or mild, temporary diarrhea or vomiting can happen after rotavirus vaccine.

Intussusception is a type of bowel blockage that is treated in a hospital and could require surgery. It happens naturally in some infants every year in the United States, and usually there is no known reason for it. There is also a small risk of intussusception from rotavirus vaccination, usually within a week after the first or second vaccine dose. This additional risk is estimated to range from about 1 in 20,000 U.S. infants to 1 in 100,000 U.S. infants who get rotavirus vaccine. Your health care provider can give you more information.

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

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

5. What if there is a serious problem?

For intussusception, look for signs of stomach pain along with severe crying. Early on, these episodes could last just a few minutes and come and go several times in an hour. Babies might pull their legs up to their chest. Your baby might also vomit several times or have blood in the stool, or could appear weak or very irritable. These signs would usually happen during the first week after the first or second dose of rotavirus vaccine, but look for them any time after vaccination. If you think your baby has intussusception, contact a health care provider right away. If you can't reach your health care provider, take your baby to a hospital. Tell them when your baby got rotavirus vaccine.

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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**.

RSV (Respiratory Syncytial Virus) Vaccine: *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

RSV vaccine can prevent lower respiratory tract disease caused by **respiratory syncytial virus (RSV)**. RSV is a common respiratory virus that usually causes mild, cold-like symptoms.

RSV can cause illness in people of all ages but may be especially serious for infants and older adults.

- Infants up to 12 months of age (especially those 6 months and younger) and children who were born prematurely, or who have chronic lung or heart disease or a weakened immune system, are at increased risk of severe RSV disease.
- Adults at highest risk for severe RSV disease include older adults, adults with chronic medical conditions such as heart or lung disease, weakened immune systems, or certain other underlying medical conditions, or who live in nursing homes or long-term care facilities.

RSV spreads through direct contact with the virus, such as droplets from another person's cough or sneeze contacting your eyes, nose, or mouth. It can also be spread by touching a surface that has the virus on it, like a doorknob, and then touching your face before washing your hands.

Symptoms of RSV infection may include runny nose, decrease in appetite, coughing, sneezing, fever, or wheezing. In very young infants, symptoms of RSV may also include irritability (fussiness), decreased activity, or apnea (pauses in breathing for more than 10 seconds).

Most people recover in a week or two, but RSV can be serious, resulting in shortness of breath and low oxygen levels. RSV can cause bronchiolitis (inflammation of the small airways in the lung) and pneumonia (infection of the lungs). RSV can sometimes lead to worsening of other medical conditions such as asthma, chronic obstructive pulmonary disease (a chronic disease of the lungs that makes it hard to breathe), or congestive heart failure (when the heart can't pump enough blood and oxygen throughout the body).

Older adults and infants who get very sick from RSV may need to be hospitalized. Some may even die.

2. RSV vaccine

CDC recommends **adults 60 years of age and older** have the option to receive a single dose of RSV vaccine, based on discussions between the patient and their health care provider.

There are two options for protection of infants against RSV: maternal vaccine for the pregnant person and preventive antibodies given to the baby. Only one of these options is needed for most babies to be protected. CDC recommends a single dose of RSV vaccine for **pregnant people from week 32 through week 36 of pregnancy** for the prevention of RSV disease in infants under 6 months of age. This vaccine is recommended to be given from September through January for most of the United States. However, in some locations (the territories, Hawaii, Alaska, and parts of Florida), the timing of vaccination may vary as RSV circulating in these locations differs from the timing of the RSV season in the rest of the U.S.

RSV vaccine may be given at the same time as other vaccines.

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

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of RSV vaccine**, or has any **severe, life-threatening allergies**

In some cases, your health care provider may decide to postpone RSV vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting RSV vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Pain, redness, and swelling where the shot is given, fatigue (feeling tired), fever, headache, nausea, diarrhea, and muscle or joint pain can happen after RSV vaccination.

Serious neurologic conditions, including Guillain-Barré syndrome (GBS), have been reported after RSV vaccination in clinical trials of older adults. It is unclear whether the vaccine caused these events.

Preterm birth and high blood pressure during pregnancy, including pre-eclampsia, have been reported among pregnant people who received RSV vaccine during clinical trials. It is unclear whether these events were caused by the vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. V*AERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**
- 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**.

Recombinant Zoster (Shingles) Vaccine: *What You Need to Know*

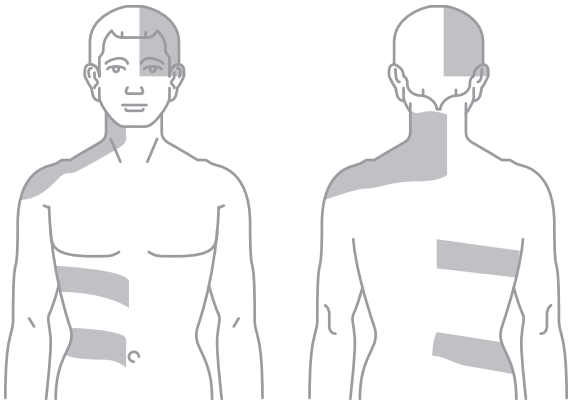
Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Recombinant zoster (shingles) vaccine can prevent **shingles**.

Shingles (also called herpes zoster, or just zoster) is a painful skin rash, usually with blisters. In addition to the rash, shingles can cause fever, headache, chills, or upset stomach. Rarely, shingles can lead to complications such as pneumonia, hearing problems, blindness, brain inflammation (encephalitis), or death.



The risk of shingles increases with age. The most common complication of shingles is long-term nerve pain called postherpetic neuralgia (PHN). PHN occurs in the areas where the shingles rash was and can last for months or years after the rash goes away. The pain from PHN can be severe and debilitating.

The risk of PHN increases with age. An older adult with shingles is more likely to develop PHN and have longer lasting and more severe pain than a younger person.

People with weakened immune systems also have a higher risk of getting shingles and complications from the disease.

Shingles is caused by varicella-zoster virus, the same virus that causes chickenpox. After you have chickenpox, the virus stays in your body and can cause shingles later in life. Shingles cannot be passed from one person to another, but the virus that causes shingles can spread and cause chickenpox in someone who has never had chickenpox or has never received chickenpox vaccine.

2. Recombinant shingles vaccine

Recombinant shingles vaccine provides strong protection against shingles. By preventing shingles, recombinant shingles vaccine also protects against PHN and other complications.

Recombinant shingles vaccine is recommended for:

- **Adults 50 years and older**
- **Adults 19 years and older who have a weakened immune system** because of disease or treatments

Shingles vaccine is given as a two-dose series. For most people, the second dose should be given 2 to 6 months after the first dose. Some people who have or will have a weakened immune system can get the second dose 1 to 2 months after the first dose. Ask your health care provider for guidance.

People who have had shingles in the past and people who have received varicella (chickenpox) vaccine are recommended to get recombinant shingles vaccine. The vaccine is also recommended for people who have already gotten another type of shingles vaccine, the live shingles vaccine. There is no live virus in recombinant shingles vaccine.

Shingles vaccine may be given at the same time as other vaccines.

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

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of recombinant shingles vaccine**, or has any **severe, life-threatening allergies**
- Is **currently experiencing an episode of shingles**
- Is **pregnant**

In some cases, your health care provider may decide to postpone shingles vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting recombinant shingles vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- A sore arm with mild or moderate pain is very common after recombinant shingles vaccine. Redness and swelling can also happen at the site of the injection.
- Tiredness, muscle pain, headache, shivering, fever, stomach pain, and nausea are common after recombinant shingles vaccine.

These side effects may temporarily prevent a vaccinated person from doing regular activities. Symptoms usually go away on their own in 2 to 3 days. You should still get the second dose of recombinant shingles vaccine even if you had one of these reactions after the first dose.

Guillain-Barré syndrome (GBS), a serious nervous system disorder, has been reported very rarely after recombinant zoster vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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**.

Td (Tetanus, Diphtheria) Vaccine:
What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Td vaccine can prevent **tetanus** and **diphtheria**.

Tetanus enters the body through cuts or wounds. Diphtheria spreads from person to person.

- **TETANUS (T)** causes painful stiffening of the muscles. Tetanus can lead to serious health problems, including being unable to open the mouth, having trouble swallowing and breathing, or death.
- **DIPHTHERIA (D)** can lead to difficulty breathing, heart failure, paralysis, or death.

2. Td vaccine

Td is only for children 7 years and older, adolescents, and adults.

Td is usually given as a **booster dose every 10 years**, or after 5 years in the case of a severe or dirty wound or burn.

Another vaccine, called "Tdap," may be used instead of Td. Tdap protects against pertussis, also known as "whooping cough," in addition to tetanus and diphtheria.

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

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of any vaccine that protects against tetanus or diphtheria**, or has any **severe, life-threatening allergies**
- Has ever had **Guillain-Barré Syndrome** (also called "GBS")
- Has had **severe pain or swelling after a previous dose of any vaccine that protects against tetanus or diphtheria**

In some cases, your health care provider may decide to postpone Td vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting Td vaccine.

Your health care provider can give you more information.

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

4. Risks of a vaccine reaction

- Pain, redness, or swelling where the shot was given, mild fever, headache, feeling tired, and nausea, vomiting, diarrhea, or stomachache sometimes happen after Td vaccination.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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**.

Tdap (Tetanus, Diphtheria, Pertussis) Vaccine: *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Tdap vaccine can prevent **tetanus, diphtheria**, and **pertussis**.

Diphtheria and pertussis spread from person to person. Tetanus enters the body through cuts or wounds.

- **TETANUS (T)** causes painful stiffening of the muscles. Tetanus can lead to serious health problems, including being unable to open the mouth, having trouble swallowing and breathing, or death.
- **DIPHTHERIA (D)** can lead to difficulty breathing, heart failure, paralysis, or death.
- **PERTUSSIS (aP),** also known as "whooping cough," can cause uncontrollable, violent coughing that makes it hard to breathe, eat, or drink. Pertussis can be extremely serious especially in babies and young children, causing pneumonia, convulsions, brain damage, or death. In teens and adults, it can cause weight loss, loss of bladder control, passing out, and rib fractures from severe coughing.

2. Tdap vaccine

Tdap is only for children 7 years and older, adolescents, and adults.

Adolescents should receive a single dose of Tdap, preferably at age 11 or 12 years.

Pregnant people should get a dose of Tdap during every pregnancy, preferably during the early part of the third trimester, to help protect the newborn from pertussis. Infants are most at risk for severe, life-threatening complications from pertussis.

Adults who have never received Tdap should get a dose of Tdap.

Also, **adults should receive a booster dose of either Tdap or Td** (a different vaccine that protects against tetanus and diphtheria but not pertussis) **every 10 years**, or after 5 years in the case of a severe or dirty wound or burn.

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

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of any vaccine that protects against tetanus, diphtheria, or pertussis**, or has any **severe, life-threatening allergies**
- Has had a **coma, decreased level of consciousness, or prolonged seizures within 7 days after a previous dose of any pertussis vaccine (DTP, DTaP, or Tdap)**
- Has **seizures or another nervous system problem**
- Has ever had **Guillain-Barré Syndrome** (also called "GBS")
- Has had **severe pain or swelling after a previous dose of any vaccine that protects against tetanus or diphtheria**

In some cases, your health care provider may decide to postpone Tdap vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting Tdap vaccine.

Your health care provider can give you more information.

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

4. Risks of a vaccine reaction

- Pain, redness, or swelling where the shot was given, mild fever, headache, feeling tired, and nausea, vomiting, diarrhea, or stomachache sometimes happen after Tdap vaccination.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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**.

Varicella (Chickenpox) Vaccine:
What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Varicella vaccine can prevent **varicella**.

Varicella, also called "chickenpox," causes an itchy rash that usually lasts about a week. It can also cause fever, tiredness, loss of appetite, and headache. It can lead to skin infections, pneumonia, inflammation of the blood vessels, swelling of the brain and/or spinal cord covering, and infections of the bloodstream, bone, or joints. Some people who get chickenpox get a painful rash called "shingles" (also known as herpes zoster) years later.

Chickenpox is usually mild, but it can be serious in infants under 12 months of age, adolescents, adults, pregnant people, and people with a weakened immune system. Some people get so sick that they need to be hospitalized. It doesn't happen often, but people can die from chickenpox.

Most people who are vaccinated with 2 doses of varicella vaccine will be protected for life.

2. Varicella vaccine

Children need 2 doses of varicella vaccine, usually:
- First dose: age 12 through 15 months
- Second dose: age 4 through 6 years

Older children, adolescents, and **adults** also need 2 doses of varicella vaccine if they are not already immune to chickenpox.

Varicella vaccine may be given at the same time as other vaccines. Also, a child between 12 months and 12 years of age might receive varicella vaccine together with MMR (measles, mumps, and rubella) vaccine in a single shot, known as MMRV. Your health care provider can give you more information.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:
- Has had an **allergic reaction after a previous dose of varicella vaccine**, or has any **severe, life-threatening allergies**
- Is **pregnant** or thinks they might be pregnant—pregnant people should not get varicella vaccine
- Has a **weakened immune system**, or has a **parent, brother, or sister with a history of hereditary or congenital immune system problems**
- **Is taking salicylates** (such as aspirin)
- Has recently **had a blood transfusion or received other blood products**
- Has **tuberculosis**
- Has **gotten any other vaccines in the past 4 weeks**

In some cases, your health care provider may decide to postpone varicella vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting varicella vaccine.

Your health care provider can give you more information.

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

4. Risks of a vaccine reaction

- Sore arm from the injection, redness or rash where the shot is given, or fever can happen after varicella vaccination.
- More serious reactions happen very rarely. These can include pneumonia, infection of the brain and/or spinal cord covering, or seizures that are often associated with fever.
- In people with serious immune system problems, this vaccine may cause an infection that may be life-threatening. People with serious immune system problems should not get varicella vaccine.

It is possible for a vaccinated person to develop a rash. If this happens, the varicella vaccine virus could be spread to an unprotected person. Anyone who gets a rash should stay away from infants and people with a weakened immune system until the rash goes away. Talk with your health care provider to learn more.

Some people who are vaccinated against chickenpox get shingles (herpes zoster) years later. This is much less common after vaccination than after chickenpox disease.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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 Consent Form

Resident: _____ Birth Date: _____

ID Number: _____ Nursing Care Center: _____

Living Unit: _____ Physician: _____

Resident/Caregiver Education Provided By: _____ ☐ Check here if reviewed with family remotely

If checked, second staff signature: _____

SPECIAL PRECAUTIONS:

- Consult with a prescriber for use in children under 3 years of age and pregnant people.
- Consult with a prescriber for use in individuals who are allergic to eggs, chicken feather, or chicken dander. Note: Beginning with the 2023-24 influenza season, ACIP voted that people with egg-allergy may receive any **flu** vaccine (egg-based or non-egg based) that is otherwise appropriate for their age and health status. Additional safety measures are no longer recommended beyond those recommended for receipt of any vaccine.
- Persons with fever should not receive this vaccine until no longer considered acutely ill.
- 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, thimerosal, or any vaccine component? _____*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) _____*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

For women of childbearing age: Is the person receiving the vaccine pregnant or considering becoming pregnant in the next month? _____YES _____NO

For COVID-19 vaccination: Have you had thrombocytopenia syndrome (TTS), myocarditis, or pericarditis after COVID-19 vaccination? _____YES _____NO

I have read the above information and VIS/EUA Factsheet for my requested vaccination and have had an opportunity to ask questions. I understand the benefits and risks of my requested vaccination(s) 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 Vaccine (standard, recombinant, high-dose, adjuvanted)

_____ PPSV23 (Pneumovax) _____ PCV15 (Vaxneuvance) _____ PCV20 (Prevnar20) _____ PCV21 (CAPVAXIVE)

_____ Shingles [Recombinant Zoster] Vaccine (Shingrix)

_____ Respiratory Syncytial Virus Vaccine (Arexvy, Abrysvo, mRESVIA)

_____ COVID-19 (Pfizer/COMIRNATY, Moderna/Spikevax, Novavax)

_____ Hepatitis B (Energix-B, Recombivax HB, Heplisav-B)

_____ Other

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: _____

_____Right Arm

_____Left Arm

____Other

Vaccine Name: _____

PharMerica®

ADULT VACCINATION DECLINATION FORM

I, _____ [Resident's Full Name], hereby acknowledge that the following denoted vaccines have been recommended to me by my _____ [corporation] healthcare provider and in accordance with the CDC Adult Immunization Schedule, and I have been offered the opportunity to ask questions and to receive education through the CDC's Vaccine Information Statements (VIS).

Vaccine (check all that apply)

- ☐ Influenza
- ☐ Pneumococcal (PCV15, PCV20, PPSV23, and PCV21)
- ☐ COVID-19
- ☐ Hepatitis A (HepA)
- ☐ Hepatitis B (HepB)
- ☐ Haemophilus influenzae type b (Hib)
- ☐ Measles, Mumps, Rubella (MMR)
- ☐ Meningococcal A,C,W,Y (MenACWY)
- ☐ Meningococcal B (MenB)
- ☐ Respiratory Syncytial Virus (RSV)
- ☐ Tetanus, Diphtheria, Pertussis (Tdap or Td)
- ☐ Varicella (VAR)
- ☐ Zoster recombinant (RZV)
- ☐ Other _____

I am choosing to decline the recommended and offered vaccination(s) noted above.

I understand that these vaccines are recommended to reduce the health risks associated with my contracting their targeted infectious diseases.

I understand that by declining the vaccination, I may be at risk of contracting otherwise preventable or mitigatable infectious diseases and experiencing associated health consequences.

I acknowledge that I have made this decision voluntarily and based on my own understanding of the risks and benefits associated with these vaccines.

I also understand that I can change my decision at any time and request to receive the vaccine in the future, subject to its availability and my healthcare provider's recommendations at that time.

By signing this document, I affirm that I am providing an informed declination of the noted vaccine(s) after receiving education and having my questions answered to my satisfaction.

Resident / Patient Signature: _____ -or- POA Signature: _____

Full Name (Printed): _____

Witness (Staff Member's Name): _____

Date: _____

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

Adverse events are possible reactions or problems that occur during or after vaccination. Items **2, 3, 4, 5, 6, 17, 18** and **21** are **ESSENTIAL** and should be completed. Patient identity is kept confidential. Instructions are provided on the last two pages.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE (Use **Continuation Page** if needed).

1. Patient name: (first) _____ (last) _____
Street address: _____
City: _____ State: _____ County: _____
ZIP code: _____ Phone: ( ) _____ Email: _____

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:

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

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: _____ State: _____ ZIP code: _____
Phone: ( ) _____ Email: _____

14. Best doctor/healthcare professional to contact about the adverse event: Name: _____ Phone: ( ) _____ Ext: _____

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name:
Fax: ( ) _____
Street address: ☐ Check if same as item 13.
City: _____
State: _____ ZIP code: _____
Phone: ( ) _____

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:
☐ Unknown

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

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). Use **Continuation Page** if needed.

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose no. in series
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.)
Use **Continuation Page** if needed.

19. Medical tests and laboratory results related to the adverse event(s): (include dates)
Use **Continuation Page** if needed.

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
☐ Emergency room or emergency department visit
☐ Hospitalization: Number of days (if known)
Hospital name:
City: State:
☐ 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

ADDITIONAL INFORMATION (Use **Continuation Page** if needed).

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	Dose no. in series
select			select	select	select
select			select	select	select

23. Has the patient ever had an adverse event following any previous vaccine?: (If yes, describe adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name).
☐ No ☐ Unknown ☐ Yes

24. Patient's race: (Check all that apply). ☐ 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). _____

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at vaccination: ☐ Active duty ☐ Reserve ☐ National Guard ☐ Beneficiary ☐ Other:

28. Vaccinated at Military/DoD site: ☐ Yes ☐ No

SAVE

17. Enter all vaccines given on the date listed in item 4 (continued):					Dose no. in series
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

22. Any other vaccines received within one month prior to the date listed in item 4 (continued):					Dose no. in series
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
select			select	select	select
select			select	select	select

Use the space below to provide any additional information (indicate Item number): RETURN TO PAGE 1

RETURN TO PAGE 1

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) 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).
- 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.

Medicare Billing Guidance for Respiratory Vaccines in LTC

#GET VACCINATED

FOR THE FOUR VACCINES (RSV, INFLUENZA, PNEUMOCOCCAL AND COVID), LONG TERM CARE (LTC) FACILITIES CAN BILL MEDICARE.

All Part B vaccines (e.g., Influenza, Pneumococcal and COVID) are subject to consolidated billing and must be submitted by the Skilled Nursing Facility (SNF) on either a separate inpatient or outpatient Part B claim. It is paid separate from any Part A bundled rate when it is for preventative and not therapeutic purposes.

Part D vaccines (which includes RSV) are covered only under Part D and are not covered by Part A or B. RSV vaccine is also not subject to consolidated billing. It can be billed by any outside pharmacy or other entity regardless of SNF Part A (if preventative) or long-stay status. Therapeutic use of a Part D vaccine (e.g., tetanus for a person exposed) during a Part A stay would be bundled into the Part A per-diem rate (Part A is primary payer) and could not be billed separately to Part D.

So, for the RSV Vaccine that is not covered by Part B benefits but is a covered Part D benefit:

- If administered for preventive purposes: Part D plan would pay any approved entity that administers the vaccine regardless of Part A status (Not subject to SNF consolidated billing).

The Medicare Claims Processing Manual Chapter 6, Section 20.4 Screening and Preventive Services (updated 11-04-2021) are copied on the subsequent pages. Key provisions are highlighted.

COVID-19 vaccine coverage under Part B is also addressed on CMS (Centers for Medicare &Medicaid Services) webpage: COVID-19 Vaccines & Monoclonal Antibodies - VACCINE PRICING and in a July 13, 2023, CMS Letter to Payors Regarding Coverage of COVID-19 Vaccines.

20.4 - Screening and Preventive Services

(Rev.4163, Issued: 11-02-18, Effective: 12-04-18, Implementation: 12-04-18)

The Part A SNF benefit is limited to services that are reasonable and necessary to "diagnose or treat" a condition that has already manifested itself. Accordingly, this benefit does not encompass screening services (which serve to check an at-risk individual for the possible presence of a specific latent condition, before it manifests any overt symptoms to diagnose or treat) or preventive services (which are aimed at warding off the occurrence of a particular condition altogether rather than diagnosing or treating it once it occurs). Coverage of screening and preventive services (e.g., screening mammography, pneumococcal pneumonia vaccine, influenza vaccine, hepatitis B vaccine) is a separate Part B inpatient benefit when rendered to beneficiaries in a covered Part A stay and is paid outside of the Part A payment rate. For this reason, screening and preventive services must not be included in the global Part A bill. However, screening and preventive services remain subject to consolidated billing and, thus, must be billed separately by the SNF under Part B.

Accordingly, even though the SNF itself must bill for these services, it submits a separate Part B inpatient bill for them rather than including them on its global Part A bill. Screening and preventive services must be billed with a 22X type of bill. Swing Bed providers must use TOB 12x for eligible beneficiaries in a Part A SNF level of care. **NOTE:** For beneficiaries residing in the Medicare non-certified area of the facility, these services should be billed on a 23x type of bill. In transmittals for A/B MAC (A) billing providing the annual update list of HCPCS codes affected by SNF consolidated billing, such services are referred to as "Major Category IV." See §10.1 above for the link to where transmittals providing current lists of HCPCS codes used for Major Category IV can be found.

There are certain limited circumstances in which a vaccine would no longer be considered preventive in nature, and this can affect how the vaccine is covered. For example, while a booster shot of tetanus vaccine would be considered preventive if administered routinely in accordance with a recommended schedule, it would not be considered preventive when administered in response to an actual exposure to the disease (such as an animal bite, or a scratch on a rusty nail).

In the latter situation, such a vaccine furnished to an SNF's Part A resident would be considered therapeutic rather than preventive in nature, as its use is reasonable and necessary for treating an existing condition.

In terms of billing for an SNF's Part A resident, a vaccine that is administered for therapeutic rather than preventive purposes would be included on the SNF's global Part A bill for the resident's covered stay. Alternatively, if a vaccine is preventive in nature and is one of the three types of vaccines (i.e., pneumococcal pneumonia, hepatitis B, or influenza virus) for which a Part B benefit category exists (see §50.4.4.2 of the Medicare Benefit Policy Manual, Chapter 15), then the SNF would submit a separate Part B bill for the vaccine. (Under section 1888(e)(9) of the Social Security Act (the Act) and the implementing regulations at 42 CFR 413.1(g)(2)(ii), payment for an SNF's Part B services is made in accordance with the applicable fee schedule for the type of service being billed (see the Medicare Claims Processing Manual, Chapter 7, §10.5).

However, when these three types of vaccines are furnished in the SNF setting, Part B makes payment in accordance with the applicable instructions contained in the Medicare Claims Processing Manual, Chapter 7, §80.1, and Chapter 18, §10.2.2.1.)

If the resident receives a type of vaccine that is preventive in nature but for which no Part B benefit category exists (e.g., diphtheria), then the vaccine would not be covered under either Parts A or B and, as a consequence, would become coverable under the Part D drug benefit. This is because priority of payment between the various parts of the Medicare law proceeds in alphabetical order: Part A is primary to Part B (see section 1833(d) of the Act), and both Parts A and B are primary to Part D (see section 1860D-2(e)(2)(B) of the Act).

Billing for Vaccines in Skilled Nursing Facilities: A Guide

February 2024

Coding

The Centers for Medicare and Medicaid Services and the American Medical Association (AMA) have established codes for billing vaccines.

There are two components to billing any vaccine administered: the vaccine product/ingredients and its administration.

