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EARLY RESULTS: IN CHILDREN, 2009 H1N1 INFLUENZA VACCINE WORKS LIKE SEASONAL FLU VACCINE

Early results from a trial testing a 2009 H1N1 influenza vaccine in children look promising, according to the trial sponsor, the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. Preliminary analysis of blood samples from a small group of trial participants shows that a single 15-microgram dose of a non-adjuvanted 2009 H1N1 influenza vaccine - the same dose that is in the seasonal flu vaccine - generates an immune response that is expected to be protective against 2009 H1N1 influenza virus in the majority of 10- to 17- year-olds eight to 10 days following vaccination.

These results are similar to those recently reported in clinical trials of healthy adults. Younger children generally had a less robust early response to the vaccine. "This is very encouraging news," says NIAID Director Anthony S. Fauci, M.D." As we had hoped, responses to the 2009 H1N1 influenza vaccine are very similar to what we see with routinely used seasonal influenza vaccines made in the same way. It seems likely that the H1N1 flu vaccine will require just one 15-microgram dose for children 10 to 17 years of age. The 2009 H1N1 influenza virus is causing widespread infections among children, so these are welcome results."

The ongoing NIAID-sponsored trial began in mid-August at five sites nationwide. The trial is assessing the safety and immune responses to one and two doses of either 15 micrograms or 30 micrograms of vaccine. Data from the trial is being compared for three age groups: children 6 months to 35 months old; 3 to 9 years old; and 10 to 17 years old. The preliminary results are based on blood samples taken eight to 10 days after the first vaccination. Immune responses were strongest among the oldest children, those 10 to 17 years old. In this group of 25 children, a strong immune response was seen in 76 percent who received one 15-microgram dose of vaccine. The immune responses in children nine years old and younger were not as strong. Among 25 volunteers aged 3 to 9 years old, a strong immune response was seen in 36 percent of those given 15 micrograms of vaccine. In the youngest group, 20 children between 6 months to 35 months old, a single 15-microgram dose of vaccine produced a strong immune response in 25 percent of recipients.

"These results are not unexpected and are both similar to what is seen with seasonal influenza vaccines and consistent with what we and our colleagues at the Food and Drug Administration anticipated," notes Dr. Fauci. Study investigators are also collecting blood samples from the volunteers approximately three weeks after both the first and second injections. It is anticipated that the immune response to the 2009 H1N1 influenza vaccine will be similar to that of seasonal influenza vaccination and will continue to rise for several weeks following vaccination, says Dr. Fauci. The study is being closely monitored by the trial physicians and staff as well as by an independent safety monitoring committee.

The vaccine being tested in this trial is manufactured by Sanofi Pasteur in Swiftwater, Pa., in the same manner as its licensed seasonal vaccine, which is used every year in millions of children, and is the same formulation recently licensed by the FDA to protect against 2009 H1N1 influenza. Like inactivated seasonal influenza vaccines, the vaccine contains a purified part of a killed virus and cannot cause flu.

NIAID is conducting trials of 2009 H1N1 influenza vaccines through its longstanding vaccine clinical trials network, the Vaccine and Treatment Evaluation Units. Additional information about the NIAID-sponsored clinical trials in children is available in an Aug. 18

Bulletin:

<http://www3.niaid.nih.gov/news/newsreleases/2009/H1N1pedvax.htm> and a Q&A: <http://www3.niaid.nih.gov/news/QA/qaH1N1pedvax.htm>. A detailed description of the trial protocol is at clinicaltrials.gov: <http://clinicaltrials.gov/show/NCT00944073>

For more information on influenza, including pandemic influenza and avian influenza, visit www.flu.gov. Also, see NIAID's Web portal at <http://www3.niaid.nih.gov/topics/Flu> NIAID conducts and supports research -- at NIH, throughout the United States, and worldwide -- to study the causes of infectious and

immune -- mediated diseases, and to develop better means of preventing, diagnosing and treating these illnesses. News releases, fact sheets and other NIAID-related materials are available on the NIAID Web site at <<http://www.niaid.nih.gov>>.

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