Vaccine Toolkit 2023

HealthCap
RISK MANAGEMENT SERVICES

Tools and Samples

- HealthCap Respiratory Immunization/Vaccination Policy and Procedure
- EUI Fact Sheet - Updated COVID-19 2023-2024
- Influenza (Flu) Vaccine (Inactivated or Recombinant): What you need to know – CDC Vaccine Information Statement
- RSV (Respiratory Syncytial Virus) Vaccine: What You Need to Know – CDC Vaccine Information Statement
- Pneumococcal Conjugate Vaccine: What You Need to Know – CDC Vaccine Information Statement
- HealthCap Respiratory Vaccine Considerations
- HealthCap Winter Respiratory Viral Season
- HealthCap COVID-19 Vaccine Policy (Staff)
- HealthCap COVID-19 Vaccine Policy (Student, volunteer, or employment arrangement)
- HealthCap COVID-19 Vaccine Medical Exemption Request
- HealthCap COVID-19 Vaccine Religious Exemption Request
- HealthCap Influenza – Highest Risk Populations
- HealthCap Flu Vaccination Exemption Request
- HealthCap Increased Interseasonal Respiratory Syncytial Virus (RSV) Activity
- 5 Reasons it is Important for Adults to Get Vaccinated
- ACIP Shared Clinical Decision-Making Recommendations
- Recommended Adult Immunization Schedule for ages 19 or older 2023
- Recommended COVID-19 vaccines for people who ARE moderately or severely immunocompromised, aged 6 months-4 years, mRNA vaccines, with vial icons and dosages, May 2023
- Talking with your LTC Staff About the Vaccines
- How Do I Safely Use A Multi-Dose Vaccine Vial - CDC
- Prevaccination Checklist for COVID-19 Vaccines - CDC

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- Pfizer-BioNTech COVID-19 Vaccine - At-A-Glance - CDC
- Pfizer-BioNTech COVID-19 Vaccine – Vaccine Preparation - CDC
- Bivalent Moderna COIVD-19 Vaccine - CDC
- FAQS for the Interim Clinical Considerations for COVID-19 Vaccination
- Healthcare Personnel Influenza Vaccination
- Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices – United States, 2023-24 Influenza Season - CDC
- Respiratory syncytial virus (RSV)
- Frequently Asked Questions About RSV Vaccine for Adults
- Respiratory Syncytial Virus Infection (RSV) - CDC
- Respiratory Syncytial Virus Infection (RSV) – Symptoms and Care - CDC
- Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices – United States, 2023 - CDC
- RSV in Older Adults and Adults with Chronic Medical Conditions
- Healthcare Providers: RSV Vaccination for Adults 60 Years of Age and Over
- Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices –United States, 2023 - CDC
- Vaccine Storage and Handling Toolkit - CDC
- Additional Resources

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Respiratory Immunization/Vaccination

Policy & Procedure

Policy

It is the policy of this facility to minimize the risk of acquiring, transmitting, or experiencing complications from respiratory viruses by educating and offering our residents, staff members, and volunteer workers annual immunizations per CDC recommendations.

General Considerations:

- The immunization program for respiratory viruses will be developed with the medical director based on national standards of practice.
- Each resident or resident representative will receive education regarding the benefits and potential side effects of immunizations.
- Residents will be offered respiratory virus immunizations beginning per local health department recommendations (October 1 through March 31) unless the immunization is medically contraindicated, or the resident has already been immunized during this time period.
- Vaccinations will be offered to residents as recommended for the facility's geographic area.
- Residents and/or resident representatives may refuse immunizations and sign a declination consent.
- The resident's medical record will include documentation that indicates, at a minimum, the following:
  - The resident and/or resident representative was provided education regarding the benefits and potential side effects of respiratory vaccines; and
  - If the resident received the vaccines or declined due to medical contraindications.
- Staff and volunteers will be assessed for medical contraindications of vaccines and receive education regarding the benefits and potential side effects.

Staff are [encouraged/mandated] to be immunized annually to prevent infection and transmission of respiratory viruses and possible complications, including death to patients, coworkers, family, and community.

Procedure

1. Assess person receiving the immunization for medical contraindications: life threatening reaction after getting an influenza vaccine, history of Guillain-Barre syndrome, temperature of 100.4 or greater.
2. Vaccinations may be administered in accordance with physician-approved "standing orders" for those with no known medical contraindications.
3. Prior to the administration of any vaccine, the person receiving the immunization, or his/her legal representative, will be provided with a copy of CDC's current vaccine information statement.

4. Individuals receiving any vaccine, or their legal representative, will sign a consent form prior to the administration of the vaccine. The completed, signed, and dated consent will be filed in the individual's medical record or employment medical record.
5. The resident's medical record will include documentation that the resident and/or the resident's representative was provided education regarding the benefits and potential side effects of immunization, and that the resident received the immunization or declined due to medical contraindication or refusal.
6. Residents, staff members, and volunteer workers retain the right to refuse immunization for religious reasons or if deemed contraindicated for medical reasons. *The facility reserves the right to require any staff member who did not receive the recommended respiratory vaccination to wear a mask at all times while in the center.*
7. A physician statement will be required for any staff members refusing vaccination for medical reasons.
8. If a person has already received the vaccine, documentation of prior vaccination will be required.
9. If there is a national shortage of vaccines or other issue with availability leading to an inability to implement the vaccine program, the facility will demonstrate:
    a. The vaccine has been ordered and the facility received either the vaccine or a confirmation of the order indicating that the vaccine has been shipped or that the product is not available but will be shipped when the supply is available.
    b. Plans are developed on how and when the vaccine will be administered when available.
    c. Residents will be screened to determine how many and which residents are eligible and wish to receive the vaccine; and
    d. Education regarding immunizations has been provided.

Documentation

Documentation regarding the administration of vaccines will include the date of vaccination**,** Lot number, expiration date, route of administration (IM/Deltoid/Right or Left), and signature of the licensed nurse who administered the vaccine.

Addendum COVID Pandemic:

- Influenza (Flu), Respiratory Syncytial Virus (RSV) and COVID-19 are contagious respiratory illnesses, however they are caused by different viruses. COVID-19 is caused by infection with a new coronavirus (called SARS-CoV-2), flu is caused by infection with influenza viruses and RSV is caused by the enus Orthopneumovirus, family Pneumoviridae.

Respiratory Immunization/Vaccination

Policy & Procedure

- Because some of the symptoms of flu, RSV, and COVID-19 are similar, it may be difficult to distinguish between them based on symptoms alone. Testing may be needed to confirm a diagnosis.
- Although flu, RSV, and COVID-19 share many characteristics, there are some key differences between them.
- It is possible to be infected with the flu virus as well as other respiratory illnesses including RSV and/or COVID-19 at the same time.
- Getting a flu vaccine will not protect against RSV or COVID-19, however flu vaccination has many other important benefits. Flu vaccines have been shown to reduce the risk of flu illness, hospitalization, and death. Getting a flu vaccine this fall will be more important than ever, not only to reduce your risk from flu but also to help conserve potentially scarce health care resources.
- Vaccination should be deferred (postponed) for people with suspected or confirmed COVID-19, regardless of whether they have symptoms, until they have met the criteria to discontinue their isolation.
- While mild illness is not a contraindication to the flu or RSV vaccination, vaccinations for people with symptoms should be postponed, in an effort to avoid exposing healthcare personnel and others to the virus that causes COVID-19.
- Prior infection with suspected or confirmed COVID-19, RSV, or flu does not protect someone from future flu infections. The best way to prevent seasonal flu is to get vaccinated every year.

References:

Center for Medicare & Medicaid Services, U.S. Department of Health and Human Services. State Operations Manual: Appendix PP – Guidance to Surveyors for Long Term Care Facilities. F883. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

I have read, understand and agree to adhere to the requirements outlined in this policy and procedure.

Resident/Legal Decision Maker:_____ Date:_____

Employee:_____Date:_____

Administrator Signature: _____ Date: _____

Medical Director Signature: _____ Date: _____

Review Dates: _____ _____ _____ _____ _____

This policy and procedure is not intended to replace the informed judgment of individual physicians, nurses or other clinicians nor is it intended as a statement of prevailing community standards or minimum standards of practice. It is a suggested method and technique for achieving optimal health care, not a minimum standard below which residents necessarily would be placed at risk.

Emergency Use Instructions (EUI) Fact Sheet for Recipients and Caregivers: Additional Doses of the Updated COVID-19 Vaccine, 2023-2024 Formula, by Pfizer-BioNTech

This Fact Sheet describes Emergency Use Instructions (EUI) that have been issued by the Centers for Disease Control and Prevention (CDC) to provide information about additional doses of the Updated COVID-19 vaccine, 2023-2024 Formula (monovalent, XBB containing), by Pfizer-BioNTech (Comirnaty) that go beyond its FDA-approved labeling. These uses under EUI are for doses for people ages 12 years and older who are moderately or severely immunocompromised. See below for more information on the uses of the updated COVID-19 vaccine by Pfizer-BioNTech under EUI.

If you are 12 years and older and you are receiving vaccination for uses provided under EUI, you have a choice of receiving the updated COVID-19 vaccine by either Pfizer-BioNTech or Moderna (see the Moderna EUI Fact Sheet for Recipients and Caregivers).

What are Emergency Use Instructions (EUI)?
EUI are issued by CDC to provide information about emergency use of FDA-approved (licensed) medical products that may not be included in or differ in some way from the information provided in the FDA-approved labeling (package insert). EUI consist of fact sheets for healthcare providers and recipients.

Why is CDC issuing EUI for the updated COVID-19 vaccine by Pfizer-BioNTech?
The updated COVID-19 vaccine by Pfizer-BioNTech is an FDA-approved COVID-19 vaccine (brand name Comirnaty, mRNA) to prevent COVID-19 in persons ages 12 years and older. CDC is issuing EUI to provide information about this vaccine for the below uses that extend beyond its FDA-approved labeling (see "Who can receive additional doses of the updated COVID-19 vaccine by Pfizer-BioNTech under the EUI?"). The updated COVID-19 vaccine by Moderna can also be used under EUI for similar uses as an alternative mRNA COVID-19 vaccine (see the Moderna EUI Fact Sheet for Recipients), and the same or similar recommendations in this EUI also apply to the use of the updated COVID-19 vaccine by Moderna under EUI.

What is COVID-19?
Coronavirus disease 2019 (COVID-19) is an infectious disease caused by a coronavirus called SARS-CoV-2. It is predominantly a respiratory illness that can affect other organs. People with SARS-CoV-2 infection have reported a wide range of symptoms, from no symptoms to severe illness leading to death. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include fever or chills, cough, shortness of breath, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, and diarrhea.

Who can receive additional doses of the updated COVID-19 vaccine by Pfizer-BioNTech under the EUI?
People who can receive the updated COVID-19 vaccine by Pfizer-BioNTech under EUI are described below.

- People ages 12 years and older who are moderately or severely immunocompromised

The updated COVID-19 vaccine by Moderna can also be used under EUI for similar uses in persons ages 12 years and older as an alternative updated mRNA COVID-19 vaccine (see the Moderna EUI Fact Sheet for Recipients).

Talk to your healthcare provider about if and when you should receive additional vaccine doses. See CDC's Interim Clinical Considerations for additional information on people who are moderately and severely immunocompromised recommended for an additional doses

Who should NOT get the updated COVID-19 vaccine by Pfizer-BioNTech?

You should not get the vaccine if you:

- Had a severe allergic reaction after a previous dose of the COVID-19 vaccine by Pfizer-BioNTech
- Had a severe allergic reaction to any ingredient of the COVID-19 vaccine by Pfizer-BioNTech

What should I mention to the vaccination provider before getting the updated COVID-19 vaccine by Pfizer-BioNTech?

Tell your vaccination provider the name, number of doses, and date(s) of COVID-19 vaccine(s) you received previously. Also, mention all of your medical conditions, including if you:

- Have any allergies
- Have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- Have a fever
- Have a bleeding disorder or are on a blood thinner
- Are immunocompromised or are on a medicine that affects your immune system
- Have ever fainted in association with an injection
- Are pregnant
- Are breastfeeding

How is the updated COVID-19 vaccine by Pfizer-BioNTech given?

COVID-19 vaccine by Pfizer-BioNTech is given as an injection into the muscle.

Has the COVID-19 vaccine by Pfizer-BioNTech been used before?

Millions of people have received a Pfizer-BioNTech COVID-19 vaccine in the United States since it became available starting in mid-December 2020. Also, in clinical trials, approximately 23,000 people ages 12 years and older received at least 1 dose of a Pfizer-BioNTech COVID-19 vaccine (original monovalent).

The updated Pfizer-BioNTech COVID-19 Vaccine is made in the same way as the Pfizer-BioNTech COVID-19 Vaccine (original monovalent) and Pfizer-BioNTech COVID-19 vaccine, Bivalent, but it encodes the spike protein of SARS-CoV-2 Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).

What are the risks of the COVID-19 vaccine by Pfizer-BioNTech?

Side effects that have been reported following administration of a Pfizer-BioNTech COVID-19 vaccine include injection site pain, fatigue, headache, chills, muscle pain joint pain, fever, injection site swelling, and injection site redness. Common side effects reported were mostly mild, but some people had side effects that affected their ability to do daily activities. Cases of myocarditis and pericarditis have rarely been reported in some people. Cases have occurred predominantly in adolescents and young adult males within the first week following vaccination. Anaphylaxis (severe allergic reaction to the vaccine) has been rarely observed following COVID-19 vaccines. These types of allergic reactions can rarely occur with any kind of vaccine or medical product.

Additional information on the common and serious side effects of the COVID-19 vaccine by Pfizer-BioNTech can be found in the package insert for Comirnaty.

What are the benefits of the COVID-19 vaccine by Pfizer-BioNTech?

The COVID-19 vaccine by Pfizer-BioNTech has been shown in multiple studies to be effective in preventing severe illness and death from COVID-19. Additional doses of the updated COVID-19 vaccine by Pfizer-BioNTech as described under EUI may help to increase immune response in people who are moderately or severely immunocompromised, which could improve protection against COVID-19. The updated COVID-19 vaccine by Pfizer-BioNTech may not protect everyone.

What are the Risks and Benefits of the updated COVID-19 vaccine by Pfizer-BioNTech?
The FDA approved Pfizer-BioNTech COVID-19 vaccines to prevent COVID-19 based on safety and efficacy data available from clinical trials. Based on available information, the use of the updated COVID-19 vaccine by Pfizer-BioNTech as described in this Fact Sheet could help improve or restore protection that may not have been sufficient or may have decreased over time after vaccination, and as such the known and potential benefits of vaccination outweigh the known and potential risks of the vaccine.

What alternative choices are available for additional doses other than the COVID-19 vaccine by Pfizer-BioNTech?
Currently, the updated Pfizer-BioNTech COVID-19 vaccine (Comirnaty) and updated Moderna COVID-19 vaccine (Spikevax) are the only FDA-approved COVID-19 vaccines for which EUI provide information about additional doses for people who are moderately or severely immunocompromised.

It is your choice to receive or not receive the updated COVID-19 vaccine by Pfizer-BioNTech as an additional dose. Should you decide not to receive it, it will not change your standard medical care.

What is the 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 www.hrsa.gov/cicp/ or call 1-855-266-2427.

How can I learn more?
- Ask the vaccination provider.
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
- Contact your local or state public health department.

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**.

VACCINE INFORMATION STATEMENT

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 is usually spread 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.

RSV can cause illness in people of all ages but may be especially serious for infants and older adults. Infants and older adults with chronic medical conditions like heart or lung disease, weakened immune systems, or who live in nursing homes or long-term care facilities, are at highest risk of serious illness and complications from RSV.

Symptoms of RSV infection may include runny nose, decrease in appetite, coughing, sneezing, fever, or wheezing. Most people recover in a week or two, but RSV can be serious, resulting in shortness of breath and low oxygen levels. RSV can also 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 through 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 and older** may receive a single dose of RSV vaccine, based on discussions between the patient and health care provider.

RSV 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 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.

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

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 very rarely after RSV vaccination in clinical trials. It is unclear whether the vaccine caused these events.

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**.

VACCINE INFORMATION STATEMENT

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.

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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.*

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RISK MANAGEMENT SERVICES

Respiratory Vaccine Considerations

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    a. The vaccines have been ordered and the facility received either the vaccines or a confirmation of the order indicating that the vaccines have been shipped or that the products are not available but will be shipped when the supply is available.
    b. Plans are developed on how and when the vaccines will be administered when available.
    c. Residents will be screened to determine how many and which residents are eligible and wish to receive the vaccines; and
    d. Education regarding immunizations has been provided.

2. Documentation regarding the administration of all vaccines will include a physician order, the date of vaccination, lot number, expiration date, route of administration (IM/Deltoid/Right or Left), and signature of the licensed nurse who administered the vaccine.

3. Influenza (Flu), Respiratory Syncytial Virus and COVID-19 are contagious respiratory illnesses, however they are caused by different viruses. COVID-19 is caused by infection with a new coronavirus (called SARS-CoV-2), flu is caused by infection with influenza viruses and RSV is caused by the genus Orthopneumovirus, family Pneumoviridae.

4. Because some of the symptoms of respiratory viruses are similar, it may be difficult to distinguish between them based on symptoms alone. Testing may be needed to confirm a diagnosis.

5. It is possible to be infected with more than one respiratory virus at the same time.

6. Getting a flu vaccine will not protect against other respiratory viruses, however the flu vaccination has many other important benefits. Flu vaccines have been shown to reduce the risk of flu illness, hospitalization, and death. Getting a flu vaccine this fall will be more important than ever, not only to reduce your risk from flu but also to help conserve potentially scarce health care resources.

7. Vaccination should be deferred (postponed) for people with suspected or confirmed COVID-19, regardless of whether they have symptoms, until they have met the criteria to discontinue their isolation.

8. Prior infection with suspected or confirmed respiratory viruses does not protect someone from future infections. The best way to prevent respiratory viruses is to get vaccinated based on current CDC recommendations.

References:

Center for Medicare & Medicaid Services, U.S. Department of Health and Human Services. State Operations Manual: Appendix PP – Guidance to Surveyors for Long Term Care Facilities. F883.
https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

Respiratory Syncytial Virus Vaccine VIS (cdc.gov)

RSV Vaccine Information Statement | CDC

Adult Immunization Schedule – Healthcare Providers | CDC

2023-2024 CDC Flu Vaccination Recommendations Adopted | CDC

I have read, understand, and agree to adhere to the requirements outlined in this policy and procedure.

Resident/Legal Decision Maker:_____ Date:_____

Employee:_____Date:_____

Administrator Signature: _____ Date: _____

Medical Director Signature: _____ Date: _____

Review Dates: _____ _____ _____ _____ _____

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Winter Respiratory Viral Season

Respiratory Virus Immunization

- Vaccination continues to be a pillar of public health, protecting individuals and the larger community.
- Adverse events from existing vaccines are rare and the cost of treating these events is minimal compared with the morbidity and mortality associated with vaccine-preventable diseases.
- Currently there are four (4) respiratory vaccines available to most nursing home residents; influenza, RSV, pneumococcal and COVID-19 vaccines.
- The Centers for Medicare and Medicaid Services (CMS) mandate that nursing homes must offer influenza, pneumococcal and COVID-19 vaccines to their residents. RSV vaccine is recommended for those over 60 years old.
- Immunization rates for these infections reveal significant room for improvement.
- If residents are unsure of their vaccine status, it is advised that they be given the vaccine.
- High-dose influenza vaccines have been developed specifically to overcome immunosenescence common among older adults.
- For people with allergies to eggs, the CDC stated that extra measures are no longer needed. People with egg allergies can receive any flu vaccine, egg-based or non-egg based.
- Even when the seasonal influenza vaccine is not a particularly good match, these immunizations reduce both the incidence and the severity of the influenza as well as help protect others through herd immunity.
- There are currently two pneumococcal vaccines licensed in the United States for use in adults:
    - 23-valent pneumococcal polysaccharide vaccines (PPSV23)
    - 13-valent pneumococcal conjugate vaccine (PCV13, PCV15, and PCV20)
- In November 2019, the Advisory Committee on Immunization Practices changed their recommendations for these vaccines in older adults.
- All adults older than 65 should continue to receive one dose of PPSV23, but recommendations for PCV13 now encourage shared clinical decision in adults older than 65 who do not have an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak.
- The Advisory Committee on Immunization Practices recommends that all nursing home employees receive an annual influenza vaccination, including those who do not have direct patient care responsibilities.
- Only about 68% of nursing home staff were vaccinated in 2020.
- Mandatory vaccination policies increase influenza vaccination rates to nearly 100%.
- AMDA's Infection Advisory Committee recommends that all nursing homes adopt a mandatory vaccination policy.
- The Centers for Disease Control and Prevention (CDC) provides numerous resources as do state and local health departments.

- Nursing home leadership might consider paid leave or other benefits to workers who receive a vaccination.
- Nursing home leadership may need to work with their local health department and health care system to provide free access to the vaccine, preferably on site and across all shifts, to promote staff participation.

Diagnosis and Treatment of Suspected Respiratory Tract Infections

- The diagnosis and treatment of suspected respiratory infections is a multifaceted process.
  - Recognizing symptoms of an acute infection.
  - Recognition of respiratory tract involvement.
  - Clinician conducts a diagnostic evaluation, initiates supportive care and considers whether bacterial pathogens are involved.
  - Decisions about prescribing an antibiotic, which antibiotic to use, what dose and for what duration.
- Diagnosing respiratory tract infections in nursing home residents is difficult as evidenced by a recent Delphi study that failed to reach consensus regarding the clinical criteria required to diagnose pneumonia.
- Adults with community-acquired pneumonia suggested that viruses may be responsible for 23% of cases, with bacteria identified in only 11% of cases.
- Pneumonia carries with it a case fatality rate of at least 25% in nursing homes; this may prompt clinicians to err on the side of antibiotic prescribing.
- This contributes to antibiotic overuse and subsequently to the growing problem of antibiotic resistance.
- Also, delays in recognizing viral respiratory infections can lead to outbreaks in nursing homes with increased mortality.
- SARS-CoV-2 can cause infections that range from asymptomatic to typical cold-like symptoms affecting only the upper respiratory tract, to involvement of the lower respiratory trace with a viral pneumonia leading to increased oxygen requirements that may progress to acute respiratory disease syndrome and death.
- The relatively prolonged incubation period of COVID-19 infections means that infected individuals shed virus for a longer time before developing clinically recognizable symptoms.
- Older adults may experience both typical and atypical signs and symptoms of COVID-19 infection.
- Typical signs include:
  - Fever
  - Cough
  - Increased oxygen requirements
- The threshold for adults to recognize fever is lower than applied to younger adults, the commonly accepted definition including any temperature > 100.0° F or repeated temperatures of > 99.0° F.
- An atypical sign of COVID-19 infection is confusion and severe confusion may indicate delirium.

- Other atypical signs include:
  - Diarrhea
  - Vomiting
  - Loss of appetite
- Typical symptoms of COVID-19 infection that older adults might report are:
  - Shortness of breath
  - Feeling feverish or chilled
  - Feeling tired or fatigued
  - Having a headache
  - Having muscle aches
  - New loss of taste or smell
- Sometimes, gastrointestinal "atypical symptoms" precede the respiratory tract symptoms by a few days.
- Nursing homes should be actively screening residents daily for signs and symptoms of COVID-19 infection.
- Any resident with a positive screen should undergo ore thorough evaluation by a clinician, using a low threshold to initiate COVID-19 testing.
- A single case of COVID-19 infection among staff or residents in a nursing home is considered an outbreak.
- During outbreaks, staff and residents should be tested for COVID-19 at least weekly until a 2-week period transpires without identification of new cases.
- If there is no outbreak, residents do not typically undergo screening tests, whereas the frequency of staff screening depends on whether there are cases of COVID-19 in the building and the level of COVID-19 in the local community. CMS recommends monthly testing if the community positivity rate in the past week was < 5% and twice weekly testing if it was > 10%.
- Antibiotic stewardship remains critical this winter. Current evidence suggests that only 8% of hospitalized patients with COVID-19 have demonstrable bacterial or fungal coinfections yet one study showed 72% of patients received antibiotics.
- Consistent with the focus of CMS on antibiotic stewardship over the past years, the core elements of antibiotic stewardship (leadership, accountability, drug expertise, action, tracking, reporting and education) can all be applied to COVID-19 management.

Important Differences Between Nursing Homes and Assisted Living

- In the United States, assisted living provides supportive care to more than 800,000 residents.
- Most residents pay for their care privately.
- Cognitive impairment affects 70-90% of assisted living residents.
- 42% of assisted living residents have moderate or severe dementia.
- Family members are more involved in monitoring their relatives' well-being and medical status than are families of nursing home residents.

- Detection is also hampered because these settings are not always required to have a medical director or licensed nurse.
- Not all states have infection control policies for assisted living.

Supporting Staff During the Winter Virus Season

- The U.S. Department of Labor's Occupational Safety and Health Administration issued a notice on nursing home worker safety including tips for employers to keep staff safe, such as reducing intra-staff exposures by:
  - Limiting crowding in break rooms, live meetings and other group gatherings
  - Making sufficient PPE available
  - Continually monitoring the PPE supply.
  - Develop plans to accommodate staff shortages as reports indicate that staff shortages persist.
  - Include preparing for potential loss of staff due to illness or exposure to COVID-19.
  - The Families First Coronavirus Response Act (FFCRA) included provisions for worker paid leave. The law was intended to encourage employers to permit their sick employees to stay home.
  - There are limitations to the act that may encourage staff to work while sick, which would expose others to infection or alternately, have these low-paid workers incur financial loss to protect the residents.
  - Emergency staffing plans should be developed to account for significant staffing shortages, including communication with the local health department and outreach to other local long-term care providers and hospitals.

Preventing the Spread of Respiratory Viruses

- Influenza, RSV, and COVID-19 spread primarily via droplets and less commonly through fomite transmission and aerosolization.
- The influence of heating systems that recirculate air on increasing the aerosol spread of respiratory viruses is not yet clear.
- We know that masks and other PPE prevent the spread of respiratory viruses.
- Inadequate PPE has demonstrably increased the death toll in nursing homes, so it is critical to have access to ample supplies this winter.
- Isolate persons with active symptoms of a respiratory virus.
- Have a workable plan for addressing new symptoms among residents, staff, and their family members.
- The plans should include a focus not only on airborne transmission and PPE but also on handwashing and surface decontamination because most respiratory viruses, other than influenza and SARS-CoV-2 may be spread by touch rather than by inhalation.

2023-2024 CDC Flu Vaccination Recommendations Adopted | CDC

I have read, understand, and agree to adhere to the requirements outlined in this policy and procedure.

Resident/Legal Decision Maker:_____ Date:_____

Employee:_____Date:_____

Administrator Signature: _____ Date: _____

Medical Director Signature: _____ Date: _____

Review Dates: _____ _____ _____ _____ _____

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RISK MANAGEMENT SERVICES

COVID-19 Vaccine Policy

Policy

As a Condition of Participation in the Medicare and Medicaid programs, the Centers for Medicare and Medicaid Services (CMS) requires that all staff be vaccinated to reduce the risk of transmitting COVID-19. It is our policy that all students, volunteers, employees, contractors and any other individual who contracts with or provides services to our residents will take necessary precautions and adhere to mandated guidelines established through this policy. The intent of this policy is to safeguard the health of our employees and their families; our customers and visitors; and the community at large from COVID-19 that may be reduced by vaccinations. This policy is consistent with all applicable laws, regulations, and guidance from federal, state and local health authorities, as applicable.

As a condition of employment or access to the center, all staff, employees, and contractors are required to receive the COVID-19 vaccination. Exemptions to this policy will be provided only for employees or contractors with an approved medical or religious exemption, as described below. Employees who do not timely receive the vaccine and do not obtain an exemption will be considered to have refused to comply with this policy and to have voluntarily resigned their employment. Contractors who refuse to comply with this policy will not be permitted to enter the center.

Guidelines

It is required that all individuals in the center receive the designated COVID-19 vaccination or provide evidence of vaccine receipt or exemption. Guidelines have been established to assist with determining the course of action to be taken in order to reach compliance with this policy.

1. It is required that all employees and contractors working within the center receive a COVID-19 vaccination as a condition of employment or access to the center unless a valid medical or religious exemption is granted. All current employees and contractors are expected to either receive the first dose of a 2-shot series or a single dose of a 1 shot COVID-19 vaccine or obtain an approved exemption from the vaccination requirement by _____, and must complete the vaccination series by _____.

2. All employees and contractors vaccinated through services other than those provided by the center (i.e., private physician office or public clinics), must provide written proof of immunization to the Human Resources department within five (5) days of receiving the vaccination. Examples of written proof of immunization include a vaccination card issued by the CDC, a physician's note, a receipt containing the vaccine information or a signed and current vaccination consent form. An employee or contractor who has not provided written proof of immunization (or has failed to secure an approved exemption or immunization), within the aforementioned time period will be

considered to have refused to comply with this policy and to have voluntarily resigned their employment and/or rescinded any verbal or written contractual relationship. Providing false written proof of immunization will be considered a violation of this policy and will result in termination.

3. An educational program will be available to all employees which includes information about the vaccine, non-vaccine infection control and prevention measures, diagnosis, transmission and impact of COVID-19, the risk to residents, and resident exposure by other individuals.

4. Any employee or contractor who obtains approval for a valid exemption will be required to wear Personal Protection Equipment (PPE) as an infection prevention and control measure when in the center and may be subject to routine COVID-19 testing in an effort to reduce the risks giving rise to the vaccine mandate.

5. New employees and contractors are required to receive COVID-19 vaccination or provide proof of vaccination or provide adequate documentation of exemption at the time of hire or entry to the center. New applicants or contractors who have not provided documentation of compliance (or have failed to secure an approved exemption or immunization), will be listed as "pending" hire and will not participate in the new employee orientation program or be allowed entry to the center.

    a. New employee applicants will be given seven (7) business days from the date of the employment health screening to provide adequate documentation of exemption or vaccination. If documentation is not received, Human Resources will advise the applicant they are not cleared for hire and may result in rescinding offer of employment.

6. Employees on leave of absence who return to work are required to be in compliance with this policy upon return and must provide documentation of policy compliance (approved exemption or immunization) prior to the scheduled return to work date. If no documentation is provided to the Human Resource office at the time of the return to work, the employee will be advised that he/she is not cleared to return to work until he/she is in compliance with this policy.

Exemption requests for medical and/or religious purposes

Exemptions from the immunization mandate may be available for medical contraindications, disability and/or sincerely held religious beliefs or practices. The approval or denial of a requested exemption will be made based upon a review of documentation submitted by the individual in accordance with established guidelines and an interactive process. The process for employees, volunteers, students and other contractual relations is as follows:

1. Exemption request forms may be obtained in the Human Resources Department. The exemption request form must be submitted to Human Resources seven (7) days after the center and/or Human Resources informs the employees that the COVID-19 vaccinations will be available to the employees. Requests will be reviewed, and the employee will be notified of exemption status within three (3) days of receipt.

2. Individuals requesting an exemption due to a medical contraindication must submit documentation in the form of a letter supporting the medical need for the exemption on his/her provider's letterhead seven (7) days after the center and/or Human Resources informs the employees that the COVID-19 vaccinations will be available to the employees. Each request for medical exemption will be evaluated by the Medical Director.

3. Individuals requesting a religious accommodation must submit a religious exemption form seven (7) days after the center and/or Human Resources informs the employees that the COVID-19 vaccinations will be available to the employees. Each request for religious exemption, regardless of the reason, will be evaluated by Human Resources.

4. If an exemption is:
    a. Granted, the individual and the Department Supervisor will be notified in writing. If an exemption is granted for a permanent condition, the individual is not required to resubmit a request each year. Otherwise, the individual will resubmit as needed.

    b. Not granted, the individual and the Department Supervisor will be notified in writing. The employee will be expected to adhere to the vaccination requirement or resubmit documentation requesting an exemption.

    c. Employees who were granted an exemption and decide to take the vaccine at a later date will be expected to immediately take the vaccine barring any change in medical or religious status.

5. Employees and contractors who obtain approval for a valid exemption, are required to wear PPE as an infection prevention control measure when in the center and routine COVID-19 testing as required by management. Failure to comply with this policy will result in disciplinary action, up to and including termination or refusal of entry to the center.

I have read, understand and agree to adhere to the requirements outlined in this policy and procedure.

Administrator Signature: _____ Date: _____

Medical Director Signature: _____ Date: _____

Review Dates: _____ _____ _____ _____ _____

This policy and procedure is not intended to replace the informed judgment of individual physicians, nurses or other clinicians nor is it intended as a statement of prevailing community standards or minimum standards of practice. It is a suggested method and technique for achieving optimal health care, not a minimum standard below which residents necessarily would be placed at risk.

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COVID-19 Vaccine Policy

Policy

As a Medicare and Medicaid recipient, we are required to mandate the COVID-19 vaccination. It is policy that all persons with a student, volunteer or employment arrangement with this center will take necessary precautions and adhere to mandated guidelines established through this policy. The intent of this policy is to safeguard the health of our employees and their families; our customers and visitors; and the community at large from COVID-19 that may be reduced by vaccinations. This policy will comply with all applicable laws and is based on guidance from federal, state and local health authorities, as applicable.

As a condition of employment, all employees are required to receive the COVID-19 vaccination. Exemptions to this policy will be provided only for employees with an approved medical or religious exemption, as described below. Employees who do not timely receive the vaccine and do not obtain an exemption will be considered to have refused to comply with this policy and to have voluntarily resigned their employment.

Guidelines

It is required that all individuals in the center receive the designated COVID-19 or provide evidence of vaccine receipt or exemption. Guidelines have been established to assist with determining the course of action to be taken in order to reach compliance with this policy.

1. It is required that all employees working within the center receive a COVID-19 vaccination as a condition of employment unless a valid medical or religious exemption is granted. All current employees are expected to either receive the first dose of a 2-shot series or a single dose of a 1 shot COVID-19 vaccine or obtain an approved exemption from the vaccination requirement by _____, and must complete the vaccination series by _____.

2. If any employee is vaccinated through services other than those provided by the center (i.e., private physician office or public clinics), he/she must provide written proof of immunization to the Human Resources department within five (5) days of receiving the vaccination. Examples of proof of immunization include a vaccination card issued by the CDC, a physician's note, a receipt containing the vaccine information or a signed and current vaccination consent form. An employee who has not provided written proof of immunization (or has failed to secure an approved exemption or immunization), within the aforementioned time period will be considered to have refused to comply with this policy and to have voluntarily resigned their employment. Providing false written proof of immunization will be considered a violation of this policy and will result in termination.

This policy and procedure is not intended to replace the informed judgment of individual physicians, nurses or other clinicians nor is it intended as a statement of prevailing community standards or minimum standards of practice. It is a suggested method and technique for achieving optimal health care, not a minimum standard below which residents necessarily would be placed at risk.

3. An educational program will be available to all employees which includes information about the vaccine, non-vaccine infection control and prevention measures, diagnosis, transmission and impact of COVID-19, the risk to residents, and resident exposure by direct care staff.

4. Any employee who obtains approval for a valid exemption will be required to wear personal protection equipment as an infection prevention and control measure when in the center as defined by the federal, state, and local health authorities, and may be subject to routine COVID-19 testing as required by management in an effort to reduce the risks giving rise to the vaccine mandate.

5. New employees will be required to receive COVID-19 vaccination or provide proof of vaccination or provide adequate documentation of exemption at the time of hire. New applicants who have not provided documentation of compliance (or have failed to secure an approved exemption or immunization), will be listed as "pending" hire and will not participate in the new employee orientation program.

    a. New employee applicants will be given seven (7) business days from the date of the employment health screening to provide adequate documentation of exemption or vaccination. If documentation is not received, Human Resources will advise the applicant they are not cleared for hire and may result in the rescission of the employment offer.

6. Employees on leave of absence who return to work are required to be in compliance with this policy upon return and must provide documentation of policy compliance (approved exemption or immunization) prior to the scheduled return to work date. If no documentation is provided to the Human Resource office at the time of the return to work, the employee will be advised that he/she is not cleared to return to work until he/she is in compliance with this policy.

Exemption requests for medical and/or religious purposes

Exemptions to immunization may be available for medical contraindications or religious beliefs. The approval or denial of a requested exemption will be based upon documentation submitted by the individual in accordance with established guidelines. The process for employees, volunteers, and students is as follows:

1. Exemption request forms may be obtained in the Human Resources Department. The exemption request form must be submitted to Human Resources seven (7) days after the center and/or Human Resources informs the employees that the COVID-19 vaccinations will be available to the employees. Requests will be reviewed, and the employee will be notified of exemption status within three (3) days of receipt.

2. Individuals requesting an exemption due to a medical contraindication must submit documentation in the form of a letter supporting the medical need for the exemption on his/her provider's letterhead seven (7) days after the center and/or Human Resources informs the employees that the COVID-19 vaccinations will be available to the employees. Each request for medical exemption will be evaluated by the Medical Director.

3. Individuals requesting a religious accommodation must submit a religious exemption form seven (7) days after the center and/or Human Resources informs the employees that the COVID-19 vaccinations will be available to the employees. Each request for religious exemption, regardless of the reason, will be evaluated by Human Resources.

4. If an exemption is:
    a. Granted, the individual and the Department Supervisor will be notified in writing. If an exemption is granted for a permanent condition, the individual is not required to resubmit a request each year. Otherwise, the individual will resubmit as needed.

    b. Not granted, the individual and the Department Supervisor will be notified in writing. The employee will be expected to adhere to the vaccination requirement or resubmit documentation requesting an exemption.

    c. Employees who were granted an exemption and decide to take the vaccine at a later date will be expected to immediately take the vaccine barring any change in medical or religious status.

5. Employees who obtain approval for a valid exemption, are required to wear PPE as an infection prevention control measure when in the center as determined by the federal, state, and local health authorities, and routine COVID-19 testing as required by management. Failure to comply with this policy will result in disciplinary action, up to and including termination.

I have read, understand and agree to adhere to the requirements outlined in this policy and procedure.

Administrator Signature: _____ Date: _____

Medical Director Signature: _____ Date: _____

Review Dates: _____ _____ _____ _____ _____

This policy and procedure is not intended to replace the informed judgment of individual physicians, nurses or other clinicians nor is it intended as a statement of prevailing community standards or minimum standards of practice. It is a suggested method and technique for achieving optimal health care, not a minimum standard below which residents necessarily would be placed at risk.

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COVID-19 Vaccine Medical Exemption Request

Instructions:

- Employee must complete and sign the Requestor Information section.
- For Medical Exemption Request, the employee's physician must complete and sign the Patient Medical Contraindication section.

Requestor Information Section

Name	Position	Department	Request Date

Requestor Acknowledgement Information:

- I understand that Facility requires all healthcare workers (employees, medical staff, volunteers, students, and contract workers) be vaccinated against COVID-19, unless granted an exemption.
- COVID-19 vaccination is recommended for me and all other healthcare workers to protect our residents from COVID-19 disease, its complications and risk of death.
- I am likely to be exposed to the coronavirus through the community and could bring the illness into the health care setting.
- If I contract COVID-19, I will shed the virus for days before COVID-19 symptoms appear. The virus shedding can spread the COVID-19 disease to residents in this facility and to my colleagues and family.
- If I become infected with COVID-19, even when my symptoms are mild or non-existent, I can spread severe illness to others.
- I understand that I cannot get COVID-19 from the COVID-19 vaccine.
- I understand that COVID-19 vaccines are available in injection form.
- The consequences of not being vaccinated could have life-threatening consequences to my health and the health of those with whom I have contact including: residents, co-workers, my family and my community.
- I understand all Facility positions and locations have the potential to expose our community to COVID-19 and therefore, all staff must be vaccinated.
- I recognize Facility requires other vaccinations as a condition of employment including Rubella, Rubeola, Varicella, Influenza, and TB.
- I understand that if this exemption is granted I will be required to wear personal protection equipment (PPE) at all times when I am in the facility and may be required to undergo routine COVID-19 testing as required by management. If I do not wear the PPE or undergo routine COVID-19 testing as required by management, I will be subject to disciplinary action, up to and including, termination.

Requestor Acknowledgement

With knowledge of the above, I am requesting medical exemption from the COVID-19 vaccination.

By my signature below, I acknowledge that:

- I have read and fully understand the information on this form.
- I understand that my request for an exemption may not be granted if it is not reasonable or creates an undue hardship on my employer or is likely to cause harm to residents or staff.
- I understand that any false or incomplete information on this form will result in corrective action up to and including termination of employment for falsification of records.
- I consent to release of this information as determined necessary for Facility to act on/carry out my request.

Print Name:	**Signature:**	**Date:**

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Patient Medical Contraindication Section

Patient Name: _____

Please certify your patient's contraindications to the COVID-19 Vaccine

Medical Provider Certification of Contraindication: I certify that my patient (named above) should not be vaccinated against COVID-19 because they have one of the following contraindications:

□ Documented anaphylactic allergic reaction or other severe adverse reaction to any COVID-19 vaccine – e.g., cardiovascular changes, respiratory distress, or history of treatment with epinephrine or other emergency medical attention to control symptoms. Generally, does not include gastro-intestinal symptoms as the sole presentation or allergy. Describe the specific reaction:	
□ Documented allergy to a component of the vaccine – does not include sore arm, local reaction or subsequent respiratory tract infection. Describe the specific reaction:	
□ Other documented contraindication. Please explain:	

Medical Certification/Verification Process

Print Name: _____ Signature: _____

Date: _____ Telephone: _____

Address: _____

_____

Reviewer Name: _____

Approved □ Date of Approval: _____

Denied □ Date of Denial: _____

State Specifically Reason(s) for Denial

_____
_____
_____
_____
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_____
_____

Signature of Reviewer: _____

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COVID-19 Vaccine Religious Exemption Request

Instructions:

- Employee must complete and sign the Requestor Information section.
- For Religious Exemption Requests, the employee's sincerely held religious beliefs and opposition to the immunization requirements must be identified. A supporting statement from the employee's religious leader will assist in evaluating the exemption request.

Requestor Information Section

Name	Position	Department	Request Date

Requestor Acknowledgement Information:

- I understand that Facility requires all healthcare workers (employees, medical staff, volunteers, students, and contract workers) be vaccinated against COVID-19, unless granted an exemption.
- COVID-19 vaccination is recommended for me and all other healthcare workers to protect our residents from COVID-19 disease, its complications and risk of death.
- I am likely to be exposed to the coronavirus through the community and could bring the illness into the health care setting.
- If I contract COVID-19, I will shed the virus for days before COVID-19 symptoms appear. The virus shedding can spread the COVID-19 disease to residents in this facility and to my colleagues and family.
- If I become infected with COVID-19, even when my symptoms are mild or non-existent, I can spread severe illness to others.
- I understand that I cannot get COVID-19 from the COVID-19 vaccine.
- I understand that COVID-19 vaccines are available in injection form.
- The consequences of not being vaccinated could have life-threatening consequences to my health and the health of those with whom I have contact including: residents, co-workers, my family and my community.
- I understand all Facility positions and locations have the potential to expose our community to COVID-19 and therefore, all staff must be vaccinated.
- I recognize Facility requires other vaccinations as a condition of employment including Rubella, Rubeola, Varicella, Influenza, and TB.
- I understand that if this exemption is granted I will be required to wear personal protection equipment (PPE) at all times when I am in the facility and may be required to undergo routine COVID-19 testing as required by management. If I do not wear the PPE or undergo routine COVID-19 testing as required by management, I will be subject to disciplinary action, up to and including, termination.

Requestor Acknowledgement

With knowledge of the above, I am requesting religious exemption from the COVID-19 vaccination.

By my signature below, I acknowledge that:

- I have read and fully understand the information on this form.
- I understand that my request for an exemption may not be granted if it is not reasonable or creates an undue hardship on my employer or is likely to cause harm to residents or staff.
- I understand that the Facility reserves the right to discontinue a previously granted accommodation if it is no longer utilized for religious purposes, or if a provided accommodation subsequently poses an undue hardship on the Facility's operations due to changed circumstances.
- I understand that any false or incomplete information on this form will result in corrective action up to and including termination of employment for falsification of records.
- I consent to release of this information as determined necessary for Facility to act on/carry out my request.

Print Name:	**Signature:**	**Date:**

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Religious Doctrine Section

Employee Name _____

Facility requires all employees to have certain immunity as a condition of employment. Employees must be vaccinated against COVID-19 to work in our organization. The above employee has requested a religious exemption from obtaining our required vaccination. In an effort to respect all religious freedom and accommodate the beliefs of our employees, we are requesting your assistance in better understanding your faith community doctrine as it relates to individual vaccinations. Please assist Facility in confirming your faith community doctrine specifically prohibiting the COVID-19 vaccination. We are seeking a description of your faith group's written doctrine as well as supporting documentation validating your denomination's doctrinal precepts.

Name of Established Faith Group or Denomination:	
Explain in your own words why you are requesting this religious exemption.	
Describe the religious principles/doctrine that guide your objection to receiving the COVID-19 vaccine.	

Please attach supporting documentation from your religious tradition's creed or doctrinal statement explicitly prohibiting vaccinations.

Religious Leader Information *(optional to assist in evaluation of request)*:

Religious Leader Name: _____ Title: _____
Religious Leader Signature: _____ Date: _____

Reviewer Name: _____

Approved □ Date of Approval: _____
Denied □ Date of Denial: _____

State Specifically Reason(s) for Denial

_____
_____
_____
_____

This policy and procedure is not intended to replace the informed judgment of individual physicians, nurses or other clinicians nor is it intended as a statement of prevailing community standards or minimum standards of practice. It is a suggested method and technique for achieving optimal health care, not a minimum standard below which residents necessarily would be placed at risk.

_____
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_____

Signature of Reviewer: _____

This policy and procedure is not intended to replace the informed judgment of individual physicians, nurses or other clinicians nor is it intended as a statement of prevailing community standards or minimum standards of practice. It is a suggested method and technique for achieving optimal health care, not a minimum standard below which residents necessarily would be placed at risk.

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Influenza – Highest Risk Populations

The best way to prevent influenza is by getting an influenza vaccination each year. While everyone aged six months or older is recommended to receive influenza vaccination, it is particularly important for people who are at increased risk of complications. Influenza can worsen underlying chronic medical conditions such as chronic obstructive pulmonary disease, asthma, heart failure and diabetes. Antiviral treatment of influenza can reduce risk of some complications, especially when started within two days of symptom onset. Therefore, people in high-risk groups should contact their primary care clinician as soon as respiratory symptoms begin. Who is at highest risk?

Groups at Increased Risk for Influenza Complications
Age Groups • Children younger than five years especially those young than two years • Adults aged 65 years and older
Chronic Medical Conditions • Asthma • Neurologic and neurodevelopmental conditions • Blood disorders (such as sickle cell disease) • Chronic lung disease (such as chronic obstructive pulmonary disease and cystic fibrosis) • Endocrine disorders (such as diabetes) • Heart disease (such as congenital heart disease, congestive heart failure and coronary artery disease) • Kidney disease • Liver disorders • Metabolic disorders (such as inherited metabolic disorders and mitochondrial disorders) • People who are obese with a body mass index of 40 or higher • People younger than 19 years old taking long-term aspirin or salicylate-containing medications • People with weakened immune system due to disease (such as people with HIV or AIDS, or some cancers such as leukemia) or medications (such as those receiving chemotherapy or radiation treatment for cancer, or persons with chronic conditions requiring long-term corticosteroids or other drugs that suppress the immune system) • People who have had a stroke
Other Groups • Pregnant women and postpartum women up to two weeks after delivery • People who live in nursing homes and other long-term care facilities
Racial and Ethnic Groups • People from certain racial and ethnic minority groups are at increased risk for hospitalization with influenza, including non-Hispanic Black persons, Hispanic or Latino persons and American Indian or Alaska Native persons

People at Higher Risk of Flu Complications | CDC
September 6, 2022

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Flu Vaccination Exemption Request

Instructions:

• Employee must complete and sign the Requestor Information section.
• For Medical Exemption Request, employee's physician must complete and sign the Patient Medical Contraindication section.
• For Religious Exemption Requests, employee's bona fide religious beliefs and opposition to the immunization requirements. A supporting statement from the employee's religious leader will assist in evaluating the exemption request.

Requestor Information Section

Name	Position	Department	Request Date

Requestor Acknowledgement Information:

• I understand that Facility requires all healthcare workers (employees, medical staff, volunteers, students, and contract workers) be vaccinated against the flu on an annual basis, unless granted an exemption.
• Flu vaccination is recommended for me and all other healthcare workers to protect our residents from the flu, its complications and risk of death.
• I am likely to be exposed to the flu virus through the community and could bring the illness into the health care setting.
• If I contract the flu, I will shed the virus for 24 to 48 hours before influenza symptoms appear. The virus shedding can spread the flu to residents in this facility and to my colleagues and family.
• If I become infected with the flu, even when my symptoms are mild or non-existent, I can spread severe illness to others.
• I understand that the strains of virus that cause the flu change almost every year, which is why a different flu vaccination is recommended each year.
• I understand that I cannot get the flu from the flu vaccine.
• I understand that the flu vaccines are available in two forms: flu shot and flu shot not cultured in egg. Egg allergies are no longer a reason for me to refuse the vaccination.
• The consequences of not being vaccinated could have life-threatening consequences to my health and the health of those with whom I have contact including: residents, co-workers, my family and my community.
• I understand all Facility positions and locations have the potential to expose our community to the flu and therefore, all staff must be vaccinated.
• I recognize Facility requires other vaccinations as a condition of employment including Rubella, Rubeola, Varicella and TB.
• I understand that if this exemption is granted, I will be required to wear a surgical mask when I am in the facility during. If I do not wear the surgical mask, I will be subject to disciplinary action, up to and including, termination.

Requestor Acknowledgement

With knowledge of the above, I am requesting an exemption from the influenza vaccination for the following reason

(Please check one): _____Medical Exemption _____Religious Exemption

By my signature below, I acknowledge that:

- I have read and fully understand the information on this form.
- I understand that my request for an exemption may not be granted if it is not reasonable or creates an undue hardship on my employer or is likely to cause harm to residents or staff.
- I understand that any false or incomplete information on this form will result in corrective action up to and including termination of employment for falsification of records.
- I consent to release of this information as determined necessary for Facility to act on/carry out my request.

Print Name:	**Signature:**	**Date:**

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Patient Medical Contraindication Section (complete for Medical Exemption)

Patient Name: _____

Please certify your patient's contraindications to the Flu Vaccine

☐ Previous reaction to flu vaccine (e.g. hives, difficulty breathing, swelling of tongue or lips)
- The above does not include sensitivity to the vaccine such as upset stomach or mild or moderate reactions such as soreness, redness, itching or swelling at the injection site.
- The above does not include subsequent upper respiratory infection or low-grade or moderate fever following a prior dose of the vaccine.

Description of Reaction	
Date of Reaction	
☐ History of Guillain-Barre Syndrome (GBS)	Date of GBS:
☐ Other - Please describe reaction and date(s).	
Description of Reaction	
Date of Reaction	

Medical Certification/Verification Process

Print Name:_____ Signature: _____

Date:_____ Telephone: _____

Address:
_____

_____

Religious Doctrine Section (complete for Religious Exemption)

Employee Name _____

Facility requires all employees to have certain immunity as a condition of employment. Employees must be vaccinated against the flu to work in our organization. The above employee has requested a religious exemption from obtaining our required vaccination. In an effort to respect all religious freedom and accommodate the beliefs of our employees, we are requesting your assistance in better understanding your faith community doctrine as it relates to individual vaccinations. Please assist Facility in confirming your faith community doctrine specifically prohibiting the flu vaccination. We are seeking a description of your faith group's written doctrine as well as supporting documentation validating your denomination's doctrinal precepts.

Name of Established Faith Group or Denomination:	
Briefly describe faith group doctrine that prohibits vaccinations	

<u>Religious Leader Information *(optional to assist in evaluation of request)*</u>:

Religious Leader Name: _____ Title:_____

Religious Leader Signature: _____ Date:_____

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Increased Interseasonal Respiratory Syncytial Virus (RSV) Activity

RSV is an RNA virus of the genus Orthopneumovirus, family Pneumoviridae, primarily spread via respiratory droplets when a person coughs or sneezes, and through direct contact with a contaminated surface. RSV is the most common cause of bronchiolitis and pneumonia in children under one year of age in the United States. Infants, young children, and older adults with chronic medical conditions are at risk of severe disease from RSV infection. Each year in the United States, RSV leads to on average approximately 58,000 hospitalizations with 100-500 deaths among children younger than 5 years old and 177,000 hospitalizations with 14,000 deaths among adults aged 65 years or older.

In the United States, RSV infections occur primarily during the fall and winter cold and flu season. In April 2020, RSV activity decreased rapidly, likely due to the adoption of public health measures to reduce the spread of COVID-19. Compared with previous years, RSV activity remained relatively low from May 2020 to March 2021. However, since late March 2021, CDC has observed an increase in RSV detections reported to the National Respiratory and Enteric Virus Surveillance System (NREVSS) https://www.cdc.gov/surveillance/nrevss/rsv/index.html, a nationwide, passive, laboratory-based surveillance network.

Due to reduced circulation of RSV during the winter months of 2020-2021, older infants and toddlers might now be at increased risk of severe RSV-associated illness since they have likely not had typical levels of exposure to RSV during the past 15 months. In infants younger than six months, RSV infection may result in symptoms of irritability, poor feeding, lethargy, and/or apnea with or without fever. In older infants and young children, rhinorrhea and decreased appetite may appear one to three days before cough, often followed by sneezing, fever, and sometimes wheezing. Symptoms in adults are typically consistent with upper respiratory tract infections, including rhinorrhea, pharyngitis, cough, headache, fatigue, and fever. There is no specific treatment for RSV infection other than symptom management https://www.cdc.gov/rsv/about/symptoms.html.

Recommendations:

1. Clinicians and caregivers should be aware of the typical clinical presentation of RSV for different age groups.
2. Clinicians should consider testing patients with a negative SARS-CoV-2 test and acute respiratory illness or the age-specific symptoms presented above for non-SARS-CoV-2 respiratory pathogens, such as RSV. Real-time reverse transcription-polymerase chain reaction (rRT-PCR) is the preferred method for testing for respiratory viruses.
3. Clinicians should report laboratory-confirmed RSV cases and suspected clusters of severe respiratory illness to local and state health departments according to their routine reporting requirements.
4. Healthcare personnel, childcare providers, and staff of long-term care facilities should avoid reporting to work while acutely ill, even if they test negative for SARS-CoV-2.
5. Clinicians can review weekly updates to the NREVSS website and refer to surveillance data collected by local hospitals and health departments for information on RSV circulation trends in their area. https://www.cdc.gov/surveillance/nrevss/rsv/index.html

Released September 2023

For more information:

- CDC – RSV Information for Healthcare Providers
- CDC – RSV National Trends – NREVSS
- CDC – RSV Symptoms and Care

I have read, understand, and agree to adhere to the requirements outlined in this policy and procedure.

Resident/Legal Decision Maker:_____ Date:_____

Employee:_____Date:_____

Administrator Signature: _____ Date: _____

Medical Director Signature: _____ Date: _____

Review Dates: _____ _____ _____ _____ _____

Vaccine Information for Adults

5 Reasons It Is Important for Adults to Get Vaccinated

1. Vaccines Have Saved Lives for Over 100 Years—But Serious Disease Is Still a Threat

Vaccines have greatly reduced diseases that once routinely harmed or killed babies, children, and adults. People all over the world—including in the United States—still become seriously ill or even die from diseases that vaccines can help prevent. It is important that you stay up to date on recommended vaccines.

The protection some vaccines provide can fade over time, and you might need additional vaccine doses (boosters) to maintain protection. For example, adults should receive a tetanus booster every 10 years to protect against infection from dirty wounds. Talk to your health care provider about vaccination to see whether you might have missed any vaccines or need a booster.

2. Vaccines Are the Best Way to Protect Yourself and Your Loved Ones from Preventable Disease

Did you know that vaccines are the best way to protect yourself from certain preventable diseases? Vaccines help your body create protective antibodies—proteins that help it fight off infections.

By getting vaccinated, you can protect yourself and also avoid spreading preventable diseases to other people in your community. Some people cannot get certain vaccines because they are too young or too old or they have a weakened immune system or other serious health condition. Those people are less likely to catch a preventable disease when you and others around them are vaccinated against it. Help protect yourself and the people you love by staying up to date on recommended vaccinations.

3. Vaccines Can Prevent Serious Illness

Some vaccine-preventable diseases can have serious complications or even lead to later illnesses. For them, vaccination provides protection not only against the disease itself but also against the dangerous complications or consequences that it can bring. Some examples:

- Seasonal influenza (flu) is a respiratory virus that sickens tens of millions of people every year in the United States. The annual flu vaccine helps you avoid infection and reduces your chances of being hospitalized or dying if you do become infected. Flu vaccine also protects you from flu-related pneumonia and flu-related heart attacks or stroke—complications that can affect anyone but are especially dangerous for persons with diabetes or chronic heart or lung conditions.

- Hepatitis B is a serious, potentially deadly infection of the liver caused by the hepatitis B virus (HBV). There is no cure, but vaccination prevents HBV infection as well as the chronic liver damage and cancer that hepatitis B can cause.
- Human papillomavirus (HPV) is a leading cause of cervical cancer and can cause other cancers in both women and men. HPV vaccine keeps you from being infected with the virus or passing it to others, protecting you and them from the immediate effects of the virus as well as from the various cancers it can trigger.

4. The Vaccines You Receive Are Safe

Vaccine safety is a high priority. CDC and other experts carefully review safety data before recommending any vaccine, then continually monitor vaccine safety after approval.

Vaccines can have side effects, but most people experience only mild side effects—if any—after vaccination. The most common side effects are fever, tiredness, body aches, or redness, swelling, and tenderness where the shot was given. Mild reactions usually go away on their own within a few days. Serious or long-lasting side effects are extremely rare, and vaccine safety is continually monitored.

5. Vaccines May Be Required

Certain vaccines are required for school, work, travel, and more. Students, military personnel, and residents of rehabilitation or care centers must be vaccinated against diseases that circulate in close quarters. Health care workers and others whose job puts them at risk of catching and spreading preventable diseases need to be vaccinated against them. And, of course, vaccination is required before travel to many places around the world. Because vaccination protects you and those around you, vaccines can be required for everyday activities as well as for extraordinary situations. It is important that you stay up to date on recommended vaccinations.

Page last reviewed: September 12, 2022

ACIP Shared Clinical Decision-Making Recommendations

Frequently Asked Questions

These frequently asked questions (FAQs) are intended to provide clarity on the Advisory Committee on Immunization Practices' (ACIP) shared clinical decision-making recommendations and guidance and implementation considerations for these recommendations.

What are ACIP's current shared clinical decision-making recommendations that appear on the immunization schedules?

ACIP has four recommendations for vaccination based on shared clinical decision-making that appear on the tables and/or notes of the immunization schedules.

- Meningococcal B (MenB) vaccination for adolescents and young adults aged 16–23 years
- Hepatitis B (HepB) vaccination for adults age 60 years and older with diabetes mellitus
- Human papillomavirus (HPV) vaccination for adults aged 27–45 years
- Pneumococcal conjugate vaccination (PCV13) for adults aged 65 years and older who do not have an immunocompromising condition, cerebrospinal fluid leak, or cochlear implant

How do shared clinical decision-making recommendations differ from routine, catch-up, and risk-based immunization recommendations?

Unlike routine, catch-up, and risk-based recommendations, shared clinical decision-making vaccinations are not recommended for everyone in a particular age group or everyone in an identifiable risk group. Rather, shared clinical decision-making recommendations are individually based and informed by a decision process between the health care provider and the patient or parent/guardian.

The key distinction between routine, catch-up, and risk-based recommendations and shared clinical decision-making recommendations is the default decision to vaccinate. For routine, catch-up, and risk-based recommendations, the default decision should be to vaccinate the patient based on age group or other indication, unless contraindicated. For shared clinical decision-making recommendations, there is no default—the decision about whether or not to vaccinate may be informed by the best available evidence of who may benefit from vaccination; the individual's characteristics, values, and preferences; the health care provider's clinical discretion; and the characteristics of the vaccine being considered. There is not a prescribed set of considerations or decision points in the decision-making process.

When does ACIP make shared clinical decision-making recommendations?

Generally, ACIP makes shared clinical decision-making recommendations when individuals may benefit from vaccination, but broad vaccination of people in that group is unlikely to have population-level impacts.

For example, in June 2019, ACIP recommended shared clinical decision-making for HPV vaccination of adults aged 27–45 years. HPV acquisition generally occurs soon after first sexual activity. Vaccine effectiveness is lower in older age groups because of prior infections and lower risk of exposure (for example, among persons who are in a long-term, mutually monogamous sexual partnership). ACIP recommended shared clinical decision-making rather than catch-up vaccination because most adults in this age group would have no or minimal benefits from vaccination. However, some individuals who are not already immune to HPV through vaccination or natural infection (e.g., a previously unvaccinated person who has never had sex) and who might be at risk for acquiring a new HPV infection in the future (e.g., plans to have sex with a new partner in the future) might benefit from vaccination.

Who is considered a health care provider with regard to shared clinical decision-making recommendations?

In this context, CDC defines a health care provider as anyone who provides or administers vaccines: primary care physicians, specialists, physician assistants, nurse practitioners, registered nurses, and pharmacists.

Which patients should providers discuss shared clinical decision-making recommendations with?

It's up to the provider. Some health care providers may choose to discuss immunizations recommended for shared clinical decision-making with all or most of their patients who could receive it, while some providers may be more selective when discussing these immunizations with their patients. Health care providers should also be receptive to patient-initiated conversations about these immunizations.

What resources are available for providers who want to implement these recommendations?

ACIP and CDC provide resources to help providers implement these recommendations.

ACIP recommendations

Health care providers can find information on ACIP's recommendations on the ACIP Vaccine Recommendations and Guidelines page.

For every ACIP recommendation, CDC publishes a policy note in the *Morbidity and Mortality Weekly Report* (MMWR), which provides background and considerations on each recommendation.

CDC resources for shared clinical decision-making

CDC will also develop vaccine-specific guidance to help clinicians understand and apply shared clinical decision-making recommendations.

- HPV Vaccination for Adults Aged 27-45 Years
- Meningococcal B Vaccination

Are shared clinical decision-making recommendations covered by private insurers?

Under the Affordable Care Act and its implementing regulations, ACIP recommendations that have been adopted by CDC "with respect to the individual involved" and are "listed on the Immunization Schedules of the Centers for Disease Control and Prevention" generally are required to be covered by group health plans and health insurance issuers offering group or individual health insurance coverage without imposing any cost-sharing requirements (such as a copayment, coinsurance, or deductible).[1] This coverage requirement includes shared clinical decision-making recommendations when they have been adopted by CDC and are listed on the immunization schedules.

Footnotes

1. Section 2713(a)(2) of the Public Health Service Act, as added by section 1001 of the Affordable Care Act, implemented at 26 CFR 54.9815-2713(a)(1)(ii), 29 CFR 2590.715-2713(a)(1)(ii), and 45 CFR 147.130(a)(1)(ii). This requirement does not apply to grandfathered health plan coverage under section 1251 of the Affordable Care Act, implemented at 26 CFR 54.9815-1251, 29 CFR 2590.715-1272, and 45 CFR 147.140.

Last Reviewed: February 10, 2020

COVID-19 vaccination recommendations have changed. Find the latest recommendations at www.cdc.gov/covidschedule

Recommended Adult Immunization Schedule for ages 19 years or older 2023

How to use the adult immunization schedule

1. Determine recommended vaccinations by age **(Table 1)**
2. Assess need for additional recommended vaccinations by medical condition or other indication **(Table 2)**
3. Review vaccine types, dosing frequencies and intervals, and considerations for special situations **(Notes)**
4. Review contraindications and precautions for vaccine types **(Appendix)**

Vaccines in the Adult Immunization Schedule*

Vaccine	Abbreviation(s)	Trade name(s)
COVID-19 vaccine	1vCOV-mRNA	Comirnaty®/Pfizer-BioNTech COVID-19 Vaccine SPIKEVAX®/Moderna COVID-19 Vaccine
	2vCOV-mRNA	Pfizer-BioNTech COVID-19 Vaccine, Bivalent Moderna COVID-19 Vaccine, Bivalent
	1vCOV-aPS	Novavax COVID-19 Vaccine
Haemophilus influenzae type b vaccine	Hib	ActHIB® Hiberix® PedvaxHIB®
Hepatitis A vaccine	HepA	Havrix® Vaqta®
Hepatitis A and hepatitis B vaccine	HepA-HepB	Twinrix®
Hepatitis B vaccine	HepB	Engerix-B® Heplisav-B® PreHevbrio® Recombivax HB®
Human papillomavirus vaccine	HPV	Gardasil 9®
Influenza vaccine (inactivated)	IIV4	Many brands
Influenza vaccine (live, attenuated)	LAIV4	FluMist® Quadrivalent
Influenza vaccine (recombinant)	RIV4	Flublok® Quadrivalent
Measles, mumps, and rubella vaccine	MMR	M-M-R II® Priorix®
Meningococcal serogroups A, C, W, Y vaccine	MenACWY-D MenACWY-CRM MenACWY-TT	Menactra® Menveo® MenQuadfi®
Meningococcal serogroup B vaccine	MenB-4C MenB-FHbp	Bexsero® Trumenba®
Pneumococcal conjugate vaccine	PCV15 PCV20	Vaxneuvance™ Prevnar 20™
Pneumococcal polysaccharide vaccine	PPSV23	Pneumovax 23®
Poliovirus vaccine	IPV	IPOL®
Tetanus and diphtheria toxoids	Td	Tenivac® Tdvax™
Tetanus and diphtheria toxoids and acellular pertussis vaccine	Tdap	Adacel® Boostrix®
Varicella vaccine	VAR	Varivax®
Zoster vaccine, recombinant	RZV	Shingrix

*Administer recommended vaccines if vaccination history is incomplete or unknown. Do not restart or add doses to vaccine series if there are extended intervals between doses. The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

Recommended by the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/acip) and approved by the Centers for Disease Control and Prevention (www.cdc.gov), American College of Physicians (www.acponline.org), American Academy of Family Physicians (www.aafp.org), American College of Obstetricians and Gynecologists (www.acog.org), American College of Nurse-Midwives (www.midwife.org), American Academy of Physician Associates (www.aapa.org), American Pharmacists Association (www.pharmacist.com), and Society for Healthcare Epidemiology of America (www.shea-online.org).

