Study: One Dose of H1N1 Vaccine May Suffice

BY DOUG BRUNK

A single 15-mcg dose of 2009 H1N1 influenza vaccine provided hemagglutination titers of 1:40 or greater in 93% of infants and children, results from a multicenter study in Australia showed.

The findings "have important public health implications given that young children are at the highest risk for hospitalization and requirement for intensive care," wrote the researchers led by Terry Nolan, Ph.D., of the Melbourne School of Population Health at the University of Melbourne. "The results are of particular added clinical significance because of the unexpected finding of the possible adequacy of a single dose given that the U.S. and U.K. governments recommend a two-dose regimen in infants and young children."

Between Aug. 3 and Sept. 4, 2009, the researchers randomized 346 infants and children aged 6 months to 9 years to receive a two-injection regimen of monovalent, unadjuvanted H1N1 vaccine 21 days apart in doses of either 15 mcg or 30 mcg (JAMA 2010;303:37-46). The vaccine was produced by CSL Ltd., of Parkville, Australia.

The researchers used hemagglutination inhibition to measure antibody titers to the H1N1 antigen at enrollment and at 21-25 days after each vaccination.

After the first dose, antibody titers of 1:40 or greater were observed in 161 of 174 (93%) infants and children in the 15-mcg group and in 168 of the 172 (98%) infants in children in the 30-mcg group. After the second dose all study participants in both groups demonstrated antibody titers of 1:40 or greater.

No deaths occurred during the study but two serious adverse events were reported. The first was a 4-day episode of fluctuating fever in an 8-year-old child in the 30-mcg dose group.

The site investigator "considered that this event was possibly related to vaccination," the researchers stated. "The data and safety monitoring board attributed the episode to a possible viral infection and the study was recommenced within 1 day of notification. This child made a full and uneventful recovery."

The second adverse event occurred in a 1-year-old child in the 15-mcg dose group, a case of viral gastroenteritis that "was considered unrelated to vaccination."

In an accompany editorial, Dr. Anthony E. Fiore and Dr. Kathleen M. Neuzil said that while the finding that one dose of H1N1 vaccine was immunogenic in most young children "is encouraging, it is premature to assume that only 1 dose will be needed to provide adequate protection for all young children based on these data" (JAMA 2010;303:73-4).

Dr. Fiore, of the National Center for Infectious Diseases at the Centers for Disease Control and Prevention, Atlanta, and Dr. Neuzil, of PATH, Seattle, emphasized that the antigen content administered to infants and children in the study was 15 mcg, "the equivalent of two doses of the 7.5 microgram vaccine currently licensed in the United States for this age group."

For now, they concluded, "it remains prudent to continue to follow current recommendations for administering 2 doses to infants and young children while awaiting definitive vaccine effectiveness data." ■

VITALS

Major Findings: One 15-mcg dose of 2009 H1N1 influenza vaccine appears adequate in 93% of infants and children.

Source of Data: In a multicenter Australian study, researchers randomized 346 infants and children to receive a two-injection regimen of H1N1 vaccine 21 days apart in doses of either 15 mcg or 30 mcg.

Disclosures: CSL Ltd. sponsored the trial with funding from the Australian government's Department of Health and Aging. Dr. Nolan disclosed that he has been an investigator on vaccine studies sponsored by CSL and other companies, but stated that he does not own shares in CSL. Dr. Fiore and Dr. Neuzil had no financial conflicts of interest to disclose.