Study Supports Seasonal Influenza Vaccine for Young Infants

*Flu Shots Seem Safe and Effective for Babies Aged 6 to 12 Weeks*

Philadelphia, Pa. (February 3, 2010) – Vaccination against seasonal influenza is safe and produces a protective immune response in infants as young as 6 to 12 weeks, concludes a study in the February issue of *The Pediatric Infectious Disease Journal*. The journal is published by Lippincott Williams & Wilkins, a part of Wolters Kluwer Health, a leading provider of information and business intelligence for students, professionals, and institutions in medicine, nursing, allied health, and pharmacy.

Although confirmatory studies are needed, the results suggest that seasonal flu vaccine could be included in the standard vaccinations for infants less than 6 months old, according to Dr. Janet A. Englund of University of Washington, Seattle, and colleagues.

**Flu Shots Yield Good Immune Response with Few Adverse Events**

In the study, 1,375 healthy U.S. infants were randomly assigned to receive two doses of the standard trivalent seasonal flu vaccine or an inactive placebo vaccine. ("Trivalent" means that the vaccine offers protection against three strains of circulating influenza virus.) The vaccines were given one month apart, in combination with standard recommended vaccines.

With close follow-up, the researchers found no differences in side effects or adverse events between infants receiving the active influenza vaccine versus placebo. In both groups, about 11 percent of infants developed a fever within three days after vaccination. Through one month, serious adverse events related to the study vaccine were rare.

Immunologic tests showed significant antibody responses to seasonal flu vaccine. Nearly half of infants receiving the trivalent vaccine developed protective antibodies against at least two of the three influenza virus strains covered. There was no evidence that influenza vaccine interfered with responses to the other routine childhood vaccinations.

Seasonal influenza vaccine is effective in preventing influenza, but no vaccine has been approved for prevention of influenza in infants less than 6 months old—a group at high risk for influenza and related complications. Trivalent influenza vaccine has been found safe and effective in infants over 6 months old, but very few studies have evaluated its use in younger babies.

The new study, in a large sample of American infants, suggests that seasonal influenza vaccines can safely be given to 6- to 12-week-old infants, in combination with routine childhood vaccines. The results show high rates of protective immune responses, which are likely to be effective in fighting influenza viruses.

"Based on the results of this study, potential protection against influenza could be safely obtained in infants less than 6 months of age who receive a standard infant dose of inactivated influenza vaccine," Dr. Englund and co-authors conclude. More research will be needed to confirm that vaccination is actually effective in preventing influenza in this young and vulnerable age group.

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