For the most up-to-date information on specific codes, visit the following websites:

Roster Billing:

Roster billing with your MAC:
www.cms.gov/medicare/payment/covid-19/definitions

Medicare Claims Processing Manual, Chapter 6 with consolidated billing guidance:
www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c06.pdf

Medicare Claims Processing Manual, Chapter 18 with vaccine guidance:
www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c18pdf.pdf

Specific Codes

Updated COVID-19 CPT codes:
www.ama-assn.org/practice-management/cpt/covid-19-cpt-vaccine-and-immunization-codes

List of CPT/HCPCS codes:
www.cms.gov/medicare/regulations-guidance/physician-self-referral/list-cpt/hcpcs-codes

In skilled nursing facilities, a vaccine may be billed by the facility or the long-term care pharmacy, depending both on whether a resident is in their Part A stay as well as what vaccine is being administered.

Staff

The LTC pharmacy can procure and bill for staff vaccination but it is typically considered out of network and not covered, leaving the facility or individual staff member to cover the bill.

The facility can choose to eat the cost of the vaccine or send staff elsewhere (eg, retail pharmacy or provider office that is a part of the insured staff person's network)

For COVID-19, uninsured staff can go to CVS/Walgreens, state they are uninsured, and use the Bridge Access Program. For other pharmacies who have applied to be Bridge Access Providers with eTrueNorth, an individual has to go online and get a QR code to prove they are uninsured.

For more information, please contact
movingneedles@paltc.org

Moving Needles
A CDC FUNDED INITIATIVE

amda The Society For Post-Acute And Long-Term Care Medicine™

Residents

Influenza, pneumococcal, and COVID-19 vaccines

Influenza, pneumococcal, and COVID-19 vaccines are billed as part of **Medicare Part B**. Hepatitis B vaccine is covered under Part B only if an individual is considered to be at high risk – residents of long term care are considered high risk.

Part A Stay Resident

FACILITY	Vaccine product and administration fee must be billed by facility using roster billing on a Part B claim
PHARMACY	The LTC pharmacy is not allowed to bill directly for Part B vaccines for residents in their Part A stay

Non-Part A/Long-term Stay Resident

FACILITY	Facility can use roster billing for both the vaccine cost and the administration fee on a Part B claim
PHARMACY	Pharmacy can bill directly for both the vaccine cost and the administration fee

If the facility staff administered the vaccine, they can ask the pharmacy to bill the administration fee and provide it back to the facility. This should be written into contracts between facilities and pharmacies.

Hospice

Because vaccinations are not part of the Medicare hospice benefit, hospice claims *(type of bill 81X or 82X)* for vaccine services must be billed on a separate institutional claim and must only include charges for the vaccine and their administration.

COVID-19: For hospice patients under Part B only, include the GW modifier on COVID-19 vaccine administration claims if either of these apply:

1. The vaccine isn't related to the patient's terminal condition.

2. The attending physician administered the vaccine.

Tdap, shingles, and RSV vaccine

Tdap, shingles, and RSV are billed through **Medicare Part D**. Hepatitis B vaccine is covered under Part D if an individual is not at high risk.

Part A Stay Resident

PHARMACY	Pharmacies must provide and bill for the cost of the vaccine product and may bill for the administration fee

Non-Part A/Long-term Stay Resident

PHARMACY	Pharmacies must provide and bill for the cost of the vaccine product and may bill for the administration fee

If the facility staff administered the vaccine, they can ask the pharmacy to bill the administration fee and provide it back to the facility. This should be written into contracts between facilities and pharmacies.

Exceptions and special circumstances

When a vaccine such as Tdap (Part D) is administered therapeutically (i.e., post exposure) instead of preventively, it is included in the Part A global bundled payment for Part A stay residents.

Seasonal Influenza

SEASONAL INFLUENZA

Summary of Recent Changes to Influenza Vaccines

PREFERRED FLU VACCINES IN OLDER ADULTS

Since the 2022-23 season, the CDC has endorsed the preferential recommendation for select flu vaccines in older adults, to include higher dose (high dose and recombinant) and adjuvanted vaccine products. Specifically, Fluzone® High-Dose, Flublok® and Fluad® flu vaccines remain the preferred vaccine in older adults ≥65 years of age. However, if one of those vaccines is not available at the time of administration, people in this age group should get a standard-dose flu vaccine instead. There remains no preferential product recommendation for flu vaccination in people ≤ 65 years of age.[1]

FLU VACCINATION FOR PEOPLE WITH EGG ALLERGIES

Since the 2023-24 season, the CDC has relaxed warnings/precautions regarding flu vaccination in those with egg allergies. Most flu vaccines today continue to be produced using an egg-based manufacturing process and therefore contain a small amount of egg proteins, such as ovalbumin. While ACIP has previously recommended that all people 6 months and older with egg allergy should be vaccinated for flu, in the past there have been additional safety measures recommended for administration of egg-based flu vaccine to people who have had severe allergic reactions to egg. ACIP voted that people with egg-allergy may receive any flu vaccine (egg-based or non-egg based) that is otherwise appropriate for their age and health status. Additional safety measures are no longer recommended for flu vaccination beyond those recommended for receipt of any vaccine.

FLU VACCINES SHIFT TO TRIVALENT FORMULATIONS

Beginning with this 2024-25 season, vaccine manufacturers are transitioning from quadrivalent (QIV; 4 strain) to trivalent (TIV; 3 strain) influenza vaccines. This comes after direct instruction from the FDA (in collaboration with the WHO) to remove the B/Yamagata influenza virus strain from vaccines.

This decision was made based on evidence from the WHO's dedicated surveillance system for tracking influenza virus circulation that showed B/Yamagata circulation in decline prior to the COVID-19 pandemic, and which has subsequently confirmed zero circulating B/Yamagata lineage viruses since March of 2020.

This transition will not impact vaccine efficacy, as the removed strain is one no longer seen in circulation. The composition of the new TIV formulations will be designed to match projected circulating strains based on the WHO's ongoing surveillance.

For the 2024-2025 season, the influenza vaccine market consists of standard, recombinant, high-dose, and adjuvanted formulations.

Standard Influenza Vaccine

The standard influenza vaccine has historically been available under a number of trade names, including Afluria®, Fluarix®, Flulaval®, Fluzone®, and Flucelvax®. These may be available as vials and/or pre-filled syringes.
Flucelvax® has been the only cell-based inactivated flu vaccine licensed for use in the USA. Since the 2019-2020 flu season, all influenza candidate vaccine viruses used in the vaccine are cell-based, making the vaccine egg-free.[2]

Recombinant Influenza Vaccine

Flublok® is a recombinant flu vaccine that is also egg-free, as its production does not require an egg-grown vaccine virus and does not use chicken eggs in the production process. It has a higher dose than standard vaccines and thus has been preferentially recommended in older adults. It is licensed for use in adults 18 years of age and older.[3]

High-Dose Influenza Vaccine

Fluzone® HD is a high-dose vaccine that contains four times the amount of antigen compared to standard influenza vaccines, approved only for persons 65 years of age and older to engender a more robust immune response.[4]

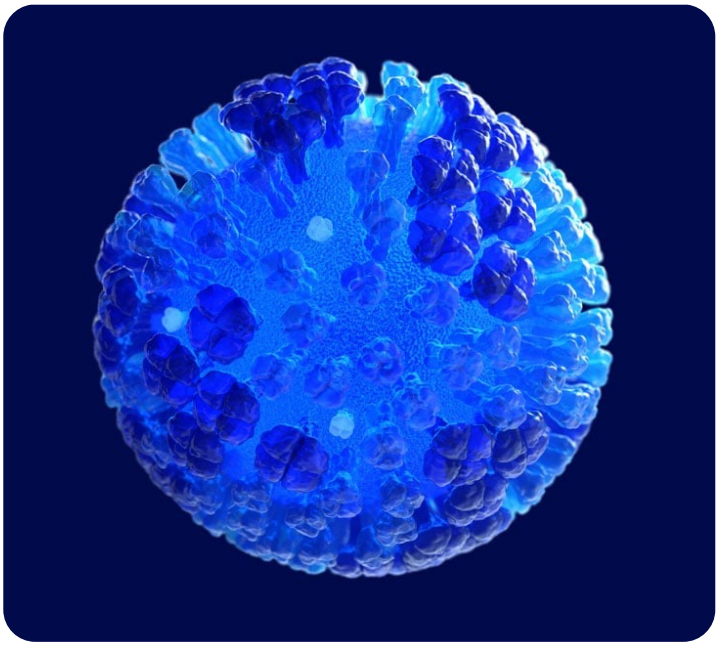
SEASONAL INFLUENZA

Adjuvanted Influenza Vaccine

Fluad® is a standard-dose inactivated flu vaccine approved only for adults 65 years of age and older that contains an adjuvant (MF59) designed to elicit a greater immune response to vaccination.[5]

This summary reflects information from the most recently published list of available influenza vaccines, based on composition, dose, and indication.

For more information, refer to the 2024-25 ACIP Summary Table here:
https://www.cdc.gov/mmwr/volumes/73/rr/rr7305a1.htm?s_cid=rr7305a1_w#T1_down



A 3D computer-generated rendering of a whole influenza (flu) virus in semi-transparent blue with a navy-blue background. The virus' hemagglutinin (HA) and neuraminidase (NA) surface proteins are displayed in semi-transparent blue sticking out of the surface of the virus. HA is a trimer (which is comprised of three subunits), while NA is a tetramer (which is comprised of four subunits and its head region resembles a 4-leaf clover)

1. Centers for Disease Control and Prevention. Influenza (Flu). 25 Aug 2023. Web. 15 Feb 2024. https://www.cdc.gov/flu/prevent/vaccinations.htm
2. Centers for Disease Control and Prevention. Cell-Based Flu Vaccines. 25 Aug 2023. Web. 15 Feb 2024. https://www.cdc.gov/flu/prevent/cell-based.htm
3. Centers for Disease Control and Prevention. Recombinant Flu Vaccine. 25 Aug 2023. Web. 5 Feb 2024. https://www.cdc.gov/flu/prevent/qa_flublok-vaccine.htm
4. Centers for Disease Control and Prevention. Fluzone High-Dose Flu Vaccine. 30 May 2023. Web. 5 Feb 2024. https://www.cdc.gov/flu/prevent/qa_fluzone.htm
5. Centers for Disease Control and Prevention. Adjuvanted Flu Vaccine. 25 Aug 2022. Web. 15 Feb 2024. https://www.cdc.gov/flu/prevent/adjuvant.htm

Influenza (Flu) Vaccine (Inactivated or Recombinant): *What you need to know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Influenza vaccine can prevent **influenza (flu)**.

Flu is a contagious disease that spreads around the United States every year, usually between October and May. Anyone can get the flu, but it is more dangerous for some people. Infants and young children, people 65 years and older, pregnant people, and people with certain health conditions or a weakened immune system are at greatest risk of flu complications.

Pneumonia, bronchitis, sinus infections, and ear infections are examples of flu-related complications. If you have a medical condition, such as heart disease, cancer, or diabetes, flu can make it worse.

Flu can cause fever and chills, sore throat, muscle aches, fatigue, cough, headache, and runny or stuffy nose. Some people may have vomiting and diarrhea, though this is more common in children than adults.

In an average year, **thousands of people in the United States die from flu**, and many more are hospitalized. Flu vaccine prevents millions of illnesses and flu-related visits to the doctor each year.

2. Influenza vaccines

CDC recommends everyone 6 months and older get vaccinated every flu season. **Children 6 months through 8 years of age** may need 2 doses during a single flu season. **Everyone else** needs only 1 dose each flu season.

It takes about 2 weeks for protection to develop after vaccination.

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against the influenza viruses believed to be likely to cause disease in the upcoming flu season.

Even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Influenza vaccine **does not cause flu**.

Influenza vaccine may be given at the same time as other vaccines.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of influenza vaccine**, or has any **severe, life-threatening allergies**
- Has ever had **Guillain-Barré Syndrome** (also called "GBS")

In some cases, your health care provider may decide to postpone influenza vaccination until a future visit.

Influenza vaccine can be administered at any time during pregnancy. People who are or will be pregnant during influenza season should receive inactivated influenza vaccine.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting influenza vaccine.

Your health care provider can give you more information.

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

4. Risks of a vaccine reaction

- Soreness, redness, and swelling where the shot is given, fever, muscle aches, and headache can happen after influenza vaccination.
- There may be a very small increased risk of Guillain-Barré Syndrome (GBS) after inactivated influenza vaccine (the flu shot).

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. Tell your health care provider if a child who is getting flu vaccine has ever had a seizure.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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**.

SEASONAL INFLUENZA

Interim Guidance for Influenza Outbreak Management in Long-Term Care and Post-Acute Care Facilities

Co-circulation of Influenza Viruses and SARS-CoV-2

New Testing and Management Considerations for Nursing Home Residents with Acute Respiratory Illness Symptoms when SARS-CoV-2 and Influenza Viruses are Co-circulating

The following guidance is current for the 2023-2024 influenza season. Please see Recommendations of the Advisory Committee on Immunization Practices – United States, 2024-2025 Season [523 KB, 32 pages] for the latest information regarding recommended influenza vaccines. Please see Antiviral Drugs: Information for Healthcare Professionals for the current summary of recommendations for clinical practice regarding the use of influenza antiviral medications. Please also refer to the Infectious Diseases Society of America (IDSA) 2018 Update on Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management of Seasonal Influenza.

Long-term care facilities may be defined as institutions, such as nursing homes and skilled nursing facilities that provide healthcare 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, healthcare personnel and by visitors. Spread of influenza can occur between and among residents, healthcare personnel 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 healthcare settings, including in long-term care facilities, requires a multi-faceted approach that includes the following:

1. Influenza Vaccination
2. Influenza Testing
3. Infection Prevention and Control Measures
4. Antiviral Treatment
5. Antiviral Chemoprophylaxis

Before an Outbreak Occurs

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

Residents

If possible, all residents should receive inactivated influenza vaccine (IIV) annually before influenza season. For persons aged ≥65 years, the following quadrivalent influenza vaccines are recommended: high-dose IIV, adjuvanted IIV, or recombinant influenza vaccine. If not available, standard-dose IIV may be given. In the majority of seasons, influenza vaccines will become available to long-term care facilities beginning in September, and influenza vaccination should be offered by the end of October. Informed consent is required to implement a standing order for vaccination, but this does not necessarily mean a signed consent must be present. Although vaccination by the end of October is recommended, influenza vaccine administered in December or later, even if influenza activity has already begun, is likely to be beneficial in the majority of influenza seasons because the duration of the season is variable, and influenza activity might not occur in certain communities until February or March.

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 shortage. This information is to be reported as part of the CMS Minimum Data Set, which tracks nursing home health parameters.

SEASONAL INFLUENZA

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

Healthcare personnel who get vaccinated may 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 complications

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, healthcare personnel, and visitors of long-term care facilities, and continued until the end of influenza season. Healthcare personnel and visitors who are identified with any illness symptoms should be excluded from the facility until their illness has resolved. Older adults 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 of influenza virus infection (e.g. behavior change), and may not have fever. Ill residents should be placed on droplet precautions with room restriction and exclusion from participating in group activities as described below.

Influenza Testing
Even if it's not influenza season, influenza testing should occur when any resident has signs and symptoms of acute respiratory illness or influenza-like illness. Information about influenza testing is available at: https://www.cdc.gov/flu/professionals/diagnosis/index.htm.

More information about testing is included below.

When there is a confirmed or suspected influenza outbreak (2 or more ill residents)

If one laboratory-confirmed influenza positive case is identified along with other cases of acute respiratory illness in a unit of a long-term care facility, an influenza outbreak might be occurring. Active surveillance for additional cases should be implemented as soon as possible once one case of laboratory-confirmed influenza is identified in a facility. When 2 cases of laboratory-confirmed influenza are identified within 72 hours of each other in residents on the same unit, outbreak control measures should be implemented as soon as possible.

Implementation of outbreak control measures can also be considered as soon as possible when one or more residents have acute respiratory illness with suspected influenza and the results of influenza molecular tests are not available the same day of specimen collection. While unusual, an influenza outbreak can occur outside of the normal influenza season; therefore, testing for influenza viruses and other respiratory pathogens should also be performed during noninfluenza 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.

*Note that older adults 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 of influenza virus infection (e.g. behavior change), and may not have fever (https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciy866/5251935).

- Determine if influenza virus is the causative agent by performing influenza testing on upper respiratory tract specimens (i.e. nasopharyngeal swab, nasal swabs, nasopharyngeal or nasal aspirates, or combined nasal and throat swabs) of ill residents with recent onset of signs and symptoms suggestive of influenza or acute respiratory illness.
- The following influenza tests are recommended: molecular assays, including rapid molecular assays, other molecular tests, or reverse transcription polymerase chain reaction (RT-PCR).
- If influenza molecular assays are not available and antigen detection tests are used such as rapid influenza diagnostic tests (RIDTs) or immunofluorescence assays, false negative results can occur because RIDTs and immunofluorescence assays have lower sensitivity than molecular assays for detection of influenza viruses. If influenza is suspected and RIDTs or immunofluorescence results are negative, perform confirmatory testing using molecular influenza assays. Information on influenza diagnostic testing is available online or by contacting your state public health laboratory.

SEASONAL INFLUENZA

- Influenza testing with molecular assays such as RT-PCR may be available at a local or state public health laboratory.
- Viral culture should be performed at a public health laboratory if additional information on influenza viruses, such as influenza A virus subtype, antigenic characterization to compare with influenza vaccine strains, or antiviral resistance data are needed.
- Determining influenza virus type or subtype of influenza A virus can help inform antiviral therapy decisions.

Implement daily active surveillance for acute respiratory illness among all residents, healthcare personnel and visitors to the facility.

- During an outbreak, once a single laboratory-confirmed case of influenza has been identified in a resident, it is likely there are other cases among exposed persons.
- Conduct daily active surveillance until at least 1 week after the last laboratory-confirmed influenza case was identified.
- Test for influenza with a molecular assay in the following:
    - o Ill persons who are in the affected unit(s) as well as previously unaffected units in the facility
    - o Persons who develop acute respiratory illness symptoms after beginning antiviral chemoprophylaxis

    **Note that older adults 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 of influenza virus infection (e.g. behavior change), and may not have fever.*
- Ensure that the laboratory performing influenza testing notifies the facility of tests results promptly.
- The local public 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 healthcare settings. Specific recommendations are highlighted below.

Standard Precautions are intended to be applied to the care of all patients in all healthcare 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 healthcare 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 healthcare 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 healthcare 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 healthcare personnel, and discouraging ill visitors from entering the facility.

SEASONAL INFLUENZA

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 chemo-prophylaxis to residents and healthcare personnel according to current recommendations.

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

Initiation of antiviral 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, have progressive illness, or meet any of the high risk criteria outlined in this document from the CDC.

Four influenza antiviral drugs approved by the U.S. Food and Drug Administration are recommended for treatment of uncomplicated influenza in the United States: neuraminidase inhibitors: 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®); and a cap-dependent endonuclease inhibitor: baloxavir marboxil (trade name Xofluza®). 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 to these drugs among circulating influenza A viruses.

The recommended dosing and duration of antiviral treatment is twice daily for 5 days for neuraminidase inhibitors (oseltamivir and zanamivir), and one dose for intravenous peramivir. Oseltamivir is recommended for treatment of influenza in people of all ages. Baloxavir is approved for early treatment of uncomplicated influenza in people 5 years and older who are otherwise healthy or in people aged 12 years and older who are at higher risk for influenza complications and have been ill for no more than 2 days. A single oral dose of baloxavir is equivalent to 5 days of twice daily oral oseltamivir. Inhaled zanamivir is approved for early treatment of influenza in persons aged 7 years and older. Peramivir is approved for early treatment of influenza in persons aged 6 months and older. Dosage adjustment may be required for children and persons with certain underlying conditions. Clinicians should consult the manufacturers' package insert for approved ages, recommended drug dosing adjustments and contraindications.

In the setting of an influenza outbreak, empiric antiviral treatment should be given as soon as possible to residents with suspected influenza without waiting for influenza testing results, especially if results will not be available on the day of specimen collection. There are no data on use of baloxavir to control influenza outbreaks in long-term care facilities. Baloxavir is not recommended for pregnant women, severely immunosuppressed persons, those with severe disease, or hospitalized influenza patients. There are no data on baloxavir in these populations.

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 CDC's influenza antiviral medication page for health professionals.

All exposed residents with influenza cases on units or wards in the long-term care facility (currently impacted wards) should receive antiviral chemoprophylaxis as soon as an influenza outbreak is determined (https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciy866/5251935).

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 with oral oseltamivir to all non-ill residents living on the same unit as the resident with

SEASONAL INFLUENZA

laboratory-confirmed influenza (outbreak affected units), regardless of whether they received influenza vaccination during the current season. Consideration may be given for extending antiviral chemoprophylaxis to residents on other unaffected units or wards in the long-term care facility based upon other factors (e.g. unavoidable mixing of residents or healthcare personnel from affected units and unaffected units).

Antiviral chemoprophylaxis is meant for 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. Oseltamivir is the recommended antiviral drug for chemoprophylaxis of influenza in long-term care settings. Baloxavir is approved for post-exposure antiviral chemoprophylaxis of influenza in persons aged 5 years and older but no data are available from clinical trials of baloxavir chemoprophylaxis of influenza in long-term care facility residents.

CDC recommends antiviral chemoprophylaxis with oseltamivir for a minimum of 2 weeks and continuing for at least 7 days after the last known laboratory-confirmed influenza case was identified on affected units.

Persons whose need for antiviral chemoprophylaxis is attributed to potential exposure to a person with laboratory-confirmed influenza should receive oral oseltamivir or inhaled zanamivir. Zanamivir should be used when persons require chemoprophylaxis as a result of exposure to influenza virus strains that are suspected or known to be oseltamivir-resistant.

(For more information see Recommended Dosage and Duration of Treatment or Chemoprophylaxis for Influenza Antiviral Medications and https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciy866/5251935.)

Antiviral chemo-prophylaxis can be considered or offered to unvaccinated personnel who provide care to persons at higher risk of influenza 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 healthcare personnel, 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, or based upon other factors (e.g. to reduce the risk of short staffing in facilities and units where clinical staff are limited and to reduce staff reluctance to provide care to residents with suspected or laboratory-confirmed influenza).

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

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

For newly vaccinated healthcare personnel, antiviral chemoprophylaxis can be considered for up to 2 weeks following inactivated influenza vaccination until vaccine-induced immunity is acquired. 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 an Antiviral 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. Persons receiving chemoprophylaxis who become sick should be switched to treatment dosing. If infection with an antiviral-resistant influenza virus is suspected, the local or state public health department should be notified promptly.

SEASONAL INFLUENZA

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 prevention and 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 healthcare 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 healthcare 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 healthcare 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 healthcare 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 older adults, children with neuromuscular disorders, and young infants, may have atypical clinical presentations. Older adults 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 of influenza virus infection (e.g. behavior change), and may not have fever (https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciy866/5251935).

Last Reviewed: February 5, 2024

SEASONAL INFLUENZA

Influenza Antiviral Medications: Summary for Clinicians

The information on this page should be considered current for the 2023-2024 influenza season for clinical practice regarding the use of influenza antiviral medications. Clinicians may also wish to consult the IDSA antiviral treatment and antiviral chemoprophylaxis recommendations, and the ATS-IDSA Adult CAP Guidelines.

Priority Groups for Antiviral Treatment of Influenza

Antiviral treatment is recommended **as soon as possible** for any patient with suspected or confirmed influenza who:

- is **hospitalized**;
- has severe, complicated, or progressive illness; or
- is at **higher risk** for influenza complications.

Decisions about starting antiviral treatment for patients with suspected influenza should not wait for laboratory confirmation of influenza virus infection. Empiric antiviral treatment should be started as soon as possible in the above priority groups.

Clinicians can consider early empiric antiviral treatment of non-higher-risk outpatients with suspected influenza based upon clinical judgment if treatment can be initiated within 48 hours of illness onset.

Antiviral Drug Options

- For hospitalized patients with suspected or confirmed influenza, initiation of antiviral treatment with oral or enterically administered oseltamivir is recommended as soon as possible.
- For outpatients with complications or progressive disease and suspected or confirmed influenza (e.g., pneumonia, or exacerbation of underlying chronic medical conditions), initiation of antiviral treatment with oral oseltamivir is recommended as soon as possible.
- For outpatients with suspected or confirmed uncomplicated influenza, oral oseltamivir, inhaled zanamivir, intravenous peramivir, or oral baloxavir may be used for treatment, depending upon approved age groups and contraindications. In one randomized controlled trial, baloxavir had greater efficacy than oseltamivir in adolescents and adults with influenza B virus infection (Ison, 2020).

Co-circulation of Influenza Viruses and SARS-CoV-2

During periods of community co-circulation of influenza viruses and SARS-CoV-2, empiric antiviral treatment of influenza is recommended as soon as possible for the following priority groups: a) hospitalized patients with respiratory illness; b) outpatients with severe, complicated, or progressive respiratory illness; and c) outpatients at higher risk for influenza complications who present with any acute respiratory illness symptoms (with or without fever).

