



Influenza Virus Vaccine Consent 2016-2017 – Afluria

This vaccine is a "trivalent" vaccine and is made to protect against three flu viruses. It is an inactivated (killed) vaccine— contains 45 mcg hemagglutinin (HA) per 0.5ml dose in the recommended ratio of 15 mcg HA of each of the following 3 influenza strains recommended for the 2016-2017 Northern Hemisphere influenza season: A/California/7/2009 (H1N1), NYMC X-413 181, A/Hong Kong/4801/2014 (H3N2), NYMC X-263B, and B/Brisbane/60/2008. The prefilled syringes are **NOT** formulated with preservative. The rubber tip cap and plunger were **NOT** made with natural rubber latex.

Why should people get vaccinated against the flu? Influenza is a serious disease that can lead to hospitalization and sometimes even death. Every flu season is different, and influenza infection can affect people differently. Even healthy people can get very sick from the flu and spread it to others. Over a period of 31 seasons between 1976 and 2007, deaths associated with the flu, in the US, range from a low of about 3,000 to a high of about 49,000. During recent flu seasons, between 80% and 90% of flu related deaths have occurred in people 65 years and older. "Flu season" in the US can begin as early as October and last as late as May. An annual seasonal flu vaccine is the best way to reduce the chances that you will get seasonal flu and spread it to others. When more people get vaccinated against the flu, less flu can spread through that community thereby protecting those at high risk of developing flu complications or death. The CDC continues to recommend influenza shots for women during pregnancy as they are considered at high risk. For more information see <http://www.cdc.gov/flu/protect/vaccine/pregnant.htm>

Can this vaccine cause the flu? AFLURIA is an inactivated vaccine that cannot cause influenza but stimulates the immune system to produce antibodies that protect against influenza.

When will I be protected from the flu? The full effect of the vaccine is generally achieved approximately 3 weeks after vaccination.

What are the risks from an inactivated influenza vaccine? A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small. Serious problems from inactivated influenza vaccine are very rare. The viruses in inactivated influenza vaccine have been killed, so you cannot get influenza from the vaccine. The most common adverse reactions for adults 18 – 64 include tenderness (≥60%), pain (≥40%), swelling (≥20%), and redness, itching (≥10%). The most common systemic adverse events were muscle aches (≥30%) and headache, malaise (≥20%).

Immunocompromised persons may have a diminished immune response to AFLURIA: Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot. In 1976, a type of inactivated influenza (swine flu) vaccine was associated with Guillain-Barre Syndrome (GBS). Since then, flu vaccines have not been clearly linked to GBS. However, if there is a risk of GBS from current flu vaccines, it would be no more than 1 or 2 cases per million people vaccinated which is much lower than the risk of severe influenza, which can be prevented. Signs of a severe allergic reaction can include difficult breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heartbeat or dizziness. If so, contact a doctor immediately or call 911.

Who should get vaccinated this season? Everyone 6 months of age and older, including pregnant women, should get a flu vaccine every season. This recommendation has been in place since 2010 when the US expanded protection against the flu to more people to create herd immunity to help prevent influenza for those who are at high risk of serious complications from influenza. Persons at risk include those who are 65 yrs and older, those with asthma, diabetes, heart disease, HIV or cancer.

Who Should Not Be Vaccinated? Anyone with severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine including egg protein, or to a previous dose of any influenza vaccine should **NOT** be vaccinated in a flu clinic setting.

Does this vaccine contain thimerosal? This prefilled inactivated influenza vaccine contains **NO** thimerosal or other preservative or natural rubber latex.

Do you have or have you ever had a/an:

- History of fainting after blood draws or injections? Y N
- Guillain-Barre syndrome in the last 6 weeks? Y N
- Severe (life-threatening) allergies, including a severe allergy to eggs, or any vaccine component? Y N
- Are you ill (i.e. > 102 F temperature)? Y N

I have read the above information and understand the benefits and risks of the flu vaccine as described. I have answered all questions. I have received the Vaccine Information Sheet (8-7-15). I request that the vaccine be given to:

Print Name

Your Signature

Employee #

Date

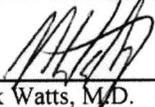
Please report any severe or unusual adverse reactions to HSD at Ext. 22475. Women who receive AFLURIA while pregnant are encouraged to participate in the exposure and surveillance study. Pregnant women can contact the pregnancy study center by calling 1-877-311-8972 or visiting the website <http://www.pregnancystudies.org>.

HSD USE ONLY

Give Afluria Vaccine 0.5 IM.

Lot # WT54306 – Expiration 6/29/2017

L R Deltoid


Rick Watts, M.D.

9/16/2016
Date

Provider Signature

Date

VACCINE INFORMATION STATEMENT

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 (“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.

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.

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.



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

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 the following:

- 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

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