New Flu Strains Pegged for The 2006-2007 Vaccine

The recipe for the 2006-2007 influenza vaccine calls for A (H3N2) and B strains that differ from last year's version, according to analyses of recently isolated flu viruses, epidemiologic data, and post-vaccination serologic studies in humans.

Vaccine manufacturers should include the A/New Caledonia/20/99-like (H1N1), A/Wisconsin/67/2005-like (H3N2), and B/Malaysia/2506/2004-like viruses in formulations of the 2006-2007 influenza vaccine, recommends the Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee (MMWR 2006;55:648-53). Last year's vaccine included the emerging strain A/California/7/2004 (H3N2) and retained the H1N1 and B strains from the previous year.

During last year's flu season (from Oct. 2, 2005 to June 3, 2006), 35 deaths were reported among children aged less than 18 years, which were linked to laboratory-confirmed influenza infections from 13 states. Of the 31 children for whom the type of virus was known, 23 were infected with the influenza A virus, and 8 were infected with the influenza B virus. A total of 11 deaths occurred in children aged 6-23 months, 4 in children younger than 6 months of age, 4 in children aged 2-4 years, and 16 in children aged 5-17 years, the Centers for Disease Control and Prevention said.

Pediatric hospitalizations with lab-confirmed influenza infections were monitored in two networks. The pediatric hospitalization rates from last year's flu season showed an overall rate of 1.21/10,000 children aged 0-17 years, based on preliminary data from the Emerging Infections Program. When broken down into younger and older age groups, the rates were 2.76/10,000 among children aged 0-5 years and 0.38/10,000 among those aged 5-17 years. Furthermore, the laboratory-confirmed influenza–associated hospitalization rate was 5.4/10,000 children for children aged 0-4 years, based on preliminary data from the New Vaccine Surveillance Network.

In the 2005-2006 season, influenza A (H1N1), A (H3N2) and B viruses cocirculated all over the world, the CDC said.

—Heidi Splete

FluMist as Safe as Flu Shot For HIV-Infected Children

BY JANE SALODOF MACNEIL
Southwest Bureau

SAN FRANCISCO — The live attenuated influenza vaccine known as FluMist is as safe as an inactivated virus vaccine for children with HIV who have CD4 percentages of 15% or greater, according to the findings of a randomized, controlled trial.

Investigators recorded similar toxicity profiles for FluMist and the trivalent inactivated virus (TIV) vaccine that is standard for this population, Dr. Sharon Nachman reported at the annual meeting of the Pediatric Academic Societies.

Prolonged shedding, a major concern, was not observed in either arm of the phase I-II trial, according to Dr. Nachman, chief of pediatric infectious diseases, department of pediatrics, State University of New York at Stony Brook.

"There were no unexpected toxicities or adverse events associated with administration of LAIV [live attenuated influenza virus] or TIV in HIV-positive children in this study," she said, summarizing 6 months of follow-up on behalf of the Pediatric AIDS Clinical Trials Group.

The investigators randomized 243 HIV-positive children aged 5-18 years at the start of the 2004-2005 flu season: 122 to intranasal LAIV and 121 to injected TIV. The LAIV arm received the FluMist formulation that is currently approved for healthy children and adults aged 5-49 years.

Entry criteria included a current viral load below 60,000 copies/mL. All participants had at least 16 weeks of stable antiretroviral therapy with three different antiretroviral agents from at least two therapeutic classes. All had been vaccinated with TIV in at least one of the two previous years as well.

"Ethnicity looks exactly like [the] demographic of perinatally infected children across the United States," Dr. Nachman said. The study arms were evenly matched with respect to mean age (11.4–11.9 years), CD4 percentage (33%-34%), and viral load (2.9 copies/mL in both groups).

Vaccine administration did not lead to clinically significant changes in CD4 count, viral load, or changes in antiretroviral therapy during the study.

Investigators detected influenza shedding in 31 of 115 LAIV recipients (27%) 3 days after they received the vaccine. By day 28 only one of 119 subjects (0.9%) was shedding virus, and the results of a follow-up culture on day 56 were negative.

During the first 28 days, eight children in the LAIV arm had nine events that may have been related to FluMist administration, including fever, conjunctivitis, sinusitis, and pharyngitis.

One child was hospitalized and recovered with antibiotic therapy, Dr. Nachman reported at the meeting, sponsored by the American Pediatric Society, Society for Pediatric Research, Ambulatory Pediatric Association, and American Academy of Pediatrics.

A coinvestigator on the study is an employee of MedImmune Inc., manufacturer of FluMist. ■

Novel Cold-Adapted FluMist Might Be Safe for Young Infants

BY JANE SALODOF MACNEIL
Southwest Bureau

SAN FRANCISCO — A Finnish trial testing an investigational, refrigerator-stable version of the FluMist vaccine in healthy infants aged 6 weeks to 6 months suggests it might be given safely to babies below the recommended age of influenza immunization in the United States.

Irritability and runny nose/nasal congestion were more common in the younger half of the trial's infant population, but these and other reactogenicity events were mild, Dr. Timo Vesikari reported at the annual meeting of the Pediatric Academic Societies.

Adverse events, including fever, were similar for babies in intranasal vaccine and placebo groups.

"I believe further investigation of CAIV-T [cold-adapted influenza vaccine, trivalent] in young infants is warranted, but we should consider the present finding in the 6- to 16-week-olds," Dr. Vesikari of the University of Tampere, Finland, said at the meeting, which was sponsored by the American Pediatric Society, Society for Pediatric Research, Ambulatory Pediatric Association, and American Academy of Pediatrics.

The study enrolled 120 healthy infants from May to December 2002. Dr. Vesikari and his colleagues stratified the population into two groups: 59 babies in a 6- to 16-week-old cohort and 61 babies in a 16- to 24-week-old cohort.

Each cohort was randomized to receive two doses of CAIV-T or placebo about 35 days apart.

Monitoring for reactogenicity 11 days after the first dose showed the 6- to 16-week-old cohort experienced nearly twice as much irritability (66.7% vs. 35.7%) and runny nose/nasal congestion (63.3% vs. 33.3%) as the placebo group. No differences were seen after the second dose. Among the older infants, the only difference seen after the second dose was that cough occurred more with the placebo group (39.3%) than with the children given CAIV-T (10.7%).

Dr. Vesikari said the investigators accepted Wyeth's invitation to do the trial in part because studies have found FluMist to be more effective than trivalent, inactive vaccine in children. ■