- Influenza and COVID-19 have overlapping signs and symptoms. Testing can help distinguish between influenza virus infection and SARS-CoV-2 infection. However, clinicians should not wait for the results of influenza testing (Table 3), SARS-CoV-2 testing, or multiplex molecular assays that detect influenza A and B viruses and SARS-CoV-2 (Table 4) to initiate empiric antiviral treatment for influenza in the above priority groups.
- Co-infection with influenza A or B viruses and SARS-CoV-2 can occur and should be considered, particularly in hospitalized patients with severe respiratory disease.
    - Clinicians should be aware that a positive SARS-CoV-2 test result does not preclude influenza virus infection. For hospitalized patients with suspected influenza who are started on empiric antiviral treatment with oseltamivir, use of influenza molecular assays (Table 3) or multiplex assays that detect both influenza viruses and SARS-CoV-2 (Table 4) can inform clinical management.
    - Clinicians should be aware that a positive influenza test result does not preclude SARS-CoV-2 infection. For hospitalized patients with a positive influenza test result, antiviral treatment of influenza with oseltamivir should be started as soon as possible, and clinicians should also follow guidelines for diagnosis and treatment of community-acquired pneumonia (community acquired pneumonia treatment guidance for adults: Metlay, 2019) and other respiratory infections, including SARS-CoV-2 infection (NIH COVID-19 treatment guidelines and IDSA COVID-19 treatment guidelines) if clinically indicated, while awaiting SARS-CoV-2 testing results. Oseltamivir does not have in-vitro activity against SARS-CoV-2 (Choy, 2020).
- Clinicians can utilize telemedicine in place of office visits for patients with acute respiratory illness. It may be useful for providers to implement phone triage lines to enable high-risk patients to discuss symptoms over the phone. Please see the Algorithm to Assist in Medical Office Telephone Evaluation of Patients with Possible Influenza.

SEASONAL INFLUENZA

- Patients at higher risk for influenza complications should be advised to call their provider as soon as possible if they have acute respiratory illness symptoms (with or without fever) for consideration of infection with influenza A or B viruses (and early antiviral treatment), SARS-CoV-2, and other respiratory pathogens.
- Clinicians can consider starting early (≤48 hours after illness onset) empiric antiviral treatment of non-higher-risk outpatients with suspected influenza, based upon clinical judgment, including without an office visit. SARS-CoV-2 and other etiologies of acute respiratory illness should also be considered.
- Clinical algorithms for the testing and treatment of influenza when SARS-CoV-2 and influenza viruses are circulating are also available.

Overview of Influenza Antiviral Medications

- Influenza antiviral prescription drugs can be used to treat influenza, and some can be used to prevent influenza.
- Six licensed prescription influenza antiviral drugs are approved in the United States.
    - Four influenza antiviral medications approved by the U.S. Food and Drug Administration (FDA) are recommended for use in the United States.
    - Three drugs are chemically related antiviral medications known as neuraminidase inhibitors that block the viral neuraminidase enzyme and have activity against both influenza A and B viruses: oral oseltamivir phosphate (available as a generic version or under the trade name Tamiflu®), inhaled zanamivir (trade name Relenza®), and intravenous peramivir (trade name Rapivab®).
    - The fourth drug is oral baloxavir marboxil (trade name Xofluza®), which is active against both influenza A and B viruses but has a different mechanism of action than neuraminidase inhibitors. Baloxavir is a cap-dependent endonuclease inhibitor that interferes with viral RNA transcription and blocks virus replication.
    - More information regarding the four recommended antiviral medications is available: Table 1.
- The two other FDA-approved influenza antiviral medications (amantadine and rimantadine) are not recommended for antiviral treatment or chemoprophylaxis because of high levels of resistance among circulating influenza A viruses.
- Clinical trials and observational data show that early antiviral treatment can shorten the duration of fever and illness symptoms, and may reduce the risk of some complications from influenza (e.g., otitis media in young children, pneumonia, and respiratory failure).
    - In hospitalized adults with influenza, early treatment with oseltamivir has been reported to reduce in-hospital death and the duration of hospitalization in some observational studies.
    - In hospitalized children, early antiviral treatment with oseltamivir has been reported to shorten the duration of hospitalization in some observational studies.
    - Clinical benefit is greatest when antiviral treatment is administered early, especially within 48 hours of influenza illness onset.

SEASONAL INFLUENZA

Table 1. Antiviral Medications Recommended for Treatment and Chemoprophylaxis of Influenza

Antiviral Agent	Activity Against	Use	Recommended For	Not Recommended for Use in	Adverse Events
Oral Oseltamivir	Influenza A and B	Treatment	Any age[1]	N/A	**Adverse events:** nausea, vomiting, headache. Post marketing reports of serious skin reactions and sporadic, transient neuropsychiatric events[2]
		Chemo-prophylaxis	3 months and older[1]	N/A	
Inhaled Zanamivir	Influenza A and B	Treatment	7 yrs and older[3]	People with underlying respiratory disease (e.g., asthma, COPD)[3]	**Adverse events:** risk of bronchospasm, especially in the setting of underlying airways disease; sinusitis, and dizziness. Post marketing reports of serious skin reactions and sporadic, transient neuropsychiatric events[2]
		Chemo-prophylaxis	5 yrs and older[3]	People with underlying respiratory disease (e.g., asthma, COPD)[3]	
Intravenous Peramivir	Influenza A and B[4]	Treatment	6 months and older[4]	N/A	**Adverse events:** diarrhea. Post marketing reports of serious skin reactions and sporadic, transient neuropsychiatric events[2]
		Chemo-prophylaxis[5]	Not recommended	N/A	
Oral Baloxavir	Influenza A and B[6]	Treatment	5 yrs and older[6]	N/A	**Adverse events:** none more common than placebo in clinical trials
		Chemo-prophylaxis[6]	Approved for post-exposure prophylaxis in persons 5 yrs and older[6]		

Abbreviations: N/A = not applicable, COPD = chronic obstructive pulmonary disease.

SEASONAL INFLUENZA

Table 1 Resources

1. Oral oseltamivir phosphate is approved by the FDA for treatment of acute uncomplicated influenza within 2 days of illness onset in people 14 days and older, and for chemoprophylaxis in people 1 year and older. Although not part of the FDA-approved indications, use of oral oseltamivir for treatment of influenza in infants less than 14 days old, and for chemoprophylaxis in infants 3 months to 1 year, is recommended by the CDC and the American Academy of Pediatrics. If a child is younger than 3 months old, use of oseltamivir for chemoprophylaxis is not recommended unless the situation is judged critical due to limited data in this age group.
2. Self-injury or delirium; mainly reported among Japanese pediatric patients.
3. Inhaled zanamivir is contraindicated in patients with underlying airways disease such as asthma or chronic obstructive pulmonary disease, and those with a history of allergy to lactose or milk protein.
4. Intravenous peramivir is approved by the FDA for treatment of acute uncomplicated influenza within 2 days of illness onset in people 6 months and older. Peramivir efficacy is based on clinical trials versus placebo in which the predominant influenza virus type was influenza A; in one trial, a very limited number of subjects infected with influenza B virus were enrolled.
5. There are no data available for use of peramivir for chemoprophylaxis of influenza.
6. Oral baloxavir marboxil is approved by the FDA for treatment of acute uncomplicated influenza within 2 days of illness onset in people aged ≥5 years who are otherwise healthy, or in people aged ≥12 years who are high risk of developing influenza-related complications. Baloxavir efficacy for initial FDA approval in October 2018 was based on clinical trials in previously healthy outpatients 12 to 64 years old (Hayden, 2018). Singledose baloxavir t reatment was superior to placebo and had similar clinical efficacy in time to alleviation of symptoms to a 5-day treatment course of oseltamivir.

In October 2019, FDA approved an indication for baloxavir treatment of acute uncomplicated influenza within 2 days of illness onset in people 12 years and older at high risk of developing influenza-related complications, based upon the findings of a clinical trial (Ison, 2020). In this clinical trial of early initiation of antiviral treatment for uncomplicated influenza in highrisk patients, baloxavir was superior to placebo and had similar overall efficacy to oseltamivir in the time to alleviation of symptoms. For patients with influenza B virus infection, baloxavir significantly reduced the median time to improvement of symptoms compared with oseltamivir by more than 24 hours.

For patients with influenza B virus infection, baloxavir significantly reduced the median time to improvement of symptoms compared with oseltamivir by more than 24 hours. However, there are no available data for baloxavir treatment of influenza in pregnant people, immunocompromised people, or in people with severe influenza who are not hospitalized.

In August 2022, FDA expanded approval of baloxavir for treatment of acute uncomplicated influenza within 2 days of illness onset in children aged 5 years to <11 years who are otherwise healthy package insert XOFLUZA [963 KB, 22 pages]. This was based upon the secondary clinical outcomes of a randomized clinical trial of baloxavir versus oseltamivir for treatment of uncomplicated influenza in children aged 1 year to <12 years (Baker, 2021).

A randomized clinical trial reported that combination neuraminidase inhibitor (primarily oseltamivir) and baloxavir for treatment of hospitalized influenza patients aged ≥12 years did not result in superior clinical benefit (time to clinical improvement) compared with neuraminidase inhibitor and placebo (Kumar, 2022).

In November 2020, FDA expanded approval of baloxavir to include post exposure prophylaxis of influenza for persons aged ≥12 years within 48 hours of contact with an individual with influenza, based on the findings of a clinical trial among household contacts of index patient with influenza (Ikematsu, 2020). In this study, baloxavir post-exposure prophylaxis (PEP) of influenza in household members (19% were younger than 12 years; 73% received baloxavir within 24 hours of onset of symptoms in the index household case who received antiviral treatment) significantly reduced the risk of laboratory confirmed by 86% among those who received baloxavir PEP than among those who received placebo (1.9% [7 of 374] vs. 13.6% [51 of 375]; adjusted risk ratio, 0.14; 95% confidence interval [CI], 0.06 to 0.30; P<0.001).

In August 2022, FDA expanded approval of baloxavir for post-exposure prophylaxis of influenza in persons aged 5 years and older within 48 hours of contact with an individual with influenza package insert XOFLUZA [963 KB, 22 pages].

SEASONAL INFLUENZA

Summary of Influenza Antiviral Treatment Recommendations

Antiviral treatment is recommended as early as possible for any patient with confirmed or suspected influenza who:

- **is hospitalized;***
- **has severe, complicated, or progressive illness;* or**
- **is at higher risk for influenza complications.**

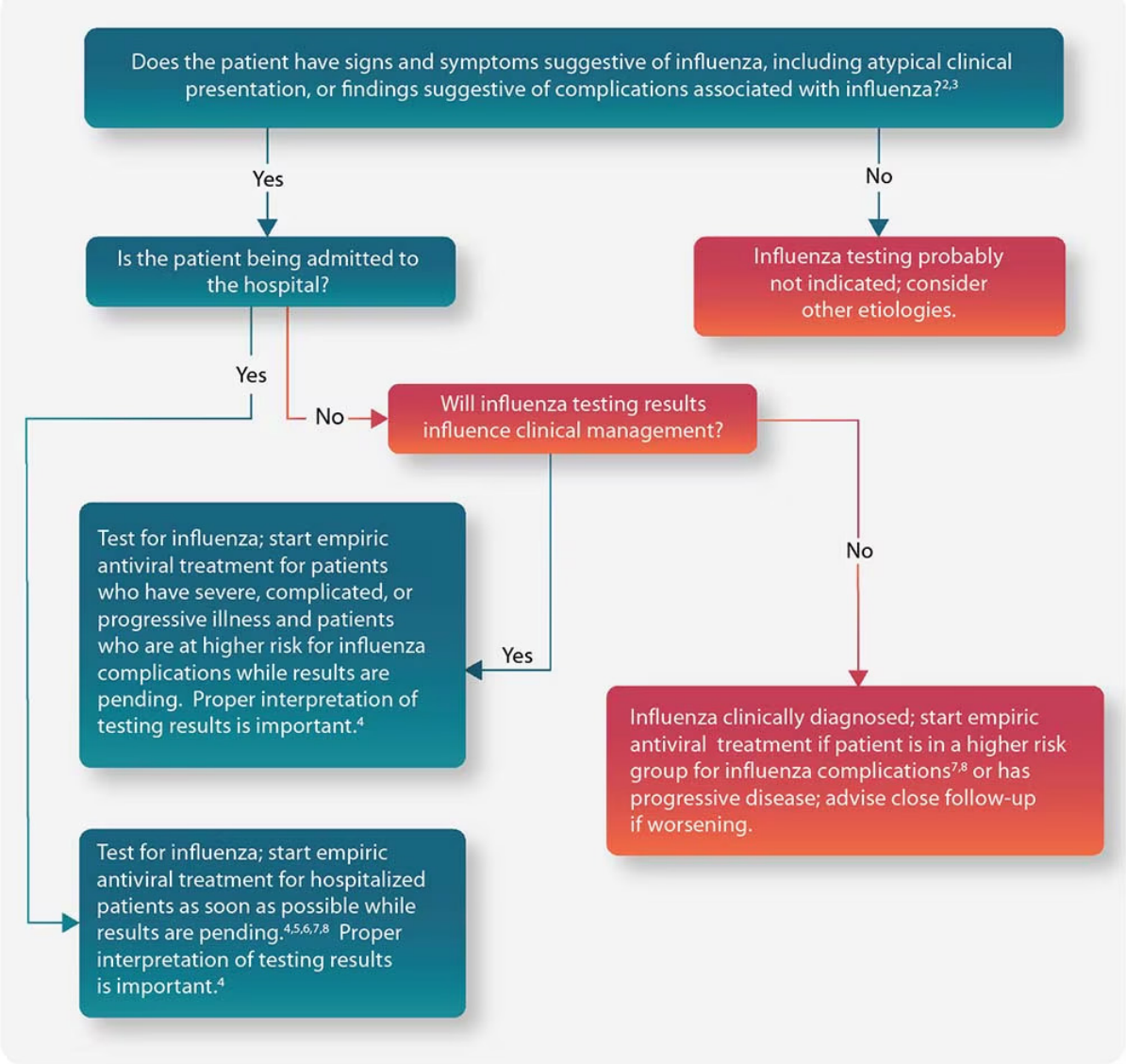
*Oral or enterically administered oseltamivir is the recommended antiviral for patients with severe, complicated, or progressive illness who are not hospitalized, and for hospitalized influenza patients. For hospitalized patients who cannot tolerate or absorb oral or enterically administered oseltamivir because of suspected or known gastric stasis, malabsorption, or gastrointestinal bleeding, intravenous peramivir may be considered (Lee, 2017; de Jong, 2014; Ison, 2014; Ison, 2013). There are insufficient data to support general use of inhaled zanamivir and intravenous peramivir in patients with severe influenza disease. There are no available data from clinical trials on use of baloxavir treatment in patients with severe influenza disease who are not hospitalized.

**Oral oseltamivir and oral baloxavir are available treatment options for patients at higher risk for influenza complication depending upon their underlying conditions and age (Table 1). Data on use of peramivir or zanamivir are very limited in high-risk outpatients with influenza.

- **Oral oseltamivir is preferred for treatment of pregnant people** (Rasmussen, 2011). Pregnant people are recommended to receive the same antiviral dosing as non-pregnant people. Multiple studies have reported safe use of neuraminidase inhibitors during pregnancy (Dunstan, 2014; Xie, 2013; Saito, 2013; Wollenhaupt, 2014; Beau, 2014; Svensson, 2011; Greer, 2010; Graner, 2017); Ehrenstien, 2018; Chambers, 2019; Bennekom, 2019; ACOG Committee, 2018). See Recommendations for Obstetric Health Care Providers Related to Use of Antiviral Medications in the Treatment and Prevention of Influenza for additional information. Baloxavir is not recommended for the treatment of influenza in pregnant or breastfeeding people, as there are no available efficacy or safety data for baloxavir in this pregnant people (Chow, 2021), and no available data on the presence of baloxavir in human milk, the effects on the breastfed infant, or the effects on milk production.
- **CDC does not recommend use of baloxavir for monotherapy of influenza in severely immunosuppressed persons.** There are no available efficacy, safety, or resistance data for baloxavir monotherapy of influenza in severely immunosuppressed patients and emergence of resistance during treatment is a concern because of prolonged influenza viral replication in these patients.
- When indicated, **antiviral treatment should be started as soon as possible after illness onset,** ideally within 48 hours of symptom onset for the greatest clinical benefit. However, observational studies have reported that antiviral treatment of influenza can have clinical benefit in patients with severe, complicated or progressive illness, and in hospitalized patients when started after 48 hours of illness onset.
- **Decisions about starting antiviral treatment should not wait for laboratory confirmation of influenza** (see resources regarding Clinical Description and Lab Diagnosis of Influenza for more information on influenza diagnostic testing).
    - Clinical benefit is greatest when antiviral treatment is started as close to illness onset as possible.
- Antiviral treatment with oral oseltamivir, inhaled zanamivir, intravenous peramivir, or oral baloxavir also can be considered for any previously healthy, symptomatic outpatient not at higher risk for influenza complications, who is diagnosed with confirmed or suspected influenza, on the basis of clinical judgment, if treatment can be initiated within 48 hours of illness onset.
    - The recommended treatment course for uncomplicated influenza is two doses per day of oral oseltamivir or inhaled zanamivir for 5 days, or one dose of intravenous peramivir or oral baloxavir for 1 day.
    - While influenza vaccination is the best way to prevent influenza illness, a history of influenza vaccination does not rule out the possibility of influenza virus infection in an ill patient with clinical signs and symptoms compatible with influenza.

SEASONAL INFLUENZA

Figure: Guide for considering influenza testing when influenza viruses are circulating in the community (regardless of influenza vaccination history)[1]



1. Confirmation of influenza virus infection by diagnostic testing is not required for decisions to prescribe antiviral medication. Decision-making should be based upon signs and symptoms consistent with influenza illness and epidemiologic factors. Initiation of empiric antiviral treatment should not be delayed while influenza testing results are pending. Antiviral treatment is clinically most beneficial when started as close to illness onset as possible. Influenza vaccine effectiveness is moderate and so a history of current season influenza vaccination does not exclude a diagnosis of influenza.
2. Signs and symptoms of uncomplicated influenza vary by age, underlying health conditions, and immune function. Common signs and symptoms include fever with nonproductive cough or other respiratory symptoms, often with myalgias or headache. Fever is not always present, including in premature and young infants, immunocompromised and immunosuppressed persons, and especially in elderly persons. Note that some persons may have atypical presentations – especially infants (e.g. sepsis-like syndrome) and elderly (e.g. confusion).
3. Complications associated with influenza can vary by age, immune status, and underlying medical conditions. Some examples include worsening of underlying chronic medical conditions (e.g. worsening of congestive cardiac failure; asthma exacerbation; exacerbation of chronic obstructive pulmonary disease); lower respiratory tract disease (pneumonia, bronchiolitis, croup, respiratory failure); invasive bacterial co-infection; cardiac (e.g. myocarditis); musculoskeletal (e.g. myositis, rhabdomyolysis); neurologic (e.g. encephalopathy, encephalitis); multi-organ failure (septic shock, renal failure, respiratory failure).

SEASONAL INFLUENZA

4. Influenza testing may be used to inform decisions on use of antiviral treatment, antibiotic treatment, need for further diagnostic tests, consideration for home care, or on recommendations for ill persons living with others who are at high risk for influenza complications. Proper interpretation of influenza testing results must consider a number of factors, including: the predictive values of the test, test sensitivity and specificity compared to a "gold standard" test, prevalence of influenza in the patient population, time from illness onset to specimen collection and whether the person may still have detectable influenza viral shedding, and source of the respiratory specimen (upper or lower respiratory tract).
   To maximize detection of influenza viruses, respiratory specimens should be collected as close to illness onset as possible (ideally <3–4 days after onset; molecular assays may detect influenza viral RNA in respiratory tract specimens for longer periods after illness onset than antigen detection assays). See this algorithm for more information. The Infectious Diseases Society of America (IDSA) recommends use of rapid influenza molecular assays over rapid influenza diagnostic tests (RIDTs) for detection of influenza viruses in respiratory specimens of outpatients. Consult the IDSA Influenza Clinical Practice Guidelines for recommendations on influenza testing and interpretation of testing results. Consult guidance on antibiotic use from the IDSA, ATS, and the AAP. Antiviral treatment is recommended as soon as possible for hospitalized patients with suspected influenza without waiting for influenza testing results of molecular assays. Guidance on antiviral treatment of influenza is available.
5. All hospitalized patients with suspected influenza should be tested with molecular assays with high sensitivity and specificity (e.g. RT-PCR) since detection of influenza virus infection and prompt initiation of antiviral therapy is most clinically beneficial, and prompt implementation of infection prevention and control measures is essential for prevention of nosocomial influenza outbreaks. The Infectious Diseases Society of America (IDSA) recommends use of RT-PCR or other molecular assays for detection of influenza viruses in respiratory specimens of hospitalized patients. Consult the IDSA Influenza Clinical Practice Guidelines for recommendations on influenza testing and interpretation of testing results. Molecular assays can detect influenza viral nucleic acids in respiratory specimens for longer periods and with much higher accuracy than antigen detection assays. For hospitalized patients with lower respiratory tract disease and suspected influenza, lower respiratory tract specimens should be collected and tested for influenza viruses by RT-PCR because influenza viral shedding in the lower respiratory tract may be detectable for longer periods than in the upper respiratory tract, if influenza testing of upper respiratory tract specimens yields a negative result. If the patient is critically ill on invasive mechanical ventilation, and has tested negative for influenza viruses on an upper respiratory tract specimen, including by a molecular assay, a lower respiratory tract specimen (endotracheal aspirate or bronchioalveolar lavage fluid) should be collected for influenza testing by RT-PCR or other molecular assays.
6. Influenza testing may help inform decisions on infection prevention and control practices.
7. Persons who are at Higher Risk of Complications from Influenza include those aged ≥65 years or <2 years; pregnant women; persons with chronic lung disease (including asthma), heart disease, renal, metabolic, hematologic and neurologic disease; immunosuppression; and morbid obesity; American Indians or Alaska Natives; and residents of chronic care facilities.
8. Antiviral treatment is recommended as soon as possible for outpatients with suspected or confirmed influenza who are at high risk for complications from influenza, or those with progressive disease not requiring hospital admission. Outpatients who are not at higher risk of complications from influenza can be considered based upon clinical judgment if presenting within 2 days of illness onset. Guidance on antiviral treatment of influenza is available.

Table 2. Recommended Dosage and Duration of Influenza Antiviral Medications for Treatment or Chemoprophylaxis

Antiviral Agent	Use	Children	Adults
Oral Oseltamivir	Treatment (5 days)[1]	**If younger than 1 yr old**[2]: 3 mg/kg/dose twice daily[3,4] **If 1 yr or older, dose varies by child's weight:** 15 kg or less, the dose is 30 mg **twice** a day >15 to 23 kg, the dose is 45 mg **twice** a day >23 to 40 kg, the dose is 60 mg **twice** a day >40 kg, the dose is 75 mg **twice** a day	75 mg **twice** daily
	Chemoprophylaxis (7 days)[5]	If child is younger than 3 months old, use of oseltamivir for chemoprophylaxis is not recommended unless situation is judged critical due to limited data in this age group. **If child is 3 months or older and younger than 1 yr old**[2] 3 mg/ kg/dose once daily[3] **If 1 yr or older, dose varies by child's weight:** 15 kg or less, the dose is 30 mg **once** a day >15 to 23 kg, the dose is 45 mg **once** a day >23 to 40 kg, the dose is 60 mg **once** a day >40 kg, the dose is 75 mg **once** a day	75 mg **once** daily
Inhaled Zanamivir[6]	**Treatment (5 days)**	10 mg (two 5-mg inhalations) **twice** daily **(FDA approved and recommended for use in children 7 yrs or older)**	10 mg (two 5-mg inhalations) **twice** daily
	Chemoprophylaxis (7 days)[5]	10 mg (two 5-mg inhalations) **once** daily **(FDA approved for and recommended for use in children 5 yrs or older)**	10 mg (two 5-mg inhalations) **once** daily
Intravenous Peramivir[7]	**Treatment (1 day)**[1]	(6 months to 12 yrs of age) One 12 mg/kg dose, up to 600 mg maximum, via intravenous infusion for a minimum of 15 minutes **(FDA approved and recommended for use in children 6 months or older)**	(13 yrs and older) One 600 mg dose, via intravenous infusion for a minimum of 15 minutes
	Chemoprophylaxis[8]	Not recommended	N/A
Oral Baloxavir[9]	**Treatment (1 day)**	(5 yrs and older weighing <20 kg: single dose of 2 mg/kg by suspension; weighing 20 kg to <80 kg: single dose of 40 mg by tablet or suspension; weighing ≥80 kg: single dose of 80 mg by tablet or suspension) **FDA approved and recommended for use in otherwise healthy children 5 yrs and older.**	Weight <80 kg: One 40 mg dose; Weight ≥80 kg: One 80 mg dose[9]
	Chemoprophylaxis[9]	**FDA approved for post-exposure prophylaxis for persons aged 5 years and older. Dosage is the same as for treatment.**	Dosage is the same as to treatment

SEASONAL INFLUENZA

Table 2 Resources

Abbreviations: N/A = not approved

1. Longer treatment duration may be needed for severely ill patients.
2. Oral oseltamivir is approved by the FDA for treatment of acute uncomplicated influenza within 2 days of illness onset with twice-daily dosing in people 14 days and older, and for chemoprophylaxis with once-daily dosing in people 1 year and older. Although not part of the FDA-approved indications, use of oral oseltamivir for treatment of influenza in infants less than 14 days old, and for chemoprophylaxis in infants 3 months to 1 year of age, is recommended by CDC and the American Academy of Pediatrics (Recommendations for Prevention and Control of Influenza in Children, 2023–2024).
3. This is the FDA-approved oral oseltamivir treatment dose for infants 14 days and older and less than 1 year old and provides oseltamivir exposure in children similar to that achieved by the approved dose of 75 mg orally twice daily for adults, as shown in two studies of oseltamivir pharmacokinetics in children (Kimberlin, 2013 [CASG 114], EU study WP2284 [3.44 MB, 74 pages], FDA Clinical Pharmacology Review [1.7 MB, 53 pages]). The American Academy of Pediatrics has recommended an oseltamivir treatment dose of 3.5 mg/kg orally twice daily for infants 9-11 months old, on the basis of data which indicated that a higher dose of 3.5 mg/kg was needed to achieve the protocol-defined targeted exposure for this cohort as defined in the CASG 114 study (Kimberlin, 2013). It is unknown whether this higher dose will improve efficacy or prevent the development of antiviral resistance. However, there is no evidence that the 3.5 mg/kg dose is harmful or causes more adverse events to infants in this age group.
4. Current weight-based dosing recommendations are not appropriate for premature infants. Premature infants might have slower clearance of oral oseltamivir because of immature renal function, and doses recommended for full-term infants might lead to very high drug concentrations in this age group. CDC recommends dosing as also recommended by the American Academy of Pediatrics (Recommendations for Prevention and Control of Influenza in Children, 2023–2024): limited data from the National Institute of Allergy and Infectious Diseases Collaborative Antiviral Study Group provide the basis for dosing preterm infants using their postmenstrual age (gestational age + chronological age): 1.0 mg/kg/dose, orally, twice daily, for those <38 weeks postmenstrual age; 1.5 mg/kg/dose, orally, twice daily, for those 38 through 40 weeks postmenstrual age; 3.0 mg/kg/dose, orally, twice daily, for those >40 weeks postmenstrual age.
5. See Special Considerations for Institutional Settings section below for details regarding duration of chemoprophylaxis for outbreaks in institutional settings.
6. Inhaled zanamivir is approved for treatment of acute uncomplicated influenza within 2 days of illness onset with twice-daily dosing in people aged ≥7 years, and for chemoprophylaxis with once-daily dosing in people aged ≥5 years.
7. Intravenous peramivir is approved for treatment of acute uncomplicated influenza within 2 days of illness onset with a single dose in people aged ≥6 months. Daily dosing for a minimum of 5 days was used in clinical trials of hospitalized patients with influenza (de Jong, 2014, Ison, 2014).
8. There are no data for use of peramivir for chemoprophylaxis of influenza.
9. Oral baloxavir marboxil is approved by the FDA for treatment of acute uncomplicated influenza within 2 days of illness onset in people aged ≥5 years who are otherwise healthy, or in people aged ≥12 years at high risk of developing influenza-related complications. Baloxavir marboxil (Xofluza) [package insert] [445 KB, 16 pages]. Baloxavir marboxil should not be administered with dairy products, calcium-fortified beverages, polyvalent cation-containing laxatives, antacids or oral supplements (e.g., calcium, iron, magnesium, selenium, or zinc); co-administration with polyvalent cation-containing products may decrease plasma concentrations of baloxavir which may reduce efficacy. There are no available published data from clinical trials for baloxavir treatment of influenza in non-hospitalized patients who are pregnant, immunocompromised, or have severe disease.
   A randomized clinical trial reported that combination neuraminidase inhibitor (primarily oseltamivir) and baloxavir for treatment of hospitalized influenza patients aged ≥12 years did not result in superior clinical benefit (time to clinical improvement) compared with neuraminidase inhibitor and placebo (Kumar, 2022).
   Oral baloxavir is approved by the FDA for post-exposure prophylaxis of influenza for persons aged ≥5 years within 48 hours of contact with an individual with influenza.

