



H1N1 Vaccine Safety

Will the 2009 H1N1 influenza vaccines be safe?

We expect the 2009 H1N1 influenza vaccine to be as safe 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 H1N1 vaccine is made the same way that seasonal vaccine is made. The only difference is that it protects against the H1N1 virus. Before it was approved, the H1N1 influenza vaccine underwent clinical trials to see how well the vaccine works. During those trials, no serious side effects were reported. The most common side effects were the same as side effects from seasonal influenza vaccines: soreness, redness, tenderness or swelling where the shot was given.

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.

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

No. An adjuvant is a substance added to a vaccine to improve the immune response so that less vaccine is needed. Only vaccines that do not contain adjuvants 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 contain adjuvants.

What is thimerosal?

Thimerosal is a mercury-based preservative that has been used for decades in the United States in multi-dose vials (vials containing more than one dose) of some vaccines to prevent the growth of microorganisms, such as bacteria and fungi, which may contaminate them.

Will the 2009 H1N1 influenza vaccine contain thimerosal?

The 2009 H1N1 influenza vaccines that U.S. Food and Drug Administration (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.

Is thimerosal safe when used as a preservative in vaccines?

The U.S. Centers for Disease Control and Prevention (CDC) places a high priority on vaccine safety, surveillance, and research. CDC is aware that the preservative thimerosal in vaccines and suggestions of a relationship to autism have raised concerns. These concerns make the decisions surrounding vaccinations confusing and difficult for some people, especially parents. Numerous studies have found no association between thimerosal exposure and autism. Since 2001, no new vaccine licensed by FDA for use in children has contained thimerosal as a preservative. In addition, all vaccines recommended by CDC for children younger

than 6 have been thimerosal-free or contain only trace amounts, except for some formulations of influenza vaccine. Unfortunately, we have not seen reductions in the numbers of children identified with autism indicating that the cause of autism is not related to a single exposure such as thimerosal.

Will there be a possibility of Guillain-Barré syndrome 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.

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, health-care 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.

Why is it important to get the H1N1 influenza vaccine?

Influenza can be a serious disease, often causing people to miss a week or more of school or work. Every year in the United States, more than 30,000 people die from seasonal influenza.

Currently, the 2009 H1N1 influenza virus seems to be causing serious health outcomes for the following people:

1. Healthy young people from birth through age 24.
2. Pregnant women.
3. Adults 25 to 64 who have underlying medical conditions.

Vaccination is the best way to prevent influenza infection and its complications. This is the reason that CDC, national health organizations, public health, and health-care providers encourage people to get vaccinated against both seasonal influenza and H1N1 influenza.

Additional Information:

Additional information is available at www.ndflu.com or by calling the North Dakota Department of Health at 800.472.2180.

Resource: U.S. Centers for Disease Control and Prevention