Report

- Suspected cases of reportable vaccine-preventable diseases or outbreaks to the local or state health department
- Clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System at www.vaers.hhs.gov or 800-822-7967

Injury claims

All vaccines included in the adult immunization schedule except PPSV23, RZV, and COVID-19 vaccines are covered by the National Vaccine Injury Compensation Program (VICP). COVID-19 vaccines that are authorized or approved by the FDA are covered by the Countermeasures Injury Compensation Program (CICP). For more information, see www.hrsa.gov/vaccinecompensation or www.hrsa.gov/cicp.

Questions or comments

Contact www.cdc.gov/cdc-info or 800-CDC-INFO (800-232-4636), in English or Spanish, 8 a.m.–8 p.m. ET, Monday through Friday, excluding holidays.

Download the CDC Vaccine Schedules app for providers at www.cdc.gov/vaccines/schedules/hcp/schedule-app.html.

Helpful information

- Complete Advisory Committee on Immunization Practices (ACIP) recommendations: www.cdc.gov/vaccines/hcp/acip-recs/index.html
- *General Best Practice Guidelines for Immunization* (including contraindications and precautions): www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/index.html
- Manual for the Surveillance of Vaccine-Preventable Diseases (including case identification and outbreak response): www.cdc.gov/vaccines/pubs/surv-manual
- Travel vaccine recommendations: www.cdc.gov/travel
- Recommended Child and Adolescent Immunization Schedule, United States, 2023: www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html
- ACIP Shared Clinical Decision-Making Recommendations: www.cdc.gov/vaccines/acip/acip-scdm-faqs.html

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

Scan QR code for access to online schedule

CS310021-C

Table 1

COVID-19 vaccination recommendations have changed. Find the latest recommendations at www.cdc.gov/covidschedule

Recommended Adult Immunization Schedule for ages 19 years or older, United States, 2023

Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
COVID-19	2- or 3- dose primary series and booster (See Notes)			
Influenza inactivated (IIV4) or **Influenza recombinant** (RIV4)	1 dose annually			
or		or		
Influenza live, attenuated (LAIV4)	1 dose annually			
Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap each pregnancy; 1 dose Td/Tdap for wound management (see notes)			
	1 dose Tdap, then Td or Tdap booster every 10 years			
Measles, mumps, rubella (MMR)	1 or 2 doses depending on indication (if born in 1957 or later)			For healthcare personnel, see notes
Varicella (VAR)	2 doses (if born in 1980 or later)		2 doses	
Zoster recombinant (RZV)	2 doses for immunocompromising conditions (see notes)		2 doses	
Human papillomavirus (HPV)	2 or 3 doses depending on age at initial vaccination or condition	27 through 45 years		
Pneumococcal (PCV15, PCV20, PPSV23)	1 dose PCV15 followed by PPSV23 OR 1 dose PCV20 (see notes)			See Notes
				See Notes
Hepatitis A (HepA)	2, 3, or 4 doses depending on vaccine			
Hepatitis B (HepB)	2, 3, or 4 doses depending on vaccine or condition			
Meningococcal A, C, W, Y (MenACWY)	1 or 2 doses depending on indication, see notes for booster recommendations			
Meningococcal B (MenB)	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations			
	19 through 23 years			
***Haemophilus influenzae* type b** (Hib)	1 or 3 doses depending on indication			

- Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of past infection
- Recommended vaccination for adults with an additional risk factor or another indication
- Recommended vaccination based on shared clinical decision-making
- No recommendation/ Not applicable

Table 2 Recommended Adult Immunization Schedule by Medical Condition or Other Indication, United States, 2023

Vaccine	Pregnancy	Immuno-compromised (excluding HIV infection)	HIV infection CD4 percentage and count		Asplenia, complement deficiencies	End-stage renal disease, or on hemodialysis	Heart or lung disease; alcoholism[a]	Chronic liver disease	Diabetes	Health care personnel[b]	Men who have sex with men
			<15% or <200 mm³	≥15% and ≥200 mm³							
COVID-19		See Notes									
IIV4 or RIV4	1 dose annually										
or										or	
LAIV4	Contraindicated						Precaution			1 dose annually	
Tdap or Td	1 dose Tdap each pregnancy	1 dose Tdap, then Td or Tdap booster every 10 years									
MMR	Contraindicated*	Contraindicated		1 or 2 doses depending on indication							
VAR	Contraindicated*	Contraindicated			2 doses						
RZV		2 doses at age ≥19 years			2 doses at age ≥50 years						
HPV	Not Recommended*	3 doses through age 26 years			2 or 3 doses through age 26 years depending on age at initial vaccination or condition						
Pneumococcal (PCV15, PCV20, PPSV23)		1 dose PCV15 followed by PPSV23 OR 1 dose PCV20 (see notes)									
HepA					2, 3, or 4 doses depending on vaccine						
HepB	3 doses (see notes)	2, 3, or 4 doses depending on vaccine or condition									
MenACWY	1 or 2 doses depending on indication, see notes for booster recommendations										
MenB	Precaution	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations									
Hib		3 doses HSCT[c] recipients only			1 dose						

- Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of past infection
- Recommended vaccination for adults with an additional risk factor or another indication
- Recommended vaccination based on shared clinical decision-making
- Precaution–vaccination might be indicated if benefit of protection outweighs risk of adverse reaction
- Contraindicated or not recommended–vaccine should not be administered.

*Vaccinate after pregnancy.

- No recommendation/ Not applicable

a. Precaution for LAIV4 does not apply to alcoholism. **b.** See notes for influenza; hepatitis B; measles, mumps, and rubella; and varicella vaccinations. **c.** Hematopoietic stem cell transplant.

Notes

COVID-19 vaccination recommendations have changed. Find the latest recommendations at www.cdc.gov/covidschedule

Recommended Adult Immunization Schedule for ages 19 years or older, United States, 2023

For vaccine recommendations for persons 18 years of age or younger, see the Recommended Child and Adolescent Immunization Schedule.

COVID-19 vaccination

Routine vaccination

- **Primary series:** 2-dose series at 0, 4-8 weeks (Moderna) or 2-dose series at 0, 3-8 weeks (Novavax, Pfizer-BioNTech)
- **Booster dose:** see www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html

Special situations

Persons who are moderately or severely immunocompromised

- **Primary series**
  - 3-dose series at 0, 4, 8 weeks (Moderna) or 3-dose series at 0, 3, 7 weeks (Pfizer-BioNTech)
  - 2-dose series at 0, 3 weeks (Novavax)
- **Booster dose:** see www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
- **Pre-exposure prophylaxis (e.g., monoclonal antibodies)** may be considered to complement COVID-19 vaccination. See www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised

For Janssen COVID-19 Vaccine recipients see COVID-19 schedule at www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html.

Note: Current COVID-19 schedule available at www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-6months-older.pdf. For more information on Emergency Use Authorization (EUA) indications for COVID-19 vaccines, please visit www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

Haemophilus influenzae type b vaccination

Special situations

- **Anatomical or functional asplenia (including sickle cell disease):** 1 dose if previously did not receive Hib; if elective splenectomy, 1 dose preferably at least 14 days before splenectomy
- **Hematopoietic stem cell transplant (HSCT):** 3-dose series 4 weeks apart starting 6–12 months after successful transplant, regardless of Hib vaccination history

Hepatitis A vaccination

Routine vaccination

- **Not at risk but want protection from hepatitis A** (identification of risk factor not required): 2-dose series HepA (Havrix 6–12 months apart or Vaqta 6–18 months apart [minimum interval: 6 months]) or 3-dose series HepA-HepB (Twinrix at 0, 1, 6 months [minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 5 months])

Special situations

- **At risk for hepatitis A virus infection:** 2-dose series HepA or 3-dose series HepA-HepB as above
  - **Chronic liver disease** (e.g., persons with hepatitis B, hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice the upper limit of normal)
  - **HIV infection**
  - **Men who have sex with men**
  - **Injection or noninjection drug use**
  - **Persons experiencing homelessness**
  - **Work with hepatitis A virus** in research laboratory or with nonhuman primates with hepatitis A virus infection
  - **Travel in countries with high or intermediate endemic hepatitis A** (HepA-HepB [Twinrix] may be administered on an accelerated schedule of 3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months)
  - **Close, personal contact with international adoptee** (e.g., household or regular babysitting) in first 60 days after arrival from country with high or intermediate endemic hepatitis A (administer dose 1 as soon as adoption is planned, at least 2 weeks before adoptee's arrival)
  - **Pregnancy** if at risk for infection or severe outcome from infection during pregnancy
  - **Settings for exposure,** including health care settings targeting services to injection or noninjection drug users or group homes and nonresidential day care facilities for developmentally disabled persons (individual risk factor screening not required)

Hepatitis B vaccination

Routine vaccination

- **Age 19 through 59 years: complete a 2- or 3- or 4-dose series**
  - 2-dose series only applies when 2 doses of Heplisav-B* are used at least 4 weeks apart
  - 3-dose series Engerix-B, PreHevbrio*, or Recombivax HB at 0, 1, 6 months [minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 8 weeks / dose 1 to dose 3: 16 weeks])
  - 3-dose series HepA-HepB (Twinrix at 0, 1, 6 months [minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 5 months])
  - 4-dose series HepA-HepB (Twinrix) accelerated schedule of 3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months

*__Note:__ Heplisav-B and PreHevbrio are not recommended in pregnancy due to lack of safety data in pregnant persons.

Notes

- **Age 60 years or older with** known risk factors for hepatitis B virus infection **should** complete a HepB vaccine series.
- **Age 60 years or older without** known risk factors for hepatitis B virus infection **may** complete a HepB vaccine series.
  - **Risk factors for hepatitis B virus infection include:**
    - **Chronic liver disease** (e.g., persons with hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice upper limit of normal)
    - **HIV infection**
    - **Sexual exposure risk** (e.g., sex partners of hepatitis B surface antigen [HBsAg]-positive persons; sexually active persons not in mutually monogamous relationships; persons seeking evaluation or treatment for a sexually transmitted infection; men who have sex with men)
    - **Current or recent injection drug use**
    - **Percutaneous or mucosal risk for exposure to blood** (e.g., household contacts of HBsAg-positive persons; residents and staff of facilities for developmentally disabled persons; health care and public safety personnel with reasonably anticipated risk for exposure to blood or blood-contaminated body fluids; persons on maintenance dialysis, including in-center or home hemodialysis and peritoneal dialysis, and persons who are predialysis; patients with diabetes)
    - **Incarceration**
    - **Travel in countries with high or intermediate endemic hepatitis B**

Special situations

- **Patients on dialysis:** complete a 3- or 4-dose series
  - 3-dose series Recombivax HB at 0, 1, 6 months (note: use Dialysis Formulation 1 mL = 40 mcg)
  - 4-dose series Engerix-B at 0, 1, 2, and 6 months (note: use 2 mL dose instead of the normal adult dose of 1 mL)

Human papillomavirus vaccination

Routine vaccination

- **HPV vaccination recommended for all persons through age 26 years:** 2- or 3-dose series depending on age at initial vaccination or condition:
  - **Age 15 years or older at initial vaccination:** 3-dose series at 0, 1–2 months, 6 months (minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 12 weeks / dose 1 to dose 3: 5 months; repeat dose if administered too soon)
  - **Age 9–14 years at initial vaccination and received 1 dose or 2 doses less than 5 months apart:** 1 additional dose
  - **Age 9–14 years at initial vaccination and received 2 doses at least 5 months apart:** HPV vaccination series complete, no additional dose needed
- **Interrupted schedules:** If vaccination schedule is interrupted, the series does not need to be restarted
- **No additional dose recommended when any HPV vaccine series has been completed using the recommended dosing intervals.**

Shared clinical decision-making

- **Some adults age 27–45 years:** Based on shared clinical decision-making, 2- or 3-dose series as above

Special situations

- **Age ranges recommended above for routine and catch-up vaccination or shared clinical decision-making also apply in special situations**
  - **Immunocompromising conditions, including HIV infection**: 3-dose series, even for those who initiate vaccination at age 9 through 14 years.
  - **Pregnancy**: Pregnancy testing is not needed before vaccination; HPV vaccination is not recommended until after pregnancy; no intervention needed if inadvertently vaccinated while pregnant

Influenza vaccination

Routine vaccination

- **Age 19 years or older:** 1 dose any influenza vaccine appropriate for age and health status annually.
  - **Age 65 years or older:** Any one of quadrivalent high-dose inactivated influenza vaccine (HD-IIV4), quadrivalent recombinant influenza vaccine (RIV4), or quadrivalent adjuvanted inactivated influenza vaccine (aIIV4) is preferred. If none of these three vaccines is available, then any other age-appropriate influenza vaccine should be used.
- For the 2022–2023 season, see www.cdc.gov/mmwr/volumes/71/rr/rr7101a1.htm
- For the 2023–2024 season, see the 2023–2024 ACIP influenza vaccine recommendations.

Special situations

- **Egg allergy, hives only:** any influenza vaccine appropriate for age and health status annually
- **Egg allergy–any symptom other than hives** (e.g., angioedema, respiratory distress or required epinephrine or another emergency medical intervention): Any influenza vaccine appropriate for age and health status may be administered. If using egg-based IIV4 or LAIV4, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions.
- **Close contacts (e.g., caregivers, healthcare workers) of severely immunosuppressed persons who require a protected environment:** these persons should not receive LAIV4. If LAIV4 is given, they should avoid contact with/caring for such immunosuppressed persons for 7 days after vaccination.
- **Severe allergic reaction (e.g., anaphylaxis) to a vaccine component or a previous dose of any influenza vaccine:** see Appendix listing contraindications and precautions

Notes

- **History of Guillain-Barré syndrome within 6 weeks after previous dose of influenza vaccine:** Generally, should not be vaccinated unless vaccination benefits outweigh risks for those at higher risk for severe complications from influenza

Measles, mumps, and rubella vaccination

Routine vaccination

- **No evidence of immunity to measles, mumps, or rubella:** 1 dose
  - **Evidence of immunity:** Born before 1957 (health care personnel, see below), documentation of receipt of MMR vaccine, laboratory evidence of immunity or disease (diagnosis of disease without laboratory confirmation is not evidence of immunity)

Special situations

- **Pregnancy with no evidence of immunity to rubella:** MMR contraindicated during pregnancy; after pregnancy (before discharge from health care facility), 1 dose
- **Nonpregnant persons of childbearing age with no evidence of immunity to rubella:** 1 dose
- **HIV infection with CD4 percentages ≥15% and CD4 count ≥200 cells/mm³ for at least 6 months and no evidence of immunity to measles, mumps, or rubella:** 2-dose series at least 4 weeks apart; MMR contraindicated for HIV infection with CD4 percentage <15% or CD4 count <200 cells/mm³
- **Severe immunocompromising conditions:** MMR contraindicated
- **Students in postsecondary educational institutions, international travelers, and household or close, personal contacts of immunocompromised persons with no evidence of immunity to measles, mumps, or rubella:** 2-dose series at least 4 weeks apart if previously did not receive any doses of MMR or 1 dose if previously received 1 dose MMR
- **In mumps outbreak settings,** for information about additional doses of MMR (including 3rd dose of MMR), see www.cdc.gov/mmwr/volumes/67/wr/mm6701a7.htm
- **Health care personnel:**
  - **Born before 1957 with no evidence of immunity to measles, mumps, or rubella:** Consider 2-dose series at least 4 weeks apart for protection against measles or mumps or 1 dose for protection against rubella
  - **Born in 1957 or later with no evidence of immunity to measles, mumps, or rubella:** 2-dose series at least 4 weeks apart for protection against measles or mumps or at least 1 dose for protection against rubella

Meningococcal vaccination

Special situations for MenACWY

- **Anatomical or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use:** 2-dose series MenACWY-D (Menactra, Menveo, or MenQuadfi) at least 8 weeks apart and revaccinate every 5 years if risk remains
- **Travel in countries with hyperendemic or epidemic meningococcal disease, or microbiologists routinely exposed to *Neisseria meningitidis*:** 1 dose MenACWY (Menactra, Menveo, or MenQuadfi) and revaccinate every 5 years if risk remains
- **First-year college students who live in residential housing (if not previously vaccinated at age 16 years or older) or military recruits:** 1 dose MenACWY (Menactra, Menveo, or MenQuadfi)
- For MenACWY **booster dose recommendations** for groups listed under "Special situations" and in an outbreak setting (e.g., in community or organizational settings and among men who have sex with men) and additional meningococcal vaccination information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm

Shared clinical decision-making for MenB

- **Adolescents and young adults age 16–23 years (age 16–18 years preferred) not at increased risk for meningococcal disease:** Based on shared clinical decision-making, 2-dose series MenB-4C (Bexsero) at least 1 month apart or 2-dose series MenB-FHbp (Trumenba) at 0, 6 months (if dose 2 was administered less than 6 months after dose 1, administer dose 3 at least 4 months after dose 2); MenB-4C and MenB-FHbp are not interchangeable (use same product for all doses in series)

Special situations for MenB

- **Anatomical or functional asplenia (including sickle cell disease), persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use, or microbiologists routinely exposed to *Neisseria meningitidis*:** 2-dose primary series MenB-4C (Bexsero) at least 1 month apart or 3-dose primary series MenB-FHbp (Trumenba) at 0, 1–2, 6 months (if dose 2 was administered at least 6 months after dose 1, dose 3 not needed; if dose 3 is administered earlier than 4 months after dose 2, a fourth dose should be administered at least 4 months after dose 3); MenB-4C and MenB-FHbp are not interchangeable (use same product for all doses in series); 1 dose MenB booster 1 year after primary series and revaccinate every 2–3 years if risk remains
- **Pregnancy:** Delay MenB until after pregnancy unless at increased risk and vaccination benefits outweigh potential risks
- For MenB **booster dose recommendations** for groups listed under "Special situations" and in an outbreak setting (e.g., in community or organizational settings and among men who have sex with men) and additional meningococcal vaccination information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm

Note: MenB vaccines may be administered simultaneously with MenACWY vaccines if indicated, but at a different anatomic site, if feasible.

Notes

Pneumococcal vaccination

Routine vaccination

- **Age 65 years or older who have:**
  - **Not previously received a dose of PCV13, PCV15, or PCV20 or whose previous vaccination history is unknown:** 1 dose PCV15 OR 1 dose PCV20. If PCV15 is used, this should be followed by a dose of PPSV23 given at least 1 year after the PCV15 dose. A minimum interval of 8 weeks between PCV15 and PPSV23 can be considered for adults with an immunocompromising condition,* cochlear implant, or cerebrospinal fluid leak to minimize the risk of invasive pneumococcal disease caused by serotypes unique to PPSV23 in these vulnerable groups.
  - **Previously received only PCV7:** follow the recommendation above.
  - **Previously received only PCV13:** 1 dose PCV20 at least 1 year after the PCV13 dose OR complete the recommended PPSV23 series as described here www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf.
  - **Previously received only PPSV23:** 1 dose PCV15 OR 1 dose PCV20 at least 1 year after the PPSV23 dose. If PCV15 is used, it need not be followed by another dose of PPSV23.
  - **Previously received both PCV13 and PPSV23 but NO PPSV23 was received at age 65 years or older:** 1 dose PCV20 at least 5 years after their last pneumococcal vaccine dose OR complete the recommended PPSV23 series as described here www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf.
  - **Previously received both PCV13 and PPSV23, AND PPSV23 was received at age 65 years or older:** Based on shared clinical decision-making, 1 dose of PCV20 at least 5 years after the last pneumococcal vaccine dose.
- For guidance on determining which pneumococcal vaccines a patient needs and when, please refer to the mobile app which can be downloaded here: www.cdc.gov/vaccines/vpd/pneumo/hcp/pneumoapp.html

Special situations

- **Age 19–64 years with certain underlying medical conditions or other risk factors** who have**
  - **Not previously received a PCV13, PCV15, or PCV20 or whose previous vaccination history is unknown:** 1 dose PCV15 OR 1 dose PCV20. If PCV15 is used, this should be followed by a dose of PPSV23 given at least 1 year after the PCV15 dose. A minimum interval of 8 weeks between PCV15 and PPSV23 can be considered for adults with an immunocompromising condition,* cochlear implant, or cerebrospinal fluid leak
  - **Previously received only PCV7:** follow the recommendation above.
  - **Previously received only PCV13:** 1 dose PCV20 at least 1 year after the PCV13 dose OR complete the recommended PPSV23 series as described here www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf.
  - **Previously received only PPSV23:** 1 dose PCV15 OR 1 dose PCV20 at least 1 year after the PPSV23 dose. If PCV15 is used, it need not be followed by another dose of PPSV23.
  - **Previously received both PCV13 and PPSV23 but have not completed the recommended series:** 1 dose PCV20 at least 5 years after their last pneumococcal vaccine dose OR complete the recommended PPSV23 series as described here www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf.
- For guidance on determining which pneumococcal vaccines a patient needs and when, please refer to the mobile app which can be downloaded here: www.cdc.gov/vaccines/vpd/pneumo/hcp/pneumoapp.html

*__Note:__ Immunocompromising conditions include chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, human immunodeficiency virus, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplants, congenital or acquired asplenia, sickle cell disease, or other hemoglobinopathies.

**__Note:__ Underlying medical conditions or other risk factors include alcoholism, chronic heart/liver/lung disease, chronic renal failure, cigarette smoking, cochlear implant, congenital or acquired asplenia, CSF leak, diabetes mellitus, generalized malignancy, HIV, Hodgkin disease, immunodeficiency, iatrogenic immunosuppression, leukemia, lymphoma, multiple myeloma, nephrotic syndrome, solid organ transplants, or sickle cell disease or other hemoglobinopathies.

Polio vaccination

Routine vaccination

Routine poliovirus vaccination of adults residing in the United States is not necessary.

Special situations

- **Adults at increased risk of exposure to poliovirus with:**
  - No evidence of a complete polio vaccination series (i.e., at least 3 doses): administer remaining doses (1, 2, or 3 doses) to complete a 3-dose series
  - Evidence of completed polio vaccination series (i.e., at least 3 doses): may administer one lifetime IPV booster

For detailed information, see: www.cdc.gov/vaccines/vpd/polio/hcp/recommendations.html

Notes

Recommended Adult Immunization Schedule, United States, 2023

Tetanus, diphtheria, and pertussis vaccination

Routine vaccination

- **Previously did not receive Tdap at or after age 11 years:** 1 dose Tdap, then Td or Tdap every 10 years

Special situations

- **Previously did not receive primary vaccination series for tetanus, diphtheria, or pertussis:** 1 dose Tdap followed by 1 dose Td or Tdap at least 4 weeks later, and a third dose of Td or Tdap 6–12 months later (Tdap can be substituted for any Td dose, but preferred as first dose), Td or Tdap every 10 years thereafter
- **Pregnancy:** 1 dose Tdap during each pregnancy, preferably in early part of gestational weeks 27–36
- **Wound management:** Persons with 3 or more doses of tetanus-toxoid-containing vaccine: For clean and minor wounds, administer Tdap or Td if more than 10 years since last dose of tetanus-toxoid-containing vaccine; for all other wounds, administer Tdap or Td if more than 5 years since last dose of tetanus-toxoid-containing vaccine. Tdap is preferred for persons who have not previously received Tdap or whose Tdap history is unknown. If a tetanus-toxoid-containing vaccine is indicated for a pregnant woman, use Tdap. For detailed information, see www.cdc.gov/mmwr/volumes/69/wr/mm6903a5.htm

Varicella vaccination

Routine vaccination

- **No evidence of immunity to varicella:** 2-dose series 4–8 weeks apart if previously did not receive varicella-containing vaccine (VAR or MMRV [measles-mumps-rubella-varicella vaccine] for children); if previously received 1 dose varicella-containing vaccine, 1 dose at least 4 weeks after first dose
  - **Evidence of immunity:** U.S.-born before 1980 (except for pregnant persons and health care personnel [see below]), documentation of 2 doses varicella-containing vaccine at least 4 weeks apart, diagnosis or verification of history of varicella or herpes zoster by a health care provider, laboratory evidence of immunity or disease

Special situations

- **Pregnancy with no evidence of immunity to varicella:** VAR contraindicated during pregnancy; after pregnancy (before discharge from health care facility), 1 dose if previously received 1 dose varicella-containing vaccine or dose 1 of 2-dose series (dose 2: 4–8 weeks later) if previously did not receive any varicella-containing vaccine, regardless of whether U.S.-born before 1980
- **Health care personnel with no evidence of immunity to varicella:** 1 dose if previously received 1 dose varicella-containing vaccine; 2-dose series 4–8 weeks apart if previously did not receive any varicella-containing vaccine, regardless of whether U.S.-born before 1980
- **HIV infection with CD4 percentages ≥15% and CD4 count ≥200 cells/mm^3 with no evidence of immunity:** Vaccination may be considered (2 doses 3 months apart); VAR contraindicated for HIV infection with CD4 percentage <15% or CD4 count <200 cells/mm^3
- **Severe immunocompromising conditions:** VAR contraindicated

Zoster vaccination

Routine vaccination

- **Age 50 years or older*:** 2-dose series recombinant zoster vaccine (RZV, Shingrix) 2–6 months apart (minimum interval: 4 weeks; repeat dose if administered too soon), regardless of previous herpes zoster or history of zoster vaccine live (ZVL, Zostavax) vaccination.

***Note:** Serologic evidence of prior varicella is not necessary for zoster vaccination. However, if serologic evidence of varicella susceptibility becomes available, providers should follow ACIP guidelines for varicella vaccination first. RZV is not indicated for the prevention of varicella, and there are limited data on the use of RZV in persons without a history of varicella or varicella vaccination.

Special situations

- **Pregnancy:** There is currently no ACIP recommendation for RZV use in pregnancy. Consider delaying RZV until after pregnancy.
- **Immunocompromising conditions (including persons with HIV regardless of CD4 count)**:** 2-dose series recombinant zoster vaccine (RZV, Shingrix) 2–6 months apart (minimum interval: 4 weeks; repeat dose if administered too soon). For detailed information, see www.cdc.gov/shingles/vaccination/immunocompromised-adults.html

****Note:** If there is no documented history of varicella, varicella vaccination, or herpes zoster, providers should refer to the clinical considerations for use of RZV in immunocompromised adults aged ≥19 years and the ACIP varicella vaccine recommendations for further guidance: www.cdc.gov/mmwr/volumes/71/wr/mm7103a2.htm

Appendix Recommended Adult Immunization Schedule, United States, 2023

Guide to Contraindications and Precautions to Commonly Used Vaccines

Adapted from Table 4-1 in Advisory Committee on Immunization Practices (ACIP) General Best Practice Guidelines for Immunization: Contraindication and Precautions available at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html *and ACIP's Recommendations for the Prevention and Control of 2022-23 Seasonal Influenza with Vaccines available at www.cdc.gov/mmwr/volumes/71/rr/rr7101a1.htm*

For COVID-19 vaccine contraindications and precautions see
www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications

Vaccine	Contraindicated or Not Recommended[1]	Precautions[2]
Influenza, egg-based, inactivated injectable (IIV4)	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[3] (excluding egg)	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Moderate or severe acute illness with or without fever
Influenza, cell culture-based inactivated injectable [(ccIIV4), Flucelvax® Quadrivalent]	• Severe allergic reaction (e.g., anaphylaxis) to any ccIIV of any valency, or to any component[3] of ccIIV4	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, RIV, or LAIV of any valency. If using ccIV4, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, recombinant injectable [(RIV4), Flublok® Quadrivalent]	• Severe allergic reaction (e.g., anaphylaxis) to any RIV of any valency, or to any component[3] of RIV4	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, ccIIV, or LAIV of any valency. If using RIV4, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, live attenuated [LAIV4, Flumist® Quadrivalent]	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[3] (excluding egg) • Anatomic or functional asplenia • Immunocompromised due to any cause including, but not limited to, medications and HIV infection • Close contacts or caregivers of severely immunosuppressed persons who require a protected environment • Pregnancy • Cochlear implant • Active communication between the cerebrospinal fluid (CSF) and the oropharynx, nasopharynx, nose, ear, or any other cranial CSF leak • Received influenza antiviral medications oseltamivir or zanamivir within the previous 48 hours, peramivir within the previous 5 days, or baloxavir within the previous 17 days.	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Asthma in persons aged 5 years old or older • Persons with underlying medical conditions (other than those listed under contraindications) that might predispose to complications after wild-type influenza virus infection [e.g., chronic pulmonary, cardiovascular (except isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus)] • Moderate or severe acute illness with or without fever

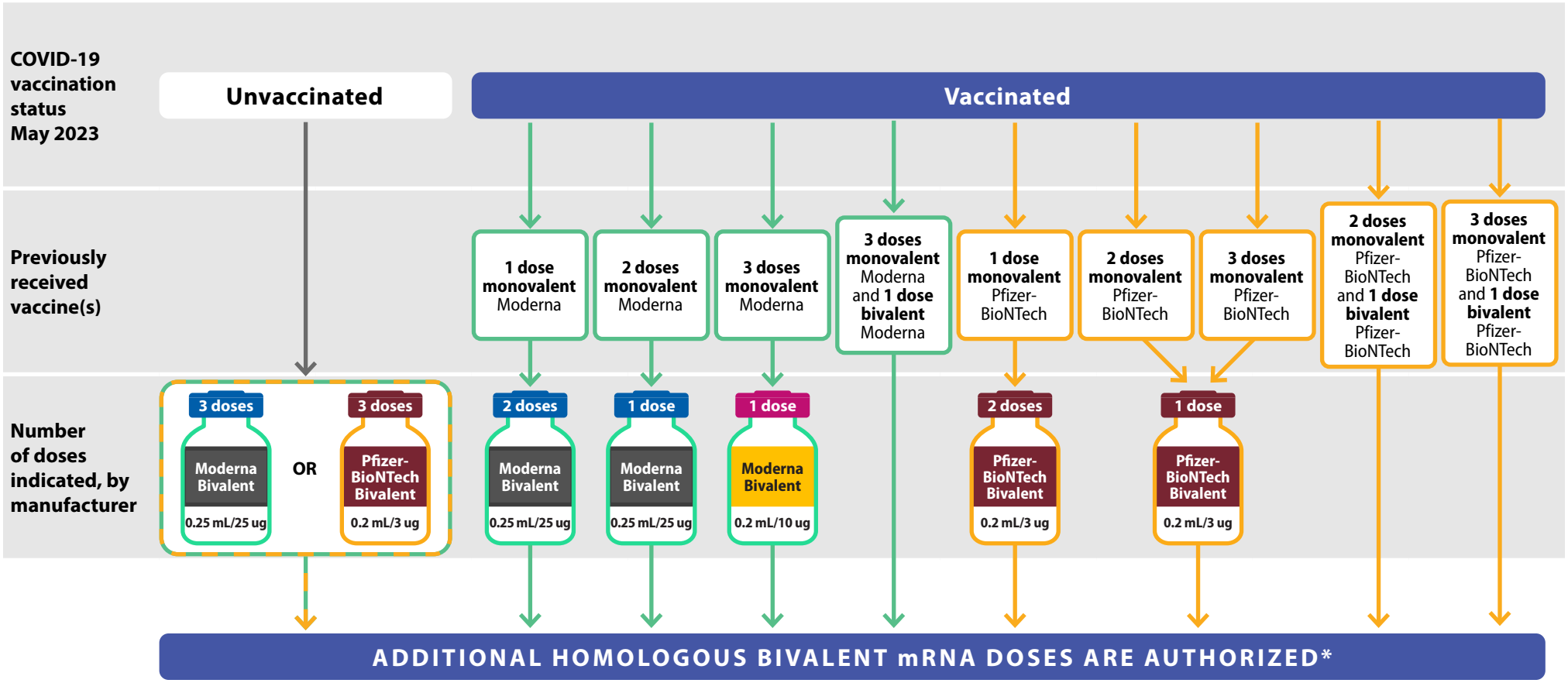
1. When a contraindication is present, a vaccine should NOT be administered. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html
3. Vaccination providers should check FDA-approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. Package inserts for U.S.-licensed vaccines are available at www.fda.gov/vaccines-blood-biologics/approved-products/vaccines-licensed-use-united-states.

Appendix Recommended Adult Immunization Schedule, United States, 2023

Vaccine	Contraindicated or Not Recommended[1]	Precautions[2]
Haemophilus influenzae type b (Hib)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For Hiberix, ActHib, and PedvaxHIB only: History of severe allergic reaction to dry natural latex	• Moderate or severe acute illness with or without fever
Hepatitis A (HepA)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin	• Moderate or severe acute illness with or without fever
Hepatitis B (HepB)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including yeast • *Pregnancy: Heplisav-B and PreHevbrio are not recommended due to lack of safety data in pregnant persons. Use other hepatitis B vaccines if HepB is indicated*[4]	• Moderate or severe acute illness with or without fever
Hepatitis A- Hepatitis B vaccine [HepA-HepB, (Twinrix®)]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin and yeast	• Moderate or severe acute illness with or without fever
Human papillomavirus (HPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • *Pregnancy: HPV vaccination not recommended*	• Moderate or severe acute illness with or without fever
Measles, mumps, rubella (MMR)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent	• Recent (≤11 months) receipt of antibody-containing blood product (specific interval depends on product) • History of thrombocytopenia or thrombocytopenic purpura • Need for tuberculin skin testing or interferon-gamma release assay (IGRA) testing • Moderate or severe acute illness with or without fever
Meningococcal ACWY (MenACWY) [MenACWY-CRM (Menveo®); MenACWY-D (Menactra®); MenACWY-TT (MenQuadfi®)]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For MenACWY-D and MenACWY-CRM only: severe allergic reaction to any diphtheria toxoid–or CRM197–containing vaccine • For MenACWY-TT only: severe allergic reaction to a tetanus toxoid-containing vaccine	• Moderate or severe acute illness with or without fever
Meningococcal B (MenB) [MenB-4C (Bexsero); MenB-FHbp (Trumenba)]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Pregnancy • For MenB-4C only: Latex sensitivity • Moderate or severe acute illness with or without fever
Pneumococcal conjugate (PCV15, PCV20)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe allergic reaction (e.g., anaphylaxis) to any diphtheria-toxoid–containing vaccine or to its vaccine component[3]	• Moderate or severe acute illness with or without fever
Pneumococcal polysaccharide (PPSV23)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever
Tetanus, diphtheria, and acellular pertussis (Tdap) Tetanus, diphtheria (Td)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For Tdap only: Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures), not attributable to another identifiable cause, within 7 days of administration of previous dose of DTP, DTaP, or Tdap	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of tetanus-toxoid–containing vaccine • History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria-toxoid–containing or tetanus-toxoid–containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid–containing vaccine • Moderate or severe acute illness with or without fever • For Tdap only: Progressive or unstable neurological disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized
Varicella (VAR)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent	• Recent (≤11 months) receipt of antibody-containing blood product (specific interval depends on product) • Receipt of specific antiviral drugs (acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination (avoid use of these antiviral drugs for 14 days after vaccination) • Use of aspirin or aspirin-containing products • Moderate or severe acute illness with or without fever
Zoster recombinant vaccine (RZV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever • Current herpes zoster infection

1. When a contraindication is present, a vaccine should NOT be administered. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html
3. Vaccination providers should check FDA-approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. Package inserts for U.S.-licensed vaccines are available at www.fda.gov/vaccines-blood-biologics/approved-products/vaccines-licensed-use-united-states.
4. For information on the pregnancy exposure registries for persons who were inadvertently vaccinated with Heplisav-B or PreHevbrio while pregnant, please visit heplisavbpregnancyregistry.com/ or www.prehevbrio.com/#safety.

Recommended COVID-19 vaccines for **people who ARE moderately or severely immunocompromised, aged 6 months–4 years,** mRNA vaccines, *with vial icons and dosages,* May 2023*



*For product- and vaccination history-specific dosages, administration intervals, and additional dose information, see Table 2 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

Key

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

Recommended COVID-19 vaccines for **people who ARE moderately or severely immunocompromised, aged 5 years,** mRNA vaccines, *with vial icons and dosages,* May 2023*

COVID-19 vaccination status May 2023

Unvaccinated

Vaccinated

Previously received vaccine(s)

- **1 dose monovalent** Moderna
- **2 doses monovalent** Moderna
- **3 doses monovalent** Moderna
- **3 doses monovalent** Moderna and **1 dose bivalent** mRNA
- **1 dose monovalent** Pfizer-BioNTech
- **2 doses monovalent** Pfizer-BioNTech
- **3 doses monovalent** Pfizer-BioNTech
- **3 doses monovalent** Pfizer-BioNTech and **1 dose bivalent** Pfizer-BioNTech

Number of doses indicated, by manufacturer

- 3 doses Moderna Bivalent 0.25 mL/25 ug **OR** 3 doses Pfizer-BioNTech Bivalent 0.2 mL/10 ug
- 2 doses Moderna Bivalent 0.25 mL/25 ug
- 1 dose Moderna Bivalent 0.25 mL/25 ug
- 1 dose Moderna Bivalent 0.25 mL/25 ug **OR** 1 dose Pfizer-BioNTech Bivalent 0.2 mL/10 ug
- 2 doses Pfizer-BioNTech Bivalent 0.2 mL/10 ug
- 1 dose Pfizer-BioNTech Bivalent 0.2 mL/10 ug

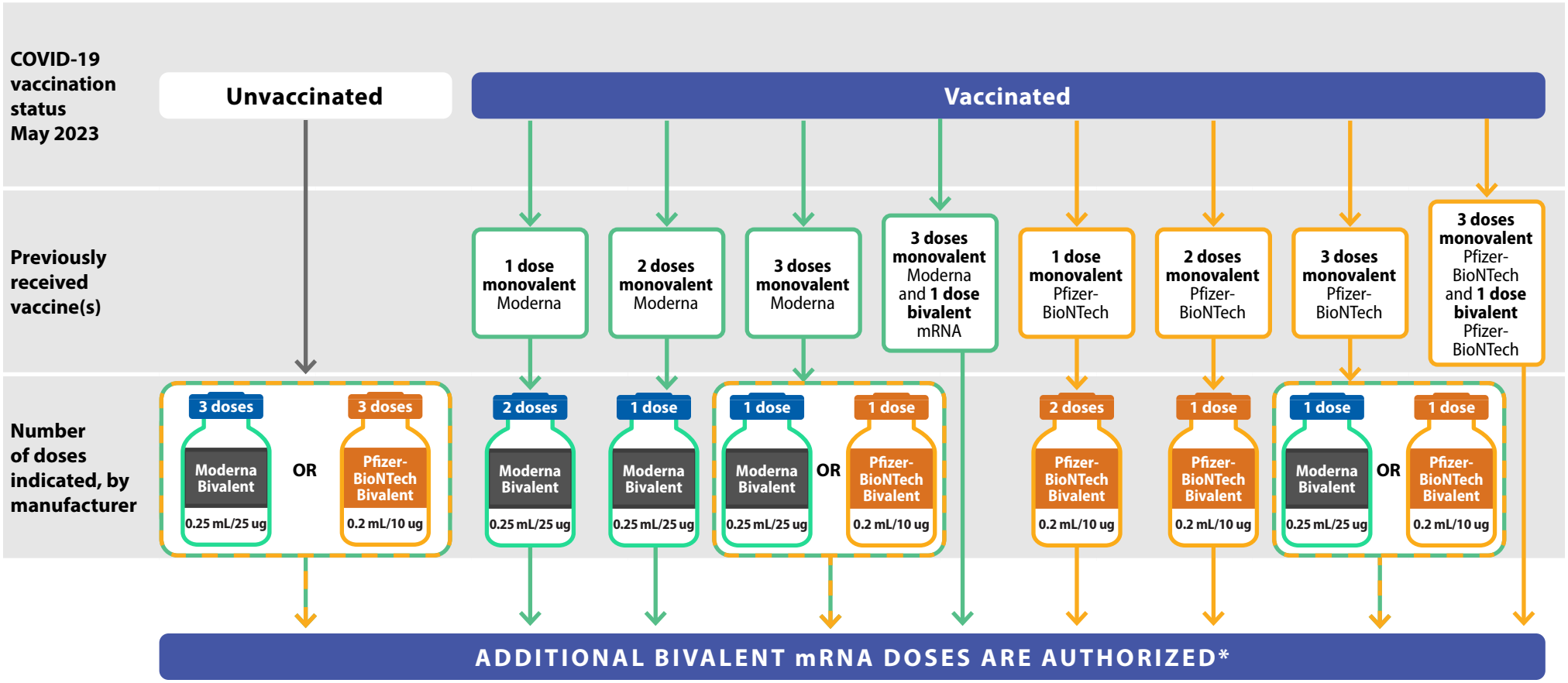
ADDITIONAL BIVALENT mRNA DOSES ARE AUTHORIZED*

*For administration intervals, additional dose information, and options for heterologous dosing, see Table 2 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

Key

- Moderna
- Pfizer-BioNTech
- Moderna **OR** Pfizer-BioNTech

Recommended COVID-19 vaccines for **people who ARE moderately or severely immunocompromised, aged 6–11 years,** mRNA vaccines, *with vial icons and dosages,* May 2023*

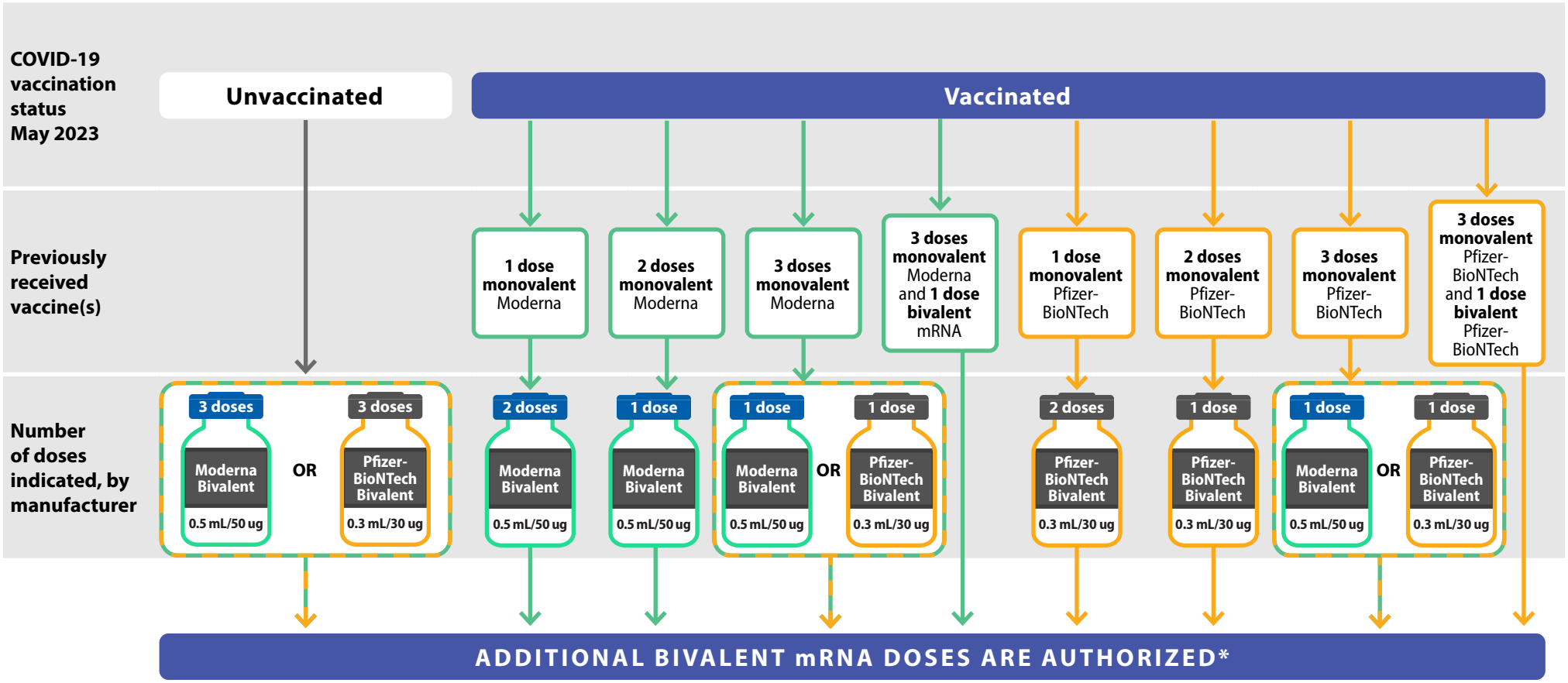


*For product-specific dosages, administration intervals, additional dose information, and options for heterologous dosing, see Table 2 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

Key

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

Recommended COVID-19 vaccines for **people who ARE moderately or severely immunocompromised, aged 12 years and older,** *mRNA vaccines, with vial icons and dosages,* May 2023*

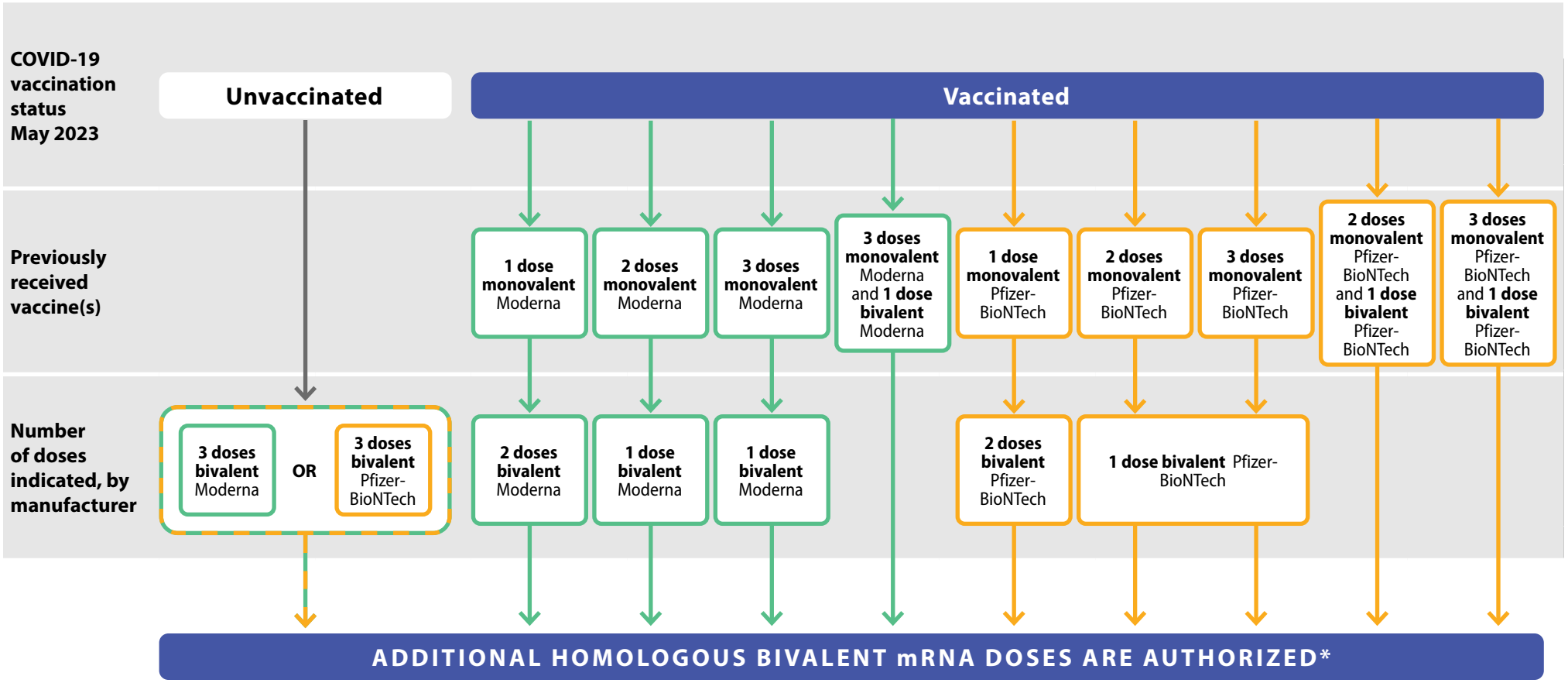


*For administration intervals, additional dose information, and options for heterologous dosing, see Table 2 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

Key

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

Recommended COVID-19 vaccines for **people who ARE moderately or severely immunocompromised, aged 6 months–4 years,** mRNA vaccines, May 2023*



*For product- and vaccination history-specific dosages, administration intervals, and additional dose information, see Table 2 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

Key

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

Recommended COVID-19 vaccines for **people who ARE moderately or severely immunocompromised, aged 5 years,** mRNA vaccines, May 2023*

COVID-19 vaccination status May 2023

Unvaccinated

Vaccinated

Previously received vaccine(s)

- **1 dose monovalent** Moderna
- **2 doses monovalent** Moderna
- **3 doses monovalent** Moderna
- **3 doses monovalent** Moderna and **1 dose bivalent** mRNA
- **1 dose monovalent** Pfizer-BioNTech
- **2 doses monovalent** Pfizer-BioNTech
- **3 doses monovalent** Pfizer-BioNTech
- **3 doses monovalent** Pfizer-BioNTech and **1 dose bivalent** Pfizer-BioNTech

Number of doses indicated, by manufacturer

- **3 doses bivalent** Moderna **OR** **3 doses bivalent** Pfizer-BioNTech
- **2 doses bivalent** Moderna
- **1 dose bivalent** Moderna
- **1 dose bivalent** Moderna **OR** **1 doses bivalent** Pfizer-BioNTech
- **2 doses bivalent** Pfizer-BioNTech
- **1 dose bivalent** Pfizer-BioNTech

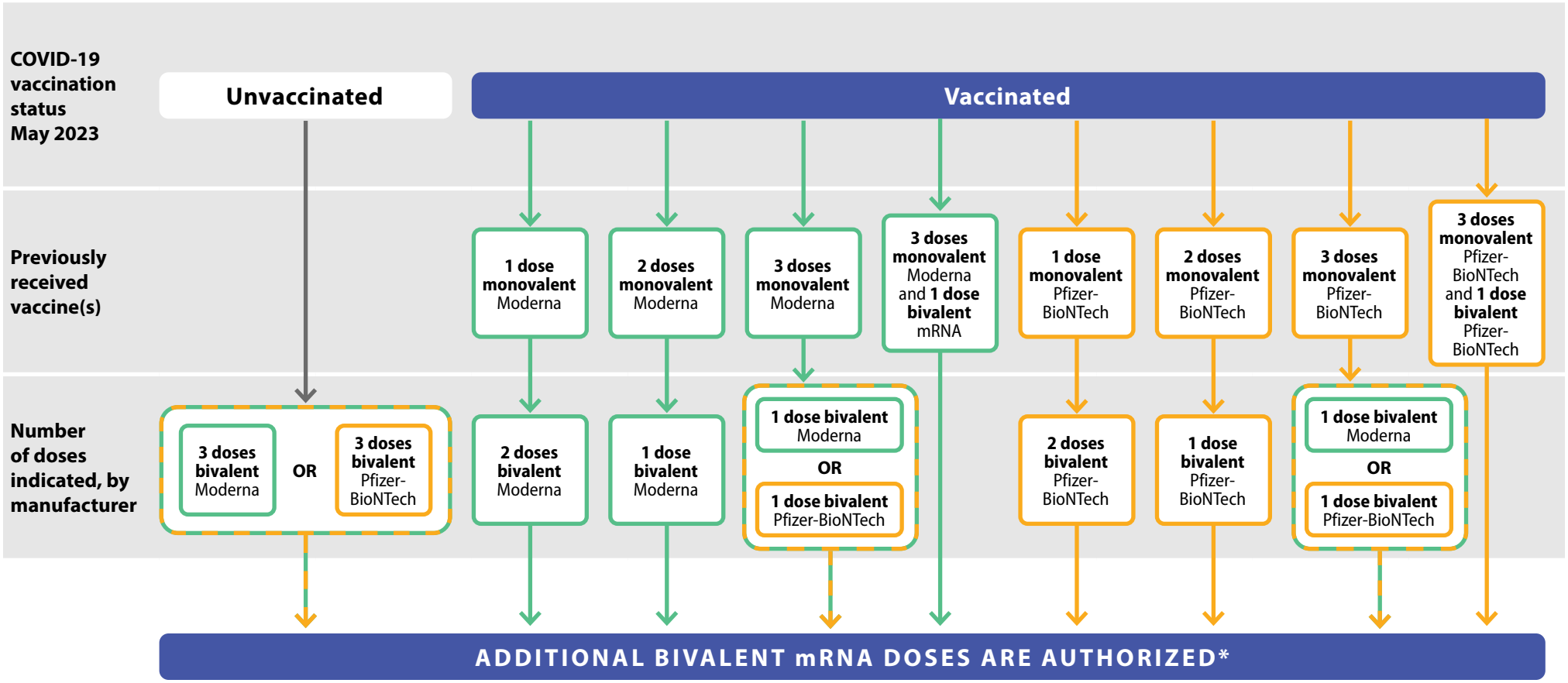
ADDITIONAL BIVALENT mRNA DOSES ARE AUTHORIZED*

*For product- and vaccination-history-specific dosages, administration intervals, additional dose information, and options for heterologous dosing, see Table 2 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

Key

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

Recommended COVID-19 vaccines for **people who ARE moderately or severely immunocompromised, aged 6 years and older,** mRNA vaccines, May 2023*

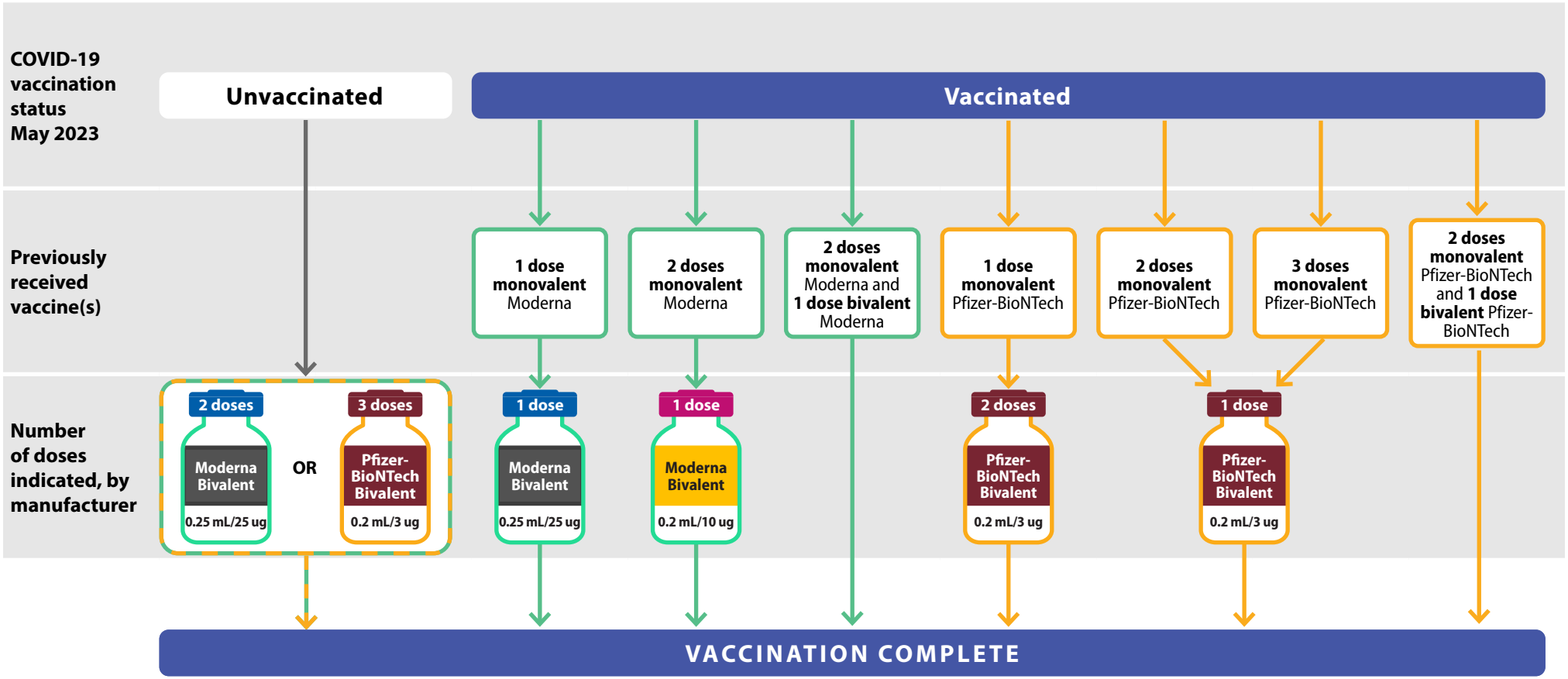


*For product-specific dosages, administration intervals, additional dose information, and options for heterologous dosing, see Table 2 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

Key

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

Recommended COVID-19 vaccines for **people without immunocompromise, aged 6 months–4 years**, mRNA vaccines, *with vial icons and dosages*, May 2023*†



*For administration intervals, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.
†Children who receive the Pfizer-BioNTech COVID-19 Vaccine and transition from age 4 years to 5 years during the 3-dose vaccination series must complete the series they start (i.e., receive the 0.2 mL/3 ug dosage supplied in vials with a maroon cap and label with a maroon border for all 3 doses).

Key

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

Recommended COVID-19 vaccines for **people without immunocompromise, aged 5 years,** mRNA vaccines, *with vial icons and dosages*, May 2023*†

COVID-19 vaccination status May 2023

Unvaccinated

Vaccinated

Previously received vaccine(s)

- **1 dose monovalent** Moderna
- **2 doses monovalent** Moderna
- **1 or more doses monovalent** Pfizer-BioNTech
- **2 doses monovalent** Moderna and **1 dose bivalent** mRNA
- **Any doses monovalent** Pfizer-BioNTech and **1 dose bivalent** Pfizer-BioNTech

Number of doses indicated, by manufacturer

- Unvaccinated: **2 doses** Moderna Bivalent 0.25 mL/25 ug **OR** **1 dose** Pfizer-BioNTech Bivalent 0.2 mL/10 ug
- 1 dose monovalent Moderna: **1 dose** Moderna Bivalent 0.25 mL/25 ug **OR** **1 dose** Pfizer-BioNTech Bivalent 0.2 mL/10 ug
- 2 doses monovalent Moderna: **1 dose** Moderna Bivalent 0.2 mL/10 ug **OR** **1 dose** Pfizer-BioNTech Bivalent 0.2 mL/10 ug
- 1 or more doses monovalent Pfizer-BioNTech: **1 dose** Pfizer-BioNTech Bivalent 0.2 mL/10 ug
- 2 doses monovalent Moderna and 1 dose bivalent mRNA
- Any doses monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer-BioNTech

VACCINATION COMPLETE

*For administration intervals, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

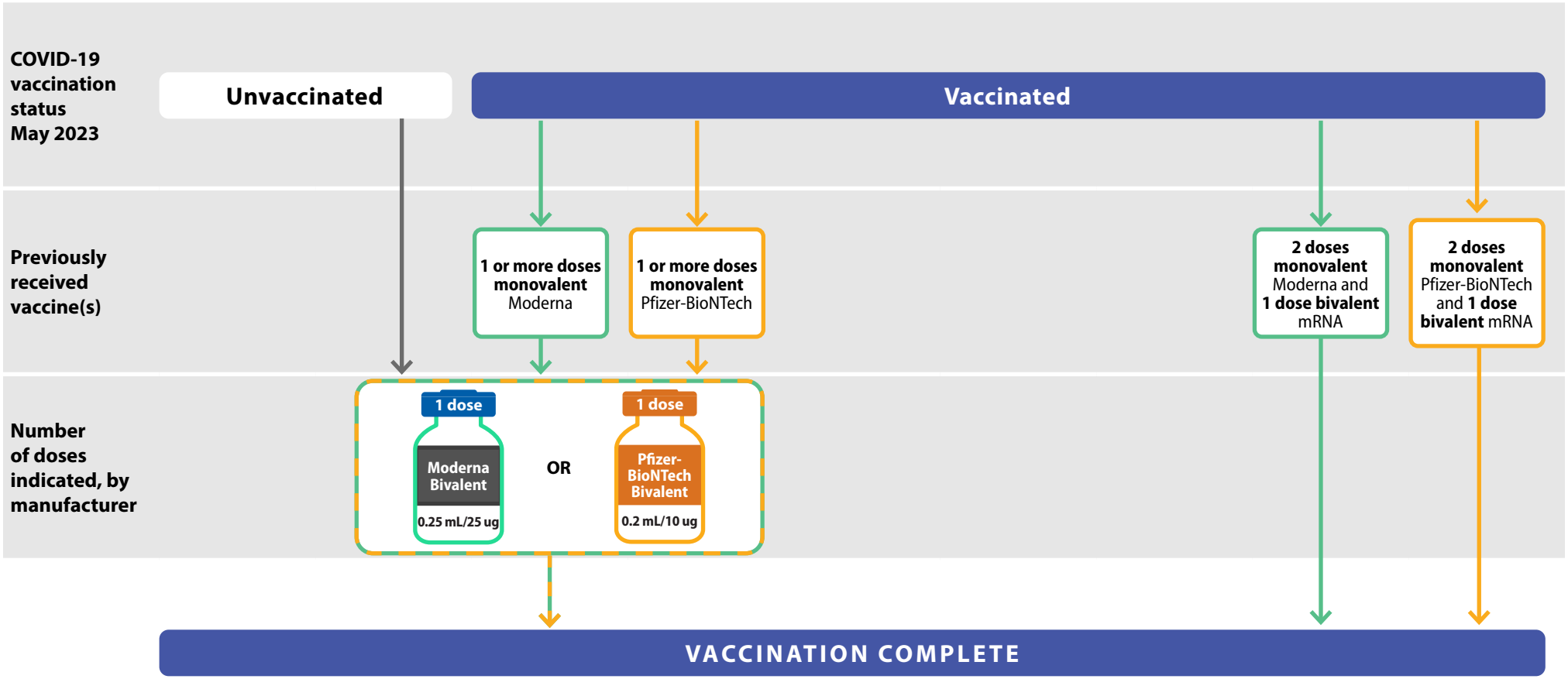
†Children who receive the Pfizer-BioNTech COVID-19 Vaccine and transition from age 4 years to 5 years during the 3-dose vaccination series must complete the series they start (i.e., receive the 0.2 mL/3 ug dosage supplied in vials with a maroon cap and label with a maroon border for all 3 doses).

Children who transition from age 5 years to 6 years during the Moderna vaccination series should receive 2 doses of Moderna COVID-19 Vaccine (0.25 mL/25 ug; dark blue cap and label with a gray border).

Key

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

Recommended COVID-19 vaccines for **people without immunocompromise, aged 6–11 years,** mRNA vaccines, *with vial icons and dosages,* May 2023*†

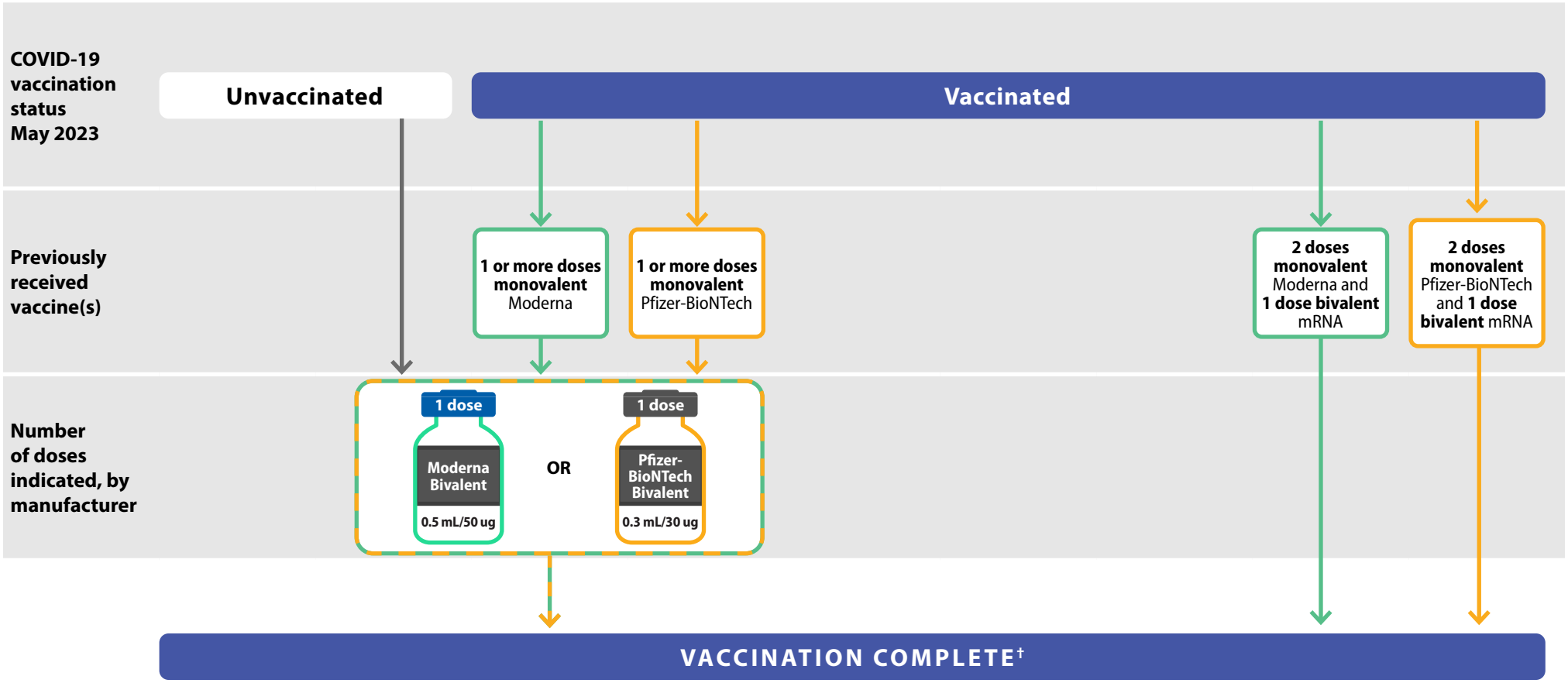


*For administration intervals, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.
†Children who transition from age 5 years to 6 years during the Moderna vaccination series should receive 2 doses of Moderna COVID-19 Vaccine (0.25 mL/25 ug; dark blue cap and label with a gray border).