SEASONAL INFLUENZA

Duration of Treatment or Chemoprophylaxis

Treatment: Recommended duration for antiviral treatment of uncomplicated influenza in outpatients is 5 days for oral oseltamivir or inhaled zanamivir. For treatment of uncomplicated influenza with intravenous peramivir or oral baloxavir, a single dose is recommended. Longer daily dosing (oral oseltamivir or intravenous peramivir) can be considered for hospitalized patients with influenza who remain severely ill after 5 days of treatment. Treatment should be started as soon as possible after symptom onset for the greatest clinical benefit.

Chemoprophylaxis: Recommended duration is 7 days (after last known exposure). For control of outbreaks in institutional settings (e.g., long-term care facilities for older adults and children) and hospitals, CDC recommends antiviral chemoprophylaxis of exposed residents with oral oseltamivir or inhaled zanamivir for a minimum of 2 weeks and continuing up to 1 week after the last known case was identified. Antiviral chemoprophylaxis is recommended for all residents, including those who have received influenza vaccination. For control of some institutional influenza outbreaks, post-exposure antiviral treatment has been used (e.g., oseltamivir twice daily for 5 days) instead of post-exposure antiviral chemoprophylaxis (Uyeki, 2019). Baloxavir is approved for post-exposure prophylaxis (single dose) of influenza in persons aged 5 years and older within 48 hours of contact with an individual with influenza.

Dosing in Adult Patients with Renal Impairment

Dose adjustment of oseltamivir is recommended for patients with creatinine clearance between 10 and 60 mL/min and patients with end-stage renal disease (ESRD) undergoing hemodialysis or continuous peritoneal dialysis receiving oseltamivir for the treatment or chemoprophylaxis of influenza. Oseltamivir is not recommended for patients with ESRD not undergoing dialysis. The recommended doses are detailed in Table 3; duration of treatment and chemoprophylaxis is the same as recommended for patients with normal renal function. The dose of intravenous peramivir should be reduced for patients with baseline creatinine clearance below 50 mL/min (see Table 3).

No dose adjustment is recommended for inhaled zanamivir for a 5-day course of treatment for patients with renal impairment. Pharmacokinetic analysis did not identify a clinically meaningful effect of renal function on the pharmacokinetics of baloxavir in patients with creatinine clearance 50 mL/min and above. The effects of severe renal impairment on the pharmacokinetics of baloxavir marboxil or its active metabolite, baloxavir, have not been evaluated.

SEASONAL INFLUENZA

Table 3. Recommended Oseltamivir and Peramivir Dose Adjustments for Treatment or Chemoprophylaxis of Influenza in Adult Patients with Renal Impairment or End Stage Renal Disease (ESRD) on Dialysis*

	Creatinine Clearance	Recommended Treatment Regimen	Recommended Chemoprophylaxis Regimen
Oral Oseltamivir[1]	Creatinine clearance 61 to 90 mL/min	75 mg twice a day	75 mg once daily
	Creatinine clearance 31 to 60 mL/min	30 mg twice a day	30 mg once daily
	Creatinine clearance 11 to 30 mL/min	30 mg once daily	30 mg every other day
	ESRD Patients on Hemodialysis Creatinine clearance ≤10 mL/min	30 mg after every hemodialysis cycle. Treatment duration not to exceed 5 days[2]	30 mg after alternate hemodialysis cycles[3]
	ESRD Patients on Continuous Ambulatory Peritoneal Dialysis[4] Creatinine clearance ≤10 mL/min	A single 30 mg dose administered immediately after a dialysis exchange	30 mg once weekly immediately after dialysis exchange
Intravenous Peramivir (single dose)[5]	Creatinine clearance ≥50 mL/min	600 mg	N/A
	Creatinine clearance 30 to 49 mL/min	200 mg	N/A
	Creatinine clearance 10 to 29 mL/min	100 mg	N/A
	ESRD Patients on Hemodialysis	Dose administered after dialysis at a dose adjusted based on creatinine clearance	

Table 3 Resources

Abbreviations: N/A = approved, not recommended

1. Renal dosing of oseltamivir is not available in the package insert for pediatric patients. However, these tables may be useful for children who qualify for adult doses based on weight >40 kg.
2. Assuming 3 hemodialysis sessions are performed in the 5- day period. Treatment can be initiated immediately if influenza symptoms develop during the 48 hours between hemodialysis sessions; however, the post-hemodialysis dose should still be administered independently of time of administration of the initial dose.
3. An initial dose can be administered prior to the start of dialysis.
4. Data derived from studies in continuous ambulatory peritoneal dialysis (CAPD) patients.
5. Renal dosing from peramivir package insert is available for pediatric patients: Creatinine clearance ≥50 mL/min: 12 mg/kg (up to maximum dose of 600 mg); Creatinine clearance 30 to 49 mL/min: 4 mg/kg; Creatinine clearance 10 to 29 mL/min: 2 mg/kg.

Last Reviewed: December 8, 2023

Pneumococcal Disease

OCTOBER 31, 2024

About Pneumococcal Disease

KEY POINTS

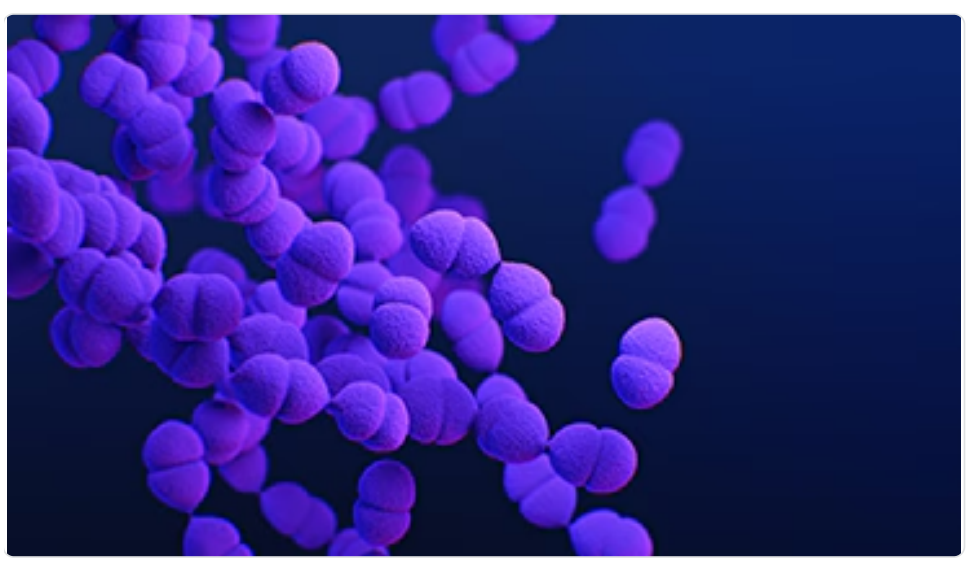
- Pneumococcal disease is a serious bacterial infection caused by *Streptococcus pneumoniae*.
- Anyone can get pneumococcal disease, but certain people are at increased risk.
- Keeping up to date with recommended vaccines is the best protection against pneumococcal disease.

MORE INFORMATION

For Everyone | Health Care Providers | Public Health

What it is

Pneumococcal disease is a name for any infection caused by bacteria called *Streptococcus pneumoniae*, or pneumococcus.



This image of *Streptococcus pneumoniae* was computer generated.

Types

S. pneumoniae bacteria can cause many types of infections, including:

- Pneumonia (lung infection)
- Meningitis (infection of the lining of the brain and spinal cord)
- Bacteremia (bloodstream infection)
- Otitis media (middle ear infection)
- Sinusitis (sinus infection)

Symptoms

Symptoms and complications depend on the part of the body that's infected.

Keep Reading:

Symptoms and Complications

Risk factors

Anyone can get pneumococcal disease, but some people are at increased risk.

Keep Reading:
Risk Factors

How it spreads

People spread pneumococcal bacteria to others through **direct contact with respiratory secretions**, like saliva or mucus.

Keep Reading:
Causes and Spread

Prevention

People can get pneumococcal disease **more than once**.

Healthcare providers generally don't prescribe antibiotics after exposure to help prevent someone from getting a pneumococcal infection.

However, there are steps people can take to help protect themselves.

Vaccination

Vaccination is the **best way to prevent** pneumococcal disease. CDC recommends pneumococcal vaccination for

- All children younger than 5 years old
- People 5 through 49 years old with certain risk conditions
- Adults 50 years or older

Keep Reading:
Pneumococcal Vaccination

Testing and diagnosis

Serious infections

If healthcare providers suspect meningitis or a bloodstream infection, they will collect samples of **cerebrospinal fluid or blood**. Cerebrospinal fluid is the fluid that surrounds the brain and spinal cord.

They then send the samples to a laboratory for testing. Growing the bacteria in a laboratory helps identify the specific type of bacteria causing the infection. Laboratories may also use molecular detection methods to test for these bacteria in samples. Knowing the cause helps healthcare providers choose the right treatment, including which antibiotic will work best.

Healthcare providers can use a **urine test** to help make a diagnosis of pneumococcal pneumonia in adults.

Mild infections

Healthcare providers usually diagnose ear and sinus infections based on a **history and physical exam** findings that support pneumococcal infection.

Treatment

Healthcare providers use **antibiotics** to treat pneumococcal disease. However, some pneumococcal bacteria have become resistant to certain antibiotics used to treat these infections. Antibiotic testing shows which antibiotics will be most successful at treating the infection.

Keep Reading:

Antibiotic-resistant *S. pneumoniae*

Resources and tools

Pneumococcal-specific resources

Pneumococcal vaccines for children

Pneumococcal disease in adults and the vaccines to prevent it

General resources

Be Antibiotics Aware

Meningitis

Pneumonia

SOURCES

CONTENT SOURCE:
National Center for Immunization and Respiratory Diseases; Division of Bacterial Diseases

OCTOBER 26, 2024

Pneumococcal Vaccination

KEY POINTS

- CDC recommends pneumococcal vaccination for people based on their age or if they have certain risk conditions.
- Pneumococcal vaccines are the best way to protect against serious pneumococcal infections.
- Talk to a vaccine provider if you have questions about pneumococcal vaccines.

Overview

There are 2 types of pneumococcal vaccines used in the United States:

- Pneumococcal conjugate vaccines (PCVs)
- Pneumococcal polysaccharide vaccine

Keep Reading:
Types of Pneumococcal Vaccines

Why getting vaccinated is important

Pneumococcal disease is common in young children, but older adults are at greatest risk of serious illness and death. Pneumococcal vaccines help protect against pneumococcal infections, including invasive disease.

Invasive disease means the bacteria invade parts of the body, such as blood, that are normally free from germs. Invasive disease is usually very serious and can sometimes result in death.

Keep Reading:
About Pneumococcal Disease

Who should and shouldn't get vaccinated

Vaccine recommendations

CDC recommends pneumococcal vaccination for

- **Children**
  - All children younger than 5 years old
  - Children 5 through 18 years old with certain risk conditions
- **Adults**
  - All adults 50 years or older
  - 19 through 49 years old with certain risk conditions

Allergies, reactions: Talk with a vaccine provider

Talk to a vaccine provider about your vaccination history and a specific vaccine's ingredients. There may be times when someone shouldn't get a pneumococcal vaccine.

Someone shouldn't get PCV15, PCV20, or PCV21 if they:

- Had a life-threatening allergic reaction after any type of PCV
- Had a life-threatening allergic reaction to any vaccine containing diphtheria toxoid
  - DTaP is an example
- Have a severe allergy to any part of these vaccines

Someone shouldn't get PPSV23 if they:

- Are younger than 2 years old
- Had a life-threatening allergic reaction after getting PPSV23
- Have a severe allergy to any part of PPSV23

Feeling sick?

Generally, vaccination is fine during mild illnesses like a cold. A vaccine provider can advise on whether to get vaccinated or wait until you feel better.

How well they work

Vaccines that help protect against pneumococcal disease work well but cannot prevent all cases.

Keep Reading:
How Well Pneumococcal Vaccines Work

Possible side effects

Most people who get a pneumococcal vaccine don't have any serious problems with it. Like with medicines, there is a chance of side effects with vaccines. These are usually mild and go away on their own within a few days, but serious reactions are possible.

Mild problems

PCV15, PCV20, or PCV21	• Redness, swelling, pain, or tenderness where the vaccine provider gave the shot • Fever or chills • Loss of appetite • Fussiness (irritability) in young children • Feeling tired • Headache • Muscle aches or joint pain
PPSV23	• Redness or pain where the vaccine provider gave the shot • Feeling tired • Fever • Muscle aches

If these problems occur, they usually go away within about 2 days.

Keep Reading:
Safety Information for Pneumococcal Vaccines

Finding and paying for vaccines

Vaccination locations

Children

Pneumococcal vaccination is part of the routine childhood immunization schedule. Therefore, pneumococcal vaccines are regularly available for children at:

- Pediatric and family practice offices
- Community health clinics
- Public health departments

Adults

For adults, a healthcare provider's office or pharmacy are usually the best places to receive recommended vaccines. If your healthcare providerC doesn't have pneumococcal vaccines, ask for a referral.

Federally funded health centers can also provide services if you don't have a regular source of health care. Locate one near you.

You can also contact your health department to learn more about where to get vaccines in your community.

Vaccine costs

There are several ways to cover the cost of a pneumococcal vaccine:

Private health insurance

Most private health insurance plans cover this vaccine. Check with your insurance provider for cost information and for a list of in-networkC vaccine providers.

Vaccines for Children program

The Vaccines for Children (VFC) program provides vaccines to children whose parents or guardians may not be able to afford them.

Resources

Vaccine schedules

Parent-friendly schedule for children (birth through 6 years)

Parent-friendly schedule for children (7 through 18 years)

Easy-to-read schedule for adults (19 years and older)

Pneumococcal Vaccine Information Statements

PCV: English | Other languages

PPSV23: English | Other languages

Vaccine requirements

Pneumococcal conjugate vaccine mandates for children in child care facilities

Other resources

Adult vaccine assessment tool: What vaccines do you need?

Cochlear implants and vaccination recommendations

Pneumococcal disease in adults and vaccines to prevent it

SOURCES

CONTENT SOURCE:
National Center for Immunization and Respiratory Diseases; Division of Bacterial Diseases

Pneumococcal Vaccine Timing for Adults

Make sure your patients are up to date with pneumococcal vaccination.

Adults ≥50 years old
Complete pneumococcal vaccine schedules

Prior vaccines	Option A	Option B
None*	**PCV20 or PCV21**	**PCV15** → ≥1 year[†] → **PPSV23**[¶]
PPSV23 only at any age	≥1 year → **PCV20 or PCV21**	≥1 year → **PCV15**
PCV13 only at any age	≥1 year → **PCV20 or PCV21**	NO OPTION B
PCV13 at any age & **PPSV23** at <65 yrs	≥5 years → **PCV20 or PCV21**	

* Also applies to people who received PCV7 at any age and no other pneumococcal vaccines
[¶] If PPSV23 is not available, PCV20 or PCV21 may be used
[†] Consider minimum interval (8 weeks) for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak (CSF) leak
[§] For adults with an immunocompromising condition, cochlear implant, or CSF leak, the minimum interval for PPSV23 is ≥8 weeks since last PCV13 dose and ≥5 years since last PPSV23 dose; for others, the minimum interval for PPSV23 is ≥1 year since last PCV13 dose and ≥5 years since last PPSV23 dose

Shared clinical decision-making for those who already completed the series with PCV13 and PPSV23

Prior vaccines	Shared clinical decision-making option for adults ≥65 years old
Complete series: PCV13 at any age & **PPSV23** at ≥65 yrs	≥5 years → **PCV20 or PCV21** — Together, with the patient, vaccine providers **may choose** to administer PCV20 or PCV21 to adults ≥65 years old who have already received PCV13 (but not PCV15, PCV20, or PCV21) at any age and PPSV23 at or after the age of 65 years old.

www.cdc.gov/pneumococcal/index.html

U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

Adults 19–49 years old with specified immunocompromising conditions
Complete pneumococcal vaccine schedules

Prior vaccines	Option A	Option B
None*	**PCV20 or PCV21**	**PCV15** → ≥8 weeks → **PPSV23**¶
PPSV23 only	≥1 year → **PCV20 or PCV21**	≥1 year → **PCV15**
PCV13 only	≥1 year → **PCV20 or PCV21**	NO OPTION B
PCV13 and **1 dose of PPSV23**	≥5 years → **PCV20 or PCV21**	
PCV13 and **2 doses of PPSV23**	≥5 years → **PCV20 or PCV21**	**No vaccines** recommended at this time. Review pneumococcal vaccine recommendations again when your patient turns 50 years old.
Immunocompromising conditions	▪ Chronic renal failure ▪ Congenital or acquired asplenia ▪ Congenital or acquired immunodeficiency§ ▪ Generalized malignancy ▪ HIV infection ▪ Hodgkin disease ▪ Iatrogenic immunosuppression¶ ▪ Leukemia ▪ Lymphoma ▪ Multiple myeloma ▪ Nephrotic syndrome ▪ Sickle cell disease/other hemoglobinopathies ▪ Solid organ transplant	

* Also applies to people who received PCV7 at any age and no other pneumococcal vaccines
¶ If PPSV23 is not available, PCV20 or PCV21 may be used
† The minimum interval for PPSV23 is ≥8 weeks since last PCV13 dose and ≥5 years since last PPSV23 dose
§ Includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease)
¶ Includes diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy

Adults 19–49 years old with a cochlear implant or cerebrospinal fluid leak
Complete pneumococcal vaccine schedules

Prior vaccines	Option A	Option B
None*	**PCV20 or PCV21**	**PCV15** → ≥8 weeks → **PPSV23¶**
PPSV23 only	≥1 year → **PCV20 or PCV21**	≥1 year → **PCV15**
PCV13 only	≥1 year → **PCV20 or PCV21**	NO OPTION B
PCV13 and **1 dose of PPSV23**	≥5 years → **PCV20 or PCV21**	**No vaccines** recommended at this time. Review pneumococcal vaccine recommendations again when your patient turns 50 years old.

* Also applies to people who received PCV7 at any age and no other pneumococcal vaccines

¶ If PPSV23 is not available, PCV20 or PCV21 may be used

Adults 19–49 years old with chronic health conditions
Complete pneumococcal vaccine schedules

Prior vaccines	Option A	Option B
None*	**PCV20 or PCV21**	**PCV15** → ≥1 year → **PPSV23**¶
PPSV23 only	≥1 year → **PCV20 or PCV21**	≥1 year → **PCV15**
PCV13† **only**	≥1 year → **PCV20 or PCV21**	NO OPTION B
PCV13† and **PPSV23**	**No vaccines** are recommended at this time. Review pneumococcal vaccine recommendations again when your patient turns 50 years old.	
Chronic health conditions	▪ Alcoholism ▪ Chronic heart disease, including congestive heart failure and cardiomyopathies ▪ Chronic liver disease	▪ Chronic lung disease, including chronic obstructive pulmonary disease, emphysema, and asthma ▪ Cigarette smoking ▪ Diabetes mellitus

* Also applies to people who received PCV7 at any age and no other pneumococcal vaccines
¶ If PPSV23 is not available, PCV20 or PCV21 may be used
† Adults with chronic medical conditions were previously not recommended to receive PCV13

Shared Clinical Decision-Making

PCV20 or PCV21 Vaccination for Adults 65 Years or Older

Adults 65 years of age or older have the option to receive supplemental PCV20 or PCV21 (not both) if they previously completed the pneumococcal vaccine series with both PCV13 and PPSV23 and meet the following criteria:

- Previously received one dose of PCV13 (but not PCV15, PCV20, or PCV21) at any age, and
- Previously received all recommended doses of PPSV23 (including 1 dose of PPSV23 at or after 65 years of age)

The determination to administer PCV20 or PCV21 is based on a shared clinical decision-making (SCDM) process between a patient and their health care provider. SCDM recommendations are optional and informed by the characteristics, values, and preferences of the patient, and the clinical discretion of the health care provider.

If you discuss supplemental PCV20 or PCV21 vaccination with a patient 65 years of age or older who previously completed the pneumococcal vaccine series with both PCV13 and PPSV23:

Remember:

PCV20 or PCV21 is not routinely recommended for these individuals as their risk of disease is lower due to prior vaccinations. Their remaining risk depends on:

- Their risk of exposure to serotypes contained in PCV20 or PCV21
- The presence of underlying medical conditions or other risk factors that increase the risk of developing severe disease
- Time since last pneumococcal vaccination (i.e., 5 or more years)

Consider:

Increased risk of exposure to PCV20 or PCV21 serotypes may occur among people who are living in:

- Nursing homes or other long-term care facilities
- Areas with low pediatric pneumococcal conjugate vaccine uptake

If exposed, people with one or more of the following health issues are at increased risk of developing severe pneumococcal disease:

- Immunocompromising condition*
- Cochlear implant
- Cerebrospinal fluid leak
- One or more of these chronic medical conditions: alcoholism; chronic heart, liver, or lung disease; cigarette smoking; or diabetes

Protection against disease from both PCV13 and PPSV23 is expected to decrease over time.

If you vaccinate:

If you and your patient decide PCV20 or PCV21 is appropriate, give one dose of PCV20 or PCV21 (no preference) at least 5 years after the patient's last pneumococcal vaccine dose.

PCV20 and PCV21 should not be administered to a patient who has had a severe allergic reaction (e.g., anaphylaxis) to a:

- Previous dose of PCV
- Component of the vaccine
- Vaccine containing diphtheria toxoid
- Component of a vaccine containing diphtheria-toxoid

*Chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, HIV, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplant, congenital or acquired asplenia, sickle cell disease or other hemoglobinopathies.

Additional Information:

CDC Adult Immunization Schedule by Age:
www.cdc.gov/vaccines/hcp/imz-schedules/adult-age.html

CDC PneumoRecs VaxAdvisor App for Vaccine Providers:
www.cdc.gov/pneumococcal/hcp/vaccine-recommendations/app.html

CDC Pneumococcal Vaccine Recommendations:
www.cdc.gov/pneumococcal/hcp/vaccine-recommendations/index.html

ACIP Contraindications Guidelines for Immunization:
www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html

Pneumococcal Conjugate Vaccine: *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Pneumococcal conjugate vaccine can prevent **pneumococcal disease**.

Pneumococcal disease refers to any illness caused by pneumococcal bacteria. These bacteria can cause many types of illnesses, including pneumonia, which is an infection of the lungs. Pneumococcal bacteria are one of the most common causes of pneumonia.

Besides pneumonia, pneumococcal bacteria can also cause:

- Ear infections
- Sinus infections
- Meningitis (infection of the tissue covering the brain and spinal cord)
- Bacteremia (infection of the blood)

Anyone can get pneumococcal disease, but children under 2 years old, people with certain medical conditions or other risk factors, and adults 65 years or older are at the highest risk.

Most pneumococcal infections are mild. However, some can result in long-term problems, such as brain damage or hearing loss. Meningitis, bacteremia, and pneumonia caused by pneumococcal disease can be fatal.

