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

1 Why get vaccinated?

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

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

Anyone can get flu. Flu strikes suddenly and can last several days. Symptoms vary by age, but can include:

• fever/chills
• sore throat
• muscle aches
• fatigue
• cough
• headache
• runny or stuffy nose

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

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

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

Flu vaccine can:

• keep you from getting flu,
• make flu less severe if you do get it, and
• keep you from spreading flu to your family and other people.

2 Inactivated and recombinant flu vaccines

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

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

3 Some people should not get this vaccine

Tell the person who is giving you the vaccine:

• If you have any severe, life-threatening allergies.
If you ever had a life-threatening allergic reaction after a dose of flu vaccine, or have a severe allergy to any part of this vaccine, you may be advised not to get vaccinated. Most, but not all, types of flu vaccine contain a small amount of egg protein.

• If you ever had Guillain-Barré Syndrome (also called GBS).
Some people with a history of GBS should not get this vaccine. This should be discussed with your doctor.

• If you are not feeling well.
It is usually okay to get flu vaccine when you have a mild illness, but you might be asked to come back when you feel better.

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

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

Flu vaccine cannot prevent:

• flu that is caused by a virus not covered by the vaccine, or
• illnesses that look like flu but are not.

It takes about 2 weeks for protection to develop after vaccination, and protection lasts through the flu season.


4 **Risks of a vaccine reaction**

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

Most people who get a flu shot do not have any problems with it.

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

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

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

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

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

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

5 **What if there is a serious reaction?**

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

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

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

VAERS does not give medical advice.

6 **The National Vaccine Injury Compensation Program**

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

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

7 **How can I learn more?**

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

Vaccine Information Statement
Inactivated Influenza Vaccine

08/07/2015

42 U.S.C. § 300aa-26
Screening Checklist for Contraindications to Inactivated Injectable Influenza Vaccination

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 health care provider to explain it.

1. Is the person to be vaccinated sick today? (yes) (no) (don't know)
2. Does the person to be vaccinated have an allergy to eggs or to a component of the vaccine? (yes) (no) (don't know)
3. Has the person to be vaccinated ever had a serious reaction to influenza vaccine in the past? (yes) (no) (don't know)
4. Has the person to be vaccinated ever had Guillain-Barré syndrome? (yes) (no) (don't know)

FORM COMPLETED BY __________________________ DATE __________
FORM REVIEWED BY __________________________ DATE __________

Other if applicable Lot: _____ Exp: _____

Site: R / L Deltoid (Please circle)

Administered by: ________________________________
Information for Health Care Professionals about the Screening Checklist for Contraindications to Inactivated Injectable Influenza Vaccination (IIV or RIV3)

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 an acute febrile 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 eggs or to a component of the vaccine?

   Allergic reactions to any vaccine component can occur. The majority of reactions probably are caused by residual egg protein. Although most current influenza vaccines contain only very small quantities of egg protein, this protein can induce immediate allergic reactions among people who have severe egg allergy.

   An egg-free recombinant vaccine (RIV3) may be used in people age 18 years and older with egg allergy of any severity who have no other contraindications. If RIV3 is not available, or if the person is younger than age 18 years (does not meet the age criteria for RIV3) and has experienced a serious systemic or anaphylactic reaction (e.g., hives, swelling of the lips or tongue, acute respiratory distress, or collapse) after eating eggs, that person should have IIV administered by a physician with experience in the recognition and management of severe allergic conditions.

   Some people who report allergy to egg might not be egg-allergic. If a person can eat lightly cooked eggs (e.g., scrambled eggs), they are unlikely to have an egg allergy. However, people who can tolerate egg in baked products (e.g., cake) might still have an egg allergy. If the person develops hives only after eating eggs, CDC recommends they receive either inactivated influenza vaccine (IIV) or, if age-eligible, RIV3 (not LAIV). If IIV is to be administered, CDC further recommends the vaccine recipient be observed for at least 30 minutes after receipt of the vaccine for signs of a reaction.

   Fluzone (sanofi pasteur) contains gelatin as a stabilizer; therefore a history of anaphylactic reaction to gelatin is a contraindication. Some inactivated influenza vaccines contain thimerosal as a preservative. Most people who have 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/packageinserts 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.

   Some vaccines also contain latex in the prefilled syringe cap which may cause allergic reactions in latex sensitive people. Check the package inserts at www.immunize.org/packageinserts for information on which vaccines are affected, or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/latex-table.pdf.

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, physicians 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


2. CDC. General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP) at www.cdc.gov/vaccines/hcp/acip-recs.