



## Frequently Asked Questions:

### 2009 H1N1 Influenza A Vaccine Safety

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

It is expected the 2009 H1N1 influenza vaccine will have a similar safety profile as seasonal flu vaccines, which already 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 side effects and LBDHHS will work with state and federal health officials to investigate any unusual events.

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

Any side effects following vaccination with the 2009 H1N1 influenza vaccine will likely be rare. Clinical trials of the 2009 H1N1 vaccine have reported only mild side effects, such as soreness at the injection site.

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  
People who have had severe side effects or allergy to any other substance in the vaccine  
Those who have had serious reactions to a flu shot in the past

#### **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.

One of the primary systems that will be used to monitor the safety of these vaccines after they are in widespread use is the Vaccine Adverse Event Reporting System (VAERS). Generally, VAERS cannot determine if an adverse event was caused by a vaccine but can help determine if further investigations are needed.

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.

More information about VAERS is available at <http://vaers.hhs.gov/>. 1-800-822-7967 (toll-free telephone); 1-877-721-0366 (free fax); [info@vaers.org](mailto:info@vaers.org) (email)

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

The 2009 H1N1 influenza vaccines that FDA is licensing (approving) is 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. These formulations, however, are currently in short supply.

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.

**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 6 months old through age 24 years old;
2. pregnant women; and
3. Adults ages 25 to 64 years old 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 vaccination is intensively promoted 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.

You are encouraged 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.

**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. GBS has been reported to occur after certain types of infections. 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, and specifically looking for any neurological events following the 2009 H1N1 vaccine, including GBS.

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

In addition to talking openly with your healthcare providers, you are also encouraged to stay informed by checking the following Web sites often for the most up-to-date news and detailed information:

General Questions and Answers on 2009 H1N1 Influenza A Vaccine Safety -

[http://www.cdc.gov/h1n1flu/vaccination/vaccine\\_safety\\_qa.htm](http://www.cdc.gov/h1n1flu/vaccination/vaccine_safety_qa.htm)

General Questions and Answers on Thimerosal -

[http://www.cdc.gov/h1n1flu/vaccination/thimerosal\\_qa.htm](http://www.cdc.gov/h1n1flu/vaccination/thimerosal_qa.htm)

General Questions and Answers on Guillain-Barré syndrome (GBS) -

[http://www.cdc.gov/h1n1flu/vaccination/gbs\\_qa.htm](http://www.cdc.gov/h1n1flu/vaccination/gbs_qa.htm)

Links to more vaccine-related information can be found here:

<http://www.cdc.gov/h1n1flu/vaccination/>.

### **Where can more information on influenza, including 2009 H1N1 flu, be found?**

[www.flu.gov](http://www.flu.gov)

[www.cdc.gov/H1N1flu](http://www.cdc.gov/H1N1flu)

### **Where can I find more information on Long Beach's influenza prevention and control activities?**

<http://www.longbeach.gov/health>