2. Pneumococcal conjugate vaccine

Pneumococcal conjugate vaccine helps protect against bacteria that cause pneumococcal disease. There are three pneumococcal conjugate vaccines (PCV13, PCV15, and PCV20). The different vaccines are recommended for different people based on age and medical status. Your health care provider can help you determine which type of pneumococcal conjugate vaccine, and how many doses, you should receive.

Infants and young children usually need 4 doses of pneumococcal conjugate vaccine. These doses are recommended at 2, 4, 6, and 12–15 months of age.

Older children and adolescents might need pneumococcal conjugate vaccine depending on their age and medical conditions or other risk factors if they did not receive the recommended doses as infants or young children.

Adults 19 through 64 years old with certain medical conditions or other risk factors who have not already received pneumococcal conjugate vaccine should receive pneumococcal conjugate vaccine.

Adults 65 years or older who have not previously received pneumococcal conjugate vaccine should receive pneumococcal conjugate vaccine.

Some people with certain medical conditions are also recommended to receive pneumococcal polysaccharide vaccine (a different type of pneumococcal vaccine, known as PPSV23). Some adults who have previously received a pneumococcal conjugate vaccine may be recommended to receive another pneumococcal conjugate vaccine.

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

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of any type of pneumococcal conjugate vaccine (PCV13, PCV15, PCV20, or an earlier pneumococcal conjugate vaccine known as PCV7), or to any vaccine containing diphtheria toxoid** (for example, DTaP), or has any **severe, life-threatening allergies**

In some cases, your health care provider may decide to postpone pneumococcal conjugate vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Redness, swelling, pain, or tenderness where the shot is given, and fever, loss of appetite, fussiness (irritability), feeling tired, headache, muscle aches, joint pain, and chills can happen after pneumococcal conjugate vaccination.

Young children may be at increased risk for seizures caused by fever after a pneumococcal conjugate vaccine if it is administered at the same time as inactivated influenza vaccine. Ask your health care provider for more information.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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**.

Pneumococcal Polysaccharide Vaccine (PPSV23): *What You Need to Know*

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Pneumococcal polysaccharide vaccine (PPSV23) can prevent **pneumococcal disease**.

Pneumococcal disease refers to any illness caused by pneumococcal bacteria. These bacteria can cause many types of illnesses, including pneumonia, which is an infection of the lungs. Pneumococcal bacteria are one of the most common causes of pneumonia.

Besides pneumonia, pneumococcal bacteria can also cause:
- Ear infections
- Sinus infections
- Meningitis (infection of the tissue covering the brain and spinal cord)
- Bacteremia (bloodstream infection)

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

Most pneumococcal infections are mild. However, some can result in long-term problems, such as brain damage or hearing loss. Meningitis, bacteremia, and pneumonia caused by pneumococcal disease can be fatal.

2 PPSV23

PPSV23 protects against 23 types of bacteria that cause pneumococcal disease.

PPSV23 is recommended for:
- All **adults 65 years or older**,
- Anyone **2 years or older with certain medical conditions that can lead to an increased risk for pneumococcal disease**.

Most people need only one dose of PPSV23. A second dose of PPSV23, and another type of pneumococcal vaccine called PCV13, are recommended for certain high-risk groups. Your health care provider can give you more information.

People 65 years or older should get a dose of PPSV23 even if they have already gotten one or more doses of the vaccine before they turned 65.

3 Talk with your health care provider

Tell your vaccine provider if the person getting the vaccine:
- Has had an **allergic reaction after a previous dose of PPSV23**, or has any **severe, life-threatening allergies**.

In some cases, your health care provider may decide to postpone PPSV23 vaccination to a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting PPSV23.

Your health care provider can give you more information.

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

4 Risks of a vaccine reaction

- Redness or pain where the shot is given, feeling tired, fever, or muscle aches can happen after PPSV23.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5 What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff do not give medical advice.*

6 How can I learn more?

- Ask your health care provider.
- 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
PPSV23 Vaccine

Office use only

10/30/2019

Shingles (Herpes Zoster)

SHINGLES (HERPES ZOSTER)

Vaccines and Preventable Diseases

Shingles Vaccination

What Everyone Should Know about the Shingles Vaccine (Shingrix)

Shingles vaccination is the only way to protect against shingles and postherpetic neuralgia (PHN), the most common complication from shingles.

CDC recommends that adults 50 years and older get two doses of the shingles vaccine called Shingrix (recombinant zoster vaccine) to prevent shingles and the complications from the disease. Adults 19 years and older who have weakened immune systems because of disease or therapy should also get two doses of Shingrix, as they have a higher risk of getting shingles and related complications.

Your doctor or pharmacist can give you Shingrix as a shot in your upper arm.

Shingrix provides strong protection against shingles and PHN. In adults 50 years and older who have healthy immune systems, Shingrix is more than 90% effective at preventing shingles and PHN. Immunity stays strong for at least the first 7 years after vaccination. In adults with weakened immune systems, studies show that Shingrix is 68%-91% effective in preventing shingles, depending on the condition that affects the immune system.

Who Should Get Shingrix?

Adults 50 years and older should get two doses of Shingrix, separated by 2 to 6 months. Adults 19 years and older who have or will have weakened immune systems because of disease or therapy should also get two doses of Shingrix. If needed, people with weakened immune systems can get the second dose 1 to 2 months after the first.

You should get Shingrix even if in the past you:

- Had shingles
- Received Zostavax*
- Received varicella (chickenpox) vaccine

There is no maximum age for getting Shingrix.

SHINGLES (HERPES ZOSTER)

If you had shingles in the past, Shingrix can help prevent future occurrences of the disease. There is no specific length of time that you need to wait after having shingles before you can receive Shingrix, but generally you should make sure the shingles rash has gone away before getting vaccinated.

Chickenpox and shingles are related because they are caused by the same virus (varicella-zoster virus). After a person recovers from chickenpox, the virus stays dormant (inactive) in the body. It can reactivate years later and cause shingles.

- You can get Shingrix whether or not you remember having had chickenpox in the past.
- More than 99% of Americans born on or before 1980 have had chickenpox, even if they don't remember having the disease.
- Adults with weakened immune systems and no documented history of chickenpox disease, chickenpox vaccination, or shingles should talk to their healthcare provider, who can refer to the CDC Clinical Considerations for Use of Recombinant Zoster Vaccine (RZV, Shingrix) in Immunocompromised Adults Aged ≥19 Years | CDC and Chickenpox (Varicella) Vaccination | CDC for further guidance.

Shingrix is available in doctor's offices and pharmacies.

If you have questions about Shingrix, talk with your healthcare provider.

* *A shingles vaccine called zoster vaccine live (Zostavax) is no longer available for use in the United States, as of November 18, 2020. If you had Zostavax in the past, you should still get Shingrix. Talk to your healthcare provider to determine the best time to get Shingrix.*

The side effects of Shingrix are temporary, and usually last 2 to 3 days. While you may experience pain for a few days after getting Shingrix, the pain will be less severe than having shingles and the complications from the disease.

Who Should Not Get Shingrix?

You should not get Shingrix if you:

- Have ever had a severe allergic reaction to any component of the vaccine or after a dose of Shingrix.
- Currently have shingles.
- Currently are pregnant. Women who are pregnant should wait to get Shingrix.

If you have a minor illness, such as a cold, you may get Shingrix. But if you have a moderate or severe illness, with or without fever, you should usually wait until you recover before getting the vaccine.

How Well Does Shingrix Work?

Two doses of Shingrix provide strong protection against shingles and postherpetic neuralgia (PHN), the most common complication of shingles.

SHINGLES (HERPES ZOSTER)

- In adults 50 to 69 years old with healthy immune systems, Shingrix was 97% effective in preventing shingles; in adults 70 years and older, Shingrix was 91% effective.
- In adults 50 years and older, Shingrix was 91% effective in preventing PHN; in adults 70 years and older, Shingrix was 89% effective.
- In adults with weakened immune systems, Shingrix was between 68% and 91% effective in preventing shingles, depending on their underlying immunocompromising condition.

In people 70 years and older who had healthy immune systems, Shingrix immunity remained high throughout 7 years following vaccination.

What Are the Possible Side Effects of Shingrix?

Studies show that Shingrix is safe. The vaccine helps your body create a strong defense against shingles. As a result, you are likely to have temporary side effects from getting the shots. The side effects might affect your ability to do normal daily activities for 2 to 3 days.

Most people got a sore arm with mild or moderate pain after getting Shingrix, and some also had redness and swelling where they got the shot. Some people felt tired, had muscle pain, a headache, shivering, fever, stomach pain, or nausea. Some people who got Shingrix experienced side effects that prevented them from doing regular activities. Symptoms went away on their own in about 2 to 3 days. Side effects were more common in younger people.

You might have a reaction to the first or second dose of Shingrix, or both doses. If you experience side effects, you may choose to take over-the-counter pain medicine such as ibuprofen or acetaminophen.

Guillain-Barré syndrome (GBS), a serious nervous system disorder, has been reported very rarely after Shingrix. There is also a very small increased risk of GBS after having shingles.

If you experience side effects from Shingrix, you should report them to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS website, or by calling 1-800-822-7967.

If you have any questions about side effects from Shingrix, talk with your doctor.

When Should I See a Doctor Because of the Side Effects I Experience from Shingrix?

Shingrix causes a strong response in your immune system, so it may produce short-term side effects. These side effects can be uncomfortable, but they are expected and usually go away on their own in 2 or 3 days. You may choose to take over-the-counter pain medicine such as ibuprofen or acetaminophen. Contact your healthcare provider if the symptoms are not improving or if they are getting worse.

In clinical trials, Shingrix was not associated with serious adverse events. In fact, serious side effects from vaccines are extremely rare. For example, for every 1 million doses of a vaccine given, only one or two people might have a severe

SHINGLES (HERPES ZOSTER)

allergic reaction. Signs of an allergic reaction happen within minutes or hours after vaccination and include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness. If you experience these or any other life-threatening symptoms, see a doctor right away.

How Can I Pay for Shingrix?

There are several ways shingles vaccine may be paid for:

Medicare

- Starting in 2023, people with Medicare Part D coverage will pay nothing out-of-pocket for the Shingrix vaccine.

Medicaid

- Medicaid may or may not cover the vaccine. Contact your insurer to find out.

SHINGLES (HERPES ZOSTER)

Vaccines and Preventable Diseases

Shingrix Recommendations

For the recommendations of the Advisory Committee on Immunization Practices (ACIP), see Shingrix (recombinant zoster vaccine) Recommendations

Summary of Recommendations

Routine Vaccination of People 50 Years Old and Older

CDC recommends Shingrix (recombinant zoster vaccine, or RZV) for the prevention of herpes zoster (shingles) and related complications. CDC recommends two doses of Shingrix separated by 2 to 6 months for immunocompetent adults aged 50 years and older:

- Whether or not they report a prior episode of herpes zoster.
- Whether or not they report a prior dose of Zostavax, a shingles vaccine that is no longer available for use in the United States.
- It is not necessary to screen, either verbally or by laboratory serology, for evidence of prior varicella.

Recombinant and adjuvanted vaccines, such as Shingrix, can be administered concomitantly, at different anatomic sites, with other adult vaccines, including COVID-19 vaccines. Coadministration of RZV with adjuvanted influenza vaccine (Fluad) and COVID-19 vaccines is being studied.

Vaccination of Immunocompromised Adults 19 Years and Older

CDC recommends two doses of RZV for the prevention of shingles and related complications in adults aged ≥19 years who are or will be immunodeficient or immunosuppressed because of disease or therapy. The second dose of RZV should typically be given 2–6 months after the first. However, for persons who are or will be immunodeficient or immunosuppressed and who would benefit from completing the series in a shorter period, the second dose can be administered 1–2 months after the first. For more detailed clinical guidance see www.cdc.gov/vaccines/vpd/shingles/hcp/immunocompromised-adults.html.

Timing Considerations for Giving Shingrix

For patients who previously had herpes zoster

There is no specific amount of time you need to wait before administering Shingrix to patients who have had herpes zoster. However, you should not give Shingrix to patients who are experiencing an acute episode of herpes zoster.

SHINGLES (HERPES ZOSTER)

For patients who previously received Zostavax

Zostavax is no longer available for use in the United States, as of November 18, 2020. Consider the patient's age and when he or she received Zostavax to determine when to vaccinate with Shingrix. Studies examined the safety of Shingrix vaccination 5 or more years after Zostavax vaccination. Shorter intervals were not studied, but there are no theoretical or data concerns to indicate that Shingrix would be less safe or effective if administered less than 5 years after a patient received Zostavax.

You may consider an interval shorter than 5 years between Zostavax and Shingrix based on the age at which the patient received Zostavax. Differences in efficacy between Shingrix and Zostavax are most pronounced among older patients. Studies have shown that the effectiveness of Zostavax wanes substantially over time, leaving recipients with reduced protection against herpes zoster. For example, the vaccine efficacy among adults aged 70 to 79 years and adults aged 80 years and older is 41% and 18%, respectively, on average during the first 3 years following Zostavax vaccination.

You should wait at least 8 weeks after a patient received Zostavax to administer Shingrix.

For patients who do not report a prior episode of varicella

When vaccinating immunocompetent adults aged 50 years and older, there is no need to screen for a history of varicella (chickenpox) or to conduct laboratory testing for serologic evidence of prior varicella. More than 99% of adults aged 50 years and older worldwide have been exposed to varicella-zoster virus, and the Advisory Committee on Immunization Practices (ACIP) considers people born in the United States prior to 1980 immune to varicella. Therefore, even if a person does not recall having chickenpox, serologic testing for varicella immunity is not recommended. It is often a barrier to herpes zoster vaccination, and false negatives are common. However, if serologic evidence of varicella susceptibility becomes available to the healthcare provider, providers should follow ACIP guidelines for varicella vaccination. Shingrix has not been evaluated in persons who are seronegative to varicella, and it is not indicated for the prevention of varicella.

For adults 19 years of age and older who are or will be immunocompromised, see www.cdc.gov/vaccines/vpd/shingles/hcp/immunocompromised-adults.html.

Contraindications and Precautions for Herpes Zoster Vaccination

Shingrix should **not** be administered to:

- A person with a history of severe allergic reaction, such as anaphylaxis, to any component of this vaccine.
- A person experiencing an acute episode of herpes zoster. Shingrix is not a treatment for herpes zoster or postherpetic neuralgia (PHN). The general guidance for any vaccine is to wait until the acute stage of the illness is over and symptoms abate.

There is currently no CDC recommendation for Shingrix use in pregnancy; therefore, providers should consider delaying vaccination until after pregnancy. There is no recommendation for pregnancy testing before vaccination with Shingrix. Recombinant vaccines such as Shingrix pose no known risk to people who are breastfeeding or to their infants. Providers may consider vaccination without regard to breastfeeding status if Shingrix is otherwise indicated.

SHINGLES (HERPES ZOSTER)

Adults with a minor acute illness, such as a cold, can receive Shingrix. Adults with a moderate or severe acute illness should usually wait until they recover before getting the vaccine.

To learn more, see Contraindications and Precautions, General Best Practice Guidelines for Immunization: Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP).

Your Patients Aged 50 Years and Older Are at Increased Risk for Herpes Zoster

Herpes zoster (HZ) is caused by reactivation of the latent **varicella-zoster virus (VZV)**. After initial exposure to VZV, resulting in chickenpox, the virus remains dormant and can reactivate later in life. The HZ rash is typically unilateral, in 1 or 2 adjacent dermatomes, on the torso or body. The rash progresses to form vesicles and usually resolves in 2 to 4 weeks.[1]

Overview of HZ

- **Up to 99.8% of people aged ≥50 years** have been infected with **VZV**[2]
- In about **1 out of 3** people during their lifetime, the dormant virus reactivates and causes **HZ**—a blistering rash that can be excruciatingly painful[1,3]
- Most people will have HZ only once; although recurrence is possible, that rate is unknown[1]

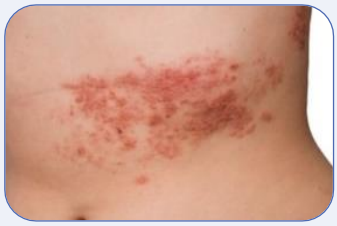


Image source: iStock Photo

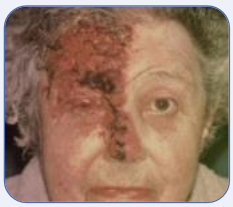
Risk factors for HZ:

- Natural decline in immunity due to[1]:
  - Increasing age (risk for HZ increases significantly after 50 years of age)
  - Immunocompromising conditions or therapies

Postherpetic neuralgia (PHN) is the most common complication of HZ[1,4,5]

- PHN is a pain that can last months to years after the rash has gone
- About 10–18% of patients with HZ develop PHN
- PHN is more common and severe in older patients

Additional complications of HZ[1,4]:



- HZ ophthalmicus (10–25% of patients)
- Possible increased short-term risk of acute cardiovascular events and stroke (based on multiple meta-analyses)[6-8]
- Disseminated HZ (nearly exclusive to immunocompromised patients)

Impact of HZ on Patients

Patients experience financial burden due to HZ[9,10]

- Based on an hourly wage rate of $20.32, a working patient with HZ is estimated to potentially lose approximately **$2,350 in income** on average due to work loss from[9]*:

Presenteeism
(i.e., being unproductive at work; 84.4 hours, on average)

Absenteeism
(31.6 hours, on average)

- Adjusted annual incremental healthcare cost of a HZ episode during a 12-month period was **$1,809** as an overall value for the HZ cohort vs. matched non-HZ controls and as high as **$7,291** for the PHN cohort vs. matched non-HZ controls[10]

Impact of HZ and PHN on Quality of Life

Data suggests that HZ interferes with quality of life[9,11]

- **Approximately 2 out of 3** adult patients with HZ surveyed reported an impact on everyday activities like shopping, work around the house, and socializing[9]*
- Pain during the acute phase of HZ can affect patients' lives across all **4 health domains**: physical, psychological, functional, and social[11]

Refer to the CDC's website to learn more about how you can help protect your patients against the reactivation of VZV.[1]

Footnote: *Data from a telephone survey of 153 working individuals with mean age of 56.6 ± 4.2 years in the United States estimating absenteeism- and presenteeism-related average work hours lost per episode of herpes zoster.[9]

Abbreviations: HZ=herpes zoster; PHN=postherpetic neuralgia.

References: 1. Centers for Disease Control and Prevention. Shingles (herpes zoster): clinical overview. https://www.cdc.gov/shingles/hcp/clinical-overview.html. Accessed September 29, 2022. **2.** Kilgore PE, et al. *J Med Virol.* 2003;70(Suppl 1):S111-S118. **3.** Kawai K, et al. *BMJ* Open. 2014;4(6):e004833. **4.** Harpaz R, et al. *MMWR Recomm Rep.* 2008;57(RR-5):1-30. **5.** Gudin J, et al. *J Manag Care Spec Pharm.* 2019;25(12):1387-1396. **6.** Erskine N, et al. *PLOS One.* 2017;12(7):e0181565. **7.** Liu X, et al. *PLoS One.* 2016;11(10):e0165203. **8.** Patterson BJ, et al. *Mayo Clin Proc.* 2019;94(5):763-75. **9.** Singhal PK, et al. *J Med Econ.* 2011;14(5):639-645. **10.** Meyers JL, et al. *Hum Vaccin Immunother.* 2017;13(8):1861-1872. **11.** Johnson RW, et al. *BMC Med.* 2010;8:37. **12.** Centers for Disease Control and Prevention. Vaccine needs assessment. https://www.cdc.gov/vaccines/hcp/adults/downloads/standards-immz-practice-assessment.pdf. Accessed September 29, 2022.

SHINGLES (HERPES ZOSTER)

Vaccines and Preventable Diseases

About the Vaccine

Shingrix Vaccine Composition

Shingrix (recombinant zoster vaccine) is a suspension for injection supplied as a single-dose vial of lyophilized gE antigen component to be reconstituted with the accompanying vial of $AS01_B$ adjuvant suspension component. A single dose after reconstitution is 0.5 mL. The shingles vaccine does not contain thimerosal (a preservative containing mercury).

Shingrix Vaccine Efficacy and Duration of Protection

Among immunocompetent adults 50 years and older, the efficacy of two doses of Shingrix for the prevention of herpes zoster (shingles) was high among all age groups. In a clinical trial of more than 30,000 participants, vaccine efficacy was 96.6% in adults aged 50 to 59 years, 97.4% in adults aged 60 to 69 years, and 91.3% in adults aged 70 years and older.

The efficacy of two doses of Shingrix for the prevention of postherpetic neuralgia (PHN) was high: 91.2% in adults aged 50 years and older, and 88.8% in adults aged 70 years and older.

Vaccine efficacy was estimated among several immunocompromised groups:

- 68.2% among adult autologous hematopoietic cell transplant recipients.
- 87.2% in a post hoc efficacy analysis of adult patients with hematologic malignancies.
- 90.5% in a post hoc efficacy analysis of adult patients with immune-mediated diseases who were not taking immunosuppressive medication.

In immunocompetent adults 70 years and older, vaccine efficacy remained high, at or above 84% in all 7 years after vaccination.

Side Effects and Counseling for Reactogenicity

In eight clinical trials of more than 10,000 immunocompetent participants 50 years or older, grade 3 reactions (vaccination-related reactions severe enough to prevent normal activities) were common after patients received Shingrix. About 1 out of 10 adults who received Shingrix reported grade 3 injection-site symptoms such as pain, redness, and swelling. Also, about 1 out of 10 reported grade 3 systemic reactions such as myalgia, fatigue, headache, shivering, fever, and gastrointestinal illness. Most people (78%) who got Shingrix reported at least some pain at the injection site.

SHINGLES (HERPES ZOSTER)

Local and systemic grade 3 reactions among immunocompromised adults were evaluated in six studies in five immunocompromised groups. Local grade 3 reactions occurred in 10.7% to 14.2% of RZV recipients, and systemic grade 3 reactions occurred in 9.9% to 22.3% of RZV recipients, compared with 0% to 0.3% and 6.0% to 15.5%, respectively, among placebo recipients. The most commonly reported systemic symptoms were fatigue and myalgia.

Healthcare providers should counsel patients about expected reactogenicity before administering Shingrix.

What to tell patients about the side effects of Shingrix:

Most people have a sore arm after they get Shingrix. Many people have redness and swelling on their arm spanning several inches where they got the shot. Many people also feel tired or have muscle pain, a headache, shivering, fever, stomach pain, or nausea.

About 1 out of 6 people had symptoms severe enough to prevent them from doing regular activities. Vaccine recipients should plan to avoid strenuous activities, such as yardwork or swimming, for a few days after vaccination.

Strongly recommend your patients get the second dose of the vaccine even if they experience these side effects to ensure maximum protection from shingles.

- If they have a reaction to the first dose of Shingrix, it does not necessarily mean they will have a reaction to the second dose.
- If they don't have a reaction to the first dose, they might or might not have a reaction to the second dose.
- Remind your patients that the pain from shingles can last a lifetime, and these side effects should only last 2 to 3 days.

Vaccine recipients may take over-the-counter pain medicine like ibuprofen or acetaminophen to ease discomfort from these side effects. It is not recommended to take these medications before vaccination.

Severe Allergic Reactions

Severe allergic reactions to Shingrix are very rare. 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.

Any adverse events following vaccination can be reported to the Vaccine Adverse Event Reporting System (VAERS). Reporting is encouraged for any clinically significant adverse event even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at VAERS website, or by calling 1-800-822-7967.

Considerations for Patients Who Previously Received Zostavax

Studies have not examined the safety and immunogenicity of Shingrix administered less than 5 years following Zostavax (zoster vaccine live) vaccination. However, there are no data or theoretical concerns to indicate that Shingrix would be less safe or less effective when given at an interval shorter than 5 years following Zostavax. Since the risk of herpes zoster increases with age, providers should weigh a patient's risk of herpes zoster with the age-specific protection expected from Zostavax to determine when to vaccinate with Shingrix.

Recombinant Zoster (Shingles) Vaccine: *What You Need to Know*

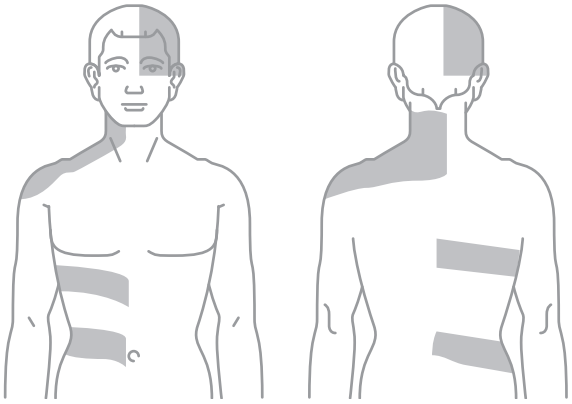
Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Recombinant zoster (shingles) vaccine can prevent **shingles**.

Shingles (also called herpes zoster, or just zoster) is a painful skin rash, usually with blisters. In addition to the rash, shingles can cause fever, headache, chills, or upset stomach. Rarely, shingles can lead to complications such as pneumonia, hearing problems, blindness, brain inflammation (encephalitis), or death.



The risk of shingles increases with age. The most common complication of shingles is long-term nerve pain called postherpetic neuralgia (PHN). PHN occurs in the areas where the shingles rash was and can last for months or years after the rash goes away. The pain from PHN can be severe and debilitating.

The risk of PHN increases with age. An older adult with shingles is more likely to develop PHN and have longer lasting and more severe pain than a younger person.

People with weakened immune systems also have a higher risk of getting shingles and complications from the disease.

Shingles is caused by varicella-zoster virus, the same virus that causes chickenpox. After you have chickenpox, the virus stays in your body and can cause shingles later in life. Shingles cannot be passed from one person to another, but the virus that causes shingles can spread and cause chickenpox in someone who has never had chickenpox or has never received chickenpox vaccine.

