



H1N1 Vaccine Safety

Is the H1N1 influenza vaccine safe?

Yes. Because the H1N1 influenza vaccine is made just like the seasonal flu vaccine it is expected to be as safe as seasonal flu vaccines. Seasonal flu vaccines have a very good safety track record. The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) will be closely monitoring any signs that the vaccine is causing unexpected adverse events.

What are the possible side effects to the H1N1 influenza vaccine?

Side effects following vaccination are expected to be rare and mild, similar to those experienced after receiving the seasonal flu vaccine. During H1N1 injection vaccine testing, a rate of 3.4 serious adverse events per **million** vaccines given was documented.

Mild problems that may be experienced include:

- Soreness
- Redness, or swelling where the shot was given
- Fainting (mainly adolescents)
- Headache
- Muscle aches
- Fever
- Nausea

If these effects occur, they usually begin soon after the shot and last 1-2 days. Life-threatening allergic reactions to vaccines are very rare and typically occur within a few hours of the shot being given. After being vaccinated, you should look for any unusual conditions, 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 an 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. You may call 1-800-822-7967 to receive a copy of the VAERS form.

Can I get the flu from the flu vaccine?

No, the flu vaccine cannot cause flu illness. The viruses contained in the flu shots are inactivated (dead), which means they cannot cause infection. Although the nasal spray flu vaccine is made with live, weakened flu viruses, they do not cause the flu either.

Do the benefits of the H1N1 influenza vaccine outweigh the risks?

Vaccination is the best way to prevent flu infection and its complication. Seasonal flu vaccines are highly effective in preventing influenza disease and the expectation is that a vaccine against the H1N1 flu virus would work in a similar fashion. The CDC and FDA believe strongly the benefits of vaccination will outweigh the risks.

Do I have to get a shot?

No, there are two types of flu vaccine: the shot and a nasal spray. If you are **healthy** and **between the ages of 2 and 49** and are **not pregnant**, you may receive the vaccine through the nasal spray.

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.



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H1N1 Vaccine Safety - Continued

October 6, 2009

Will two doses of the H1N1 influenza vaccine be required?

The FDA has approved the use of one dose of H1N1 flu vaccine for persons 10 years of age and older and two doses for children under the age of ten years. As with the seasonal flu vaccine, children ages six months through 35 months get two doses of H1N1 flu vaccine that contains one-half the dose used for older children and adults.

How much time has to pass between the 1st and 2nd dose for children under the age of 10?

This will not be known until clinical trials are complete, however, it is expected that it will be 21-28 days between the first and second vaccination.

Can the seasonal and H1N1 flu vaccines be given at the same time?

Seasonal and H1N1 flu shots may be given on the same day but need to be given at different locations on the body (i.e. one in the left arm and the other shot in the right arm). The H1N1 nasal spray cannot be given at the same time as the seasonal flu nasal spray.

Will the H1N1 influenza vaccine contain thimerosal (a preservative)?

The H1N1 flu vaccine will be manufactured in several formulations. Some will come in multi-dose vials and will contain thimerosal as a preservative to prevent potential contamination after the vial is opened. There is no evidence that thimerosal is harmful to pregnant women or their fetus. However, because some women are concerned about exposure to thimerosal, manufacturers are producing preservative-free seasonal and H1N1 flu vaccines in single dose syringes. The CDC states pregnant women may get the flu vaccine with or without thimerosal. The nasal spray vaccine will not contain thimerosal.

How can I get more information?

For more information on H1N1, call the Sedgwick County Health Department at 660-5558 or email flu@sedgwick.gov.

Will there be a possibility of Guillain-Barré Syndrome (GBS) cases following the H1N1 influenza 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, individuals 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. The 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. Two studies suggested that approximately **one additional person** out of **one million vaccinated** people may be at risk for GBS associated with the seasonal influenza vaccine. The FDA and CDC will be closely monitoring reports of serious problems following the H1N1 flu vaccines, including GBS.