



2010-2011 SEASONAL INFLUENZA Q AND A

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1. What is Influenza (also called flu)?

The flu is a contagious respiratory illness caused by influenza viruses. It can cause mild to severe illness, and at times can lead to death. The best way to prevent the flu is by getting a flu vaccine each year.

2. What are the symptoms of flu?

People who have the flu often feel some or all of these symptoms:

- Fever* or feeling feverish/chills
- Cough
- Sore throat
- Runny or stuffy nose
- Muscle or body aches
- Headaches
- Fatigue (very tired)

*Some people may have vomiting and diarrhea, though this is more common in children than adults.

**It's important to note that not everyone with flu will have a fever.*

3. How does the flu spread?

Most experts believe that flu viruses spread mainly by droplets made when people with flu cough, sneeze or talk. These droplets can land in the mouths or noses of people who are nearby. Less often, a person might also get flu by touching a surface or object that has flu virus on it and then touching their own mouth, eyes or nose.

4. How long is a person with the flu contagious?

You may be able to pass on the flu to someone else before you know you are sick, as well as while you are sick. Most healthy adults may be able to infect others beginning 1 day **before** symptoms develop and up to 5-7 days **after** becoming sick. Some people, especially children and people with weakened immune systems, might be able to infect others for an even longer time.

5. How serious is the flu?

Flu is unpredictable and how severe it is can vary widely from one season to the next depending on many things, including:

- What flu viruses are spreading
- How much flu vaccine is available
- When vaccine is available
- How many people get vaccinated, and
- How well the flu vaccine is matched to flu viruses that are causing illness

Certain people are at greater risk for serious complications if they get the flu. This includes older people, young children, pregnant women and people with certain health conditions (such as asthma, diabetes, or heart disease).

One study found that during the 1990s, flu-related deaths ranged from an estimated 17,000 during the mildest season to 52,000 during the most severe season (36,000 average). Studies going back to 1976 have found that flu-related deaths ranged from a low of 4,700 to a high of 56,600 (average 25,500). During a regular flu season, about 90 percent of deaths occur in people 65 years and older.

During 2009-2010, a new and very different flu virus (called 2009 H1N1) spread worldwide causing the first flu pandemic in more than 40 years. It is estimated that the 2009 H1N1 pandemic resulted in more than 12,000 flu-related deaths in the U.S. In contrast to seasonal flu, nearly 90 percent of the deaths occurred among people younger than 65 years of age.

6. What are some common complications of the flu?

Complications of flu can include bacterial pneumonia, ear infections, sinus infections, dehydration, and worsening of chronic medical conditions, such as congestive heart failure, asthma, or diabetes.

7. What is the best way to prevent getting the flu?

The single best way to prevent the flu is to get a flu vaccine each season.

8. What types of flu vaccine exist?

There are two types of flu vaccines:

- **The "flu shot"**—an inactivated vaccine (containing killed virus) that is given with a needle. The seasonal flu shot is approved for use in people 6 months of age and older, including healthy people, people with chronic medical conditions and pregnant women.
- **The nasal-spray flu vaccine**—a vaccine made with live, weakened flu viruses that do not cause the flu (sometimes called LAIV for "Live Attenuated Influenza Vaccine"). LAIV is approved for use in healthy* people 2-49 years of age who are not pregnant.

About two weeks after vaccination, antibodies develop that protect against influenza virus infection. Flu vaccines will not protect against flu-like illnesses caused by non-influenza viruses.

The seasonal flu vaccine protects against the three influenza viruses that research suggests will be most common. The 2010-2011 flu vaccine will protect against 2009 H1N1, and two other influenza viruses (an H3N2 virus and an influenza B virus).

9. When should one receive a flu vaccination?

Yearly flu vaccination should begin as soon as vaccine is available, and continue throughout the flu season which can last as late as May. This is because the timing and duration of flu seasons vary. While flu season can begin early as October, most of the time seasonal flu activity peaks in January or later.

