

# The Race to Test H1N1 (Swine) Flu Vaccines

Besides pumpkins and turkeys, one thing on everyone's mind this autumn is the H1N1 (swine) flu.

Pharmaceutical companies and government agencies are working feverishly to test and produce a vaccine that will protect the population. Companies have produced vaccines they believe will work, and now vaccines are going through clinical trials to test for safety; test for the best dosage, and assess whether the vaccines work as hoped.

Following is the most up-to-date information on H1N1 flu vaccine from published information at the [National Association of Allergy and Infectious Diseases \(NIAID\)](#) web site.

Some laboratory tests that help scientists learn more about the virus are done on animals. For example, tests on ferrets showed that 2009 H1N1 virus grew and spread in the respiratory tract faster than the regular seasonal flu. But clinical trials on human volunteers are at the heart of learning whether the proposed vaccines will be safe and useful. Volunteers don't need to worry about getting the flu from the vaccines: The National Institute of Allergy and Infectious Diseases states that it is not possible to become infected with 2009 H1N1 influenza virus from the vaccine.

Five drug companies are testing their own 2009 H1N1 flu vaccines in concert with the US Department of Health and Human Services. Also, the NIAID began conducting five clinical trials of two candidate H1N1 flu vaccines through its Vaccine and Treatment Evaluations Units (VTEUs). VTEU sites exist in eight locations around the country.

The NIAID trials began in July, 2009. The initial set of five trials will enroll about 3,000 people. Researchers want to learn: are the vaccines safe in healthy people of different ages; how large a dose should be given; how many doses are needed to produce an immune response; whether the H1N1 flu vaccine can be safely given along with the regular season flu vaccine, and if so, will both vaccines provide protection?

Three of the five clinical trials are enrolling healthy adults (18 to 64 years) and senior volunteers (65 years old and older). The two candidate 2009 H1N1 flu vaccines are made by Sanofi Pasteur and by CSL Limited (from Melbourne Australia).

## Clinical trials of H1N1 flu vaccine for pregnant women

Pregnant women are at a greater risk of complications from both seasonal flu and H1N1 flu virus. Since September, 2009, 6 percent of the deaths from H1N1 flu were pregnant women, according to the Centers for Disease Control and Prevention (CDC). Pregnant women who get H1N1 flu also need to be hospitalized more often than does the general public who get H1N1 flu.

Public health officials consider pregnant women as among the top priority groups to receive the 2009 H1N1 flu vaccine when it is available.

One NIAID clinical trial began enrolling pregnant women volunteers in September, 2009. The study will enroll up to 120 women ages 18 to 39 who are in their second or third trimester of pregnancy (14 to 32 weeks).

All volunteers will get two injections of the vaccine three weeks apart; half will receive 15 mg doses and the other half will receive 30 mg doses.

The clinical trial size for pregnant women is small since the amount of vaccine available is limited, and because in this case, results from a small sample of people can provide researchers with the information they need. More information is available at the [NIAID website](#).

## Clinical trial of H1N1 flu vaccine for children

Pediatric (child) trials began in August, 2009, after a panel of experts from the Safety Monitoring Committee reviewed vaccine safety data. The trials are enrolling children between ages 6 months and 17 years.

One pediatric trial will test how large a vaccine dose should be given and how many doses of vaccine are needed to produce a protective immune response. The other trial will determine whether the H1N1 flu vaccine can be safely given at the same time or after the seasonal flu vaccine is given; and if both vaccines will then produce a protective immune response. Eleven medical centers are taking part in the pediatric clinical trials.

These trials will help researchers and public policy experts select the vaccines that will be used to protect the nation. The trials illustrate the vital role and contribution of the clinical trials volunteer. More information is available at the [NIAID website](#).



Volunteer getting flu injection from doctor