Key

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

Recommended COVID-19 vaccines for **people without immunocompromise, aged 12 years and older,** mRNA vaccines, *with vial icons and dosages,* May 2023*†

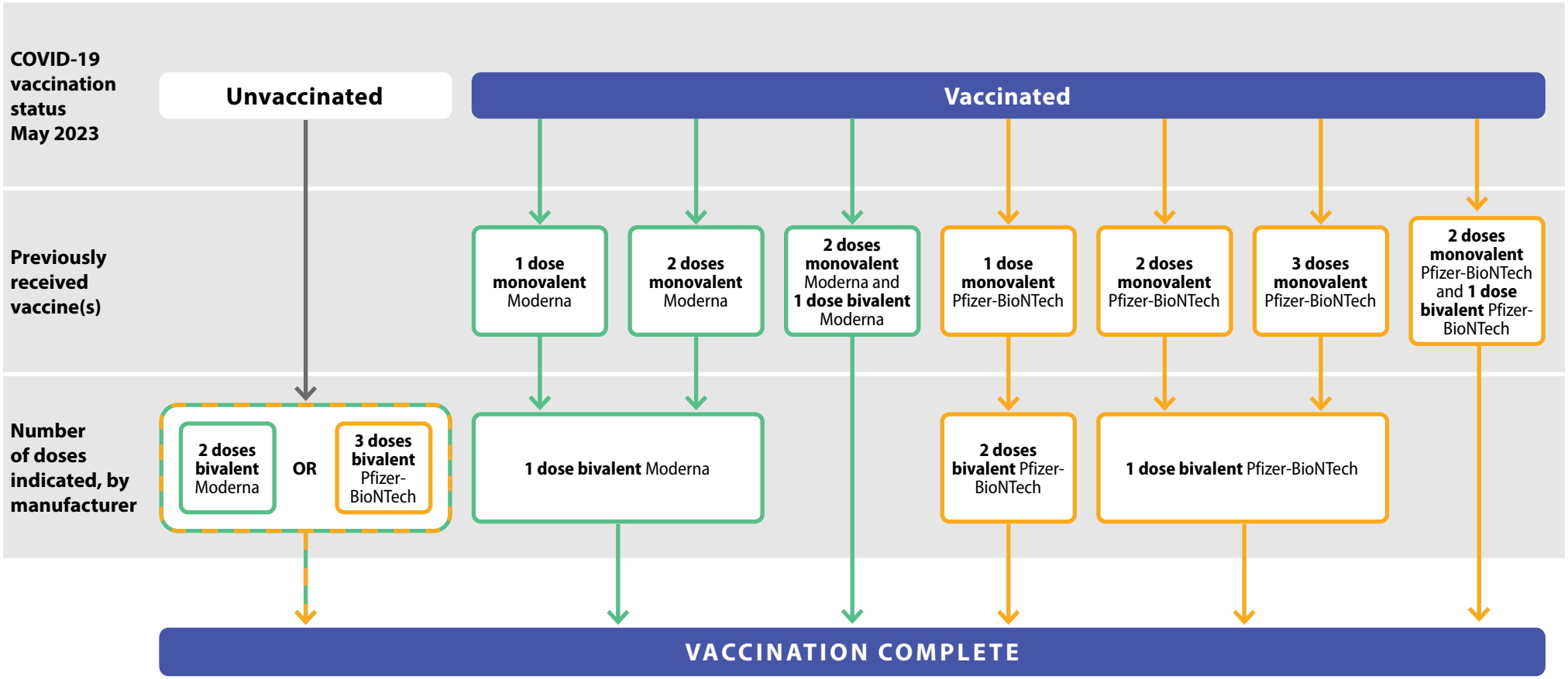


*For administration intervals, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.
†People ages 65 years and older have the option to receive 1 additional bivalent mRNA dose at least 4 months after the first dose of a bivalent mRNA vaccine; see Table 1 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

Key

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

Recommended COVID-19 vaccines for **people without immunocompromise, aged 6 months–4 years**, mRNA vaccines, May 2023*



*For product- and vaccination history-specific dosages and administration intervals, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

Key

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

Recommended COVID-19 vaccines for **people without immunocompromise, aged 5 years,** mRNA vaccines, May 2023*

COVID-19 vaccination status May 2023

Unvaccinated

Vaccinated

Previously received vaccine(s)

- **1 dose monovalent** Moderna
- **2 doses monovalent** Moderna
- **1 or more doses monovalent** Pfizer-BioNTech
- **2 doses monovalent** Moderna and **1 dose bivalent** mRNA
- **Any doses monovalent** Pfizer-BioNTech and **1 dose bivalent** Pfizer-BioNTech

Number of doses indicated, by manufacturer

- **2 doses bivalent** Moderna **OR** **1 dose bivalent** Pfizer-BioNTech
- **1 dose bivalent** Moderna **OR** **1 dose bivalent** Pfizer-BioNTech
- **1 dose bivalent** Pfizer-BioNTech

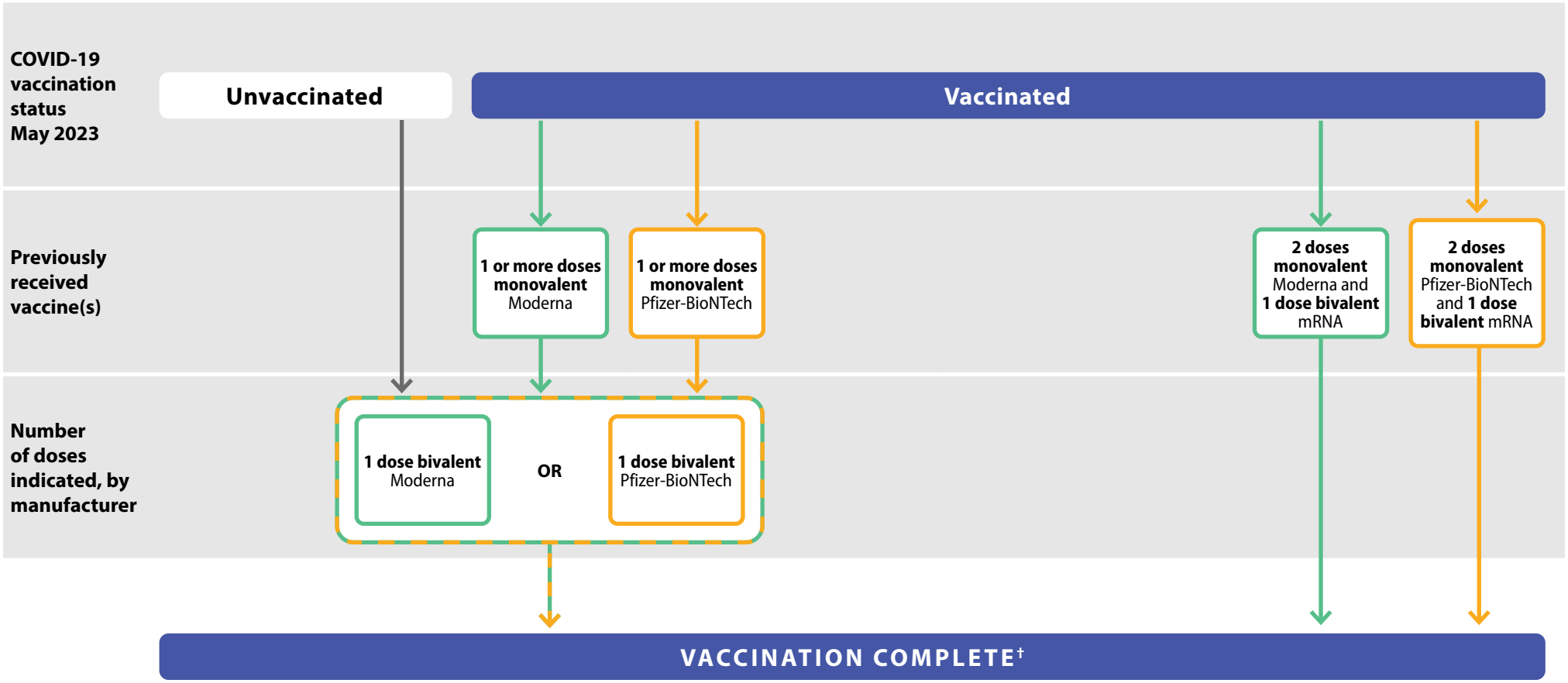
VACCINATION COMPLETE

*For product- and vaccination history-specific dosages and administration intervals, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

Key

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

Recommended COVID-19 vaccines for **people without immunocompromise, aged 6 years and older,** mRNA vaccines, May 2023*



*For product-specific dosages and administration intervals, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.
†People ages 65 years and older have the option to receive 1 additional bivalent mRNA dose at least 4 months after the first dose of a bivalent mRNA vaccine; see Table 1 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

Key

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

Talking With Your LTC Staff About the COVID-19 Vaccine & Booster

How to Talk With LTC Staff About the Vaccines

- Be empathetic and acknowledge the challenges of the COVID-19 pandemic.
- Show appreciation for everything staff has done. Recognize that they have a hard job, made even more difficult by the pandemic.
- Listen to and hear staff concerns. Respond without judgement or reproach.
- Reinforce their feelings with phrases like, “That is a great question.”
- Speak openly about the vaccine and be confident in your responses.
- Address all staff concerns. If you are asked an unfamiliar question, it’s okay to say, “Let me find more information on that,” but be sure to follow through. There are multiple resources, such as the AHCA/NCAL #GetVaccinated webpage to help answer questions.
- Make eye contact to establish trust and show compassion.
- If possible, hold one-on-one conversations between leadership and staff. They may feel more comfortable asking questions in this setting.
- Provide follow up information and resources after having conversations to reinforce any concerns. Make sure follow-up is tailored to specific issues/concerns of staff.

Key Talking Points with LTC Staff

- We recognize that this has been an extremely challenging time for long term care staff and residents, as well as their loved ones. [Show empathy.]
- It is very encouraging that the U.S. Food and Drug Administration (FDA) has found COVID-19 vaccines to be safe and effective.
- We encourage as many staff as possible to get this vaccine and subsequent boosters to remain up to date.

- The elderly population has a much higher risk for getting very sick, being hospitalized, or dying from COVID-19. The vaccine has been shown to provide a great deal of protection against serious illness due to COVID-19.

- The more of us that get vaccinated, the better we can protect our families and our community against potential outbreaks. We can save lives.

- While we still have to be careful, getting vaccinated will reduce restrictions the pandemic has placed on your daily life. The CDC has also released guidance indicating that individuals who are fully vaccinated can refrain from quarantine if exposed to COVID-19, and staff do not have to be routinely tested.

- The vaccines have gone through testing and clinical trials to ensure they meet the highest safety standards. It also is safe to get if you already had the virus.

- All approved vaccines require two doses. You will need to get both doses to ensure the best results. The second dose will be delivered approximately 21 to 28 days after the first dose.

- Three vaccines – Moderna, Pfizer, and Johnson & Johnson – have also been approved for a booster. The purpose of a booster is to help build back immunity against new coronavirus variants. Booster shots help you maintain protection against the virus.

- Potential side effects are listed on the fact sheet for each vaccine. You will find that these side effects are similar to the potential side effects of the flu shot, but they occur in more people.

- Please feel free to reach back out to us if you have any additional questions. We are here to help make sure you feel comfortable with this process. Frequently asked questions can be found on the AHCA/NCAL GetVaccinated website.

Please visit getvaccinated.us more ideas on promoting staff vaccine uptake and other COVID-19 vaccine resources.

HOW DO I SAFELY USE A **MULTI-DOSE VACCINE VIAL?**

You vaccinate patients to protect them. Correctly using multi-dose vials keeps your patients safe from germs that can spread from contaminated vials, needles, and syringes.

CHECK THAT YOU ARE USING MULTI-DOSE VACCINE VIALS SAFELY ***EVERY TIME.***

- **Always prepare multi-dose vial injections away from patient care spaces in a clean designated area**
- **Clean your hands** before touching the vial
- **Check the label** to make sure it is a multi-dose vaccine vial
- Check to make sure the vaccine is **not expired or "beyond use"**
- **Look and see** if the vaccine appears the way the vaccine maker tells you it should
- Use **brand-new, sterile needles and syringes** for every vaccine dose
- **Disinfect the top** part of the vial (the vial stopper) with an alcohol prep pad—**every time**
- Make sure the **top is dry** before sticking the needle in it
- When you first put a needle in, **write the date and time** on the label
- Follow the vaccine maker's **instructions for storage**
- **Never "pool" doses** (combine partial doses from multiple vials to make one dose for a patient)

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

PROJECT FIRSTLINE

Prevaccination Checklist for COVID-19 Vaccines

Information for Healthcare Professionals

Using the prevaccination checklist completed by the recipient, review clinical guidance based on the answers to the questions to determine if COVID-19 vaccine can be given. Use this guidance with:

- Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States
- Advisory Committee on Immunization Practices on Immunization General Best Practice Guidelines
- Interim COVID-19 Immunization Schedule for Ages 6 Months and Older
- COVID-19 Vaccination Clinical & Professional Resources for each vaccine product

Vaccine Administration:

COVID-19 vaccines are administered by IM injection and can be given at the same clinical visit as other routinely administered vaccines using separate needles, syringes and injection sites. Exception: Orthopoxvirus vaccines (mpox) have additional considerations. See section 8 of this guidance. Other routine vaccines can also be administered any time before or after COVID-19 vaccination.

Syncope (fainting) might occur in association with any injectable vaccine, especially in adolescents. Consider observing vaccine recipients, vaccination providers, particularly when vaccinating adolescents, for 15 minutes after vaccination.

Additionally, providers should consider observing some people with a history of allergic reactions for 30 minutes after COVID-19 vaccination. See Sections 6 and 7 in this guidance and Management of Anaphylaxis at COVID-19 Vaccination Sites | CDC for guidance.

1. How old is the person to be vaccinated?

Clinical considerations based on the age of the recipient include:

COVID-19 vaccines products (monovalent and bivalent) have different age indications.

- Janssen COVID-19 Vaccine (monovalent) can be administered to persons 18 years of age and older in certain limited situations due to safety considerations.
- Novavax COVID-19 Vaccine (monovalent) can be administrated to persons 12 years of age and older.
- Moderna COVID-19 Vaccine (monovalent, bivalent) can be administered to persons ages 6 months of age and older.
- Pfizer-BioNTech COVID-19 Vaccine (monovalent, bivalent) can be administered to persons 6 months of age and older.

Use the manufacturers' fact sheets for healthcare professionals and CDC clinical materials for healthcare professionals and to identify the correct product based on the vaccine composition and recipient's age.

People receiving mRNA or Novavax COVID-19 vaccines, especially males ages 12–39 years, should be made aware of the rare risk of myocarditis and/or pericarditis following receipt of these COVID-19 vaccines and the benefit of COVID-19 vaccination in reducing the risk of severe outcomes from COVID-19, including the possibility of cardiac sequelae. Counseling should include the need to seek care if symptoms of myocarditis or pericarditis, such as chest pain, shortness of breath, or tachycardia develop after vaccination, particularly in the week after vaccination. Extending the interval between these vaccines dose to 8 weeks might reduce the risk.

Note: There are some persons the extended interval should not be considered including those who are:

- Moderately or severely immunocompromised
- Adults ages 65 years and older;
- In situations in which there is increased concern about COVID-19 community levels or an individual's higher risk of severe disease.

Additional recipient education materials

2. Is the person to be vaccinated sick today?

People with mild illnesses can be vaccinated. Do not withhold vaccination if a person is taking antibiotics.

While there is no evidence acute illness reduces vaccine efficacy or increases adverse reactions, as a precaution, **delay vaccinating patients with moderate or severe illness** until the illness has improved.

Defer vaccination of people with current SARS-CoV-2 infection. For those with

- Symptoms: defer vaccination until recovery from the acute illness and isolation has been discontinued.
- Asymptomatic infection: defer vaccination until isolation has been discontinued.

This recommendation applies regardless of whether the SARS-CoV-2 infection occurred before the recipient received an initial dose or between doses. Viral or serological testing to assess for current or prior infection solely for the purpose of vaccine-decision making is not recommended.

3. Has the person to be vaccinated ever received a dose of COVID-19 vaccine?

COVID-19 vaccination is recommended for everyone 6 months of age and older. For the primary series, Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines are recommended. The same vaccine product should be used for all primary series doses.

Moderna and Pfizer-BioNTech are recommended for booster doses. **A bivalent booster dose of COVID-19 vaccine is recommended for persons 6 months of age and older with the exception of children ages 6 months through 4 years who completed a primary series of Pfizer-BioNTech COVID-19 Vaccine; regardless of which Pfizer-BioNTech vaccine (i.e., monovalent or bivalent) was administered for the third primary series dose.**

A monovalent Novavax booster dose (instead of a bivalent mRNA booster dose) may be used in limited situations for persons ages 18 years and older who completed any monovalent primary series, and have not received **ANY** previous booster dose(s), and are unable (i.e., contraindicated or not available) or unwilling to receive an mRNA vaccine and would otherwise not receive a booster dose.

Janssen COVID-19 Vaccine can be administered to persons 18 years of age and older in certain limited situations due to safety considerations.

To determine previously administered COVID-19 doses, check medical records, immunization information systems, and vaccination record cards. If the vaccine product previously administered cannot be determined, is no longer available, or contraindicated, any age-appropriate COVID-19 vaccine product may be administered at least 28 days after the first dose.

Use the Interim Immunization Schedule for Ages 6 Months and Older to schedule doses

Persons who received COVID-19 vaccine outside the United States

Vaccination guidance for people vaccinated outside of the United States can be found in the link Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendices, References, and Previous Updates | CDC

4. Does the recipient have a health condition or undergoing treatment that makes them moderately or severely immunocompromised?

People with moderate or severe immunocompromising conditions or people who take immunosuppressive medications or therapies are at increased risk for severe COVID-19 disease. COVID-19 vaccines may be administered to people with underlying medical conditions, such as HIV infection or other immunocompromising conditions, or who take immunosuppressive medications or therapies, and who have no contraindications to vaccination. People can self-report if they are moderately or severely immunocompromised. Vaccinators should not deny COVID-19 vaccination to a person due to lack of documentation of immune status.

Use the Interim Immunization Schedule for Ages 6 Months and Older to schedule doses

5. Has the person to be vaccinated received a hematopoietic cell transplant (HCT) or CAR-T-cell therapy since receiving COVID-19 vaccine?

HCT and CAR-T-cell recipients who received doses of COVID-19 vaccine prior to or during HCT or CAR-T cell therapy, should be revaccinated for any monovalent primary series and bivalent booster doses received before or during treatment at least 3 months (12 weeks) after transplant or CAR-T-cell therapy. After revaccination with the primary series, the patient should receive 1 bivalent booster dose. There is no revaccination for monovalent booster doses. Additional information can be found at: Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States

6. Has the person to be vaccinated ever had an allergic reaction to:

- A previous dose OR a component of any COVID-19 vaccine
- A previous dose of COVID-19 vaccine?

People with a severe allergic reaction* to a previous COVID-19 vaccine dose or a known (diagnosed) allergy to a component of the vaccine have a contrainidcation to the same type of COVID-19 vaccine (mRNA, Novavax, Janssen).

People who had an immediate (less than 4 hours), but non-severe allergic reaction to a previous dose of COVID-19 vaccine, have a precaution to receiving the same type of COVID-19 vaccine product. Although they can receive the same product, a different COVID-19 vaccine product can also be administered. **Providers should consider observing these patients for 30 minutes after vaccination**

People with a contraindication to one type of COVID-19 vaccine (e.g., mRNA) should not receive any doses of that type of vaccine and have a precaution to the other types of vaccine†.

For COVID-19 vaccine components see the vaccine product's package insert or healthcare provider facts sheet:

www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

Potential characteristics of allergic reactions, vasovagal reactions, and vaccine side effects following COVID-19 vaccination

In patients who experience post-vaccination symptoms, determining the etiology (including allergic reaction, vasovagal reaction, or vaccine side effects) is important to determine whether a person can receive additional doses of the vaccine. Additional information can be found at Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination.

7. Has the person to be vaccinated ever had anaphylaxis after another vaccine (other than COVID-19 vaccine) or another injectable medication?

A history of anaphylaxis to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of COVID-19 vaccines) is a precaution to COVID-19 vaccines. This also applies if the non-COVID-19 vaccine or therapy has multiple components, one or more of which is a component of a COVID-19 vaccine, and it is unknown which component elicited the allergic reaction. Vaccine may be given, but counsel patients about unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination. Deferral of vaccination and/or consultation with an allergist-immunologist should be considered. **Providers should consider observing these patients for 30 minutes after vaccination.**

* When vaccine recipients report a history of an immediate allergic reaction, providers should attempt to determine whether reactions reported following vaccination are consistent with immediate allergic reactions versus other types of reactions commonly observed following vaccination, such as vasovagal reaction or postvaccination side effects (which are not contraindications to receiving additional doses of that vaccine).

† People with a known allergy to polysorbate have a contraindication to both Novavax and Janssen COVID-19 vaccines and a precaution to mRNA COVID-19 vaccines. In all other cases, an allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the other types.

8. Clinical Considerations:

Response	Consideration
History of myocarditis or pericarditis	■ Development of myocarditis or pericarditis after a dose of an mRNA (Moderna, Pfizer-BioNTech) or Novavax COVID-19 vaccine is a precaution to a subsequent dose of any COVID-19 vaccine and subsequent doses should generally be avoided. ■ If after a risk assessment, the decision is made to receive a subsequent COVID-19 vaccine dose, the person should wait until after their episode has resolved. Considerations for subsequent COVID-19 vaccination may include: ○ The myocarditis or pericarditis was considered unrelated to vaccination with Moderna, Novavax, or Pfizer-BioNTech (e.g., due to SARS-CoV-2 or other viruses), especially if the myocarditis or pericarditis diagnosis occurred more than 3 weeks after the most recent dose of COVID-19 vaccine ○ Personal risk of severe acute COVID-19 (e.g., age, underlying conditions) ○ Timing of any immunomodulatory therapies; Consult ACIP's *General Best Practice Guidelines for Immunization* ■ For information on potential use of Janssen COVID-19 Vaccine in this situation, see Appendix A ■ Persons who have a history of myocarditis or pericarditis unrelated to mRNA (Moderna, Pfizer-BioNTech) or Novavax COVID-19 vaccination may receive any currently FDA-approved or -authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has resolved.
History of multisystem inflammatory syndrome; either MIS-C (children) or MIS-A (adults)	■ Persons with a history of multisystem inflammatory syndrome; either MIS-C (children) or MIS-A (adults) is a precaution to receipt of COVID-19 vaccine. ■ Considerations when conducting a risk assessment for potential COVID-19 vaccination ■ Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment Project
History of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as heparin-induced thrombocytopenia (HIT)	■ Janssen COVID-19 vaccine is not recommended for persons with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as spontaneous or classic HIT. ■ These persons should receive an mRNA (ie. Moderna or Pfizer-BioNTech) or Novavax COVID-19 vaccine.
History of thrombosis with thrombocytopenia syndrome (TTS)	■ Janssen COVID-19 vaccine is contraindicated for persons with a history of TTS following a dose of Janssen COVID-19 vaccine (or other COVID-19 vaccines not currently authorized in the U.S. that are based on adenovirus vectors, e.g., AstraZenca). ■ These persons should receive a booster dose of bivalent mRNA vaccine (Moderna, Pfizer-BioNTech). For addtional guidance see Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendix A
History of Guillain-Barré Syndrome (GBS)	■ A history of GBS, either before or after COVID-19 vaccination, is a precaution for receipt of Janssen COVID-19 Vaccine. An mRNA or Novavax COVID-19 vaccine is recommended. ■ Persons who develop GBS within 6 weeks of Janssen COVID-19 vaccination should only receive an mRNA COVID-19 vaccine.

Response	Consideration
History of prior COVID-19 disease in the last 3 months	■ COVID-19 vaccination is recommended for everyone ages 6 months and older, regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection. People who recently had COVID-19 disease or SARS-CoV-2 infection (within the last 3 months) may consider **delaying their primary series or booster dose dose by 3 months from symptom onset or positive test (if infection was asymptomatic)**. ■ Individual factors such as risk of severe disease, COVID-19 community level, or characteristics of the predominant SARS-CoV-2 strain should be considered when determining whether to delay getting a booster dose after infection. ■ **NOTE: Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection is NOT RECOMMENDED for the purpose of vaccine decision-making.**
Been vaccinated with mpox vaccine in the last 4 weeks?	■ If an orthopoxvirus vaccine is recommended for prophylaxis in the setting of an orthopoxvirus (e.g., mpox) outbreak, orthopoxvirus vaccination should not be delayed because of recent receipt of a Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccine; no minimum interval between COVID-19 vaccination with these vaccines and orthopoxvirus vaccination is necessary. ■ People, particularly adolescent or young adult males, might consider waiting 4 weeks after orthopoxvirus vaccination (either JYNNEOS or ACAM2000) before receiving a Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccine because of the observed risk for myocarditis and pericarditis after receipt of ACAM2000 orthopoxvirus vaccine and mRNA (i.e., Moderna or Pfizer-BioNTech) and Novavax COVID-19 vaccines and the unknown risk for myocarditis and pericarditis after JYNNEOS.

Pfizer-BioNTech COVID-19 Vaccine

At-A-Glance

Guidance below summarizes basic storage, preparation, scheduling, and administration for ALL Pfizer-BioNTech COVID-19 Vaccine products.

Ages: 6 months through 4 years
(Maroon capped vial and bordered label)
BIVALENT

Ages: 5 through 11 years
(Orange capped vial and bordered label)
BIVALENT

Ages: 12 and older
(Gray capped vial and bordered label)
BIVALENT

Storage and Handling Basics

Find additional guidance on storing the vaccine properly at:

- Vaccine Storage and Handling Toolkit-Updated with COVID-19 Vaccine Storage and Handling Information
- Pfizer-BioNTech COVID-19 Vaccines | FDA
- Pfizer-BioNTech COVID-19 Vaccine | cvdvaccine.com

Vial cap color	BIVALENT Maroon Cap	BIVALENT Orange Cap	BIVALENT Gray Cap
Ages	**6 months through 4 years**	**5 through 11 years**	**12 years and older**
Supplied in:	MDV: 10 doses per vial **Requires diluent**	MDV: 10 doses per vial **Requires diluent**	MDV: 6 doses per vial SDV: 1 dose **No diluent**
Storage Temperature: Before Puncture **Do NOT store vaccine in a standard freezer**	**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 **NOTE:** The beyond-use date (10 weeks) replaces the manufacturer's expiration date but NEVER extends it. Always use the earliest date. Do NOT use vaccine if the expiration date or beyond-use date has passed.		
Thawing Frozen Vaccine **Do NOT refreeze thawed vaccine**	**Between:** 2°C and 8°C (36°F and 46°F) OR Up to 25°C (77°F) Amount of time needed to thaw vaccine varies based on temperature and number of vials.		
Storage Temperature: After 1st Puncture **Do NOT use after 12 hours**	**Between:** 2°C and 25°C (36°F and 77°F) for up to 12 hours. Discard vial and any unused vaccine after 12 hours.		

* Vaccine expires 18 months after the manufacture date on the vial. Use Pfizer-BioNTech expiration date tool at lotexpiry.cvdvaccine.com

Pfizer-BioNTech COVID-19 Vaccine
At-A-Glance

Preparation and Administration Basics

Find additional guidance on preparing and administering vaccine properly at:

- Vaccine Administration Resource Library | CDC
- Pfizer-BioNTech COVID-19 Vaccines | FDA
- Pfizer-BioNTech COVID-19 Vaccine | cvdvaccine.com

Preparation Bivalent Vaccine

Vial cap color	Bivalent Maroon Cap	Bivalent Orange Cap	Bivalent Gray Cap	Bivalent Gray Cap
Ages	**6 months through 4 years**	**5 through 11 years**	**12 years and older**	
Vial type	Multidose vial (MDV)	Multidose vial (MDV)	Multidose vial (MDV)	Single-dose vial (SDV)
Diluent*	2.2 mL per vial	1.3 mL per vial	**No diluent**	**No diluent**
Beyond-use date/time	After mixing with diluent, use within 12 hours.		After 1st puncture, use within 12 hours.	N/A
Do NOT use a punctured multidose vial after 12 hours	If using a multidose vial for the 1st time, record the date and time the vial was punctured. **NOTE:** The beyond-use time (12 hours) replaces the manufacturer's expiration date but NEVER extends it. Always use the earliest date. Do NOT use vaccine if the expiration date or beyond-use time has passed.			Vial contains 1 dose

Administration

- COVID-19 vaccine may be administered at the same clinical visit as other routinely recommended vaccines.
- **Do NOT** "pool vaccine" from more than 1 vial to obtain a dose. If a full dose cannot be withdrawn, discard the multidose vial and any remaining vaccine.
- Withdraw 1 dose from a single-dose vial. After withdrawing the dose, discard the vial and any residual vaccine. Do NOT save used single-dose vials.
- Gently swirl vaccine to mix. **Do NOT** shake.

Recipient's Age	Vial Cap/Label Color	Administer	Route	Needle gauge and length	Site
6 months through 4 years	**Bivalent Maroon cap and maroon bordered label**	3 µg/0.2 mL	IM injection	22–25 gauge, 1"	**6 months – 2 years of age:** Vastus lateralis muscle in the anterolateral thigh* **3 years and older:** Deltoid muscle in the upper arm†
5 through 11 years	**Bivalent Orange cap and orange bordered label**	10 µg/0.2 mL	IM injection	22–25 gauge, 1"	Deltoid muscle in the upper arm†
12 years of age and older	**Bivalent Gray cap and gray bordered label** Single-dose Vials and Multidose Vials	30 µg/0.3 mL	IM injection	22–25 gauge, 1 – 1½"	Deltoid muscle in the upper arm†

* The deltoid muscle in the upper arm may be used if the muscle mass is adequate.

† Vastus lateralis muscle in the anterolateral thigh may be used.

Pfizer-BioNTech COVID-19 Vaccine

At-A-Glance

Scheduling Doses

- The number of bivalent doses varies by age, vaccine, previous COVID-19 vaccines received, and the presence of moderate or severe immune compromise. Review CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States for detailed clinical guidance when scheduling doses, and the Interim COVID-19 Immunization Schedule.
  - Children who turn from 4 to 5 years of age: Use vaccine from the maroon-capped vial (0.3mL/3 mcg) for all doses.
- Consider observing persons after vaccination to monitor for allergic reactions and syncope:
  - **30 minutes for persons with:**
    - An allergy-related contraindication to a different type of COVID-19 vaccine
    - A history of non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine
    - A history of anaphylaxis after non-COVID-19 vaccines or injectable therapies
  - **15 minutes:** All other persons

Document the vaccination

For each vaccine recipient, record

- Both in their medical record and on their vaccination card: vaccination date and vaccine administered (product name, manufacturer, lot number)
- In their medical record: vaccination site and route, vaccinator's name and title.
- On their vaccination card: name/location of clinic or health care professional, note bivalent dose if possible.

Report the vaccination to the appropriate state/local immunization information system (IIS)

Contraindications and precautions

Screen for contraindications and precautions before administering EACH dose — even if the vaccine was previously administered. Use CDC's Prevaccination Checklist for COVID-19 Vaccination to determine whether the vaccine may be administered.

Contraindications

History of:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Known diagnosed allergy to a component of the COVID-19 vaccine

Precautions

History of:

- Anaphylaxis after any vaccine other than COVID-19 vaccine or after any injectable therapy, including intramuscular, intravenous, or subcutaneous vaccines or therapies, but excluding subcutaneous immunotherapy for allergies (i.e., "allergy shots").
- Non-severe, immediate (onset less than 4 hours) allergic reaction after a dose of one type of COVID-19 vaccine have a precaution to the same type of COVID-19 vaccine
- An allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the other types of COVID-19 vaccines
- Moderate to severe acute illness, with or without fever
- Multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)
- Myocarditis or pericarditis after a dose of an mRNA or Novavax COVID-19 vaccine

Report adverse reactions and administration errors

Healthcare professionals are required to report to the Vaccine Adverse Event Reporting System (VAERS) including:

- Vaccine administration errors (whether associated with an adverse event [AE] or not)
- Serious AEs (irrespective of attribution to vaccination)
- Multisystem inflammatory syndrome (MIS) in adults and children
- Cases of myocarditis
- Cases of pericarditis
- Cases of COVID-19 that result in hospitalization or death
- Any additional AEs and revised safety requirements per the Food and Drug Administration's conditions for use of an authorized vaccine throughout the duration of the EUA
- Healthcare professionals are encouraged to report to VAERS clinically important adverse events even if unsure whether the vaccine caused the adverse event.

6 Months and Older

Pfizer-BioNTech COVID-19 Vaccine

Vaccine Preparation

Prepare the injection with the correct needle length based on the recipient's age. Gender and weight should be considered for adults 19 years of age and older.

- Use aseptic technique to mix the vaccine and prepare the injection.
- Prepare the vaccine using a **NEW** vial of diluent and a **NEW** vial of vaccine **EVERY TIME**.
- Prepare the injection using a new, sterile needle and syringe **EVERY TIME**.

Mixing Vaccine

Do

Use the needles and syringes labeled for mixing vaccine and diluent in the ancillary supply kit.

Use 0.9% sodium chloride (normal saline, preservative-free) ONLY.

Slowly inject the proper volume of diluent into the vial of thawed vaccine*:

- 6 months through 4 years (maroon cap vial), use 2.2 mL of diluent.
- 5 through 11 years (orange cap vial), use 1.3 mL of diluent.

Gently invert the vial 10 times before and after adding the diluent.

Discard the diluent vial after mixing the vaccine.

Don't

Do **NOT** use needles and syringes designated for administration to mix vaccine and diluent.

Do **NOT** use bacteriostatic normal saline or other diluents.

Do **NOT** use all the diluent in the vial.

Do **NOT** shake the vial.

Do **NOT** use or save any remaining diluent to mix with additional vials of vaccine or for other uses.

*Using a 21-gauge or narrower needle

Withdrawing doses of vaccine from the vial

After mixing, use low dead-volume syringes and/or needles to withdraw doses of vaccine. If sufficient quantities of low-dead volume syringes are not available to withdraw all doses, use a combination of low dead-volume syringes and non low-dead volume syringes.

Do

When mixing and withdrawing vaccine, insert the needle into different places on the vial septum.

Leave needle in vial to remove air bubbles, when applicable.

If the amount of vaccine left in the vial is not a full dose, discard the vial and remaining vaccine.

Don't

Do **NOT** use the same insertion point every time. This may cause vaccine to leak from the vial.

Do **NOT** remove air bubbles with the needle outside of the vial as vaccine can be easily lost in the process.

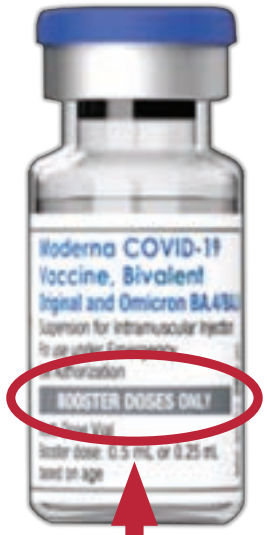
Do **NOT** combine remaining vaccine from multiple vials to obtain a full dose.

Bivalent Moderna COVID-19 Vaccine

When to Use the Pink Versus Blue-Capped Vial

For most people (those who are NOT moderately or severely immunocompromised)

There are 2 different vials of Moderna bivalent COVID-19 vaccine. Determining which presentation and dosage to use is based on the recipient's age and vaccination history and the presence of moderate or severe immune compromise. Label bins in storage units to help staff correctly identify the vials.



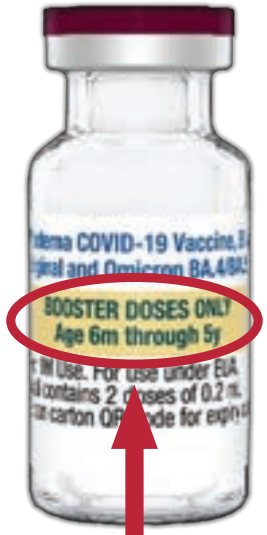
"Booster Doses Only" does not apply

Administer vaccine from this vial based on age, vaccination history and the presence of moderate or severe immune compromise.

Age:	Vaccination history:
6 months through 5 years	■ NEVER been vaccinated with ANY COVID-19 vaccine ■ Previously vaccinated with 1 dose of monovalent COVID-19 vaccine ■ Previously vaccinated with 1 dose of bivalent COVID-19 vaccine
6 years and older	■ Never been vaccinated with ANY COVID-19 vaccine ■ Previously vaccinated with 1 or more doses of only monovalent COVID-19 vaccine ■ Previously vaccinated with 1 or more doses of bivalent COVID-19 vaccine

Age:	Route:	Dose:
6 months through 11 years	Intramuscular (IM) injection	0.25 mL/25 *µg*
12 years and older		0.5 mL/50 *µg*

Note: For inventory purposes each vial contains 5 doses regardless which dosage is withdrawn.



"Booster Doses Only" does not apply

Administer vaccine from this vial based on age, vaccination history and the presence of moderate or severe immune compromise.

Age:	Vaccination history:
6 months through 5 years	■ Previously vaccinated with 2 doses of monovalent COVID-19 vaccine

Route:	Dose:
Intramuscular (IM) injection	0.2 mL/10 *µg*

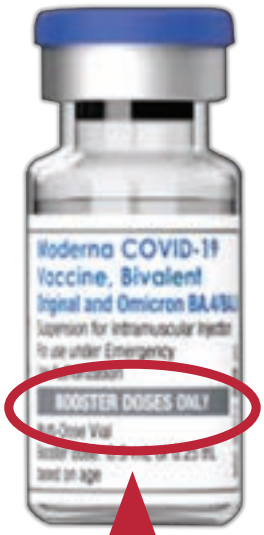
Note: This vial contains 2 doses. It is **NOT** a single dose vial.

Bivalent Moderna COVID-19 Vaccine

When to Use the Pink Versus Blue-Capped Vial

For people who ARE moderately or severely immunocompromised

There are 2 different vials of Moderna bivalent COVID-19 vaccine. Determining which presentation and dosage to use is based on the recipient's age and vaccination history and the presence of moderate or severe immune compromise. Label bins in storage units to help staff correctly identify the vials.



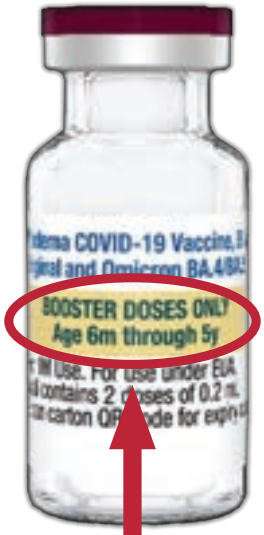
"Booster Doses Only" does not apply

Administer vaccine from this vial based on age, vaccination history and the presence of moderate or severe immune compromise.

Age:	Vaccination history:
6 months through 4 years	■ NEVER been vaccinated with ANY COVID-19 vaccine ■ Previously vaccinated with 1 or 2 doses of monovalent COVID-19 vaccine* ■ Previously vaccinated with 1 or 2 doses of bivalent COVID-19 vaccine*
5 years	■ NEVER been vaccinated with ANY COVID-19 vaccine ■ Previously vaccinated with 1 or more doses of monovalent COVID-19 vaccine* ■ Previously vaccinated with 1 or more doses of bivalent COVID-19 vaccine*
6 years and older	■ Never been vaccinated with ANY COVID-19 vaccine ■ Previously vaccinated with 1 or more doses of only monovalent COVID-19 vaccine* ■ Previously vaccinated with 1 or more doses of bivalent COVID-19 vaccine*

Age:	Route:	Dose:
6 months through 11 years	Intramuscular (IM) injection	0.25 mL/25 *µg*
12 years and older		0.5 mL/50 *µg*

Note: For inventory purposes each vial contains 5 doses regardless which dosage is withdrawn.



"Booster Doses Only" does not apply

Administer vaccine from this vial based on age, vaccination history and the presence of moderate or severe immune compromise.

Age:	Vaccination history:
6 months through 4 years	■ Previously vaccinated with 3 doses of monovalent COVID-19 vaccine*

Route:	Dose:
Intramuscular (IM) injection	0.2 mL/10 *µg*

Note: This vial contains 2 doses. It is **NOT** a single dose vial.

* Additional bivalent mRNA vaccines are authorized for people who are moderately or severely immunocompromised. See Table 2 of Interim Clinical Consideration for Use of COVID-19 Vaccines for additional guidance.

Vaccines & Immunizations

FAQs for the Interim Clinical Considerations for COVID-19 Vaccination

This page has answers to commonly asked questions about the Interim Clinical Considerations for COVID-19 Vaccination.

For information about COVID-19 vaccine storage, preparation, and administration, see U.S. COVID-19 Vaccine Product Information.

Vaccine Use and Schedule

Is there a preferred COVID-19 vaccine?

Yes, **bivalent** mRNA COVID-19 vaccines (Moderna or Pfizer-BioNTech) are recommended. The **monovalent** mRNA vaccines are no longer used in the United States.

Novavax COVID-19 Vaccine may also be used. Janssen COVID-19 Vaccine is no longer available or recommended in the United States.

For more information, see COVID-19 vaccines.

Are monovalent mRNA COVID-19 vaccines still recommended in the United States?

No, monovalent mRNA COVID-19 vaccines are no longer recommended in the United States; only bivalent mRNA vaccines (Moderna or Pfizer-BioNTech) are recommended.

Who is recommended to receive bivalent mRNA COVID-19 vaccine?

Everyone ages 6 months and older is recommended to receive bivalent mRNA COVID-19 vaccine. Most people need only 1 bivalent mRNA vaccine dose; the number of doses a person needs depends on their age, COVID-19 vaccination history, and immune status.

For information on the current COVID-19 vaccination schedule, see the vaccination schedule for people who are not immunocompromised and people who are moderately or severely immunocompromised.

Is an additional bivalent mRNA vaccine dose recommended for people ages 65 years and older?

People ages 65 years and older who previously received 1 dose of a bivalent mRNA vaccine have the option to receive 1 additional dose at least 4 months after the first bivalent dose.

For additional information, see the vaccination schedule for people who are not immunocompromised.

Can people ages 65 years and older receive more than 1 dose of bivalent COVID-19 vaccine?

People ages 65 years and older are recommended to receive 1 dose of a bivalent mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech). They have the option to receive 1 additional vaccine dose, for a total of 2 bivalent vaccine doses, regardless of the number of previous monovalent vaccine doses received. The additional bivalent vaccine dose should be administered at least 4 months after the first bivalent vaccine dose.

For additional information, see the vaccination schedule for people who are not immunocompromised. For people ages 65 years and older who are moderately or severely immunocompromised, see the vaccination schedule for people who are moderately or severely immunocompromised.

What is the recommendation for administering a bivalent mRNA vaccine dose to people who previously received Novavax COVID-19 Vaccine?

People ages 12 years and older who previously received 1 or more doses of Novavax COVID-19 Vaccine are recommended to receive 1 dose of a bivalent mRNA vaccine. Either Moderna or Pfizer-BioNTech COVID-19 vaccine may be used.

For additional information see Novavax COVID-19 Vaccine.

What is the current guidance for use of the monovalent Novavax COVID-19 Vaccine?

Monovalent Novavax COVID-19 Vaccine is authorized for:

- Primary series vaccination: In people ages 12 years and older.
- Booster vaccination in limited situations as follows: In people ages 18 years and older who previously completed a monovalent primary series with any COVID-19 vaccine; have not received any previous booster dose(s); and are unable (i.e., vaccine is contraindicated or not available) or unwilling to receive an mRNA vaccine.

For additional information on the use of the vaccine and schedule, see Novavax COVID-19 Vaccine.

Does the 4-day grace period apply to COVID-19 vaccine?

Yes. Doses administered up to 4 days before the minimum interval, known as the 4-day grace period, are considered valid. Do not use the grace period to schedule doses.

If a dose is administered earlier than the grace period, see Appendix C for guidance on corrective actions. It is considered a vaccine administration error; you are required to report COVID-19 vaccine administration errors to the Vaccine Adverse Event Reporting System (VAERS) .

Doses administered at any time after the recommended interval are valid.

For information on dosing intervals for COVID-19 vaccines, see the vaccination schedule for people who are not immunocompromised and people who are moderately or severely immunocompromised.

Can COVID-19 vaccines and other vaccines be administered at the same time?

In accordance with general best practices for immunizations, routine administration of all age-appropriate doses of vaccines simultaneously is recommended for children, adolescents, and adults for whom no specific contraindications exist at the time of the healthcare visit. This includes simultaneous administration of COVID-19 vaccine and other vaccines. However, there are additional considerations applicable to all COVID-19 vaccines if administering an orthopoxvirus (mpox) vaccine.

For more information, see Coadministration of COVID-19 vaccines with other vaccines.

Can COVID-19 vaccines be administered at the same time as an orthopoxvirus (mpox) vaccine?

- There is no required minimum interval between receiving a dose of any COVID-19 vaccine and an orthopoxvirus vaccine, either JYNNEOS or ACAM2000 vaccine (e.g., for mpox prevention), regardless of which vaccine is administered first.
- Use of JYNNEOS vaccine should be prioritized over ACAM2000 when co-administering a COVID-19 vaccine and an orthopoxvirus vaccine.
- People, particularly adolescent or young adult males, who are recommended to receive both vaccines might consider waiting 4 weeks between vaccines. This is because of the observed risk for myocarditis and pericarditis after receipt of ACAM2000 orthopoxvirus vaccine and COVID-19 vaccines, and the hypothetical risk for myocarditis and pericarditis after JYNNEOS vaccine. However, if a patient's risk for mpox or severe disease due to COVID-19 is increased, administration of mpox and COVID-19 vaccines should not be delayed.

For more information, see:

- Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. Mpox Outbreak
- Coadministration of COVID-19 vaccines with other vaccines

Vaccine Dosage and Formulation

What should be done if a monovalent mRNA vaccine is administered instead of a bivalent mRNA vaccine?

If a monovalent mRNA vaccine is administered instead of a bivalent mRNA vaccine, the dose should be repeated with a bivalent mRNA vaccine. If it is the first bivalent dose, administer the repeat dose at least 28 days after the dose given in error. If it is a second or subsequent bivalent dose, administer the repeat dose by at least the minimum interval (see Table 1 and Table 2).

Are mRNA COVID-19 vaccines from different manufacturers (Moderna and Pfizer-BioNTech) interchangeable?

Use of mRNA COVID-19 vaccines interchangeably from different manufacturers (Moderna and Pfizer-BioNTech) varies by recipient age, vaccination history, and vaccine product:

- **Ages 6 months–4 years**: Children who are unvaccinated or previously received 1 or more doses of a monovalent mRNA vaccine are authorized to receive only bivalent mRNA vaccine dose(s) from the **same** vaccine manufacturer.
- **Age 5 years:** Children who are unvaccinated or previously received 1 or more doses of:
  - Monovalent Moderna COVID-19 Vaccine are authorized to receive either bivalent Moderna or bivalent Pfizer-BioNTech COVID-19 vaccine.

    - Monovalent Pfizer-BioNTech COVID-19 are authorized to receive only bivalent Pfizer-BioNTech COVID-19 Vaccine.
- **Ages 6 years and older**: People who are unvaccinated or previously received 1 or more doses of any monovalent COVID-19 vaccine are authorized to receive either bivalent Moderna or bivalent Pfizer-BioNTech COVID-19 vaccine.

For additional information, see Interchangeability of COVID-19 vaccines. The COVID-19 vaccination schedules for People who are not moderately or severely immunocompromised and People who are moderately or severely immunocompromised should be consulted for age-specific information; see also Appendix C for recommended actions following interchangeability-related errors or deviations in administration of COVID-19 vaccines.

How many doses of bivalent mRNA vaccine are recommended for children ages 6 months–5 years initiating COVID-19 vaccination?

The number of doses of bivalent mRNA COVID-19 vaccine recommended for children initiating COVID-19 vaccination differs depending on age group and vaccine:

- **Ages 6 month-4 years**
    - Moderna: 2 doses
    - Pfizer-BioNTech: 3 doses
- **Age 5 years**
    - Moderna: 2 doses
    - Pfizer-BioNTech: 1 dose

For information on the schedule, including the dosage and interval between doses, see the COVID-19 vaccination schedule for people who are not moderately or severely immunocompromised.

For children ages 6 months–5 years initiating COVID-19 vaccination and who require more than 1 bivalent mRNA vaccine dose, should all doses be from the same manufacturer?

Children ages 6 months–5 years who are unvaccinated and are recommended to receive more than 1 bivalent mRNA vaccine dose for initial vaccination should receive all doses from the same manufacturer.

In the following exceptional situations, a different age-appropriate COVID-19 vaccine may be administered when FDA authorization requires that a vaccine from the same manufacturer be used. A VAERS report is not required for these exceptional situations:

- Same vaccine not available
- Previous dose unknown
- Person would otherwise not complete the vaccination series
- Person starts but unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication

For information on the schedule, including the dosage and interval between doses, see the COVID-19 vaccination schedule for people who are not moderately or severely immunocompromised.

What is the recommendation for children ages 6 month–4 years who are initiating vaccination and received 2 doses of bivalent mRNA vaccine from different manufacturers (i.e., 1 Moderna and 1 Pfizer-BioNTech dose)?

Children ages 6 months–4 years who receive different bivalent mRNA vaccines for the first 2 doses of an mRNA COVID-19 vaccine series should follow a 3-dose schedule. A third dose of either mRNA vaccine (Moderna of Pfizer-BioNTech) should be administered at least 8 weeks after the second dose:

- If Moderna is used, administer 0.25 mL/25 ug (dark blue cap and label with gray border)
- If Pfizer-BioNTech is used, administer 0.2 mL/3 ug (maroon cap and label with maroon border)

For additional information, see Interchangeability of COVID-19 vaccines.

What is the recommendation for children ages 6 month–4 years who previously received 2 doses of monovalent mRNA vaccine from different manufacturers (i.e., 1 Moderna and 1 Pfizer-BioNTech dose)?

Children ages 6 months–4 years who previously received 2 doses of monovalent mRNA vaccine from different manufacturers (i.e., 1 Moderna and 1 Pfizer-BioNTech monovalent dose) should receive 1 dose of a bivalent mRNA vaccine from either manufacturer (Moderna or Pfizer-BioNTech). The bivalent vaccine dose should be administered at least 8 weeks after the last (i.e., second) monovalent dose:

- If Moderna is used, administer 0.25 mL/25 ug (dark blue cap and label with gray border)
- If Pfizer-BioNTech is used, administer 0.2 mL/3 ug (maroon cap and label with maroon border)

For additional information, see Interchangeability of COVID-19 vaccines.

There are two presentations of Moderna COVID-19 Vaccine (pink cap and label with yellow line; dark blue cap and label with gray border): when should each be used?

The two presentations of Moderna COVID-19 Vaccine and recommended dosages are as follows:

- Pink cap and label with yellow line (0.2 mL/10 µg)
- Dark blue cap and label with gray border (25 mL/25 µg; 0.5 mL/50 µg)

The presentation and dosage are determined by the recipient's age, vaccination history, and the presence of moderate or severe immune compromise; for patient-specific guidance see:

- Moderna Bivalent Vaccine Vial Infographic
- Vaccination schedule for people who are not immunocompromised
- Vaccination schedule for people who are moderately or severely immunocompromised

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What should be done if the incorrect vaccine formulation is administered based on a patient's age?

If the incorrect formulation is administered:

- Resulting in a higher-than-authorized dose: Do not repeat dose.
- Resulting in a lower-than-authorized dose: Repeat the dose immediately (no minimum interval) with the age-appropriate dose and formulation. Some experts suggest delaying the repeat dose for 8 weeks after the invalid dose based on the potential for increased reactogenicity and the rare risk of myocarditis and pericarditis associated with Moderna, Novavax, and Pfizer-BioNTech vaccines, especially in males ages 12–39 years. See Considerations for extended intervals for COVID-19 vaccine primary series.

For more information, see:

- Timing, spacing, age transitions, and coadministration of COVID-19 vaccines

- COVID-19 vaccination schedule for people who are not immunocompromised and people who are moderately or severely immunocompromised

Age Transitions

What vaccine product and dosage should be used for a person who is moving from a younger age group with a lower dose formulation to an older age group with a higher dose formulation?

In general, CDC recommends that people receive the age-appropriate vaccine dosage based on their age on the day of vaccination. If a person moves from a younger age group to an older age group between vaccine doses, they should receive the vaccine product and dosage for the older age group for all subsequent doses with two exceptions described in the following two FAQs in this section.

What is the guidance for children who transition from age 4 years to 5 years during the 3-dose Pfizer-BioNTech COVID-19 vaccination series?

Children who transition from age 4 years to 5 years during the 3-dose bivalent Pfizer-BioNTech COVID-19 vaccination series must complete the series they start (i.e., receive the 0.2 mL/3 ug dosage supplied in vials with a maroon cap and label with a maroon border for all 3 doses).

Children who previously received 1 or 2 doses of monovalent Pfizer-BioNTech vaccine at age 4 years and transition to age 5 years should receive the remaining dose(s) needed to complete the 3-dose series with bivalent Pfizer-BioNTech vaccine for ages 6 months–4 years (0.2 mL/3 ug; maroon cap and label). Dose 1 and 2 are separated by 3–8 weeks and dose 2 and 3 are separated by at least 8 weeks.

For additional information, see:

- Timing, spacing, age transitions, and coadministration of COVID-19 vaccines
- COVID-19 vaccination schedule for people who are not immunocompromised and people who are moderately or severely immunocompromised

What is the guidance for children who transition from age 5 years to 6 years during the 2-dose Moderna COVID-19 vaccination series?

Children who transition from age 5 years to 6 years during the 2-dose bivalent Moderna COVID-19 vaccination series should receive 2 doses of Moderna (0.25 mL/25 ug; dark blue cap and label with a gray border).

Children who previously received 1 dose of monovalent Moderna vaccine at age 5 years and transition to age 6 years should receive 1 dose of bivalent Moderna vaccine (0.25 mL/25 ug; dark blue cap and label with a gray border). The bivalent Moderna vaccine dose is administered 4–8 weeks after the monovalent Moderna vaccine dose.

For additional information, see:

- Timing, spacing, age transitions, and coadministration of COVID-19 vaccines
- COVID-19 vaccination schedule for people who are not immunocompromised and people who are moderately or severely immunocompromised

People who are Moderately or Severely Immunocompromised

Are there special considerations for vaccinating people who are moderately or severely immunocompromised?

Yes. For COVID-19 vaccination guidance for people who are moderately or severely immunocompromised, see Guidance for COVID-19 vaccination for people who are moderately or severely immunocompromised.

Can people who are moderately or severely immunocompromised receive additional doses of bivalent mRNA vaccine?

Yes, people who are moderately or severely immunocompromised have the option to receive 1 additional dose of an age-appropriate bivalent mRNA vaccine at least 2 months following the last recommended bivalent COVID-19 vaccine dose. Further additional dose(s) of bivalent mRNA vaccine may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose.

The vaccine (Moderna or Pfizer-BioNTech) and dosage for the additional doses depend on age and vaccination history (i.e., whether Moderna or Pfizer-BioNTech was received for the initial bivalent mRNA doses).

For additional information, see the COVID-19 vaccination schedule for people who are moderately or severely immunocompromised.

Which vaccine (Moderna or Pfizer-BioNTech) should be administered to people who are moderately or severely immunocompromised for their additional doses?

For people who are moderately or severely immunocompromised, the vaccine (Moderna or Pfizer-BioNTech) for the additional doses depends on the age and whether they received Pfizer or Moderna for their initial bivalent mRNA dose(s).

- Age 6 months-4 years
  - Previously received Moderna: Only Moderna
  - Previously received Pfizer-BioNTech: Only Pfizer-BioNTech
- Age 5 years
  - Previously received Moderna: Either Moderna or Pfizer-BioNTech
  - Previously received Pfizer-BioNTech: Only Pfizer-BioNTech
- Age 6 years and older
  - Either Moderna or Pfizer-BioNTech regardless of which vaccine was received for their initial bivalent doses

For children ages 6 months–4 years or age 5 years who are moderately or severely immunocompromised and receiving Moderna COVID-19 Vaccine for their additional doses, which Moderna formulation should be used?

For children ages 6 months–4 years or age 5 years who are moderately or severely immunocompromised and receiving Moderna COVID-19 Vaccine for their additional doses, Moderna 0.2mL/10 ug (dark pink cap and label with a yellow boarder) is recommended. However, Moderna 0.25 mL/25 ug (dark blue cap and label with a gray border) is also authorized and it is not an error to administer this dosage. For additional information, see COVID-19 vaccination schedule for people who are moderately or severely immunocompromised.

How do I verify if a person is moderately or severely immunocompromised?

People can self-attest to their moderately or severely immunocompromised status and should be vaccinated according to the schedule for people who are moderately or severely immunocompromised. Health care professionals, vaccinators and clinic administrators should not deny COVID-19 vaccination to a person because of a lack of documentation.

Should people who undergo hematopoietic cell transplant (HCT) or chimeric antigen receptor (CAR)-T cell therapy be revaccinated?

Recipients of HCT or CAR-T cell therapy who received 1 or more doses of COVID-19 vaccine prior to or during treatment should be revaccinated. Revaccination should start at least 3 months after treatment and follow the currently recommended schedule for people who are unvaccinated.

For additional information, see:

- Considerations for COVID-19 revaccination
- COVID-19 vaccination schedule for people who are moderately or severely immunocompromised.

My patient is moderately or severely immunocompromised and previously received EVUSHELD™(tixagevimab/cilgavimab). Should they be vaccinated against COVID-19?

Yes. Everyone ages 6 months and older is recommend to be vaccinated against COVID-19, including people who are moderately or severely immunocompromised and who previously received EVUSHELD™ for pre-exposure prophylaxis.

COVID-19 vaccines can be administered any time after receipt of EVUSHELD™.

For additional information, see the COVID-19 vaccination schedule for people who are moderately or severely immunocompromised.

Vaccination and SARS-CoV-2 Laboratory Testing

What do antibody tests tell us about immunity, and should these tests influence the decision to vaccinate or revaccinate?

Antibody testing is **not** currently recommended to assess the need for vaccination in an unvaccinated person or to assess immunity to SARS-CoV-2 following COVID-19 vaccination or after SARS-CoV-2 infection. Antibody tests for SARS-CoV-2 look for the presence of antibodies made in response to a previous infection or vaccination. Antibodies are an indicator of the body's efforts to fight off the SARS-CoV-2 virus. None of the currently authorized SARS-CoV-2 antibody tests have been validated to assess specific immunity or protection from SARS-CoV-2 infection or vaccination.

For additional information, see:

- Interim Guidelines for COVID-19 Antibody Testing
- COVID-19 Testing: What you Need to Know
- Antibody (Serology) Testing for COVID-19: Information for Patients and Consumers

Vaccination and SARS-CoV-2 Infection

Can people with prior or current SARS-CoV-2 infection receive a COVID-19 vaccine?

CDC recommends COVID-19 vaccination for all people ages 6 months and older, including people with a history of SARS-CoV-2 infection.

Prior infection: Offer vaccination regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection, including to people with prolonged post-COVID-19 symptoms and people who experienced SARS-CoV-2 infection (symptomatic or asymptomatic) after vaccination. People who recently had SARS-CoV-2 infection may consider delaying their COVID-19 vaccine dose by 3 months from symptom onset or positive test (if infection was asymptomatic).

Current infection: Defer vaccination of people with known current SARS-CoV-2 infection until the person has recovered from acute illness (if the person has symptoms) and until criteria have been met for them to discontinue isolation.

Laboratory testing is not recommended for the purpose of vaccine decision-making.

For more information, see COVID-19 vaccination and SARS-CoV-2 infection.

Special Populations and Situations

Can pregnant or breastfeeding people be vaccinated?

Yes. CDC recommends COVID-19 vaccination for all people who are pregnant, breastfeeding, recently pregnant, trying to get pregnant now, or who might become pregnant in the future. mRNA vaccines are recommended for all vaccine-eligible populations including people who are pregnant or lactating.

For more information, see COVID-19 Vaccines While Pregnant or Breastfeeding.

What is the guidance for vaccinating preterm infants?

In accordance with general best practices, preterm infants (infants born before 37 weeks' gestation), regardless of birth weight, should receive COVID-19 vaccination at their chronological age and according to the same schedule and guidance as for full-term infants and children.

What is the guidance for vaccinating infants of mothers who received COVID-19 vaccine and/or had COVID-19 or SARS-CoV-2 infection before or during pregnancy?

Infants of mothers who were vaccinated and/or had COVID-19 or SARS-CoV-2 infection before or during pregnancy should be vaccinated according to the recommended schedule.

If my patient received a SARS-CoV-2 antibody product (anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma) can they be vaccinated?

People who previously received SARS-CoV-2 antibody products (anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment, post-exposure prophylaxis, or pre-exposure prophylaxis can be vaccinated at any time; COVID-19 vaccination does not need to be delayed following receipt of monoclonal antibodies or convalescent plasma.

Which COVID-19 vaccines are recommended for people with a history of Bell's palsy?

Rare cases of Bell's palsy (acute peripheral facial nerve palsy) were reported following vaccination of participants in mRNA COVID-19 vaccine clinical trials, but FDA was not able to determine whether these cases were causally related to vaccination. People with a history of Bell's palsy may receive any currently FDA-authorized COVID-19 vaccine, though mRNA vaccines (Moderna or Pfizer-BioNTech) are recommended.

For additional information, see the COVID-19 vaccination schedule for people who are not immunocompromised and people who are moderately or severely immunocompromised.

Which COVID-19 vaccines are recommended for people with a history of Guillain-Barré syndrome (GBS)?

For people with a history of GBS, there is no contraindication to administering an mRNA (Moderna or Pfizer-BioNTech) or Novavax COVID-19 vaccine. No increased risk of GBS has been identified with receipt of mRNA COVID-19 vaccines.

For additional information, see the COVID-19 vaccination schedule for people who are not immunocompromised and people who are moderately or severely immunocompromised.

Last Reviewed: June 14, 2023

Healthcare Personnel Influenza Vaccination

Print as PDF

PERCENTAGE OF EMPLOYEES VACCINATED ⓘ

83.14% in 2021/2022.

VACCINE PERCENTAGES BY EMPLOYEE TYPE ⓘ

Employee: 83.14%
Licensed Independent Practitioners: 65.28%
Adult Student/Trainee & Volunteer: 83.01%

in 2021/2022.

EMPLOYEE REASONS FOR NOT VACCINATING ⓘ

Declined: 5.91%
Medical Contraindication: 0.83%
Unknown: 10.12%

in 2021/2022.

Healthcare Personnel Influenza Vaccination

The Advisory Committee on Immunization Practices (ACIP) recommends that all persons six months of age and older, including healthcare personnel (HCP) and persons in training for healthcare professions, should be vaccinated annually against influenza.

Vaccination of working-age adults, including HCP, has been associated with reduced risk of influenza illness, and reduced work absenteeism, antibiotic use, and medical visits. In addition, influenza vaccination of HCP has reduced deaths among nursing home residents, and elderly hospitalized patients.

DATA SOURCE

2021-2022

RESOURCES

ACIP Influenza Vaccine Recommendations | CDC

https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html

NHSN HPS Flu Vaccine Protocol 2022

https://www.cdc.gov/nhsn/pdfs/hps-manual/vaccination/hps-flu-vaccine-protocol-508.pdf

Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022–23 Influenza Season | MMWR (cdc.gov)

https://www.cdc.gov/mmwr/volumes/71/rr/rr7101a1.htm

Weekly Influenza Vaccination Data Reporting FAQs | NHSN | CDC

https://www.cdc.gov/nhsn/faqs/vaccination/weekly-fluvax.html

HCP Flu Vaccination | HPS | NHSN | CDC

https://www.cdc.gov/nhsn/hps/vaccination/index.html

Healthcare Personnel Safety Component (HPS) | NHSN | CDC

https://www.cdc.gov/nhsn/hps/index.html

HCP Influenza Vaccination Summary Reporting in NHSN | NHSN | CDC

https://www.cdc.gov/nhsn/faqs/vaccination/faq-influenza-vaccination-summary-reporting.html

GEOGRAPHIC LOCATIONS

HCP INFLUENZA VACCINATION BY STATE

VIEW BY

Overall

This graph shows the percentage of HCP in Acute Care facilities that received the Influenza vaccination by State for the 2021/2022 Influenza season.

HCP REASONS FOR NOT COMPLETING INFLUENZA VACCINATION, BY STATE

VIEW BY **DeclinedMedical ContraindicationUnknown**

This chart shows the percentage of HCP in Acute Care facilities that did not receive the Influenza vaccination, and the reason for not vaccinating, by state for the 2021/2022 influenza season.

