

## NIAID launches 2009 H1N1 influenza vaccine trial in pregnant women

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The first trial testing a candidate 2009 H1N1 influenza vaccine in pregnant women is launching this week, the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, announced today.

"Women are at higher risk of developing severe illness if they become infected with influenza virus while pregnant, which is why they are strongly encouraged to receive the seasonal influenza vaccine every year," says NIAID Director Anthony S. Fauci, M.D. "Data indicate that [pregnant women](#) are at higher risk for complications from the 2009 H1N1 influenza virus as well, so this trial will provide critical information for [public health](#) planning."

The trial is being conducted through the NIAID-funded national network of Vaccine and Treatment Evaluation Units (VTEUs).

"The American public has shown once again its remarkable willingness to step up and help during an emergency. The interest in this trial has been extraordinary, and participating medical centers expect to fill all the available slots for volunteers soon," Dr. Fauci adds.

Up to 120 women 18 to 39 years of age who are in their second or third trimester (14 to 34 weeks) of pregnancy will be enrolled into this initial trial. Volunteers will receive 15 micrograms or 30 micrograms of a candidate 2009 H1N1 influenza vaccine manufactured by Sanofi Pasteur. All women will receive an initial injection and a second

injection 21 days later. Safety data will be collected and assessed continuously throughout the trial by the study investigators and by an independent safety monitoring committee. Study investigators will take blood samples to determine how the immune system responds to the vaccine (for example, by producing antibodies) at set time points before and following each injection. Cord blood will also be collected to measure maternal antibodies transferred to the infants through the placenta.

Because the vaccine contains inactivated virus, it is impossible to become infected with the 2009 H1N1 [influenza virus](#) by receiving this vaccine. The vaccine contains no thimerosal, a preservative, or adjuvant, a substance added to some vaccines to improve the body's response to vaccine.

The design of this trial in pregnant women is patterned after clinical trials that opened in August through NIAID's VTEU network. Those trials are testing the same vaccine in various groups of healthy individuals, including adults, the elderly and children. The candidate vaccine is also being tested in pregnant women because they represent a population who public health officials have recommended to receive a licensed 2009 H1N1 influenza vaccine when it becomes available this fall.

The trial is taking place at the following six medical centers: Baylor College of Medicine VTEU in Houston; Group Health Cooperative Center for Health Studies VTEU in Seattle; Saint Louis University VTEU; Vanderbilt University VTEU in Nashville; Duke University in Durham, N.C.; and Scott and White Memorial Hospital and Clinic in Temple, Tex.

In a paper published Aug. 8 in *The Lancet*, researchers from the Centers for Disease Control and Prevention reported that six of 45 people (13

percent) who died from 2009 H1N1 influenza between mid-April and mid-June were pregnant women. In addition, during the first month of the H1N1 outbreak, the estimated rate of hospitalization for H1N1 infection in pregnant women was approximately four times higher than it was in the general population. U.S. public health officials, following the recommendation of CDC's Advisory Committee on Immunization Practices, have designated pregnant women among the top priority groups to receive the 2009 [H1N1 influenza vaccine](#) when it becomes available.

More information: Detailed information about this study can be found on the ClinicalTrials.gov Web site at [www.clinicaltrials.gov/ct2/show ... m=NCT00963430&rank=1](http://www.clinicaltrials.gov/ct2/show/study?rank=1&term=NCT00963430) H1N1 Vaccine in Pregnant Women NCT0093430.

Source: NIH/National Institute of Allergy and Infectious Diseases ([news](#) : [web](#))

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