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# Vaccine Safety

Vaccine Safety Home

# Influenza (Flu)Vaccines

**Safety Information** 

## About Influenza (Flu)

**Influenza (flu)** is a contagious respiratory illness caused by influenza viruses that infect the nose, throat, and sometimes the lungs. It can cause mild to severe illness. Serious complications of flu infection can result in hospitalization or death. Some people, such as older people, young children, and people with certain health conditions, are at higher risk for developing serious flu complications.

There are two main types of influenza (flu) viruses: Types A and B. Influenza A and B viruses that routinely spread in people (human influenza viruses) are responsible for seasonal flu epidemics each year. Learn more about flu.

There are safe vaccines that can help reduce the risk from flu and its potentially serious complications.

#### Vaccine Information Statements

Vaccine Information Statements (VISs) are information sheets produced by CDC that explain both the benefits and risks of a vaccine.

#### Flu - Inactivated or Recombinant Shot

Inactivated influenza vaccines (IIV) and recombinant influenza vaccines (RIV) are shots that can be given to children and adults, with age-specific formulas available

#### Flu - Live, Intranasal Spray

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



#### Child and Adult Immunization Schedules

Get CDC's official recommended immunization schedules for children, adolescents, and adults.

### **Available Vaccines**

In the United States, there are currently two ways someone can get a flu vaccine—by injection (a shot) or nasal spray. There is no preferential recommendation for any one flu vaccine over another. Note: In any given flu season, there are multiple FDA-licensed flu vaccines from different manufacturers available for use.

#### INJECTABLE FLU VACCINES

Flu shots include inactivated influenza vaccines (IIV) and recombinant influenza vaccines (RIV). Flu shots do not contain live flu viruses. These vaccines come in various types of trivalent, quadrivalent, high-dose, adjuvanted, cell-based, and recombinant formulations.

#### NASAL SPRAY FLU VACCINE

Also known as live, attenuated influenza vaccine (LAIV), this nasal spray contains live viruses. However, the viruses are attenuated (weakened), so that they will not cause influenza

Learn more about different types of flu vaccines.

#### Who Should Get Flu Vaccine

Talk with your healthcare provider about vaccines.

They can answer questions and offer advice based on your specific health needs.

CDC recommends annual influenza vaccination for everyone 6 months and older with any flu vaccine licensed by the Food and Drug Administration (FDA) that is appropriate for the recipient's age and health status.

Vaccination is particularly important for people who are at high risk of developing serious complications from influenza.

Specific high-risk groups include:

- Adults 65 and older
- People who have diabetes
- Pregnant women
- People who have compromised immune systems, such as that due to HIV/AIDS, other medical conditions, and medications
- Young children
- People who have cancer
- Children with neurologic conditions
- People with asthma
- People with a history of heart disease and stroke
- People with some other chronic medical conditions, such as kidney, liver, blood, and metabolic disorders

For more information, see Who Needs a Flu Vaccine and When.

## Manufacturer Package Inserts

These FDA-licensed vaccine products are available in the United States for the 2021-2022 flu season. The composition of U.S. flu vaccines is reviewed annually and updated as needed to match circulating flu viruses. This season, only **quadrivalent formulations** are available. They are designed to protect against four flu viruses.

Flu Vaccines for Children and Adults



Afluria Quadrivalent [PDF – 29 Pages] : The Food and Drug Administration (FDA) approved this vaccine for use in persons 6 months of age and older.

FluLaval Quadrivalent [PDF – 26 Pages] 🗹 : FDA approved this vaccine for use in persons 6 months of age and older.

FluMist Quadrivalent [PDF – 27 Pages] : FDA approved this live attenuated influenza virus (LAIV) nasal spray vaccine for persons 2 through 49 years of age. This is the only LAIV nasal spray vaccine available for use during the 2021-2022 season.

Fluarix Quadrivalent [PDF – 20 Pages] : FDA approved this vaccine for use in persons 6 months of age and older.

Flucelvax Quadrivalent [PDF – 19 Pages] : FDA approved this vaccine for use in persons aged 2 years and older. This is the only cell-based inactivated influenza vaccine that has been licensed by the FDA for using during the 2021-2022 flu season.

Flublok Quadrivalent [PDF – 15 Pages] : FDA approved this recombinant vaccine for use in persons 18 years of age and older.

Fluzone Quadrivalent [PDF – 41 Pages] 🖸 : FDA approved this vaccine for use in persons 6 months of age and older.

#### Flu Vaccines for People 65 years of age and older



Fluad Quadrivalent [PDF – 15 Pages] : FDA approved this adjuvanted flu vaccine for use in persons 65 years of age and older.

