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# **General Questions and Answers on 2009 H1N1 Influenza A Vaccine Safety**

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## **Will the 2009 H1N1 influenza vaccines be safe?**

We expect the 2009 H1N1 influenza vaccine to have a similar safety profile as seasonal flu vaccines, which have a very good safety track record. Over the years, hundreds of millions of Americans have received seasonal flu vaccines. The most common side effects following flu vaccinations are mild, such as soreness, redness, tenderness or swelling where the shot was given. The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) will be closely monitoring for any signs that the vaccine is causing unexpected adverse events and we will work with state and local health officials to investigate any unusual events.

## **Are there any side effects to the 2009 H1N1 influenza vaccine?**

CDC expects that any side effects following vaccination with the 2009 H1N1 influenza vaccine would be rare. If side effects occur, they will likely be similar to those experienced following seasonal influenza vaccine. Mild problems that may be experienced include soreness, redness, or swelling where the shot was given, fainting (mainly adolescents), headache, muscle aches, fever, and nausea. If these problems occur, they usually begin soon after the shot and last 1-2 days. Life-threatening allergic reactions to vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot is given.

After vaccination you should look for any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, swelling around the eyes or lips, hives, paleness, weakness, a fast heart beat or dizziness. If any unusual condition occurs following vaccination, seek medical attention right away. Tell your doctor what happened, the date and time it happened, and when the vaccination was given. Ask your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report yourself through the VAERS Web site at [www.vaers.hhs.gov](http://www.vaers.hhs.gov). You may call 1-800-822-7967 to receive a copy of the VAERS form. VAERS is not able to provide medical advice.

## **Are there some people who should not receive this vaccine?**

People who have a severe (life-threatening) allergy to chicken eggs or to any other substance in the vaccine should not be vaccinated.

## **How will the 2009 H1N1 influenza vaccines be monitored for safety?**

The CDC and FDA closely monitor the safety of seasonal influenza and other vaccines licensed for use in the United States in cooperation with state and local health departments, healthcare providers, and other partners.

The purpose of vaccine safety monitoring is timely identification of clinically significant adverse events following immunization that may be of public health concern. Adverse events, or possible side effects, following immunization may be coincidental to (meaning occurring around the same time but not related to vaccination) or caused by vaccination. The purpose of vaccine safety

monitoring is timely identification of clinically significant adverse events following immunization that might be of public health concern.

CDC and its partners will use multiple systems to monitor the safety of 2009 H1N1 influenza vaccine. Two of the primary systems that will be used to monitor the safety of these vaccines after they are in widespread use are: the Vaccine Adverse Event Reporting System (VAERS), which is jointly operated with FDA, and the Vaccine Safety Datalink (VSD) Project.

- **Vaccine Adverse Event Report System (VAERS)**

VAERS is a national program managed by both CDC and FDA to monitor the safety of all vaccines licensed in the United States. Healthcare providers are encouraged to voluntarily report possible adverse events of concern after vaccination, even if they are not certain that the vaccine caused the event. Anyone can file a VAERS report. VAERS relies on information included in these reports to monitor for clinically serious adverse events or health problems that follow vaccination. Generally, VAERS cannot determine if an adverse event was caused by a vaccine but can help determine if further investigations are needed. FDA and CDC use VAERS data to help identify potential clinically serious vaccine adverse events or health outcomes. If concerns are identified in VAERS, usually further investigation is needed. One important system used to further evaluate concerns identified in VAERS is the Vaccine Safety Datalink (VSD) Project. More information about VAERS is available at <http://vaers.hhs.gov/>.

- **Vaccine Safety Datalink (VSD) Project**

The VSD Project is a vaccine safety system used to both identify and confirm adverse outcomes after immunization. This project is a collaboration between CDC and eight large managed care organizations (MCOs), in which comprehensive medical information is collected on approximately 9 million people. The VSD project monitors their data weekly for certain adverse events that could be associated with newly licensed vaccines. VSD conducts studies of vaccine safety adverse events and health outcomes that may arise with any vaccine.

Additionally, CDC will work with numerous partners including other federal agencies, state and local health departments, professional organizations, and academic institutions to actively follow individuals after vaccination to monitor for any potential adverse events.