PERCENTAGE DECLINED TO VACCINATE

ALABAMA	5.9%
ALASKA	6.3%

SHOW ALL

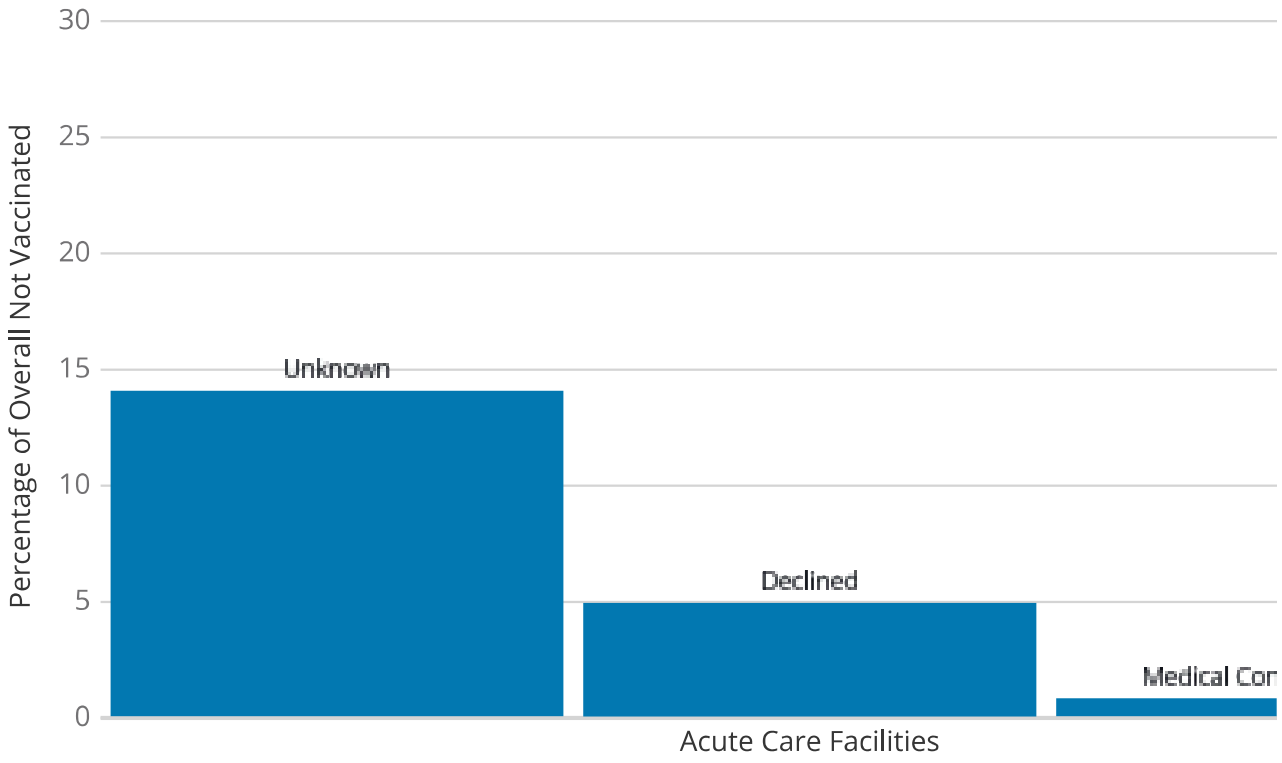
HEALTHCARE PERSONNEL TYPE

HCP INFLUENZA REASONS FOR NOT VACCINATING

VIEW BY

Overall

This graph displays the percentage of HCP in Acute Care facilities employees that have not received the Influenza vaccination for the 2021/2022 season by the reason for not receiving the vaccination.



FOOTNOTES

- Medical contraindication represents healthcare personnel (HCP) with (1) severe allergic reaction (for example, anaphylaxis) after a previous vaccine dose or to a vaccine component, including egg protein, and (2) history of Guillain-Barré Syndrome within 6 weeks after a previous influenza vaccination.
- Declination represents HCP who (1) declined vaccination because of conditions other than those included as medical contraindications, (2) declined vaccination and did not provide any other information, (3) did not receive vaccination because of religious or philosophical exemptions, or (4) deferred vaccination for the entire influenza season (for example, from October 1 through March 31).
- Unknown represents HCP with an unknown vaccination status OR HCP that 1) did not report receiving the influenza vaccination, 2) did not decline vaccination, and 3) does not have a medical contraindication to the influenza vaccination.
- States and territories with less than 5 facilities reporting are shown as having insufficient data.

Centers for Disease Control and Prevention

Morbidity and Mortality Weekly Report (*MMWR*)

Morbidity and Mortality Weekly Report (MMWR) Home

Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023–24 Influenza Season

Recommendations and Reports / August 25, 2023 / 72(2);1–25

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View suggested citation

Summary

This report updates the 2022–23 recommendations of the Advisory Committee on Immunization Practices (ACIP) concerning the use of seasonal influenza vaccines in the United States (MMWR Recomm Rep 2022;71[No. RR-1]:1–28*). Routine annual influenza vaccination is recommended for all persons aged ≥6 months who do not have contraindications. All seasonal influenza vaccines expected to be available in the United States for the 2023–24 season are quadrivalent, containing hemagglutinin (HA) derived from one influenza A(H1N1)pdm09 virus, one influenza A(H3N2) virus, one influenza B/Victoria lineage virus, and one influenza B/Yamagata lineage virus. Inactivated influenza vaccines (IIV4s), recombinant influenza vaccine (RIV4), and live attenuated influenza vaccine (LAIV4) are expected to be available.*

For most persons who need only 1 dose of influenza vaccine for the season, vaccination should ideally be offered during September or October. However, vaccination should continue after October and throughout the season as long as influenza viruses are circulating and unexpired vaccine is available. Influenza vaccines might be available as early as July or August, but for most adults (particularly adults aged ≥65 years) and for pregnant persons in the first or second trimester, vaccination during July and August should be avoided unless there is concern that vaccination later in the season might not be possible. Certain children aged 6 months through 8 years need 2 doses; these children should receive the first dose as soon as possible after vaccine is available, including during July and August. Vaccination during July and August can be considered for children of any age who need only 1 dose for the season and for pregnant persons who are in the third trimester during these months if vaccine is available.

ACIP recommends that all persons aged ≥6 months who do not have contraindications receive a licensed and age-appropriate seasonal influenza vaccine. With the exception of vaccination for adults aged ≥65 years, ACIP makes no preferential recommendation for a specific vaccine when more than one licensed, recommended, and age-appropriate vaccine is available. ACIP recommends that adults aged ≥65 years preferentially receive any one of the following higher dose or adjuvanted influenza vaccines: quadrivalent high-

dose inactivated influenza vaccine (HD-IIV4), quadrivalent recombinant influenza vaccine (RIV4), or quadrivalent adjuvanted inactivated influenza vaccine (aIIV4). If none of these three vaccines is available at an opportunity for vaccine administration, then any other age-appropriate influenza vaccine should be used.

Primary updates to this report include the following two topics: 1) the composition of 2023–24 U.S. seasonal influenza vaccines and 2) updated recommendations regarding influenza vaccination of persons with egg allergy. First, the composition of 2023–24 U.S. influenza vaccines includes an update to the influenza A(H1N1)pdm09 component. U.S.-licensed influenza vaccines will contain HA derived from 1) an influenza A/Victoria/4897/2022 (H1N1)pdm09-like virus (for egg-based vaccines) or an influenza A/Wisconsin/67/2022 (H1N1)pdm09-like virus (for cell culture-based and recombinant vaccines); 2) an influenza A/Darwin/9/2021 (H3N2)-like virus (for egg-based vaccines) or an influenza A/Darwin/6/2021 (H3N2)-like virus (for cell culture-based and recombinant vaccines); 3) an influenza B/Austria/1359417/2021 (Victoria lineage)-like virus; and 4) an influenza B/Phuket/3073/2013 (Yamagata lineage)-like virus. Second, ACIP recommends that all persons aged ≥6 months with egg allergy should receive influenza vaccine. Any influenza vaccine (egg based or nonegg based) that is otherwise appropriate for the recipient's age and health status can be used. It is no longer recommended that persons who have had an allergic reaction to egg involving symptoms other than urticaria should be vaccinated in an inpatient or outpatient medical setting supervised by a health care provider who is able to recognize and manage severe allergic reactions if an egg-based vaccine is used. Egg allergy alone necessitates no additional safety measures for influenza vaccination beyond those recommended for any recipient of any vaccine, regardless of severity of previous reaction to egg. All vaccines should be administered in settings in which personnel and equipment needed for rapid recognition and treatment of acute hypersensitivity reactions are available.

This report focuses on recommendations for the use of vaccines for the prevention and control of seasonal influenza during the 2023–24 influenza season in the United States. A brief summary of the recommendations and a link to the most recent Background Document containing additional information are available at: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html. These recommendations apply to U.S.-licensed influenza vaccines used according to Food and Drug Administration–licensed indications. Updates and other information are available from CDC's influenza website (https://www.cdc.gov/flu). Vaccination and health care providers should check this site periodically for additional information.

Introduction

Influenza viruses typically circulate annually in the United States, most commonly from the late fall through the early spring. Most persons who become ill after influenza virus infection recover without serious complications or sequelae. However, influenza can be associated with serious illnesses, hospitalizations, and deaths, particularly among older adults, very young children, pregnant persons, and persons of all ages with certain chronic medical conditions (*1–7*). Influenza also is an important cause of missed work and school (*8–10*).

Routine annual influenza vaccination for all persons aged ≥6 months who do not have contraindications has been recommended by CDC and the Advisory Committee on Immunization Practices (ACIP) since 2010 (*11*). Vaccination provides important protection from influenza illness and its potential complications. The effectiveness of influenza vaccination varies depending on multiple factors, such as the age and health of the recipient; the type of vaccine administered; the types, subtypes (for influenza A), and lineages (for influenza B) of circulating influenza viruses; and the degree of similarity between circulating viruses and those included in the vaccine (*12*). During each of the six influenza seasons from 2010–11 through 2015–16, influenza vaccination prevented an estimated 1.6–6.7 million illnesses, 790,000–3.1 million outpatient medical visits, 39,000–87,000 hospitalizations, and 3,000–10,000 respiratory and circulatory deaths each season in the United States (*13*). During the severe 2017–18 season, notable for an unusually long duration of widespread high influenza activity throughout the United States and higher rates of outpatient visits and hospitalizations compared with recent seasons, vaccination prevented an estimated 7.1 million illnesses, 3.7 million medical visits, 109,000 hospitalizations, and 8,000 deaths (*14*), despite an overall estimated vaccine effectiveness of 38% (62% against influenza A[H1N1]pdm09 viruses, 22% against influenza A[H3N2] viruses, and 50% against influenza B viruses) (*14*).

Influenza circulated at historically low levels in the United States and globally during the 2020–21 influenza season, coincident with widespread implementation of nonpharmaceutical interventions (e.g., masking, social distancing, and suspension of in-person work and school) intended to prevent transmission of SARS-CoV-2 (the virus that causes COVID-19) (*15*). The 2021–22 influenza season saw increased activity compared with 2020–21, with influenza activity remaining elevated later into the spring than any previous season for which data are available (*16*). The 2022–23 season was marked by early influenza activity peaking in late November to early December (*17*). The timing, intensity, and severity of the 2023–24 influenza season cannot be predicted. Influenza vaccination remains an important tool for the prevention of potentially severe respiratory illness.

This report updates the 2022–23 ACIP recommendations regarding the use of seasonal influenza vaccines (*18*) and provides recommendations and guidance for vaccination providers regarding the use of influenza vaccines in the United States for the 2023–24 season. Various formulations of influenza vaccines are available (Table 1). Contraindications and precautions for the use of influenza vaccines are summarized (Tables 2 and 3). Abbreviations are used in this report to denote the various types of vaccines (Box). A summary of these recommendations and a Background Document containing additional information on influenza, influenza-associated illness, and influenza vaccines are available at https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html.

Methods

ACIP provides annual recommendations for the use of influenza vaccines for the prevention and control of seasonal influenza in the United States. The ACIP Influenza Work Group meets by teleconference once to twice per month throughout the year. Work Group membership includes multiple voting members of ACIP, representatives of ACIP liaison organizations, and consultants. Discussions include topics such as influenza surveillance, vaccine effectiveness and safety, vaccination coverage, program feasibility, cost effectiveness, and vaccine supply. Presentations are requested from invited experts and published and unpublished data are discussed.

The Background Document that supplements this report contains literature related to recommendations made in previous seasons. The information included in the Background Document for such topics is not a systematic review; it is intended to provide an overview of background literature and is periodically updated with articles being identified primarily through a broad search for English-language articles on influenza and influenza vaccines. In general, longstanding recommendations in this document that were made in previous seasons reflect expert opinion, and systematic review and assessment of evidence was not performed. Systematic review and evidence assessment are not performed for minor wording changes to existing recommendations, changes in the Food and Drug Administration (FDA)–recommended viral antigen composition of seasonal influenza vaccines, and minor changes in guidance for the use of influenza vaccines (e.g., guidance for timing of vaccination and other programmatic issues, guidance for dosage in specific populations, guidance for selection of vaccines for specific populations that are already recommended for vaccination, and changes that reflect use that is consistent with FDA-licensed indications and prescribing information).

Typically, systematic review and evaluation of evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (*19*) are performed for new recommendations or substantial changes in the current recommendations (e.g., expansion of the recommendation for influenza vaccination to new populations not previously recommended for vaccination or potential preferential recommendations for specific vaccines).

Evidence is reviewed with the ACIP influenza Work Group, and Work Group considerations are included within the ACIP Evidence to Recommendations framework (EtR) (*20*) to inform the development of recommendations that are proposed for vote by the ACIP. Systematic review, GRADE, and the ACIP EtR framework were used in the development of the updated recommendations for influenza vaccination of persons with egg allergy discussed in this report.

Primary Changes and Updates

Primary changes and updates to the recommendations described in this report include 1) the composition of 2023–24 U.S. seasonal influenza vaccines; 2) updated recommendations regarding influenza vaccination of persons with egg allergy. Information relevant to these changes includes the following:

- The composition of the 2023–24 U.S. seasonal influenza vaccines includes an update to the influenza A(H1N1)pdm09 component. For the 2023–24 season, U.S.-licensed influenza vaccines will contain hemagglutinin (HA) derived from 1) an influenza A/Victoria/4897/2022 (H1N1)pdm09-like virus (for egg-based vaccines) or an influenza A/Wisconsin/67/2022 (H1N1)pdm09-like virus (for cell culture-based and recombinant vaccines); 2) an influenza A/Darwin/9/2021 (H3N2)-like virus (for egg-based vaccines) or an influenza A/Darwin/6/2021 (H3N2)-like virus (for cell culture-based and recombinant vaccines); 3) an influenza B/Austria/1359417/2021 (Victoria lineage)-like virus; and 4) an influenza B/Phuket/3073/2013 (Yamagata lineage)-like virus.
  Recommendations for the composition of Northern Hemisphere influenza vaccines are made by the World Health Organization (WHO), which organizes a consultation, usually in February of each year. Surveillance data are reviewed and candidate vaccine viruses are discussed. Information about the WHO meeting of February 2023 for selection of the 2023–24 Northern Hemisphere influenza vaccine composition is available at https://www.who.int/publications/m/item/recommended-composition-of-influenza-virus-vaccines-for-use-in-the-2023-2024-northern-hemisphere-influenza-season . Subsequently, FDA, which has regulatory authority over vaccines in the United States, convenes a meeting of its Vaccines and Related Biological Products Advisory Committee (VRBPAC). This committee considers the recommendations of WHO, reviews and discusses similar data, and makes a final decision regarding the composition of influenza vaccines licensed and marketed in the United States. Materials from the VRBPAC discussion on March 7, 2023, during which the composition of the 2023–24 U.S. influenza vaccines was discussed, are available at https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-march-7-2023-meeting-announcement .
- Regarding influenza vaccination of persons with egg allergy, ACIP recommends that all persons aged ≥6 months with egg allergy should receive influenza vaccine. Any influenza vaccine (egg based or nonegg based) that is otherwise appropriate for the recipient's age and health status can be used. It is no longer recommended that persons who have had an allergic reaction to egg involving symptoms other than urticaria should be vaccinated in an inpatient or outpatient medical setting supervised by a health care provider who is able to recognize and manage severe allergic reactions if an egg-based vaccine is used. Egg allergy alone necessitates no additional safety measures for influenza vaccination beyond those recommended for any recipient of any vaccine, regardless of severity of previous reaction to egg. All vaccines should be administered in settings in which personnel and equipment needed for rapid recognition and treatment of acute hypersensitivity reactions are available.
  To inform this recommendation, a systematic review and GRADE of evidence concerning safety of influenza vaccination for egg-allergic persons was conducted. A summary of this review and the GRADE evidence tables is available at https://www.cdc.gov/vaccines/acip/recs/grade/influenza-egg-allergy.html. A summary of the ACIP EtR framework is available at https://www.cdc.gov/vaccines/acip/recs/grade/influenza-egg-allergy-etr.html.

Recommendations for the Use of Influenza Vaccines, 2023–24

Groups Recommended for Vaccination

Routine annual influenza vaccination of all persons aged ≥6 months who do not have contraindications continues to be recommended. Influenza vaccines expected to be available for the 2023–24 season, their age indications, and their presentations are described (Table 1). Available influenza vaccines and age indications are expected to be similar to those of

the 2022–23 season. Recommendations regarding timing of vaccination, considerations for specific populations, the use of specific vaccines, and contraindications and precautions are summarized in the sections that follow.

Timing of Vaccination

Because timing of the onset, peak, and decline of influenza activity varies the ideal time to start vaccinating cannot be predicted each season. Decisions about timing necessitate balancing considerations regarding this unpredictability of the influenza season, possible waning of vaccine-induced immunity over the course of a season, and programmatic considerations. For most persons who need only 1 dose of influenza vaccine for the season, vaccination should ideally be offered during September or October. However, vaccination should continue after October and throughout the influenza season as long as influenza viruses are circulating and unexpired vaccine is available.

Influenza vaccines might be available as early as July or August; however, vaccination during these months is not recommended for most groups because of the possible waning of immunity over the course of the influenza season (*21*–*37*). However, vaccination of such persons during July and August can be considered in instances where there is concern that the recipient will not be vaccinated at a later date. Considerations for timing of vaccination include the following:

- **For most adults (particularly adults aged ≥65 years) and for pregnant persons in the first or second trimester:** Vaccination during July and August should be avoided unless there is concern that vaccination later in the season might not be possible.
- **Children who require 2 doses:** Certain children aged 6 months through 8 years require 2 doses of influenza vaccine for the season (see Children Aged 6 Months Through 8 Years: Number of Influenza Vaccine Doses) (Figure). These children should receive their first dose as soon as possible (including during July and August, if vaccine is available) to allow the second dose (which must be administered ≥4 weeks later) to be received, ideally, by the end of October.
- **Children who require only 1 dose:** Vaccination during July and August can be considered for children of any age who need only 1 dose of influenza vaccine for the season. Although waning of immunity after vaccination over the course of the season has been observed among all age groups (*21*–*37*), there are fewer published studies reporting results specifically among children (*21*,*30*,*32*,*33*,*37*). Moreover, children in this group might visit health care providers during the late summer months for medical examinations before the start of school. Vaccination can be considered at this time because it represents a vaccination opportunity.
- **Pregnant persons in the third trimester:** Vaccination during July and August can be considered for pregnant persons who are in the third trimester during these months because vaccination has been associated in multiple studies with reduced risk for influenza illness in their infants during the first months after birth, when they are too young to receive influenza vaccine (*38*–*41*). For pregnant persons in the first or second trimester during July and August, waiting to vaccinate until September or October is preferable, unless there is concern that later vaccination might not be possible.

Community vaccination programs should balance maximizing the likelihood of persistence of vaccine-induced protection through the season with avoiding missed opportunities to vaccinate or vaccinating after onset of influenza circulation occurs. Efforts should be structured to optimize vaccination coverage before influenza activity in the community begins. Vaccination should continue to be offered as long as influenza viruses are circulating and unexpired vaccine is available. To avoid missed opportunities for vaccination, providers should offer vaccination during routine health care visits and hospitalizations. No recommendation is made for revaccination (i.e., providing a booster dose) later in the season of persons who have been fully vaccinated for the season, regardless of when the current season vaccine was received.

Optimally, vaccination should occur before onset of influenza activity in the community. However, because timing of the onset, peak, and decline of influenza activity varies, the ideal time to start vaccinating cannot be predicted each season. Moreover, more than one outbreak might occur in a community in a single season. In the United States, localized outbreaks indicating the start of seasonal influenza activity can occur as early as October. However, in 30 (77%) of 39 influenza seasons from 1982–83 through 2021–22, peak influenza activity did not occur until January or later, and in 24 (62%) seasons, the peak was in February or later (*42*). Activity peaked in February in 17 (44%) of these seasons (*42*).

An increasing number of observational studies (*21*–*37*) have reported decreases in vaccine effectiveness with increasing time postvaccination within a single influenza season. Waning effects have not been observed consistently across age groups, influenza viruses (types, subtypes, and lineages), or seasons. Certain studies suggest waning occurs to a greater degree against influenza A(H3N2) viruses than against influenza A(H1N1) or influenza B viruses (*25*,*31*,*35*). This effect also might vary with recipient age; in certain studies, waning was more pronounced among older adults (*21*,*22*,*24*,*31*,*34*) and younger children (*21*). Relatively fewer reports include results specific to children (*21*,*30*,*32*,*33*,*37*); findings suggestive of waning have been

reported in certain studies (*21*,*32*,*33*,*37*) but not others (*30*). Rates of decline in vaccine effectiveness also varied. A multiseason (2011–12 through 2014–15) analysis from the U.S. Influenza Vaccine Effectiveness (U.S. Flu VE) Network found that vaccine effectiveness decreased by approximately 7% per month for influenza A(H3N2) and influenza B and 6%–11% per month for influenza A(H1N1)pdm09 (*23*). A prospective test-negative case control study of the 2015–16 through 2019–20 seasons observed an average decline in vaccine effectiveness against influenza-associated hospitalizations of 1.3% per month among children aged ≤8 years and 4.7% per month among those aged 9 through 17 years (*37*). In the Hospitalized Adult Influenza Vaccine Effectiveness Network (HAIVEN) during the 2015–16 through 2018–19 seasons, vaccine effectiveness against influenza-associated hospitalizations declined by approximately 8%–9% per month for all adults and approximately 10%–11% per month for those aged ≥65 years (*24*). An analysis of the 2010–11 through 2013–14 seasons noted estimated effectiveness ranging from 54% to 67% during days 0–180 postvaccination; estimated vaccine effectiveness was not significant during the period between days 181 and 365 (*32*). A multiseason analysis (2010–11 through 2014–15) conducted in Europe noted a decline in vaccine effectiveness to 0% at 111 days postvaccination against influenza A(H3N2) viruses. Vaccine effectiveness against influenza B viruses decreased more slowly, and vaccine effectiveness against influenza A(H1N1)pdm09 viruses remained roughly stable at 50%–55% throughout the influenza season (*25*). A meta-analysis of 14 studies examining waning of influenza vaccine effectiveness using the test-negative design found a significant decline in effectiveness within 180 days after vaccination against influenza A(H3N2) and influenza B but not against influenza A(H1N1) (*43*). In addition to the factors observed to be associated with waning immunity across studies, observed decreases in protection might be at least in part attributable to bias, unmeasured confounding, or the late-season emergence of antigenic drift variants of influenza viruses that are less well-matched to the vaccine viruses.

Varying data concerning the presence and rate of waning immunity after influenza vaccination, coupled with the unpredictable timing of the influenza season each year, prevent determination of an optimal time to vaccinate each season. Programmatic issues also are a consideration. Although delaying vaccination might result in greater immunity later in the season, deferral also might result in missed opportunities to vaccinate as well as difficulties in vaccinating a population within a more constrained period. The potential contributions of these factors among persons aged ≥65 years have been assessed using a simulated mathematical model examining various scenarios of vaccination timing, timing of onset of the influenza season, vaccine effectiveness, and rate of waning (*44*). In this model, during an influenza season beginning in October and peaking in January, delaying vaccination until October resulted in more hospitalizations if >14% of persons aged ≥65 years who would have been vaccinated in August or September did not get vaccinated. However, these predictions varied considerably with assumed timing of season onset, rate of waning immunity, and vaccine effectiveness.

Vaccination efforts should continue throughout the season because the duration of the influenza season varies, and influenza activity might not occur in certain communities until February, March, or later (*17*). Providers should offer influenza vaccine at healthcare visits to those not yet vaccinated, and organized vaccination campaigns should continue throughout the influenza season, including after influenza activity has begun in the community. Although vaccination by the end of October is recommended, vaccine administered in December or later, even if influenza activity has already begun, might be beneficial in most influenza seasons. Providers should offer influenza vaccination to unvaccinated persons who have already become ill with influenza during the season because the vaccine might protect them against other circulating influenza viruses.

Guidance for Influenza Vaccination in Specific Populations and Situations

Populations at Higher Risk for Medical Complications Attributable to Severe Influenza

All persons aged ≥6 months who do not have contraindications should be vaccinated annually. However, vaccination to prevent influenza is particularly important for persons who are at increased risk for severe illness and complications from influenza and for influenza-related outpatient, emergency department, or hospital visits. When vaccine supply is limited, vaccination efforts should focus on vaccination of persons at higher risk for medical complications attributable to severe influenza who do not have contraindications. These persons include the following (order of listing does not imply hierarchy or prioritization among these populations):

- All children aged 6 through 59 months.
- All persons aged ≥50 years.
- Adults and children who have chronic pulmonary (including asthma), cardiovascular (excluding isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus).
- Persons who are immunocompromised due to any cause (including but not limited to immunosuppression caused by medications or HIV infection).
- Persons who are or will be pregnant during the influenza season.

- Children and adolescents (aged 6 months through 18 years) who are receiving aspirin- or salicylate-containing medications and who might be at risk for experiencing Reye syndrome after influenza virus infection.
- Residents of nursing homes and other long-term care facilities.
- American Indian or Alaska Native persons.
- Persons who are extremely obese (body mass index ≥40 for adults).

An age-appropriate IIV4 or RIV4 is suitable for all persons recommended for vaccination, including those in the risk groups listed. LAIV4 is not recommended for certain populations, including certain of these listed groups. Contraindications and precautions for the use of LAIV4 are noted (Table 2).

Persons Who Live with or Care for Persons at Higher Risk for Influenza-Related Complications

All persons aged ≥6 months without contraindications should be vaccinated annually. However, emphasis also should be placed on vaccination of persons who live with or care for those who are at increased risk for medical complications attributable to severe influenza. When vaccine supply is limited, vaccination efforts should focus on administering vaccination to persons at higher risk for influenza-related complications as well as persons who live with or care for such persons, including the following:

- Health care personnel, including all paid and unpaid persons working in health care settings who have the potential for exposure to patients or to infectious materials. These personnel might include but are not limited to physicians, nurses, nursing assistants, nurse practitioners, physician assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff members, and others not directly involved in patient care but who might be exposed to infectious agents (e.g., clerical, dietary, housekeeping, laundry, security, maintenance, administrative, and billing staff members and volunteers). ACIP guidance for vaccination of health care personnel has been published previously (*45*).
- Household contacts (including children aged ≥6 months) and caregivers of children aged ≤59 months (<5 years) and adults aged ≥50 years, particularly contacts of children aged <6 months.
- Household contacts (including children aged ≥6 months) and caregivers of persons with medical conditions that put them at higher risk for severe complications from influenza.

Health care personnel and persons who are contacts of persons in these groups (with the exception of contacts of severely immunocompromised persons who require a protected environment) may receive any influenza vaccine that is otherwise indicated. Persons who care for severely immunocompromised persons requiring a protected environment should not receive LAIV4. ACIP and the Healthcare Infection Control Practices Advisory Committee (HICPAC) have previously recommended that health care personnel who receive LAIV should avoid providing care for severely immunocompromised persons requiring a protected environment for 7 days after vaccination and that hospital visitors who have received LAIV should avoid contact with such persons for 7 days after vaccination (*46*). However, such persons need not be restricted from caring for or visiting less severely immunocompromised persons.

Influenza Vaccination of Persons with COVID-19

Specific data concerning the optimal timing of influenza vaccination of persons with COVID-19 illness are not available. For those who have moderate or severe COVID-19, vaccination should usually be deferred until they have recovered from the acute illness, consistent with General Best Practice Guidelines for Immunization (*47*). For those with mild or asymptomatic COVID-19, further deferral might be considered to avoid confusing COVID-19 symptoms with potential postvaccination reactions. Other considerations for determination of when to vaccinate include current local influenza activity, the recipient's individual risk for severe influenza illness, current or recent use of immunosuppressive therapeutic agents that might blunt immune response to vaccines, and risk for exposing others in the vaccination setting to COVID-19. Information concerning precautions for persons with COVID-19 is available at https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html.

Children Aged 6 Through 35 Months: Influenza Vaccine Dose Volumes

Five IIV4s are approved for children aged ≥6 months (Table 1). Four of these vaccines are egg based (Afluria Quadrivalent, Fluarix Quadrivalent, FluLaval Quadrivalent, and Fluzone Quadrivalent), and one is cell culture–based (Flucelvax Quadrivalent). For these vaccines, the approved dose volumes for children aged 6 through 35 months are as follows (Table 4):

- Afluria Quadrivalent: 0.25 mL per dose. However, 0.25-mL prefilled syringes are no longer available. For children aged 6 through 35 months, a 0.25-mL dose must be obtained from a multidose vial (*48*).
- Fluarix Quadrivalent: 0.5 mL per dose (*49*).
- Flucelvax Quadrivalent: 0.5 mL per dose (*50*).
- FluLaval Quadrivalent: 0.5 mL per dose (*51*).
- Fluzone Quadrivalent: Either 0.25 mL or 0.5 mL per dose. Per the package insert, each dose may be given at either volume (*52*); however, 0.25-mL prefilled syringes are no longer available.

For all of these IIV4s, persons aged ≥36 months (≥3 years) should receive 0.5 mL per dose. Alternatively, healthy children aged ≥24 months (≥2 years) can receive LAIV4, 0.2 mL intranasally (0.1 mL in each nostril) (*53*). LAIV4 is not recommended for certain populations and is not approved for children aged <2 years or adults >49 years (see Contraindications and Precautions for the Use of LAIV4) (Table 2). RIV4 is not approved for children aged <18 years (*54*). High-dose inactivated influenza vaccine (HD-IIV4) (*55*) and adjuvanted inactivated influenza vaccine (aIIV4) (*56*) are not approved for persons aged <65 years.

Care should be taken to administer an age-appropriate vaccine at the appropriate volume for each dose. For IIV4s, the recommended volume may be administered from a prefilled syringe containing the appropriate volume (as supplied by the manufacturer), a single-dose vial, or a multidose vial. Single-dose vials should be used for only 1 dose, and multidose vials should be used only for the maximum number of doses specified in the package insert. Any vaccine remaining in a vial after the maximum number of doses has been removed should be discarded, regardless of the volume of the doses obtained or any remaining volume in the vial.

Children Aged 6 Months Through 8 Years: Number of Influenza Vaccine Doses

Children aged 6 months through 8 years require 2 doses of influenza vaccine administered a minimum of 4 weeks apart during their first season of vaccination for optimal protection (*57*–*60*). Determination of the number of doses needed is based on 1) the child's age at the time of the first dose of 2023–24 influenza vaccine and 2) the number of doses of influenza vaccine received in previous influenza seasons.

- For children aged 6 months through 8 years, the number of doses of influenza vaccine needed for the 2023–24 influenza season is determined as follows (Figure):
  - Those who have previously received ≥2 total doses of trivalent or quadrivalent influenza vaccine ≥4 weeks apart before July 1, 2023, require only 1 dose for the 2023–24 season. The previous 2 doses of influenza vaccine do not need to have been received in the same season or consecutive seasons.
  - Those who have not previously received ≥2 doses of trivalent or quadrivalent influenza vaccine ≥4 weeks apart before July 1, 2023, or whose previous influenza vaccination history is unknown, require 2 doses for the 2023–24 season. The interval between the 2 doses should be ≥4 weeks. Children aged 6 months through 8 years who require 2 doses of influenza vaccine should receive their first dose as soon as possible (including during July and August, if vaccine is available) to allow the second dose (which must be administered ≥4 weeks later) to be received, ideally, by the end of October. For children aged 8 years who require 2 doses of vaccine, both doses should be administered even if the child turns age 9 years between receipt of dose 1 and dose 2.
- Adults and children aged ≥9 years need only 1 dose of influenza vaccine for the 2023–24 season.

Pregnant Persons

Pregnant and postpartum persons have been observed to be at higher risk for severe illness and complications from influenza, particularly during the second and third trimesters. Influenza vaccination during pregnancy is associated with reduced risk for respiratory illness and influenza among pregnant and postpartum persons as well as infants during the first months of life (*38*–*41*,*61*). ACIP and the American College of Obstetricians and Gynecologists recommend that persons who are pregnant or who might be pregnant or postpartum during the influenza season receive influenza vaccine (*62*). Any licensed, recommended, and age-appropriate IIV4 or RIV4 may be used. LAIV4 should not be used during pregnancy but can be used postpartum. Influenza vaccine can be administered at any time during pregnancy (i.e., during any trimester), before and during the influenza season. Early vaccination (i.e., during July and August) can be considered for persons who are in the third trimester during these months if vaccine is available because this can provide protection for the infant during the first months of life when they are too young to be vaccinated (*38*–*41*,*61*).

Although experience with the use of IIVs during pregnancy is substantial, data specifically reflecting administration of influenza vaccines during the first trimester are limited. Most studies have not noted an association between influenza vaccination and adverse pregnancy outcomes, including spontaneous abortion (miscarriage) (*63*–*73*). One observational

Vaccine Safety Datalink (VSD) study conducted during the 2010–11 and 2011–12 seasons noted an association between receipt of IIV containing influenza A(H1N1)pdm09 and risk for miscarriage in the 28 days after receipt of IIV, when an H1N1pdm09-containing vaccine also had been received the previous season (*74*). However, in a larger VSD follow-up study, IIV was not associated with an increased risk for miscarriage during the 2012–13, 2013–14, and 2014–15 seasons, regardless of previous season vaccination (*75*).

There is less experience with the use of more recently licensed influenza vaccines (e.g., quadrivalent, cell culture-based, and recombinant vaccines) during pregnancy compared with previously available products. For ccIIV, a review of Vaccine Adverse Event Reporting System (VAERS) reports from 2013 through 2020 (*76*) and a prospective cohort study conducted from 2017 through 2020 (*77*) did not reveal unexpected safety events among pregnant persons. Data from a randomized clinical trial conducted at Clinical Immunization Safety Assessment (CISA) Project sites comparing the safety of RIV4 versus IIV4 in 382 pregnant persons supported the safety of RIV4 in pregnancy (*78*). Pregnancy registries and surveillance studies exist for certain products, for which information can be found in package inserts.

Older Adults

ACIP recommends that adults aged ≥65 years preferentially receive any one of the following higher dose or adjuvanted influenza vaccines: quadrivalent high-dose inactivated influenza vaccine (HD-IIV4), quadrivalent recombinant influenza vaccine (RIV4), or quadrivalent adjuvanted inactivated influenza vaccine (aIIV4). If none of these three vaccines is available at an opportunity for vaccine administration, then any other age-appropriate influenza vaccine should be administered (*79*,*80*).

Older adults (aged ≥65 years) are at increased risk for severe influenza-associated illness, hospitalization, and death compared with younger persons (*4*,*17*,*81*). Influenza vaccines are often less effective in this population (*82*). HD-IIV, RIV, and aIIV have been evaluated in comparison with nonadjuvanted SD-IIVs in this age group. Two of these vaccines, HD-IIV and RIV, are higher dose vaccines, which contain an increased dose of HA antigen per virus compared with nonadjuvanted SD-IIVs (60 μg for HD-IIV4 and 45 μg for RIV4, compared with 15 μg for standard-dose inactivated vaccines). The adjuvanted vaccine contains 15 μg of HA per virus, similarly to nonadjuvanted SD-IIVs, but contains the adjuvant MF59.

HD-IIV, RIV, and aIIV have shown relative benefit compared with SD-IIVs in certain studies, with the most evidence available for HD-IIV3. Randomized efficacy studies comparing these vaccines with nonadjuvanted SD-IIVs against laboratory-confirmed influenza outcomes are few in number (*83*–*85*) and cover few influenza seasons. Observational studies, predominantly retrospective cohort studies using diagnostic code–defined (rather than laboratory-confirmed) influenza outcomes, are more numerous and include more influenza seasons (*86*–*96*). Certain observational studies have reported relative benefit for HD-IIV, RIV, and aIIV in comparison with nonadjuvanted SD-IIVs, particularly in prevention of influenza-associated hospitalizations. The size of this relative benefit has varied from season to season and is not observed in all studies in all seasons, making it difficult to generalize the findings to all or most seasons. Studies directly comparing HD-IIV, RIV, and aIIV with one another are few and do not support a conclusion that any one of these vaccines is consistently superior to the others across seasons (*86*–*88*,*91*,*97*,*98*).

During the 2020–21 season, quadrivalent formulations of high-dose (HD-IIV4) and adjuvanted (aIIV4) influenza vaccines were introduced. Trivalent formulations of these vaccines are no longer available. Data summarizing comparisons of these newer quadrivalent formulations relative to nonadjuvanted SD-IIV4s are limited. In a pragmatic randomized open-label feasibility study of HD-IIV4 compared with SD-IIV4 conducted in Denmark among persons aged 65 through 79 years during the 2021–22 influenza season that collected data from health registries, HD-IIV4 was associated with lower risk for diagnostic code–defined pneumonia and influenza hospitalizations (relative vaccine effectiveness 64.4; 95% CI = 24.4–84.6) (*99*).

Immunocompromised Persons

ACIP recommends that persons with compromised immunity (including but not limited to persons with congenital and acquired immunodeficiency states, persons who are immunocompromised due to medications, and persons with anatomic and functional asplenia) should receive an age-appropriate IIV4 or RIV4. ACIP recommends that LAIV4 not be used for these groups because of the uncertain but biologically plausible risk for disease attributable to the live vaccine virus. Use of LAIV4 in persons with these and other conditions is discussed in more detail (see Dosage, Administration, Contraindications, and Precautions) (Table 2).

Immunocompromised states comprise a heterogeneous range of conditions with varying risks for severe infections. In many instances, limited data are available regarding the effectiveness of influenza vaccines in the setting of specific immunocompromised states (*100*). Timing of vaccination might be a consideration (e.g., vaccinating during a period either before or after an immunocompromising intervention). The Infectious Diseases Society of America has published detailed

guidance for the selection and timing of vaccines for persons with specific immunocompromising conditions (*101*). Immune response to influenza vaccines might be blunted in persons with certain conditions, such as congenital immune deficiencies, and in persons receiving cancer chemotherapy, posttransplant regimens, or immunosuppressive medications.

Persons with a History of Guillain-Barré Syndrome After Influenza Vaccination

A history of Guillain-Barré syndrome (GBS) within 6 weeks of a previous dose of any type of influenza vaccine is considered a precaution for influenza vaccination (Table 2). Persons who are not at higher risk for severe influenza complications (see Populations at Higher Risk for Medical Complications Attributable to Severe Influenza) and who are known to have experienced GBS within 6 weeks of a previous influenza vaccination typically should not be vaccinated. As an alternative to vaccination, providers might consider using influenza antiviral chemoprophylaxis for these persons (*102*). However, the benefits of influenza vaccination might outweigh the possible risks for certain persons who have a history of GBS within 6 weeks after receipt of influenza vaccine and who also are at higher risk for severe complications from influenza.

Persons with a History of Egg Allergy

ACIP recommends that all persons aged ≥6 months with egg allergy should receive influenza vaccine. Any influenza vaccine (egg based or nonegg based) that is otherwise appropriate for the recipient's age and health status can be used (https://www.cdc.gov/vaccines/acip/recs/grade/influenza-egg-allergy.html; https://www.cdc.gov/vaccines/acip/recs/grade/influenza-egg-allergy-etr.html). It is no longer recommended that persons who have had an allergic reaction to egg involving symptoms other than urticaria should be vaccinated in an inpatient or outpatient medical setting supervised by a health care provider who is able to recognize and manage severe allergic reactions if an egg-based vaccine is used. Egg allergy alone necessitates no additional safety measures for influenza vaccination beyond those recommended for any recipient of any vaccine, regardless of severity of previous reaction to egg. All vaccines should be administered in settings in which personnel and equipment needed for rapid recognition and treatment of acute hypersensitivity reactions are available.

Most available influenza vaccines, with the exceptions of RIV4 (Flublok Quadrivalent, licensed for persons aged ≥18 years) and ccIIV4 (Flucelvax Quadrivalent, licensed for persons aged ≥6 months), are prepared by propagation of virus in embryonated eggs and might contain trace amounts of egg proteins, such as ovalbumin. Among those U.S.-licensed influenza vaccines for which ovalbumin content is reported, quantities are generally small (≤1 μg/0.5mL dose) (Table 1).

The Joint Task Force on Practice Parameters of the American Academy of Allergy, Asthma & Immunology (AAAAI) and the American College of Allergy, Asthma, & Immunology (ACAAI) have recommended that administration of influenza vaccine to egg allergic persons requires no additional precautions other than those recommended for administration of any vaccine to any individual (*103*). Since the 2016–17 influenza season, the American Academy of Pediatrics (AAP) has recommended that no additional precautionary measures are needed when administering influenza vaccine to egg-allergic persons (*104*). A review of 20 studies (16 of IIVs, one of virosomal influenza vaccine, and three of LAIV) that examined reactions after administration of seasonal influenza vaccines to egg-allergic persons via either full single-dose or split-dose administration protocols (of which 13 reported inclusion of persons with a history of severe reaction or anaphylaxis to egg) included no reports of anaphylaxis (certainty level: very low) (*105*–*122*). Less severe reactions not described as anaphylaxis but involving cardiovascular symptoms, respiratory symptoms, angioedema, or generalized urticaria, or which involved treatment with medications or outpatient or emergency department attention occurred with low frequency (<1%). A similar profile was noted among 13 studies of monovalent H1N1pdm09 influenza vaccine, with no reported instances of anaphylaxis; frequency of reactions involving cardiovascular symptoms, respiratory symptoms, angioedema, or generalized urticaria events of <1%, and of events involving treatment with medications or outpatient or emergency department attention of approximately 1.5% (certainty level: very low) (*114*,*115*,*123*–*132*). One instance of anaphylaxis meeting a surveillance case definition (i.e., Brighton Level 1 criteria) in a person with possible egg allergy was noted in a summary of VAERS reports after administration of monovalent H1N1pdm09 influenza vaccine during the 2009–10 influenza season; no denominator of doses administered was available but it was noted that approximately 127 million doses of monovalent IIV were distributed in the United States that season (*133*). Of note, severe allergic reactions after administration of the egg-free vaccine RIV to egg-allergic persons have been noted in VAERS reports (*134*–*136*). These reports highlight both the possibility that observed reactions after egg-based influenza vaccines might be caused by substances other than egg proteins and the importance of being prepared to recognize and manage serious hypersensitivity reactions when administering any vaccine to any recipient (regardless of allergy history).

Severe and life-threatening reactions to vaccines can rarely occur with any vaccine and in any vaccine recipient, regardless of allergy history. Providers are reminded that all vaccines should be administered in settings in which personnel and equipment needed for rapid recognition and treatment of acute hypersensitivity reactions are available. All vaccination providers should be familiar with their office emergency plan and be certified in cardiopulmonary resuscitation (*47*). No postvaccination

observation period is recommended specifically for egg-allergic persons. However, ACIP recommends that vaccination providers consider observing patients (seated or supine) for 15 minutes after administration of any vaccine to decrease the risk for injury should syncope occur (*47*).

Although egg allergy is neither a contraindication nor precaution to the use of any influenza vaccine, there are contraindications and precautions related to allergies to vaccine components other than egg and to previous allergic reactions to influenza vaccines (see Persons with Previous Allergic Reactions to Influenza Vaccines and Dosage, Administration, Contraindications, and Precautions) (Tables 2 and 3).

Persons with Previous Allergic Reactions to Influenza Vaccines

As is the case for all vaccines, influenza vaccines contain various components that might cause allergic and anaphylactic reactions. Most influenza vaccine package inserts list among contraindications to their use a history of previous severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or to a previous dose of any influenza vaccine (*48*,*49*,*51*–*53*,*55*,*56*). For ccIIV4 and RIV4, a history of a severe allergic reaction to any vaccine component is listed as a contraindication; no labeled contraindication is specified for a history of allergic reaction to any other influenza vaccine (*50*,*54*). However, severe allergic reactions, although rare, can occur after influenza vaccination, even among persons with no previous reactions or known allergies. Vaccine components and excipients can be found in package inserts. However, identifying the causative agent without further evaluation (i.e., through evaluation and testing for specific allergies) can be difficult. Severe allergic reactions after vaccination with an RIV have been reported to VAERS, certain of which have occurred among persons reporting previous allergic reactions to egg or to influenza vaccines and that might represent a predisposition to development of allergic manifestations in affected persons (*134*–*136*). Because these rare but severe allergic reactions can occur, ACIP recommends the following for persons with a history of severe allergic reaction to a previous dose of an influenza vaccine (Table 3):

- For egg-based IIV4s and LAIV4:
  - A history of severe allergic reaction (e.g., anaphylaxis) to any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) is a contraindication to future receipt of all egg-based IIV4s and LAIV4. Each individual egg-based IIV4 and LAIV4 is also contraindicated for persons who have had a severe allergic reaction (e.g., anaphylaxis) to any component of that vaccine (excluding egg; see Persons with a History of Egg Allergy).
- For ccIIV4:
  - A history of a severe allergic reaction (e.g., anaphylaxis) to any egg-based IIV, RIV, or LAIV of any valency is a precaution for the use of ccIIV4. If ccIIV4 is administered in such instances, vaccination should occur in an inpatient or outpatient medical setting and should be supervised by a health care provider who is able to recognize and manage severe allergic reactions. Providers also can consider consultation with an allergist to help determine the vaccine component responsible for the allergic reaction.
  - A history of a severe allergic reaction (e.g., anaphylaxis) to any ccIIV of any valency or to any component of ccIIV4 is a contraindication to future receipt of ccIIV4.
- For RIV4:
  - A history of a severe allergic reaction (e.g., anaphylaxis) to any egg-based IIV, ccIIV, or LAIV of any valency is a precaution for the use of RIV4. If RIV4 is administered in such instances, vaccination should occur in an inpatient or outpatient medical setting and should be supervised by a health care provider who is able to recognize and manage severe allergic reactions. Providers can also consider consultation with an allergist to help determine the vaccine component responsible for the allergic reaction.
  - A history of a severe allergic reaction (e.g., anaphylaxis) to any RIV of any valency or to any component of RIV4 is a contraindication to future receipt of RIV4.

Vaccination Issues for Travelers

In temperate climate regions of the Northern and Southern Hemispheres, influenza activity is seasonal, occurring during approximately October–May in the Northern Hemisphere and April–September in the Southern Hemisphere. In the tropics, influenza might occur throughout the year (*137*). The timing of influenza activity and predominant types and subtypes of influenza viruses in circulation vary by geographic region (*138*). Travelers can be exposed to influenza when traveling to an area where influenza is circulating or when traveling as part of large tourist groups (e.g., on cruise ships) that include persons from areas of the world where influenza viruses are circulating (*139*–*142*).

Travelers who want to reduce their risk for influenza should consider influenza vaccination, preferably at least 2 weeks before departure. In particular, persons who live in the United States and are at higher risk for influenza complications and who were not vaccinated with influenza vaccine during the previous Northern Hemisphere fall or winter should consider receiving influenza vaccination before departure if they plan to travel to the tropics, to the Southern Hemisphere during the Southern Hemisphere influenza season (April–September), or with organized tourist groups or on cruise ships to any location. Persons at higher risk who received the previous season's influenza vaccine before travel should consult with their health care provider to discuss the risk for influenza and other travel-related diseases before embarking on travel during the summer. All persons (regardless of risk status) who are vaccinated in preparation for travel before the upcoming influenza season's vaccine is available, or who received the immediately preceding Southern Hemisphere influenza vaccine, should receive the current U.S. seasonal influenza vaccine the following fall or winter.

Influenza vaccine formulated for the Southern Hemisphere might differ in viral composition from the Northern Hemisphere vaccine. For persons traveling to the Southern Hemisphere during the Southern Hemisphere influenza season, receipt of a current U.S.-licensed Southern Hemisphere influenza vaccine formulation before departure might be reasonable but might not be feasible because of limited access to or unavailability of Southern Hemisphere formulations in the United States. Most Southern Hemisphere influenza vaccine formulations are not licensed in the United States, and they are typically not commercially available. More information on influenza vaccines and travel is available at https://wwwnc.cdc.gov/travel/diseases/influenza-seasonal-zoonotic-and-pandemic. Additional information on global influenza surveillance by region is available at https://www.who.int/tools/flunet .

Use of Influenza Antiviral Medications

Administration of any IIV4 or RIV4 to persons receiving influenza antiviral medications for treatment or chemoprophylaxis of influenza is acceptable. Data concerning vaccination with LAIV4 in the setting of influenza antiviral use are not available. However, influenza antiviral medications might interfere with the action of LAIV4 because this vaccine contains live influenza viruses.

The package insert for LAIV4 notes that influenza antiviral agents might reduce the effectiveness of the vaccine if administered within the interval from 48 hours before to 14 days after vaccination (*53*). However, the newer influenza antivirals peramivir and baloxavir have longer half-lives than oseltamivir and zanamivir, approximately 20 hours for peramivir (*143*) and 79 hours for baloxavir (*144*), and could interfere with the replication of LAIV4, if administered >48 hours before vaccination. Potential interactions between influenza antivirals and LAIV4 have not been studied, and the ideal intervals between administration of these medications and LAIV4 are not known. Assuming a period of at least 5 half-lives for substantial decrease in drug levels (*145*), a reasonable assumption is that that peramivir might interfere with the mechanism of LAIV4 if administered from 5 days before through 2 weeks after vaccination and baloxavir might interfere if administered from 17 days before through 2 weeks after vaccination. The interval between influenza antiviral receipt and LAIV4 during which interference might occur could be further prolonged in the presence of medical conditions that delay medication clearance (e.g., renal insufficiency). Persons who receive these medications during these periods before or after receipt of LAIV4 should be revaccinated with another appropriate influenza vaccine (e.g., IIV4 or RIV4).

Administration of Influenza Vaccines with Other Vaccines

IIV4s and RIV4 can be administered simultaneously or sequentially with other inactivated vaccines or live vaccines. Injectable vaccines that are given concomitantly should be administered at separate anatomic sites. COVID-19 vaccines that are administered at the same time as influenza vaccines that might be more likely to be associated with local injection site reactions (e.g., HD-IIV4 and aIIV4) should be given in different limbs, if possible. LAIV4 can be administered simultaneously with other live or inactivated vaccines. However, if two live vaccines are not given simultaneously, at least 4 weeks should pass after administration of one live vaccine (such as LAIV4) before another live vaccine is administered (*47*).

In recent years, multiple vaccines containing nonaluminum adjuvants have been licensed for use in the United States for the prevention of various infectious diseases. Examples include $AS01_B$ (in Shingrix, recombinant zoster subunit vaccine) (*146*), $AS01_E$ (in Arexy, respiratory syncytial virus vaccine) (*147*) MF59 (in Fluad Quadrivalent [aIIV4]) (*56*), and cytosine phosphoguanine oligodeoxynucleotide (in Heplisav-B, a recombinant hepatitis B surface antigen vaccine) (*148*). Data are limited regarding coadministration of these vaccines with other adjuvanted or nonadjuvanted vaccines, including COVID-19 vaccines. Coadministration of Shingrix with nonadjuvanted IIV4 has been studied, and no evidence of decreased immunogenicity or safety concerns was noted (*149*). Data on the immunogenicity and safety of simultaneous or sequential administration of two nonaluminum adjuvant–containing vaccines are limited, and the ideal interval between such vaccines when given sequentially is not known. In the study of Shingrix and IIV4 (*149*), most reactogenicity symptoms resolved within 4 days. Because of the limited data on the safety of simultaneous administration of two or more vaccines containing

nonaluminum adjuvants and the availability of nonadjuvanted influenza vaccine options, selection of a nonadjuvanted influenza vaccine may be considered in situations in which influenza vaccine and another vaccine containing a nonaluminum adjuvant are to be administered concomitantly. However, influenza vaccination should not be delayed if a specific vaccine is not available. As recommended for all vaccines, vaccines with nonaluminum adjuvants should be administered at separate anatomic sites from other vaccines that are given concomitantly (*47*).

For more recently introduced and new vaccines (e.g., respiratory syncytial virus [RSV] vaccine) data informing simultaneous administration with influenza vaccines might be limited or evolving. Providers should consult current CDC/ACIP recommendations and guidance for up-to-date information.

Influenza Vaccine Composition and Available Vaccines

Influenza Vaccine Composition for the 2023–24 Season

All influenza vaccines licensed in the United States will contain components derived from influenza viruses antigenically similar to those recommended by FDA (https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-march-7-2023-meeting-announcement). All influenza vaccines expected to be available in the United States for the 2023–24 season will be quadrivalent vaccines. For the 2023–24 season, U.S. egg-based influenza vaccines (i.e., vaccines other than ccIIV4 and RIV4) will contain HA derived from

- an influenza A/Victoria/4897/2022 (H1N1)pdm09-like virus,
- an influenza A/Darwin/9/2021 (H3N2)-like virus,
- an influenza B/Austria/1359417/2021 (Victoria lineage)-like virus, and
- an influenza B/Phuket/3073/2013 (Yamagata lineage)-like virus.

For the 2023–24 season, U.S. cell culture–based inactivated (ccIIV4) and recombinant (RIV4) influenza vaccines will contain HA derived from

- an influenza A/Wisconsin/67/2022 (H1N1)pdm09-like virus,
- an influenza A/Darwin/6/2021 (H3N2)-like virus,
- an influenza B/Austria/1359417/2021 (Victoria lineage)-like virus, and
- an influenza B/Phuket/3073/2013 (Yamagata lineage)-like virus.

Vaccines Available for the 2023–24 Season

Availability of specific types and brands of licensed seasonal influenza vaccines in the United States is determined by the manufacturers of the vaccines. Information presented concerning vaccines expected to be available and their approved indications and usage reflects current knowledge and is subject to change.

Various influenza vaccines will be available for the 2023–24 season (Table 1). For many vaccine recipients, more than one type or brand of vaccine might be appropriate within approved indications and ACIP recommendations. A licensed influenza vaccine that is appropriate for the recipient's age and health status should be used. Specific age indications for licensed influenza vaccines are summarized (Table 1). Current prescribing information should be consulted for authoritative, up-to-date information. Contraindications and precautions for the different types of influenza vaccines are summarized (Tables 2 and 3), as are dose volumes (Table 4).

Not all influenza vaccines are likely to be uniformly available in any specific practice setting or geographic locality. Vaccination should not be delayed to obtain a specific product when an appropriate one is available. Within these guidelines and approved indications, ACIP makes no preferential recommendation for the use of any one influenza vaccine over another when more than one licensed, recommended, and age-appropriate vaccine is available, with the exception of selection of influenza vaccines for persons aged ≥65 years (see Older Adults).

Dosage, Administration, Contraindications, and Precautions

Quadrivalent Inactivated Influenza Vaccines (IIV4s)

Available Vaccines. As in recent seasons, various inactivated influenza vaccines (IIVs) are expected to be available for 2023–24 (Table 1); all are expected to be quadrivalent (IIV4s). Standard-dose, nonadjuvanted IIV4s are licensed for persons aged as young as 6 months. However, for certain IIV4s, the approved dose volume for children aged 6 through 35 months differs from that for older children and adults (Table 4). Two IIV4s, the MF59-adjuvanted IIV4 (aIIV4) and the high-dose IIV4 (HD-IIV4), are approved only for persons aged ≥65 years. Care should be taken to administer the appropriate dose volume of an age-appropriate vaccine to each recipient.

Standard-dose, nonadjuvanted IIV4s contain 15 μg of HA per vaccine virus in a 0.5-mL dose (7.5 μg of HA per vaccine virus in a 0.25-mL dose). For 2023–24, this category is expected to include five different vaccines (Table 1). Four of these are egg-based vaccines, and one is a cell culture–based vaccine (Flucelvax Quadrivalent [ccIIV4]). All are approved for persons aged ≥6 months. Egg-based and cell culture–based vaccines differ in the substrate in which reference vaccine viruses supplied to the manufacturer are propagated in quantities sufficient to produce the needed number of doses of vaccine. For the IIV4s Afluria Quadrivalent (*48*), Fluarix Quadrivalent (*49*), FluLaval Quadrivalent (*51*), and Fluzone Quadrivalent (*52*), reference vaccine viruses are propagated in eggs. For Flucelvax Quadrivalent (ccIIV4), reference vaccine viruses are propagated in Madin-Darby canine kidney cells instead of eggs (*50*).

Two additional IIV4s that will be available for the 2023–24 season are approved only for persons aged ≥65 years. These vaccines are egg based. Quadrivalent high-dose inactivated influenza vaccine (Fluzone High-Dose Quadrivalent; HD-IIV4) contains 60 μg of HA per vaccine virus (240 μg total) in a 0.7-mL dose (*55*). Quadrivalent adjuvanted inactivated influenza vaccine (Fluad Quadrivalent; aIIV4) contains 15 μg of HA per vaccine virus (60 μg total) and MF59 adjuvant (*56*).

Dosage and Administration. Standard-dose nonadjuvanted IIV4s are approved for children aged as young as 6 months. Certain of these IIV4s are approved at different dose volumes for very young children than for older children and adults. Care should be taken to administer an age-appropriate vaccine at the approved dose volume for each needed dose (see Children Aged 6 Through 35 Months: Influenza Vaccine Dose Volumes) (Tables 1 and 4):

- Afluria Quadrivalent: The approved dose volume for children aged 6 through 35 months is 0.25 mL per dose. Persons aged ≥36 months (≥3 years) should receive 0.5 mL per dose (*48*).
- Fluarix Quadrivalent: The approved dose volume is 0.5 mL per dose for all persons aged ≥6 months (*49*).
- Flucelvax Quadrivalent: The approved dose volume is 0.5 mL per dose for all persons aged ≥6 months (*50*).
- FluLaval Quadrivalent: The approved dose volume is 0.5 mL per dose for all persons aged ≥6 months (*51*).
- Fluzone Quadrivalent: The approved dose volume for children aged 6 through 35 months is either 0.25 mL or 0.5 mL per dose. Persons aged ≥36 months (≥3 years) should receive 0.5 mL per dose (*52*).

If prefilled syringes are not available, the appropriate volume can be administered from a single-dose or multidose vial. If a 0.5-mL single-dose vial is used for a 0.25-mL dose for a child aged 6 through 35 months, only one half of the vial volume should be administered, and the remaining one half should be discarded. Of note, dose volume is distinct from the number of doses. Children in this age group who require 2 doses for 2023–24 need 2 separate doses administered ≥4 weeks apart, regardless of the specific IIV4 used and volume given for each dose (see Children Aged 6 Months Through 8 Years: Number of Influenza Vaccine Doses) (Figure).

For children aged 36 months (3 years) through 17 years and adults aged ≥18 years, the dose volume for IIV4s is 0.5 mL per dose, with the exception of Fluzone High-Dose Quadrivalent (HD-IIV4, licensed for persons aged ≥65 years), for which the correct volume is 0.7 mL per dose. If a smaller vaccine dose (e.g., 0.25 mL) is inadvertently administered to a person aged ≥36 months, the remaining volume needed to make a full dose should be administered during the same vaccination visit or, if measuring the needed remaining volume is a challenge, administering a repeat dose at the full volume is acceptable. If the error is discovered later (after the recipient has left the vaccination setting), a full dose should be administered as soon as the recipient can return. Vaccination with a formulation approved for adult use should be counted as a single dose if inadvertently administered to a child.

IIV4s are administered intramuscularly (IM). For adults and older children, the deltoid muscle is the preferred site. Infants and younger children should be vaccinated in the anterolateral thigh. Additional specific guidance regarding site selection and needle length for IM injection is provided in the General Best Practice Guidelines for Immunization (*47*). One IIV4, Afluria Quadrivalent, is licensed for IM injection via the PharmaJet Stratis jet injector for persons aged 18 through 64 years (*48*). Persons in this age group may receive Afluria Quadrivalent via either needle and syringe or this specific jet injection device. Children aged 6 months through 17 years and adults aged ≥65 years should receive this vaccine by needle and syringe only. No other IIV4s are licensed for administration by jet injector.

Contraindications and Precautions for the Use of IIV4s. Manufacturer package inserts and updated CDC and ACIP guidance should be consulted for information on contraindications and precautions for individual influenza vaccines. Each IIV, whether egg based or cell culture based, has a labeled contraindication for persons with a history of a severe allergic reaction to any component of that vaccine (Tables 2 and 3). However, although egg is a component of all IIV4s other than ccIIV4, ACIP makes specific recommendations for the use of influenza vaccine for persons with egg allergy (see Persons with a History of Egg Allergy). All egg-based IIV4s are contraindicated in persons who have had a severe allergic reaction (e.g., anaphylaxis) to a previous dose of any influenza vaccine (any egg-based IIV, ccIIV, RIV, or LAIV of any valency). Use of ccIIV4 is contraindicated in persons who have had a severe allergic reaction (e.g., anaphylaxis) to any ccIIV of any valency. A history of severe allergic reaction (e.g., anaphylaxis) to any other influenza vaccine (i.e., any egg-based IIV, RIV, or LAIV of any valency) is a precaution for the use of ccIIV4 (see Persons with Previous Allergic Reactions to Influenza Vaccines) (Tables 2 and 3). If ccIIV4 is administered in such an instance, vaccination should occur in an inpatient or outpatient medical setting and should be supervised by a health care provider who is able to recognize and manage severe allergic reactions. Providers can also consider consultation with an allergist to help identify the vaccine component responsible for the reaction. Information about vaccine components can be found in the package inserts for each vaccine. Prophylactic use of antiviral agents is an option that can be considered for preventing influenza among persons who cannot receive vaccine, particularly for those who are at higher risk for medical complications attributable to severe influenza (*102*).

Moderate or severe acute illness with or without fever is a general precaution for vaccination (*47*). A history of GBS within 6 weeks after receipt of a previous dose of influenza vaccine is considered a precaution for the use of all influenza vaccines (Table 2).

Quadrivalent Recombinant Influenza Vaccine (RIV4)

Available Vaccine. One recombinant influenza vaccine, Flublok Quadrivalent (RIV4), is expected to be available during the 2023–24 influenza season. RIV4 is approved for persons aged ≥18 years. This vaccine contains recombinant HA produced in an insect cell line using genetic sequences from cell-derived influenza viruses and is manufactured without the use of influenza viruses or eggs (*54*).

Dosage and Administration. RIV4 is administered by IM injection via needle and syringe. A 0.5-mL dose contains 45 μg of HA derived from each vaccine virus (180 μg total).

Contraindications and Precautions for the Use of RIV4. Manufacturer package inserts and updated CDC and ACIP guidance should be consulted for information on contraindications and precautions for individual influenza vaccines. RIV4 is contraindicated in persons who have had a severe allergic reaction (e.g., anaphylaxis) to a previous dose of any RIV of any valency or to any component of RIV4. A history of a severe allergic reaction (e.g., anaphylaxis) to any other influenza vaccine (i.e., any egg-based IIV, ccIIV, or LAIV of any valency) is a precaution for the use of RIV4. If RIV4 is administered in such an instance, vaccination should occur in an inpatient or outpatient medical setting and should be supervised by a health care provider who is able to recognize and manage severe allergic reactions. Providers can also consider consulting with an allergist to help identify the vaccine component responsible for the reaction (Tables 2 and 3).

Moderate or severe acute illness with or without fever is a general precaution for vaccination (*47*). A history of GBS within 6 weeks after receipt of a previous dose of influenza vaccine is considered a precaution for the use of all influenza vaccines (Table 2). RIV4 is not licensed for children aged <18 years.

Quadrivalent Live Attenuated Influenza Vaccine (LAIV4)

Available Vaccine. One live attenuated influenza vaccine, FluMist Quadrivalent (LAIV4), is expected to be available during the 2023–24 influenza season. LAIV4 is approved for persons aged 2 through 49 years. LAIV4 contains live attenuated influenza viruses that are propagated in eggs. These viruses are cold adapted (so that they replicate efficiently at 25°C [77°F]) and temperature sensitive (so that their replication is restricted at higher temperatures, 39°C [102.2°F] for influenza A viruses and 37°C [98.6°] for influenza B viruses). The live attenuated vaccine viruses replicate in the nasopharynx, which is necessary to promote an immune response (*53*). No preference is expressed for LAIV4 versus other influenza vaccines used within specified indications.

Dosage and Administration. LAIV4 is administered intranasally using the supplied prefilled, single-use sprayer containing 0.2 mL of vaccine. Approximately 0.1 mL (i.e., one half of the total sprayer contents) is sprayed into the first nostril while the recipient is in the upright position. An attached dose-divider clip is removed from the sprayer to permit administration of the second half of the dose into the other nostril. Sniffing of the dose is not necessary. If the recipient sneezes immediately after administration, the dose should not be repeated. However, if nasal congestion is present that might impede delivery of the

vaccine to the nasopharyngeal mucosa, deferral of administration should be considered until resolution of the illness, or another appropriate vaccine should be administered instead. Each total dose of 0.2 mL contains $10^{6.5–7.5}$ fluorescent focus units of each vaccine virus (*53*).

Contraindications and Precautions for the Use of LAIV4. Manufacturer package inserts and updated CDC and ACIP guidance should be consulted for information on contraindications and precautions for individual influenza vaccines. Conditions considered by ACIP to be contraindications and precautions for the use of LAIV4 are summarized (Table 2). These include two labeled contraindications that appear in the package insert (*53*) and other conditions for which there is either uncertain but biologically plausible potential risk associated with live viruses or limited data for use of LAIV. Contraindications to use of LAIV4 include the following (Tables 2 and 3):

- Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or to a previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency; a labeled contraindication noted in the package insert). However, although egg is a component of LAIV4, ACIP makes specific recommendations for the use of influenza vaccine for persons with egg allergy (see Persons with a History of Egg Allergy).
- Children and adolescents receiving concomitant aspirin- or salicylate-containing medications, because of the potential risk for Reye syndrome (a labeled contraindication noted in the package insert).
- Children aged 2 through 4 years who have received a diagnosis of asthma or whose parents or caregivers report that a health care provider has told them during the preceding 12 months that their child had wheezing or asthma or whose medical record indicates a wheezing episode has occurred during the preceding 12 months.
- Children and adults who are immunocompromised due to any cause, including but not limited to immunosuppression caused by medications, congenital or acquired immunodeficiency states, HIV infection, anatomic asplenia, or functional asplenia (such as that due to sickle cell anemia).
- Close contacts and caregivers of severely immunosuppressed persons who require a protected environment.
- Pregnancy.
- Persons with active communication between the cerebrospinal fluid (CSF) and the oropharynx, nasopharynx, nose, or ear or any other cranial CSF leak.
- Persons with cochlear implants, because of the potential for CSF leak that might exist for a period after implantation (providers might consider consultation with a specialist concerning the risk for persistent CSF leak if an age-appropriate inactivated or recombinant vaccine cannot be used).
- Receipt of influenza antiviral medication within the previous 48 hours for oseltamivir and zanamivir, previous 5 days for peramivir, and previous 17 days for baloxavir. The interval between influenza antiviral receipt and LAIV4 during which interference might potentially occur might be further prolonged in the presence of medical conditions that delay medication clearance (e.g., renal insufficiency).

