

Influenza Vaccine

What You Need to Know

(Flu Vaccine,
Inactivated or
Recombinant)
2014-2015

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 (“flu”) is a contagious disease that spreads around the United States every winter, 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, but the risk of getting flu is highest among children. Symptoms come on suddenly and may last several days. They can include:

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

Flu can make some people much sicker than others. These people include young children, people 65 and older, pregnant women, and people with certain health conditions—such as heart, lung or kidney disease, nervous system disorders, or a weakened immune system. Flu vaccination is especially important for these people, and anyone in close contact with them.

Flu can also lead to pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children.

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

Flu vaccine is the best protection against flu and its complications. Flu vaccine also helps prevent spreading flu from person to person.

2 Inactivated and recombinant flu vaccines

You are getting an injectable flu vaccine, which is either an **“inactivated”** or **“recombinant”** vaccine. These vaccines do not contain any live influenza virus. They are given by injection with a needle, and often called the “flu shot.”

A different, **live, attenuated** (weakened) influenza vaccine is sprayed into the nostrils. *This vaccine is described in a separate Vaccine Information Statement.*

Flu vaccination is recommended every year. Some children 6 months through 8 years of age might need two doses during one year.

Flu viruses are always changing. Each year’s flu vaccine is made to protect against 3 or 4 viruses that are likely to cause disease that year. Flu vaccine cannot prevent all cases of flu, but it is the best defense against the disease.

It takes about 2 weeks for protection to develop after the vaccination, and protection lasts several months to a year.

Some illnesses that are not caused by influenza virus are often mistaken for flu. Flu vaccine will not prevent these illnesses. It can only prevent influenza.

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

3 Some people should not get this vaccine

Tell the person who gives 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, including (for example) an allergy to gelatin, antibiotics, or eggs, 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** (a severe paralyzing illness, 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 advised to wait until you feel better. You should come back when you are better.



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4 Risks of a vaccine reaction

With a vaccine, like any medicine, there is a chance of side effects. These are usually mild and go away on their own.

Problems that could happen after any vaccine:

- Brief fainting spells can happen after any 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.
- Severe shoulder pain and reduced range of motion in the arm where a shot was given can happen, very rarely, after a vaccination.
- Severe allergic reactions from a vaccine are very rare, estimated at less than 1 in a million doses. If one were to occur, it would usually be within a few minutes to a few hours after the vaccination.

Mild problems following inactivated flu vaccine:

- 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.

Moderate problems following inactivated flu vaccine:

- Young children who get inactivated flu vaccine and pneumococcal vaccine (PCV13) at the same time may be at increased risk for seizures 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.

Inactivated flu vaccine does not contain live flu virus, so you cannot **get the flu from this vaccine**.

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 behavior changes.

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

Vaccine Information Statement (Interim) Inactivated Influenza Vaccine

08/19/2014

42 U.S.C. § 300aa-26

Office Use Only



VACCINE INFORMATION STATEMENT

Tdap Vaccine

(Tetanus, Diphtheria,
and Pertussis)

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y en muchos otros idiomas. Visite www.immunize.org/vis

What You Need to Know

1 Why get vaccinated?

Tetanus, diphtheria and pertussis can be very serious diseases, even for adolescents and adults. Tdap vaccine can protect us from these diseases.

TETANUS (Lockjaw) causes painful muscle tightening and stiffness, usually all over the body.

- It can lead to tightening of muscles in the head and neck so you can't open your mouth, swallow, or sometimes even breathe. Tetanus kills about 1 out of 5 people who are infected.

DIPHtheria can cause a thick coating to form in the back of the throat.

- It can lead to breathing problems, paralysis, heart failure, and death.

PERTUSSIS (Whooping Cough) causes severe coughing spells, which can cause difficulty breathing, vomiting and disturbed sleep.

- It can also lead to weight loss, incontinence, and rib fractures. Up to 2 in 100 adolescents and 5 in 100 adults with pertussis are hospitalized or have complications, which could include pneumonia or death.

These diseases are caused by bacteria. Diphtheria and pertussis are spread from person to person through coughing or sneezing. Tetanus enters the body through cuts, scratches, or wounds.

Before vaccines, the United States saw as many as 200,000 cases a year of diphtheria and pertussis, and hundreds of cases of tetanus. Since vaccination began, tetanus and diphtheria have dropped by about 99% and pertussis by about 80%.

2 Tdap vaccine

Tdap vaccine can protect adolescents and adults from tetanus, diphtheria, and pertussis. One dose of Tdap is routinely given at age 11 or 12. People who did *not* get Tdap at that age should get it as soon as possible.

Tdap is especially important for health care professionals and anyone having close contact with a baby younger than 12 months.

Pregnant women should get a dose of Tdap during *every* pregnancy, to protect the newborn from pertussis. Infants are most at risk for severe, life-threatening complications from pertussis.

A similar vaccine, called Td, protects from tetanus and diphtheria, but not pertussis. A Td booster should be given every 10 years. Tdap may be given as one of these boosters if you have not already gotten a dose. Tdap may also be given after a severe cut or burn to prevent tetanus infection.

Your doctor can give you more information.

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

3 Some people should not get this vaccine

- If you ever had a life-threatening allergic reaction after a dose of any tetanus, diphtheria, or pertussis containing vaccine, OR if you have a severe allergy to any part of this vaccine, you should not get Tdap. Tell your doctor if you have any severe allergies.
- If you had a coma, or long or multiple seizures within 7 days after a childhood dose of DTP or DTaP, you should not get Tdap, unless a cause other than the vaccine was found. You can still get Td.
- Talk to your doctor if you:
 - have epilepsy or another nervous system problem,
 - had severe pain or swelling after any vaccine containing diphtheria, tetanus or pertussis,
 - ever had Guillain-Barré Syndrome (GBS),
 - aren't feeling well on the day the shot is scheduled.



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4 Risks of a vaccine reaction

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

Brief **fainting spells** can follow a vaccination, leading to injuries from falling. Sitting or lying down for about 15 minutes can help prevent these. Tell your doctor if you feel dizzy or light-headed, or have vision changes or ringing in the ears.

Mild problems following Tdap

(Did not interfere with activities)

- Pain where the shot was given (about 3 in 4 adolescents or 2 in 3 adults)
- Redness or swelling where the shot was given (about 1 person in 5)
- Mild fever of at least 100.4°F (up to about 1 in 25 adolescents or 1 in 100 adults)
- Headache (about 3 or 4 people in 10)
- Tiredness (about 1 person in 3 or 4)
- Nausea, vomiting, diarrhea, stomach ache (up to 1 in 4 adolescents or 1 in 10 adults)
- Chills, body aches, sore joints, rash, swollen glands (uncommon)

Moderate problems following Tdap

(Interfered with activities, but did not require medical attention)

- Pain where the shot was given (about 1 in 5 adolescents or 1 in 100 adults)
- Redness or swelling where the shot was given (up to about 1 in 16 adolescents or 1 in 25 adults)
- Fever over 102°F (about 1 in 100 adolescents or 1 in 250 adults)
- Headache (about 3 in 20 adolescents or 1 in 10 adults)
- Nausea, vomiting, diarrhea, stomach ache (up to 1 or 3 people in 100)
- Swelling of the entire arm where the shot was given (up to about 3 in 100).

Severe problems following Tdap

(Unable to perform usual activities; required medical attention)

- Swelling, severe pain, bleeding and redness in the arm where the shot was given (rare).

A **severe allergic reaction** could occur after any vaccine (estimated less than 1 in a million doses).

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VAERS is only for reporting reactions. They do not give medical advice.

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Tdap Vaccine

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