2. Recombinant shingles vaccine

Recombinant shingles vaccine provides strong protection against shingles. By preventing shingles, recombinant shingles vaccine also protects against PHN and other complications.

Recombinant shingles vaccine is recommended for:

- **Adults 50 years and older**
- **Adults 19 years and older who have a weakened immune system** because of disease or treatments

Shingles vaccine is given as a two-dose series. For most people, the second dose should be given 2 to 6 months after the first dose. Some people who have or will have a weakened immune system can get the second dose 1 to 2 months after the first dose. Ask your health care provider for guidance.

People who have had shingles in the past and people who have received varicella (chickenpox) vaccine are recommended to get recombinant shingles vaccine. The vaccine is also recommended for people who have already gotten another type of shingles vaccine, the live shingles vaccine. There is no live virus in recombinant shingles vaccine.

Shingles vaccine may be given at the same time as other vaccines.

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

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of recombinant shingles vaccine**, or has any **severe, life-threatening allergies**
- Is **currently experiencing an episode of shingles**
- Is **pregnant**

In some cases, your health care provider may decide to postpone shingles vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting recombinant shingles vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- A sore arm with mild or moderate pain is very common after recombinant shingles vaccine. Redness and swelling can also happen at the site of the injection.
- Tiredness, muscle pain, headache, shivering, fever, stomach pain, and nausea are common after recombinant shingles vaccine.

These side effects may temporarily prevent a vaccinated person from doing regular activities. Symptoms usually go away on their own in 2 to 3 days. You should still get the second dose of recombinant shingles vaccine even if you had one of these reactions after the first dose.

Guillain-Barré syndrome (GBS), a serious nervous system disorder, has been reported very rarely after recombinant zoster vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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**.

Respiratory Syncytial Virus (RSV)

RESPIRATORY SYNCYTIAL VIRUS (RSV)

Respiratory Syncytial Virus Infection (RSV)

AUGUST 30, 2024

RSV in Older Adults

WHAT TO KNOW

- RSV can be dangerous for older adults, especially those who have certain medical conditions, are elderly or frail, or live in a nursing home.
- CDC recommends everyone ages 75 and older get an RSV vaccine.
- CDC recommends adults ages 60–74 who are at increased risk of severe RSV disease get an RSV vaccine.
- If you have already gotten an RSV vaccine, you do not need to get another one at this time.

Overview

RSV can be dangerous for certain adults. Each year, an estimated 100,000–160,000 adults ages 60 and older in the United States are hospitalized due to RSV. Adults at highest risk for severe RSV disease include:

- Adults ages 75 and older
- Adults with chronic heart or lung disease
- Adults with weakened immune systems
- Adults with certain other underlying medical conditions, including some adults with diabetes or obesity
- Adults living in nursing homes

For the complete list of risk factors for severe RSV disease, see RSV Clinical Overview.

Spotlight

CDC's Respiratory Virus Guidance provides actions you can take to protect yourself and others from health risks caused by RSV and other respiratory viruses.

Severe RSV

When an adult gets RSV, they typically have mild cold-like symptoms, but some may develop pneumonia (an infection in the lungs). Adults who get very sick from RSV may need to be hospitalized. Severe RSV can be fatal for some adults.

RSV can sometimes also lead to worsening of serious conditions such as:

- Asthma
- Chronic obstructive pulmonary disease (COPD) – a chronic disease of the lungs that makes it hard to breathe
- Heart failure – when the heart can't pump enough blood and oxygen through the body

Adults 60 and older who are at increased risk include those with certain chronic medical conditions, those who are elderly or frail, and those living in nursing homes.

When to seek emergency care

Call your healthcare professional if you have difficulty breathing, have trouble eating or drinking, feel chest pain or pressure, experience sudden dizziness or confusion, or experience worsening of symptoms.

RESPIRATORY SYNCYTIAL VIRUS (RSV)

RSV vaccine for older adults

CDC recommends an RSV vaccine if you are ages 75 or older or if you are ages 60–74 and are at increased risk for severe RSV.

Vaccines for Older Adults

Information on vaccines to protect adults ages 60 and older against RSV.

AUG. 30, 2024

Resources

RSV in Older Adults Flyer

Flyer with information about RSV for older adults

Download or print PDF: English PDF | Español PDF

RESPIRATORY SYNCYTIAL VIRUS (RSV)

Respiratory Syncytial Virus Infection (RSV)

JUNE 5, 2024

ESPAÑOL

Symptoms of RSV

WHAT TO KNOW

- RSV usually causes mild, cold-like symptoms. Most RSV infections go away on their own.
- RSV can be serious for babies, some young children, and older adults.
- There is no treatment for RSV, but you can manage symptoms with over-the-counter medications.

Overview

People infected with RSV usually show symptoms within 4 to 6 days after getting infected. Symptoms of RSV infection usually include:

- Runny nose
- Decrease in appetite
- Coughing
- Sneezing
- Fever
- Wheezing

These symptoms usually appear in stages and not all at once.

When to seek emergency care

Call your healthcare professional if you are having difficulty breathing, not drinking enough fluids, or experiencing worsening symptoms.

Care

Antiviral medication is not routinely recommended to fight infection. Most RSV infections go away on their own in a week or two. However, RSV can cause severe illness in some people.

Take steps to relieve symptoms

- **Manage fever and pain** with over-the-counter fever reducers and pain relievers, such as acetaminophen or ibuprofen. (Never give aspirin to children.)
- **Drink enough fluids.** It is important for people with RSV infection to drink enough fluids to prevent dehydration (loss of body fluids).
- **Talk to your healthcare provider** before giving a child non-prescription cold medicine. Some medicines contain ingredients that are not good for children.

RESPIRATORY SYNCYTIAL VIRUS (RSV)

Respiratory Syncytial Virus Infection (RSV)

AUGUST 30, 2024

How RSV Spreads

WHAT TO KNOW

- RSV can spread when an infected person coughs or sneezes, by direct contact with someone who has RSV, or by touching a contaminated surface.
- In most regions of the United States, RSV season generally starts during the fall and peaks in the winter.
- Everyone can take action to help prevent the spread of RSV.

RSV transmission

RSV can spread when:

- A person who has RSV coughs or sneezes near you
- You get virus droplets from a cough or sneeze in your eyes, nose, or mouth
- You have direct contact with the virus, like kissing the face of a child with RSV
- You touch a surface that has the virus on it, like a doorknob, and then touch your face before washing your hands

Anyone can get RSV, but typically most people get RSV for the first time as an infant or toddler. Nearly all children will get RSV before their second birthday. However, repeat infections may occur throughout life.

Who is at risk?

Infants, some young children, and older adults are at increased risk of severe RSV. Learn about RSV immunizations.

People with RSV are usually contagious for 3 to 8 days and may become contagious a day or two before they start showing signs of illness. However, some infants and people with weakened immune systems can continue to spread the virus for 4 weeks or longer, even after they stop showing symptoms. Children are often exposed to and infected with RSV outside the home, such as in school or childcare centers. They can then transmit the virus to other members of the family.

RSV can survive for many hours on hard surfaces, such as tables and crib rails. It typically lives on soft surfaces, such as tissues and hands, for shorter amounts of time.

How to prevent spread

Everyone can take actions to help reduce the spread of RSV and other respiratory viruses.

- Practice good hygiene by covering your coughs and sneezes, washing or sanitizing your hands often, and cleaning frequently touched surfaces.
- Take steps for cleaner air, such as bringing in fresh outside air, purifying indoor air, or gathering outdoors.
- Stay home and away from others when you are sick.

You can also use additional tools like masks, physical distancing, and testing.

RESPIRATORY SYNCYTIAL VIRUS (RSV)

When is RSV season?

In most regions of the United States and other areas with similar climates, RSV season generally starts during fall and peaks in the winter. The timing and severity of RSV season in a given community can vary from year to year.

Over the course of each fall and winter respiratory virus season, RSV reaches all corners of the continental United States. For these reasons, it is important to be aware of local RSV activity in your area.

Tracking RSV

CDC monitors RSV activity in the United States. You can check CDC's Respiratory Illness Data Channel to see RSV activity in your area.

SOURCES

CONTENT SOURCE:
National Center for Immunization and Respiratory Diseases; Coronavirus and Other Respiratory Viruses Division

RESPIRATORY SYNCYTIAL VIRUS (RSV)

Respiratory Syncytial Virus Infection (RSV)

AUGUST 30, 2024

Clinical Overview of RSV

WHAT TO KNOW

- RSV usually causes mild symptoms, but it can cause severe illness. This is more likely in infants, some young children, people with compromised immune systems, and older adults.
- CDC recommends a single dose of RSV vaccine to protect all adults ages 75 and older and adults ages 60–74 who are at increased risk of severe RSV.
- To protect infants and some young children, CDC recommends the maternal vaccine (Pfizer's Abrysvo) for pregnant people during weeks 32–36 of pregnancy, or an RSV monoclonal antibody (nirsevimab) for babies given after birth and for some young children ages 8–19 months.

Overview

Respiratory syncytial virus (RSV) causes respiratory illness among persons of all age groups. RSV is one of the most common causes of childhood illness and is the most common cause of hospitalization in infants. It also causes severe disease and hospitalizations in older adults, especially those with certain chronic medical conditions.

In most regions of the United States, RSV season starts in the fall and peaks in the winter, but the timing and severity of RSV season in a given community can vary from year to year.

Healthcare providers should consider RSV in the differential diagnosis of patients with respiratory illness, particularly during the RSV season.

For more information about recommended infection prevention and control practices in healthcare settings, see CDC's Isolation Precautions Guideline: Preventing Transmission of Infectious Agents in Healthcare Settings.

RSV Immunizations

There are immunizations to protect people who are at increased risk of severe RSV.

- CDC recommends RSV vaccination for all adults ages 75 and older and for adults ages 60–74 who are at increased risk of severe RSV.
- To protect infants from severe RSV, CDC recommends an RSV vaccine for pregnant people (Pfizer's Abrysvo) or a monoclonal antibody (nirsevimab) given to the baby.
  - Nirsevimab is also recommended for a small group of young children ages 8–19 months before or entering their second RSV season.

Keep in mind

A recommendation from a healthcare provider is one of the most important factors that influences a patient's choice to accept a new prevention product or vaccine.

Clinical features

In infants and young children

RSV infection can cause a variety of respiratory illnesses and symptoms in infants and young children. It most commonly causes a cold-like illness but can also cause lower respiratory infections, like bronchiolitis and pneumonia. Two to three percent of infants under 6 months of age are hospitalized with RSV every year. Severe disease most commonly occurs in very young infants, including healthy babies without underlying conditions.

Additionally, children with any of the following underlying conditions are considered at increased risk of severe RSV disease:

- Premature infants

RESPIRATORY SYNCYTIAL VIRUS (RSV)

- Children with suppressed or weakened immune systems
- Children who have neuromuscular disorders or a congenital anomaly, including those who have difficulty swallowing or clearing mucus secretions
- Children with severe cystic fibrosis

Infants and young children with RSV infection may have rhinorrhea and a decrease in appetite before any other symptoms appear. Cough usually develops 1 to 3 days later. Soon after the cough develops, sneezing, fever, and wheezing may occur. Symptoms in very young infants can include irritability, decreased activity, and apnea.

Most otherwise healthy infants and young children who are infected with RSV do not need hospitalization. Those who are hospitalized may require oxygen, rehydration, and mechanical ventilation. Most improve with supportive care and are discharged in a few days.

In adults ages 60 and older

Adults who get RSV usually have mild or no symptoms. Symptoms are usually consistent with an upper respiratory tract infection, which can include rhinorrhea, pharyngitis, cough, headache, fatigue, and fever. Milder illness in adults typically resolves in 1–2 weeks. However, RSV can also cause severe disease and hospitalization in adults.

RSV can sometimes also lead to exacerbation of serious conditions such as:

- Asthma
- Chronic obstructive pulmonary disease (COPD)
- Heart failure

Epidemiologic evidence indicates that all adults ages 75 or older and adults ages 60–74 with certain risk factors are at increased risk of severe RSV.

Conditions that increase the risk for severe RSV

The following conditions increase the risk of severe RSV:*

- Chronic cardiovascular disease (e.g., heart failure, coronary artery disease, or congenital heart disease [excluding isolated hypertension])
- Chronic lung or respiratory disease (e.g., chronic obstructive pulmonary disease, emphysema, asthma, interstitial lung disease, or cystic fibrosis)
- End-stage renal disease or dependence on hemodialysis or other renal replacement therapy
- Diabetes mellitus complicated by chronic kidney disease, neuropathy, retinopathy, or other end-organ damage, or requiring treatment with insulin or sodium-glucose cotransporter-2 (SGLT2) inhibitor
- Neurologic or neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness (e.g., poststroke dysphagia, amyotrophic lateral sclerosis, or muscular dystrophy [excluding history of stroke without impaired airway clearance])
- Chronic liver disease (e.g., cirrhosis)
- Chronic hematologic conditions (e.g., sickle cell disease or thalassemia)
- Severe obesity (body mass index ≥40 kg/m^2)
- Moderate or severe immune compromise[†]
- Residence in a nursing home
- Other chronic medical conditions or risk factors that a health care provider determines would increase the risk for severe disease due to viral respiratory infection (e.g., frailty,[§] situations in which health care providers have concern for presence of undiagnosed chronic medical conditions, or residence in a remote or rural community where transportation of patients with severe RSV disease for escalation of medical care is challenging[¶])

RESPIRATORY SYNCYTIAL VIRUS (RSV)

* Patient attestation is sufficient evidence of the presence of a risk factor. Vaccinators should not deny RSV vaccination to a person because of lack of medical documentation.

† A list of moderately or severely immunocompromising conditions can be found in the COVID-19 vaccination interim clinical considerations.

§ Frailty is a multidimensional geriatric syndrome that reflects a state of increased vulnerability to adverse health outcomes. Although no consensus definition exists, one frequently used tool for determination is the Fried frailty phenotype assessment in which frailty is defined as a clinical syndrome with three or more of the following symptoms present: unintentional weight loss (10 lbs [4.5 kg] in the past year), self-reported exhaustion, weakness (grip strength), slow walking speed, or low physical activity.

¶ Health care providers caring for adults aged 60–74 years residing in these communities may use clinical judgement, knowledge of local RSV epidemiology, and community incidence of RSV-associated hospitalization to recommend vaccination for a broader population in this age group.

Resources

- RSV Immunization Guidance for Infants and Young Children
- RSV Vaccine Guidance for Pregnant People
- RSV Vaccine Guidance for Older Adults

SOURCES

CONTENT SOURCE:
National Center for Immunization and Respiratory Diseases; Coronavirus and Other Respiratory Viruses Division

RSV (Respiratory Syncytial Virus) Vaccine: *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

RSV vaccine can prevent lower respiratory tract disease caused by **respiratory syncytial virus (RSV)**. RSV is a common respiratory virus that usually causes mild, cold-like symptoms.

RSV can cause illness in people of all ages but may be especially serious for infants and older adults.

- Infants up to 12 months of age (especially those 6 months and younger) and children who were born prematurely, or who have chronic lung or heart disease or a weakened immune system, are at increased risk of severe RSV disease.
- Adults at highest risk for severe RSV disease include older adults, adults with chronic medical conditions such as heart or lung disease, weakened immune systems, or certain other underlying medical conditions, or who live in nursing homes or long-term care facilities.

RSV spreads through direct contact with the virus, such as droplets from another person's cough or sneeze contacting your eyes, nose, or mouth. It can also be spread by touching a surface that has the virus on it, like a doorknob, and then touching your face before washing your hands.

Symptoms of RSV infection may include runny nose, decrease in appetite, coughing, sneezing, fever, or wheezing. In very young infants, symptoms of RSV may also include irritability (fussiness), decreased activity, or apnea (pauses in breathing for more than 10 seconds).

Most people recover in a week or two, but RSV can be serious, resulting in shortness of breath and low oxygen levels. RSV can cause bronchiolitis (inflammation of the small airways in the lung) and pneumonia (infection of the lungs). RSV can sometimes lead to worsening of other medical conditions such as asthma, chronic obstructive pulmonary disease (a chronic disease of the lungs that makes it hard to breathe), or congestive heart failure (when the heart can't pump enough blood and oxygen throughout the body).

Older adults and infants who get very sick from RSV may need to be hospitalized. Some may even die.

2. RSV vaccine

CDC recommends **adults 60 years of age and older** have the option to receive a single dose of RSV vaccine, based on discussions between the patient and their health care provider.

There are two options for protection of infants against RSV: maternal vaccine for the pregnant person and preventive antibodies given to the baby. Only one of these options is needed for most babies to be protected. CDC recommends a single dose of RSV vaccine for **pregnant people from week 32 through week 36 of pregnancy** for the prevention of RSV disease in infants under 6 months of age. This vaccine is recommended to be given from September through January for most of the United States. However, in some locations (the territories, Hawaii, Alaska, and parts of Florida), the timing of vaccination may vary as RSV circulating in these locations differs from the timing of the RSV season in the rest of the U.S.

RSV vaccine may be given at the same time as other vaccines.

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

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of RSV vaccine**, or has any **severe, life-threatening allergies**

In some cases, your health care provider may decide to postpone RSV vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting RSV vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Pain, redness, and swelling where the shot is given, fatigue (feeling tired), fever, headache, nausea, diarrhea, and muscle or joint pain can happen after RSV vaccination.

Serious neurologic conditions, including Guillain-Barré syndrome (GBS), have been reported after RSV vaccination in clinical trials of older adults. It is unclear whether the vaccine caused these events.

Preterm birth and high blood pressure during pregnancy, including pre-eclampsia, have been reported among pregnant people who received RSV vaccine during clinical trials. It is unclear whether these events were caused by the vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**
- 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**.

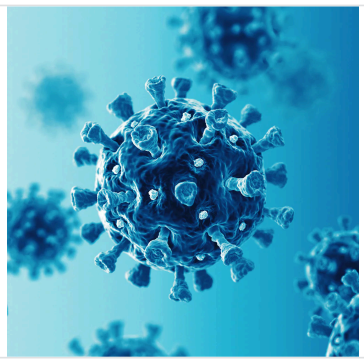
COVID-19

JUNE 13, 2024

About COVID-19

KEY POINTS

- COVID-19 (coronavirus disease 2019) is a disease caused by the SARS-CoV-2 virus.
- It can be very contagious and can spread quickly.
- As of June 1, 2024, nearly 1.2 million people have died of COVID-19 in the U.S.



MORE INFORMATION

For Everyone | Health Care Providers | Public Health

On October 23, 2024, CDC updated COVID-19 vaccine recommendations for people 65 years and older and for people who are moderately or severely immunocompromised. This page will be updated soon to align with the new recommendations. Read the media statement.

Learn about COVID-19 and how it spreads

About COVID-19

COVID-19 most often causes respiratory symptoms that can feel much like a cold, the flu, or pneumonia. COVID-19 may attack more than your lungs and respiratory system. Other parts of your body may also be affected by the disease. Most people with COVID-19 have mild symptoms, but some people become severely ill.

Keep Reading:
Symptoms of COVID-19

Some people, including those with minor or no symptoms, will develop Post-COVID Conditions – also called "Long COVID."

Keep Reading:
Long COVID Basics

How COVID-19 spreads

COVID-19 spreads when an infected person breathes out droplets and very small particles that contain the virus. Other people can breathe in these droplets and particles, or these droplets and particles can land on others' eyes, nose, or mouth. In some circumstances, these droplets may contaminate the surfaces they touch.

Anyone infected with COVID-19 can spread it, even if they do **NOT** have symptoms. COVID-19 can even spread from people to animals in some situations.

Risk factors for severe illness from COVID-19

Some people are more likely than others to get very sick if they get COVID-19. This includes people who:

- are older
- are immunocompromised (have a weakened immune system)
- have certain disabilities or
- have underlying health conditions

Understanding your COVID-19 risk and the risks that might affect others can help you make decisions to protect yourself and others.

Keep Reading:
People with Certain Medical Conditions and COVID-19 Risk Factors

About variants

Viruses are constantly changing, including the virus that causes COVID-19. These changes occur over time and can lead to the emergence of variants that may have new characteristics, including different ways of spreading. Slowing the spread of the virus, by protecting yourself and others, can help slow new variants from developing.

Prevention

There are many actions you can take to help protect you, your household, and your community from COVID-19. CDC's Respiratory Virus Guidance provides actions you can take to lower the risk of COVID-19 transmission (catching and spreading COVID-19) and lower the risk of severe illness if you get sick.

Keep Reading:
Staying Up to Date with COVID-19 Vaccines

Keep Reading:
Respiratory Virus Guidance

SOURCES

CONTENT SOURCE:
National Center for Immunization and Respiratory Diseases (NCIRD)

COVID-19

JUNE 24, 2024

People with Certain Medical Conditions and COVID-19 Risk Factors

WHAT TO KNOW

- If you have any medical conditions listed below, you are more likely to get very sick with COVID-19.
- This list does not include all conditions.
- If you have symptoms consistent with COVID-19 and are ages 50 years or older OR have a condition placing you at higher risk of getting very sick, you are eligible for treatment.

Overview

This information is for a general audience. Healthcare professionals should see Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19 for more detailed information.

Stay Up to Date With COVID-19 Vaccines

Staying up to date with COVID-19 vaccines and following preventive measures are especially important if you are older or have one or more health conditions, including those listed below.

COVID-19 vaccines are safe and effective

Stay Up To Date

If you have one or more of the conditions listed below, you are more likely to get very sick from COVID-19 and be hospitalized, need intensive care, require a ventilator to breathe, and/or die.

Risk factors for getting very sick with COVID-19

- Older adults are at highest risk of getting very sick from COVID-19. More than 81% of COVID-19 deaths occur in people over age 65. The number of deaths among people over age 65 is 97 times higher than among people ages 18-29 years.
- Your risk of severe illness from COVID-19 increases as the number of your underlying medical conditions increase.
- Some people are at increased risk of getting very sick or dying from COVID-19 because of where they live or work, or because they can't get health care. This includes many people from racial and ethnic minority groups and people with disabilities.

Specific information on children and teens

People of all ages, including children and teens, can get very sick from COVID-19, especially those with underlying medical conditions. This includes children and teens with:

- Medical complexity
- Genetic, neurologic, or metabolic conditions
- Congenital heart disease

Like adults, children and teens with obesity, diabetes, asthma or chronic lung disease, sickle cell disease, or who are immunocompromised can also be at increased risk for getting very sick from COVID-19. Check out COVID-19 Vaccines for Children and Teens for more information on vaccinating your child.

Learn how CDC develops COVID-19 vaccination recommendations.

Contact Your Healthcare Provider

If you have questions about a condition not included on this list or questions on how to manage your condition and protect yourself from COVID-19 and severe illness.

For treatment options. You must start treatment within 5-7 days from the time your symptoms start. Treatment can reduce your risk of hospitalization by more than 50% and reduce your risk of death.

You can also visit a Test to Treat location.

Conditions that can increase risk

- The conditions on this list are in alphabetical order. They are not in order of risk.
- CDC reviewed each medical condition on this list to ensure they met criteria for inclusion. If there is new evidence, other conditions might be added to the list.
- This list does not include all medical conditions that place a person at higher risk of severe illness from COVID-19. Rare medical conditions, including many conditions that mostly affect children, may not be included.
- A person with a condition that is not listed may still be at greater risk of getting very sick from COVID-19 than other people. It is important to talk with your healthcare provider about your risk.

Having the following diseases, conditions, or behaviors can make you more likely to get very sick from COVID-19.

Cancer

Treatments for many types of cancer can weaken your body's ability to fight off disease.

Get more information:

- Cancer
- COVID-19: What People with Cancer Should Know – National Cancer Institute

Cerebrovascular disease

Including stroke which affects blood flow to the brain.

Get more information:

- Stroke

Chronic kidney disease (at any stage)

Get more information:

- Chronic Kidney Disease
- National Kidney Foundation: Kidney Disease and COVID-19

Chronic liver disease

This includes alcohol-related liver disease, non-alcoholic fatty liver disease, autoimmune hepatitis, and cirrhosis (or scarring of the liver).

Get more information:

- Liver Disease
- American Liver Foundation: Your Liver and COVID-19

Chronic lung disease

Chronic lung disease can include:

- Asthma (moderate to severe)
- Bronchiectasis (thickening of the lungs' airways)
- Bronchopulmonary dysplasia (chronic lung disease affecting newborns)
- Chronic obstructive pulmonary disease (COPD), including emphysema and chronic bronchitis
- Damaged or scarred lung tissue (interstitial lung disease including idiopathic pulmonary fibrosis)
- Pulmonary embolism (blood clot in the lungs)
- Pulmonary hypertension (high blood pressure in the lungs)

Get more information:

- COPD
- Asthma
- People with Moderate to Severe Asthma
- American Lung Association: Controlling Chronic Lung Diseases Amid COVID-19

Cystic fibrosis

With or without lung or other solid organ transplant (like kidney, liver, intestines, heart, and pancreas).

Get more information:

- Cystic fibrosis
- Cystic Fibrosis Foundation: CF and Coronavirus (COVID-19)

Dementia or other neurological conditions

Get more information:

- Dementia
- Alzheimer's Association: COVID-19, Alzheimer's and Dementia

Diabetes (type 1 or type 2)

Get more information:

- Diabetes
- American Diabetes Association: How COVID-19 Impacts People with Diabetes

Disabilities

People with some types of disabilities may be more likely to get very sick from COVID-19 because of underlying medical conditions, living in congregate settings, or systemic health and social inequities, including:

- People with any type of disability that makes it more difficult to do certain activities or interact with the world around them, including people who need help with self-care or daily activities
- People with attention-deficit/hyperactivity disorder (ADHD)
- People with cerebral palsy
- People with birth defects
- People with intellectual and developmental disabilities
- People with learning disabilities
- People with spinal cord injuries

- People with Down syndrome

Get more information:

- People with Disabilities

Heart conditions

This includes heart failure, coronary artery disease, cardiomyopathies, and possibly high blood pressure (hypertension).

