

H1N1 Vaccine Safety

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This information is from the CDC and NIH has been compiled by physician leaders from Milwaukee County.

Is the H1N1 vaccine “experimental”?

No. The H1N1 vaccine is not new or experimental. It is a different strain that is not currently in the seasonal flu vaccine. The H1N1 vaccine is produced using the same processes and facilities as the seasonal flu vaccine. The vaccine is licensed by the Food and Drug Administration (FDA), based on the same standards established for the seasonal flu vaccine.

Is the H1N1 vaccine safe?

The CDC expects the H1N1 vaccine to be as safe as the seasonal flu vaccine. The risk of a vaccine causing serious harm is extremely small. Life-threatening allergic reactions from vaccines are very rare. If they occur it is usually within a few minutes to a few hours after vaccination.

The CDC expects that any side effects from the H1N1 vaccine would be mild and would last only 1 to 2 days. Mild problems that may occur include:

- Soreness, redness, or swelling at the injection site
- Fainting (mainly adolescents)
- Headache, muscle aches
- Fever
- Nausea

Is the 2009 H1N1 flu shot safe for pregnant women?

The seasonal flu shot has been given to millions of pregnant women over many years. Flu shots have not been shown to cause harm to pregnant women or their babies. The 2009 H1N1 flu vaccine is being made in the same way and at the same places where the seasonal flu vaccine is made.

Will the CDC and FDA be monitoring the H1N1 vaccine, even though it is licensed?

Yes. The CDC and FDA will work with state and local health departments, closely monitoring for any signs that the vaccine is causing adverse events. Usually, monitoring vaccine safety finds that there are no serious reactions that have been missed in earlier testing of a new vaccine.

Can health care providers get the live attenuated influenza vaccine (FluMist)?

Yes. LAIV is a very good option for most health care providers who are healthy, younger than 50 years old, and not pregnant. However, health care providers should not get LAIV if they are providing medical care for patients who require special environments in the hospital because they are profoundly immunocompromised (e.g., those who work in bone marrow transplant units). Although no immunocompromised patient has been shown to be harmed by use of LAIV among health care workers, the recommendation against the use of LAIV in health care workers with this type of patient contact is intended as an extra precaution for fragile immunocompromised patients. Health care workers with this type of patient contact can get LAIV, but if they do, they should wait 7 days after being vaccinated before returning to duties that include care of severely immunocompromised patients in special environments.

Will there be a possibility of Guillain-Barre Syndrome (GBS) cases following vaccination?

In 1976 there was a small risk of GBS following vaccination for swine flu (about 1 additional case per 100,000 people who received the swine flu vaccine). Since then, numerous studies have been done to evaluate if other flu vaccines were linked with GBS. Most of those studies found no link, but two studies suggested that about 1 additional person out of 1 million vaccinated people may be at risk for GBS associated with the seasonal influenza vaccine. For the H1N1 vaccine, the CDC has set up an intense surveillance system to closely monitor reports of GBS-like symptoms.

What if a provider observes any unusual vaccine reaction?

The CDC has increased the capacity of its Vaccine Adverse Event Reporting System (VAERS). Providers

should complete and submit a VAERS report if any of the following reactions to the vaccine are observed or reported:

- High fever
- Behavior changes
- Serious allergic reaction (difficulty breathing, hoarseness or wheezing, swelling around the eyes or lips, hives, paleness, weakness, rapid heartbeat, or dizziness)

The VAERS report can be found on the Flu Resource Center iConnect site or at www.vaers.hhs.gov.

If the FDA licensed the H1N1 vaccine, why are “clinical trials” being conducted?

The clinical trials are not related to licensing the vaccine. The NIH and the manufacturers are conducting the trials in order to determine proper dosage and whether the vaccine can be given simultaneously with the seasonal vaccine.

What were the preliminary results of the dosing trials? (Announced on September 21, 2009)

Preliminary analysis of blood samples from a small group of trial participants showed that a single 15-microgram dose of a non-adjuvanted 2009 H1N1 influenza vaccine generated an immune response that is expected to be protective against 2009 H1N1 influenza virus in the majority of 10- to 17-year-olds, 8 to 10 days following vaccination. Younger children generally had a less robust early response to the vaccine. Children 10 and younger require two doses.

Will the H1N1 vaccine contain thimerosal?

The vaccine will be available in several forms:

- Multi-dose vials of injectable vaccine, which will contain thimerosal as a preservative (like the seasonal vaccine multi-dose vials)
- Single-dose units of injectable vaccine, which will not contain thimerosal
- Single units of intranasal vaccine, which will not contain thimerosal

There is NO evidence of any safety concerns due to thimerosal, including no relationship with autism.

Does the H1N1 vaccine contain adjuvants?

No. Only unadjuvanted vaccines will be used in the U.S. during the 2009 season.

Can the H1N1 vaccine be given at the same time as the seasonal flu vaccine?

YES – unless they are both given intranasally. If both vaccines are intranasal, they need to be spaced 4 weeks apart.

Where can you get more information?

For up-to-date news and information visit the **Flu Resource Center** within your organization.

- Look under **Guidelines and Tools** for H1N1 Administration Guidelines, H1N1 Q&A for providers, H1N1 manufacturer package inserts.
- Look under **Patient Education** for a patient handout on H1N1 Facts about Vaccine and Its Safety.
- Look under **Employee Health** for Dr.Phelan’s Grand Rounds PowerPoint presentation, specifically slides 47-55 for clinical trial information.
- For clinical trial information from the National Institutes of Health, visit:
<http://www3.niaid.nih.gov/news/QA/qaH1N1pedvax.htm>
- www.cdc.gov/H1N1flu

Questions?

- Email the CDC directly at nipinfo@cdc.gov