

Influenza Vaccine

What You Need to Know

(Flu Vaccine, Live, Intranasal)

2013-2014

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 the influenza virus, and can be spread 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, or a weakened immune system. Flu vaccine 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 we have from flu and its complications. Flu vaccine also helps prevent spreading flu from person to person.

2 Live, attenuated flu vaccine—LAIV, Nasal Spray

There are two types of influenza vaccine:

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 can’t make you sick.

A different vaccine, the “flu shot,” is an **inactivated** vaccine (not containing live virus). It is given by

injection with a needle. *This vaccine is described in a separate Vaccine Information Statement.*

Flu vaccine is recommended every year. Children 6 months through 8 years of age should get two doses the first year they get vaccinated.

Flu viruses are always changing. Each year’s flu vaccine is made to protect from viruses that are most likely to cause disease that year. While flu vaccine cannot prevent all cases of flu, it is our best defense against the disease. LAIV protects against 4 different influenza viruses.

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.

LAIV may be given to people **2 through 49 years of age**, who are not pregnant. 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 an allergy to eggs. 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 a dose.
- **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 gotten any other vaccines in the past 4 weeks, or if you are not feeling well.** They might suggest waiting. But you should come back.



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Centers for Disease Control and Prevention

- **You should get the flu shot instead of the nasal spray if you:**
 - are pregnant
 - have a weakened immune system
 - have certain long-term health problems
 - are a young child with asthma or wheezing problems
 - are a child or adolescent on long-term aspirin therapy
 - have close contact with someone who needs special care for an extremely weakened immune system
 - are younger than 2 or older than 49 years. (Children 6 months and older can get the flu shot. Children younger than 6 months can't get either vaccine.)

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.

Serious side effects are also possible, but are very rare. LAIV is made from weakened virus and **does not cause flu**.

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

Severe problems that could follow LAIV:

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

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?

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

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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.

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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)
Live Attenuated Influenza Vaccine

07/26/2013

42 U.S.C. § 300aa-26

Office Use Only



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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, or a weakened immune system. Flu vaccine 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 we have from flu and its complications. Flu vaccine also helps prevent spreading flu from person to person.

2 Inactivated flu vaccine

There are two types of influenza vaccine:

You are getting an **inactivated** flu vaccine, which does not contain any live influenza virus. It is 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 vaccine is recommended every year. Children 6 months through 8 years of age should get two doses the first year they get vaccinated.

Flu viruses are always changing. Each year’s flu vaccine is made to protect from viruses that are most likely to cause disease that year. While flu vaccine cannot prevent all cases of flu, it is our best defense against the disease. Inactivated flu vaccine protects against 3 or 4 different influenza viruses.

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.

A “high-dose” flu vaccine is available for people 65 years of age and older. The person giving you the vaccine can tell you more about it.

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, you may be advised not to get a dose. Most, but not all, types of flu vaccine contain a small amount of egg.
- **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.** They might suggest waiting until you feel better. But you should come back.



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Control and Prevention

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.

Serious side effects are also possible, but are very rare. Inactivated flu vaccine does not contain live flu virus, so **getting flu from this vaccine is not possible.**

Brief fainting spells and related symptoms (such as jerking movements) can happen after any medical procedure, including vaccination. **Sitting or lying down for about 15 minutes after a vaccination can help prevent fainting and injuries caused by falls.** Tell your doctor if you feel dizzy or light-headed, or have vision changes or ringing in the ears.

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.

Severe problems following inactivated flu vaccine:

- A **severe allergic reaction** could occur after any vaccine (estimated less than 1 in a million doses).
- There is a small possibility that inactivated flu vaccine could be associated with Guillain-Barré Syndrome (GBS), no more than 1 or 2 cases per million people vaccinated. This is much lower than the risk of severe complications from flu, which can be prevented by flu vaccine.

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

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- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.

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