10. Who should get vaccinated?

On February 24, 2010 vaccine experts voted that everyone 6 months and older should get a flu vaccine each year starting with the 2010-2011 influenza season. CDC's Advisory Committee on Immunization Practices (ACIP) voted for "universal" flu vaccination in the U.S. to expand protection against the flu to more people. While everyone should get a flu vaccine each flu season, it's especially important that certain people get vaccinated either because they are at high risk of having serious flu-related complications or because they live with or care for people at high risk for developing flu-related complications.

11. Who is at higher risk for developing flu-related complications?

- Children younger than 5, but especially children younger than 2 years old,
- Adults 65 years of age and older
- Pregnant women, and,
- People who have medical conditions including:
 1. Asthma (even if it's controlled or mild)
 2. Neurological and neurodevelopmental conditions [including disorders of the brain, spinal cord, peripheral nerve, and muscle such as cerebral palsy, epilepsy (seizure disorders), stroke, intellectual disability (mental retardation), moderate to severe developmental delay, muscular dystrophy, or spinal cord injury]
- Chronic lung disease (such as chronic obstructive pulmonary disease [COPD] and cystic fibrosis)
- Heart disease (such as congenital heart disease, congestive heart failure and coronary artery disease)
- Blood disorders (such as sickle cell disease)
- Endocrine disorders (such as diabetes mellitus)
- Kidney disorders

- Liver disorders
- Metabolic disorders (such as inherited metabolic disorders and mitochondrial disorders)
- Weakened immune system due to disease or medication (such as people with HIV or AIDS, or cancer, or those on chronic steroids)
- People younger than 19 years of age who are receiving long-term aspirin therapy
- People with Chronic Obstructive Pulmonary Disease (COPD)
- People who are morbidly obese (Body Mass Index (BMI) of 30 or greater)
- Also, last flu season, American Indians and Alaskan Natives seemed to be at higher risk of flu complications

12. Who else should get vaccinated?

Other people for whom vaccination is especially important are:

- People who live in nursing homes and other long-term care facilities
- People who live with or care for those at high risk for complications from flu, including:
- Health care workers
- Household contacts of persons at high risk for complications from the flu
- Household contacts and caregivers of children younger than 5 years of age with particular emphasis on vaccinating contacts of children younger than 6 months of age (children younger than 6 months are at highest risk of flu-related complications but are too young to get vaccinated)

13. Who can receive the nasal spray seasonal flu vaccine?

Vaccination with the nasal-spray flu vaccine is an option for healthy* people 2-49 years of age who are not pregnant. Even people who live with or care for those in a high risk group (including health care workers) can get the nasal-spray flu vaccine as long as they are healthy themselves and are not pregnant. The one exception is health care workers who care for people with severely weakened immune systems who require a protected hospital environment; these people should get the inactivated flu vaccine (flu shot).

14. Who should not receive a seasonal flu vaccination?

Some people should not be vaccinated without first consulting a physician. They include:

- People who have a severe allergy to chicken eggs
- People who have had a severe reaction to an influenza vaccination in the past
- People who developed Guillian-Barré syndrome (GBS) within 6 weeks of getting an influenza vaccine previously
- Children younger than 6 months of age (influenza vaccine is not approved for use in this age group)
- People who have a moderate or severe illness with a fever should wait to get vaccinated until their symptoms lessen

15. How are the viruses selected to make flu vaccine each year?

The viruses used in making seasonal flu vaccines are chosen each year based on information collected over the previous year about which influenza viruses are spreading and what vaccine viruses would offer the best protection against circulating viruses. Viruses gathered by 130 national influenza centers in 101 countries as well as information on disease trends are further analyzed by the four World Health Organization (WHO) Collaborating Centers for Reference and Research on Influenza located in Atlanta, USA (Centers for Disease Control and Prevention, CDC); London, United Kingdom (National Institute for Medical Research); Melbourne, Australia (Victoria Infectious Diseases Reference Laboratory); Tokyo, Japan (National Institute for Infectious Diseases). The seasonal flu vaccine is usually a trivalent vaccine (a three component vaccine) with each component selected to protect against one of the three groups of influenza viruses circulating most commonly in humans. (The 2009 H1N1 vaccine that was made to protect against the pandemic virus first detected in April was a monovalent (one-component) vaccine that only protected against the 2009 H1N1 viruses.)