Fluzone High-Dose Quadrivalent [PDF – 23 Pages] : FDA approved this vaccine for use in persons 65 years of age and older. This is a quadrivalent vaccine that contains four times the antigen of standard-dose inactivated influenza vaccines.

## **Common Side Effects**

Vaccines, like any medicine, can have side effects. Many people who get an annual flu vaccine have no side effects at all. Most side effects from flu vaccination are mild and go away on their own in a few days without any treatment.



#### Severe allergic reactions following vaccination are rare, but can be life threatening.

Symptoms of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness.

If such reactions occur, call 9-1-1 and get the person to the nearest hospital.

## Inactivated Influenza Vaccine (IIV) and Recombinant Influenza Vaccine (RIV)

#### **Common Side Effects**

- Injection site reactions that include soreness, redness and swollen arm
- Fever
- Muscle Aches
- Headache

Fatigue

#### Who Should Not Get IIV or RIV (flu shot)

#### People should not get a flu shot if they:

- Are younger than 6 months of age.
- Have severe, life-threatening allergies to flu vaccine or any ingredient in the vaccine. This might include gelatin, antibiotics, or other ingredients. See Special Considerations Regarding Egg Allergy for more information about egg allergies and flu vaccine.

#### People should talk to their healthcare provider before getting a flu shot if they:

- Have an allergy to eggs or any of the ingredients in the vaccine.
- Have ever had Guillain-Barré Syndrome (GBS). Some people with a history of GBS should not get a flu vaccine.

People who are moderately or severely ill should usually wait until they recover before getting a flu shot.

In some cases, the healthcare provider may decide to postpone influenza vaccination to a future visit.

## Live, Attenuated Influenza Vaccine (LAIV, nasal spray)

#### **Side Effects**

In children, side effects from the nasal spray may include:

- Runny nose
- Wheezing
- Headache
- Vomiting
- Muscle aches
- Fever (low grade)

In adults, side effects from the nasal spray vaccine may include:

- Runny nose
- Headache
- Sore throat
- Cough

### Who Should Not Get LAIV (flu nasal spray vaccine)

#### People should not get a nasal spray flu vaccine if they:

- Are younger than 2 years of age.
- Are 50 years of age and older.
- Are pregnant.
- Have severe, life-threatening allergies to nasal spray flu vaccine or any ingredient in the vaccine.
- Are between 2-17 years of age and are receiving aspirin, aspirin-containing, or salicylate-containing products.
- Have weakened immune systems (immunosuppression).
- Care for or are close contacts of severely immunocompromised persons who require a protected environment (or otherwise avoid contact with those persons for 7 days after getting the nasal spray vaccine).

- Are 2 years through 4 years and have asthma or have had a history of wheezing in the past 12 months.
- Have recently taken influenza antiviral drugs. People who have taken these medications should talk with their healthcare provider about which influenza antiviral was taken, and when the last dose was taken.
- LAIV is not recommended for people with some kinds of chronic health conditions because the safety and effectiveness of this vaccine in people with those conditions has not been established. (See Prevention and Control of Seasonal Influenza with Vaccines ACIP Recommendations for a list of contraindications and precautions for the nasal spray vaccine.)

#### People should talk to their healthcare provider before getting a nasal spray flu vaccine if they:

- Are 5 years and older and have asthma.
- Have other underlying medical conditions that can put them at high risk of developing serious flu complications.
   These include conditions such as chronic lung diseases, heart disease (except isolated hypertension), kidney disease, liver disorders, neurologic and neuromuscular disorders, blood disorders, or metabolic disorders (such as diabetes).
- Have moderate or severe acute illness with or without fever.
- Have had Guillain-Barré Syndrome after a previous dose of influenza vaccine.

People who are moderately or severely ill should usually wait until they recover before getting a flu vaccine.

In some cases, the healthcare provider may decide to postpone influenza vaccination to a future visit or suggest a different influenza vaccine.

More information about vaccine contraindications and precautions.

## Report Possible Adverse Events To VAERS

The Vaccine Adverse Event Reporting System (VAERS) is an early warning system, co-managed by CDC and FDA, that monitors for potential vaccine safety problems.

Healthcare providers and vaccine manufacturers are required by law to report certain adverse events following vaccination to VAERS; patients and caregivers can also submit reports.

For more information, see How to submit a report to VAERS .

### **More Information**

### Influenza-Related Questions and Answers

Learn more about the influenza virus and the vaccines that provide protection

#### Who Should Not Get Vaccinated?

Some people should not get certain vaccines or should wait before getting them. Read the CDC guidelines for each vaccine.

#### Influenza Vaccine - ACIP Recommendations and Guidance

Official guidance on influenza vaccine from the Advisory Committee on Immunization Practices (ACIP).

#### Seasonal Influenza Vaccine Safety: A Summary for Clinicians

Information for clinicians on the safety of the seasonal influenza vaccine.