Precautions to the use of LAIV4 include the following (Tables 2 and 3):

- Moderate or severe acute illness with or without fever.
- History of GBS within 6 weeks after receipt of any influenza vaccine.
- Asthma in persons aged ≥5 years.
- Other underlying medical condition (other than those listed under contraindications) that might predispose to complications after wild-type influenza virus infection (e.g., chronic pulmonary, cardiovascular [except isolated hypertension], renal, hepatic, neurologic, hematologic, or metabolic disorders [including diabetes mellitus]).

Storage and Handling of Influenza Vaccines

In all instances, approved manufacturer packaging information should be consulted for authoritative guidance concerning storage and handling of specific influenza vaccines. Typically, influenza vaccines should be protected from light and stored at temperatures that are recommended in the package insert. Recommended storage temperatures are typically 36°F–46°F (2°C–8°C) and should be maintained at all times with adequate refrigeration and temperature monitoring. Vaccine that has frozen should be discarded. Specific recommendations for appropriate refrigerators and temperature monitoring equipment can be found in the Vaccine Storage and Handling Toolkit, available at https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html.

Vaccines should not be used beyond the expiration date on the label. In addition to the expiration date, multidose vials also might have a beyond-use date (BUD), which specifies the number of days the vaccine can be kept once first accessed. After being accessed for the first dose, multidose vials should not be used after the BUD. If no BUD is provided, then the listed expiration date is to be used. Multidose vials should be returned to recommended storage conditions between uses. Package information might also specify a maximum number of doses contained in multidose vials (regardless of remaining volume). No more than the specified number of doses should be removed, and any remainder should be discarded. Single-dose vials should not be accessed for more than 1 dose. Providers should contact the manufacturer for information on permissible temperature excursions and other departures from recommended storage and handling conditions that are not discussed in the package labeling.

Additional Sources of Information Regarding Influenza and Influenza Vaccines

Influenza Surveillance, Prevention, and Control

Updated information regarding influenza surveillance, detection, prevention, and control is available at https://www.cdc.gov/flu. U.S. surveillance data are updated weekly throughout the year on FluView (https://www.cdc.gov/flu/weekly) and can be viewed in FluView Interactive (https://www.cdc.gov/flu/weekly/fluviewinteractive.htm). In addition, periodic updates regarding influenza are published in MMWR (https://www.cdc.gov/mmwr/index.html). Additional information regarding influenza and influenza vaccines can be obtained from CDCINFO by calling 1-800-232-4636. State and local health departments should be consulted about availability of influenza vaccines, access to vaccination programs, information related to state or local influenza activity, reporting of influenza outbreaks and influenza-related pediatric deaths, and advice concerning outbreak control.

Vaccine Adverse Event Reporting System (VAERS)

The National Childhood Vaccine Injury Act of 1986 requires health care providers to report any adverse event listed by the vaccine manufacturer as a contraindication to future doses of the vaccine or any adverse event listed in the VAERS Table of Reportable Events Following Vaccination (https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf) that occurs within the specified period after vaccination. In addition to mandated reporting, health care providers are encouraged to report any clinically significant adverse event after vaccination to VAERS. Information on how to report a vaccine adverse event is available at https://vaers.hhs.gov/index.html .

National Vaccine Injury Compensation Program (VICP)

The National Vaccine Injury Compensation Program (VICP), established by the National Childhood Vaccine Injury Act of 1986, as amended, is a no-fault alternative to the traditional tort system. It provides compensation to people found to be injured by certain vaccines. VICP covers most vaccines routinely given in the United States. The Vaccine Injury Table (https://www.hrsa.gov/sites/default/files/hrsa/vicp/vaccine-injury-table-01-03-2022.pdf) lists the vaccines covered by VICP and the associated injuries and conditions that might receive a legal presumption of causation. If the injury or condition is not in the table or does not meet the requirements in the table, persons must prove that the vaccine caused the injury or condition. Claims must be filed within specified time frames. Persons of all ages who receive a VICP-covered vaccine might be eligible to file a claim. Additional information is available at https://www.hrsa.gov/vaccine-compensation or by calling 1-800-338-2382.

Additional Resources

ACIP Statements

- Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States: https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html
- Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States: https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html
- Immunization of Health Care Personnel: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2011. MMWR Recomm Rep 2011;60(No.RR-7):1–45: https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6007a1.htm

General Best Practices Guidelines for Immunization:

- General Best Practice Guidelines for Immunization: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

COVID-19 Vaccine Recommendations and Guidance

- ACIP recommendations for the use of COVID-19 vaccines: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html
- Clinical Care Considerations for COVID-19 Vaccination: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html
- Use of COVID-19 Vaccines in the United States — Interim Clinical Considerations: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html
- FDA COVID-19 Vaccines page: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

Vaccine Information Sheets

- IIV4 and RIV4: https://www.cdc.gov/vaccines/hcp/vis/vis-statements/flu.pdf
- LAIV4: https://www.cdc.gov/vaccines/hcp/vis/vis-statements/flulive.pdf

Influenza Vaccine Package Inserts

- https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states

CDC Influenza Antiviral Guidance

- Influenza Antiviral Medications: Summary for Clinicians: https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm

Infectious Diseases Society of America Influenza Antiviral Guidance

- Clinical Practice Guidelines by the Infectious Diseases Society of America: 2018 Update on Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management of Seasonal Influenza: https://academic.oup.com/cid/article/68/6/e1/5251935

American Academy of Pediatrics Guidance

- American Academy of Pediatrics Recommendations for Prevention and Control of Influenza in Children (Red Book Online): https://publications.aap.org/redbook

Infectious Diseases Society of America Guidance for Vaccination of Immunocompromised Hosts

- 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host: https://academic.oup.com/cid/article/58/3/e44/336537

American College of Obstetricians and Gynecologists

- Influenza Vaccination During Pregnancy, ACOG Committee Opinion No. 732: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/04/influenza-vaccination-during-pregnancy

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CDC Adoption of ACIP Recommendations for MMWR Recommendations and Reports, MMWR Policy Notes, and Immunization Schedules (Child/Adolescent, Adult)

Recommendations for routine use of vaccines in children, adolescents, and adults are developed by the Advisory Committee on Immunization Practices (ACIP). ACIP is chartered as a Federal Advisory Committee to provide expert external advice and guidance to the Director of CDC on use of vaccines and related agents for the control of vaccine preventable diseases in the civilian population of the United States. Recommendations for routine use of vaccines in children and adolescents are harmonized to the greatest extent possible with recommendations made by the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the American College of Obstetricians and Gynecologists (ACOG). Recommendations for routine use of vaccinations in adults are harmonized with recommendations of AAFP, ACOG, and the American College of Physicians (ACP). ACIP recommendations are forwarded to CDC's Director and once adopted become official CDC policy. These recommendations are then published in CDC's Morbidity and Mortality Weekly Report (MMWR). Additional information is available at https://www.cdc.gov/vaccines/acip.

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TABLE 1. Influenza vaccines — United States, 2023–24 influenza season*

Trade name (manufacturer)	Presentation	Age indication	µg HA (IIV4s and RIV4) or virus count (LAIV4) for each vaccine virus (per dose)	Route	Mercury (from thimerosal, if present) µg/0.5 mL
IIV4 (standard-dose, egg-based vaccines†)					
Afluria Quadrivalent (Seqirus)	0.5-mL PFS§	≥3 yrs§	15 µg/0.5 mL	IM¶	—**
	5.0-mL MDV§	≥6 mos§ (needle and syringe) 18 through 64 yrs (jet injector)	7.5 µg/0.25 mL 15 µg/0.5 mL	IM¶	24.5
Fluarix Quadrivalent (GlaxoSmithKline)	0.5-mL PFS	≥6 mos	15 µg/0.5 mL	IM¶	—
FluLaval Quadrivalent (GlaxoSmithKline)	0.5-mL PFS	≥6 mos	15 µg/0.5 mL	IM¶	—
Fluzone Quadrivalent (Sanofi Pasteur)	0.5-mL PFS††	≥6 mos††	15 µg/0.5 mL	IM¶	—
	0.5-mL SDV††	≥6 mos††	15 µg/0.5 mL	IM¶	—
	5.0-mL MDV††	≥6 mos††	7.5 µg/0.25 mL 15 µg/0.5 mL	IM¶	25
ccIIV4 (standard-dose, cell culture–based vaccine)					
Flucelvax Quadrivalent (Seqirus)	0.5-mL PFS	≥6 mos	15 µg/0.5 mL	IM¶	—
	5.0-mL MDV	≥6 mos	15 µg/0.5 mL	IM¶	25
HD-IIV4 (high-dose, egg-based vaccine†)					
Fluzone High-Dose Quadrivalent (Sanofi Pasteur)	0.7-mL PFS	≥65 yrs	60 µg/0.7 mL	IM¶	—
aIIV4 (standard-dose, egg-based vaccine† with MF59 adjuvant)					

Trade name (manufacturer)	Presentation	Age indication	μg HA (IIV4s and RIV4) or virus count (LAIV4) for each vaccine virus (per dose)	Route	Mercury (from thimerosal, if present) μg/0.5 mL
Fluad Quadrivalent (Seqirus)	0.5-mL PFS	≥65 yrs	15 μg/0.5 mL	IM¶	—
RIV4 (recombinant HA vaccine)					
Flublok Quadrivalent (Sanofi Pasteur)	0.5-mL PFS	≥18 yrs	45 μg/0.5 mL	IM¶	—
LAIV4 (egg-based vaccine†)					
FluMist Quadrivalent (AstraZeneca)	0.2-mL prefilled single-use intranasal sprayer	2 through 49 yrs	$10^{6.5–7.5}$ fluorescent focus units/0.2 mL	NAS	—

Abbreviations: ACIP = Advisory Committee on Immunization Practices; HA = hemagglutinin; IIV4 = inactivated influenza vaccine, quadrivalent; IM = intramuscular; LAIV4 = live attenuated influenza vaccine, quadrivalent; MDV = multidose vial; PFS = prefilled syringe; RIV4 = recombinant influenza vaccine, quadrivalent; SDV = single-dose vial.

* Manufacturer package inserts and updated CDC and ACIP guidance should be consulted for additional information concerning, but not limited to, indications, contraindications, warnings, and precautions. Package inserts for U.S.-licensed vaccines are available at https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states . Availability and characteristics of specific products and presentations might change or differ from what is described in this table and in the text of this report.

† Although a history of severe allergic reaction (e.g., anaphylaxis) to egg is a labeled contraindication to the use of egg-based IIV4s and LAIV4, ACIP recommends that all persons aged ≥6 months with egg allergy should receive influenza vaccine and that any influenza vaccine (egg based or nonegg based) that is otherwise appropriate for the recipient's age and health status can be used (see Persons with a History of Egg Allergy).

§ The approved dose volume for Afluria Quadrivalent is 0.25 mL for children aged 6 through 35 months and 0.5 mL for persons aged ≥3 years. However, 0.25-mL prefilled syringes are no longer available. For children aged 6 through 35 months, a 0.25-mL dose must be obtained from a multidose vial.

¶ IM-administered influenza vaccines should be administered by needle and syringe only, with the exception of the MDV presentation of Afluria Quadrivalent, which may alternatively be given by the PharmaJet Stratis jet injector for persons aged 18 through 64 years only. For older children and adults, the recommended site for IM influenza vaccination is the deltoid muscle. The preferred site for infants and young children is the anterolateral aspect of the thigh. Additional specific guidance regarding site selection and needle length for IM administration is available in the General Best Practice Guidelines for Immunization available at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html.

** Not applicable.

†† Fluzone Quadrivalent is approved for children aged 6 through 35 months at either 0.25 mL or 0.5 mL per dose; however, 0.25-mL prefilled syringes are no longer available. If a prefilled syringe of Fluzone Quadrivalent is used for a child in this age group, the dose volume will be 0.5 mL per dose.

TABLE 2. Contraindications and precautions for the use of influenza vaccines — United States, 2023–24 influenza season*

Return

Vaccine type	Contraindications	Precautions

Vaccine type	Contraindications	Precautions
Egg-based IIV4s	• History of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine† or to a previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV)§	• Moderate or severe acute illness with or without fever • History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine
ccIIV4	• History of severe allergic reaction (e.g., anaphylaxis) to a previous dose of any ccIIV or any component of ccIIV4§	• Moderate or severe acute illness with or without fever • History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine • History of severe allergic reaction to a previous dose of any other influenza vaccine (i.e., any egg-based IIV, RIV, or LAIV)¶
RIV4	• History of severe allergic reaction (e.g., anaphylaxis) to a previous dose of any RIV or any component of RIV4§	• Moderate or severe acute illness with or without fever • History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine • History of severe allergic reaction to a previous dose of any other influenza vaccine (i.e., any egg-based IIV, ccIIV, or LAIV)¶
LAIV4	• History of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine† or to a previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV)§ • Concomitant aspirin- or salicylate-containing therapy in children and adolescents§ • Children aged 2 through 4 years who have received a diagnosis of asthma or whose parents or caregivers report that a health care provider has told them during the preceding 12 months that their child had wheezing or asthma or whose medical record indicates a wheezing episode has occurred during the preceding 12 months • Children and adults who are immunocompromised due to any cause, including but not limited to immunosuppression caused by medications, congenital or acquired immunodeficiency states, HIV infection, anatomic asplenia, or functional asplenia (e.g., due to sickle cell anemia) • Close contacts and caregivers of severely immunosuppressed persons who require a protected environment • Pregnancy • Persons with active communication between the CSF and the oropharynx, nasopharynx, nose, or ear or any other cranial CSF leak • Persons with cochlear implants** • Receipt of influenza antiviral medication within the previous 48 hours for oseltamivir and zanamivir, previous 5 days for peramivir, and previous 17 days for baloxavir††	• Moderate or severe acute illness with or without fever • History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine • Asthma in persons aged ≥5 years • Other underlying medical conditions that might predispose to complications after wild-type influenza infection (e.g., chronic pulmonary, cardiovascular [except isolated hypertension], renal, hepatic, neurologic, hematologic, or metabolic disorders [including diabetes mellitus])

Abbreviations: ACIP = Advisory Committee on Immunization Practices; ccIIV = cell culture–based inactivated influenza vaccine (any valency); ccIIV4 = cell culture–based inactivated influenza vaccine, quadrivalent; CSF = cerebrospinal fluid; IIV = inactivated influenza vaccine (any valency); IIV4 = inactivated influenza vaccine, quadrivalent; LAIV = live attenuated influenza vaccine (any valency); LAIV4 = live attenuated influenza vaccine, quadrivalent; RIV = recombinant influenza vaccine (any valency); RIV4 = recombinant influenza vaccine, quadrivalent.

* Manufacturer package inserts and updated CDC and ACIP guidance should be consulted for additional information concerning, but not limited to, indications, contraindications, warnings, and precautions. When a contraindication is present, a vaccine should not be administered. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction (see the General Best Practice Guidelines for Immunization, available at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html). Package inserts for U.S.-licensed vaccines are available at https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states

† Although a history of severe allergic reaction (e.g., anaphylaxis) to egg is a labeled contraindication to the use of egg-based IIV4s and LAIV4, ACIP recommends that all persons aged ≥6 months with egg allergy should receive influenza vaccine, and that any influenza vaccine (egg based or nonegg based) that is otherwise appropriate for the recipient's age and health status can be used (see Persons with a History of Egg Allergy).

§ Labeled contraindication noted in package insert.

¶ If administered, vaccination should occur in a medical setting and should be supervised by a health care provider who can recognize and manage severe allergic reactions. Providers can consider consultation with an allergist in such cases to assist in identification of the component responsible for the allergic reaction.

** Age-appropriate injectable vaccines are recommended for persons with cochlear implant because of the potential for CSF leak, which might exist for a period after implantation. Providers might consider consultation with a specialist concerning risk for persistent CSF leak if an age-appropriate inactivated or recombinant vaccine cannot be used.

†† Use of LAIV4 in context of influenza antivirals has not been studied; however, interference with activity of LAIV4 is biologically plausible, and this possibility is noted in the package insert for LAIV4. In the absence of data supporting an adequate minimum interval between influenza antiviral use and LAIV4 administration, the intervals provided are based on the half-life of each antiviral. The interval between influenza antiviral receipt and LAIV4 for which interference might potentially occur might be further prolonged in the presence of medical conditions that delay medication clearance (e.g., renal insufficiency). Influenza antivirals might also interfere with LAIV4 if initiated within 2 weeks after vaccination. Persons who receive antivirals during the period starting with the specified time before receipt of LAIV4 through 2 weeks after receipt of LAIV4 should be revaccinated with an age-appropriate IIV or RIV4.

TABLE 3. Influenza vaccine contraindications and precautions for persons with a history of severe allergic reaction to a previous dose of an influenza vaccine* — United States, 2023–24 influenza season

Vaccine (of any valency) associated with previous severe allergic reaction (e.g., anaphylaxis)	Available 2023–24 influenza vaccines		
	Egg-based IIV4s and LAIV4	ccIIV4	RIV4
Any egg-based IIV or LAIV	Contraindication†	Precaution§	Precaution§
Any ccIIV	Contraindication†	Contraindication†	Precaution§
Any RIV	Contraindication†	Precaution§	Contraindication†
Unknown influenza vaccine	Allergist consultation recommended		

Abbreviations: ACIP = Advisory Committee on Immunization Practices; ccIIV = cell culture–based inactivated influenza vaccine (any valency); ccIIV4 = cell culture–based inactivated influenza vaccine, quadrivalent; IIV = inactivated influenza vaccine (any valency); IIV4 = inactivated influenza vaccine, quadrivalent; LAIV = live attenuated influenza vaccine (any valency); LAIV4 = live attenuated influenza vaccine, quadrivalent; RIV = recombinant influenza vaccine (any valency); RIV4 = recombinant influenza vaccine, quadrivalent.

* Manufacturer package inserts and updated CDC and ACIP guidance should be consulted for additional information, including, but not limited to indications, contraindications, warnings, and precautions. Package inserts for U.S.-licensed vaccines are available at https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states .

† When a contraindication is present, a vaccine should not be administered, consistent with the General Best Practice Guidelines for Immunization (Source: Kroger A, Bahta L, Hunter P. General best practice guidelines for immunization; https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html). In addition to the contraindications based on history of severe allergic reaction to influenza vaccines that are noted in the table, each individual influenza vaccine is contraindicated for persons who have had a severe allergic reaction (e.g., anaphylaxis) to any component of that vaccine. Vaccine components

can be found in package inserts. Although a history of severe allergic reaction (e.g., anaphylaxis) to egg is a labeled contraindication to the use of egg-based IIV4s and LAIV4, ACIP recommends that all persons aged ≥6 months with egg allergy should receive influenza vaccine, and that any influenza vaccine (egg based or nonegg based) that is otherwise appropriate for the recipient's age and health status can be used (see Persons with a History of Egg Allergy).

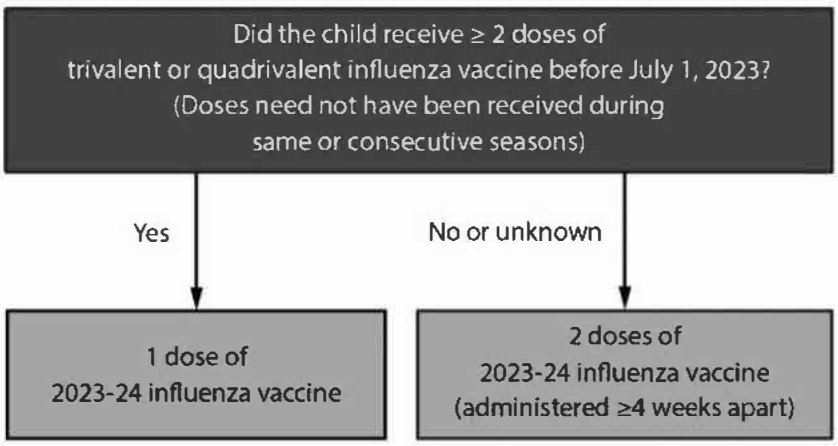
[§] When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction, consistent with the General Best Practice Guidelines for Immunization (Source: Kroger A, Bahta L, Hunter P. General best practice guidelines for immunization; https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html). Providers can consider using the following vaccines in these instances; however, vaccination should occur in an inpatient or outpatient medical setting with supervision by a health care provider who is able to recognize and manage severe allergic reactions: 1) for persons with a history of severe allergic reaction (e.g., anaphylaxis) to any egg-based IIV or LAIV of any valency, the provider can consider administering ccIIV4 or RIV4; 2) for persons with a history of severe allergic reaction (e.g., anaphylaxis) to any ccIIV of any valency, the provider can consider administering RIV4; and 3) for persons with a history of severe allergic reaction (e.g., anaphylaxis) to any RIV of any valency, the provider can consider administering ccIIV4. Providers can also consider consulting with an allergist to help determine which vaccine component is responsible for the allergic reaction.

BOX. Abbreviation conventions for influenza vaccines discussed in this report

Return

- Main influenza vaccine types:
  - IIV = inactivated influenza vaccine
  - RIV = recombinant influenza vaccine
  - LAIV = live attenuated influenza vaccine
- Numerals following letter abbreviations indicate valency (the number of influenza virus hemagglutinin antigens represented in the vaccine):
  - 4 for quadrivalent vaccines: one A(H1N1), one A(H3N2), and two B viruses (one from each lineage)
  - 3 for trivalent vaccines: one A(H1N1), one A(H3N2), and one B virus (from one lineage)
- All influenza vaccines expected to be available in the United States for the 2023–24 season are quadrivalent vaccines. However, abbreviations for trivalent vaccines (e.g., IIV3) might be used in this report when discussing information specific to trivalent vaccines.
- Abbreviations for general vaccine categories (e.g., IIV) might be used when discussing information that is not specific to valency or to a specific vaccine in that category.
- Prefixes are used when necessary to refer to certain specific IIVs:
  - a for MF59-adjuvanted inactivated influenza vaccine (e.g., aIIV3 and aIIV4)
  - cc for cell culture–based inactivated influenza vaccine (e.g., ccIIV3 and ccIIV4)
  - HD for high-dose inactivated influenza vaccine (e.g., HD-IIV3 and HD-IIV4)
  - SD for standard-dose inactivated influenza vaccine (e.g., SD-IIV3 and SD-IIV4)

FIGURE. Influenza vaccine dosing algorithm for children aged 6 months through 8 years* — Advisory Committee on Immunization Practices, United States, 2023–24 influenza season



* Children aged 6 months through 8 years who require 2 doses of influenza vaccine should receive their first dose as soon as possible (including during July and August, if vaccine is available) to allow the second dose (which must be administered ≥4 weeks later) to be received, ideally, by the end of October. For children aged 8 years who require 2 doses of vaccine, both doses should be administered even if the child turns age 9 years between receipt of dose 1 and dose 2.

TABLE 4. Dose volumes for inactivated influenza vaccines approved for children aged 6 through 35 months* — United States, 2023–24 influenza season Return

Trade name (manufacturer)	Dose volume for children aged 6 through 35 mos (μg HA per vaccine virus)
Afluria Quadrivalent (Seqirus)	0.25 mL (7.5 μg)†
Fluarix Quadrivalent (GlaxoSmithKline)	0.5 mL (15 μg)
Flucelvax Quadrivalent (Seqirus)	0.5 mL (15 μg)
FluLaval Quadrivalent (GlaxoSmithKline)	0.5 mL (15 μg)
Fluzone Quadrivalent (Sanofi Pasteur)	0.5 mL (15 μg)§

Abbreviation: HA = hemagglutinin.
* For persons aged ≥36 months (≥3 years), the dose volume is 0.5 mL per dose for all inactivated influenza vaccines with the exception of Fluzone High-Dose Quadrivalent (HD-IIV4), which is licensed for persons aged ≥65 years and for which the dose volume is 0.7 mL per dose.
† The approved dose volume for Afluria Quadrivalent is 0.25 mL for children aged 6 through 35 months and 0.5 mL for persons aged ≥3 years. However, 0.25-mL prefilled syringes are no longer available. For children aged 6 through 35 months, a 0.25-mL dose must be obtained from a multidose vial.
§ Per the package insert, Fluzone Quadrivalent is approved for children aged 6 through 35 months at either 0.25 mL or 0.5 mL per dose; however, 0.25-mL prefilled syringes are no longer available. If a prefilled syringe of Fluzone Quadrivalent is used for a child in this age group, the dose volume will be 0.5 mL per dose. The 0.5-mL single-dose vials should be accessed for only 1 dose and multidose vials for only 10 doses, regardless of the volume of the doses obtained or any remaining volume in the vial. Any vaccine remaining in a vial after the maximum number of doses has been removed should be discarded.

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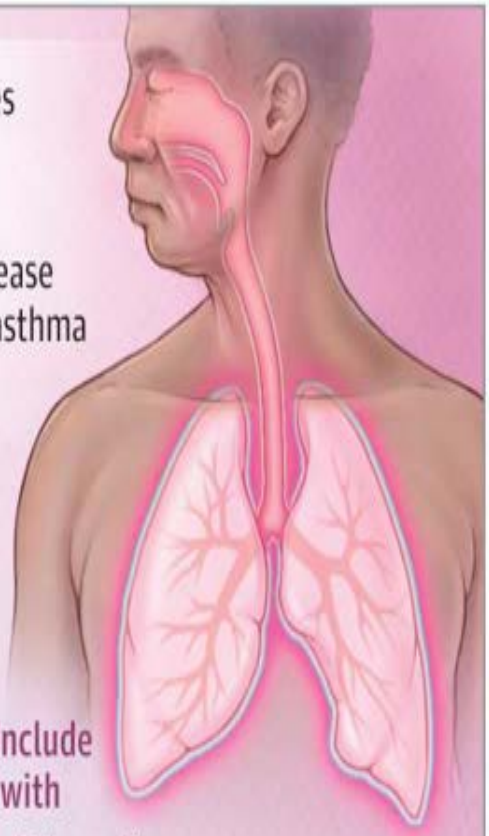
Last Reviewed: August 22, 2023

Respiratory syncytial virus (RSV) causes respiratory infections with symptoms such as cough, runny nose, sore throat, and headache.

In older adults, RSV can cause more severe disease including pneumonia, or worsen symptoms of asthma or chronic obstructive pulmonary disease.



Adults at highest risk of severe RSV infection include those older than age 60 with

- Lung disease
- Heart disease
- Diabetes
- Neurologic disease
- Kidney disease
- Liver disease
- Blood disorders
- Immunosuppression

The RSV vaccine is given in a single dose and is moderately to highly effective in preventing severe RSV infections in adults aged 60 years or older.

Frequently Asked Questions About RSV Vaccine for Adults

Two Respiratory Syncytial Virus (RSV) vaccines are approved for people ages 60 years and older.

- Arexvy (GSK adjuvanted RSV vaccine)
- Abrysvo (Pfizer RSV vaccine)

CDC recommends that adults ages 60 years and older may receive RSV vaccination, using shared clinical decision-making (SCDM) ■ . This means that health care providers should talk to these individuals about whether RSV vaccination is appropriate for them.

Is RSV an important cause of disease among older adults?

RSV is a common cause of respiratory illness in infants and young children, as well as older adults. Each season, RSV causes substantial morbidity and mortality in older adults, including lower respiratory tract disease, hospitalization, and death. There are an estimated 60,000–160,000 hospitalizations and 6,000–10,000 deaths annually due to RSV among adults ages 65 years and older.

What vaccines are approved for prevention of RSV, and is there a difference between them?

There are two RSV vaccines approved for adults ages 60 years and older – RSVPreF3 (Arexvy, GSK) and RSVpreF (Abrysvo, Pfizer). Both vaccines are recombinant protein vaccines that cause the immune system to produce RSV antibodies. Both are currently approved as a single dose and were shown in clinical trials protect against symptomatic lower respiratory tract disease caused by RSV in adults ages 60 and older, with more than 80% percent efficacy in the first RSV season after vaccination. GSK's vaccine includes an adjuvant (the same adjuvant used in GSK's recombinant zoster vaccine [Shingrix]), which is a component that is intended to enhance the immune response to vaccination. Pfizer's vaccine does not contain an adjuvant. CDC does not have a preferential recommendation for either vaccine. Patients who are 60 years and older may receive whichever vaccine is available.

What does it mean to use a shared clinical decision-making (SCDM) recommendation for RSV vaccine?

CDC recommends that older adults ages 60 years and older may receive a single dose of RSV vaccine using SCDM. A SCDM recommendation differs from routine age-based and risk-based vaccine recommendations for which the default decision is to vaccinate all persons in a specified age group or risk group. With a SCDM recommendation, there is no group in which the vaccine is universally recommended. Rather, the decision to vaccinate a patient is based on individual health characteristics and informed by discussions between the patient and health care provider (anyone who provides or administers vaccines, including primary care physicians, specialists, physician assistants, nurse practitioners, registered nurses, and pharmacists). Health care providers may consider multiple factors when discussing RSV

vaccination with patients, including whether the patient has any risk factors for severe RSV disease, the safety profile of the RSV vaccine products, a patient's preferences for RSV vaccination, and the clinical discretion of the health care provider in that patient's case.

To learn more about SCDM vaccination recommendations, see the ACIP background on the topic. For additional guidance on the SCDM recommendation for RSV vaccination, and which patients are most likely to benefit from RSV vaccination, see CDC's provider job aid and the MMWR report on use of RSV vaccines in adults ages 60 years and older.

Which adults are most likely to benefit from RSV vaccination?

Although RSV infection generally causes mild upper respiratory disease in healthy adults, RSV can cause serious illness in adults with certain underlying medical conditions or other risk factors. Adults ages 60 years and older who are at higher risk for severe RSV disease include:

- those with chronic medical conditions such as:
  - lung diseases (e.g., chronic obstructive pulmonary disease, asthma)
  - cardiovascular diseases (e.g., congestive heart failure, coronary artery disease)
  - neurologic or neuromuscular conditions
  - kidney disorders
  - liver disorders
  - hematologic disorders
  - diabetes mellitus
  - moderate or severe immune compromise (either attributable to a medical condition or receipt of immunosuppressive medications or treatment)
- those who are frail
- those of advanced age
- those who reside in nursing homes or other long-term care facilities
- those with other underlying medical conditions or factors that a health care provider determines might increase the risk of severe respiratory disease

For examples of medical conditions or treatments that may cause people to become moderate to severely immunocompromised, visit CDC's page, People Who Are Immunocompromised.

For additional guidance on the SCDM recommendation for RSV vaccination, and which patients are most likely to benefit from RSV vaccination, see CDC's provider job aid and the MMWR report on use of RSV vaccines in adults 60 years and older.

What should I tell patients about the side effects of RSV vaccine?

The most common side effects after RSV vaccination reported from clinical trials included pain, redness, and swelling where the shot is given, fatigue, fever, headache, nausea, diarrhea, and muscle or joint pain. These side effects were usually mild.

Serious neurologic events, including Guillain-Barré syndrome (GBS) and other inflammatory neurologic events, were reported after RSV vaccination in clinical trials. Whether these events occurred due to chance or whether RSV vaccination increases the risk for inflammatory neurologic events is currently unknown. Until additional evidence is available to clarify the risk of inflammatory neurologic events after vaccination, RSV vaccination in older adults should be directed to those who are at highest risk for severe RSV disease and therefore most likely to benefit from vaccination. As for all FDA-approved vaccines, CDC will conduct post-marketing safety surveillance to further inform RSV vaccine recommendations. For more information, see CDC's vaccine safety surveillance webpages.

How should I administer RSV vaccine?

You should administer either Arexvy (GSK adjuvanted RSV vaccine) or Abrysvo (Pfizer RSV vaccine) intramuscularly in the deltoid region of the upper arm with a 1- to 1.5-inch needle. For additional information on vaccine administration, see job aid on giving intramuscular vaccines to adults .

Do I need to reconstitute RSV vaccine?

Yes. Guidance below summarizes the preparation for both Arexvy (GSK adjuvanted RSV vaccine) or Abrysvo (Pfizer RSV vaccine). After reconstitution, both vaccines should be discarded if not used within 4 hours.

- **Arexvy (GSK)**
  - Prepare by reconstituting the lyophilized antigen component (a sterile white powder) with the accompanying adjuvant suspension component (an opalescent, colorless to pale brownish sterile liquid). The reconstituted vaccine should be an iridescent, colorless to pale brownish liquid. Either administer Arexvy immediately or store protected from light in the refrigerator (36°F to 46°F [2°C to 8°C]) or at room temperature up to 77°F (25°C) and use within 4 hours. Do not freeze reconstituted vaccine. Package Insert – AREXVY (fda.gov)

- **Abrysvo (Pfizer)**
  - Prepare by reconstituting the lyophilized antigen component (a sterile white powder) with the accompanying prefilled syringe containing sterile water diluent component. Either administer Abrysvo immediately or store at room temperature at 59°F to 86°F (15°C to 30°C) and use within 4 hours. Do not freeze reconstituted vaccine; **do not** store reconstituted vaccine under refrigerated conditions (36°F to 46°F [2°C to 8°C]). Use within 4 hours. Package Insert – ABRYSVO (fda.gov)

Where should I store RSV vaccine?

Storage for Arexvy (GSK adjuvanted RSV vaccine) and Abrysvo (Pfizer RSV vaccine) is as follows:

- **Arexvy**
  - Arexvy adjuvant suspension component vial and lyophilized antigen component vials must be refrigerated in the original package at temperature of 36°F to 46°F (2°C to 8°C). Protect vials from light. Do not freeze. Discard if the adjuvant suspension component or antigen component has been frozen. Package Insert – AREXVY (fda.gov)

- **Abrysvo**
  - Abrysvo kit (vial of lyophilized antigen component [a sterile white powder] and prefilled syringe containing sterile water and diluent component) must be refrigerated at 36°F to 46°F (2°C to 8°C) in the original carton. Do not freeze. Discard if any component has been frozen. Package Insert – ABRYSVO (fda.gov)

How many doses of RSV vaccine do I give?

So far, RSV vaccines appear to provide some protection for at least **two RSV seasons.** Additional surveillance and evaluation activities are planned to assess how long the vaccines protect against RSV and whether additional doses will be needed.

What is the best time of year to give RSV vaccine?

Optimally, vaccination should occur before the onset of the fall and winter RSV season. However, typical RSV seasonality was disrupted by the COVID-19 pandemic and has not returned to pre-pandemic patterns. For the 2023–24 RSV season, providers recommending RSV vaccine based on SCDM should administer RSV vaccine as early as vaccine supply becomes available.

Can I give RSV vaccine with other adult vaccines?

Administration of RSV vaccine on the same day with other adult vaccines is acceptable. However, according to results of coadministration studies of RSV vaccines with influenza vaccines, common side effects, such as fever and soreness at the injection site, may be increased when these two vaccines are administered on the same day. Some studies also suggest it's possible that the RSV and flu vaccines may not produce as strong of an immune response if they're given on the same day, but the clinical significance of this is unknown. Additional research is ongoing to further inform guidance on same-day administration of the RSV vaccine and other adult vaccines, including the COVID-19 vaccine.

Last Reviewed: August 30, 2023

For Healthcare Providers

Respiratory syncytial virus (RSV) is recognized as one of the most common causes of childhood illness and is the most common cause of hospitalization in infants. It causes annual outbreaks of respiratory illnesses in all age groups. 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 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 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

RSV Vaccines are available to protect older adults from severe RSV. Monoclonal antibody products are available to protect infants and young children from severe RSV. A healthcare provider's recommendation is one of the most important factors in whether patients choose to accept a new prevention product or vaccine.

Vaccines for Older Adults

New vaccines against RSV are available for adults 60 and older. CDC recommends that adults 60 and older may receive an RSV vaccine, using shared clinical decision-making. The decision to vaccinate an individual patient should be based on a discussion between the healthcare provider and the patient. It may be informed by the patient's risk of severe RSV disease and their characteristics, values, and preferences; the healthcare provider's clinical discretion; and the characteristics of the vaccine.

Healthcare providers should be aware of underlying conditions that may increase the risk of severe RSV illness, and who might be most likely to benefit from these new vaccines.

RSV vaccine is recommended as a single dose. Studies are ongoing to determine whether (and if so, when) revaccination may be needed.

Monoclonal Antibody Products for Infants and Young Children

Nirsevimab (Beyfortus) is a monoclonal antibody product designed to protect infants and young children at increased risk from severe RSV disease. It is administered by intramuscular injection. It is long-acting, providing protection for at least 5 months (the average length of one season), and only one dose is recommended for an RSV season. However, immune protection will wane over time. All infants younger than 8 months who are born during – or entering – their first RSV season should receive one dose of nirsevimab. For some children between the ages of 8 and 19 months who are at increased risk of severe RSV disease, a dose is recommended at the start of their second RSV season.

Palivizumab (Synagis) is a monoclonal antibody product recommended by the American Academy of Pediatrics (AAP) for administration to infants and young children who are at increased risk of severe RSV disease based on gestational age and certain underlying medical conditions. It is given in monthly intramuscular injections during RSV season. For the latest palivizumab guidance, please consult the AAP policy statement . An accompanying AAP technical report provides additional context and rationale for the guidance. Interim guidance addressing the disruption in typical RSV seasonal patterns during the pandemic has also been provided: Updated Guidance: Use of Palivizumab Prophylaxis to Prevent Hospitalization From Severe Respiratory Syncytial Virus Infection During the 2022-2023 RSV Season (aap.org)

Clinical Description and Diagnosis

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 with RSV infection may need to be hospitalized. Severe disease most commonly occurs in very young infants. Additionally, children with any of the following underlying conditions are considered at increased risk:

- Premature infants
- Infants, especially those 6 months and younger
- Children younger than 2 years old with chronic lung disease or congenital heart disease
- 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/or 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/or mechanical ventilation. Most improve with supportive care and are discharged in a few days.

In Older Adults and Adults with Chronic Medical Conditions

Adults who get infected with 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. Disease usually lasts less than 5 days.

Some adults, however, may have more severe symptoms consistent with a lower respiratory tract infection, such as pneumonia. Epidemiologic evidence indicates that people 60 and older who are at highest risk of severe RSV disease include those with any of the following chronic conditions:

- Lung disease (such as chronic obstructive pulmonary disease [COPD] and asthma)
- Chronic cardiovascular diseases (such as congestive heart failure and coronary artery disease)
- Diabetes mellitus
- Neurologic conditions
- Kidney disorders
- Liver disorders
- Hematologic disorders
- Immune compromise
- Other underlying conditions that a health care provider determines might increase the risk for severe respiratory disease

Other underlying factors that the provider determines might increase the risk of severe RSV-associated respiratory illness may include the following:

- Frailty
- Advanced age
- Residence in a nursing home or other long-term care facility
- Other underlying factors that a health care provider determines might increase the risk for severe respiratory disease

RSV can sometimes also lead to exacerbation of serious conditions such as:

- Asthma
- Chronic obstructive pulmonary disease (COPD)
- Congestive heart failure

Clinical Laboratory Testing

Clinical symptoms of RSV are nonspecific and can overlap with other viral respiratory infections, as well as some bacterial infections. Several types of laboratory tests are available for confirming RSV infection. These tests may be performed on upper and lower respiratory specimens.

The most commonly used types of RSV clinical laboratory tests are

- Real-time reverse transcription-polymerase chain reaction (rRT-PCR), which is more sensitive than culture and antigen testing
- Antigen testing, which is sensitive in children but less sensitive in adults

Less commonly used tests include:

- Viral culture
- Serology, which is usually only used for research and surveillance studies

Some tests can differentiate between RSV subtypes (A and B), but the clinical significance of these subtypes is unclear. Consult your laboratorian for information on what type of respiratory specimen is most appropriate to use.

For Infants and Young Children

Both rRT-PCR and antigen detection tests are effective methods for diagnosing RSV infection in infants and young children. The sensitivity of RSV antigen detection tests generally ranges from 80% to 90% in this age group. Healthcare providers should consult experienced laboratorians for more information on interpretation of results.

For Older Children, Adolescents, and Adults

Healthcare providers should use highly sensitive rRT-PCR assays when testing older children and adults for RSV. rRT-PCR assays are now commercially available for RSV. The sensitivity of these assays often exceeds the sensitivity of virus isolation and antigen detection methods. Antigen tests are not sensitive for older children and adults because they may have lower viral loads in their respiratory specimens. Healthcare providers should consult experienced laboratorians for more information on interpretation of results.

Related Links

Red Book® Online

Last Reviewed: August 4, 2023

Symptoms and Care

Symptoms

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. In very young infants with RSV, the only symptoms may be irritability, decreased activity, and breathing difficulties.

Almost all children will have had an RSV infection by their second birthday.

Call your healthcare professional if you or your child is 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 your child nonprescription cold medicines. Some medicines contain ingredients that are not good for children.

RSV can cause more serious health problems

RSV can also cause more severe infections such as bronchiolitis, an inflammation of the small airways in the lung, and pneumonia, an infection of the lungs. It is the most common cause of bronchiolitis and pneumonia in children younger than 1 year of age.

Healthy adults and infants infected with RSV do not usually need to be hospitalized. But some people with RSV infection, especially older adults and infants younger than 6 months of age, may need to be hospitalized if they are having trouble breathing or are dehydrated. In the most severe cases, a person may require additional oxygen, or IV fluids (if they can't eat or drink enough), or intubation (have a breathing tube inserted through the mouth and down to the airway) with mechanical ventilation (a machine to help a person breathe). In most of these cases, hospitalization only lasts a few days.

Learn more about people at high risk for severe RSV infection.

Transmission

How this virus spreads

Prevention

Ways to help stop RSV from spreading

Last Reviewed: August 16, 2023

Centers for Disease Control and Prevention

Morbidity and Mortality Weekly Report (*MMWR*)

Morbidity and Mortality Weekly Report (MMWR) Home

Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023

Weekly / August 25, 2023 / 72(34);920–925

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View suggested citation

Summary

What is already known about this topic?

In July 2023, the Food and Drug Administration approved nirsevimab, a long-acting monoclonal antibody, for prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in infants.

What is added by this report?

On August 3, 2023, the Advisory Committee on Immunization Practices recommended nirsevimab for infants aged <8 months born during or entering their first RSV season and for infants and children aged 8–19 months who are at increased risk of severe RSV disease entering their second RSV season.

What are the implications for public health practice?

Nirsevimab can prevent severe RSV disease among infants and children aged <20 months at increased risk for severe RSV disease.

Abstract

Respiratory syncytial virus (RSV) is the leading cause of hospitalization among U.S. infants. In July 2023, the Food and Drug Administration approved nirsevimab, a long-acting monoclonal antibody, for passive immunization to prevent RSV-associated lower respiratory tract infection among infants and young children. Since October 2021, the Advisory Committee on Immunization Practices (ACIP) Maternal and Pediatric RSV Work Group has reviewed evidence on the safety and efficacy of nirsevimab among infants and young children. On August 3, 2023, ACIP recommended nirsevimab for all infants aged <8 months who are born during or entering their first RSV season and for infants and children aged 8–19 months who are at increased risk for severe RSV disease and are entering their second RSV season. On the basis of pre–COVID-19 pandemic patterns, nirsevimab could be administered in most of the continental United States from October through the end of March. Nirsevimab can prevent severe RSV disease among infants and young children at increased risk for severe RSV disease.

Full Issue PDF

Introduction

In July 2023, the Food and Drug Administration (FDA) approved nirsevimab (Beyfortus, Sanofi and AstraZeneca), a long-acting monoclonal antibody, for the prevention of respiratory syncytial virus (RSV)–associated lower respiratory tract infection (LRTI) among infants and children aged <24 months (*1*).* Nirsevimab is administered as a 1-dose intramuscular injection shortly before or during the RSV season (typically fall through spring).† Since October 2021, the Advisory Committee on Immunization Practices (ACIP) Maternal and Pediatric RSV Work Group (Work Group) has reviewed data on RSV among infants and young children and evidence regarding the safety and efficacy of nirsevimab, and assessed the quality of the efficacy and safety evidence using the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) framework (*2*,*3*). The Evidence to Recommendation (EtR) Framework was used to develop recommendations (*4*,*5*). Evidence regarding potential use of nirsevimab was presented to ACIP at meetings during June 2022–August 2023. On August 3, 2023, ACIP recommended nirsevimab for infants aged <8 months who are born during or entering their first RSV season and for infants and children aged 8–19 months who are at increased risk for severe RSV disease and are entering their second RSV season.

RSV Among Infants and Young Children

RSV infection is the leading cause of hospitalization among U.S. infants (*6*); most children are infected during the first year of life, and nearly all have been infected by age 2 years (*7*,*8*). Infants with RSV infection frequently develop bronchiolitis, an LRTI that can be severe and result in hospitalization. Approximately 50,000–80,000 RSV-associated hospitalizations (*9*,*10*) and 100–300 RSV-associated deaths (*11*,*12*) occur annually among U.S. infants and children aged <5 years.

The rate of RSV-associated hospitalization among infants born at ≤30 weeks' gestation (premature) is three times that of term infants (*13*). Premature infants also have higher rates of RSV-associated intensive care unit (ICU) admission (*14*). Although prematurity is a recognized risk factor for RSV-associated hospitalization, RSV is also the leading cause of hospitalization among healthy term infants. An estimated 79% of infants and children aged <2 years hospitalized with RSV have no underlying medical conditions (*13*).

Before licensure of nirsevimab, the only FDA-approved product to prevent severe RSV disease among infants and young children was palivizumab, another monoclonal antibody. However, the American Academy of Pediatrics (AAP) recommends palivizumab only for children with certain underlying medical conditions (comprising <5% of all infants), and its use is further limited by high cost and the requirement for monthly dosing (*15*,*16*).

Methods

Since October 2021, the Work Group has conducted a systematic literature search and reviewed available evidence regarding the efficacy and safety of nirsevimab (*2*,*3*). The Work Group considered a priori outcomes that were critical or important to policy decisions.§ For infants born during or entering their first RSV season, evidence regarding efficacy and safety was derived from multicountry trials¶ that randomized infants, in a 2:1 ratio, to receive nirsevimab or placebo; a phase 2b trial that enrolled 1,453 preterm infants born at 29–34 weeks' gestation (phase 2b trial) (*17*); and a phase 3 trial that enrolled 3,012 late preterm and term infants born at ≥35 weeks' gestation (phase 3 trial) (*18*).** For children at increased risk for severe disease entering their second RSV season, evidence regarding efficacy and safety was obtained from a multicountry trial that randomized children to receive nirsevimab or palivizumab (*19*). The Work Group used the GRADE approach to assess the certainty of evidence for outcomes related to nirsevimab, rated on a scale of very low to high certainty (*2*,*3*). The Work Group then used the EtR Framework to guide its deliberations on recommendation of nirsevimab, reviewing data on the public health problem, benefits and harms, value to the target population, acceptability to key stakeholders, feasibility, resource use, and equity (*4*,*5*).

Nirsevimab Efficacy and Safety

Among infants aged <8 months who were born during or entering their first RSV season, efficacy was evaluated through 150 days after injection. For the GRADE assessment, results from the phase 3 and phase 2b trials were pooled (*17*,*18*). Only infants who received the recommended dose of nirsevimab were included in pooled estimates.†† Pooled efficacy in preventing medically attended RSV-associated LRTI§§ was 79.0% (95% CI = 68.5%–86.1%; 31 of 2,579 in nirsevimab arm and 80 of 1,293 in placebo arm), efficacy in preventing RSV-associated LRTI with hospitalization was 80.6% (95% CI = 62.3%–90.1%; 12 of 2,579 in nirsevimab arm and 33 of 1,293 in placebo arm), and efficacy in preventing RSV-associated LRTI with ICU admission was 90.0% (95% CI = 16.4%–98.8%; one of 2,579 in nirsevimab arm and six of 1,293 in placebo arm). No deaths attributable to RSV were reported in either trial.¶¶ The incidence of serious adverse events*** was not increased in the nirsevimab arm compared with that in the placebo arm.††† The overall evidence certainty using GRADE criteria was rated as moderate. The GRADE evidence

profile and supporting evidence for the EtR Framework are available at https://www.cdc.gov/vaccines/acip/recs/grade/nirsevimab-season1-rsv-infants-children.html and https://www.cdc.gov/vaccines/acip/recs/grade/nirsevimab-season1-rsv-infants-children-etr.html.

Among infants at increased risk for severe disease who are entering their second RSV season, evidence was derived from a single trial that enrolled 615 preterm infants born at <35 weeks' gestation who were eligible to receive palivizumab and 310 infants with either chronic lung disease requiring medical intervention within 6 months of randomization or hemodynamically significant congenital heart disease (CHD) (*19*). Participants were randomized to receive nirsevimab or palivizumab.[§§§] Efficacy against medically attended RSV-associated LRTI was extrapolated from pharmacokinetic data.[¶¶¶] Nirsevimab concentration levels among infants and children aged ≤24 months with chronic lung disease or CHD who received 200 mg nirsevimab entering their second RSV season were comparable to levels among those who received 50 mg if weighing <5 kg (<11 lb) and 100 mg if weighing ≥5 kg (≥11 lb) in their first RSV season. During the participants' second RSV season, the incidence of serious adverse events did not significantly differ between the nirsevimab and palivizumab arms. The overall evidence certainty using GRADE criteria was rated as very low. Because nirsevimab appears to have efficacy as high as, or higher than, palivizumab (although no head-to-head efficacy trials exist) (*20*), and is assumed to be less costly (*21*), replacing palivizumab with nirsevimab for the palivizumab-eligible children entering their second season is expected to be cost saving. The GRADE evidence profile and supporting evidence for the EtR Framework are available at https://www.cdc.gov/vaccines/acip/recs/grade/nirsevimab-season2-rsv-infants-children.html and https://www.cdc.gov/vaccines/acip/recs/grade/nirsevimab-season2-rsv-infants-children-etr.html.

Cost Effectiveness

The cost effectiveness for use of nirsevimab for infants aged <8 months born during or entering their first RSV season (at $445 per dose) was estimated to be $102,811 per quality adjusted life year (*21*). Because infants and children entering their second RSV season are at reduced risk for severe RSV disease compared with infants during their first RSV season, cost effectiveness for use of nirsevimab for the general population of children entering their second season (at $890 per dose)**** was estimated to be $1,557,544 per quality adjusted life year (*21*). Data to assess the incidence of severe RSV disease and death by type of chronic disease during their second RSV season are limited (*21*), as are data on efficacy and safety of nirsevimab among infants and children in their second RSV season.

Recommendations for Use of Nirsevimab

ACIP recommends 1 dose of nirsevimab for all infants aged <8 months born during or entering their first RSV season (50 mg for infants weighing <5 kg [<11 lb] and 100 mg for infants weighing ≥5 kg [≥11 lb]). ACIP recommends 1 dose of nirsevimab (200 mg, administered as two 100 mg injections given at the same time at different injection sites) for infants and children aged 8–19 months who are at increased risk for severe RSV disease and entering their second RSV season[††††] (Box). The recommendations for nirsevimab apply to infants and children recommended to receive palivizumab by AAP.[§§§§] These recommendations will be updated as new evidence becomes available.

Clinical Guidance

Timing of Nirsevimab Administration

Providers should administer nirsevimab to infants aged <8 months and to infants and children aged 8–19 months who are at increased risk for severe RSV disease beginning shortly before the start of the RSV season. On the basis of pre–COVID-19 pandemic patterns, nirsevimab could be administered in most of the continental United States from October through the end of March. Infants born shortly before or during the RSV season should receive nirsevimab within 1 week of birth. Nirsevimab administration can occur during the birth hospitalization or in the outpatient setting. Optimal timing for nirsevimab administration is shortly before the RSV season begins; however, nirsevimab may be administered to age-eligible infants and children who have not yet received a dose at any time during the season. Only a single dose of nirsevimab is recommended for an RSV season. Infants with prolonged birth hospitalizations related to prematurity or other causes should receive nirsevimab shortly before or promptly after hospital discharge.[¶¶¶¶] No evidence is available to support use of nirsevimab for prevention of hospital-acquired RSV infection, and nirsevimab is not recommended for this indication.

Because the timing of the onset, peak, and decline of RSV activity might vary geographically, providers can adjust administration schedules based on local epidemiology. RSV seasonality in tropical climates (including southern Florida, Guam, Hawaii, Puerto Rico, U.S.-affiliated Pacific Islands, and U.S. Virgin Islands) might differ from that of most of the continental

United States or be unpredictable (*21*–*23*). In Alaska, RSV seasonality is less predictable, and the duration of RSV activity is often longer than the national average duration (*24*). Providers in these jurisdictions should consult state, local, or territorial guidance on timing of nirsevimab administration.

Coadministration with Routine Childhood Vaccines

On the basis of limited data from clinical trials, coadministration of nirsevimab with routine vaccines resulted in a similar rate of adverse events compared with administration of vaccines alone (*25*). Nirsevimab is not expected to interfere with the immune response to other routine childhood immunizations (*26*). In accordance with general best practices for immunization, simultaneous administration of nirsevimab with age-appropriate vaccines is recommended (*27*).

Infants and Children Aged 8–19 Months at Increased Risk for Severe RSV Disease and Entering Their Second RSV Season

Infants and children aged 8–19 months who are at increased risk for severe RSV disease and who are entering their second RSV season (timing of season as defined above) are recommended to receive nirsevimab. Replacing palivizumab with nirsevimab is expected to be cost saving, and ACIP recommends nirsevimab for eligible children entering their second RSV season, similar to groups of children recommended by AAP for palivizumab during their second RSV season (*16*) (Box). In addition, research suggests that some American Indian or Alaska Native (AI/AN) children experience high rates of severe RSV disease. A recent study found that incidence of RSV-associated hospitalization among some AI/AN children aged 12–23 months was four to 10 times that of similar-aged children across seven sites in the United States (*28*). These studies have been limited to specific populations and might not be broadly representative of risk in all AI/AN children. Some AI/AN communities live in remote regions, making transportation of children with severe RSV more challenging (*16*). Given the available evidence, ACIP also recommends nirsevimab for AI/AN children entering their second RSV season.

Precautions and Contraindications

When administering nirsevimab to children with increased risk for bleeding, providers should follow ACIP's general best practice guidelines for immunization (*27*). Nirsevimab is contraindicated in persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a product component. Adverse reactions might occur after administration of nirsevimab alone; these reactions may be reported to MedWatch online (https://www.fda.gov/medwatch), by fax, by mail, or by contacting FDA at 1-800-FDA-1088.*****

Adverse reactions might occur after the coadministration of nirsevimab with a vaccine; these reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS), and reports should specify that the patient received nirsevimab on the VAERS form.†††† Reports can be submitted to VAERS online, by fax, or by mail. Additional information about VAERS is available by telephone (1-800-822-7967) or online (https://vaers.hhs.gov). When adverse reactions that occur after the coadministration of nirsevimab with a vaccine are reported to VAERS, additional reporting of the same adverse reactions to MedWatch is not necessary.

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***** https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-prevent-rsv-babies-and-toddlers

[†] The recommended dosage for infants born during or entering their first RSV season and weighing <5 kg (<11 lb) is 50 mg; for those weighing ≥5 kg (≥11 lb), the recommended dosage is 100 mg. The recommended dosage for infants and children aged 8–19 months at increased risk for severe disease entering their second RSV season is 200 mg (2 x 100 mg injections).

[§] Critical outcomes include medically attended RSV-associated LRTI, RSV-associated LRTI with hospitalization, RSV-associated LRTI with ICU admission, and RSV-associated death. Important outcomes include all-cause medically attended LRTI, all-cause LRTI-associated hospitalization, and serious adverse events.

[¶] Phase 2b trial locations: Argentina, Australia, Brazil, Bulgaria, Canada, Chile, Czechia, France, Hungary, Italy, New Zealand, Poland, Russia, South Africa, Spain, United Kingdom, and United States; phase 3: Austria, Belgium, Bulgaria, Canada, Czechia, Estonia, Finland, France, Germany, Israel, Japan, Latvia, Lithuania, Poland, Russia, South Africa, South Korea, Spain, Sweden, United Kingdom, and United States.

****** An additional trial was conducted that enrolled 615 preterm infants born at <35 weeks' gestation and who were eligible to receive palivizumab and 310 infants with either chronic lung disease and requiring medical intervention within 6 months of randomization or hemodynamically significant CHD. Participants were randomized (2:1) to either receive 1 dose of nirsevimab or monthly injections of palivizumab. The trial was designed as a pharmacokinetic study and was not designed to measure efficacy. A nirsevimab concentration target was established based on the phase 2b and phase 3 trials. The preterm, CHD, and chronic lung disease cohorts all met the threshold. In addition, day 150 postinjection concentrations in the increased risk trial were comparable or higher than in the phase 3 trial. This study did not meet criteria for inclusion in GRADE for efficacy of infants in their first RSV season because there was no placebo control group.

[††] In the phase 2b trial, all infants in the treatment arm received 50 mg nirsevimab. Among infants who weighed ≥5 kg (≥11 lb), nirsevimab concentrations and efficacy were found to be lower. In the phase 3 trial, the dose remained 50 mg for those who weighed <5 kg (<11 lb) and increased to 100 mg for those who weighed ≥5 kg (≥11 lb). Among 969 infants in the phase 2b trial treatment arm, 399 (41%) were excluded from pooled analyses.

§§ Medically attended LRTI was defined as at least one documented physical examination finding localized to the lower respiratory tract, clinical signs and symptoms of severe respiratory disease, an inpatient or outpatient encounter, and a positive RSV polymerase chain reaction test result.

¶¶ For benefit outcomes rated as important for policy decisions by the Work Group, nirsevimab lowered the risk for all-cause medically attended LRTI (efficacy = 34.8% [95% CI = 23.0%–44.7%]) and all-cause LRTI-associated hospitalization (efficacy = 44.9% [95% CI = 24.9%–59.6%]).

*** Serious adverse events were defined in the protocol as any adverse event that results in death, is immediately life-threatening, requires inpatient hospitalization or prolongs an existing hospitalization, results in persistent or significant disability/incapacity, or is an important medical event that might jeopardize the subject or might require medical intervention to prevent one of the outcomes listed.

††† No adverse events of anaphylaxis or immune complex disease were reported. Two adverse events of special interest, both thrombocytopenia, were reported. One event was diagnosed as heparin-induced thrombocytopenia, and one occurred in a patient with a diagnosis of sepsis; neither was assessed as being attributable to or related to nirsevimab. Among the initially enrolled 1,490 infants in the phase 3 trial, the incidence of medically attended RSV-associated LRTI 351–510 days after injection was not significantly different in the nirsevimab (0.7%) and control (0.2%) arms, suggesting that protection provided from nirsevimab does not result in a shift in the RSV burden to the second year of life. The incidence of new onset chronic disease was similar in the nirsevimab (0.3%) and placebo (0.4%) arms. Among all participants in the phase 2b and phase 3 trials, adverse events were reported in 1.2% of participants who received nirsevimab within 360 days of the injection. Most (97%) of these were mild to moderate in intensity. Adverse reactions that were more common among infants who received nirsevimab than placebo were rash occurring within 14 days of injection (0.9% of nirsevimab recipients versus 0.6% of placebo recipients) and injection site reactions occurring within 7 days of injection (0.3% of nirsevimab recipients versus 0% of placebo recipients).

§§§ Among infants in their first RSV season, those in the nirsevimab arm received 50 mg if they weighed <5 kg (<11 lb) and 100 mg if they weighed ≥5 kg (≥11 lb). Participants with chronic lung disease or CHD who received nirsevimab in season 1 also received nirsevimab in season 2, and those who received palivizumab in season 1 were rerandomized in a 1:1 ratio to receive nirsevimab or palivizumab in season 2. In season 2, nirsevimab was administered as a 200 mg dose followed by four monthly injections of placebo. Palivizumab was administered as 5 monthly 15 mg/kg doses.

¶¶¶ Pharmacokinetic extrapolation was used and based on comparable pharmacokinetic levels from efficacy data among infants aged <12 months for prevention of the first medically attended RSV-associated LRTI to pharmacokinetic levels among infants and children aged ≤24 months with chronic lung disease or CHD entering their second RSV season. On the basis of pharmacokinetic and efficacy data from the phase 2b and phase 3 (MELODY) trials, a target area under the curve nirsevimab concentration of >12.8 mg*day/mL was established. For the chronic lung disease cohort, 129 of 132 (98%) participants met the target nirsevimab concentration, and for the CHD cohort, all participants met the target. In addition, the concentration of nirsevimab 150 days after injection was higher compared with the 150-day concentration in the phase 3 trial nirsevimab arm population.

**** Assumes that the cost of 200 mg of nirsevimab will be twice that of 100 mg. The cost of 50 mg and 100 mg of nirsevimab was assumed to be the same. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-08-3/02-RSV-jones-508.pdf

†††† Infants and children aged ≥8 months have likely experienced an RSV season and are at decreased risk for severe RSV-associated disease compared with younger infants without previous RSV exposure. Children aged ≥20 months have likely experienced two RSV seasons and are at decreased risk for severe disease compared with younger children who have experienced only one RSV season.

§§§§ AAP has released guidance on the use of palivizumab and nirsevimab.
https://publications.aap.org/redbook/resources/25379

¶¶¶¶ Consistent with general best practices for immunization, the chronologic (not corrected) age of preterm infants should be used to determine timing and eligibility for nirsevimab administration.

***** Adverse events can be reported to MedWatch because FDA has classified nirsevimab as a drug.

ttttt Specifically, in Section 9: "Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination."

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BOX. Infants and children aged 8–19 months with increased risk for severe disease who are recommended to receive nirsevimab when entering their second respiratory syncytial virus season

Return

- Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season
- Children with severe immunocompromise
- Children with cystic fibrosis who have either 1) manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable), or 2) weight-for-length <10th percentile
- American Indian or Alaska Native children

Abbreviation: RSV = respiratory syncytial virus.

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RSV in Older Adults and Adults with Chronic Medical Conditions

RSV infections can be dangerous for certain adults. Each year, it is estimated that between 60,000-160,000 older adults in the United States are hospitalized and 6,000-10,000 die due to RSV infection. Adults at highest risk for severe RSV infection include:

- Older adults
- Adults with chronic heart or lung disease
- Adults with weakened immune systems
- Adults with certain other underlying medical conditions
- Adults living in nursing homes or long-term care facilities

An RSV vaccine protects against serious disease

RSV vaccine can help protect adults aged 60 years and older from RSV. Talk to your healthcare provider to see if vaccination is right for you.

Severe RSV Infection

When an adult gets RSV infection, they typically have mild cold-like symptoms, but some may develop a lung infection or pneumonia.

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
- Congestive heart failure – when the heart can't pump enough blood and oxygen through the body

Older adults who get very sick from RSV may need to be hospitalized. Some may even die. Older adults are at greater risk than young adults for serious complications from RSV because our immune systems weaken when we are older.

What you should do if you or a loved one is at high risk for severe RSV disease

RSV season in most regions of the U.S. starts in the fall and peaks in winter. If you are at high risk for severe RSV infection, or if you interact with an older adult, you should take extra care to keep them healthy:

- **Wash your hands often**
  Wash your hands often with soap and water for at least 20 seconds. If soap and water are not available, use an alcohol-based hand sanitizer. Washing your hands will help protect you from germs.
- **Keep your hands off your face**
  Avoid touching your eyes, nose, and mouth with unwashed hands. Germs spread this way.
- **Avoid close contact with sick people**
  Avoid close contact, such as kissing, and sharing cups or eating utensils with people who have cold-like symptoms.
- **Cover your coughs and sneezes**
  Cover your mouth and nose with a tissue or your upper shirt sleeve when coughing or sneezing. Throw the tissue in the trash afterward.
- **Clean and disinfect surfaces**
  Clean and disinfect surfaces and objects that people frequently touch, such as toys, doorknobs, and mobile devices. When people infected with RSV touch surfaces and objects, they can leave behind germs. Also, when they cough or sneeze, droplets containing germs can land on surfaces and objects.
- **Stay home when you are sick**
  If possible, stay home from work, school, and public areas when you are sick. This will help protect others from catching your illness.

Last Reviewed: July 14, 2023

Vaccines and Preventable Diseases

Healthcare Providers: RSV Vaccination for Adults 60 Years of Age and Over

Vaccine recommendations

There are two RSV vaccines licensed for use in adults aged 60 years and older in the United States: RSVPreF3 (Arexvy, GSK) and RSVpreF (Abrysvo, Pfizer). For additional details on the recommendations of the Advisory Committee on Immunization Practices (ACIP) for RSV vaccination, see Adult RSV ACIP Vaccine Recommendations | CDC.

Adults aged 60 years and older:

CDC recommends that adults 60 years of age and older may receive a single dose of RSV vaccine using shared clinical decision-making (SCDM). This means that health care providers and their patients should have a conversation to determine if RSV vaccination will be beneficial. This recommendation differs from routine age-based and risk-based vaccine recommendations for which the default decision is to vaccinate all persons in a specified age group or risk group. Under SCDM, there is no default. Rather, the decision whether to vaccinate a patient is individually based and informed by discussions between the patient and health care provider (anyone who provides or administers vaccines, including primary care physicians, specialists, physician assistants, nurse practitioners, registered nurses, and pharmacists).

The decision may be informed by a patient's health status, their risk of severe RSV disease (see Risk Factors for Severe RSV disease below), the health care provider's clinical judgment, the patient's preferences, the safety profile of the RSV vaccine products (see Vaccine Safety section below) and other factors. The SCDM recommendation for RSV vaccination is intended to allow providers and patients flexibility based on what is best for each individual patient.

Risk factors for severe RSV disease

Epidemiologic evidence indicates that persons aged 60 years and older who are at highest risk for severe RSV disease and who might be most likely to benefit from vaccination include those with chronic medical conditions such as:

- Cardiopulmonary disease,
- Kidney disorders,
- Liver disorders,
- Neurologic or neuromuscular conditions,
- Hematologic disorders,
- Diabetes mellitus, and
- Moderate or severe immune compromise (either attributable to a medical condition or receipt of immunosuppressive medications or treatment);

as well as:

- Persons who are frail*;
- persons of advanced age†;

- persons who reside in nursing homes or other long-term care facilities; and
- persons with other underlying conditions or factors that the provider determines might increase the risk for severe respiratory disease.

