FluMist, MMR, Varicella Vaccines OK  

BY JANE SALODOF McNEIL  
Southwest Bryce  

S AN FRANCISCO — Physicians can administer the live attenuated influenza vaccine marketed as Flurist as the same healthy infant visit in which they administer the measles-mumps-rubella and varicella vaccines and without diminishing the safety or effectiveness of any of the vaccines, according to the results of a phase III trial reported at the annual meeting of the Pediatric Academic Societies.

The study randomized healthy infants at 44 sites in the United States during the 2001-2002 flu season, from May to October 2002. Infants also were randomized from November to May in 2001 and 2002 at three additional sites in Australia, where Dr. Nolan was the head of the school of medical research at the University of Melbourne.

Investigators used the formulation of Flurist that is currently approved for healthy children and adults aged 5-49 years in the United States. MedImmune Vaccines Inc. of Gaithersburg, Md., manufacturer of Flurist, has announced that it has submitted an NDA for its formulation to be used in children as young as 6 months.

The principal change in the new product is that it can be refrigerated—the current formulation must be stored in a freezer and delivered in a lower dose.

MedImmune sponsored Dr. Nolan’s trial. Both Flurist formulations are delivered as an intranasal spray. This gives Flurist an advantage over the trivalent inactivated influenza vaccine (TIV) that is already approved for inoculation of healthy infants.

The vaccine (Flurist) is easier to give to babies because it is not an injection. They don’t cry. They love it,” he said. “And it’s a lot less expensive than the injectable vaccine. So it’s a very promising vaccine for the future.”

Dr. Nolan’s study randomized infants into three groups:

► In Group 1, 411 infants received the measles-mumps-rubella (MMR II) and varicella (Varivax) vaccines and a placebo on the first visit. They were given Flurist on the second and third visits.

► In Group 2, 422 infants received MMR II, Varivax, and Flurist on their first visit. They were given Flurist on the second visit, and a placebo on the third visit.

► In Group 3, the remaining 412 infants received Flurist alone during the first and second visits. They were given MMR II and Varivax on the third visit.

Investigators collected serum samples during office visits on days 0, 42, and 72 of the study. They reported that concurrent administration of Flurist with the other vaccines did not affect seroreponse rates or geometric mean titer to MMR II and Varivax vaccines. Similarly there was not a significant change in the strain-specific seroreconversion or geometric mean titer for each of the three vaccine strains in the Flurist vaccine.

A comparison of the first and second groups showed that children in Group 2 who were given concurrent vaccinations had significantly more rhinorrhea and nasal congestion during the following 42 days than did those in Group 1 (84% vs. 78%, respectively). Differences in other reactivity events were not statistically significant at 42 days.

During the first 10 days after the first dose of Flurist, however, children in Group 2 who were given concurrent vaccinations had significantly more rhinorrhea (60% vs. 52%), fever over 101°F (29% vs. 14%), and vomiting (14% vs. 9%) than did children in Group 3 who received Flurist alone.

The most frequently reported adverse event following concurrent vaccination (Group 2) was diarrhea (17%) and otitis media (8%). Nine serious adverse events (including pneumonia, bronchitis, croup, viral chest infection and/or bronchospasm) may have been related to the study vaccines.

The investigators concluded that concurrent administration was safe and well tolerated.

The meeting was sponsored by the American Pediatric Society, Society for Preadolescent and Pediatric Research, Ambulatory Pediatric Association, and American Academy of Pediatrics.