Get more information:

- Heart Disease
- American Heart Association: COVID-19
- NHLBI Information and Resources on COVID-19

Hemoglobin blood disorders

Get more information:

- Sickle Cell Disease
- Thalassemia

HIV infection (Human Immunodeficiency Virus)

Get more information:

- HIV Infection
- Interim Guidance for COVID-19 and Persons with HIV

Immunocompromised condition or weakened immune system

People who are immunocompromised or are taking medicines that weaken their immune system may not be protected even if they are up to date on their vaccines. Examples include:

- People who have cancer and are on chemotherapy
- People who have had a solid organ transplant and are taking medication to keep their transplant
- People who use some medicines for a long time, like corticosteroids
- Primary immunodeficiency

Talk with your healthcare provider about what additional precautions may be necessary. Additionally, people who are moderately or severely immunocompromised may benefit from additional doses of updated COVID-19 vaccine. Because their immune response following COVID-19 vaccination may differ, specific guidance has been developed.

Get more information:

- Types of Primary Immune Deficiency Diseases
- Jeffrey Modell Foundation
- Immune Deficiency Foundation
- Primary Immunodeficiency (PI)

You Might Be Eligible for Pemivibart (Pemgarda™)

People who are moderately or severely immunocompromised, are ages 12 and older, and who weigh at least 88 pounds may be eligible to get Pemivibart (Pemgarda™), a monoclonal antibody authorized to help protect against COVID-19. Pemgarda may provide another layer of protection against COVID-19 in addition to protection provided through vaccination and can be given at least 2 weeks after receiving a COVID-19 vaccine. Pemgarda is not a treatment for COVID-19. Talk to your healthcare provider to see if Pemgarda is right for you.

Mental health conditions

Mood disorders including depression and schizophrenia spectrum disorders.

Get more information:

- National Institute of Mental Health (NIMH) Shareable Resources on Coping with COVID-19
- National Institute of Mental Health (NIMH) Depression
- Mood Disorders

Overweight and obesity

Overweight (defined as a body mass index (BMI) is 25 kg/m^2 or higher, but under 30 kg/m^2), obesity (BMI is 30 kg/m^2 or higher, but under 40 kg/m^2), or severe obesity (BMI is 40 kg/m^2 or higher). The risk of severe illness from COVID-19 increases sharply with higher BMI.

Get more information:

- Overweight and Obesity
- Obesity, Race/Ethnicity, and COVID-19
- Obesity Action Coalition: COVID-19 and Obesity

Physical inactivity

Being physically active is important to being healthy. Get more information on physical activity and health, physical activity recommendations, how to become more active, and how to create activity-friendly communities:

- Physical Activity
- *Physical Activity Guidelines for Americans*, 2nd edition
- Move Your Way®
- Strategies to Increase Physical Activity
- National Center on Health, Physical Activity and Disability – Building Healthy Inclusive Communities

Pregnancy

Get more information:

- Pregnant and Recently Pregnant People (for at least 42 days following end of pregnancy)

Smoking - current or former

It's never too late to quit smoking. Quitting smoking improves your health, regardless of age or how long you have smoked.

You do not have to quit smoking alone. Find free resources to help you quit and stay quit.

Get more information:

- How to Quit Smoking
- Health Benefits of Quitting Smoking

Solid organ or blood stem cell transplant

Get more information:

- Transplant Safety
- COVID-19 Resources for Transplant Community

Substance use disorders

Such as alcohol, opioid, or cocaine use disorder.

Get more information:

- Treatment of Substance Use Disorder

- Substance Use Disorder and Teens
- Drug Overdose

Tuberculosis (TB)

Get more information:

- About TB
- Public Health Emergencies

SOURCES

CONTENT SOURCE:
National Center for Immunization and Respiratory Diseases (NCIRD)

COVID-19

JUNE 25, 2024

Symptoms of COVID-19

KEY POINTS

- People with COVID-19 have a wide range of symptoms ranging from mild symptoms to severe illness.
- Symptoms may appear 2-14 days after exposure to the virus.
- Symptoms may start as mild, and some people will progress to more severe symptoms.

Signs and Symptoms

The following list does not include all possible symptoms. Symptoms may change with new COVID-19 variants and can vary depending on vaccination status. Possible symptoms include:

- Fever or chills
- Cough
- Shortness of breath or difficulty breathing
- Sore throat
- Congestion or runny nose
- New loss of taste or smell
- Fatigue
- Muscle or body aches
- Headache
- Nausea or vomiting
- Diarrhea

CDC will continue to update this list as we learn more about COVID-19.

Feeling Sick?

Stay home and away from others (including people you live with who are not sick) if you have symptoms that aren't better explained by another cause.

Seek health care promptly for testing and/or treatment if you have risk factors for severe illness; treatment may help lower your risk of severe illness.

When to seek emergency help

Look for emergency warning signs* for COVID 19:

- Trouble breathing
- Persistent pain or pressure in the chest
- New confusion

- Inability to wake or stay awake
- Depending on skin tone, lips, nail beds and skin may appear pale, gray, or blue.

If someone is showing any of these signs, call 911 or call ahead to your local emergency facility. Notify the operator that you are seeking care for someone who has or may have COVID-19.

**This list does not include all possible symptoms. Please call your medical provider for any other symptoms that are severe or concerning to you.*

Difference between flu and COVID-19

Influenza (Flu) and COVID-19 are both contagious respiratory illnesses, but they are caused by different viruses. COVID-19 is caused by infection with a coronavirus named SARS-CoV-2, and flu is caused by infection with one of the influenza viruses. You cannot tell the difference between flu and COVID-19 by symptoms alone because some of the symptoms are the same.

Some nucleic acid amplification tests (NAATs), including PCR tests, can differentiate between flu and COVID-19 at the same time. If one of these tests is not available, many testing locations provide flu and COVID-19 tests separately.

Keep Reading:
Similarities and Differences between Flu and COVID-19

Resources

Videos

Symptoms of Coronavirus Disease 2019 (youtube.com)

SOURCES

CONTENT SOURCE:
National Center for Immunization and Respiratory Diseases (NCIRD)

SOURCES

- National Center for Immunization and Respiratory Diseases (NCIRD)

COVID-19

JULY 12, 2024

How to Protect Yourself and Others

WHAT TO KNOW

- CDC's Respiratory Virus Guidance provides strategies you can use to help protect yourself and others from health risks caused by COVID-19 and other respiratory viruses.
- These actions can help you lower the risk of COVID-19 transmission (spreading or catching COVID-19) and lower the risk of severe illness if you get sick.

Core Prevention Strategies

CDC recommends that all people use core prevention strategies to protect themselves and others from COVID-19:

- Stay up to date with COVID-19 vaccines.
  - Although vaccinated people sometimes get infected with the virus that causes COVID-19, staying up to date on COVID-19 vaccines significantly lowers the risk of getting very sick, being hospitalized, or dying from COVID-19.
- Practice good hygiene (practices that improve cleanliness)
- Take steps for cleaner air

When you are sick:

- Use precautions to prevent spread, including staying home and away from others (including people you live with who are not sick) if you have respiratory symptoms.
  - Learn when you can go back to your normal activities.
- Seek health care promptly for testing and/or treatment if you have risk factors for severe illness. Treatment may help lower your risk of severe illness, but it needs to be started within a few days of when your symptoms begin.

Additional Prevention Strategies

In addition, there are other prevention strategies that you can choose to further protect yourself and others.

- Wearing a mask and putting distance between yourself and others can help lower the risk of COVID-19 transmission.
- Testing for COVID-19 can help you decide what to do next, like getting treatment to reduce your risk of severe illness and taking steps to lower your chances of spreading COVID-19 to others.

What to watch out for

Using these prevention strategies can be especially helpful when:

- Respiratory viruses, such as COVID-19, flu, and RSV, are causing a lot of illness in your community
- You or those around you have risk factors for severe illness
- You or those around you were recently exposed to a respiratory virus, are sick, or are recovering

Check Your Community

Find out if respiratory viruses are causing a lot of illness in your community. Data updated weekly.

Check the latest data

SOURCES

CONTENT SOURCE:

National Center for Immunization and Respiratory Diseases (NCIRD)

National Center for Immunization and Respiratory Diseases

JULY 3, 2024

COVID-19 can surge throughout the year

AT A GLANCE

Many respiratory virus illnesses peak during the winter due to environmental conditions and human behaviors. COVID-19 has peaks in the winter and also at other times of the year, including the summer, driven by new variants and decreasing immunity from previous infections and vaccinations. You can protect yourself from serious illness by staying up to date with vaccinations, getting treated if you have medical conditions that make you more likely to get very sick from COVID-19, and using other strategies outlined in CDC's respiratory virus guidance.

Summary

What CDC knows

In the United States, respiratory virus illnesses typically peak during the fall and winter. These peaks are due to several factors, including human behaviors and environmental conditions that can affect the ability of viruses to survive and spread.

Since the start of the COVID-19 pandemic, infections with SARS-CoV-2, the virus that causes COVID-19, have peaked during the winter and also surged at other times of the year. These periodic surges are due in part to the emergence of new variants and decreasing immunity from previous infections and vaccinations. Because the evolution of new variants remains unpredictable, SARS-CoV-2 is not a typical “winter” respiratory virus.

What CDC is doing

CDC continues to monitor seasonal trends of COVID-19 and the factors driving these trends, including the emergence of new variants, and to collaborate with state and local health departments, commercial laboratories, and global partners. On June 27, the Advisory Committee on Immunization Practices (ACIP), an independent advisory group to CDC, recommended that persons ≥6 months of age receive the 2024–2025 COVID-19 vaccines when they become available this fall.

Why do many respiratory viruses spread more in the winter?

Many respiratory viruses have increased circulation during the winter. Factors that drive these seasonal patterns fall into a few broad categories:

- **Environmental conditions**: Temperature and humidity can affect the ability of viruses to survive and spread. Dry conditions, which are particularly common in winter, can cause water to evaporate more quickly from respiratory droplets produced by coughing or sneezing, resulting in smaller particles that last longer in the air and travel longer distances. SARS-CoV-2, the virus that causes COVID-19, survives longer in colder temperatures, and increased spread has been associated with lower fall/winter temperatures.
- **Immune susceptibility:** Dry and cold air interfere with the ability of the body to sweep viruses out of the upper respiratory tract, which is the first line of the immune system's defense. At the population level, protection from prior infection and vaccination wanes over time. This results in more people being susceptible in the winter when respiratory viruses are spreading the most.
- **Behavioral patterns**: Spending more time indoors with less ventilation during the colder months, as well as holiday gatherings and travel, can increase spread. That's because viruses spread between people more easily indoors than outdoors in part because the concentration of these particles is often higher indoors. Similar conditions can also happen in summer when people spend more time indoors, keep windows closed while using air conditioning, and travel for summer vacations.

COVID-19 seasonality

COVID-19 activity tends to fluctuate with the seasons, meaning it has some seasonal patterns. Data from four years of COVID-19 cases, hospitalizations, and deaths show that COVID-19 has winter peaks (most recently in late December 2023 and early January 2024), but also summer peaks (most recently in July and August of 2023). There is no distinct COVID-19 season like there is for influenza (flu) and respiratory

syncytial virus (RSV). While flu and RSV have a generally defined fall/winter seasonality and circulate at low levels in most parts of the United States in the summer, meaningful COVID-19 activity occurs at other times of the year.

Understanding when COVID-19 tends to peak helps to better tailor public health prevention strategies and recommendations, prepare our healthcare system, and allocate resources. That's especially important because the winter peak tends to overlap with those for flu, RSV, and many other viruses. Getting an updated COVID-19 vaccine in the fall can help better protect you through the winter peak. People who might benefit from additional doses of COVID-19 vaccine this summer include those who are:

- 65 years of age and older,
- Moderately or severely immunocompromised or with underlying medical conditions,
- Living in long-term care facilities,
- Of any age and have never received COVID-19 vaccine, and
- Pregnant, especially in late pregnancy.

CDC's Advisory Committee on Immunization Practices (ACIP) met on June 27 and recommended that persons ≥6 months of age receive the 2024–2025 COVID-19 vaccines when they become available this fall. The U.S. Food and Drug Administration recently selected strains for the vaccine based on currently circulating variants.

New variants affect patterns of COVID-19 activity

The emergence of new SARS-CoV-2 variants has been associated with COVID-19 surges, including an increase in the magnitude of winter peaks and additional peaks at other times of the year. Peaks in COVID-19 activity often, but not exclusively, occur in winter (blue bar in chart, below) and in summer (pink bar in chart). New variants, such as Delta and Omicron, contributed to several peaks.

Although the future pace of SARS-CoV-2 evolution is unpredictable, surges outside the winter season will likely continue as long as **new variants emerge** and immunity from previous infections and vaccinations decreases over time.

CDC continues to track the emergence of new variants through genomic sequencing, in collaboration with state and local health departments, commercial laboratories, and global partners. CDC also continues to monitor trends in COVID-19 to inform vaccine recommendations, and to publish weekly data so that the public can make informed decisions regarding their individual risk throughout the year.

Percentage of positive SARS-CoV-2 tests reported to the National Respiratory and Enteric Virus Surveillance System (NREVSS) -- March 2020 to June 2024

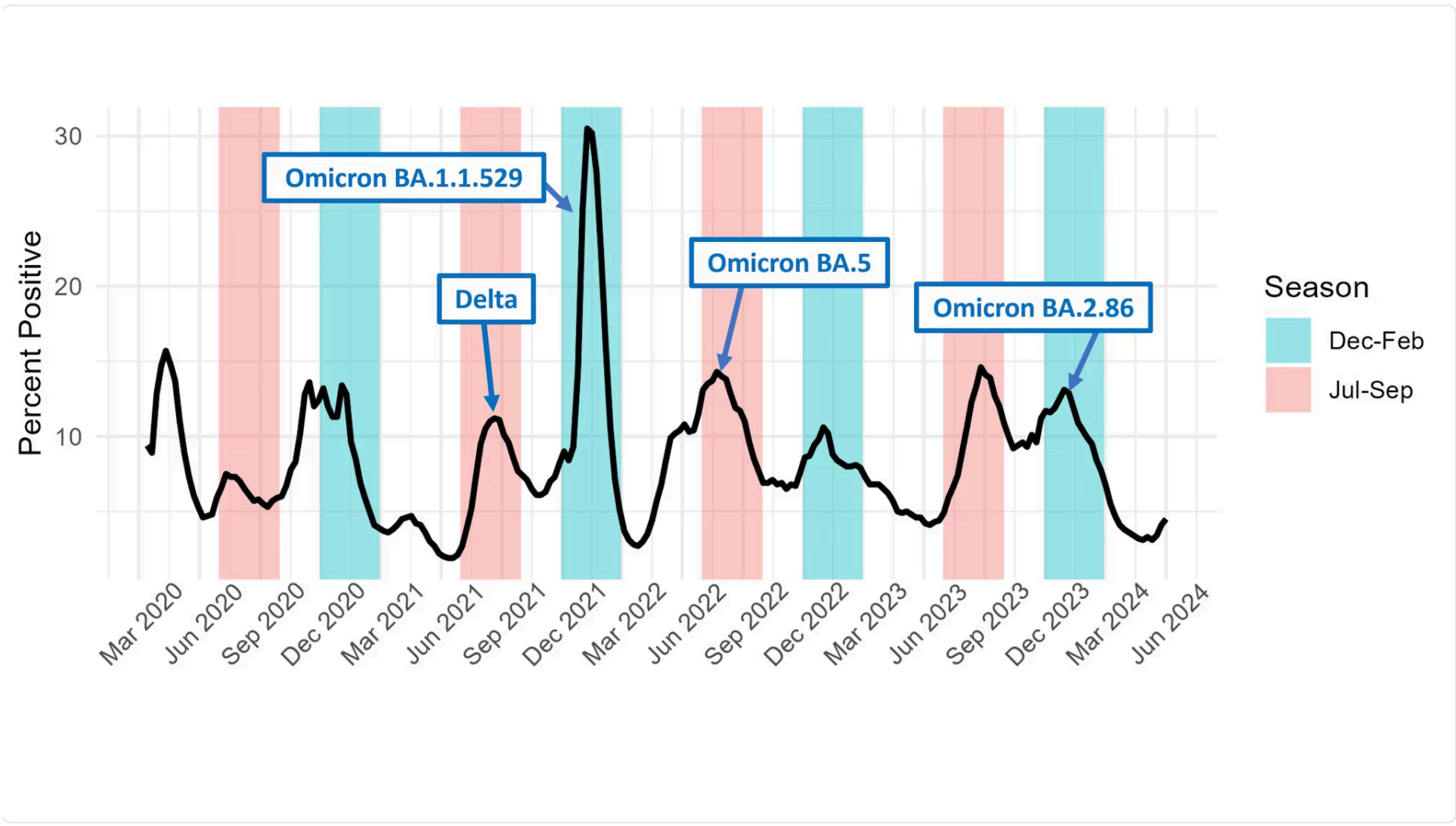


Figure 1: Percentage of positive SARS-CoV-2 tests from March 2020 to June 2024 reported to the National Respiratory and Enteric Virus Surveillance System (NREVSS). Peaks have been observed during winter (blue), summer (pink), and at other times throu...

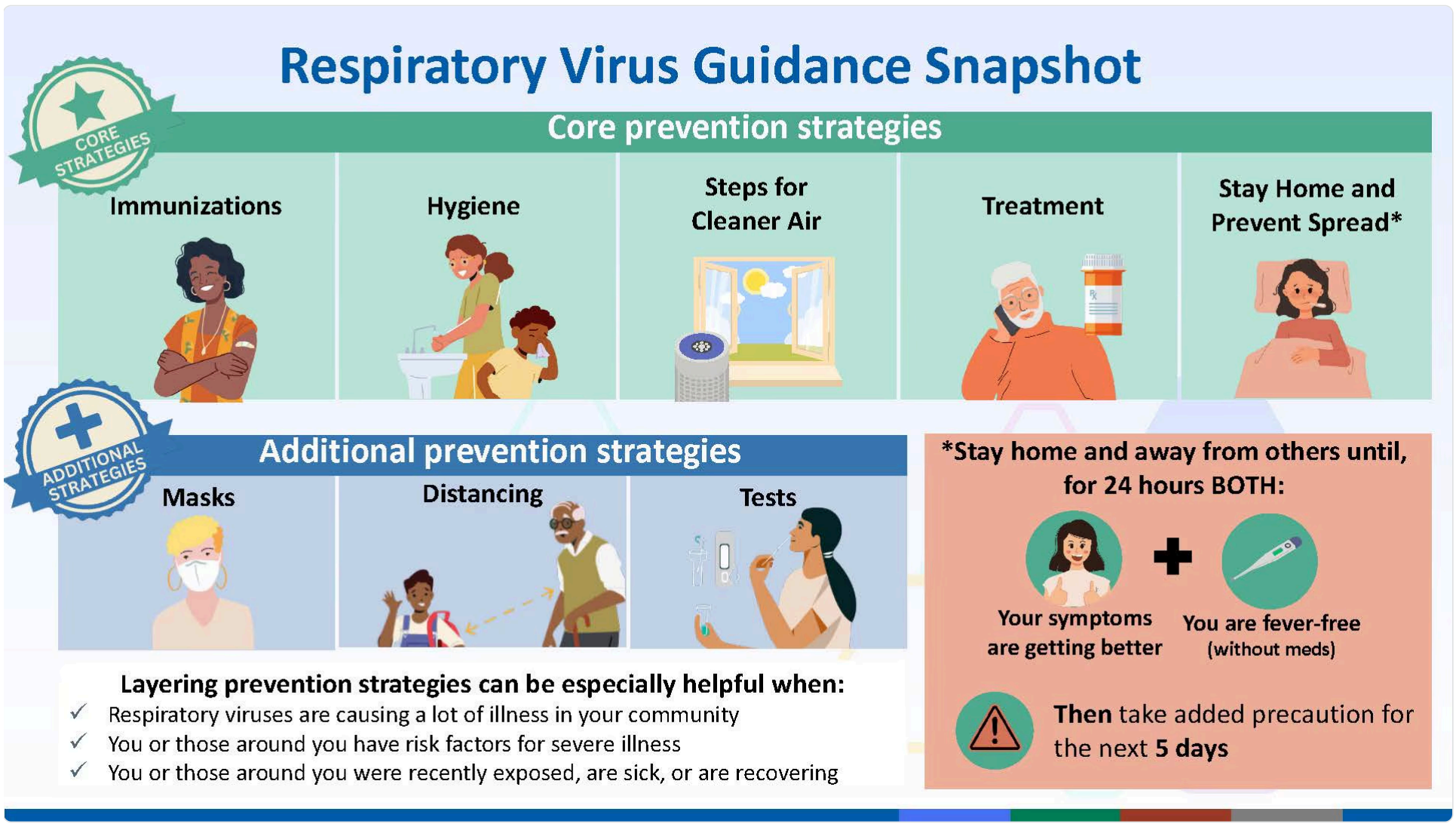
Show More

This past winter, COVID-19 peaked in early January, declined rapidly in February and March, and by May 2024 was lower than at any point since March 2020. Over the past few weeks, some surveillance systems have shown small national increases in COVID-19; widespread as well as local surges are possible over the summer months. Although COVID-19 is not the threat it once was, it is still associated with thousands of hospitalizations and hundreds of deaths each week in the United States, and can lead to Long COVID.

Protect yourself and others with practical actions

During the summer and throughout the year, you can use many effective tools to prevent spreading COVID-19 or becoming seriously ill. CDC's Respiratory Virus Guidance provides recommendations and information that can help people lower their risk from many common respiratory viral illnesses. These actions can help protect yourself and others from health risks caused by these viruses.

COVID-19 is here to stay, but taking simple actions will help protect you and your loved ones from infection and serious illness.



Respiratory Virus Guidance

SOURCES

CONTENT SOURCE:

National Center for Immunization and Respiratory Diseases (NCIRD); About NCIRD; NCIRD Divisions and Offices

COVID-19 Vaccine:
What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

COVID-19 vaccine can prevent **COVID-19** disease. Vaccination can help reduce the severity of COVID-19 disease if you get sick.

COVID-19 is caused by a coronavirus called SARS-CoV-2 that spreads easily from person to person. COVID-19 can cause mild to moderate illness lasting only a few days, or severe illness requiring hospitalization, intensive care, or a ventilator to help with breathing. COVID-19 can result in death.

If an infected person has symptoms, they may appear 2 to 14 days after exposure to the virus. Anyone can have mild to severe symptoms.

- Possible symptoms include fever or chills, cough, shortness of breath or difficulty breathing, fatigue (tiredness), muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, or diarrhea.
- More serious symptoms can include trouble breathing, persistent pain or pressure in the chest, new confusion, inability to wake or stay awake, or pale, gray, or blue-colored skin, lips, or nail beds, depending on skin tone.

Older adults and people with certain underlying medical conditions (like heart or lung disease or diabetes) are more likely to get very sick from COVID-19.

2. COVID-19 vaccine

Updated (2023–2024 Formula) COVID-19 vaccine is recommended for everyone 6 months of age and older.

COVID-19 vaccines for infants and children 6 months through 11 years of age are available under Emergency Use Authorization from the U. S. Food and Drug Administration (FDA). Please refer to the Fact Sheets for Recipients and Caregivers for more information.

For people 12 years of age and older, updated COVID-19 vaccines, manufactured by ModernaTX, Inc. or Pfizer, Inc., are approved by FDA.

- **Everyone 12 years and older** should get 1 dose of an FDA-approved, updated 2023–2024 COVID-19 vaccine. If you have received a COVID-19 vaccine recently, you should wait at least 8 weeks after your most recent dose to get the updated 2023–2024 COVID-19 vaccine.
- **Certain people who have medical conditions or are taking medications that affect the immune system** may get additional doses of COVID-19 vaccine. Your health care provider can advise you.

Some people 12 years of age and older might get a different COVID-19 vaccine called Novavax COVID-19 Vaccine, Adjuvanted (2023–2024 Formula) instead. This vaccine is available under Emergency Use Authorization from FDA. Please refer to the Fact Sheet for Recipients and Caregivers for more information.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of COVID-19 vaccine** or an ingredient in the COVID-19 vaccine, or has any **severe, life-threatening allergies**
- Has had **myocarditis** (inflammation of the heart muscle) or **pericarditis** (inflammation of the lining outside of the heart)
- Has had **multisystem inflammatory syndrome** (called MIS-C in children and MIS-A in adults)
- Has a **weakened immune system**

In some cases, your health care provider may decide to postpone COVID-19 vaccination until a future visit.

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

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover. People with current COVID-19 infection should wait to get vaccinated until they have recovered from their illness and discontinued isolation.

Pregnant people with COVID-19 are at increased risk for severe illness. COVID-19 vaccination is recommended for people who are pregnant, breastfeeding, or trying to get pregnant now, or who might become pregnant in the future.

COVID-19 vaccine may be given at the same time as other vaccines.

4. Risks of a vaccine reaction

- Pain, swelling, or redness where the shot is given, fever, tiredness (fatigue), headache, chills, muscle pain, joint pain, nausea, vomiting, and swollen lymph nodes can happen after COVID-19 vaccination.
- Myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart) have been seen rarely after COVID-19 vaccination. This risk has been observed most commonly in males 12 through 39 years of age. The chance of this occurring is low.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

Seek medical attention right away if the vaccinated person experiences chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heart after COVID-19 vaccination. These could be symptoms of myocarditis or pericarditis.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. Countermeasures Injury Compensation Program

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit the program's website at **www.hrsa.gov/cicp**, or call **1-855-266-2427**.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for COVID-19 Fact Sheets, package inserts, and additional information at **www.fda.gov/vaccines-blood-biologics/industry-biologics/coronavirus-covid-19-cber-regulated-biologics**.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's COVID-19 vaccines website at **www.cdc.gov/coronavirus**.

