

VACCINE INFORMATION STATEMENT

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 doctor.
- 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

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VACCINE INFORMATION STATEMENT

Influenza Vaccine

What You Need to Know

(Flu Vaccine, Live,
Intranasal)

2014-2015

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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 Live, attenuated flu vaccine—LAIV, Nasal Spray

You are getting a **live, attenuated influenza vaccine** (called LAIV), which is sprayed into the nose. “Attenuated” means weakened. The viruses in the vaccine have been weakened so they won’t give you the flu.

There are other “inactivated” and “recombinant” flu vaccines that do not contain live virus. These “flu shots” are given by injection with a needle.

Injectable flu vaccines are 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 viruses that are likely to cause disease that year. LAIV protects against 4 different influenza viruses. 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 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.

LAIV may be given to people **2 through 49 years of age**. It may safely be given at the same time as other vaccines.

LAIV does not contain thimerosal or other preservatives.

3 Some people should not get this vaccine

Tell the person who gives you the vaccine:

- **If you have any severe, life-threatening allergies**, including (for example) an allergy to gelatin or antibiotics. 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 should not get vaccinated.
- **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 have long-term health problems**, such as certain heart, breathing, kidney, liver, or nervous system problems, your doctor can help you decide if you should get LAIV.



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- **If you have gotten any other vaccines in the past 4 weeks, or 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.
- **You should get the flu shot instead of the nasal spray if you:**
 - are pregnant
 - have a weakened immune system
 - are allergic to eggs
 - are a young child with asthma or wheezing problems
 - are a child or adolescent on long-term aspirin therapy
 - will provide care for, or visit someone, within the next 7 days who needs special care for an extremely weakened immune system (ask your health care provider)
 - have taken influenza antiviral medications in the past 48 hours

The person giving you the vaccine can give you more information.

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:

- 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 that have been reported following LAIV:

Children and adolescents 2-17 years of age:

- runny nose, nasal congestion or cough
- fever
- headache and muscle aches
- wheezing
- abdominal pain or occasional vomiting or diarrhea

Adults 18-49 years of age:

- runny nose or nasal congestion
- sore throat
- cough, chills, tiredness/weakness
- headache

LAIV is made from weakened virus and **does not cause flu.**

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/

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What if there is a serious reaction?

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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?

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- 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.

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