*Frailty is a multidimensional geriatric syndrome and reflects a state of increased vulnerability to adverse health outcomes. Although there is no consensus definition, one frequently used tool is the Fried frailty phenotype 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, and low physical activity.

†Among adults aged ≥60 years, RSV incidence increases with advancing age. Although age may be considered in determining an older adult patient's risk for severe RSV-associated disease, there is no specific age threshold at which RSV vaccination is more strongly recommended within the age group of adults aged ≥60 years.

To learn more about SCDM vaccination recommendations, see ACIP's webpage on the topic. For additional guidance on the SCDM recommendation for RSV vaccination, and which patients are most likely to benefit from RSV vaccination, see CDC's provider job aid and the MMWR report on use of RSV vaccines in adults 60 or older.

Timing of RSV vaccination and number of doses

Optimally, vaccination should occur before the onset of the fall and winter RSV season. However, typical RSV seasonality was disrupted by the COVID-19 pandemic and has not returned to pre-pandemic patterns. For the 2023–24 RSV season, providers should offer RSV vaccination as early as vaccine supply becomes available.

Currently, the RSV vaccine series consists of a **single dose**. Studies are ongoing to determine whether older adults might benefit from receiving additional RSV vaccines in the future. So far, RSV vaccines appear to provide some protection for at least two RSV seasons. Additional surveillance and evaluation activities are planned to assess how long the vaccines protect against RSV and whether additional doses will be needed.

Contraindications and precautions:

RSVPreF3 (Arexvy, GSK) should not be administered to a person with a history of severe allergic rection, such as anaphylaxis, to any component of this vaccine. Information about Arexvy can be found in the manufacturer's package insert .

RSVpreF (Abrysvo, Pfizer) should not be administered to a person with a history of severe allergic reaction, such as anaphylaxis, to any component of this vaccine. Information about Abrysvo can be found in the manufacturer's package insert.

Adults with a minor acute illness, such as a cold, can receive RSV vaccination. Moderate or severe acute illness, with or without fever, is a precaution to vaccination; vaccination should generally be deferred until the patient recovers.

To learn more, see ACIP Contraindications Guidelines for Immunization | CDC, General Best Practice Guidelines for Immunization.

Types and composition of RSV vaccines

In May 2023, the Food and Drug Administration (FDA) licensed two RSV vaccines for use in U.S. adults ages 60 years and older:

RSVPreF3 (Arexvy, GSK) consists of a recombinant RSV F protein antigen (based on the RSV-A subtype), stabilized in the prefusion conformation (preF), and $AS01_E$ adjuvant. The AS01 adjuvant system is the same used in GSK's recombinant zoster vaccine (RZV, Shingrix), but at a lower dose. The vaccine is supplied as a single-dose vial of 120 µg of lyophilized preF antigen component to be reconstituted with the accompanying vial of $AS01_E$ adjuvant suspension component. A single dose after reconstitution is 0.5 mL. Consult the package insert for proper storage and handling details, shelf life, and reconstitution instructions: Package Insert – AREXVY (fda.gov) .

RSVpreF (Abrysvo, Pfizer) consists of a recombinant RSV F protein antigen (based on both the RSV-A and RSV-B subtypes), stabilized in the prefusion conformation (preF). The vaccine is supplied as a single-dose vial of 120 μg of lyophilized preF antigen component (60 μg from RSV-A, 60 μg from RSV-B) to be reconstituted with the accompanying vial of sterile water diluent component. A single dose after reconstitution is approximately 0.5 mL. Consult the package insert for proper storage and handling details, shelf life, and reconstitution instructions: Package Insert – ABRYSVO (fda.gov) .

Vaccine efficacy

RSVPreF3 (Arexvy, GSK)

Vaccine efficacy data are available from one large phase 3 randomized, blinded, placebo-controlled clinical trial in participants aged 60 years and older (1–3). In this trial, a single dose of the GSK RSV vaccine reduced symptomatic RSV lower respiratory tract disease (LRTD) by 82.6% during the first RSV season after vaccination compared to a placebo, and by 56.1% during the second RSV season. Statistically significant efficacy against RSV LRTD was demonstrated in participant subgroups including those aged 70 years and older, those with and without at least one chronic medical condition, those classified as fit, and those classified as pre-frail. Due to insufficient participant enrollment among certain subgroups, the trial was underpowered to demonstrate efficacy against RSV LRTD in adults 80 years and older and those classified as frail.

Efficacy against medically attended RSV LRTD, inclusive of inpatient and outpatient medical attention, was similar to efficacy against all RSV LRTD. The trial was underpowered to demonstrate efficacy against RSV-associated hospitalization and RSV-associated death.

The duration of vaccine efficacy beyond two RSV seasons after vaccination is unknown.

RSVpreF (Abrysvo, Pfizer)

Vaccine efficacy data are available from one large phase 3 randomized, blinded, placebo-controlled clinical trial in participants aged 60 years and older (2–4). In this trial, a single dose of the Pfizer RSV vaccine reduced RSV lower respiratory tract illness (LRTI) with 3 or more lower respiratory signs and symptoms by 88.9% during the first RSV season after vaccination compared to a placebo, and by 78.6% during a partial second RSV season (interim estimate; the second season efficacy will be updated upon study completion). Statistically significant efficacy against 3-symptom RSV LRTI was demonstrated in participant subgroups including those aged 70 years and older, and those with and without at least one chronic medical condition. Due to insufficient enrollment of participants aged 80 years and older, the trial was underpowered to demonstrate efficacy against RSV LRTI in this age group. Participant frailty was not assessed in this clinical trial.

Efficacy against medically attended RSV LRTI, inclusive of inpatient and outpatient medical attention, was similar to efficacy against all RSV LRTI. The trial was underpowered to demonstrate efficacy against RSV-associated hospitalization and RSV-associated death.

The duration of vaccine efficacy beyond two RSV seasons after vaccination is unknown.

Vaccine safety

RSVPreF3 (Arexvy, GSK)

In clinical trials, most adults aged 60 years and older who received the GSK RSV vaccine experienced vaccine-related reactions. The most common reactions in the large phase 3 clinical trial were pain at the injection site (61%), fatigue (34%), myalgia (29%), and headache (27%) (1). Grade 3 reactions (severe enough to prevent normal daily activities) occurred in 4% of vaccine recipients.

Across all clinical trials in adults aged 60 years and older, inflammatory neurologic events were reported in three of 17,922 participants within 42 days after receipt of the GSK RSV vaccine (2). All three events occurred in trials without a placebo arm. The reported cases included one case of Guillain-Barré syndrome (GBS) with symptom onset 9 days postvaccination in an open-label phase 3 clinical trial and two cases of acute disseminated encephalomyelitis (ADEM) among participants in a randomized phase 3 coadministration study. The two ADEM cases were reported in participants after concomitant receipt of the GSK RSV vaccine and standard dose seasonal influenza vaccine; symptom onset occurred 7 and 22 days postvaccination,

and one case was fatal. In both ADEM cases, the diagnosis was based on symptoms and clinical findings only; diagnostic testing (including brain imaging, cerebrospinal fluid testing, and nerve conduction studies) was not performed, leading to uncertainty in the diagnoses. The site investigator in the fatal case later revised the diagnosis from ADEM to hypoglycemia and dementia.

In the large phase 3 clinical trial, a higher number of participants who received the GSK RSV vaccine than those who received placebo reported atrial fibrillation within 30 days after injection (10 vs. 4 participants) (2).

RSVpreF (Abrysvo, Pfizer)

In clinical trials among adults aged 60 years and older, vaccine-related reactions were common among participants who received the Pfizer RSV vaccine. The most common reactions in the large phase 3 clinical trial were fatigue (16%), headache (13%), and pain at the injection site (11%) (4). Grade 3 reactions (severe enough to prevent normal daily activities) occurred in approximately 1% of vaccine recipients.

Across all clinical trials in adults aged 60 years and older, inflammatory neurologic events were reported in three of 20,255 participants within 42 days after receipt of the Pfizer RSV vaccine (2). The events included one case of GBS with symptom onset 14 days postvaccination, one case of Miller Fisher syndrome (a GBS variant) with symptom onset 10 days postvaccination; and one case of undifferentiated motor-sensory axonal polyneuropathy with worsening of preexisting symptoms 21 days postvaccination.

In the large phase 3 clinical trial, a higher number of participants who received the Pfizer RSV vaccine than those who received placebo reported atrial fibrillation within the 30 days after injection (10 vs. 4 participants) (2).

Ongoing Studies and Surveillance

Due to the small number of inflammatory neurologic events and atrial fibrillation events in the clinical trials, it is not known at this time whether these events occurred due to random chance, or whether RSV vaccination increases the risk of these events. According to FDA post-marketing requirements and commitments, both manufacturers will conduct safety studies to evaluate the risk of these adverse events following RSV vaccination. CDC will also monitor adverse events, including cases of GBS, ADEM, and other inflammatory neurologic events following RSV vaccination through its vaccine safety surveillance systems. This information will be updated with results from post-marketing safety studies and from vaccine safety surveillance, as they become available.

For more information on vaccine safety, see Vaccine Information and Safety Studies | Vaccine Safety | CDC.

Adverse events after RSV vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS), even if it is not clear that the vaccine caused the adverse event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov/index.html or by telephone at 1-800-822-7967.

References

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Storage and handling for RSV vaccines

Proper vaccine storage and handling practices play an important role in protecting individuals and communities from vaccine-preventable diseases. For general recommendations and guidance, see Vaccine Storage and Handling. Provided below is guidance specific to RSV vaccines.

RSVPreF3 (Arexvy, GSK):

GSK's vaccine is supplied in two vials that must be reconstituted prior to administration. One vial is a lyophilized antigen component and the second is a liquid diluent adjuvant suspension. You MUST use the diluent provided by the manufacturer. Refer to the manufacturer's package insert for specific instructions on reconstituting the vaccine: Package Insert – AREXVY (fda.gov) .

Before reconstitution:

- Store vaccine and diluent refrigerated between 2°C and 8°C (36°F and 46°F).
  - Store these in their original package and keep them together in the refrigerator to optimize organization.
- Never freeze the vaccine or diluent.
- Protect the vial from light.

After reconstitution:

- Immediately administer the vaccine; you should prepare the vaccine only when ready for use.
- If you do not immediately administer the vaccine, there are some minor differences in storage:
  - Store the reconstituted refrigerated between 2°C and 8°C (36°F and 46°F) **OR at room temperature** [up to 25°C (77°F)]. The difference is due to the allowance of storage at room temperature.
  - Never freeze the reconstituted vaccine, and
  - Protect it from light.
- Once you've reconstituted the vaccine, you begin a 4-hour beyond-use date clock. This means that you must use the reconstituted vaccine within 4 hours; otherwise discard it.

RSVpreF (Abrysvo, Pfizer):

Pfizer's vaccine is supplied in a kit with three components: a vial of Lyophilized Antigen Component (a sterile white powder), a prefilled syringe containing Sterile Water Diluent Component, and a vial adapter. Refer to the manufacturer's package insert for specific instructions on reconstituting the vaccine: Package Insert – ABRYSVO (fda.gov) .

Before reconstitution:

- Store vaccine and diluent refrigerated between 2°C and 8°C (36°F and 46°F).
  - Store these components in their original package and keep them together in the refrigerator to optimize organization.
- Never freeze the vaccine or diluent.

After reconstitution:

- Immediately administer the vaccine; you should prepare the vaccine only when ready for use. If you do not immediately administer the vaccine, there are some minor differences in storage:
  - Store the reconstituted vaccine **ONLY at room temperature** [15^0C to 30^0C (59^0F to 86^0F)].
  - Do **NOT** This is very different than other reconstituted vaccines. Typically, storage after reconstitution is refrigerated storage only or refrigerated or room temperature storage. For this vaccine, do NOT put it back in the refrigerator.
  - Never freeze the vaccine or diluent.
- Once you've reconstituted the vaccine, you begin a 4-hour beyond-use date clock. This means that you must use the reconstituted vaccine within 4 hours; otherwise discard it.

Administering RSV vaccines

This page provides a summary of guidance for administering FDA-licensed RSV vaccines for use in U.S. adults aged 60 years and older RSV vaccines, including route, number of doses, and co-administration with other vaccines.

Do not use any RSV vaccine beyond the expiration date printed on the label.

Route

Administer RSV vaccine intramuscularly. The preferred site of administration is the deltoid region of the upper arm. Do not administer RSV vaccine intravenously, intradermally, or subcutaneously.

Number and Timing of Doses

RSV vaccination is currently approved and recommended for administration as a single dose; sufficient evidence does not exist at this time to determine the need for revaccination. Optimally, vaccination should occur before the onset of the RSV season; however, typical RSV seasonality was disrupted by the COVID-19 pandemic and may be gradually returning to pre-pandemic patterns. For the 2023–24 season, clinicians should offer RSV vaccination to adults aged 60 years and older using shared clinical decision-making as early as vaccine supply becomes available and should continue to offer vaccination year-round to eligible adults who remain unvaccinated.

Administration with other vaccines

Coadministration of RSV vaccines with other adult vaccines during the same visit is acceptable. Available data on immunogenicity of coadministration of RSV vaccines and other vaccines are currently limited. Coadministration of RSV and seasonal influenza vaccines met noninferiority criteria for immunogenicity with the exception of the FluA/Darwin H3N2 strain when the GSK RSV vaccine was coadministered with adjuvanted quadrivalent inactivated influenza vaccine. RSV and influenza antibody titers were somewhat lower with coadministration; however, the clinical significance of this is unknown.

Administering RSV vaccine with one or more other vaccines at the same visit might increase local or systemic reactogenicity. Data are only available for coadministration of RSV and influenza vaccines, and evidence is mixed regarding increased reactogenicity. Data are lacking on the safety of coadministration with other vaccines that might be recommended for persons in this age group, such as COVID-19 vaccines; pneumococcal vaccines; adult tetanus, diphtheria, and pertussis vaccines; and the recombinant zoster vaccine (the recombinant zoster vaccine and GSK's RSV vaccine contains the same adjuvant). When deciding whether to coadminister other vaccines with an RSV vaccine, providers should consider whether the patient is up to date with currently recommended vaccines, the feasibility of the patient returning for additional vaccine doses, risk for acquiring vaccine-preventable disease, vaccine reactogenicity profiles, and patient preferences. Post-licensure efficacy and safety monitoring of coadministered RSV vaccines with other vaccines will further direct guidance.

Resources

Recommendations for RSV Vaccination

- Adult RSV ACIP Vaccine Recommendations | CDC

Clinician Education

- Clinician job aid to implement shared clinical decision-making for RSV vaccination
- RSV Clinical Overview

Materials for Patients

- CDC RSV Website
- RSV Vaccine Information Statement

References and Resources

- Melgar M, Britton A, Roper LE, et al. Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023. MMWR Morb Mortal Wkly Rep 2023;72:793–801. DOI: http://dx.doi.org/10.15585/mmwr.mm7229a4 .
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- CDC RSV Surveillance & Research

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Centers for Disease Control and Prevention

Morbidity and Mortality Weekly Report (*MMWR*)

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Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023

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View suggested citation

Summary

What is already known about this topic?

Respiratory syncytial virus (RSV) causes substantial morbidity and mortality in older adults. In May 2023, the Food and Drug Administration approved the first two vaccines for prevention of RSV lower respiratory tract disease (LRTD) for use in adults aged ≥60 years.

What is added by this report?

For both vaccine products, vaccination with a single RSV vaccine dose demonstrated moderate to high efficacy in preventing symptomatic RSV-associated LRTD among adults aged ≥60 years. On June 21, 2023, the Advisory Committee on Immunization Practices recommended that persons aged ≥60 years may receive a single dose of RSV vaccine, using shared clinical decision-making.

What are the implications for public health practice?

RSV vaccination might prevent substantial morbidity in older adults at risk for severe RSV disease; postmarketing surveillance for safety and effectiveness will direct future guidance.

Abstract

Respiratory syncytial virus (RSV) is a cause of severe respiratory illness in older adults. In May 2023, the Food and Drug Administration approved the first vaccines for prevention of RSV-associated lower respiratory tract disease in adults aged ≥60 years. Since May 2022, the Advisory Committee on Immunization Practices (ACIP) Respiratory Syncytial Virus Vaccines Adult Work Group met at least monthly to review available evidence regarding the safety, immunogenicity, and efficacy of these vaccines among adults aged ≥60 years. On June 21, 2023, ACIP voted to recommend that adults aged ≥60 years may receive a single dose of an RSV vaccine, using shared clinical decision-making. This report summarizes the body of evidence considered for this recommendation and provides clinical guidance for the use of RSV vaccines in adults aged ≥60 years. RSV vaccines have demonstrated moderate to high efficacy in preventing RSV-associated lower respiratory tract disease and have the potential to prevent substantial morbidity and mortality among older adults; postmarketing surveillance will direct future guidance.

Introduction

In the United States, respiratory syncytial virus (RSV) causes seasonal epidemics of respiratory illness. Although the COVID-19 pandemic interrupted seasonal RSV circulation, the timing and number of incident cases of the 2022–23 fall and winter epidemic suggested a likely gradual return to prepandemic seasonality (*1*).

Each season, RSV causes substantial morbidity and mortality in older adults, including lower respiratory tract disease (LRTD), hospitalization, and death. Incidence estimates vary widely and are affected by undertesting and potentially low sensitivity of standard diagnostic testing among adults (*2*–*5*). Most adult RSV disease cases occur among older adults with an estimated 60,000–160,000 hospitalizations and 6,000–10,000 deaths annually among adults aged ≥65 years (*5*–*10*).

Adults with certain medical conditions, including chronic obstructive pulmonary disease, asthma, congestive heart failure, coronary artery disease, cerebrovascular disease, diabetes mellitus, and chronic kidney disease, are at increased risk for RSV-associated hospitalization (*11*–*13*), as are residents of long-term care facilities (*14*), and persons who are frail* or of advanced age (incidence of RSV-associated hospitalization among adults increases with age, with the highest rates among those aged ≥75 years) (*6*,*15*). RSV can also cause severe disease in persons with compromised immunity, including recipients of hematopoietic stem cell transplantation and patients taking immunosuppressive medications (e.g., for solid organ transplantation, cancer treatment, or other conditions) (*16*,*17*).

In May 2023, the Food and Drug Administration (FDA) approved the first vaccines for prevention of RSV-associated LRTD in adults aged ≥60 years. RSVPreF3 (Arexvy, GSK) is a 1-dose (0.5 mL) adjuvanted ($AS01_E$) recombinant stabilized prefusion F protein (preF) vaccine (*18*). RSVpreF (Abrysvo, Pfizer) is a 1-dose (0.5 mL) recombinant stabilized preF vaccine (*19*).

Methods

Since May 2022, CDC's Advisory Committee on Immunization Practices (ACIP) RSV Vaccines Adult Work Group (Work Group) met at least monthly to review available evidence regarding the safety, immunogenicity, and efficacy of the GSK and Pfizer RSV vaccines among adults aged ≥60 years. A systematic review of published and unpublished evidence of the efficacy and safety of these vaccines among persons aged ≥60 years was conducted. The body of evidence consisted of one phase 3 randomized controlled trial and one combined phase 1 and 2 (phase 1/2) randomized controlled trial for each vaccine. The Work Group used the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach to independently determine the certainty of evidence for outcomes related to each vaccine, rated on a scale of high to very low certainty.[†] In evaluating safety, the Work Group defined inflammatory neurologic events as cases of Guillain-Barré syndrome (GBS), chronic inflammatory demyelinating polyneuropathy, and acute central nervous system inflammation (e.g., transverse myelitis or acute disseminated encephalomyelitis [ADEM]) occurring within 42 days after vaccination. The Work Group then employed the Evidence to Recommendation Framework to guide its deliberations on recommendation for RSV vaccination, reviewing data on the public health problem, benefits and harms, value to the target population, acceptability to key stakeholders, feasibility, resource use, and equity.[§] Work Group conclusions regarding evidence for the use of RSV vaccines among adults aged ≥60 years were presented to ACIP at public meetings on February 23 and June 21, 2023 (*10*,*15*).

Vaccine Efficacy and Safety

GSK Vaccine

Evaluated efficacy evidence for the GSK RSV vaccine consisted of data from one ongoing randomized, double-blind, placebo-controlled phase 3 clinical trial conducted in 17 countries and including 24,973 immunocompetent participants aged ≥60 years randomized 1:1 to receive 1 dose of vaccine (intervention group, 120 μg preF protein with $AS01_E$ adjuvant) or saline placebo (control group) (*20*). Efficacy findings were based on analyses of data collected during May 2021–March 2023, which included two complete RSV seasons for Northern Hemisphere participants and one complete RSV season for Southern Hemisphere participants. Efficacy analyses for season one spanned May 2021–April 2022, while efficacy analyses for season two spanned August 2022–March 2023; exact study-defined season dates were site-dependent. Mean time from vaccination to end of efficacy follow-up across both seasons was approximately 15 months per participant.

The efficacy of 1 dose of the GSK vaccine in preventing symptomatic, laboratory-confirmed RSV-associated LRTD[¶] was 82.6% (96.95% CI = 57.9%–94.1%) during the first RSV season and 56.1% (95% CI = 28.2%–74.4%) during the second season (Table 1).** Efficacy of 1 dose over two seasons was 74.5% (97.5% CI = 60.0%–84.5%) in preventing RSV-associated LRTD and 77.5% (95% CI = 57.9%–89.0%) in preventing medically attended RSV-associated LRTD.[††] The study was not powered to estimate efficacy against hospitalization (intervention group = one event; control group = five events), severe RSV illness requiring respiratory support (intervention group = one event; control group = five events),[§§] or death (no events).[¶¶]

Evidence regarding safety of the GSK vaccine consisted of data from two randomized, double-blind, placebo-controlled clinical trials, including the same ongoing phase 3 trial (*20*) and a phase 1/2 trial with 201 participants aged ≥60 years who received either the vaccine formulation used in phase 3 or placebo (*21*). Across both clinical trials, severe reactogenicity events (grade 3 solicited local or systemic reactions recorded during days 0–4 [phase 3 trial] and days 0–7 [phase 1/2 trial] after vaccination) occurred in 3.8% of the intervention group participants, compared with 0.9% of the control group participants (pooled relative risk [RR] = 4.10; 95% CI = 1.99–8.45) (Table 2). The frequency of serious adverse events (SAEs)*** across both trials was similar in the intervention (4.4%) and control (4.3%) groups (pooled RR = 1.02; 95% CI = 0.91–1.15). A higher number of participants in the intervention group than in the control group reported atrial fibrillation as an unsolicited event within the 30 days after injection (intervention = 10 events [0.1%]; control = four events [<0.1%]), eight of which were SAEs [intervention = seven; control = one]; three of the SAEs corresponded to new onset atrial fibrillation (intervention = two; control = one) (*22*).

Across all GSK vaccine clinical trials in older adults, inflammatory neurologic events were reported in three of 17,922 participants within 42 days after receipt of the GSK vaccine (*23*). All three events occurred in trials excluded from GRADE because of lack of an unvaccinated comparator arm. The reported cases included one case of GBS in a participant aged 78 years from Japan with symptom onset 9 days postvaccination in an open-label phase 3 clinical trial and two cases of ADEM among participants in a randomized phase 3 coadministration study (*15*,*22*). The two ADEM cases were reported in participants aged 71 years from the same site in South Africa after concomitant receipt of the GSK vaccine and standard dose seasonal influenza vaccine; symptom onset occurred 7 and 22 days postvaccination, and one case was fatal. In both ADEM cases, the diagnosis was based on symptoms and clinical findings only; diagnostic testing (including brain imaging, cerebrospinal fluid testing, and nerve conduction studies) was not performed, leading to uncertainty in the diagnoses. The investigator in the fatal case later revised the diagnosis from ADEM to hypoglycemia and dementia (*15*,*22*).

Pfizer Vaccine

Evaluated efficacy evidence for the Pfizer vaccine consisted of data from one ongoing, randomized, double-blind, placebo-controlled phase 3 clinical trial conducted in seven countries and including 36,862 immunocompetent participants aged ≥60 years randomized 1:1 to receive 1 dose of vaccine (intervention group, 120 μg preF protein) or placebo containing the same buffer ingredients as the vaccine but without active components (control group) (*24*). Efficacy findings were based on analyses of data collected during August 2021–January 2023, which included one complete RSV season for Northern and Southern Hemisphere participants and a partial second season for Northern Hemisphere participants only. Efficacy analyses for season one spanned August 2021–October 2022, while efficacy analyses for season two spanned July 2022–January 2023; exact study-defined season dates were site-dependent. Mean follow-up time from vaccination to end of efficacy follow-up across both seasons, including a gap in RSV surveillance between the first and second RSV seasons, was approximately 12 months per participant.

Efficacy of 1 dose of the Pfizer vaccine in preventing symptomatic, laboratory-confirmed RSV-associated LRTD[†††] was 88.9% (95% CI = 53.6%–98.7%) during the first RSV season and 78.6% (95% CI = 23.2%–96.1%) during the partial second season (Table 3).[§§§] Efficacy of a single dose over two seasons was 84.4% (95% CI = 59.6%–95.2%) in preventing RSV-associated LRTD and

81.0% (95% CI = 43.5%–95.2%) in preventing medically attended RSV-associated LRTD.[¶¶¶] The study was not powered to estimate efficacy against hospitalization (intervention group = one event; control group = three events), severe RSV illness requiring respiratory support (intervention group = one event; control group = one event),**** or death (no events).[††††]

Evidence regarding safety of the Pfizer vaccine consisted of data from two randomized, double-blind, placebo-controlled clinical trials, including the same ongoing phase 3 trial (*24*), and a phase 1/2 trial with 91 participants aged ≥65 years who received either the vaccine formulation used in phase 3 or placebo (*25*). Across both clinical trials, severe reactogenicity events (grade 3 or higher local or systemic reactions recorded during days 0–7 after vaccination) occurred in 1.0% of the intervention group participants, compared with 0.7% of the control group participants (pooled RR = 1.43; 95% CI = 0.85–2.39) (Table 4). The frequency of SAEs across both trials was similar in the intervention (4.3%) and control (4.1%) groups (pooled RR = 1.04; 95% CI = 0.94–1.15). A higher number of participants in the intervention group than in the control group reported atrial fibrillation as an unsolicited event within the 30 days after injection (intervention = 10 events [<0.1%]; control = four events [<0.1%], of which seven were SAEs [intervention = four; control = three]). Among participants who reported atrial fibrillation, a medical history of atrial fibrillation was reported by six of 10 Pfizer vaccine recipients and two of four placebo recipients (*26*).

Across all Pfizer vaccine clinical trials among older adults, inflammatory neurologic events were reported in three of 20,255 participants within 42 days after receipt of the vaccine (*15*,*26*,*27*). The events included GBS in a participant aged 66 years from the United States with symptom onset 14 days postvaccination; Miller Fisher syndrome (a GBS variant) in a participant aged 66 years from Japan with symptom onset 10 days postvaccination; and undifferentiated motor-sensory axonal polyneuropathy with worsening of preexisting symptoms 21 days postvaccination in a participant aged 68 years from Argentina (*15*,*26*,*27*).

Rationale for Recommendations

Vaccination with a single dose of the GSK or Pfizer RSV vaccines demonstrated moderate to high efficacy in preventing symptomatic RSV-associated LRTD over two consecutive RSV seasons among adults aged ≥60 years. Although trials were underpowered to estimate efficacy against RSV-associated hospitalization and death, prevention of LRTD, including medically attended LRTD, suggests that vaccination might prevent considerable morbidity from RSV disease among adults aged ≥60 years.

Although both vaccines were generally well-tolerated with an acceptable safety profile, six cases of inflammatory neurologic events (including GBS, ADEM, and others) were reported after RSV vaccination in clinical trials. Whether these events occurred due to chance, or whether RSV vaccination increases the risk for inflammatory neurologic events is currently unknown. Until additional evidence becomes available from postmarketing surveillance clarifying the existence of any potential risk, RSV vaccination in older adults should be targeted to those who are at highest risk for severe RSV disease and therefore most likely to benefit from vaccination. The recommendation for shared clinical decision-making is intended to allow flexibility for providers and patients to consider individual risk for RSV disease, while taking into account patient preferences.

Recommendations for Use of RSV Vaccines in Older Adults

On June 21, 2023, ACIP recommended that adults aged ≥60 years may receive a single dose of RSV vaccine, using shared clinical decision-making.[§§§§]

Clinical Guidance

Shared Clinical Decision-Making for Adults Aged ≥60 years. Unlike routine and risk-based vaccine recommendations, recommendations based on shared clinical decision-making do not target all persons in a particular age group or an identifiable risk group. For RSV vaccination, the decision to vaccinate a patient should be based on a discussion between the health care provider and the patient, which might be guided by the patient's risk for disease and their characteristics, values, and preferences; the provider's clinical discretion; and the characteristics of the vaccine.

As part of this discussion, providers and patients should consider the patient's risk for severe RSV-associated disease. Epidemiologic evidence indicates that persons aged ≥60 years who are at highest risk for severe RSV disease and who might be most likely to benefit from vaccination include those with chronic medical conditions such as lung diseases, including chronic obstructive pulmonary disease and asthma; cardiovascular diseases such as congestive heart failure and coronary artery disease; moderate or severe immune compromise (either attributable to a medical condition or receipt of immunosuppressive medications or treatment)[¶¶¶¶]; diabetes mellitus; neurologic or neuromuscular conditions; kidney

disorders, liver disorders, and hematologic disorders; persons who are frail; persons of advanced age; and persons with other underlying conditions or factors that the provider determines might increase the risk for severe RSV-associated respiratory disease (Box). Adults aged ≥60 years who are residents of nursing homes and other long-term care facilities are also at risk for severe RSV disease. It should be noted that the numbers of persons enrolled in the trials who were frail, were of advanced age, and lived in long-term care facilities were limited, and persons with compromised immunity were excluded (some of whom might have an attenuated immune response to RSV vaccination). However, adults aged ≥60 years in these populations may receive vaccination using shared clinical decision-making given the potential for benefit.

RSV Vaccination Timing

RSV vaccination is currently approved and recommended for administration as a single dose; sufficient evidence does not exist at this time to determine the need for revaccination. Optimally, vaccination should occur before the onset of the RSV season; however, typical RSV seasonality was disrupted by the COVID-19 pandemic and has not returned to prepandemic patterns. For the 2023–24 season, clinicians should offer RSV vaccination to adults aged ≥60 years using shared clinical decision-making as early as vaccine supply becomes available and should continue to offer vaccination to eligible adults who remain unvaccinated.

Vaccine Administration, Including Coadministration with Other Vaccines

Coadministration of RSV vaccines with other adult vaccines during the same visit is acceptable.***** Available data on immunogenicity of coadministration of RSV vaccines and other vaccines are currently limited. Coadministration of RSV and seasonal influenza vaccines met noninferiority criteria for immunogenicity with the exception of the FluA/Darwin H3N2 strain when the GSK RSV vaccine was coadministered with adjuvanted quadrivalent inactivated influenza vaccine (*28*,*29*). RSV and influenza antibody titers were somewhat lower with coadministration; however, the clinical significance of this is unknown.

Administering RSV vaccine with one or more other vaccines at the same visit might increase local or systemic reactogenicity. Data are only available for coadministration of RSV and influenza vaccines, and evidence is mixed regarding increased reactogenicity. Data are lacking on the safety of coadministration with other vaccines that might be recommended for persons in this age group, such as COVID-19 vaccines; pneumococcal vaccines; adult tetanus, diphtheria, and pertussis vaccines; and the recombinant zoster vaccine (the recombinant zoster vaccine and GSK's RSV vaccine contains the same adjuvant). When deciding whether to coadminister other vaccines with an RSV vaccine, providers should consider whether the patient is up to date with currently recommended vaccines, the feasibility of the patient returning for additional vaccine doses, risk for acquiring vaccine-preventable disease, vaccine reactogenicity profiles, and patient preferences. Postlicensure efficacy and safety monitoring of coadministered RSV vaccines with other vaccines will further direct guidance.

Precautions and Contraindications

As with all vaccines, RSV vaccination should be delayed for persons experiencing moderate or severe acute illness with or without fever (precaution). RSV vaccines are contraindicated for and should not be administered to persons with a history of severe allergic reaction, such as anaphylaxis, to any component of the vaccine (*30*,*31*).

Reporting of Vaccine Adverse Events

Adverse events after vaccination should 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 https://vaers.hhs.gov/index.html or by telephone at 1-800-822-7967.

Future Research and Monitoring Priorities

CDC will monitor adverse events, including cases of GBS, ADEM, and other inflammatory neurologic events after RSV vaccination through VAERS and the Vaccine Safety Datalink https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html). CDC will also prioritize estimating vaccine effectiveness against RSV-associated hospitalization. These data will be evaluated by CDC and ACIP as soon as they are available.

According to FDA postmarketing requirements and commitments, GSK will conduct a study evaluating risk for GBS, ADEM, and atrial fibrillation after vaccination with RSVPreF3 (*18*). Pfizer will conduct two studies, one evaluating risk for GBS and a second evaluating risk for atrial fibrillation after vaccination with RSVpreF (*19*). Pfizer will also evaluate the safety and immunogenicity of a second RSVpreF dose in a subset of participants in the main phase 3 trial; GSK will evaluate safety, immunogenicity, and efficacy of RSVPreF3 revaccination as part of its main phase 3 trial.

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* Frailty is a multidimensional geriatric syndrome and reflects a state of increased vulnerability to adverse health outcomes. Although there is no consensus definition, one frequently used tool is the Fried frailty phenotype in which frailty is defined as a clinical syndrome with three or more of the following signs or symptoms: unintentional weight loss (10 lbs [4.5 kg] in the past year), self-reported exhaustion, weakness (grip strength), slow walking speed, and low physical activity.

† GRADE tables are available online for both the GSK RSV vaccine (https://www.cdc.gov/vaccines/acip/recs/grade/GSK-Adjuvanted-RSVPreF3-adults.html) and the Pfizer RSV vaccine (https://www.cdc.gov/vaccines/acip/recs/grade/Pfizer-Bivalent-RSVpreF-adults.html). For the GSK RSV vaccine, the efficacy estimates presented differ slightly from efficacy estimates included in the GRADE tables because the manufacturer used a different method from CDC to calculate vaccine efficacy. Estimates in this report are those of the manufacturer, and estimates in the GRADE tables are those calculated by CDC.

§ Evidence to Recommendation documents are available for the GSK vaccine (https://www.cdc.gov/vaccines/acip/recs/grade/GSK-Adjuvanted-RSVPreF3-adults-etr.html) and Pfizer RSV vaccines (https://www.cdc.gov/vaccines/acip/recs/grade/Pfizer-Bivalent-RSVpreF-adults-etr.html).

¶ RSV-associated LRTD (RSVPreF3 trial): two or more lower respiratory symptoms (new or increased sputum, cough, and dyspnea) or signs (new or increased wheezing, crackles or rhonchi detected during chest auscultation, respiratory rate ≥20 respirations per minute, low or decreased oxygen saturation, and need for oxygen supplementation) for ≥24 hours (including one or more lower respiratory signs) or three or more lower respiratory symptoms for ≥24 hours.

** Manufacturer-calculated efficacy. Includes events >14 days after injection and person-time available from the manufacturer's pivotal phase 3 trial. Estimates are adjusted for participant age and region.

†† Medically attended RSV-associated LRTD (RSVPreF3 trial): LRTD plus attendance at one or more inpatient or outpatient health care service. Estimates not included in per-protocol assessments.

§§ Persons with severe RSV illness requiring respiratory support (RSVPreF3 trial): RSV-associated illness requiring oxygen supplementation, positive airway pressure, or other types of mechanical ventilation. If participant was already receiving any of these, significant change or adaptation was considered.

¶¶ The limited number of hospitalizations, severe RSV illnesses, and deaths observed in the trial might have been partially due to limited enrollment of persons at highest risk for RSV disease including those who were frail, of advanced age, and those living in long-term care facilities and the exclusion of persons with immune compromise. The 2021–22 RSV season was also disrupted by the COVID-19 pandemic, and RSV incidence was lower than expected based on prepandemic surveillance studies.

*** Serious adverse events were defined as any untoward medical occurrence that resulted in death, was life threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent disability or incapacity, or was a congenital anomaly or birth defect.

††† RSV-associated LRTD (RSVpreF trial): the trial had two co-primary endpoints, defined as RSV lower respiratory tract illness (LRTI) with two or more lower respiratory signs or three or more lower respiratory symptoms (including new or worsened cough, sputum production, wheezing, shortness of breath, and tachypnea) lasting >1 day. For RSVpreF estimates in this report, LRTD refers to the RSVpreF trial endpoint of LRTI with three or more signs or symptoms.

§§§ Manufacturer-calculated efficacy. Includes events occurring >14 days after injection and person-time available from the manufacturer's pivotal phase 3 trial. Estimates are not adjusted.

¶¶¶ Medically attended RSV-associated LRTD (RSVpreF trial): LRTD prompting any health care visit. Estimates not included in per-protocol assessments.

**** Severe RSV illness requiring respiratory support (RSVpreF trial): RSV-associated acute respiratory illness with new or increased oxygen supplementation or mechanical ventilation.

†††† The limited number of hospitalizations, severe RSV illnesses, and deaths observed in the trial might have been partially due to limited enrollment of persons at highest risk for RSV disease including those who were frail, of advanced age, and those living in long-term care facilities and the exclusion of persons with immune compromise. The 2021–22 RSV season was also disrupted by the COVID-19 pandemic, and RSV incidence was lower than expected based on prepandemic surveillance studies.

§§§§ Votes: 1) Adults aged 60–64 years may receive a single dose of RSV vaccine, using shared clinical decision-making (13–0 vote in favor, one abstention), and 2) Adults aged ≥65 years may receive a single dose of RSV vaccine, using shared clinical decision-making (nine to five in favor). Several ACIP members who voted no for shared clinical decision-making in adults aged ≥65 years were in favor of a routine recommendation for all persons in this age group.
https://www.cdc.gov/media/releases/2023/s0629-rsv.html

¶¶¶¶ https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-who-are-immunocompromised.html

***** When administering more than one vaccine at the same clinical visit, providers should separate injection sites by at least 1 inch if possible and consider administering vaccines that are associated with an enhanced local reaction in separate limbs.

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TABLE 1. Efficacy of 1 dose of GSK respiratory syncytial virus RSVpreF3 vaccine against respiratory syncytial virus–associated disease among adults aged ≥60 years — multiple countries, 2021–2023

Return

	Vaccine efficacy against outcome*	
Efficacy evaluation period	RSV-associated LRTD†	RSV-associated medically attended LRTD§
Season 1¶	82.6 (57.9–94.1)**	87.5 (58.9–97.6)††
Season 2§§	56.1 (28.2–74.4)††	—¶¶
Combined seasons 1 and 2 (interim)***	74.5 (60.0–84.5)†††	77.5 (57.9–89.0)††

Abbreviations: LRTD = lower respiratory tract disease; RSV = respiratory syncytial virus.

* Manufacturer-calculated efficacy. Includes events >14 days after injection and person-time available from the manufacturer's pivotal phase 3 trial. Estimates adjusted for participant age and region.

† LRTD defined as two or more lower respiratory symptoms (new or increased sputum, cough, and dyspnea) or signs (new or increased wheezing, crackles or rhonchi detected during chest auscultation, respiratory rate ≥20 respirations per minute, low or decreased oxygen saturation [<95% or ≤90% if baseline was <95%], and need for oxygen supplementation) for ≥24 hours, including one or more lower respiratory signs, or three or more lower respiratory symptoms for ≥24 hours.
§ Medically attended RSV-associated LRTD defined as LRTD plus attention at one or more inpatient or outpatient health care services. Estimates were not included in per-protocol assessments.
¶ Season 1 vaccine efficacy estimates reflect efficacy against first events occurring during the first complete RSV season for Northern Hemisphere participants and a partial first RSV season for Southern Hemisphere participants (May 2021–April 2022; exact study-defined season dates were site-dependent).
** 96.95% CI; the CI for primary trial endpoint was adjusted for multiplicity.
†† 95% CI.
§§ Season 2 vaccine efficacy estimates reflect efficacy against first events occurring during the second complete Northern Hemisphere RSV season for Northern Hemisphere participants (August 2022–March 2023; exact study-defined season dates were site-dependent). In addition to Northern Hemisphere participants, Southern Hemisphere participants were also included in these analyses, but this time span reflects an interseason period with low RSV incidence in the Southern Hemisphere.
¶¶ Interim analysis underpowered to estimate efficacy.
*** Combined season 1 and 2 (interim) vaccine efficacy estimates reflect efficacy against first events occurring any time during Season 1 or Season 2. The mean time from start to end of efficacy surveillance was approximately 15 months per participant.
††† 97.5% CI; the CI for primary trial endpoint was adjusted for multiplicity.

TABLE 2. Safety* of 1 dose of GSK respiratory syncytial virus RSVPreF3 vaccine in adults aged ≥60 years — multiple countries, 2021–2023

Return

Safety event	Risk for event		
	RSVPreF3 recipients no./No. (%)†	Placebo recipients no./No. (%)§	Relative risk (95% CI)¶
Serious AE**	549/12,570 (4.4)	540/12,604 (4.3)	1.02 (0.91–1.15)
Severe reactogenicity events††	37/979 (3.8)	9/976 (0.9)	4.10 (1.99–8.45)
Inflammatory neurologic events§§	3 events in trials without placebo recipients¶¶	—¶¶	—¶¶

Abbreviations: AE = adverse event; GBS = Guillain-Barré syndrome.
* Includes serious adverse events and severe reactogenicity events observed in GSK's pivotal phase 3 trial (https://pubmed.ncbi.nlm.nih.gov/36791160/) and phase 1/2 trial (https://pubmed.ncbi.nlm.nih.gov/35904987/). Inflammatory neurologic events include those observed across all GSK clinical trials, including an open-label study (https://clinicaltrials.gov/ct2/show/NCT04732871) and a coadministration study (https://clinicaltrials.gov/ct2/show/NCT04841577). Additional data provided by GSK.
† Represents number of events and percentage of all participants experiencing events observed among RSVPreF3 vaccine recipients across all included trials for each outcome.
§ Represents number of events and percentage of all participants experiencing events observed among placebo recipients across all included trials for each outcome.
¶ Pooled relative risk for events in all included trials for each outcome.
** Serious AEs were defined as any untoward medical occurrence (during 6 months after injection in the phase 3 trial and 60 days after injection in the phase 1/2 trial) that resulted in death, was life threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent disability or incapacity, or was a congenital anomaly or birth defect.
†† Severe reactogenicity events were defined as grade 3–solicited local reaction (injection site pain, redness and swelling) or systemic reactions (fatigue, fever, headache, gastrointestinal symptoms [nausea, vomiting, diarrhea, or abdominal pain], arthralgia, myalgia, and shivering) recorded during days 0–4 after vaccination in the phase 3 trial and days 0–7 after vaccination in the phase 1/2 trial. For injection site redness and swelling, grade 3 corresponded to a diameter >3.9" (>100

mm). For fever, grade 3 corresponded to a temperature >102.2°F (>39°C). For all other reactions, grade 3 corresponded to reactions that prevented normal, everyday activities. Grade 4 events were not defined in these trials.
[§§] Defined by the Advisory Committee on Immunization Practices Respiratory Syncytial Virus Vaccines Adult Work Group as GBS (including GBS variants), chronic inflammatory demyelinating polyneuropathy, or acute central nervous system inflammation (e.g., transverse myelitis or acute disseminated encephalomyelitis) occurring ≤42 days after vaccination.
[¶¶] No inflammatory neurologic events were reported in either the phase 3 or phase 1/2 trials. However, across all RSVPreF3 trials inflammatory neurologic events were reported in three of 17,922 adults vaccinated with RSVPreF3. Events included one case of GBS in an open-label phase 3 clinical trial, and two cases of acute disseminated encephalomyelitis among participants in a randomized phase 3 study of coadministration of RSVPreF3 and standard dose seasonal influenza vaccine. Relative risk could not be calculated because neither trial had a placebo-controlled comparator group.

TABLE 3. Efficacy of 1 dose of Pfizer respiratory syncytial virus RSVpreF vaccine against respiratory syncytial virus–associated disease among adults aged ≥60 years — multiple countries, 2021–2023

Return

	Vaccine efficacy against outcome, % (95% CI)*	
Efficacy evaluation period	RSV-associated LRTD[†]	RSV-associated medically attended LRTD[§]
Season 1[¶]	88.9 (53.6–98.7)	84.6 (32.0–98.3)
Season 2 (interim)**	78.6 (23.2–96.1)	—[††]
Combined seasons 1 and 2 (interim)[§§]	84.4 (59.6–95.2)	81.0 (43.5–95.2)

Abbreviations: LRTD = lower respiratory tract disease; LRTI = lower respiratory tract illness; RSV = respiratory syncytial virus.
* Manufacturer-calculated efficacy. Includes events >14 days after injection and person-time available from the manufacturer's pivotal phase 3 trial. Estimates are unadjusted.
[†] The RSVpreF trial had two co-primary endpoints, defined as RSV LRTI with two or more lower respiratory signs or symptoms lasting >1 day, and RSV LRTI with three or more lower respiratory signs or symptoms lasting >1 day. Lower respiratory signs and symptoms included new or worsened cough, sputum production, wheezing, shortness of breath, and tachypnea. For RSVpreF estimates in this report, LRTD refers to the RSVpreF trial endpoint of RSV LRTI with three or more lower respiratory signs or symptoms.
[§] Medically attended RSV-associated LRTD was defined as LRTD prompting any health care visit (any outpatient or inpatient visit such as hospitalization, emergency department visit, urgent care visit, home health care services, primary care physician office visit, pulmonologist office visit, specialist office visit, other visit, or telehealth contact). Estimates were not included in per-protocol assessments.
[¶] Season 1 vaccine efficacy estimates reflect efficacy against first events occurring during the first complete RSV season for Northern and Southern Hemisphere participants (August 2021–October 2022; exact study-defined season dates were site-dependent).
** Season 2 (interim) vaccine efficacy estimates reflect efficacy against first events occurring during the second complete RSV season for Northern Hemisphere participants only (July 2022–January 2023; Southern Hemisphere data not yet available).
[††] Interim analysis underpowered to estimate efficacy.
[§§] Combined season 1 and 2 (interim) vaccine efficacy estimates reflect efficacy against first events occurring any time during season 1 or season 2. The mean time from start to end of efficacy surveillance was approximately 12 months per participant.

TABLE 4. Safety* of 1 dose of Pfizer respiratory syncytial virus RSVpreF vaccine in adults aged ≥60 years — multiple countries, 2021–2023

Return

	Risk for event		
Safety event	RSVpreF recipients no./No. (%)[†]	Placebo recipients no./No. (%)[§]	Relative risk (95% CI)[¶]
Serious AE**	792/18619 (4.3%)	749/18334 (4.1%)	1.04 (0.94–1.15)

Safety event	Risk for event		
	RSVpreF recipients no./No. (%)†	Placebo recipients no./No. (%)§	Relative risk (95% CI)¶
Severe reactogenicity events††	36/3673 (1.0%)	24/3491 (0.7%)	1.43 (0.85–2.39)
Inflammatory neurologic events§§	3/18622 (—)¶¶	0/18335 (—)	—¶¶

Abbreviations: AE = adverse events; GBS = Guillain-Barré syndrome.
* Safety events observed in Pfizer's pivotal phase 3 trial (https://pubmed.ncbi.nlm.nih.gov/37018468/) and phase 1/2 trial (https://pubmed.ncbi.nlm.nih.gov/34932102/). There were no additional inflammatory neurologic events observed in any Pfizer clinical trials other than the two trials included. Additional data provided by Pfizer.
† Represents number of events and percent of all participants experiencing events observed among RSVpreF vaccine recipients across phase 3 and phase 1/2 trials.
§ Represents number of events and percent of all participants experiencing events observed among placebo recipients across phase 3 and phase 1/2 trials.
¶ Pooled relative risk for events in phase 3 and phase 1/2 trials.
** Serious AEs were defined as any untoward medical occurrence (during all available follow-up time [safety follow-up through February 2023] after injection in the phase 3 trial and 60 days for the phase 1/2 trial) that resulted in death, was life threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent disability or incapacity, or was a congenital anomaly or birth defect.
†† Severe reactogenicity events were defined as grade 3 or higher local reaction (injection site pain, redness and swelling) or systemic reaction (fever, fatigue or tiredness, headache, nausea, muscle pain, joint pain, vomiting, diarrhea, and other systemic event) recorded during days 0–7 after vaccination. For injection site redness and swelling, grade 3 corresponded to a diameter >3.9" (>100 mm) from e-diary or severe grade from adverse event case report form. For fever, grade 3 corresponded to a temperature >102°F (>38.9°C) from e-diary or severe grade from adverse event case report form. For all other reactions, grade 3 corresponded to reactions that prevented normal, everyday activities. Grade 4 event corresponded only to a fever >104°F (>40°C).
§§ Defined by the Advisory Committee on Immunization Practices Work Group as GBS (including GBS variants), chronic inflammatory demyelinating polyneuropathy, or acute central nervous system inflammation (e.g., transverse myelitis or acute disseminated encephalomyelitis) occurring ≤42 days after vaccination.
¶¶ Across all RSVpreF clinical trials, including trials other than the phase 3 and phase 1/2 trials summarized in this table, inflammatory neurologic events were reported in three of 20,255 adults ≤42 days after vaccination with RSVpreF (all in the phase 3 trial). The events included GBS, Miller Fisher syndrome (a GBS variant), and undifferentiated motor-sensory axonal polyneuropathy. Relative risk could not be calculated because no events were observed in the placebo-controlled comparator group.

BOX. Underlying medical conditions and other factors associated with increased risk for severe respiratory syncytial virus disease

Return

Chronic underlying medical conditions associated with increased risk

- Lung disease (such as chronic obstructive pulmonary disease and asthma)
- Cardiovascular diseases (such as congestive heart failure and coronary artery disease)
- Moderate or severe immune compromise*
- Diabetes mellitus
- Neurologic or neuromuscular conditions
- Kidney disorders
- Liver disorders

• Hematologic disorders

• Other underlying conditions that a health care provider determines might increase the risk for severe respiratory disease

Other factors associated with increased risk

• Frailty[†]

• Advanced age[§]

• Residence in a nursing home or other long-term care facility

• Other underlying factors that a health care provider determines might increase the risk for severe respiratory disease

Abbreviation: RSV = respiratory syncytial virus.

* A list of potentially immune compromising conditions is available at https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-who-are-immunocompromised.html.

† Frailty is a multidimensional geriatric syndrome and reflects a state of increased vulnerability to adverse health outcomes. Although there is no consensus definition, one frequently used tool is the Fried frailty phenotype 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, and low physical activity.

§ Among adults aged ≥60 years, RSV incidence increases with advancing age. Although age may be considered in determining an older adult patient's risk for severe RSV-associated disease, there is no specific age threshold at which RSV vaccination is more strongly recommended within the age group of adults aged ≥60 years.

Suggested citation for this article: Melgar M, Britton A, Roper LE, et al. Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023. MMWR Morb Mortal Wkly Rep 2023;72:793–801. DOI: http://dx.doi.org/10.15585/mmwr.mm7229a4 .

Vaccine Storage and Handling Toolkit

Updated with COVID-19 and Mpox Vaccines Storage and Handling Information
Addendum added January, 2023

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

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Table of Contents

The Vaccine Storage and Handling Toolkit has been updated with an addendum to address proper storage, handling, transport, and emergency handling of COVID-19 and mpox vaccines. The addendum will be updated as new vaccine products are approved and vaccination information evolves. Please check the CDC Vaccine Storage and Handling Toolkit website (www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html) regularly for the most current version of the toolkit. The addendum can be found starting on page 51.

Disclaimer: This document provides best practices and Centers for Disease Control and Prevention (CDC) recommendations on storage, handling, and transport of vaccines and diluents. It also provides information on vaccine storage and handling requirements related to the Vaccines for Children program. Use of trade names and commercial sources in this toolkit is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services (DHHS), the U.S. Public Health Service (PHS), or CDC.

Introduction

Proper vaccine storage and handling are important factors in preventing and eradicating many common vaccine-preventable diseases. Yet, each year, storage and handling errors result in revaccination of many patients and significant financial loss due to wasted vaccines. Failure to store and handle vaccines properly can reduce vaccine potency, resulting in inadequate immune responses in patients and poor protection against disease. Patients can lose confidence in vaccines and providers if they require revaccination because the vaccines they received may have been compromised.

This toolkit provides information, recommendations, and resources to assist you in properly storing and handling your vaccine supply. The Centers for Disease Control and Prevention (CDC) *Vaccine Storage and Handling Toolkit* brings together best practices from the Advisory Committee on Immunization Practices (ACIP) General Best Practice Guidelines for Immunization,* product information from vaccine manufacturers, and results of scientific studies. Implementing these best practices and recommendations will help protect your patients, safeguard your vaccine supply, and avoid the unnecessary costs of revaccinating patients and replacing expensive vaccines.

For specific, detailed storage and handling protocols for individual vaccines, always refer to the manufacturers' product information and package inserts,* or contact the manufacturer directly.

Vaccines for Children Program

The Vaccines for Children (VFC) program provides vaccines at no cost to eligible children. VFC providers are important partners in making sure VFC-eligible children receive viable, properly handled vaccine.

This toolkit provides general background information on many of the VFC storage and handling requirements and illustrates best practices essential to safeguarding the public vaccine supply.

If you are a VFC provider or receive other vaccines purchased with public funds, consult your state or local immunization program (referred to throughout this document as "immunization program"*) to ensure you are meeting all mandatory storage and handling requirements that are specific or tailored to your jurisdiction.

You may see vendors use terms such as "VFC-compliant," "CDC-compliant," or "satisfies VFC requirements" in their marketing materials or on their websites. In this context, "compliance" and related terms may lead consumers to incorrectly believe that CDC or the VFC program has independently assessed and verified the quality of these products. CDC/VFC is not authorized to assess, validate, verify, or endorse the products or services of private companies. Should you encounter this type of language in vendor marketing materials, please keep in mind that neither CDC nor the VFC program has validated any product or service for compliance with CDC or VFC program requirements or standards.

COVID-19 and Mpox Vaccine Storage and Handling Addendum

At this time, all COVID-19 and mpox vaccines are available to enrolled providers through the CDC's COVID-19 and Mpox Vaccination Programs (COVID-19 vaccination provider and Mpox vaccination provider program). This addendum provides specific guidance regarding proper storage and handling practices for these vaccines. Carefully review the information for these vaccines and considerations when integrating them into existing storage and handling practices. If you are a VFC provider or receive other vaccines purchased with public funds, consult your state or local immunization program (referred to throughout this document as "immunization program"*) to ensure you are meeting all mandatory storage and handling requirements that are specific or tailored to your jurisdiction.

* ACIP recommendations: www.cdc.gov/vaccines/hcp/acip-recs/index.html
Manufacturers' package inserts: www.immunize.org/fda/
Immunization programs: www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html

Introduction

How to Use the Vaccine Storage and Handling Toolkit

This toolkit outlines CDC recommendations for vaccine storage and handling.

This list shows the icons you will see throughout the toolkit and their meanings:

ICON	DESCRIPTION
	CDC Recommendation – CDC recommends this as a minimal action to protect your vaccine supply.
	CDC Best Practice – CDC recommends best practices as additional actions, practices, and procedures to enhance protection of your vaccine supply.

Additional CDC vaccine storage and handling information is available at:

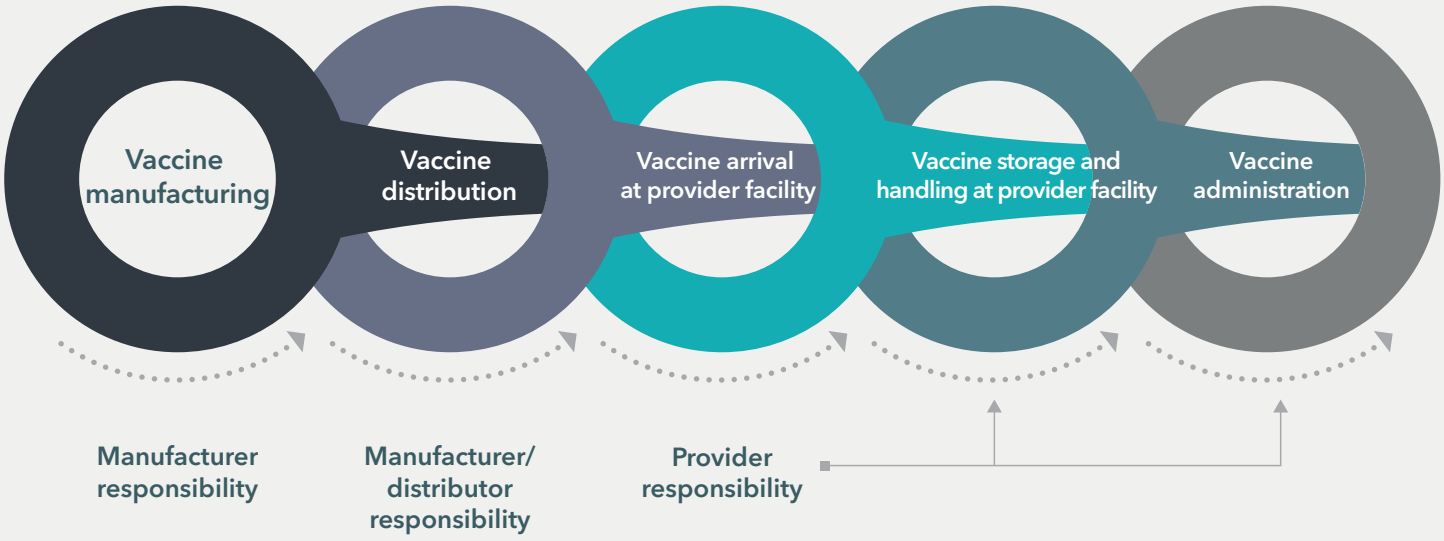
- Vaccine storage and handling home page:
  www.cdc.gov/vaccines/hcp/admin/storage-handling.html
  (sign up for notifications about updates)
- Educational webinars and continuing education for health care providers:
  www.cdc.gov/vaccines/ed/courses.html
- Contact information for state/local immunization programs:
  www.cdc.gov/vaccines/imz- managers/awardee-imz-websites.html
- E-mail specific questions to CDC: NIPInfo@cdc.gov

Proper vaccine storage and handling play critical roles in efforts to prevent vaccine-preventable diseases. Vaccines exposed to storage temperatures outside the recommended ranges may have reduced potency, creating limited protection and resulting in the revaccination of patients and thousands of dollars in wasted vaccine.

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

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

Cold Chain Flowchart



If the cold chain is not properly maintained, vaccine potency may be lost, resulting in an unusable vaccine supply.

Vaccines must be stored properly from the time they are manufactured until they are administered. Potency is reduced every time a vaccine is exposed to an improper condition. This includes overexposure to heat, cold, or light at any step in the cold chain. Once lost, potency cannot be restored.

Exposure to any inappropriate conditions can affect potency of any refrigerated vaccine, but a single exposure to freezing temperatures (0° C [32° F] or colder) can actually destroy potency. Liquid vaccines containing an adjuvant can permanently lose potency when exposed to freezing temperatures.

When the cold chain fails

Ensuring vaccine quality and maintaining the cold chain are shared responsibilities among manufacturers, distributors, public health staff, and health care providers.

An effective cold chain relies on three main elements:

- Well-trained staff
- Reliable storage and temperature monitoring equipment
- Accurate vaccine inventory management

Results of a cold chain failure can be costly.[1,2,3] ACIP's *General Best Practice Guidelines for Immunization* states, "vaccine exposed to inappropriate temperatures that is inadvertently administered should generally be repeated."[4]

A break in the cold chain can mean extra doses for patients, increased costs for providers, and damage to public confidence in vaccines.

More importantly, patients refusing revaccination can remain unprotected from serious, vaccine-preventable diseases.

Vaccine appearance is not a reliable indicator that vaccines have been stored in appropriate conditions. For example, inactivated vaccines—even when exposed to freezing temperatures—may not appear frozen, giving no indication of reduced or lost potency.

By following a few simple steps and implementing CDC-recommended storage and handling practices, providers can ensure patients receive high-quality vaccine that has not been compromised.

1. Department of Health and Human Services, Office of Inspector General. Vaccines for Children Program: Vulnerabilities in Vaccine Management, June 2012, oig.hhs.gov/oei/reports/oei-04-10-00430.asp.
2. Gazmararian JA, Oster NV, Green DC, Schuessler L, Howell K, et al. Vaccine storage practices in primary care physician offices: assessment and intervention. *Am J Prev Med* 2002;23(4):246–53.
3. Bell KN, Hogue CJR, Manning C, Kendal AP. Risk factors for improper vaccine storage and handling in private provider offices. *Pediatrics* 2001;107(6):1–5.
4. Centers for Disease Control and Prevention. ACIP's *General Best Practice Guidelines for Immunization*, www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html.

Vaccine storage and handling practices are only as effective as the staff that implements them. Staff that is well-trained in general storage and handling principles and organization-specific storage and handling standard operating procedures (SOPs) is critical to ensuring vaccine supply potency and patient safety.

Staff Training

All staff members who receive vaccine deliveries as well as those who handle or administer vaccines should be trained in vaccine-related practices and be familiar with your facility's storage and handling SOPs. If you are a VFC provider or have vaccines purchased with public funds, contact your immunization program* for specific state requirements related to training, policies, and procedures.

Online Training Resources

CDC's *You Call the Shots*: Vaccine Storage and Handling† is a free, online training module focused on storage and handling requirements.

Check with your immunization program* and professional organizations to see what vaccine storage and handling training resources they offer.

† *You Call the Shots*: Vaccine Storage and Handling: www.cdc.gov/vaccines/ed/youcalltheshots.html

Storage and Handling SOPs

CDC recommends your facility develop and maintain clearly written, detailed, and up-to-date storage and handling standard operating procedures (SOPs). SOPs will help your facility stay organized, serve as a reference and training tool, and ensure proper vaccine management. SOPs help ensure proper procedures are followed and problems are identified, reported, and corrected. SOPs should also provide guidance for emergencies such as equipment malfunctions, power failures, or natural disasters.

Storage and handling plans and SOPs should contain plans and information for three major areas (see the **Vaccine Storage and Handling SOP Worksheet**):

- General information—include contact information for vaccine manufacturers, equipment service providers, and important facility staff, as well as job descriptions, regularly used forms, and staff training requirements
- Routine storage and handling SOPs—include information for all aspects of vaccine inventory management, from ordering to monitoring storage conditions
- Emergency vaccine storage, handling, and transport SOPs—outline steps to be taken in the event of equipment malfunctions, power failures, natural disasters, or other emergencies that might compromise vaccine storage conditions

Worksheets to assist you in developing your organization's routine and emergency SOPs are located in the resources section.

Train staff on routine vaccine storage and handling and emergency SOPs. Keep SOPs near vaccine storage units and make sure staff knows where to find them. Document all training completed with dates and participant names.

Storage and handling training should be completed:

- As part of new employee orientation
- Annually as a refresher for all staff involved in immunization and vaccine storage and handling activities
- Whenever new vaccines are added to inventory
- Whenever recommendations for storage and handling of vaccines are updated

* Immunization programs: www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html

Vaccine Coordinator Recommendations

Designate a primary vaccine coordinator. This person will be responsible for ensuring all vaccines are stored and handled correctly and should be an expert on your facility's storage and handling SOPs.

Coordinator responsibilities should include:

- Ordering vaccines
- Overseeing proper receipt and storage of vaccine deliveries
- Documenting vaccine inventory information
- Organizing vaccines within storage units
- Setting up temperature monitoring devices
- Checking and recording minimum/maximum temperatures at start of each workday*
- Reviewing and analyzing temperature data at least weekly for any shifts in temperature trends
- Rotating stock at least weekly so vaccines with the earliest expiration dates are used first
- Removing expired vaccine from storage units
- Responding to temperature excursions (out-of-range temperatures)
- Maintaining all documentation, such as inventory and temperature logs
- Organizing vaccine-related training and ensuring staff completion of training
- Monitoring operation of vaccine storage equipment and systems
- Overseeing proper vaccine transport (when necessary) per SOPs
- Overseeing emergency preparations per SOPs:
  - Tracking inclement weather conditions†
  - Ensuring appropriate handling of vaccines during a disaster or power outage‡

Coordinator responsibilities may be completed by the coordinator or delegated to appropriate staff. Ensure the coordinator has trained the delegate(s) and documented competency for the specific tasks assigned.

Staff Training and SOP Best Practices

» Review and update SOPs annually.
» Appoint an alternate vaccine coordinator to act in the absence of the primary coordinator.
» The alternate coordinator, like the primary coordinator, should be an expert in routine and emergency SOPs.

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*This is a VFC provider requirement.

†The Federal Emergency Management Agency (FEMA) offers a wide range of information on disaster preparedness: www.fema.gov/. The Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) offers information concerning the storage and use of temperature-sensitive biological products that have been involved in a temporary electrical power failure or flood conditions: www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/.

‡The National Oceanic and Atmospheric Administration (NOAA) provides up-to-date information on U.S. weather conditions: www.weather.gov/ www.goes.noaa.gov/

SECTION THREE: Vaccine Storage and Temperature Monitoring Equipment

It is important your facility has proper storage and monitoring equipment that is set up correctly, maintained appropriately, and repaired as needed. This equipment protects patients from inadvertently receiving compromised vaccine and your facility against costs of revaccinating patients, replacing expensive vaccines, and losing patient confidence in your practice.

Vaccine Storage Units: Refrigerator and Freezer Recommendations

There are several types of vaccine storage units available. Purpose-built units are specifically designed to store vaccines. However, household-grade units are also an acceptable option for vaccine refrigeration under the right conditions.

- **Use purpose-built or pharmaceutical-grade units designed to either refrigerate or freeze**. These units can be compact, under-the-counter style or large.

Purpose-built units, sometimes referred to as "pharmaceutical-grade," are designed specifically for storage of biologics, including vaccines. These units often have:

- Microprocessor-based temperature control with a digital temperature sensor (thermocouple, resistance temperature detector [RTD], or thermistor)
- Fan-forced air circulation with powerful fans or multiple cool air vents promoting uniform temperature and fast temperature recovery from an out-of-range temperature.

