



H1N1 Flu Vaccine Safety: Frequently Asked Questions

The Rhode Island Department of Health (HEALTH)
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1. Is the H1N1 vaccine safe?

Licensed vaccines, including flu vaccines, are developed using the highest standards of safety. National regulatory authorities will approve and license new H1N1 vaccines using the same process they use to license seasonal flu vaccines. In addition to the usual testing done for seasonal flu vaccines, there will be clinical testing in people to determine the most effective dose needed.

Source:

http://www.who.int/csr/disease/swineflu/frequently_asked_questions/vaccine_preparedness/safety_approval/en/index.html

2. How will the government make sure the H1N1 vaccine is safe before it goes on the market?

The H1N1 vaccine will be manufactured, tested, and licensed using the same process and facilities as are used for seasonal flu vaccines. This means that the H1N1 vaccine will be held to the same safety standards as seasonal flu vaccines. There are many different strains of the flu, including H1N1. The seasonal flu vaccine protects against the three strains of the flu most likely to make people sick each year. A separate vaccine for the H1N1 strain is only being produced this year because H1N1 emerged after seasonal flu vaccine production had begun. The manufacturing process for both vaccines is exactly the same. Next year, the H1N1 strain will be included in the regular seasonal flu vaccine.

3. How will the government monitor vaccine safety after the H1N1 vaccine goes on the market?

Vaccines continue to be closely monitored after they are licensed. The Centers for Disease Control and Prevention (CDC) uses the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD) Project to identify potential new vaccine safety concerns. Anyone can report a health problem to VAERS. Any potential problem with a vaccine prompts further investigation by the CDC and the Food and Drug Administration (FDA).

Source: <http://www.cdc.gov/vaccines/vac-gen/safety/default.htm>

4. Does the H1N1 vaccine have any side effects?

Some people may experience mild side effects after receiving the H1N1 vaccine, just like they do after receiving the seasonal flu vaccine. Side effects may include soreness, redness, or swelling where the shot was given, aches, or a low-grade fever. If these problems occur, they begin soon after the shot and last about 1-2 days. The likelihood of serious side effects to flu vaccines is very low, and officials continually monitor new vaccines for safety and efficacy.

<http://www.cdc.gov/flu/protect/keyfacts.htm>

5. What kinds of clinical trials are being performed on the H1N1 vaccine?

A number of clinical trials testing the H1N1 vaccine in children and adults are underway. These trials will help experts determine the most effective number of doses needed to provide optimum protection from H1N1. The trials will also determine the amount of time necessary between doses. The National Institute of Allergies and Infectious Diseases (NIAID) are conducting the trials.

Source: http://www.cdc.gov/h1n1flu/vaccination/pregnant_qa.htm#HCP

6. Can I get the flu from the flu vaccine?

No. Flu vaccines contain killed or weakened flu viruses, and it is biologically impossible for these viruses to cause illness in people. Sometimes, people may experience flu-like symptoms (e.g., fever, cough, and sore throat) after receiving flu vaccines, but this does not mean that they have the flu. Many different types of viruses can cause flu-like symptoms in people. On average, only about 1/3 of people with influenza-like illness (ILI) actually have the flu. You cannot get H1N1 from the H1N1 vaccine, just as you cannot get seasonal flu from the seasonal flu vaccine.

7. Can I get Guillain-Barre Syndrome from the H1N1 vaccine?

In 1976, an earlier type of swine flu vaccine was associated with cases of Guillain-Barre Syndrome (GBS), a severe paralytic illness, at a rate of approximately 1 case of GBS per 100,000 persons vaccinated. Some studies since then have shown a small risk of GBS in persons vaccinated for seasonal flu, but this risk is not more than 1 case of GBS per 1 million persons vaccinated. Since 1976, flu vaccines have not been clearly linked to GBS, which can also occur in a person who has never received a flu vaccine. The benefits of flu vaccination in preventing serious illness, hospitalization, and death substantially outweigh these estimates of risk for vaccine-associated GBS. If you have ever had GBS, talk to your doctor before receiving the flu vaccine.

Source: http://www.cdc.gov/h1n1flu/vaccination/pregnant_qa.htm#HCP

8. Is it safe to receive the H1N1 vaccine and the seasonal flu vaccine at the same time?

It is expected that people will be able to receive the H1N1 vaccine and the seasonal flu vaccine at the same time. However, the seasonal flu vaccine will be available sooner than the H1N1 vaccine. For this reason, the Rhode Island Department of Health (HEALTH) encourages people to get their seasonal flu vaccines as soon as possible instead of waiting for the H1N1 vaccine to arrive.

9. Is the 2009 H1N1 vaccine safe for pregnant women?

Yes. Flu vaccines have not been shown to cause harm to a pregnant woman or her baby. Vaccination is especially important for pregnant women, since they are at high risk of serious illness from the flu. The best way for pregnant women to protect themselves and their developing babies from the flu is to receive both the seasonal flu and H1N1 vaccines. The seasonal flu vaccine is proven as safe and already recommended for pregnant women. The H1N1 vaccine will be made using the same process and facilities that are used to make seasonal flu vaccines.

Source: http://www.cdc.gov/H1N1flu/vaccination/pregnant_qa.htm

10. Does the H1N1 vaccine contain thimerosal?

The majority of H1N1 vaccine will be packaged in multi-dose vials and will contain thimerosal, a preservative found in some vaccines. There is no evidence that thimerosal is harmful to anyone, including pregnant women and their developing babies. However, because some women are concerned about being exposed to preservatives during pregnancy, a limited supply of preservative-free seasonal flu vaccine and H1N1 vaccine will be available for pregnant women and small children. The Centers for Disease Control and Prevention (CDC) recommends that pregnant women may safely receive flu vaccine with or without thimerosal.

Source: <http://www.cdc.gov/h1n1flu/vaccination/statelocal/ga.htm>
Source: http://www.cdc.gov/H1N1flu/vaccination/pregnant_ga.htm

11. Who can safely receive the H1N1 vaccine?

All adults and all children older than 6 months can safely receive flu vaccines, including the new H1N1 vaccine. People who have a severe allergy to chicken eggs or who have had a severe reaction to a flu vaccine in the past should talk to their providers before getting vaccinated. In addition, people with moderate to severe illness and a fever should wait until they recover to get vaccinated.

Source: <http://www.cdc.gov/flu/protect/keyfacts.htm>

12. Which type of flu vaccine should I receive?

There are two types of flu vaccines: the flu shot and the nasal-spray flu vaccine (or FluMist). The flu shot contains killed virus and is given with a needle, usually in the arm. Anyone older than 6 months, including healthy people and people with chronic medical conditions, can receive the flu shot. The nasal-spray flu vaccine is made with live, weakened flu viruses that cannot cause the flu. Healthy people 2-49 years of age can receive the nasal-spray flu vaccine. Pregnant women and people with underlying health conditions who are at high risk for flu-related complications should not receive the nasal-spray vaccine. Instead, these people should receive the flu shot. Your provider can give you more information about which type of flu vaccine is right for you.

Source: <http://www.cdc.gov/flu/protect/keyfacts.htm>