The three vaccine viruses are chosen to maximize the likelihood that the main circulating viruses during each upcoming flu season will be well covered by the vaccine. WHO recommends specific vaccine viruses for vaccine production, but then each individual country makes their own decision for licensing of vaccines in their country. In the United States, the US Food and Drug Administration (FDA) determines what viruses will be used in U.S.-licensed vaccines.

16. What flu viruses are included in the seasonal vaccine for 2010-2011 and how did they get selected?

WHO recommended that the Northern Hemisphere's 2010–2011 seasonal influenza vaccine contain the following three vaccine viruses:

- an A/California/7/2009 (H1N1)-like virus,
- an A/Perth/16/2009 (H3N2)-like virus, and a
- B/Brisbane/60/2008-like virus.

The U.S. FDA has also determined that 2010-11 influenza vaccines for the United States contain the same three vaccine viruses.

The H1N1 virus recommended for inclusion in the 2010-2011 seasonal influenza vaccine is a pandemic 2009 H1N1 virus and is the same vaccine virus that was used in the 2009 H1N1 monovalent vaccine. This recommended composition of the seasonal vaccine for the Northern Hemisphere, including the United States, is the same composition that was recommended for the Southern Hemisphere's 2010 influenza vaccines.

17. Has flu started circulating for the 2010-11 season?

A recent CDC Health Advisory (HAN) reported that Influenza A (H3N2) virus infections have been detected in people in a number of states across the U.S., including two small localized outbreaks. Although the specimens from these outbreaks are still being tested, they are expected to be similar to the H3N2 strain found in the 2010-11 seasonal influenza vaccine.

18. Has any flu vaccine being pulled from the U.S. market for the 2010-11 season?

Based on recent data suggesting an increased risk of febrile seizures in children aged 6 months through 4 years, and a higher frequency of fever in children aged 5 years through 8 years, ACIP recommends the following for the 2010-11 influenza season in the United States:

- Afluria should not be used in children aged 6 months through 8 years.
- Other age-appropriate, licensed seasonal influenza vaccine formulations should be used for prevention of influenza in children aged 6 months through 8 years.
- If no other age-appropriate, licensed seasonal influenza vaccine is available for a child aged 5 years through 8 years old who has a medical condition that increases their risk for influenza complications, Afluria may be given, and providers should discuss the benefits and risks of influenza vaccination with the parents or caregivers before administering Afluria.

19. What is Fluzone High-Dose flu vaccine?

This product was licensed in December 2009 for persons 65 years of age and older. Persons 65 years of age and older comprise 15% of the U.S. population, but account for 65% of hospitalizations and 90% of deaths attributable to flu and its complications. Typical flu vaccine provides substantial protection, but older adults respond less well to standard-dose flu vaccines compared with younger adults. Fluzone High-Dose is formulated so that each 0.5 mL dose contains a total of 180 micrograms (mcg) of influenza virus hemagglutinin (HA) which is made up of 60 mcg of each of the three influenza virus strains which is four times greater than the vaccine contained in other currently licensed adult seasonal flu vaccines.

20. Has there been a change to the expiration dates on Sanofi Pasteur's Influenza A (H1N1) 2009 Monovalent vaccine?

All lots of Influenza A (H1N1) 2009 Monovalent Vaccine in multidose vials distributed by Sanofi Pasteur in the U.S. will expire on September 15, 2010.

21. What is the status of latex free influenza vaccines?

You may be aware of a recent issue involving labeling of latex containing syringe tip caps. Specifically, the tip caps of the prefilled syringes of the following vaccines may contain natural rubber latex which may cause allergic reactions in latex sensitive individuals.

Although no adverse event reports have prompted labeling changes, each of the affected manufacturers is working on this issue with FDA to ensure that the prescribing information, package labeling, and provider communications contain important information about the latex content of flu and non-flu vaccines.