## A Closer Look at the Safety Data

Findings from vaccine safety monitoring systems and scientific studies have shown that the flu vaccines have an excellent safety profile. Hundreds of millions of Americans have safely received flu vaccines for more than 50 years and the body of scientific evidence overwhelmingly supports their safety.

The safety of flu vaccines is monitored by CDC and FDA. Certain safety outcomes are commonly evaluated, including Guillain-Barré Syndrome, maternal and infant safety, and febrile seizures.

#### **Guillain-Barré Syndrome (GBS)**

The data on an association between seasonal inactivated influenza vaccine and GBS have been variable from season-to-season. When there has been an increased risk, it has been in the range of 1-2 additional GBS cases per million flu vaccine doses administered. The data also indicate that a person is more likely to get GBS after flu disease than after getting a flu vaccine. Learn more about Guillain-Barré Syndrome.

#### **Maternal and Infant Safety**

Pregnant women are considered at high risk for developing serious complications from flu. Several studies have shown that influenza vaccination can protect pregnant women during and after pregnancy and protect the baby from influenza infection for several months after birth. More information on flu vaccine effectiveness in pregnant women and their babies.

• Using the Vaccine Safety Datalink (VSD), CDC conducted a study looking at the long-term outcomes of infants born to mothers who were vaccinated with tetanus, diphtheria and acellular pertussis (Tdap) and the influenza vaccine during their pregnancy. The study found that influenza and Tdap vaccines in pregnancy are not associated with an increased risk of hospitalization or death in infants during the first six months of life.

Source: Infant Hospitalizations and Mortality After Maternal Vaccination [Pediatrics. 2018]

• CDC and other scientific institutions have conducted multiple studies that have examined the risk of miscarriage following influenza vaccination. The extensive body of evidence does not suggest a link between influenza vaccination and miscarriage.

#### Sources:

Inactivated Influenza Vaccine and Spontaneous Abortion in the Vaccine Safety Datalink in 2012-13, 2013-14, and 2014-15 [Vaccine. 2019]

Association of Spontaneous Abortion with Receipt of Inactivated Influenza Vaccine Containing H1N1pdm09 in 2010-2011 and 2011-2012 [Vaccine. 2017]

Trivalent Inactivated Influenza Vaccine and Spontaneous Abortion [Obstet Gynecol. 2013] 🗹

#### **Febrile Seizure**

Febrile seizures are seizures caused by fevers in young children. They can occur in all children, including those who have no serious underlying health issues. Febrile seizures can occur after common childhood febrile illnesses, like colds and flu. Less commonly, febrile seizures can occur as a result of post-vaccination fever. Although febrile seizures can be frightening for parents, children recover quickly and are not at increased risk for seizure disorders later in life. Children eventually outgrow them.

• A CDC study showed that children aged 6-23 months had an increased risk for febrile seizure after simultaneously receiving inactivated influenza vaccine (IIV), pneumococcal conjugate vaccine (PCV) and diphtheria-tetanus-acellular pertussis vaccine (DTaP).

Source: Febrile Seizure Risk After Vaccination in Children 6 to 23 Months [Pediatrics. 2016]

## **How CDC Monitors Vaccine Safety**

CDC and FDA monitor the safety of vaccines after they are approved or authorized. If a problem is found with a vaccine, CDC and FDA will inform health officials, health care providers, and the public.

CDC uses 3 systems to monitor vaccine safety:

- The Vaccine Adverse Event Reporting System (VAERS): an early warning system, co-managed by CDC and FDA, to monitor for potential vaccine safety problems. Anyone can report possible vaccine side effects to VAERS.
- The Vaccine Safety Datalink (VSD): a collaboration between CDC and 13 healthcare organizations that conducts vaccine safety monitoring and research.
- The Clinical Immunization Safety Assessment (CISA) Project: a partnership between CDC and several medical research centers that provides expert consultation and conducts clinical research on vaccine-associated health risks.

#### **Additional Resources**

Guillain-Barré syndrome and Flu Vaccine

Questions and answers about GBS and flu vaccines.

Childhood Vaccines and Febrile Seizures

Information on febrile seizures and childhood vaccines.

Flu Vaccine Safety and Pregnancy

Questions and answers on the safety of flu vaccines in pregnant women.

Thimerosal in Flu Vaccine

Questions and answers on what thimerosal is and the role it has in flu vaccines.

## **Related Scientific Articles**

2019



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Moro P, Baumblatt J, Lewis P, Cragan J, Tepper, Cano M. Surveillance of Adverse Events After Season Influenza Vaccination in Pregnant Women and Their Infants in the Vaccine Adverse Event Reporting System, July 2010-May 2016. Drug Saf. 2017 Feb; 40(2): 145-152

2016 and Prior



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