2024–25 Formula Moderna COVID-19 Vaccine

At-A-Glance

Guidance below summarizes basic storage, preparation, scheduling, administration, and dosage for all 2024–25 Moderna COVID-19 vaccine products.

Distributed in:

Ages: 6 months through 11 years

- **Manufacturer-filled syringe**

Ages: 12 years and older

- **Manufacturer-filled syringe**

Storage and Handling

Find additional guidance on storing vaccine properly at:

- CDC Vaccine Storage and Handling Toolkit
- Spikevax | FDA
- Moderna COVID-19 FACT SHEET
- Moderna COVID-19 Vaccines | Modernatx.com

Ages	6 months through 11 years	12 Years and Older
Supplied in:	Manufacturer-filled syringe (MFS)	Manufacturer-filled syringe (MFS)*
Storage temperature before puncture	**Between**: ▪ -50°C and -15°C (-58°F and 5°F) until the expiration date. ▪ 2°C and 8°C (36°F and 46°F) for up to 60 days. ▪ 8°C and 25°C (46°F and 77°F) for a total of 12 hours. During storage, minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light. Thawed syringes can be handled in room light conditions. **Do NOT refreeze once thawed.** **NOTE:** The beyond-use date (60 days) replaces the manufacturer's expiration date but **NEVER** extends it. Always use the earliest date. Do NOT use vaccine after the expiration date or beyond-use date.	
Thawing frozen vaccine	▪ Between 2°C and 8°C (36°F and 46°F): o One syringe: Thaw for 1 hour. o Carton of 10 syringes: Thaw for 2 hours and 30 minutes. OR ▪ Between 15°C and 25°C (59°F and 77°F): o One syringe: Thaw for 45 minutes. o Carton of 10 syringes: Thaw for 2 hours and 15 minutes. **Do NOT refreeze once thawed.**	

* Single-dose vials for people 12 years and older are not available in the U.S., but may be available in other countries

09/11/2024 CS321571-P

2024–25 Formula Moderna COVID-19 Vaccine

At-A-Glance

Preparation and Administration Basics

Find additional guidance on preparing and administering vaccine properly at:

- Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC
- Vaccine Administration Resource Library | CDC
- COVID-19 Vaccines | FDA
- Package Insert - SPIKEVAX (fda.gov)
- Spikevax® (COVID-19 Vaccine, MRNA) 2024-2025 Formula (modernatx.com)

Preparation

- Check that vial or syringe states 2024-25 Formula.
- If the vaccine is frozen, thaw before use.
- Do not refreeze frozen vaccine.
- Check syringe label to ensure the expiration date or beyond-use date/time (if applicable) has not passed.
  - Use Moderna expiration date tool at https://modernacovid19global.com/vial-lookup
- **Do NOT shake.**
- Refer to package insert or EUA Fact Sheet for detailed instructions.

Administration

- COVID-19 vaccines may be administered at the same clinical visit as other routinely recommended vaccines.
- Administer intramuscularly.

Recipient's Age	Dosage	Route	Needle gauge and length	Site
6 months through 11 years of age	0.25 mL/25 *ug*	IM injection	22–25 gauge, 1 inch*	**6 months–2 years of age:** Vastus lateralis muscle in the anterolateral thigh†
				3–11 years of age: Deltoid muscle in the upper arm‡
12 years of age and older	0.5 mL/50 *ug*	IM injection	22–25 gauge, 1–1.5 inch*§	Deltoid muscle in the upper arm‡

* A 5/8 inch needle may be used if administering the vaccine in the deltoid muscle AND the skin is stretched tightly and the subcutaneous tissue is not bunched for children and adolescents ages 1–18 years and adults ages 19 years and older who weigh less than 130 pounds.

†The deltoid muscle in the upper arm may be used if the muscle mass is adequate in children ages 1–2 years.

‡ The vastus lateralis muscle in the anterolateral thigh may be used as an alternate site.

§ See Vaccine Administration: Needle Gauge and Length chart for more details

2024–25 Formula Moderna COVID-19 Vaccine

At-A-Glance

Scheduling Doses

The number of recommended 2024–25 COVID-19 vaccine doses varies by age, vaccine, vaccination history, and the presence of moderate or severe immune compromise. Review CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States for detailed clinical guidance when scheduling doses, and the Interim COVID-19 Immunization Schedule for summary information.

Contraindications, Precautions, and Post-Vaccination Observation

Screen for contraindications and precautions before administering EACH dose — even if the vaccine was previously administered.

Contraindications

History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine

Precautions

History of:

- A diagnosed non-severe allergy to a component of the COVID-19 vaccine
- Non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of one COVID-19 vaccine type, if receiving the same vaccine type
- Current moderate to severe acute illness, with or without fever
- Multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)
- Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine

Consider observing persons after vaccination to monitor for allergic reactions and syncope:

- 30 minutes for persons with:
  - A history of a non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of one COVID-19 vaccine type, if receiving the same vaccine type
  - A history of a diagnosed non-severe allergy to a component of the COVID-19 vaccine, if receiving the same vaccine type
- 15 minutes: All other persons

Reporting of Vaccine Adverse Events

For licensed Moderna COVID-19 vaccines (for people ages 12 years and older), healthcare providers are **strongly encouraged** to report to VAERS:

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether or not it is clear that a vaccine caused the adverse event
- Vaccine administration errors, whether or not associated with an adverse event

For Moderna COVID-19 vaccines given under an Emergency Use Authorization (for persons 11 years of age and younger) Vaccination providers are **required** to report to VAERS:

- Vaccine administration errors whether or not associated with an adverse event(AE)
- Serious AEs regardless of causality. Serious AEs per FDA are defined as:
  - Death
  - A life-threatening AE
  - Inpatient hospitalization or prolongation of existing hospitalization
  - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
  - A congenital anomaly/birth defect
  - An important medical event that based on appropriate medical judgment may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above
- Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults
- Cases of myocarditis
- Cases of pericarditis
- Cases of COVID-19 that result in hospitalization or death

Reporting is also encouraged for other clinically significant adverse events, even if it is uncertain whether the vaccine caused the event.

Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.

In addition, anyone can register in About V-safe | Vaccine Safety Systems | CDC after their COVID-19 vaccination to receive health check-ins via text messages or email.

NOVAVAX COVID-19 VACCINE, ADJUVANTED (2024–2025 FORMULA)

At-A-Glance

Guidance below summarizes basic storage, preparation, scheduling, and administration for 2024–25 Novavax COVID-19 Vaccine product.

Ages: 12 years of age and older

Manufactured-filled syringe

Storage and Handling Basics

Find additional guidance on storing the vaccine properly at:

- CDC Vaccine Storage and Handling Toolkit
- Novavax COVID-19 Vaccine, Adjuvanted | FDA
- Investigational Vaccine Candidate | Novavax COVID-19 Vaccine (novavaxcovidvaccine.com)

Age	12 years and older
Supplied in:	Manufacturer-filled syringe (MFS)
Storage Temperature before use	**Between:** 2°C and 8°C (36°F and 46F°) until expiration date.* **Do not Freeze.** Protect from light.

* Check expiration date by scanning the QR on the outer carton or go to: www.novavax.com

Preparation and Administration Basics

Find additional guidance on preparing and administering vaccine properly at:

- Interim Clinical Consideration for use of COVID-19 Vaccine | CDC
- Vaccine Administration Resource Library | CDC
- Novavax COVID-19 Vaccine, Adjuvanted | FDA
- Novavax COVID-19 Vaccine (novavaxcovidvaccine.com)

Preparation

- Check syringe label to ensure it states Novavax Covid-19 Vaccine, Adjuvanted (2024 – 2025 Formula).
- Check syringe label to ensure the expiration date has not passed.
- **Do NOT** use vaccine after the expiration date.
- Refer to EUA Fact Sheet for detailed instructions.

Administration

- COVID-19 vaccine may be administered at the same clinical visit as other vaccines.
- Administer intramuscularly.

Recipient's Age	Dosage	Route	Needle gauge and length	Site
12 years of age and older	0.5 mL/5 *µg* rS protein and 50 *µg* of Matrix-M™ adjuvant	IM injection	22–25 gauge, 1 inch†	Deltoid muscle in the upper arm‡

† See Vaccine Administration: Needle Gauge and Length chart for more details.

‡ Vastus lateralis muscle in the anterolateral thigh may be used.

NOVAVAX COVID-19 VACCINE, ADJUVANTED (2024–2025 FORMULA)

At-A-Glance

Scheduling Doses

- The number of recommended 2024–25 COVID-19 vaccine doses varies by vaccine, vaccination history, and the presence of moderate or severe immune compromise.
- Review CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States for detailed clinical guidance when scheduling doses and the Interim COVID-19 Immunization Schedule for summary information.

Contraindications, Precautions, and Post-Vaccination Observation

Screen for contraindications and precautions before administering EACH dose — even if the vaccine was previously administered.

Contraindications

A severe allergic reaction (e.g., anaphylaxis) after previous dose or to a component of Novavax COVID-19 vaccine.*

Precautions

History of:

- A diagnosed non-severe allergy to a component of Novavax COVID-19 vaccine
- Non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of Novavax COVID-19 vaccine
- Current moderate to severe acute illness, with or without fever
- Multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)
- Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine

Consider observing persons after vaccination to monitor for allergic reactions and syncope:

- **30 minutes for persons with:**
  - A history of non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of Novavax COVID-19 vaccine
  - A history of a diagnosed non-severe allergy to a component of the Novavax COVID-19 vaccine
- **15 minutes:** All other persons

* See FDA fact sheet for a full list of vaccine ingredients.

Reporting of Vaccine Adverse Events

For the Novavax COVID-19 vaccine, which is given under an Emergency Use Authorization, vaccination providers are **required** to report to VAERS:

- Vaccine administration errors, whether or not associated with an adverse event (AE)
- Serious AEs, irrespective of attribution to vaccination. Serious AEs are per FDA defined as:
  - Death
  - A life-threatening AE
  - Inpatient hospitalization or prolongation of existing hospitalization
  - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
  - A congenital anomaly/birth defect
  - An important medical event that based on appropriate medical judgment may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.
- Multisystem Inflammatory Syndrome (MIS) in adults or children
- Cases of myocarditis
- Cases of pericarditis
- Cases of COVID-19 that result in hospitalization or death

Reporting is also encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event.

Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-9767.

In addition, anyone can register in V-safe after their COVID-19 vaccination to receive health check-ins via text messages or email.

2024-2025 Formula Pfizer-BioNTech COVID-19 Vaccine

At-A-Glance

Guidance below summarizes basic storage, preparation, scheduling, administration, and dosage for all 2024–25 Pfizer-BioNTech COVID-19 vaccine products.

Distributed in:

Ages: 6 months through 4 years
- **Multi-dose vial**
  yellow cap and yellow label

Ages: 5 through 11 years
- **Single-dose vial**
  blue cap and blue label

Ages: 12 years and older
- **Manufacturer-filled syringe**

Storage and Handling

Find additional guidance on storing vaccine properly at:

- CDC Vaccine Storage and Handling Toolkit
- Comirnaty | FDA
- Pfizer COVID-19 FACT SHEET
- Pfizer-BioNTech COVID-19 Vaccine | cvdvaccine.com

Ages	6 months through 4 years	5 through 11 years	12 Years and Older
Supplied in:	3-dose multi-dose vial (MDV) with diluent	Single-dose vial (SDV)	Manufacturer-filled syringe (MFS)*
Cap and/or label color:	Yellow cap and yellow label	Blue cap and blue label	Not Applicable
Storage temperature before puncture or use after puncture	Between: -90°C and -60°C (-130°F and -76°F) until the expiration date. 2°C and 8°C (36°F and 46°F) for up to 10 weeks. 8°C and 25°C (46°F and 77°F) for up to 12 hours prior to the first puncture. **Do NOT store in a standard freezer.** Once vials are thawed, they should not be refrozen. **Minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.** **NOTE:** The beyond-use date (10 weeks) replaces the manufacturer's expiration date but **NEVER** extends it. Always use the earliest date.		Between 2°C and 8°C (36°F and 46°F) until the expiration date. **Do NOT FREEZE.** **Note:** The total time out of refrigeration (at temperatures between 8°C and 25°C [46°F and 77°F]) must not exceed 12 hours. **Minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.**
Thawing frozen vaccine	If not previously thawed at 2°C to 8°C (36°F and 46°F), allow MDV or SDV to thaw at room temperature up to 25°C (77°F) for 30 minutes. Cartons of MDV with yellow caps and labels and cartons of SDV with blue caps and labels may take up to **2 hours** to thaw at 2°C to 8°C (36°F and 46°F) temperature. Once vials are thawed, they should not be refrozen.		Not Applicable
Storage temperature for punctured vials or activated manufactured-filled syringe	After dilution, MDV should be held between 2°C to 25°C (35° to 77°F). **Note:** MDV should be discarded 12 hours after dilution.		After removing the tip cap and attaching an appropriate needle, the glass prefilled syringe should be used immediately. If it cannot be used immediately, it must be used within 4 hours or discarded. **DO NOT FREEZE.**

* Single-dose vials for people 12 years and older are not available in the U.S. but may be available in other countries.

2024-2025 Formula Pfizer-BioNTech COVID-19 Vaccine

At-A-Glance

Preparation and Administration Basics

Find additional guidance on preparing and administering vaccine properly at:

- Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC
- Vaccine Administration Resource Library | CDC
- COVID-19 Vaccines | FDA
- Package Insert and FDA Approved Patient Labeling - COMIRNATY
- Pfizer-BioNTech COVID-19 Vaccine | cvdvaccine.com

Preparation

- Check that vial or syringe states 2024-25 Formula.
- If the vaccine is frozen, thaw before use.
- Check the vial or syringe label to ensure the expiration date or beyond-use date/time (if applicable) has not passed.
- Product for ages 6 months through 4 years: Mix with diluent.
  - Mix vial with 1.1 mL of diluent provided by the manufacturer. If using the MDV for the first time, record the date and time the vial was punctured. After dilution, MDV contain 3 doses of 0.3 mL each. If the amount of vaccine in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. **Do not pool excess vaccine from multiple vials.**
  - **NOTE:** The beyond-use time of 12 hours after dilution replaces the manufacturer's expiration date but NEVER extends it. Always use the earliest date.
  - **Do NOT use vaccine after the expiration date or beyond-use time.**
- Products for ages 5 years and older: **Do NOT dilute.**
- **For MDV:** Gently invert the vaccine vial 10 times to mix. **Do NOT shake.**
- **For SDV:** Prior to withdrawing the dose, mix by inverting the vial gently 10 times. **Do Not Shake**
- **Discard vial and any excess volume.**
- Refer to package insert or EUA Fact Sheet for detailed instructions.

Administration

- COVID-19 vaccines may be administered at the same clinical visit as other routinely recommended vaccines.
- Administer intramuscularly.

Recipient's Age	Dosage	Route	Needle gauge and length	Site
6 months through 4 years of age	0.3 mL/3 *µg*	IM injection	22–25 gauge, 1 inch*	**6 months–2 years of age:** Vastus lateralis muscle in the anterolateral thigh†
				2 through 4 years: Deltoid muscle in the upper arm‡
5 through 11 years of age	0.3 mL/10 *µg*L	IM injection	22–25 gauge, 1 inch*	Deltoid muscle in the upper arm‡
12 years of age and older	0.3 mL/30 *µg*	IM injection	22–25 gauge, 1–1.5 inch*§	Deltoid muscle in the upper arm‡

* A 5/8 inch needle may be used if administering the vaccine in the deltoid muscle AND the skin is stretched tightly and the subcutaneous tissue is not bunched for children and adolescents ages 1–18 years and adults ages 19 years and older who weigh less than 130 pounds.

† The deltoid muscle in the upper arm may be used if the muscle mass is adequate for children ages 1–2 years.

‡ The vastus lateralis muscle in the anterolateral thigh may be used as an alternate site.

§ See Vaccine Administration: Needle Gauge and Length chart for more details.

2024-2025 Formula Pfizer-BioNTech COVID-19 Vaccine

At-A-Glance

Scheduling Doses

The number of recommended 2024–25 COVID-19 vaccine doses varies by age, vaccine, vaccination history, and the presence of moderate or severe immune compromise. Review CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States for detailed clinical guidance when scheduling doses, and the Interim COVID-19 Immunization Schedule for summary information.

Contraindications, Precautions, and Post-Vaccination Observation

Screen for contraindications and precautions before administering EACH dose — even if the vaccine was previously administered.

Contraindications

History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine

Precautions

History of:

- A diagnosed non-severe allergy to a component of the COVID-19 vaccine
- Non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of one COVID-19 vaccine type, if receiving the same vaccine type
- Current moderate to severe acute illness, with or without fever
- Multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)
- Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine

Consider observing persons after vaccination to monitor for allergic reactions and syncope:

- **30 minutes** for persons with:
  - A history of a non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of one COVID-19 vaccine type, if receiving the same vaccine type
  - A history of a diagnosed non-severe allergy to a component of the COVID-19 vaccine, if receiving the same vaccine type
- **15 minutes:** All other persons

Reporting of Vaccine Adverse Events

For licensed Pfizer-BioNTech COVID-19 vaccines (for people ages 12 years and older), healthcare providers are **strongly encouraged** to report to VAERS:

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether or not it is clear that a vaccine caused the adverse event
- Vaccine administration errors, whether or not associated with an adverse event

For Pfizer-BioNTech COVID-19 vaccines given under an Emergency Use Authorization (for persons 11 years of age and younger)Vaccination providers are **required** to report to VAERS:

- Vaccine administration errors whether or not associated with an adverse event(AE)
- Serious AEs regardless of causality. Serious AEs per FDA are defined as:
  - Death
  - A life-threatening AE
  - Inpatient hospitalization or prolongation of existing hospitalization
  - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
  - A congenital anomaly/birth defect
  - An important medical event that based on appropriate medical judgment may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above
- Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults
- Cases of myocarditis
- Cases of pericarditis
- Cases of COVID-19 that result in hospitalization or death

Reporting is also encouraged for other clinically significant adverse events, even if it is uncertain whether the vaccine caused the event.

Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.

In addition, anyone can register in About V-safe | Vaccine Safety Systems | CDC after their COVID-19 vaccination to receive health check-ins via text messages or email.

COVID-19

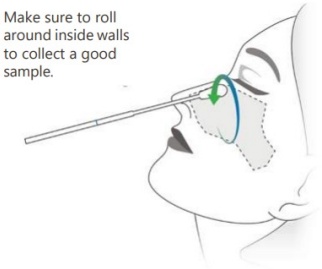
LUCIRA® - COVID-19 & Flu Test

The LUCIRA by Pfizer COVID-19 & Flu Test is a point-of-care test kit that is authorized for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B viral RNA in nasal swab specimens collected from individuals (2 years of age or older) who are suspected of a respiratory viral infection by their health care provider.

This product has not been FDA cleared or approved but has been granted authorization for emergency use due to the significant potential for a public health emergency that can be caused by Covid-19 related infections. Patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation are authorized to utilize this device for the Point-of-Care (POC) detection of Covid-19 or Influenza A and B respiratory infections.

How Does It Work?

LUCIRA is a battery-operated testing device that utilizes nucleic acid amplification to detect the presence of Covid-19, Influenza A, or Influenza B viral RNA in collected nasal specimens. The test kit is unable to detect the presence of Influenza C RNA and should not be used for this purpose.



To effectively perform the LUCIRA test, healthcare professionals should begin by collecting the resident's nasal specimen by gently inserting a cotton swab into the nostril until resistance is met. Gently rotate the swab five times against the nostril wall to collect a sufficient specimen. This process should be repeated for the remaining nostril as well.

Once the specimen has been collected, place the swab into the sample vial containing the buffer solution and gently stir 15 times to mix. After stirring, discard the swab and replace the cap on the vial, a "ready light" should blink to indicate test is running. If the ready light does not appear to be blinking, try pressing vial firmly into the device to start the test.

After approximately 30 minutes, the ready light will dim, and result lights will illuminate indicating that the test is ready to be read. Lights illuminated to the left of the infection name displayed indicate a negative test result while lights illuminated to the right indicate a positive test result. If both left and right lights blink for one or all infections, as in the image to the right, the test is considered invalid. A retest will need to be administered. Individuals who receive an invalid test result may obtain a free retest by contacting Pfizer at 1-888-LUCIRA-4.

How to Interpret Results?

A positive test will confirm the presence of Covid or Influenza RNA, however, a positive test result should not be used solely for the diagnosis of a suspected respiratory infection. Positive results also do not rule out presence of bacterial infections or other co-infections with other pathogens. Pertinent diagnostic information such as past medical history, clinical presentation, and symptom duration should be used to confirm the diagnosis.

Similarly, a negative test result should not be used as a confirmation of the absence of infection. Instead, however, results should be considered presumptive and followed up other clinical considerations such as signs and symptoms, recent exposure, and compliance with recommended vaccinations.

Billing and Coding for LUCIRA

Coverage for LUCIRA may vary across commercial payers, Medicare, and Medicaid. The following serves as an abridged reference of commonly encountered codes for healthcare providers when submitting claims or reports. Providers should verify payer-specific coding requirements prior to submission.

Scan the QR code
for more information and instructional videos!

PharMerica®

COVID-19

LUCIRA® NATIONAL DRUG CODES

TYPE OF CODE	10 - DIGIT	11 - DIGIT	DESCRIPTION	UNITS
NDC Code	**0069-9701-31**	**00069-9701-31**	LUCIRA Covid-19 & Flu Test in Vitro Kit	Units 1 "EACH"

CODING FOR LUCIRA ADMINISTRATION SERVICES

TYPE OF CODE	CODE AND DESCRIPTOR	RELEVANT SITES OF SERVICE
Administration: CPT® codes	**87636:** Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and influenza virus types A and B, multiplex amplified probe technique	Physician office and hospital outpatient department
Administration: CPT® modifier	**QW*:** Clinical Laboratory Improvement Amendment (CLIA) waived test	

DIAGNOSIS CODING FOR LUCIRA

Code	Description
J22	Unspecified acute lower respiratory infection
U07.1	COVID-19
Z20.822	Contact with and (suspected) exposure to COVID-19
Z20.828	Contact with and (suspected) exposure to other viral communicable diseases
J09.X2	Influenza due to identified novel influenza A virus with other respiratory manifestations
J09.X3	Influenza due to identified novel influenza A virus with gastrointestinal manifestations
J09.X9	Influenza due to identified novel Influenza A virus with other manifestations
J00	Acute nasopharyngitis (common cold)
R05.1	Acute cough
R06.2	Wheezing
R07.1	Chest pain on breathing
R43,9	Unspecified disturbances of smell and taste

** This list is not all inclusive but serves to highlight the most commonly used ICD-10 codes encountered with LUCIRA use. Check with your resident's insurance provider for a complete list of permissible codes.*

APPENDIX

APPENDIX

Appendix A
Influenza and COVID-19 Vaccine Codes and Reimbursement

Table 1. Flu Vaccine CPT-Reimbursement

Adult Influenza Vaccinations					
Approved Age Range for Adults	**Older Adults Ages 65+**		**All Adults Ages 18+**		
Brand Names	**Fluad**	**Fluzone HD**	**Flublok**	**Flucelvax**	**Afluria, Fluarix, Flulaval, Fluzone**
Vaccine Type	Adjuvanted Trivalent Vaccine (aIIV3)	High-Dose Trivalent Vaccine (HD-IIV3)	Recombinant Trivalent Vaccine (RIV3)	Cell-Cultured Standard Trivalent Vaccine (ccIIV3)	Standard Trivalent Vaccines (IIV3)
Preferentially Recommended in Age 65+?	✓	✓	✓	×	×
Unique Development	Contains adjuvant "booster" (MF59) to increase immune response	Contains 4x the amount of antigen vs standard trivalent vaccine to increase immune response	Contains 3x the amount of antigen vs standard trivalent vaccine and is produced via recombinant technology (egg free)	Produced using cell cultures (egg free)	-

2024-25 CMS Influenza Vaccine Reimbursements							
Brand Names	**Fluad**	**Fluzone HD**	**Flublok**	**Flucelvax**		**Standard Influenza Vaccines**	
Package Type	Prefilled Syringes	Prefilled Syringes	Prefilled Syringes	Prefilled Syringes	Multi-dose Vial	Prefilled Syringes	Multi-dose Vial
2024-2025 CPT Reimbursement Rate	$83.49	$83.49	$83.49	$36.85	$36.85	$22.35	$21.86
2024-2025 CPT Code	90653	90662	90673	90661	90661	90656	90658

APPENDIX

Appendix A
Influenza and COVID-19 Vaccine Codes and Reimbursement, Continued

Table 2. COVID-19 Vaccine CPT-Reimbursement

Adult COVID-19 Vaccinations			
Approved Age Range for Adults	All Adults (and Adolescents) Ages 12+		
Brand Names	SPIKEVAX (2024-25 Formula)	COMIRNATY (2024-25 Formula)	NOVAVAX COVID-19 Vaccine (2024-25 Formula)
Vaccine Type	mRNA	mRNA	Protein Subunit
Manufacturer	Moderna	Pfizer-BioNTech	Novavax
FDA-Approved?	✓	✓	× Under EUA

2024-25 CMS COVID-19 Vaccine Reimbursements			
Brand Names	SPIKEVAX	COMIRNATY	NOVAVAX COVID-19
Package Type	Prefilled Syringes	Prefilled Syringes	Prefilled Syringes
2024-2025 CPT Reimbursement Rate	$161.65	$155.90	$161.54
2024-2025 CPT Code	91322	91320	91304

Influenza
and
Adult Immunization Guide

PharMerica®

2024 - 2025