Household-grade units can be an acceptable alternative to pharmaceutical-grade vaccine storage units. As the name implies, these units are primarily designed and marketed for home use. However, the freezer compartment of this type of unit is not recommended to store vaccines and there may be other areas of the refrigerated compartment that should be avoided as well. If your facility provides frozen vaccine, a separate freezer unit is necessary.

Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.

These units have a single exterior door and an evaporator plate/cooling coil, usually located in an icemaker/freezer compartment. These units pose a significant risk of freezing vaccines, even when used for temporary storage. (Note: Not all small storage units are dormitory- or bar-style units. Compact, purpose-built units for biologics can be used to store vaccines.)

Storage unit doors

A door that is not sealed properly or left open unnecessarily not only affects the temperature in a unit, it also exposes vaccines to light, which can reduce potency of some vaccines. Consider using safeguards to ensure the doors of the unit remain closed—for example, self-closing door hinges, door alarms, or door locks.

Storage Unit Best Practices

To fully ensure the safety of vaccines, equipment should include a recommended unit with enough space to accommodate your maximum inventory without crowding.

Storage Unit Placement

Good air circulation around the outside of the storage unit is important. Place a storage unit in a well-ventilated room, leaving space between the unit, ceiling, and any wall. Nothing should block the cover of the motor compartment. The unit should be firm and level, with the bottom of the unit above the floor. Make sure the unit door opens and closes smoothly and fits squarely against the body of the unit. If not secured properly, unit doors pose a particular risk to maintaining appropriate internal temperatures of vaccine storage units. Studies find most units work best when placed in an area with standard indoor room temperatures, usually between 20° C and 25° C (68° F and 77° F). Check the manufacturer-supplied owner's manual for additional guidance on placement and spacing.

You may see vendors use terms such as "VFC-compliant," "CDC-compliant," or "satisfies VFC requirements" in their marketing materials or on their websites. In this context, "compliance" and related terms may lead consumers to incorrectly believe that CDC or the VFC program has independently assessed and verified the quality of these products. CDC/VFC is not authorized to assess, validate, verify, or endorse the products or services of private companies. Should you encounter this type of language in vendor marketing materials, please keep in mind that neither CDC nor the VFC program has validated any product or service for compliance with CDC or VFC program requirements or standards.

Stabilizing Temperatures in New and Repaired Units

It may take 2 to 7 days to stabilize the temperature in a newly installed or repaired refrigerator and 2 to 3 days for a freezer.

Before using a unit for vaccine storage, check and record the minimum and maximum temperatures each workday for 2 to 7 days. If temperatures cannot be recorded digitally, check and record temperatures a minimum of two times each workday. Once you have 2 consecutive days of temperatures recorded within the recommended range, your unit is stable and ready for use.

Temperature Ranges

Refrigerators should maintain temperatures between 2° C and 8° C (36° F and 46° F)*. Freezers should maintain temperatures between -50° C and -15° C (-58° F and +5° F). Ultra-cold freezers should maintain temperatures between -90° C and -60° C (-130° F and -76° F) . Refrigerator or freezer thermostats should be set at the factory-set or midpoint temperature, which will decrease the likelihood of temperature excursions.

Consult the owner's manual for instructions on how to operate the thermostat. Thermostats are marked in various ways and, in general, show levels of coldness rather than temperatures. The only way to know the temperature where vaccines are stored is to measure and monitor it with a temperature monitoring device.

Temperature Monitoring Device (TMD)

Every vaccine storage unit must have a TMD. An accurate temperature history that reflects actual vaccine temperatures is critical for protecting your vaccines. Investing in a reliable device is less expensive than replacing vaccines wasted due to the loss of potency that comes from storage at out-of-range temperatures.

- **CDC recommends a specific type of TMD called a "digital data logger" (DDL).** A DDL provides the most accurate storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range (referred to as a "temperature excursion"). Unlike a simple minimum/maximum thermometer, which only shows the coldest and warmest temperatures reached in a unit, a DDL provides detailed information on all temperatures recorded at preset intervals.

Many DDLs use a buffered temperature probe, which is the most accurate way to measure actual vaccine temperatures. Temperatures measured by a buffered probe match vaccine temperatures more closely than those measured by standard thermometers, which tend to reflect only air temperature. However, not all DDLs can measure ultra-cold temperatures. For accurate ultra-cold temperature monitoring, it is essential to use an air-probe or a probe designed specifically for ultra-cold temperatures.

Temperature data from a DDL can either be downloaded to a computer using special software or retrieved from a website. The software or website may also allow you to set the frequency of temperature readings. Reviewing DDL data is critical for vaccine viability, so it is important to decide whether independent software or a website program works best for your facility.

* Probes that are permanently embedded in a buffer are acceptable as long as the temperature monitoring system for the entire unit can be calibration-tested.

Keep the data for 3 years so they can be analyzed for long-term trends and/or recurring problems. Those receiving public vaccine may need to keep records longer as required by state regulations.

Use a DDL or other appropriate TMD for:

- Each vaccine storage unit
- Each transport unit (emergency or non-emergency)

Have at least one backup TMD in case a primary device breaks or malfunctions.

Use DDLs with the following features:

- Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon®)*
- Alarm for out-of-range temperatures
- Low-battery indicator*
- Current, minimum, and maximum temperature display†
- Recommended uncertainty of +/-0.5° C (+/-1° F)
- Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures at least every 30 minutes

Use DDLs with a current and valid Certificate of Calibration Testing.

Certificate of Calibration Testing

Calibration testing is done to ensure the accuracy of a temperature monitoring device's readings against nationally accepted standards.

A DDL's Certificate of Calibration Testing should include:

- Model/device name or number
- Serial number
- Date of calibration (report or issue date)
- Confirmation that the instrument passed testing (or instrument is in tolerance)
- Recommended uncertainty of +/-0.5° C (+/-1° F) or less

To determine if a Certificate of Calibration Testing or Report of Calibration was issued by an appropriate entity, check to see if the certificate indicates one or more of the following items about calibration testing:

- Conforms to International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 international standards for calibration testing and traceability
- Performed by a laboratory accredited by International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body
- Traceable to the standards maintained by the National Institute of Standards and Technology (NIST)
- Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 Tolerance Class F or higher
- Refers to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points

Calibration testing should be done every 2 to 3 years or according to the manufacturer's suggested timeline. TMDs can experience a "drift" over time, affecting their accuracy. This testing ensures the accuracy of the device continues to conform to nationally accepted standards.

Mishandling a TMD can affect its accuracy. If a TMD is dropped, hit against the side of a storage unit, or is potentially damaged in any way, its accuracy should be checked against another calibrated TMD. If there is any question about accuracy, the device should be replaced or sent for calibration testing.

* Since these devices are typically battery-operated, you should have a supply of extra batteries on hand. If you are storing ultra-cold vaccine, make sure your DDL is appropriate for ultra-cold monitoring. See the COVID-19 Vaccine Storage and Handling Addendum for more information.

† Battery changes may affect temperature accuracy and may warrant checking against a known, calibrated TMD. Check with the device's manufacturer for specific information on battery changes.

Monitoring Vaccine Temperature and Vaccine Equipment

Monitoring vaccine storage equipment and temperatures are daily responsibilities to ensure the viability of your vaccine supply and the safety of your patients. Implementing routine monitoring activities can help you identify temperature excursions quickly and take immediate action to correct them, preventing loss of vaccines and the potential need for revaccination of patients.

Power Supply

Even with appropriate equipment and temperature monitoring practices in place, power disruption can result in destruction of the entire vaccine supply. Precautions should always be taken to protect the storage unit's power supply.

- **Plug in only one storage unit per electrical outlet to avoid creating a fire hazard or triggering a safety switch that turns the power off.**
- **Use a safety-lock plug or an outlet cover to prevent the unit from being unplugged.**
- **Post "DO NOT UNPLUG" warning signs at outlets and on storage units to alert staff, custodians, electricians, and other workers not to unplug units.**
- **Label fuses and circuit breakers to alert people not to turn off power to a storage unit.**
- **Use caution when using power outlets that can be tripped or switched off and avoid using:**
  - Built-in circuit switches (may have reset buttons)
  - Outlets that can be activated by a wall switch
  - Multi-outlet power strips

If built-in circuit switches, Uninterruptible Power Supply (UPS) unit, or power strip surge protection must be used, make sure the device is rated to carry the maximum current as specified by the manufacturer of the refrigerator or freezer. Additionally, consider how the device manages when the power is restored. Whether the device automatically restarts and allows the equipment to run or has to be manually switched on should be considered and represented in Emergency Plans and SOPs. Contact the unit manufacturer for any additional questions or guidance regarding circuit switches, power strips, UPI, or surge protection.

If the entire storage unit is affected by a temperature excursion because of a power supply issue or unit malfunction, refer to your facility's emergency SOPs.

Certain types of TMDs have significant limitations and should not be used to measure temperatures in a vaccine storage unit. These devices can be difficult to read and, because they only show the temperature at the exact time they are checked, may fail to detect temperatures outside the recommended range.

CDC does not recommend the following TMDs:

- Alcohol or mercury thermometers, even if placed in a fluid-filled, biosafe, liquid vial
- Bimetal stem TMDs
- TMDs used for food
- Chart recorders
- Infrared TMDs
- TMDs that do not have a current and valid Certificate of Calibration Testing

Please note: Some devices sold in hardware and appliance stores are designed to monitor temperatures for household food storage. They are not calibrated and not accurate enough to ensure vaccines are stored within the correct temperature range. Using these devices can pose a significant risk of damaging vaccines.

Organizing and Storing Vaccine

Correctly organizing and placing vaccines in a storage unit helps prevent conditions that could reduce vaccine potency or cause vaccine failure.

- **Store vaccines in their original packaging with lids closed until ready for administration.** Vials and manufacturer-filled syringes should always be stored in their original packaging. Loose vials or syringes may be exposed to unnecessary light, potentially reducing potency, and may be more difficult to track for expiration dates. They may also impact inventory management and increase the risk of administration errors because they may be confused with other vaccines. For certain purpose-built units, it is recommended that vaccine be stored outside of the packaging. If this is the case, follow the manufacturer's guidance for vaccine storage.

- **Check and record storage unit minimum and maximum temperatures at the start of each workday.** If your TMD does not read minimum/maximum temperatures, then check and record the current temperature a minimum of two times per workday (at the start and end of the workday).

  Record:

  - Minimum/maximum temperature
  - Date
  - Time
  - Name of person who checked and recorded the temperature
  - Any actions taken if a temperature excursion occurred

If a reading is missed, leave a blank entry in the log.

Food and beverages should never be stored in the unit with vaccines. If other biologics are stored in the unit, vaccines should be stored on the shelf above them.

Temperature Monitoring

Regular checks provide an opportunity to inspect the storage unit, reorganize any misplaced vaccines, and remove any expired vaccines. Check the temperature each time vaccines are accessed in the unit.

Review storage unit temperature readings and review continuous DDL software or website information weekly for changes in temperature trends that might require action.

If there appears to be any fluctuation in temperature, troubleshoot the problem based on additional information provided in this toolkit, manufacturer manuals, and/or your office storage and handling SOPs.

How to Store Vaccines

Place water bottles on the top shelf and floor and in the door racks. Putting water bottles in the unit can help maintain stable temperatures caused by frequently opening and closing unit doors or a power failure.

Water bottles are not recommended for use with certain pharmaceutical-grade and purpose-built units. For such units, follow the manufacturer's guidance.

Organizing and Storing Vaccine

To confirm vaccines are stored correctly and to minimize the risk of administration errors, implement the following practices:

» Store each type of vaccine or diluent in its original packaging and in a separate container.

» Position vaccines and diluents 2 to 3 inches from the unit walls, ceiling, floor, and door. If using a household-grade unit, avoid storing vaccines and diluents in any part of the unit that may not provide stable temperatures or sufficient air flow, such as directly under cooling vents; in deli, fruit, or vegetable drawers; or on refrigerator door shelves. The instability of temperatures and air flow in these areas may expose vaccines to inappropriate storage temperatures.

» Label shelves and containers to clearly identify where each type of vaccine and diluent is stored.

» Store vaccines and diluents with similar packaging or names or with pediatric and adult formulations on different shelves.

» Whenever possible, store diluent with the corresponding refrigerated vaccine. Never store diluent in a freezer.

» Avoid placing or storing any items other than vaccines, diluents, and water bottles inside storage units.

- If other medications and biological products must be stored in the same unit as vaccines, they must be clearly marked and stored in separate containers or bins from vaccines.
  - —Potentially contaminated items (e.g., blood, urine, stool) should be properly contained and stored below vaccines due to risk of contamination from drips or leaks.
  - —The freezer of a household-grade unit may be used for non-vaccine, medical storage, so long as the use does not compromise the temperature range within the refrigerator compartment where vaccine is stored.

» Arrange vaccines and diluents in rows and allow space between them to promote air circulation.

» Place vaccines and diluents with the earliest expiration dates in front of those with later expiration dates.

Temperature Excursions

Temperature excursions or inappropriate storage conditions for any vaccine require immediate action. Any temperature reading outside the recommended ranges in the manufacturers' package inserts* is considered a temperature excursion. In general, manufacturers analyze information about the magnitude of the temperature excursion and the total amount of time that temperatures were out of range, as well as information about the vaccine in question, to determine whether a vaccine is likely to still be viable.

CDC recommends the following steps in the event of a temperature excursion:

1. Any staff who hears an alarm or notices a temperature excursion on the DDL should notify the primary or alternate vaccine coordinator immediately or report the problem to their supervisor.
2. Notify staff by labeling exposed vaccines "DO NOT USE" and placing them in a separate container apart from other vaccines (do not discard these vaccines).
3. The vaccine coordinator, supervisor, or if necessary, the person reporting the problem, should begin to document the event with the following information†:
   a. Date and time of the temperature excursion
   b. Storage unit temperature as well as room temperature, if available (including minimum/maximum temperatures during the time of the event, if available)
   c. Name of the person completing the report and description of the event‡:
      — General description of what happened
      — The length of time vaccine may have been affected, if using a DDL
      — Inventory of affected vaccines
      — List of items in the unit (including water bottles) other than vaccines
      — Any problems with the storage unit and/or affected vaccines before the event
      — Other relevant information
4. Implement your facility SOPs to adjust unit temperature to the appropriate range. At a minimum, check the TMD to make sure it is appropriately placed in the center of the vaccines.
5. Contact your immunization program and/or vaccine manufacturers per your SOPs for further guidance on whether to use affected vaccines and for information about whether patients will need to be recalled for revaccination. Be prepared to provide documentation of the event (e.g., temperature log data) to ensure you receive the best guidance.
6. Complete your documentation of the event, including:
   a. Action taken
      — What you did with vaccine and how long it took to take action
      — Whom you contacted and instructions received
      — What you did to prevent a similar future event
   b. Results
      — Final disposition of affected vaccines (e.g., shortened expiration date per manufacturer, discarded, or returned)
      — Other comments

* Manufacturers' vaccine package inserts: www.immunize.org/fda/. Vaccines under an Emergency Use Authorization (EUA) will provide an EUA Fact Sheet for Healthcare Providers with this information.

† The Immunization Action Coalition has developed a Temperature Monitoring Log and a Vaccine Storage Troubleshooting Record to support these activities.

‡ Responses from vaccine manufacturers to events depend on information given by the provider to the manufacturer. If different information about the same event is provided to the same manufacturer, this can lead to different recommendations on whether vaccine can be used or whether patients need to be revaccinated. In addition, each event is unique, and manufacturer recommendations based on existing stability data cannot be applied to future events that may appear to be similar.

Regular Maintenance of Vaccine Storage Units and Temperature Monitoring Devices

Storage units and TMDs need regular maintenance to ensure proper operation.

Never allow vaccines to remain in a malfunctioning unit for an extended period of time. If you believe your unit has failed, implement your emergency SOPs.

Conduct routine maintenance for all vaccine storage units and related equipment so that your equipment functions at maximum efficiency.

- Check seals and door hinges.
- Clean coils and other components per manufacturer direction.
- Defrost manual-defrost freezers when the frost exceeds either 1 cm or the manufacturer's suggested limit. Follow the manufacturer's instructions. While defrosting, store vaccines temporarily in another unit with appropriate freezer temperatures.
- Clean the interior of each unit to discourage bacterial and fungal growth. Do so quickly to minimize the risk of a temperature excursion.
- Test any backup generator quarterly and have it serviced annually.

Troubleshooting Equipment Problems

Adjusting Storage Unit Temperatures

Storage unit temperatures may need to be adjusted over time. In some situations, thermostats may need to be reset in summer and winter, depending on room temperature.

Temperature adjustments should be:

- Made by the primary or alternate vaccine coordinator, based on information from the TMD and temperature monitoring log
- Performed at a time that is not during a busy workday when the unit door is being frequently opened and closed

Remember that temperatures within any storage unit will vary slightly, even with normal use. Therefore, before making any adjustment:

- Confirm the unit is securely plugged into a power source.
- Check the temperature inside the storage unit.
- Wait 30 minutes, without opening the door, to allow the temperature to stabilize and then check it again to determine if the thermostat should be adjusted.

If you believe there could be an issue with your TMD, use your backup device to confirm the temperature.

If you confirm that an adjustment is needed:

1. Refer to the owner's manual for detailed instructions.
2. Make a small adjustment toward a warmer or colder setting by turning the thermostat knob slowly to avoid going outside the correct temperature range.
3. Once the adjustment is made, allow the temperature inside the unit to stabilize for 30 minutes without opening the door.
4. Recheck the temperature.

5. Repeat these steps as needed until the temperature has stabilized
   - between 2° C and 8° C (36° F and 46° F) for a refrigerator,
   - between -50° C and -15° C (-58° F and +5° F) for a freezer, and
   - between -90° C and -60° C (-130° F and -76° F) for an ultra-cold freezer.
6. Consider placing additional water bottles in the unit to help improve temperature stability.

Do not leave vaccines in a storage unit that does not maintain temperatures within the recommended range. If you are unable to stabilize the temperature in your unit within the required range, or temperatures in the unit are consistently at the extreme high or low end of the range, your vaccine supply is at high risk. Use your SOPs to identify an alternative unit with appropriate temperatures and sufficient storage space until the primary unit can be repaired or replaced.

If you are using a combination storage unit, note that adjustments to the freezer temperature can adversely affect the refrigerator compartment temperature, possibly resulting in frozen vaccines in the refrigerator.

Repeated Alarm Alerts

If the temperature alarm goes off repeatedly, do not disconnect the alarm until you have determined and addressed the cause. Do basic checks of the unit door, power supply, and thermostat settings. If the alarm continues to trigger or the temperature remains out of range, transfer vaccines to a backup unit as directed by your SOPs. A repair technician should check your equipment to determine the need for repair or replacement.

Proper vaccine inventory management is essential for appropriate vaccine ordering and stock rotation, and ensures your facility has the vaccines your patients need. Vaccines are expensive, so making sure they are unpacked, stored, prepared, administered, and transported correctly is critical.

Vaccine Delivery

Scheduling and Receiving Deliveries

Maintaining the cold chain is the first step in vaccine inventory management. Staff members who might accept vaccine deliveries should be trained to immediately notify the vaccine coordinator or alternate coordinator when deliveries arrive. Vaccines must always be immediately checked and stored properly upon arrival.

Unpacking Deliveries

Vaccines and diluents must be carefully unpacked, stored at recommended temperatures, and documented immediately after they arrive. Do not place an unopened and/or unpacked shipment box in a vaccine storage unit because the cool packs shipped with the vaccine may make the packaged vaccine too cold if placed inside the storage unit.

Never leave a vaccine shipping container unpacked and unattended. If vaccines and diluents get too warm, they cannot be used. Be sure all staff knows that vaccine deliveries require immediate attention.

Immediately examine shipments for signs of damage and to guarantee receipt of the appropriate vaccine types and quantities.

- Examine the shipping container and vaccines for signs of physical damage.
- Check the contents against the packing list to be sure they match.
  - For frozen vaccines, the packing list will show the maximum time vaccines can be in transit based on shipment date.
- If the shipment includes lyophilized (freeze-dried) vaccines, make sure they came with the correct type and quantity of diluents.
- Immediately check both vaccine and diluent expiration dates to ensure you have not received any expired or soon-to-expire products.
- Immediately check the cold chain monitor (CCM), a device used to monitor vaccine temperatures during transport (if one was included) for any indication of a temperature excursion during transit.

Vaccine Inventory Accounting

Stock Counts

Stock records are used to determine the type and amount of vaccines your facility should stock to meet the needs of your patients. At least once a month and before placing any vaccine order, count all vaccine and diluent doses to make sure the number of doses in the storage unit matches the number of doses documented in the stock record. Always check expiration dates while counting stock and remove any expired doses immediately. **Tally Sheets**

Stock Records

Use a stock record to account for and document every dose of vaccine. This record will help you keep track of your inventory and can be in either paper or electronic form. This record should be updated weekly and include the vaccine delivery information below:

- Date of delivery and initials of the person who unpacked the box
- Vaccine and diluent name and manufacturer
- Number and expiration date for each lot
- Number of doses received
- Condition of each vaccine and diluent upon arrival
- CCM reading if included in the shipping container
- Number of doses used
- Balance of remaining doses after subtracting the amount used

Note: State and local programs that have an immunization information system (IIS) with vaccine inventory accounting functions will require VFC providers to use the IIS to track their inventory.

Tally sheets can help keep stock records up-to-date. Place tally sheets outside the storage unit door (or another easily accessible location), and have staff use tick marks to keep a count of every dose removed from the unit.

If the numbers in the storage unit do not match the doses documented in the stock record, enter the correct number based on your count on a separate line below the old balance on your stock record. Make a note next to the new entry indicating that your count confirmed the new balance and sign it. Use the corrected balance for calculating stock quantities in the future.

If you receive multiple doses of the same vaccine in the same presentation from the same lot with the same expiration date, you can document these doses as one entry on the stock record. Indicate the total number of doses received, regardless of how many vials or syringes the doses came in. For example, if you receive 10 single-dose vials of the same vaccine with the same lot number and expiration date, you can make a single entry on the stock record, noting that 10 doses were received.

If there are discrepancies between the contents and the packing list or other concerns about the contents, immediately notify the vaccine manufacturer. If you are a VFC provider or receive vaccines purchased with public funds, contact your immunization program.*

Diluents should be documented on a separate stock record and should equal quantities of corresponding vaccines.

At the end of each month, determine the total number of vaccine and diluent doses used that month and the amount of stock still available. At the end of each year, use your stock record to determine the number of doses received for the year and add up your monthly dose counts to get a total number of doses used. This information will help you determine your facility's needs and guide you in ordering so you can minimize future waste and reduce the need for transfer and transport of vaccines. It will also help to make sure you have a sufficient supply to meet your patients' needs.

Vaccine Ordering

Order and stock only enough vaccine to meet patient needs.†

Storing a larger volume than your facility needs can increase the risk of wasting vaccines if they expire before they can be used or they are compromised in some way (e.g., due to mechanical failure of a storage unit).

Most facilities should also reorder based on patient needs after checking stock count. Vaccine orders usually arrive within 1 to 2 weeks, but there can be delays. When possible, avoid placing last-minute or rush orders to lessen the risk of running out of vaccines.

Stock Rotation and Removal

Vaccine stock should be rotated and checked for expired doses regularly. Any expired vaccines and diluents should be removed immediately to avoid inadvertently administering them. Arrange stock for each vaccine type so that doses with the earliest expiration dates are placed in front of those with later expiration dates.

Contact your immunization program* to find out if expired vaccines purchased with public funds can be returned.

Arranging Your Stock

The vaccine coordinator (or other designated person) should rotate vaccine and diluent stock at least once a week, as well as each time your facility receives a vaccine delivery. This will ensure that vaccines expiring sooner are used first.

* Contact your immunization program for details about specific state or local regulations impacting this activity.
† An adequate supply of vaccine varies for most providers, facilities, or immunization programs. It is recommended that reordering is done when stock has been reduced to a 4-week inventory.

Understanding Expiration Dates

All vaccine products, like other medications, have an expiration date, sometimes referred to as the expiry date. The expiration date is determined by the **manufacturer**.

The expiration date is **the final day that the vaccine can be administered**. Vaccines past the expiration date should NEVER be used.

Determining when a vaccine or diluent expires is a critical step in maintaining proper storage and handling. Understanding vaccine expiration dates can help save your practice time and money.

Expiration Dates

The vaccine coordinator (or other designated person) should remove expired vaccine and diluent immediately from the inventory.

When the expiration date has only a month and year, the product may be used up to and including the last day of that month. If a day is included with the month and year, the product may only be used through the end of that day.

In some instances, such as the examples for beyond-use date (BUD) below, vaccines must be used before the expiration date on the label.

Beyond-Use Dates

Some vaccines have a beyond-use date/time. **The Beyond-use date** is different from expiration date. The beyond-use date, or BUD, is the last date or time that a vaccine can be safely used after it has been moved from one storage state to another (e.g., frozen to refrigerated) or prepared for patient use. It is a new deadline after which the product should not be used. The BUD varies by product and type of transition. This is sometimes also called a beyond-use time if it falls on the same day at a different time of day.

Unlike the expiration date that is determined by the manufacturer, the BUD is determined by the health care provider using guidance provided by the manufacturer. The BUD replaces the manufacturer's expiration date but never extends it. Always use the earlier date between the two.

Not all vaccine products have a BUD. The package insert or Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers will specify if there is a BUD and how to calculate it. Always review this informational material to determine if a BUD applies. Examples of BUD include:

Reconstituted vaccines have a limited period for use once the vaccine is mixed with a diluent.

Multidose vials might have a specified period for use once they have been punctured with a needle. For example, the package insert may state that the vaccine must be discarded 28 days after the first puncture with a needle. If the vial is first punctured on 06/01/2023, the BUD is 06/29/2023. The vaccine should not be used after the BUD.

Manufacturer-shortened expiration dates may apply when vaccine is exposed to inappropriate storage conditions. The manufacturer might determine the vaccine can still be used, but will expire on an earlier date than the date on the label. The BUD should be noted on the vial label along with the initials of the person making the calculation.

Vaccine Disposal

General vaccine disposal guidelines for:

- **Expired or compromised vaccine**—sometimes unused vaccine and diluent doses, unopened vials, expired vials, and potentially compromised vaccine may be returned for credit, even if they must be discarded. Contact your immunization program* and/or the vaccine manufacturer for vaccine-specific information.
- **Open and broken vials and syringes, manufacturer-filled syringes that have been activated, and vaccine predrawn by providers**—these cannot be returned and should be discarded according to your state requirements.
- **Empty vaccine vials**—most are not considered hazardous or pharmaceutical waste and do not require disposal in a biomedical waste container.† However, check and comply with your state requirements for disposal.

Medical waste disposal requirements may vary from state to state because they are set by state environmental agencies. Contact your immunization program* or state environmental agency for guidance to ensure your facility's vaccine disposal procedures comply with state and federal regulations.

* Contact your immunization program for details about specific state or local regulations impacting this activity.
† While vials are not usually considered hazardous or pharmaceutical waste, an empty RV dispensing tube or oral applicator is considered medical waste and should be disposed of in a medical waste container.

Preparing Vaccine for Administration

Vaccine preparation is the final step in the cold chain before administration. Handling vaccines with care is equally as important as storing them properly.

Vaccine Preparation

- Prepare vaccines in a designated area away from any space where potentially contaminated items are placed.
- Only prepare vaccines when you are ready to administer them.
- Before preparing the vaccine, always check the:
  - Vial to ensure it is the correct vaccine
  - Expiration date or beyond-use date/time to ensure it has not passed
- Always check expiration dates and confirm that you have selected the correct vaccine.
- Only administer vaccines you have prepared. This is a quality control and patient safety issue and a best practice standard of medication administration.

Different types of vaccine vials

Single-Dose Vials

A single-dose vial (SDV) contains one dose and should be used one time for one patient. SDVs do not contain preservatives to help prevent microorganism growth. Never combine leftover vaccine from one SDV with another to obtain a dose.

Only open an SDV when ready to use. Before you remove the protective cap, always check the vial to make sure you have the correct vaccine. Once you remove the cap, you must use the vaccine because it may not be possible to determine if the rubber seal has been punctured. Discard any unused SDVs without a protective cap at the end of the workday.

Multidose Vials

A multidose vial (MDV) contains more than one dose of vaccine. Because MDVs typically contain a preservative to help prevent the growth of microorganisms, they can be entered or punctured more than once. Only the number of doses indicated in the manufacturer's package insert should be withdrawn from the vial. After the maximum number of doses has been withdrawn, the vial should be discarded, even if there is residual vaccine or the expiration date has not been reached.

MDVs can be used until the expiration date printed on the vial unless the vaccine is contaminated or compromised in some way or there is a BUD noted in the package insert.

Never use partial doses from two or more vials to obtain a dose of vaccine.

Based on safe injection practices, CDC does NOT recommend the use of vial adapters, spikes, or other vial access devices when withdrawing vaccine from a multidose vial. Leaving a vial access device inserted into a vial septum provides a direct route for microorganisms to enter the vial and contaminate the fluid.

Manufacturer-Filled Syringes

A manufacturer-filled syringe (MFS) is prepared and sealed under sterile conditions by the manufacturer. **Activate an MFS (i.e., remove the syringe cap or attach the needle) only when ready to use.**

An MFS does not contain a preservative to help prevent the growth of microorganisms. Once the sterile seal has been broken, the vaccine should be used or discarded by the end of the workday.

Reconstitution of Vaccine

Lyophilized (freeze-dried) vaccines are in either powder or pellet form and must be mixed with a liquid (diluent) in a process known as "reconstitution" before being administered.

Diluents vary in volume and composition and are specifically designed to meet volume, pH balance, and the chemical requirements of their corresponding vaccines. Refer to the manufacturer's package insert for guidance on storage and handling.

Diluents are not interchangeable unless specified by the manufacturer.

- Some diluents contain an antigen or an adjuvant needed for vaccine effectiveness. Even if the diluent is composed of sterile water or saline, use only the diluent supplied with the vaccine to reconstitute it.

Never use a stock vial of sterile water or normal saline to reconstitute vaccines.

Never administer vaccine reconstituted with the wrong diluent.

- If an incorrectly reconstituted vaccine has already been administered, contact your immunization program* or the vaccine manufacturer for revaccination guidance.

Always check expiration dates on both diluents and vaccines before reconstituting them.†

† If you are a VFC provider or have other vaccines purchased with public funds and must transfer vaccine to another facility so it can be used before it expires, contact your immunization program* for guidance on vaccine transport.

* Immunization programs: www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html

Predrawing Vaccine

Predrawing vaccines can result in waste if more are drawn up than needed.

- **Draw up vaccines only at the time of administration.** The practice of prefilling syringes is discouraged for several reasons. However, there may be rare instances when the only option is to predraw vaccine.

If vaccines must be predrawn, adhere to the following best practices:

- Set up a separate administration station for each vaccine type to prevent medication errors.
- Draw up vaccines only after arriving at the clinic site or mass vaccination event. Drawing up doses days or even hours before administering them is not a best practice because general-use syringes are not designed for storage.
- Each person administering vaccines should draw up no more than one MDV or 10 doses at one time.
- Once each predrawn dose is prepared, label the syringe with the vaccine name and dosage, the beyond-use date and time, lot number, and the preparer's initials. Additional pertinent information can be added, such as age range or primary or booster dose, as needed.
- Monitor patient flow to avoid drawing up unnecessary doses.
- Predraw reconstituted vaccine into a syringe only when you are ready to administer it. If a predrawn vaccine is not used within 30 minutes of being reconstituted, follow manufacturer guidance for storage conditions and time limits. A manufacturer may specify that an unused reconstituted vaccine can only be stored in the vial for a specified amount of time.
- Predrawn syringes must be stored at the manufacturer-recommended temperatures throughout the clinic day.
- Discard any remaining vaccine in predrawn syringes at the end of the workday.

Never transfer predrawn reconstituted vaccine back into a vial for storage.

As an alternative to predrawing vaccines, use manufacturer-filled syringes for large vaccination clinics.

Instructions for transport of some COVID-19 vaccine products may be different from those for other vaccines. Carefully review this section as well as the COVID-19 vaccine storage and handling addendum for information on specific COVID-19 vaccine products to ensure the vaccine is transported safely and the vaccine cold chain is maintained.

Transport, as described in this section, involves the movement of vaccine between providers or other locations over a short distance and time frame and is appropriate for events such as an emergency or off-site clinic or to ensure vaccines that are about to expire can be used rather than wasted.

Vaccine Transport Situations

Vaccine transport to off-site or satellite facilities is different from both shipping and emergency transport. Shipping usually involves a professional carrier and a longer distance and time frame for moving vaccines between locations. Emergency transport usually involves relocating vaccines to protect them when a facility's ability to store vaccines is compromised (e.g., because of power loss). Depending on the situation, some transport recommendations may be the same, but there are also some differences.

Vaccine Transport

Vaccines from your supply should not be routinely transported. In instances where the transport of vaccine from your supply is necessary, take appropriate precautions to protect your supply. Vaccines should only be transported using appropriate packing materials that provide the maximum protection.

Protecting Your Vaccine Supply

- Vaccine that will be used at an off-site or satellite facility should be delivered directly to that facility.
- If delivery to the specific site is not possible, then vaccine can be transported in a stable storage unit and monitored with a TMD. If the facility doesn't have the capacity to refrigerate the vaccines, then a portable vaccine storage unit or qualified container and packout may be used with a DDL.
- Develop an emergency plan or SOPs for transporting vaccines and include procedures and protocols for packing and transport.

Partially used vials cannot be transferred between providers OR across state lines.**

* Contact your immunization program for details about specific state or local regulations impacting this activity.

- **The total time for transport alone or transport plus clinic workday should be a maximum of 8 hours† (e.g., if transport to an off-site clinic is 1 hour each way, the clinic may run for up to 6 hours), unless guidance from the manufacturer differs.**
- **Use a transport temperature monitoring log to document temperatures and how long the vaccine is in the portable storage container.**
- **Transport diluents with their corresponding vaccines to ensure there are always equal amounts of vaccines and diluents for reconstitution.**
- **Your facility should have a sufficient supply of materials needed for vaccine transport of your largest annual inventory. Appropriate materials include:**
  - Portable vaccine refrigerator/freezer/ultra-cold freezer units (preferred option)
  - Qualified containers and packouts
  - Hard-sided insulated containers or Styrofoam™ (Use in conjunction with the *Packing Vaccines for Transport during Emergencies*‡ tool. This system is only to be used in an emergency.)
  - Coolant materials such as phase change materials (PCMs) or frozen water bottles that can be conditioned between 4° C and 5° C (39° F and 41° F)
  - Insulating materials such as bubble wrap and corrugated cardboard—enough to form two layers per container
  - TMDs for each container

†COVID-19 vaccine transport times may be different. Refer to COVID-19 vaccine product specific information in the COVID-19 Vaccine Addendum.
‡Packing Vaccines for Transport during Emergencies: www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf

Soft-sided containers specifically engineered for vaccine transport are acceptable. Do not use commercially available soft-sided food or beverage coolers because most are poorly insulated and likely to be affected by room or outdoor temperatures.

The same shipping materials the vaccines were initially shipped in should rarely, if ever, be used as they are not meant for reuse. This could put the cold chain and, ultimately, the viability of the vaccine, at risk.

Transport of Vaccines

It is always safest to have vaccines delivered directly to a facility with a vaccine storage unit ready to receive the shipment, but this is not always possible. If necessary, vaccines may be transported using a portable vaccine refrigerator with a temperature monitoring device placed with the vaccines. If a portable vaccine refrigerator is not available, qualified containers and packouts with a TMD in each container can be used. For transport to an off-site clinic, bring only what is needed for the workday.

Transport System Recommendations

	Emergency Transport	Transport for Off-Site Clinic, Satellite Facility, or Relocation of Stock
Portable Vaccine Refrigerator or Freezer	Yes	Yes
Qualified Container and Packout	Yes	Yes
Conditioned Water Bottle Transport System*	Yes	No
Manufacturer's Original Shipping Container	Yes (last resort only)	No
Food/Beverage Coolers	No	No

Coolants for Transport

PCMs between 4° C and 5° C (39° F and 41° F) can also be purchased to maintain proper temperatures. Follow the manufacturer's instructions† for use to reduce the risk of freezing vaccines during transport.

Do not use frozen gel packs or coolant packs from original vaccine shipments to pack refrigerated vaccines. They can still freeze vaccines even if they are conditioned or appear to be "sweating."

In emergency situations, a system using conditioned water bottles can be used. Manufacturers' original shipping containers may also be used as a last resort in an emergency situation.

The *Packing Vaccines for Transport during Emergencies** tool describes a system in which properly conditioned frozen water bottles can be used as a coolant when transporting vaccine during emergency situations.

Transport Planning and Preparation

Improper packing for transport is as risky for vaccines as a failed storage unit.

Include vaccine packing and transport protocols in your routine and emergency storage and handling SOPs. At a minimum, include the following procedures and protocols:

For all staff-facilitated transport:

- Identify trained staff to pack vaccines as well as primary and backup vehicles and drivers for transport in advance.
- Consider renting a refrigerated truck if you have a large quantity of vaccines or need to transport vaccines an extended distance.
- Take an inventory of your vaccines and record actions to protect the vaccines during transport.
- Open unit doors only when necessary and only after completing all preparation for packing and moving vaccines.
- If using a company or personal vehicle, only transport vaccines inside the passenger compartment (not in the trunk or bed of a truck, which may be too hot or too cold).
- Move transport containers directly to a vehicle that is already at a comfortable temperature, neither too hot nor too cold.
- Avoid leaving containers in areas where they are exposed to direct sunlight.
- Check vaccine temperature upon arrival at the alternative vaccine storage facility and store vaccines at recommended temperatures immediately.
- Check with your immunization program‡ for additional guidance and resources on emergency transport of vaccines, particularly in major emergencies.

* Packing Vaccines for Transport during Emergencies: www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf
† Manufacturers' vaccine package inserts: www.immunize.org/fda/
‡ Immunization programs: www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html

Transporting Opened Multidose Vials

If absolutely necessary, a partially used vial may be transported to or from an off-site/satellite facility operated by the same provider, as long as the cold chain is properly maintained. However, **a partially used vial cannot be transferred from one provider to another or across state lines.**

Transporting Predrawn Syringes

CDC recommends transporting vaccine in vials. However, there may be instances when the only option is to transport predrawn vaccine in a syringe. U.S. Pharmacopeia includes guidance for transporting predrawn vaccine in syringes in the USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners.

Transporting Diluents

Transport diluents with their corresponding vaccines so there are always equal amounts of vaccines and diluents for reconstitution. Follow the manufacturer's guidance* for specific temperature requirements.

If diluents stored at room temperature (20° C to 25° C [68° F to 77° F]) are going to be transported with refrigerated vaccines, they should be refrigerated in advance for as long as possible so they do not raise the container temperature when placed with refrigerated vaccines.

Never freeze diluents—not even during transport.

Place an insulating barrier like bubble wrap between the diluents and conditioned water bottles or phase change materials.

Transporting Frozen Vaccines

If frozen vaccines must be transported, use a portable vaccine freezer unit or qualified container and packout that maintains temperatures between -50° C and -15° C (-58° F and +5° F) or -90° C and -60° C (-130° F and -76° F) for ultra-cold transport.

Follow these steps for transporting frozen vaccines:

- Place a TMD (preferably with a buffered probe) in the container as close as possible to the vaccines.
- Immediately upon arrival at the destination, unpack the vaccines and place them in a freezer at a temperature range between -50° C and -15° C (-58° F and +5° F) or -90° C and -60° C (-130° F and -76° F) for ultra-cold freezer storage. Any stand-alone freezer that maintains these temperatures is acceptable.
- Record the time that vaccines are removed from the storage unit and placed in the transport container, the temperature during transport, and the time at the end of transport when vaccines are placed in a stable storage unit.

Do not use dry ice, even for temporary storage†. Dry ice might expose the vaccines to temperatures colder than -50° C (-58° F).

Temperature Monitoring During Transport

Use a continuous TMD, preferably a DDL with the capability to measure minimum/maximum temperatures, for monitoring and recording temperatures while transporting vaccines:

- The TMD should have an accuracy of +/-0.5° C (+/-1° F).
- Place buffered probe material in a sealed vial directly with the vaccines.
- Keep the TMD display on top of vaccines so you can easily see the temperature.
- Record the time and minimum/maximum temperature at the beginning of transport.

* Manufacturers' vaccine package inserts: www.immunize.org/fda/

† The only exception to this is for transport of COVID-19 Vaccine (Pfizer) which can be transported at ultra-cold temperatures using dry ice. See the COVID-19 Vaccine Storage and Handling Addendum for more information.

Temperature Monitoring after Transport

Immediately upon arrival at the destination, vaccines should be stored in an appropriate storage unit with a TMD. Be sure to follow these guidelines for monitoring and recording storage unit temperature:

- If the device displays minimum/maximum temperatures, this information should be checked and recorded.
- If the device does not display minimum/maximum temperatures, then the current temperature should be checked and recorded a minimum of two times (at the start and end of the workday).

If vaccines cannot be stored in an on-site storage unit, they should be kept in the portable vaccine storage unit using the following guidance:

- If using a DDL that records minimum/maximum temperatures, only check and record temperatures each time the portable vaccine storage unit is opened. If the TMD measures current temperatures only, place the probe as close as possible to the vaccines, and check and record temperatures hourly.
- Keep the container closed as much as possible.
- For off-site clinic use, remove only one multidose vial or 10 doses at a time for preparation and administration by each person administering vaccines.

SECTION SEVEN: Emergency Vaccine Storage and Handling

Instructions for handling some COVID-19 vaccine products during an emergency may be different from those for other vaccines. Carefully review this section as well as the COVID-19 vaccine storage and handling addendum for information on specific COVID-19 vaccine products to ensure the vaccine cold chain is maintained during an emergency.

Emergencies like equipment failures, power outages, severe weather conditions, or natural disasters usually happen without warning and may compromise vaccine storage conditions. In addition to vaccine transport planning, you should make plans to prepare for emergencies.*

Emergency Equipment Backup Options

Alternative Storage Facility

No piece of vaccine storage equipment is infallible. At some point, equipment will fail because of a power outage, breakdown, or normal wear and tear.

- **Establish a working agreement with at least one alternative storage facility even if you have a generator as backup equipment.** Make sure you have 24-hour access to this facility. Hospitals, long-term care facilities, state depots, the Red Cross, fire stations, packing plants, and commercial pharmacies are some of the facilities that may be able to assist you.

Your facility may also choose to have a backup storage unit so that vaccine may not have to be packed and/or moved to an alternative storage facility if the primary storage unit fails.

Accessing Your Building after Hours

Emergency situations can arise outside of normal business hours, so maintain a relationship with your facility's building manager and/or security staff. Ensure all staff members are familiar with emergency SOPs, including after-hours roles and responsibilities. **Your facility's storage and handling SOPs should include instructions for accessing your vaccine storage units when the building is closed, with a building map/diagram and locations of:**

- Spare batteries
- Flashlights
- Keys
- Locks
- Circuit breakers
- Emergency transport equipment and materials

Keep information on after-hours building access and security procedures with SOPs and with building management and security staff, if appropriate, and also make sure relevant staff has copies of this information available at home.

* The Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) offers information concerning the storage and use of temperature-sensitive biological products that have been involved in a temporary electrical power failure or flood conditions: www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ProductSecurity/ucm147243.htm.

Vaccines may remain inside a nonfunctioning unit as long as appropriate temperatures are maintained. Monitor your DDL to determine when additional action should be taken.

Generators and backup battery power sources

Having an on-site generator prevents the need to transport vaccines to an alternative storage facility during a power outage.

- Keep sufficient fuel on hand to continuously run the generator for at least 72 hours.
- A generator should be tested quarterly and serviced annually.

A backup battery power source can be used in lieu of a generator.

- Backup battery power sources should be tested quarterly and serviced annually.
- Check the manufacturer's guide for testing

If an alternative vaccine storage facility is not available

If you cannot find an alternative vaccine storage facility within a reasonable distance, or if you cannot reach your alternative facility, you can use portable vaccine refrigerator/freezer units (if power source is available), qualified containers and packouts, or a hard-sided insulated container or Strofoam™ using the *Packing Vaccines for Transport during Emergencies* tool. Always place a TMD with the vaccines and carefully monitor the TMD to ensure vaccines remain within the appropriate temperature range. Temporary storage containers should remain closed, and vaccines can only be stored safely for as long as the containers are validated to maintain proper storage temperatures.

Power Outages

Monitoring Unit Temperature during a Power Outage

If your storage unit has an external temperature monitoring display that you can check without opening the unit door, take the following steps:

- Record room temperature (if possible) and the temperature inside the unit as soon as the power goes out.
- Record minimum and maximum temperatures reached inside the unit during the outage.
- Temperature excursions should be avoided, if possible, by using emergency plans and SOPs for transport and alternative storage. However, if temperatures have fallen outside of the recommended range, follow your procedures for temperature excursions.

If you cannot monitor the temperature inside the unit without opening the door and you do not have an alternative facility with power where the vaccines can be stored or other emergency vaccine storage SOPs, wait until power is restored and then take the following steps:

- Record the room temperature (if possible) and the temperature inside the unit.
- If using a DDL, document the length of time the power was off and the minimum and maximum temperatures during that period.
- If temperatures inside the unit have already fallen outside of the recommended range, follow your procedures for temperature excursions. Even if an excursion has occurred, move your vaccines to an alternative storage unit or location where they can be stored at appropriate temperatures, if possible. Make sure to separate and mark these vaccines "Do NOT Use" until a decision can be made about whether the vaccines can still be used.

During a power outage, only open the storage unit door if:

» Power is restored.

» It is determined that the vaccines need to be packed in separate storage containers and/or transported to an alternative storage facility.

Buffered temperature probe	Temperature probe designed to prevent false readings by protecting the thermometer from sudden changes in temperature that can occur when opening a refrigerator door. A probe is "buffered" by immersing it in a vial filled with liquid (e.g., glycol, ethanol, glycerin), loose media (e.g., sand, glass beads), or a solid block of material (e.g., Teflon®, aluminum).
Beyond-use date (BUD)	The date or time after which a vaccine should not be administered, stored, or transported. The BUD should never exceed the manufacturer's original expiration date.
Calibration	Professional measurement of the accuracy of a temperature monitoring device's readings against nationally accepted standards.
Cold chain monitor (CCM)	Generally, a single-use device that monitors the temperature inside a vaccine shipping container. CCMs should be thrown away after being checked. CCMs are stored in a separate compartment of the shipping container (a CCM may not be included when vaccines are shipped directly from the manufacturer).
Conditioned water bottles	Frozen water bottles that have been submerged under lukewarm water until the ice block inside can spin freely.
Digital data logger (DDL)	An electronic device that records data digitally over time or in relation to location either with a built-in or external instrument or sensor.
Diluent	A diluting agent (e.g., a liquid) added to reconstitute lyophilized vaccine before administration. Manufacturers of these vaccines also supply the matching diluent.
Dormitory-style (bar-style) storage unit	A combination refrigerator/freezer unit with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator. These units have been shown to pose a significant risk of freezing vaccines, even when used for temporary storage.
Fan-forced air circulation	Technology using powerful fans or multiple cool air vents inside the unit that promote uniform temperature and fast temperature recovery.
Household-grade storage unit	A storage unit that is primarily sold for home use.
Lyophilized	Freeze-dried; usually referring to a vaccine that is freeze-dried into a powder or wafer.
Minimum/maximum temperature	A vaccine storage unit's coldest and warmest temperature readings during a set period of time.

Phase change materials (PCMs)	Engineered packing supplies that help control container temperatures during vaccine transport or shipping.
Portable vaccine storage unit	A type of powered refrigerator or freezer unit specifically designed for use during vaccine transport. These are passive units that require a power source to function. Please note that some active units are "qualified" to maintain desired temperatures for a set amount of time in the event of a power loss.
Potency	A vaccine's strength or effectiveness; in the context of this toolkit, potency refers to a vaccine's response to environmental conditions.
Presentation	Type of packaging for a vaccine (e.g., single-dose vial, multidose vial, manufacturer-filled syringe, etc.).
Purpose-built /pharmaceutical-grade unit	Unit that are specifically designed to store vaccines.
Qualified container and packout	A type of container and supplies specifically designed for use when packing vaccines for transport. They are passive containers that do not require a power source and are "qualified" through laboratory testing under controlled conditions to ensure they achieve and maintain desired temperatures for a set amount of time.
Standard operating procedures (SOPs)	A set of step-by-step instructions compiled by an organization to help workers carry out complex routine or emergency operations. SOPs aim to achieve efficiency, quality output, and uniformity of performance, while reducing miscommunication and preventing failure to comply with industry regulations and best practices.
Stand-alone storage unit	A storage unit that operates independently of any other device or system for its desired function (i.e., a refrigerator that only functions as a refrigerator or a freezer that only functions as a freezer).
Temperature excursion	Any temperature reading that is outside the recommended range for vaccine storage as defined in the manufacturer's package insert.
Tolerance	Compliance with nationally accepted standards for the calibration limits of temperature monitoring equipment. The equipment can either be considered "in" or "out" of tolerance.
Traceability	An unbroken chain of measurements and associated uncertainties.
Uncertainty	The quantification of the doubt about the measurement result.

REFERENCE: Purpose-Built Vaccine Storage Units

Numerous vaccine storage units have entered the market that are designed specifically for the storage of vaccines. These units can take many physical forms. Some look like traditional stand-alone units, while others can take the form of dispensing or vending units, either with or without doors. Although these units may be similar to pharmaceutical-grade or medical-grade units, they are unique in that they are designed and tested to keep vaccines in appropriate storage conditions. If you are a VFC provider, your immunization program determines which purpose-built units meet VFC program requirements. Always check with your immunization program before purchasing any unit that will be used to store VFC vaccines. Features and considerations related to these types of units include the following:

VFC vaccine management

» Purpose-built units must have the ability to allow the user to separate public and private vaccine stock physically or virtually.

» If stock is separated virtually, an inventory printout† must be accessible upon request.

» If unable to physically remove expired vaccine from a purpose-built unit immediately, the unit must be able to make expired vaccine inaccessible.

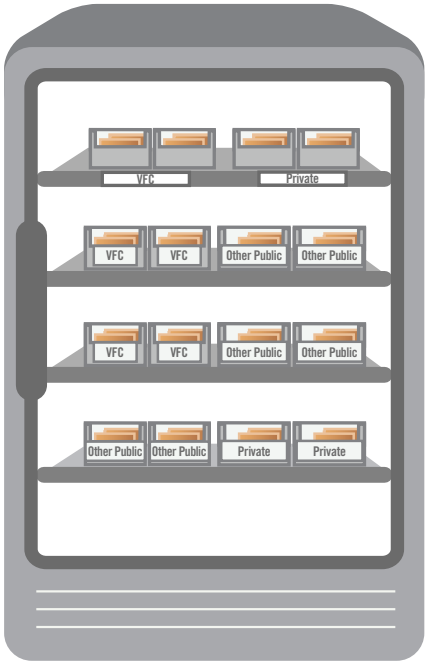
†The inventory printout should be used to answer storage and handling and inventory sections of the site visit reviewers guide.

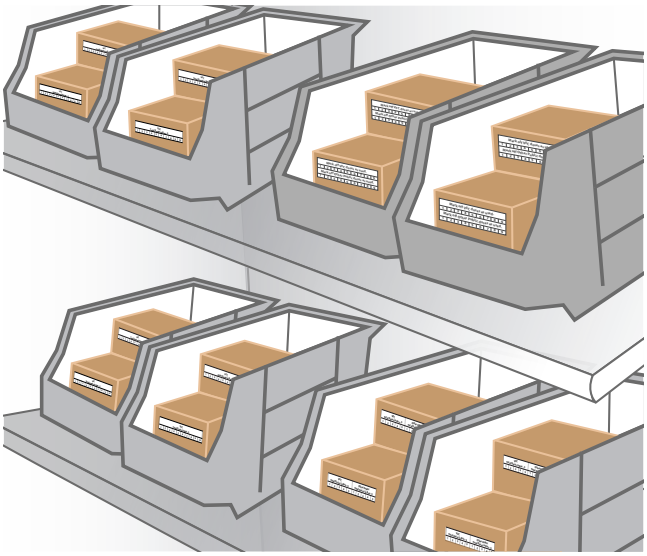
Temperature Monitoring

- Many purpose-built units have multiple temperature probes or sensors. It is important that these probes or sensors have current Certificates of Calibration.
- Many of the purpose-built closed or doorless units may utilize air sensors (non-buffered probes). Since these units have very limited exposure to ambient air, the use of a buffered probe is not essential.
- Many purpose-built units will have built-in digital data loggers with electronic interfaces that will allow you to track the continuous temperatures and/or provide min/max temperatures. If you are a VFC provider, always check to make sure that these satisfy the VFC program data logger requirements.

Vaccine Storage

- Many purpose-built units have undergone testing and temperature mapping so that the probe is in the most appropriate location.
- Although purpose-built units can have multiple temperature probes, a backup DDL is still needed for transport to a backup facility in an emergency.
- Many purpose-built units do not need water bottles to serve as thermal ballast.





WORKSHEET: Vaccine Storage and Handling SOPs

Complete the following checklist and forms and store this information in an easily accessible area near the vaccine storage unit.

CHECKLIST OF GENERAL INFORMATION

» Up-to-date contact information
- Primary vaccine coordinator
- Alternate vaccine coordinator
- Additional staff to assist in emergencies
- Immunization program
- Vaccine manufacturers
- Refrigerator and freezer maintenance and repair companies
- Temperature monitoring device (TMD) companies
- Utility/power company
- Vaccine storage unit alarm company (if applicable)
- Generator repair company (if applicable)
- Sources for qualified containers and packouts

» Descriptions of the roles and responsibilities of the primary and alternate vaccine coordinators

» Information for each storage unit, including serial number, links to equipment websites, installation dates, and routine maintenance and repair records

» Samples of all vaccine-related forms used in your facility

» Protocols for staff education and training

CHECKLIST FOR ROUTINE STORAGE AND HANDLING

» Protocols for:
- Ordering and accepting vaccine deliveries
- Unpacking deliveries
- Managing inventory
- Storing each vaccine and diluent
- Placing vaccines and diluents in storage units
- Handling vaccines prior to administration
- Disposing of vaccines and supplies
- Monitoring storage unit and temperature
- Maintaining storage equipment and TMDs
- Responding to storage and handling problems
- Transporting vaccines to off-site/satellite facilities

CHECKLIST FOR EMERGENCY VACCINE STORAGE, HANDLING, AND TRANSPORT

» All contact information in Checklist for General Information as well as up-to-date contact information for:
- Alternative vaccine storage facility (one or more)
- Transportation of vaccines

» Vaccine storage unit specifications (type, brand, model number, serial number)

» Diagram of facility showing important elements, including doors, flashlights, packing materials, batteries, circuit breakers

» Keep a copy of emergency SOPs with emergency supplies and at multiple off-site locations such as homes of vaccine coordinator and alternate coordinator and with building manager, security staff, and alternative storage facility.

» Protocols for:
- Monitoring vaccines during a power outage
- Packing vaccines and diluents for emergency transport
- Transporting vaccines to and from an alternative vaccine storage facility
- Assessing whether vaccine can be used after an emergency
- Accessing your building and facility after hours

WORKSHEET: Vaccine Storage and Handling SOPs

Store emergency information with emergency supplies.

STAFF CONTACT LIST			
Name	Title	Telephone Numbers home/cell/other	E-mail Address
	Primary Vaccine Coordinator		
	Alternate Vaccine Coordinator		

EMERGENCY STAFF CONTACT LIST			
Name	Title	Telephone Numbers home/cell/other	E-mail Address
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			

List contacts in order of preference. Determine whether all or certain persons on the list should be contacted or if the first person reached is sufficient.

WORKSHEET: Vaccine Storage and Handling SOPs

GENERAL RESOURCES CONTACT LIST

Resources	Contact Person Name/Title	Telephone Numbers home/cell/other	E-mail Address
Local Health Department Immunization Program			
State Health Department Immunization Program			
Vaccine Manufacturers			
Refrigerator Repair Company			
Freezer Repair Company			
Utility/Power Company			
Temperature Monitoring Device Company			
Vaccine Storage Unit Alarm Company (if applicable)			
Generator Repair Company (if applicable)			

ALTERNATIVE VACCINE STORAGE FACILITIES

Alternative Vaccine Storage Facility Name/Address	Contact Person Name/Title	Telephone Numbers home/cell/other	E-mail Address
1.			
2.			
3.			
4.			

TRANSPORTATION TO ALTERNATIVE VACCINE STORAGE FACILITIES

Emergency Resources Name/Address	Contact Person Name/Title	Telephone Numbers home/cell/other	E-mail Address
Refrigeration Company			
Refrigeration Company (alternative)			
Private Vehicle			
Private Vehicle (alternative)			

WORKSHEET: Vaccine Storage and Handling SOPs

PACKING MATERIAL SUPPLIERS CONTACT LIST

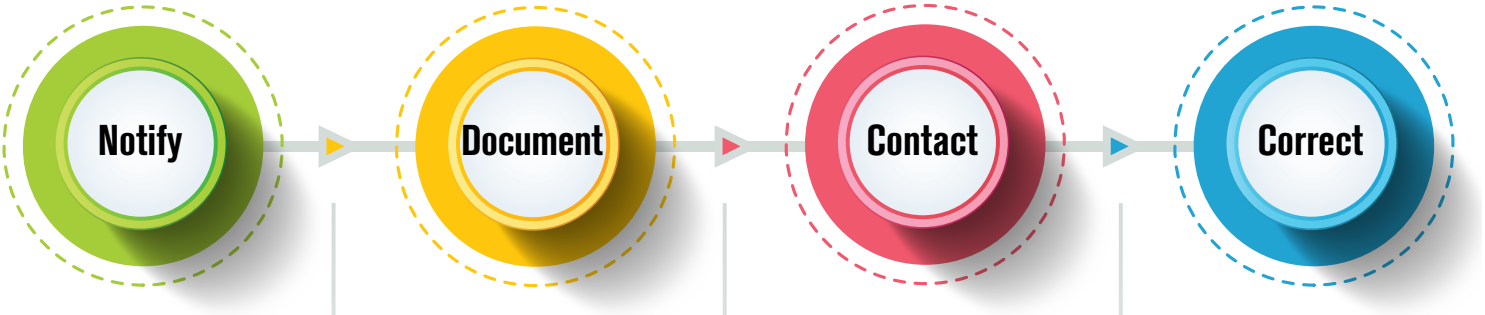
Emergency Resources	Company Name	Contact Person Name/Title	Telephone Numbers home/cell/other	E-mail Address
Portable vaccine refrigerator/freezer units				
Qualified containers and packout materials				
Qualified containers and packout materials (alternative)				
Packing materials				
Packing materials (alternative)				

VACCINE STORAGE UNIT SPECIFICATIONS

Type of Unit (Refrigerator or Freezer)	Brand	Model Number	Serial Number
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

Handling a Temperature Excursion in Your Vaccine Storage Unit

Any temperature reading outside ranges recommended in the manufacturers' package inserts is considered a temperature excursion. Identify temperature excursions quickly and take immediate action to correct them. This can prevent vaccine waste and the potential need to revaccinate patients.



Notify

» Notify the primary or alternate vaccine coordinator immediately or report the problem to a supervisor.

» Notify staff by labeling exposed vaccines, "DO NOT USE," and placing them in a separate container apart from other vaccines in the storage unit. Do not discard these vaccines.

Document

» Document details of the temperature excursion:

- Date and time
- Storage unit temperature (including minimum/maximum temperatures during the time of the event, if available)
- Room temperature, if available
- Name of the person completing the report
- General description of the event (i.e., what happened)
- If using a digital data logger (DDL), determine the length of time vaccine may have been affected
- Inventory of affected vaccines
- List of items in the unit other than vaccines (including water bottles)
- Any problems with the storage unit and/or affected vaccines before the event
- Other relevant information

Contact

» Contact your immunization program and/or vaccine manufacturer(s) for guidance per your standard operating procedures (SOPs).

» Be prepared to provide the immunization program or manufacturer with documentation and DDL data so they can offer you the best guidance.

Contact manufacturer for excursions:	
Dynavax	1-844-375-4728
GlaxoSmithKline	1-888-825-5249
Massachusetts Biological Labs	1-888-825-5249
MedImmune	1-877-633-4411
Merck	1-800-672-6372
Pfizer	1-800-438-1985
Sanofi Pasteur	1-800-822-2463
Seqirus	1-855- 358-8966

Correct

» If the temperature alarm goes off repeatedly, do not disconnect the alarm until you have determined and addressed the cause.

» Check the basics, including:

- Power supply
- Unit door(s)
- Thermostat settings

» If the excursion was the result of a temperature fluctuation, refer to the section, "Vaccine Storage and Temperature Monitoring Equipment," in CDC's *Vaccine Storage and Handling Toolkit* for detailed guidance on adjusting storage unit temperature to the appropriate range.

» If you believe the storage unit has failed, implement your emergency vaccine storage and handling SOPs. Never allow vaccines to remain in a nonfunctioning unit following a temperature excursion.

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

Fahrenheit to Celsius and Celsius to Fahrenheit Conversion

°F	°C	°F	°C	°F	°C
-22	-30	**21**	-6.1	**64**	17.8
-21	-29.4	**22**	-5.6	**65**	18.3
-20	-28.9	**23**	-5	**66**	18.9
-19	-28.3	**24**	-4.4	**67**	19.4
-18	-27.8	**25**	-3.9	**68**	20
-17	-27.2	**26**	-3.3	**69**	20.6
-16	-26.7	**27**	-2.8	**70**	21.1
-15	-26.1	**28**	-2.2	**71**	21.7
-14	-25.6	**29**	-1.7	**72**	22.2
-13	-25	**30**	-1.1	**73**	22.8
-12	-24.4	**31**	-0.6	**74**	23.3
-11	-23.9	**32**	0	**75**	23.9
-10	-23.3	**33**	0.6	**76**	24.4
-9	-22.8	**34**	1.1	**77**	25
-8	-22.2	**35**	1.7	**78**	25.6
-7	-21.7	**36**	2.2	**79**	26.1
-6	-21.1	**37**	2.8	**80**	26.7
-5	-20.6	**38**	3.3	**81**	27.2
-4	-20	**39**	3.9	**82**	27.8
-3	-19.4	**40**	4.4	**83**	28.3
-2	-18.9	**41**	5	**84**	28.9
-1	-18.3	**42**	5.6	**85**	29.4
0	-17.8	**43**	6.1	**86**	30
1	-17.2	**44**	6.7	**87**	30.6
2	-16.7	**45**	7.2	**88**	31.1
3	-16.1	**46**	7.8	**89**	31.7
4	-15.6	**47**	8.3	**90**	32.2
5	-15	**48**	8.9	**91**	32.8
6	-14.4	**49**	9.4	**92**	33.3
7	-13.9	**50**	10	**93**	33.9
8	-13.3	**51**	10.6	**94**	34.4
9	-12.8	**52**	11.1	**95**	35
10	-12.2	**53**	11.7	**96**	35.6
11	-11.7	**54**	12.2	**97**	36.1
12	-11.1	**55**	12.8	**98**	36.7
13	-10.6	**56**	13.3	**99**	37.2
14	-10	**57**	13.9	**100**	37.8
15	-9.4	**58**	14.4	**101**	38.3
16	-8.9	**59**	15	**102**	38.9
17	-8.3	**60**	15.6	**103**	39.4
18	-7.8	**61**	16.1	**104**	40
19	-7.2	**62**	16.7		
20	-6.7	**63**	17.2		

°C	°F	°C	°F
-30	**-22**	13	**55.4**
-29	**-20.2**	14	**57.2**
-28	**-18.4**	15	**59**
-27	**-16.6**	16	**60.8**
-26	**-14.8**	17	**62.6**
-25	**-13**	18	**64.4**
-24	**-11.2**	19	**66.2**
-23	**-9.4**	20	**68**
-22	**-7.6**	21	**69.8**
-21	**-5.8**	22	**71.6**
-20	**-4**	23	**73.4**
-19	**-2.2**	24	**75.2**
-18	**-0.4**	25	**77**
-17	**1.4**	26	**78.8**
-16	**3.2**	27	**80.6**
-15	**5**	28	**82.4**
-14	**6.8**	29	**84.2**
-13	**8.6**	30	**86**
-12	**10.4**	31	**87.8**
-11	**12.2**	32	**89.6**
-10	**14**	33	**91.4**
-9	**15.8**	34	**93.2**
-8	**17.6**	35	**95**
-7	**19.4**	36	**96.8**
-6	**21.2**	37	**98.6**
-5	**23**	38	**100.4**
-4	**24.8**	39	**102.2**
-3	**26.6**	40	**104**
-2	**28.4**		
-1	**30.2**		
0	**32**		
1	**33.8**		
2	**35.6**		
3	**37.4**		
4	**39.2**		
5	**41**		
6	**42.8**		
7	**44.6**		
8	**46.4**		
9	**48.2**		
10	**50**		
11	**51.8**		
12	**53.6**		

SAMPLE: Stock Record and Tally Sheet

STOCK RECORD

Instructions: Use the monthly stock record to document inventory from new vaccine/diluent shipments and track weekly accounts of doses used. At the end of each month, count inventory in storage unit(s) and compare with recorded balance. If physical count and recorded balance are different, record the actual (physical count) balance next to the previous recorded balance. Note the cause of the discrepancy or if it is unknown. Start a new stock record every month, listing at the top the previous month's balance as the new month's starting balance.

Vaccine Type: PPSV23 Month and Year: August 2023

Date Received or Usage Tallied	Person Receiving Shipment*	Arrival Condition**	Vaccine or Diluent Name	Manufacturer	Vial Type (SDV, MDV, MFS)***	Lot Number	Expiration Date	Expiration Date After Reconstitution	Doses Received/ Balance Forward	Doses Used†	Balance (Doses)††
08/02/23	BEGINNING BALANCE FOR THE MONTH								2	N/A	2
08/09/23										1	1
08/15/23	LST	G	PPSV23	Merck	MDV	03958	02/15/24	N/A	5	3	3
08/23/23										1	2
08/29/23										0	2
Vaccine Totals									7	5	2

* The initials of the person who unpacked and checked the vaccines/diluents upon arrival
** G = Vaccines/diluents arrived in good condition
? = Condition of vaccines/diluents questionable and state and local health department immunization program and vaccine manufacturer(s) contacted. Document details/outcome on reverse side of stock record.
*** SDV = Single-dose vial
MDV = Multidose vial
MFS = Manufacturer-filled syringe
† Includes number of doses administered, wasted, unusable, expired, or transferred.
†† Enter the sum of "Total Doses Received/Balance Forward" minus "Total Doses Used."

