

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 of age and older, pregnant women, 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.

Each 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 vaccine

CDC recommends everyone 6 months of age 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 three or four viruses that are 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 vaccine 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 to a future visit.

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

Your health care provider can give you more information.



4 Risks of a vaccine reaction

- Soreness, redness, and swelling where shot is given, fever, muscle aches, and headache can happen after influenza vaccine.
- 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 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. 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. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your healthcare provider.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's www.cdc.gov/flu

Vaccine Information Statement (Interim)
**Inactivated Influenza
Vaccine**



Office use only

Information for Healthcare Professionals about the Screening Checklist for Contraindications to Inactivated Injectable Influenza Vaccination (IIV or RIV)

Are you interested in knowing why we included a certain question on the screening checklist? If so, read the information below. If you want to find out even more, consult the sources listed at the bottom of this page.

1. Is the person to be vaccinated sick today?

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events. People with a moderate or severe illness usually should not be vaccinated until their symptoms have improved. Minor illnesses with or without fever do not contraindicate use of influenza vaccine. Do not withhold vaccination if a person is taking antibiotics.

2. Does the person to be vaccinated have an allergy to a component of the vaccine?

All vaccines, including influenza vaccines, contain various components that might cause allergic and anaphylactic reactions. Not all such reactions are related to egg proteins. However, the possibility of a reaction to influenza vaccines in egg-allergic people might be of concern to both the person and vaccine providers.

An egg-free recombinant influenza vaccine (RIV) is available for people age 18 years and older and an egg-free cell culture-based IIV (ccIIV, Flucelvax) is approved for persons age 4 years and older. ACIP does not state a preference for the use of RIV for egg-allergic people although some providers may choose to administer RIV to their severely egg-allergic patients.

Reviews of studies of egg-culture based IIV and LAIV indicate that severe allergic reactions to egg-based influenza vaccines in persons with egg allergy are unlikely. ACIP recommends that persons with a history of egg allergy who have experienced only hives after exposure to egg should receive influenza vaccine. Any recommended and age-appropriate influenza vaccine (IIV, RIV, or LAIV) may be used. Providers should consider observing all patients for 15 minutes after vaccination to decrease the risk for injury should they experience syncope.

Persons who report having had reactions to egg involving symptoms other than hives, such as angioedema, respiratory distress, lightheadedness, or recurrent vomiting; or who required epinephrine or another emergency medical intervention, may also receive any recommended and age-appropriate influenza vaccine (IIV, RIV, or LAIV). The vaccine should be administered in a medical setting (e.g., a health department or physician office). Vaccine administration should be supervised by a healthcare provider who is able to recognize and manage severe allergic conditions.

Inactivated influenza vaccines provided in multi-dose vials contains thimerosal as a preservative. Most people who had sensitivity to thimerosal when it was used in contact lens solution do not have reactions to thimerosal when it is used in vaccines. Check the package insert at www.immunize.org/fda for a list of the vaccine components (i.e., excipients and culture media) used

in the production of the vaccine, or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.

For the 2019–2020 influenza season, no vaccine or packaging contains latex.

3. Has the person to be vaccinated ever had a serious reaction to influenza vaccine in the past?

Patients reporting a serious reaction to a previous dose of inactivated influenza vaccine should be asked to describe their symptoms. Immediate – presumably allergic – reactions are usually a contraindication to further vaccination against influenza.

Fever, malaise, myalgia, and other systemic symptoms most often affect people who are first-time vaccinees. These mild-to-moderate local reactions are not a contraindication to future vaccination. Also, red eyes or mild upper facial swelling following vaccination with inactivated injectable influenza vaccine is most likely a coincidental event and not related to the vaccine. These people can receive injectable vaccine without further evaluation.

4. Has the person to be vaccinated ever had Guillain-Barré syndrome?

It is prudent to avoid vaccinating people who are not at high risk for severe influenza complications (see source 3) and who are known to have developed Guillain-Barré syndrome (GBS) within 6 weeks after receiving a previous influenza vaccination. As an alternative, clinicians might consider using influenza antiviral chemoprophylaxis for these people. Although data are limited, the established benefits of influenza vaccination for the majority of people who have a history of GBS, and who are at high risk for severe complications from influenza, justify yearly vaccination.

SOURCES

1. CDC. *Epidemiology & Prevention of Vaccine-Preventable Diseases*, Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. at www.cdc.gov/vaccines/pubs/pinkbook/index.html
2. CDC. *Best practices guidance of the Advisory Committee on Immunization Practices Committee (ACIP)* at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
3. CDC. *Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices – United States, ...* Access links to current ACIP recommendations at www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html

Screening Checklist for Contraindications to Inactivated Injectable Influenza Vaccination

PATIENT NAME _____

DATE OF BIRTH _____ / _____ / _____
month day year

For patients (both children and adults) to be vaccinated: The following questions will help us determine if there is any reason we should not give you or your child inactivated injectable influenza vaccination today. If you answer “yes” to any question, it does not necessarily mean you (or your child) should not be vaccinated. It just means additional questions must be asked. If a question is not clear, please ask your healthcare provider to explain it.

	yes	no	don't know
1. Is the person to be vaccinated sick today?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Does the person to be vaccinated have an allergy to a component of the vaccine?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Has the person to be vaccinated ever had a serious reaction to influenza vaccine in the past?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Has the person to be vaccinated ever had Guillain-Barré syndrome?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

FORM COMPLETED BY _____ DATE _____

FORM REVIEWED BY _____ DATE _____