**Will the 2009 H1N1 vaccines that are currently recommended contain adjuvants?**

No. According to current federal plans, only unadjuvanted vaccines will be used in the United States during the 2009 flu season. This includes all of the 2009 H1N1 and seasonal influenza vaccines that will be available for children and adults in both the injectable and nasal spray formulations. None of these influenza vaccines will contain adjuvants.

2009 H1N1 vaccines with adjuvants are being studied to determine if they are safe and effective. Experts will review these data when they are available. There is no plan at this time to recommend a 2009 H1N1 influenza vaccine with an adjuvant.

**Will the 2009 H1N1 influenza vaccine contain thimerosal?**

The 2009 H1N1 influenza vaccines that FDA is licensing (approving) will be manufactured in several formulations. Some will come in multi-dose vials and will contain thimerosal as a

preservative. Multi-dose vials of seasonal influenza vaccine also contain thimerosal to prevent potential contamination after the vial is opened.

Some 2009 H1N1 influenza vaccines will be available in single-dose units, which will not require the use of thimerosal as a preservative. In addition, the live-attenuated version of the vaccine, which is administered intranasally (through the nose), is produced in single-units and will not contain thimerosal. For more information on thimerosal.

### **Will the benefits of the 2009 H1N1 influenza vaccines outweigh the risks? Is this something I should talk to my healthcare provider about?**

Currently the 2009 H1N1 influenza virus (sometimes called “swine flu”) virus seems to be causing serious health outcomes for:

1. healthy young people from birth through age 24;
2. pregnant women; and
3. adults 25 to 64 who have underlying medical conditions.

Seasonal influenza vaccines are highly effective in preventing influenza disease. The expectation is that a vaccine against 2009 H1N1 influenza would probably work in a similar fashion to the seasonal influenza vaccines. CDC and FDA believe that the benefits of vaccination with the 2009 H1N1 influenza vaccine will far outweigh the risks.

Vaccination is the best way to prevent influenza infection and its complications. This is the reason that CDC, national health organizations, and healthcare providers intensively promote vaccination for seasonal influenza, and the reason why so much work is being done to have a vaccine available in the fall for the 2009 H1N1 influenza virus.

Influenza vaccines do not protect against other viruses that cause respiratory illnesses. Even after you are vaccinated, it is still important to wash your hands well and often, to cover your coughs and sneezes, and to stay home if you are sick.

CDC and FDA encourage you to ask your healthcare provider any questions you may have about the 2009 H1N1 influenza vaccine and the seasonal influenza vaccines that will be available during the 2009-2010 influenza season. Your healthcare provider is an excellent source for information on the benefits and risks of vaccination for protection against 2009 H1N1 influenza for you, your children, and other family members.

CDC is working continuously to provide the public with the most current information about 2009 H1N1 influenza and the 2009 H1N1 influenza vaccine and its safety.

### **Will there be a possibility of Guillain-Barré Syndrome (GBS) cases following the 2009 H1N1 vaccine?**

Guillain-Barré syndrome (GBS) is a rare disease in which the body damages its own nerve cells, causing muscle weakness and sometimes paralysis. It is not fully understood why some people develop GBS, but it is believed that stimulation of the body’s immune system may play a role in its development. Infection with the bacterium Campylobacter jejuni, which can cause diarrhea, is one of the most common risk factors for GBS. People can also develop GBS after having the flu or other infections (such as cytomegalovirus and Epstein Barr virus). On very rare occasions, they may develop GBS in the days or weeks following receiving a vaccination.

In 1976, there was a small risk of GBS following influenza (swine flu) vaccination (approximately 1 additional case per 100,000 people who received the swine flu vaccine). That number of GBS cases was slightly higher than what is normally seen in the population, whether or not people were vaccinated. Since then, numerous studies have been done to evaluate if other flu vaccines were associated with GBS. In most studies, no association was found, but two studies suggested that approximately 1 additional person out of 1 million vaccinated people may be at risk for GBS associated with the seasonal influenza vaccine. FDA and CDC will be closely monitoring reports of serious problems following the 2009 H1N1 influenza vaccines, including GBS.

**What is the best source of information for 2009 H1N1 influenza vaccine safety?**

In addition to talking openly with your healthcare providers, CDC also encourages you to stay informed by checking the following Web sites often for the most up-to-date news and information: [www.cdc.gov/H1N1flu](http://www.cdc.gov/H1N1flu) and [www.flu.gov](http://www.flu.gov).

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