Physical Stock Check (In Doses)	2
Difference ("Balance" minus Physical Stock)	0
Balance Carried Forward (In Doses)	2

Some state or local health department immunization programs have developed their own stock record for immunization providers. Contact program staff for information. If stock records are not available from your state or local health department or an immunization information system (IIS), this stock record may be used.

TALLY SHEET

Instructions: Place a copy of this sheet on or near the refrigerator and freezer doors. Record the week (by date or week number). Write the vaccine/diluent names and indicate the storage location (refrigerator = R, freezer = F). Make a tick mark in the appropriate box for each dose of vaccine/diluent removed from the unit (i.e., each dose administered, wasted, unusable, expired, or transferred). At the end of the week, add the tick marks for each vaccine/diluent and update the totals on the appropriate stock record. File the completed tally sheet and replace with a new sheet.

Week: August 19—23, 2023 (Week 3)

Storage Location (R or F)*	Vaccine or Diluent Name	Doses Administered	Doses Wasted	Doses Expired	Doses Unusable**	Doses Transferred (Viable)***	Total
F	VAR	𝍸 III (8)					8
R	DTaP	𝍸 𝍸 II (12)					12
R	HepB	𝍸 𝍸 II (12)					12
R	IPV	𝍸 𝍸 II (12)		II			14
R	HepA (pediatric)	II (2)					2
R	PPSV23	I (1)					1

* R = Refrigerator F = Freezer
** Some unusable doses (VFC vaccines or other vaccines purchased with public funds) may need to be returned to your state or local health department immunization program.
*** Viable vaccine doses transferred to your state or local health department immunization program or another facility.

Some state or local health department immunization programs have developed their own tally sheets for immunization providers. Contact program staff for information. If tally sheets are not available from your state or local health department immunization program or an immunization information system (IIS), this tally sheet may be used.

Instructions: Use the monthly stock record to document inventory from new vaccine/diluent shipments and track weekly accounts of doses used. At the end of each month, count inventory in storage unit(s) and compare with recorded balance. If physical count and recorded balance are different, record the actual (physical count) balance next to the previous recorded balance. Note the cause of the discrepancy or if it is unknown. Start a new stock record every month, listing at the top the previous month's balance as the new month's starting balance.

Vaccine Type: _____ Month and Year: _____

Date Received or Usage Tallied	Person Receiving Shipment*	Arrival Condition**	Vaccine or Diluent Name	Manufacturer	Vial Type (SDV, MDV, MFS)***	Lot Number	Expiration Date	Expiration Date After Reconstitution	Doses Received/ Balance Forward	Doses Used†	Balance (Doses)††
	BEGINNING BALANCE FOR THE MONTH									**N/A**	

* The initials of the person who unpacked and checked the vaccines/diluents upon arrival

** G = Vaccines/diluents arrived in good condition
? = Condition of vaccines/diluents questionable and state and local health department immunization program and vaccine manufacturer(s) contacted. Document details/outcome on reverse side of stock record.

*** SDV = Single-dose vial
MDV = Multidose vial
MFS = Manufacturer-filled syringe

† Includes number of doses administered, wasted, unusable, expired, or transferred.

†† Enter the sum of "Total Doses Received/Balance Forward" minus "Total Doses Used."

Vaccine Totals	
Physical Stock Check (In Doses)	
Difference ("Balance" minus Physical Stock)	
Balance Carried Forward (In Doses)	

Some state or local health department immunization programs have developed their own stock record for immunization providers. Contact program staff for information. If stock records are not available from your state or local health department or an immunization information system (IIS), this stock record may be used.

Tally Sheet

Instructions: Place a copy of this sheet on or near the refrigerator and freezer doors. Record the week (by date or week number). Write the vaccine/diluent names and indicate the storage location (refrigerator = R, freezer = F). Make a tick mark in the appropriate box for each dose of vaccine/diluent removed from the unit (i.e., each dose administered, wasted, unusable, expired, or transferred). At the end of the week, add the tick marks for each vaccine/diluent and update the totals on the appropriate stock record. File the completed tally sheet and replace with a new sheet.

Week: _____

Storage Location (R or F)*	Vaccine or Diluent Name	Doses Administered	Doses Wasted	Doses Expired	Doses Unusable**	Doses Transferred (Viable)***	Total

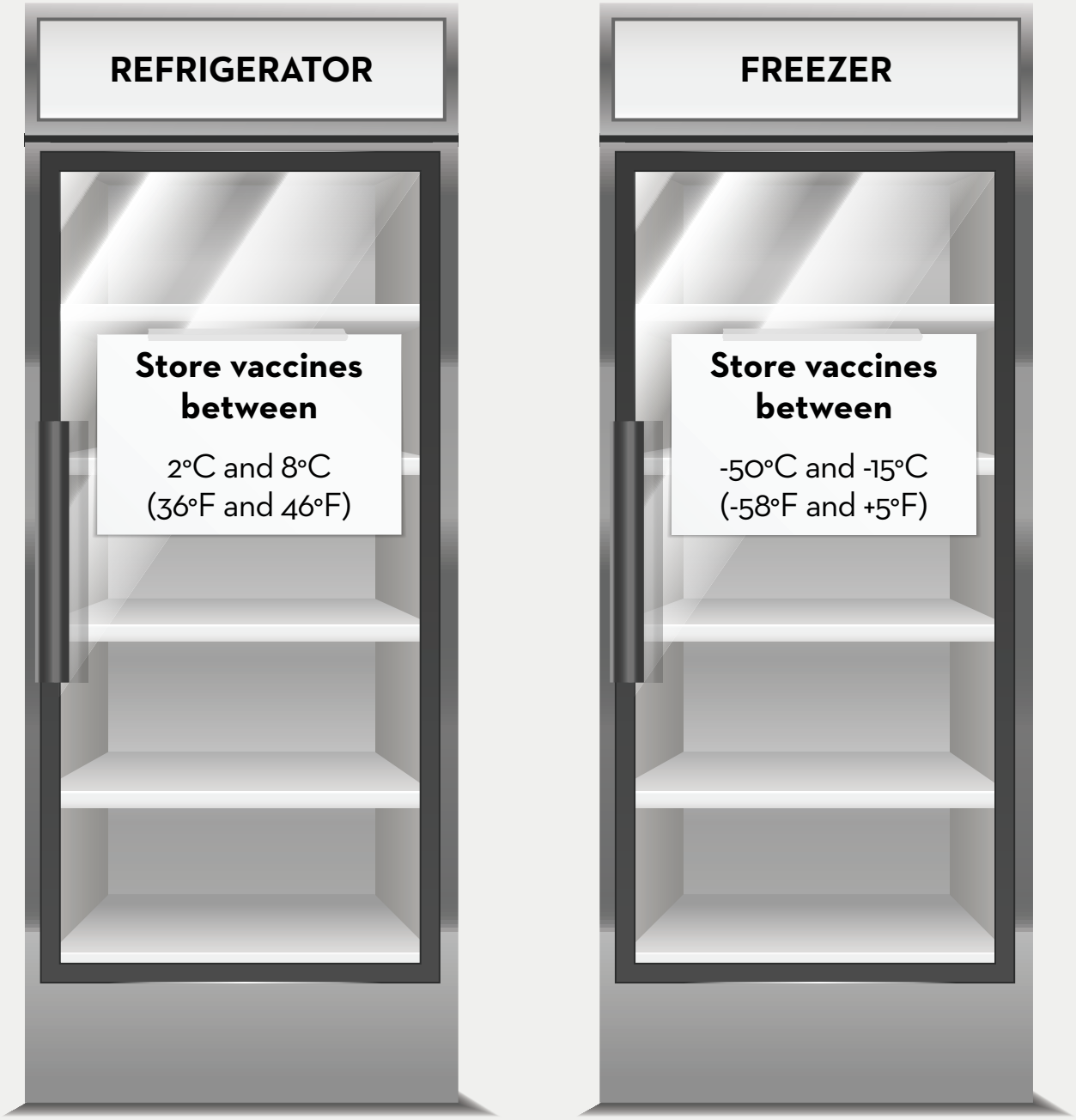
* R = Refrigerator F = Freezer

** Some unusable doses (VFC vaccines or other vaccines purchased with public funds) may need to be returned to your state or local health department immunization program.

*** Viable vaccine doses transferred to your state or local health department immunization program or another facility.

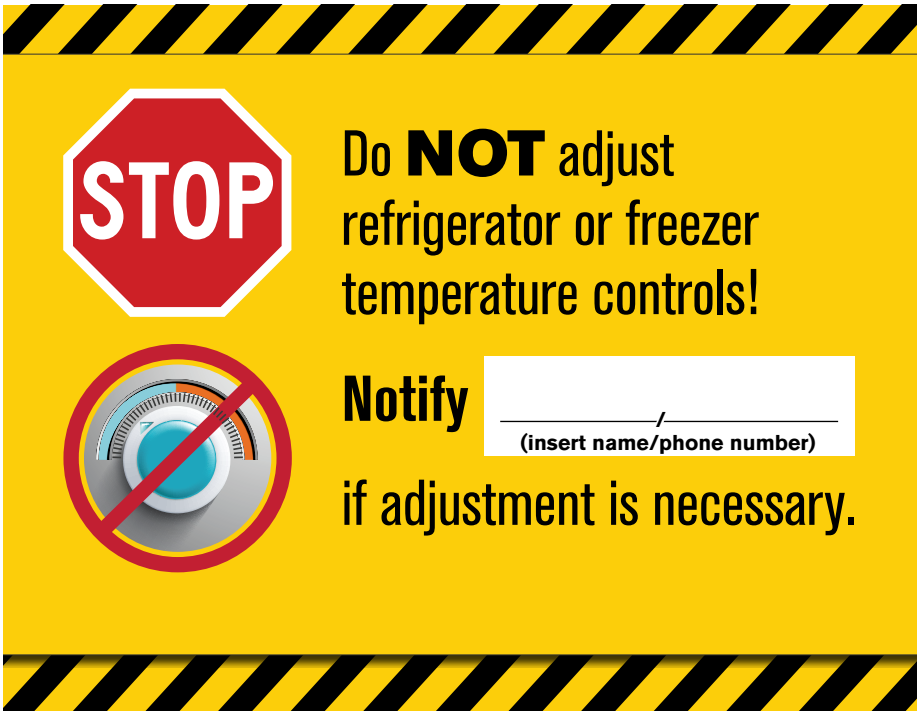
Some state or local health department immunization programs have developed their own tally sheets for immunization providers. Contact program staff for information. If tally sheets are not available from your state or local health department immunization program or an immunization information system (IIS), this tally sheet may be used.

HANDLE WITH CARE: Protect Your Vaccine | Protect Your Patients

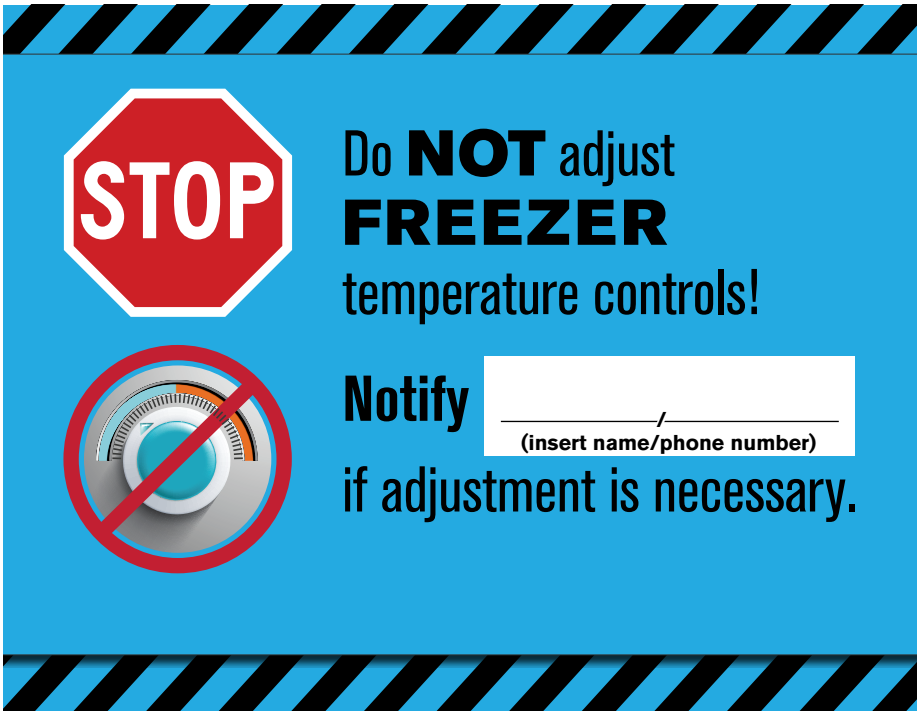


- Keep your storage units and vaccines within the appropriate temperature ranges.
- Check and record storage unit min/max temperatures at start of each workday. If your device does not display min/max temperatures, then check and record current temperature a minimum of 2 times (at start and end of workday). Also check current temperature before accessing and administering vaccine.
- Take immediate action if temperatures are out of range.
- Keep vaccines in their original packages.
- Many vaccines should be protected from light (consult manufacturer's product information).
- Check expiration dates and rotate your vaccine stock to keep most recent expiration dates at the front.

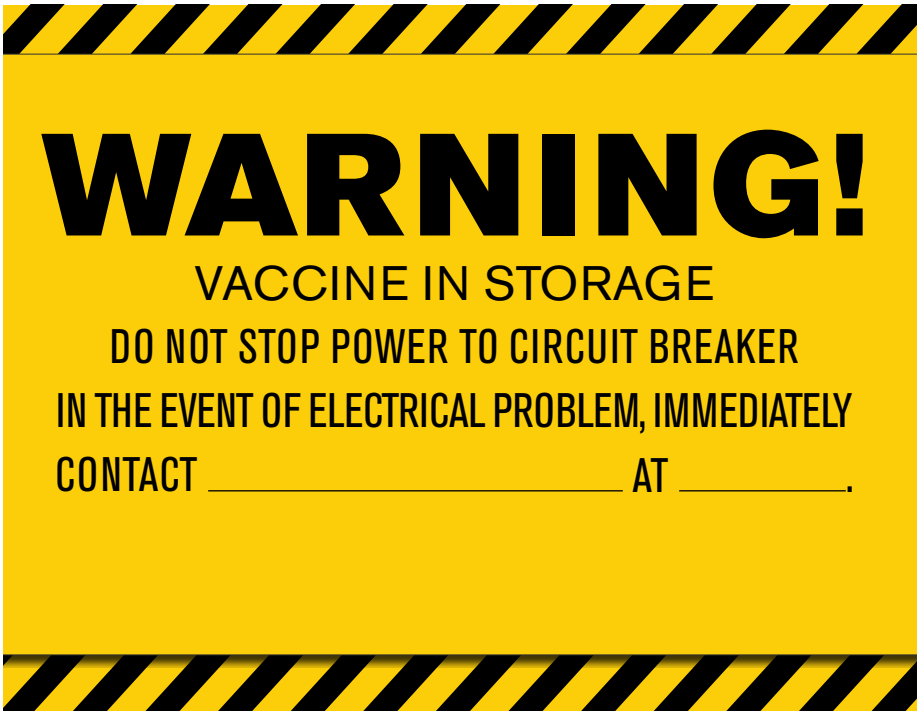
WARNING LABELS: Do Not Adjust Refrigerator Controls



WARNING LABELS: Do Not Adjust Freezer Controls



WARNING LABELS: Warning! Do Not Stop Power to Circuit Breaker



WARNING LABELS: Warning! Do Not Unplug Refrigerator

WARNING!

DO **NOT** UNPLUG THE **REFRIGERATOR** OR BREAK CIRCUIT.

VACCINE IN STORAGE.

IN THE EVENT OF ELECTRICAL PROBLEM, IMMEDIATELY CONTACT: _____/_____.

(insert name/phone number)

¡AVISO!

NO DESCONECTE EL **REFRIGERADOR** NI CORTE EL CIRCUITO.

¡CONTIENE VACUNAS!

SI HAY UN PROBLEMA CON LA ELECTRICIDAD, COMUNIQUESE INMEDIATAMENTE CON:

_____/_____.

(inserte nombre y número de teléfono aqui)

WARNING LABELS: Warning! Do Not Unplug Freezer

WARNING!

DO **NOT** UNPLUG THE **FREEZER** OR BREAK CIRCUIT.

VACCINE IN STORAGE.

IN THE EVENT OF ELECTRICAL PROBLEM, IMMEDIATELY CONTACT: _____/_____.

(insert name/phone number)

¡AVISO!

NO DESCONECTE EL **CONGELADOR** NI CORTE EL CIRCUITO.

¡CONTIENE VACUNAS!

SI HAY UN PROBLEMA CON LA ELECTRICIDAD, COMUNIQUESE INMEDIATAMENTE CON:

_____/_____.

(inserte nombre y número de teléfono aqui)

TRANSPORT LABELS: Refrigerate/Freeze Upon Arrival

TRANSPORT LABELS: Open Immediately: Refrigerate/Freeze Upon Receipt

TRANSPORT LABELS: Fragile: Handle with Care

TRANSPORT LABELS: Perishable: Rush

COVID-19 AND MPOX VACCINES STORAGE AND HANDLING

This addendum to the *Vaccine Storage and Handling Toolkit* (January, 2023) provides information, recommendations, and resources to assist COVID-19 and mpox vaccination providers in properly storing and handling COVID-19 vaccines to meet the requirements of the Vaccination Program Provider Agreement. The toolkit brings together best practices from the Advisory Committee on Immunization Practices (ACIP) General Best Practice Guidelines for Immunization, product information from vaccine manufacturers, and results of scientific studies. Implementing the toolkit best practices and recommendations will help to safeguard the vaccine supply and ensure patients receive safe and effective vaccines.

This addendum provides information on storage and handling best practices for COVID-19 vaccines and mpox vaccines. This addendum will be updated with specific storage and handling information for each vaccine product as it is authorized under an Emergency Use Authorization or approved by the Food and Drug Administration (FDA).

Vaccination Provider Requirements

All COVID-19 and mpox vaccination providers participating in the U.S. COVID-19 Vaccination Program and U.S. Monkeypox Vaccination Program are required to sign a Vaccination Program Provider Agreement to receive delivery of any COVID-19 or mpox vaccine from the distributor or a vaccine manufacturer. The agreement must be completed by all public and private providers, provider organizations, and government-affiliated federal, state, territorial, and local providers.

As part of the agreement, providers are required to:

- Store and handle vaccines under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with an EUA or vaccine package insert, manufacturer guidance, and CDC guidance in this toolkit.
- Monitor storage unit temperatures at all times, using equipment and practices that comply with guidance in this toolkit.
- Comply with immunization program guidance for handling temperature excursions.
- Monitor and comply with vaccine expiration dates and beyond-use dates/times.
- Preserve all records related to vaccine management for a minimum of three years.
- Comply with federal instructions and timelines for disposing of vaccine and diluent (if applicable), including unused doses.

Emergency Use Authorization Storage and Handling Information

Specific, detailed storage and handling protocols for individual vaccines are provided in manufacturer package inserts for vaccines licensed by the Food and Drug Administration (FDA). However, some vaccines are currently authorized for use under an EUA so vaccination providers should refer to the Fact Sheet for Healthcare Providers Administering Vaccine and manufacturer information for detailed storage and handling information for each vaccine.

Vaccine Cold Chain

Vaccines require a temperature-controlled environment. A cold chain is a temperature-controlled supply chain that includes all vaccine-related equipment and procedures. It begins with vaccine manufacturing and ends with vaccine administration. Vaccines must be stored properly from the time they are manufactured until they are administered. Potency is reduced every time a vaccine is exposed to an improper condition. This includes overexposure to heat, cold, or light at any step in the cold chain. Once lost, potency cannot be restored.

An effective cold chain relies on three main elements:

- Well-trained staff
- Reliable storage and temperature monitoring equipment
- Accurate vaccine inventory management

Vaccine appearance is not a reliable indicator that vaccines have been stored in appropriate conditions.

COVID-19 AND MPOX VACCINES STORAGE AND HANDLING

Staff and Training

All staff members who receive vaccine deliveries as well as those who handle or administer vaccines should be trained in vaccine-related practices and procedures. As a resource for staff, this toolkit highlights storage and handling best practices to help protect the vaccine supply. In addition, CDC's *You Call the Shots*: Vaccine Storage and Handling is a free, online training module focused on storage and handling requirements. Jurisdictions may also have specific requirements for storage and handling training, policies, and procedures.

All facilities must designate a primary vaccine coordinator and an alternate (backup) coordinator who will be responsible for ensuring all vaccines are stored and handled correctly. The primary and alternate vaccine coordinators should be experts on your facility's storage and handling procedures.

See Section Two, "Staff and Training," in the toolkit for more detailed information.

Vaccine Storage and Temperature Monitoring Equipment

COVID-19 and mpox vaccination providers must have proper storage and temperature monitoring equipment to meet the specific needs of the vaccine product(s) in their inventory. This includes the correct vaccine storage unit(s), whether a refrigerator, regular freezer, or ultra-cold freezer. Purpose-built, also referred to as "pharmaceutical-grade," units are preferred and designed specifically for storage of biologics, including vaccines. However, household-grade units can be an acceptable alternative in some situations. Most standard freezer units do not meet ultra-cold freezer requirements for storing vaccine between -60° C and -90° C (-76° F and -130° F).

It is essential that each vaccine storage unit has a temperature monitoring device (TMD) to ensure that vaccines are stored within the correct temperature range. CDC requires a specific type of TMD called a "digital data logger" (DDL) to monitor COVID-19 and mpox vaccines. A DDL provides the most accurate storage unit temperature information. Additionally, in the event of a temperature excursion (temperatures outside the correct range), a DDL can indicate how long and the temperatures the vaccine has been exposed to. This information is needed to determine the viability of the vaccine.

Always use a DDL that can continously monitor storage unit temperatures and has a:

- Buffered temperature probe
- Current and valid certificate of Calibration Testing

CDC recommends developing and maintaining clearly written, detailed, and up-to-date storage and handling standard operating procedures (SOPs). SOPs help ensure proper procedures are followed and problems are identified, reported, and corrected. SOPs should also provide direction for handling emergencies such as equipment malfunctions, power failures, or natural disasters.

Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.

These units have a single exterior door and an evaporator plate/cooling coil, usually located in an icemaker/freezer compartment. These units pose a significant risk of freezing vaccines, even when used for temporary storage. (Note: Not all small storage units are dormitory- or bar-style units. Compact, purpose-built units for biologics can be used to store vaccines.)

Diluents

Vaccines often need to be mixed with a liquid product before administration. A diluent may be a normal saline product or may contain an adjuvant for vaccine effectiveness. Always follow the vaccine manufacturer's guidance for use of the diluent. Diluents are not interchangeable and can only be used with the product for which they are provided.

DDLs for Ultra-Cold Temperatures

DDLs using a buffered temperature probe provide the most accurate measurement of vaccine temperatures. However, many manufacturers use pure propylene glycol (freezing point -59° C (-74° F)) or a glycol mixture with a warmer freezing point. For accurate ultra-cold temperature monitoring, it is essential to use an air-probe or a probe designed specifically for ultra-cold temperatures with the DDL.

COVID-19 AND MPOX VACCINES STORAGE AND HANDLING

Temperature Monitoring Requirements

Staff must check and record temperatures at the beginning of each workday to determine if any excursions have occurred since the last temperature check.* Monitor and record storage unit temperatures following one of these options.

When recording include:

- Minimum/maximum temperature†
- Date
- Time
- Name of person checking and recording temperature
- Actions taken if a temperature excursion occurred

Food and beverages should never be stored in the unit with vaccines. If other biologics are stored in the unit, vaccines should be stored on the shelf above them.

CDC has temperature logs can that can be used for recording this information. Temperature records must be kept for a minimum of three years, or longer if required by your jurisdiction.

Storing vaccines correctly in a vaccine storage unit is also critical to protect the vaccine and reduce the chance of vaccine administration errors if COVID-19 or mpox vaccine are stored with other vaccines. Best practices include:

- Place water bottles on the top shelf, floor, and in the door racks of vaccine storage units to help maintain stable temperatures that might be disrupted by frequently opening and closing unit doors. (Note: Water bottles are not recommended for use in in ultra-cold freezers or in all purpose-built or pharmaceutical-grade units—see manufacturer guidance.)
- Avoid placing or storing any items other than vaccines, refrigerated diluents, and water bottles inside storage units.
- Store vaccines and diluents in original packaging.
- Position vaccines and diluents two to three inches from the storage unit walls, ceiling, floor, and door. If using a household-grade unit, avoid storing vaccines and diluents in any part of the unit that may not provide stable temperatures or sufficient air flow.
- Arrange vaccines and diluents in rows and allow space between them to promote air circulation.

Place vaccines and diluents with the earliest expiration dates in front of those with later expiration dates. Of note, EUA vaccine labels may not include expiration dates. To help providers track expiration dates and beyond-use dates (BUDs), CDC has a COVID-19 Vaccine Expiration Date Tracking Tool on its website available. Also note that expiration dates may change as additional stability data become available. In addition, mpox vaccine and some COVID-19 vaccines must be used within a certain time frame (beyond-use date) if moved from one state to another (e.g., frozen to refrigerated). Providers should monitor/track the BUD to ensure vaccine is not used after the BUD has been reached.

See Section Three, "Vaccine Storage and Temperature Monitoring Equipment," for more detailed information about storage units, temperature monitoring equipment, and vaccine placement in vaccine storage units.

"Temperature Excursions"

Any temperature reading outside the range recommended by the manufacturer is considered a temperature excursion and requires immediate action. To determine whether a vaccine is likely to still be viable, vaccine manufacturers will analyze information about the magnitude of the temperature excursion, including the total amount of time that temperatures were out of range. To provide the manufacturer with sufficient information to determine vaccine viability, CDC requires taking the following steps after a temperature excursion:

- Label the vaccine "Do Not Use" and store at the recommended temperature range until you receive manufacturer guidance. If it is a frozen vaccine that has been thawed, store in the refrigerator between 2° C and 8° C (36° F and 46° F) until you receive manufacturer guidance, as refreezing the vaccine may damage it.
- Document the date and length of time of the excursion, the storage unit temperature (minimum/maximum, if available), and inventory affected.
- Record any other relevant information.
- Contact the manufacturer and/or immunization program for guidance on whether to use affected vaccines and whether patients need to be recalled for revaccination.
- Document the event and actions taken for record-keeping requirements.

* Monitoring requirements may vary if you are using the manufacturer-provided shipping container for storage.
† If the DDL cannot display the minimum/maximum temperatures, record the current temperature at the beginning and end of each work day.

COVID-19 AND MPOX VACCINES STORAGE AND HANDLING

It is important to note that vaccine manufacturer responses to temperature excursion reports are dependent on information given by the provider to the manufacturer. Different information about the same event can lead to different recommendations on whether vaccine can be used or whether patients need to be revaccinated. In addition, each event is unique, and manufacturer recommendations cannot be applied to future events that may appear similar to past events. For manufacturer contact information for vaccine- and temperature-related questions, see the COVID-19 or mpox vaccines specific product information page in this addendum.

See Section Three, "Vaccine Storage and Temperature Monitoring Equipment," for more additional information about recording and reporting temperature excursions.

Vaccine Deliveries and Vaccine Inventory Management

Proper vaccine inventory management is essential for appropriate vaccine ordering and stock rotation and ensures your facility has the vaccines your patients need.

Maintaining the cold chain is the first step in vaccine inventory management. Vaccine deliveries must only be scheduled at times when staff is guaranteed to be present because vaccines can never be left unattended. To support efficient distribution of vaccine, full-day receiving hours should be available. When that is not possible, locations receiving vaccine and ancillary supply shipments must be available during a four-hour window on a weekday other than Monday. All COVID-19 vaccine and ancillary kit deliveries will require a signature. Deliveries of mpox vaccine do not require a signature.

Upon arrival, all shipments of vaccine must be immediately examined for signs of damage, for indication of a temperature excursion during transit, and to confirm receipt of the appropriate vaccine types and quantities. Before opening a vaccine shipment, ensure the vaccine and any diluent, if applicable, is immediately:

- Stored at recommended storage conditions.
- Documented using your facility's vaccine inventory management process.

Vaccine inventory accounting includes keeping stock records to determine the type and amount of COVID-19 and mpox vaccines your facility should stock to meet the needs of your patients. It also involves checking expiration dates regularly and rotating stock so that doses with the earliest expiration dates are placed in front of those with later dates.

COVID-19 Vaccine Ancillary Supplies

COVID-19 vaccine shipments will include ancillary supplies:

- Needles (various sizes for the population served)
- Syringes
- Alcohol prep pads
- Surgical masks and face shields for vaccinators
- COVID-19 vaccination record cards for vaccine recipients
- Vaccine needle and length guide
- Diluent and mixing supplies (based on vaccine product)

Mpox vaccine shipments do **NOT** include ancillary supplies.

Never leave a vaccine shipping container unpacked and unattended. If vaccines and diluents get too warm, they cannot be used. Be sure all staff knows that vaccine deliveries require immediate attention.

See Section Four, "Vaccine Inventory Management," for additional information about vaccine inventory accounting measures.

Expired Vaccine

Determining when a vaccine or diluent expires is a critical step in proper storage and handling.

Expired vaccines and diluents must be removed immediately from storage units to avoid inadvertently administering them. Manufacturers may have specific guidance on how to handle expired or compromised vaccines. However, open or broken vials and vaccine predrawn by providers cannot be returned and must be discarded according to your jurisdiction's requirements.

To help vaccination providers track expiration dates and beyond-use dates (BUDs), CDC has developed product specific tracking tools and labels:

- COVID-19 Vaccine
- Mpox Vaccine

COVID-19 AND MPOX VACCINES STORAGE AND HANDLING

Vaccine Disposal

Medical waste disposal requirements are set by state environmental agencies and may vary from state to state. Your jurisdiction's immunization program or environmental agency can provide guidance to ensure your facility's vaccine disposal procedures comply with state and federal regulations. Vaccine manufacturers should also provide guidance about proper disposal of their products, including any unused vaccine. In some instances, unused vaccine may be returned to the manufacturer. Empty vaccine vials are usually not considered hazardous or pharmaceutical waste and do not require disposal in a biomedical waste container. However, check and comply with your jurisdiction's requirements for disposal.

Vaccine Preparation

Preparing vaccine properly is critical to maintaining the integrity of the vaccine during transfer from the manufacturer's vial to the syringe and, ultimately, to the patient. CDC recommends preparing and drawing up vaccines just before administration. It is important to follow vaccine preparation instructions provided in the vaccine product's Fact Sheet for Vaccination Providers or the manufacturer package insert.

Vaccine products may have different preparation requirements. Some should not be shaken, or the vaccine will be compromised and cannot be used. Carefully follow the manufacturer's vaccine preparation guidance. Diluents, if applicable, are not interchangeable unless specified by the manufacturer. Vaccine mixed with the wrong diluent should never be administered.

See Section Five, "Vaccine Preparation," for detailed information about vaccine preparation.

Vaccine Preparation Best Practices

- Prepare vaccines in a designated area away from any space where potentially contaminated items are placed.
- Always follow the manufacturer's instructions for preparing vaccine.
- Only prepare vaccines when you are ready to administer them.
- Always check expiration dates. If your facility stocks multiple vaccine products, always confirm you have selected the correct vaccine.
- Only administer vaccines you have prepared. This is a quality control and patient safety issue and a best practice standard of medication administration.

Predrawing vaccine can result in waste when more is drawn up than needed. In the rare instances when it is necessary to predraw vaccines, it is important to follow recommended guidance to avoid compromising and wasting vaccine and to maintain the cold chain. Carefully follow the toolkit best practices for predrawing vaccine as well as any manufacturer guidance.

COVID-19 Vaccine Transport

In most instances, vaccine will be delivered directly to the facility where it will be administered to maintain the vaccine cold chain. However, there may be circumstances where vaccine needs to be redistributed or transported. This can occur if:

- A CDC Supplemental COVID-19 Vaccine Redistribution Agreement is in place for vaccine to be redistributed beyond the identified primary CDC ship-to site (i.e., for larger organizations whose vaccine is shipped to a central depot and requires redistribution to additional clinic locations).
- A jurisdiction immunization program or commercial partner needs to redistribute vaccine within the jurisdiction based on need or to keep vaccine from being wasted.
- Vaccine needs to be transported for satellite, temporary, or off-site clinics, including programs at long-term care facilities, or for administration to patients such as those in a home healthcare program.

Mpox Vaccine Transport

Mpox vaccine is shipped from Strategic National Stockpile (SNS) sites to vaccine depots. Before storing vaccine,

- Examine the shipment for signs of damage.
- Check TempTale temperature monitoring device or DDL for temperature excursions.

If vaccine needs to be further transported (i.e., from vaccine depots to health departments or clinics), unpack vaccine from Credo Crates and repackage into an appropriate transport system as outlined in the Transport guidance here. Expiration date should be recorded when vials are separated from original packaging.

COVID-19 AND MPOX VACCINES STORAGE AND HANDLING

In these instances, appropriate precautions must be taken to protect the vaccine. Vaccine must only be transported using appropriate packing materials that provide maximum protection. Follow specific jurisdiction and federal direction for transporting vaccine products.

Transporting vaccine requires planning and preparation to ensure the cold chain is maintained. As a vaccination provider, you should carefully review Section Six, "Vaccine Transport," to ensure your facility has the appropriate procedures and supplies in place to safely transport vaccine. Transport guidance may vary based on the specific vaccine product.

The chart below shows general transport recommendations to maintain the vaccine cold chain in two situations: emergency transport and transport for use at off-site clinics or satellite facilities or for relocation of stock. Recommendations vary based on the situation. Some vaccine products may have specific transport guidance to ensure the cold chain is maintained and vaccine is protected. Refer to the relevant vaccine product information in this addendum for additional information.

COVID-19 Vaccine Transport Requirements

- Vaccine must be transported in a stable storage unit and monitored with a DDL. Record the time and minimum/maximum temperature at the beginning of transport. In most instances, packing materials that vaccines were initially shipped in are not meant for reuse (the most common exception is ultra-cold vaccine shipping materials).
- Transport equal amounts of vaccines, diluent (if needed), and supplies needed to administer and document vaccines.
- Immediately upon arrival at the destination, the time and minimum/maximum temperature must be recorded. Vaccines should be stored in an appropriate storage unit with a DDL. If this is not possible, vaccines should be kept in the portable storage unit and the unit temperature recorded every time the portable unit is opened.

CDC recommends transporting vaccine in vials. However, there may be instances when the only option is to transport vaccine in a predrawn syringe prepared by the provider. This should only occur when vaccine is in a multidose vial. U.S. Pharmacopeia includes guidance for transporting predrawn vaccine in syringes in the USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners.

A partially used vial cannot be transferred from one provider to another or across state lines.

General Transport System Recommendations	Emergency Transport	Transport for Off-Site Clinic, Satellite Facility, or Relocation of Stock
Portable Vaccine Refrigerator, Freezer, or Ultra-cold Freezer	Yes	Yes
Qualified Container and Packout	Yes	Yes
Conditioned Water Bottle Transport System	Yes	**No**
Manufacturer's Original Shipping Container	Yes (last resort only)	No
Food/Beverage Coolers	No	No

Emergency Storage and Handling

Emergencies such as equipment failures, power outages, severe weather conditions, or natural disasters usually happen without warning and may compromise storage conditions. It is critical that vaccination providers have plans in place for emergency situations. Some key issues to remember include:

- Vaccines may remain inside a nonfunctioning unit as long as appropriate temperatures are maintained. Monitor your DDL to determine when additional action should be taken.
- Having an on-site generator(s) prevents the need to transport vaccines to an alternative storage facility during a power outage.
- Emergency situations can arise outside of normal business hours, so your office staff as well your facility's building manager and/or security staff, if appropriate, must understand how to implement your emergency operation plans or access your facility if necessary.
- Ensure your facility has the resources on hand to safely pack vaccines for transport during emergencies.

See Section Seven, "Emergency Vaccine Storage and Handling," for additional information about monitoring and handling vaccine during an emergency.

COVID-19 AND MPOX VACCINES STORAGE AND HANDLING

Additional Resources

- ACIP's *General Best Practice Guidelines for Immunization*: www.cdc.gov/vaccines/hcp/ acip-recs/general-recs/index.html
- Educational webinars and continuing education for healthcare providers: www.cdc.gov/vaccines/ed/courses.html
- Emergency Use Authorization: www.youtube.com/watch?v=iGkwaESsGBQ&feature=youtu.be
- *Epidemiology and Prevention of Vaccine-Preventable Diseases*: www.cdc.gov/vaccines/pubs/pinkbook/index.html
- FDA Center for Biologics Evaluation and Research (CBER) information concerning the storage and use of temperature-sensitive biological products that have been involved in a temporary electrical power failure or flood conditions: www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/
- Federal Emergency Management Agency (FEMA) information on disaster preparedness: www.fema.gov/
- Immunization Action Coalition Refrigerator and Freezer Temperature Log Sheets and Vaccine Troubleshooting Record: www.immunize.org/va/va52_temperature-logs-iac.pdf
- Jurisdiction immunization programs: www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html
- Packing Vaccines for Transport during Emergencies: www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf
- *You Call the Shots*: Vaccine Administration: www2.cdc.gov/vaccines/ed/vaxadmin/va/ce.asp
- *You Call the Shots*: Vaccine Storage and Handling: www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp
- Vaccine Administration home page: www.cdc.gov/vaccines/hcp/admin/admin-protocols.html
- Vaccine Storage and Handling home page: www.cdc.gov/vaccines/recs/storage/default.htm (sign up for notifications about updates)
- *Vaccine Storage and Handling Toolkit* web page: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

Disclaimer: *Use of trade names and commercial sources in the addendum is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services (DHHS), the U.S. Public Health Service (PHS), or the Centers for Disease Control and Prevention (CDC). You may see vendors use terms such as "CDC-compliant," or "satisfies federal COVID-19 vaccine response requirements" in their marketing materials or on their websites. In this context, "compliance" and related terms may lead consumers to incorrectly believe that CDC has independently assessed and verified the quality of these products. CDC is not authorized to assess, validate, verify, or endorse the products or services of private companies. Should you encounter this type of language in vendor marketing materials, please keep in mind that CDC has not validated any product or service for compliance with vaccination provider requirements or standards as outlined in the COVID-19 and Mpox Vaccination Provider Agreement.*

COVID-19 Vaccine (Pfizer-BioNTech)

Products: Pfizer-BioNTech COVID-19 Vaccine (Monovalent/Bivalent Gray cap Age 12 and Older), (Monovalent/Bivalent Orange Cap Ages 5 through 11), (Monovalent/Bivalent Maroon Cap Ages 6 months through 4 years)

Manufacturer Website: www.cvdvaccine.com

Manufacturer Phone Number: 1-877-829-2619 (1-877-VAX-CO19)

CDC Clinical Guidance for Pfizer-BioNTech COVID-19 Vaccine: www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html

Ages: 6 months through 4 years
(Maroon capped vial and bordered label)

- **MONOVALENT Primary Series** (Dose 1 & 2)
- **BIVALENT Primary Series** (Dose 3)

Ages: 5 through 11 years
(Orange capped vial and bordered label)

- **MONOVALENT Primary Series**
- **BIVALENT Booster Dose**

Ages: 12 and older
(Gray capped vial and bordered label)

- **MONOVALENT Primary Series**
- **BIVALENT Booster Dose** Single-dose and Multidose Vials

Vaccine Temperature Ranges:

- Ultra-cold: -90°C and -60°C (-130°F and -76°F) until the expiration date
- Refrigerated: 2°C and 8°C (36°F and 46°F) for up to 10 weeks

Vaccine Storage Unit(s):

- Ultra-cold freezer
- Refrigerator

Temperature Monitoring Device: For accurate temperature monitoring, use a digital data logger (DDL) able to measure minimum and maximum temperatures..

- **Ultra-cold freezer**: Use a DDL with an air-probe or a probe designed specifically for ultra-cold temperatures.
- **Refrigerator:** Use a DDL with a detachable probe that best reflects vaccine temperatures (e.g., probe buffered with glycol, glass beads, or Teflon®).

Delivery:

- Vaccine arrives in a thermal shipping container at temperatures between -90°C and -60°C (-130°F and -76°F) with dry ice or between -25°C and -15°C (-13°F and 5°F).
- Ancillary supplies kit(s), including diluent if needed, will arrive in a separate shipment from the the vaccine. Each kit includes the number of supplies needed to support the number of doses ordered. Vaccine for ages:
  - » 6 months through 4 years requires diluent
  - » 5 through 11 years requires diluent
  - » 12 years and older does NOT require diluent
- Follow the manufacturer's guidance for unpacking the vaccine and returning the temperature monitoring device and container, if indicated. (www.cvdvaccine-us.com/5-11-yearsold/storage-and-handling).
- Dispose of the single-use thermal shipping container. Do **NOT** use the thermal shipping container for storage.
- Ancillary supply kits will be delivered separately from the vaccine and have been reconfigured to support the number of doses ordered. **Note:** There are no ancillary supplies for Pfizer-BioNTech vaccine for persons 12 years of age and older (gray-capped vial)

COVID-19 Vaccine (Pfizer-BioNTech)

Storage Information: Vaccine can be stored in an ultra-cold freezer or a refrigerator following routine storage and handling best practices. Do **NOT** store in the thermal shipping container or a freezer.

Ultra-Cold Freezer

Store unpunctured vials between -90°C and -60°C (-130°F and -76°F) until the expiration date.

» Store vials upright in the tray or box protected from light
» Use Pfizer-BioNTech's expiration date tool at lotexpiry.cvdvaccine.com

Refrigerator

Store unpunctured vials between 2°C and 8°C (36°F and 46°F) for up to 10 weeks

» Store the vaccine vials upright.
» Protect from light.
» Do **NOT** refreeze thawed vaccine.
» Use CDC's beyond-use date labels for Pfizer-BioNTech COVID-19 Vaccine.

Temperature Monitoring:

Ultra-cold freezer or refrigerator:

Storage unit temperatures must be monitored regularly, checked, and recorded to determine if any temperature excursions have occurred since the last temperature check. For accurate temperature monitoring, use a digital data logger (DDL) with a detachable probe that best reflects vaccine temperatures.

» Most digital data loggers display the minimum maximum (min/max) temperatures. Check and record the min/max temperature at the start of each workday. (preferred method)
» If the digital data logger is unable to display min/max temperatures, check and record the current temperature at the start and end of each workday.

Transport:

CDC does not recommend routine transport of vaccines. Ideally, vaccines should be delivered directly to the facility where they will be used. If vaccines must be transported, follow:

- Manufacturer's guidance
- CDC Pfizer-BioNTech COVID-19 Transport Summary
- Routine vaccine storage and handling transport guidance outlined in this toolkit.

CDC recommends transporting vaccine in vials. However, there may be instances when the only option is to transport vaccine in a predrawn syringe. U.S. Pharmacopeia includes guidance for transporting predrawn vaccine in syringes in the USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners.

COVID-19 Vaccine (Pfizer-BioNTech)

Vaccine Preparation and Administration:

Use the correct product based on the age of the recipient.

Vial cap color	Monovalent Maroon Cap	Bivalent Maroon Cap	Monovalent Orange Cap	Bivalent Orange Cap	Monovalent Gray Cap	Bivalent Gray Cap
Ages	**6 months through 4 years**		**5 through 11 years**		**12 years and older**	
Supplied in:	MDV*: 10 doses per vial **Requires diluent**	MDV*: 10 doses per vial **Requires diluent**	MDV*: 10 doses per vial **Requires diluent**	MDV*: 10 doses per vial **Requires diluent**	MDV*: 6 doses per vial **No diluent**	MDV*: 6 doses per vial SDV*: 1 dose **No diluent**

* MDV=multidose vial; SDV=single-dose vial

- Frozen vaccine must be thawed prior to use.
- Thaw vaccine between 2°C and 8°C (36°F and 46°F) or between 8° C and 25° C (46° F and 77° F). The amount of time needed to thaw vaccine varies based on the temperature and number of vials.
  - » **Unpunctured vials** may be held between 8° C and 25° C (46° F and 77° F) for a total of 12 hours.
- Single-dose vials contain 1 dose of vaccine. Use a new vial for each recipient.
- Mix vaccine with diluent if indicated. Use a new vial of diluent for each vial.

Diluent	Maroon capped vial 6 months through 4 years		Orange capped vial 5 through 11 years		Gray capped vial 12 years and older	
0.9% sodium chloride; preservative free diluent	Monovalent	Bivalent	Monovalent	Bivalent	Monovalent	Bivalent SDV and MDV
	2.2 mL	2.2mL	1.3 mL	1.3 mL	NONE	NONE

- During vaccine preparation, gently swirl after thawing and between each withdrawal from a multidose vial. Do not shake the vial. If shaken, contact the manufacturer.
- Administer by intramuscular (IM) injection using a new needle and syringe for each injection.
  - » **Punctured vials** maybe be kept between 2°C and 25°C (35°F to 77°F) for up to 12 hours. Discard the vial and any remaining vaccine after 12 hours.
- Discard vials (multidose or single dose) when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.

Special Considerations:

- To determine the expiration date use Pfizer-BioNTech's expiration date tool at lotexpiry.cvdvaccine.com.
- If unable to access the tracking tool, count out 12 months using the month printed on the vial as month 1. The vaccine expires on the last day of the 12th month. For example, the vial has January 2023 printed on it. December 2022 would be the 12th month and the vaccine would be expired December 31, 2023.
- Expired vaccine or vaccine past the BUD, should NEVER be administered. To prevent this, use CDC expiration date and BUD tracking tools.

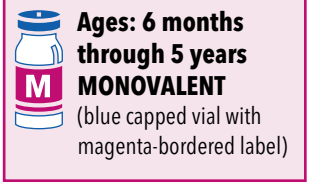
COVID-19 Vaccine (Moderna)

Products: Moderna COVID-19 Vaccine (Monovalent primary series 6 months through 5 years, Monovalent primary series 6 through 11 years, Monovalent primary series12 years and older, Bivalent booster doses 6 months through 5 years of age and Bivalent booster doses 6 years and older)

Manufacturer Website: www.modernatx.com/covid19vaccine

Manufacturer Phone Number: 1-866-MODERNA (1-866-663-3762)

CDC Clinical Guidance for Moderna COVID-19 Vaccine: www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html



Ages: 6 months through 5 years
MONOVALENT
(blue capped vial with magenta-bordered label)

Ages: 6 months through 5 years
BIVALENT
(pink capped vial with yellow-bordered label)

Ages: 6 through 11 years
MONOVALENT
(blue capped vial with purple-bordered label)

Ages: 12 years and older
MONOVALENT
(red capped vial with blue-bordered label)

Ages: 6 years and older
BIVALENT
(blue capped vial with gray-bordered label)

Vaccine Temperature Ranges:

Unpunctured vials may be stored:

- Frozen: -50°C and -15°C (-58°F and 5°F) until the expiration date
- Refrigerated: 2°C and 8°C (36°F and 46°F) up to 30 days

Vaccine Storage Unit(s):

Unpunctured vials may be stored in the:

- Freezer
- Refrigerator

Temperature Monitoring Device: For accurate temperature monitoring, use a digital data logger (DDL) with a detachable probe that best reflects vaccine temperatures (e.g., probe buffered with glycol, glass beads, or Teflon®) able to measure minimum and maximum temperatures.

Delivery:

- Vaccine arrives frozen between -50°C and -15°C (-58°F and 5°F). Examine the shipment for signs of damage.
- Ancillary supplies kit(s), including diluent if needed, will arrive in a separate shipment from the the vaccine. Each kit includes the number of supplies needed to support the number of doses ordered.
- Follow the manufacturer's guidance for unpacking the vaccine. Each box has a TagAlert temperature monitoring device that should be checked.

COVID-19 Vaccine (Moderna)

Storage Information: Vaccine can be stored in a freezer or refrigerator following routine storage and handling best practices.

Freezer

Store unpunctured vials between -50°C and -15°C (-58°F and 5°F) until the expiration date.*

- » Store vials upright in the tray or box protected from light
- » Do not store with dry ice or below -50°C (-58°F)
- » Determine the expiration date by scanning the QR code on the outer carton or go to modernacovid19global.com/vial-lookup

Refrigerator

Store unpunctured vials between 2°C and 8°C (36°F and 46°F).

- » Do NOT refreeze thawed vaccine.
- » Store vials upright in the tray or box protected from light.
- » Use tracking labels to monitor the beyond-use date.

Punctured vials may be stored between 2°F and 25°C (36°F and 77°F) for up to 12 hours.

Transport:

CDC does not recommend routine transport of vaccines. Ideally, vaccines should be delivered directly to the facility where they will be used. If vaccines must be transported, follow:

- Manufacturer's guidance
- CDC Moderna COVID-19 Transport Summary
- Routine vaccine storage and handling transport guidance outlined in this toolkit
- CDC recommends transporting vaccine in vials. However, there may be instances when the only option is to transport vaccine in a predrawn syringe. U.S. Pharmacopeia includes guidance for transporting predrawn vaccine in syringes in the *USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners*.

Vaccine Preparation and Administration:

Use the correct product based on the age of the recipient.

Vial cap color	Monovalent Blue capped vials with magenta-bordered label	Bivalent Pink capped vials with yellow-bordered label	Monovalent Blue capped vial with purple-bordered label	Monovalent Red capped vial with blue-bordered label	Bivalent Dark blue capped vial with gray-bordered label
Supplied in multidose vial	10 doses per vial	**2 doses per vial** **These vials should not be confused with single dose vials.** Once 2 doses have been removed, discard the vial.	5 doses per vial	10 primary doses	**6 through11 years of age:** 10 doses per vial **12 years of age and older:** 5 doses per vial

* These temperatures are within the appropriate range for routinely recommended vaccines BUT the temperature range for this vaccine is tighter. If storing the vaccine in a freezer with routinely recommended vaccines, carefully adjust the freezer temperature to the correct temperature range for this vaccine.

COVID-19 Vaccine (Moderna)

- Frozen vaccine must be thawed prior to use.
- Thaw vaccine between 2°C and 8°C (36°F and 46°F) or between 8° C and 25° C (46° F and 77° F). The amount of time needed to thaw vaccine varies based on the temperature and number of vials.
- Unpunctured vials may be held between 8°C and 25°C (46°F and 77°F) for a total of 24 hours.
- Do **NOT** dilute.
- During vaccine preparation, gently swirl after thawing and between each withdrawal from a multidose vial. DO not shake the vial. If shaken, contact the manufacturer.
- Administer by intramuscular (IM) injection using a new needle and syringe for each injection.
- Punctured vials maybe be kept between 8°C and 25°C (46°F and 77°F) for up to 12 hours. Discard the vial and any remaining vaccine after 12 hours.
- Discard the multidose vial when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.

Special Considerations:

- To determine the expiration date of a vial, scan the QR code located on the vial or carton. The QR code will bring up a website. Choose the lookup option, enter the lot number, and the expiration date will be displayed. You can also access the website directly: www.modernatx.com/covid19vaccine-eua.

COVID-19 Vaccine (Janssen)

Product: Janssen COVID-19 Vaccine (Johnson & Johnson)
Manufacturer Website: www.janssencovid19vaccine.com
Manufacturer Phone Number: 1-800-565-4008
CDC Clinical Guidance for Janssen COVID-19 Vaccine: www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html

Vaccine Temperature Range:

- Refrigerated: 2°C and 8°C (36°F and 46°F) until the expiration date*

Vaccine Storage Unit:

- Refrigerator

Temperature Monitoring Device: For accurate temperature monitoring, use a digital data logger (DDL) with a detachable probe that best reflects vaccine temperatures (e.g., probe buffered with glycol, glass beads, or Teflon®).

Delivery:

- Vaccine arrives refrigerated between 2°C and 8°C (36°F and 46°F). Examine the shipment for signs of damage. Shipments have two cartons; each carton contains 10 multidose vials (50 doses), 100 doses total.
- Each box has two temperature monitoring devices (WarmMark monitor and FreezeMark indicator) that should be checked following the manufacturer's guidance.
- Ancillary kits will be delivered separately from the vaccine and include enough supplies to administer 100 doses of vaccine.

Storage Information: Vaccine can be stored in a refrigerator following routine storage and handling best practices.

Refrigerator

Store between 2°C and 8°C (36°F and 46°F)

» Unpunctured vaccine vials should be stored until the expiration date.
» The expiration date may be extended as more stability data become available. Contact the manufacturer to determine if the expiration date has been extended prior to discarding vaccine. Use CDC's expiration date tracking tool to document expiration date changes.
» Punctured vaccine vials may be stored in the refrigerator for up to 6 hours.
» Protect vaccine from light.
» **DO NOT FREEZE.**

* These temperatures are within the appropriate range for routinely recommended vaccines BUT the temperature range for this vaccine is tighter. If storing the vaccine in a refrigerator with routinely recommended vaccines, carefully adjust the refrigerator temperature to the correct temperature range for this vaccine.

COVID-19 Vaccine (Janssen)

Transport:

CDC does not recommend routine transport of vaccines. Ideally, vaccines should be delivered directly to the facility where they will be used. If vaccines must be transported, follow routine vaccine storage and handling transport guidance outlined in this toolkit. Use CDC's transport temperature log to record temperatures and time in transport. Adhere to the following transport requirements:

Refrigerated transport (2° C to 8° C; 36° F to 46° F):

- Vaccine must be transported in insulated containers qualified to maintain a temperature range of 2°C to 8°C (36°F to 46°F) for the duration of transport.
- Take care to ensure vaccine does not freeze during transport.
- CDC recommends the total time for transport alone or transport plus clinic workday should be a maximum of 8 hours.
- Punctured vials can be transported at refrigerated temperatures. Once punctured, the refrigerated vials must be used within 6 hours. Transport time counts as part of the 6-hour time limit.
- Vaccine vials may be transported more than once.
- When transport is complete, vaccine should immediately be placed in a vaccine storage unit between 2°C and 8°C (36°F and 46°F).
- CDC recommends transporting vaccine in vials. However, there may be instances when the only option is to transport predrawn vaccine in a syringe. U.S. Pharmacopeia includes guidance for transporting predrawn vaccine in syringes in the *USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners*.
- Transportation guidance and considerations are outlined in CDC's Transportation Summary for this product.

Vaccine Preparation and Administration:

- After puncturing the multidose vial stopper, store vaccine in the refrigerator for up to 6 hours (2°C to 8°C [36°F to 46°F]) or at room temperature for up to 2 hours (maximally 25°C [77°F]).
  - » Discard the vaccine if not used during this time.
- Each multidose vial contains 5 doses.
- Do NOT mix vaccine with diluent.
- During vaccine preparation, gently swirl before first puncture and between each withdrawal. Do NOT shake the vial. If the vial is shaken, contact the manufacturer.
- Discard vial when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.
- Administer by IM injection

Special Considerations:

- The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:
  - » Scan the QR code on the outer carton, or
  - » Call 1-800-565-4008, or
  - » Visit www.vaxcheck.jnj.
- Write the expiration date on the carton. Use CDC's expiration date tracking tool to document expiration date changes.

COVID-19 Vaccine (Novavax)

Product: Novavax COVID-19 Vaccine (recombinant, adjuvanted), 12 years and older (Royal blue cap primary and booster series)
Manufacturer Website: www.novavaxcovidvaccine.com
Manufacturer Phone Number: 1-844-NOVAVAX (1-844-668-2829)
CDC Clinical Guidance for Novavax COVID-19 Vaccine: www.cdc.gov/vaccines/covid-19/info-by-product/novavax/index.html

Vaccine Temperature Range:

- Refrigerated: 2°C and 8°C (36°F and 46°F) until the expiration date

Vaccine Storage Unit:

- Refrigerator

Temperature Monitoring Device: For accurate temperature monitoring, use a digital data logger (DDL).

- **Refrigerator:** Use a DDL with a detachable probe that best reflects vaccine temperatures (e.g., probe buffered with glycol, glass beads, and or Teflon®).

Delivery:

- Vaccine arrives in a qualified shipping container at temperatures between 2°C and 8°C (36°F and 46°F). The vial has a royal blue cap and royal blue border on the label.
- Unpack vaccine immediately upon arrival at clinic and check the cold chain monitor (CCM) for any indication of a temperature excursion during transit.
- Check expiration date by scanning the QR on the outer carton or go to www.novavaxcovidvaccine.com
- Ancillary supplies including needles, syringes, and vaccination record cards will arrive separately from the vaccine.

Storage Information: Vaccine can be stored in a refrigerator following routine storage and handling best practices.

Refrigerator

Store between 2°C and 8°C (36°F and 46°F) until the expiration date.

- Store vaccine in the original packaging.
- Protect from light.
- Use storage labels to help staff easily identify the vaccine within the storage unit.
- Once punctured, Novavax COVID-19 Vaccine must be used within 6 hours.
  - Note when (time) the vial is first punctured and use within 6 hours.
  - Discard vial and any remaining vaccine after 6 hours.

COVID-19 Vaccine (Novavax)

Transport:

CDC does not recommend routine transport of vaccines. Ideally, vaccines should be delivered directly to the facility where they will be used. If vaccines must be transported, follow routine vaccine storage and handling transport guidance outlined in this toolkit. Use CDC's transport temperature log to record temperatures and time in transport. Adhere to the following transport requirements:

Refrigerated transport (2° C to 8° C; 36° F to 46° F):

- Vaccine must be transported in insulated containers qualified to maintain a temperature range of 2°C to 8°C (36°F to 46°F) for the duration of transport.
- Take care to ensure vaccine does not freeze during transport.
- CDC recommends the total time for transport alone or transport plus clinic workday should be a maximum of 8 hours.
- Punctured vials can be transported at refrigerated temperatures. Once punctured, the refrigerated vials must be used within 6 hours. Transport time counts as part of the 6-hour time limit.
- Vaccine vials may be transported more than once.
- When transport is complete, vaccine should immediately be placed in a vaccine storage unit between 2°C and 8°C (36°F and 46°F).
- CDC recommends transporting vaccine in vials. However, there may be instances when the only option is to transport predrawn vaccine in a syringe. U.S. Pharmacopeia includes guidance for transporting predrawn vaccine in syringes in the *USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners*.
- Transportation guidance and considerations are outlined in CDC's Transportation Summary for this product.

Vaccine Preparation and Administration:

- After puncturing the multidose vial stopper, store vaccine in refrigerator for up to 6 hours (2°C to 25°C (35°F to 77°F).
  - » Discard the vaccine if not used during this time.
- Each multidose vial contains 10 doses.
- Do NOT mix vaccine with diluent.
- During vaccine preparation, gently swirl before first puncture and between each withdrawal. Do NOT shake the vial. If the vial is shaken, contact the manufacturer.
- Discard vial when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.
- Administer by IM injection.

Special Considerations:

- The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date, visit www.novavaxcovidvaccine.com.
- Write the expiration date on the carton. Use CDC's expiration date tracking tool to document expiration date changes.

MPOX Vaccine (JYNNEOS)

Product: JYNNEOS (Smallpox and Monkeypox Vaccine, Live, Nonreplicating)
Manufacturer Website: jynneos.com
Manufacturer Phone Number: 1-844-422-8274
CDC Clinical Guidance for Mpox Vaccine: www.cdc.gov/poxvirus/monkeypox/clinicians/vaccines/vaccine-considerations.html

Vaccine Temperature Range:

Unpunctured vials may be stored:

- Frozen: Between -25°C and -15°C (-13°F and 5°F) until the expiration date
- Refrigerated: Between 2°C and 8°C (36°F and 46°F) for up to 8 weeks

Punctured vials may be stored:

- Refrigerated between 2°C and 8°C (36°F and 46°F) for up to 8 hours

Temperature Monitoring Device: For accurate temperature monitoring, use a digital data logger (DDL) with a detachable probe that best reflects vaccine temperatures (e.g., probe buffered with glycol, glass beads, or Teflon®).

Delivery:

- Vaccine is shipped from Strategic National Stockpile (SNS) sites to vaccine depots.
- Vaccine arrives frozen between -25°C and -15°C (between -13°F and 5°F)
- Examine the shipment for signs of damage. Each box contains 20 vials.
- Each box has a TempTale temperature monitoring device or DDL that should be checked following SNS guidance.
- If vaccine needs to be further transported (i.e., from vaccine depots to health departments or clinics), unpack vaccine from Credo Crates and repackage into an appropriate transport system as outlined in the Transport guidance below. Expiration date should be recorded when vials are separated from original packaging.

Storage Information: Vaccine can be stored in a freezer or refrigerator following routine storage and handling best practices. Individual guidance for each storage unit is as follows:

Freezer

Unpunctured vials may be stored frozen between -25°C and -15°C (-13°F and 5°F) until the expiration date.*

- » The expiration date may be extended as more stability data become available. As the expiration date approaches, contact the manufacturer to determine if the expiration date has been extended prior to discarding vaccine.
- » Store vaccine vials upright in the original package when possible.
- » Protect vaccine from light.

* These temperatures are within the appropriate range for routinely recommended vaccines BUT the temperature range for this vaccine is narrower. If storing the vaccine in a freezer with routinely recommended vaccines, carefully adjust the freezer temperature to the correct temperature range for this vaccine.

MPOX Vaccine (JYNNEOS)

Refrigerator

Unpunctured vials may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 8 weeks from thawing. This updated information has been provided by the vaccine manufacturer based on available supportive stability data. Please note that this differs from the package insert, which states that the vaccine may be kept at 2°C to 8°C (36°F to 46°F) for 12 hours (Section 2.2 Preparation and Administration and 16.2 Storage Conditions).

- Once thawed, vaccine cannot be refrozen.
- Use CDC's JYNNEOS beyond-use date (BUD) labels to track how long the vaccine has been in the refrigerator.
  - If the expiration date shown on the carton is earlier than the 8 weeks after vial was first thawed, write the expiration date on the box or container holding the vaccine vials.
  - As the 8-week deadline approaches, contact the manufacturer to determine if the expiration date has been extended prior to discarding vaccine.
- Store vaccine vials upright.
- Protect vaccine from light.
- Use vaccine vials stored in the refrigerator before removing additional vials from the freezer.

Punctured vials should be stored at refrigerated temperatures (between 2°C and 8°C) for up to 8 hours. Place the vial back in the refrigerator after drawing up each dose. Do NOT leave vaccine vial out at room temperatures in between doses.

Transport:

Frozen transport is preferred if vaccine must be transported.

Frozen transport:

JYNNEOS vaccine may be transported frozen between -25°C and -15°C (-13°F and 5°F) for 72 cumulative hours (e.g., vaccine transported for 2 hours today has 70 hours of transport time remaining).

- Transport using a portable freezer or qualified container to maintain between -25°C and -15°C (-13°F and 5°F) with DDLs.
- When you have completed the vaccine transport for the day, remove any remaining vials from the transport container, and place vials immediately in freezer.
- Complete the information on the bottom portion of the label indicating the time in transport and hours remaining for transport.
- Store vaccine upright in the freezer between -25°C and -15°C (-13°F and 5°F) until the expiration date, if freezer capacity is available, or in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 8 weeks from thawing.

Refrigerated transport:

JYNNEOS vaccine may be transported between 2°C and 8°C (36°F and 46°F) for 12 cumulative hours (e.g., vaccine transported for 2 hours today has 10 hours of transport time remaining).

- Transport using a portable refrigerator or qualified container to maintain between 2°C and 8°C (36°F and 46°F) with digital data loggers.
- When you have completed vaccine transport for the day, remove any remaining vials from the transport container and then place vials immediately in refrigerator.
- Complete the information on the bottom portion of the label indicating the time in transport and hours remaining for transport.
- Store vaccine upright in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 8 weeks.

MPOX Vaccine (JYNNEOS)

Vaccine Preparation and Administration:

- Each vial contains one subcutaneous dose or approximately five intradermal doses.
- Discard vial when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.
- Frozen vaccine must be thawed at room temperature for 10 minutes before using.
- Do **NOT** refreeze thawed vaccine.
- With the vial upright, gently swirl the vaccine for 30 seconds.
- Examine the vaccine. It should be a milky light yellow to pale white colored suspension. Do not use if liquid contains other particulate matter or is discolored.
- Once punctured, the vaccine must be stored in the refrigerator and used within 8 hours.
- Administer by subcutaneous or intradermal injection.

Special Considerations:

- Unpunctured vials may be held at room temperature for up to 6 cumulative hours. No additional stability data at room temperature is available.

Predrawn vaccine

Predrawing vaccines can result in waste if more are drawn up than needed. In addition, once vaccines are drawn into syringes, it is difficult to tell them apart, which can lead to administration errors, and such errors must be reported to the Vaccine Adverse Event Reporting System. However, there may be rare instances when the only option is to predraw JYNNEOS vaccine. If vaccines must be predrawn:

- » Predrawn vaccine must be labeled with vaccine name, lot number, date and time prepared, preparer's initials, and MUST BE refrigerated.
- » Predrawn syringes must be stored at the manufacturer-recommended refrigerated temperatures throughout the clinic day.
- » A separate clean administration station for each vaccine type should be set up to prevent medication errors.
- » Vaccines should be drawn up into syringes only after arriving at the clinic site, or mass vaccination event. Drawing up doses days or even hours before administering them is not a best practice because general-use syringes are not designed for storage.
- » Each person administering vaccines should draw up no more than 10 doses at one time.
- » Patient flow should be monitored to avoid drawing up unnecessary doses.
- » If a predrawn vaccine is not used within 8 hours of being drawn, the dose should be discarded.
- » Predrawn vaccine should never be transferred back into a vial for storage.

Additional Resources:

Healthcare Personnel Vaccination Module - Influenza Vaccination Summary - LTCF - Bing video

Older Adults Should Get High-Dose Flu Shot, Says CDC (aarp.org)

A Flu Vaccine is More Important than Ever! (30 second) - YouTube

Five reasons to get your flu vaccination - YouTube

Health officials warn that the upcoming flu season could be severe | Watch (msn.com)

CDC: Flu shots working well this season - YouTube