Febrile Children's Treatment Improved by Rapid Flu Test

BY ROBERT FINN
San Francisco Bureau

SAN FRANCISCO — The rapid diagnostic test kit for influenza significantly improves the management of infants and young children who are presenting to the emergency department with fever of unknown origin, according to a poster presentation by Dr. Javier Benito-Fernández at the annual meeting of the Pediatric Academic Societies.

Among 206 children aged 0-36 months, those who tested positive on the rapid diagnostic test underwent fewer laboratory tests and fewer radiographs, had a shorter length of stay in the emergency department, were less likely to be admitted to the hospital, and were much less likely to be treated with antibiotics.

The prospective study was conducted during the influenza seasons of 2003-2004 and 2004-2005 at Hospital Cruces, University of the Basque Country, Baracaldo, Vizcaya, Spain. All infants less than 3 months old with a fever of unknown origin received a rapid diagnostic test, the Directigen Flu A+B test.

Infants and children 3-36 months of age received the test only if their temperature was over 39° C and the pediatrician thought that laboratory tests were necessary to rule out a bacterial infection. Of the 206 children, 84 tested positive and 122 tested negative on the rapid diagnostic test.

There were no significant differences between the positive and negative groups in mean age (about 6.75 months), mean temperature (about 39.3° C), and several demographic factors.

Children who tested positive were significantly less likely to undergo urinalysis (81% vs. 100%), blood tests (33% vs. 100%), chest x-rays (14% vs. 32%), and lumbar puncture (2% vs. 21%).

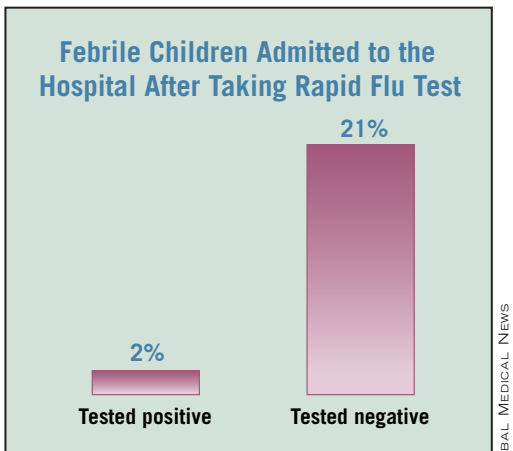
None of the children who tested positive received antibiotics, compared with 39% of the children who tested negative.

Children who tested positive also spent significantly less time in the emergency department, an average of 214 minutes versus 470 minutes for those testing negative.

Moreover, those testing positive were less likely to be admitted to hospital (2% vs. 21%).

There was no significant difference, however, in the rate of children returning to the emergency department for additional medical care: 11.9% of the children testing positive versus 11.5% of those testing negative.

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



Two Dozen Electronic Health Record Vendors Are in the Certification Pipeline

BY MARY ELLEN SCHNEIDER
New York Bureau

More than two dozen health information technology vendors have applied to have their electronic health record systems independently certified this summer.

The inspection process is underway and the Certification Commission for Health Information Technology (CCHIT) is expected to make the first announcement of certified products this month, according to CCHIT chair Dr. Mark Leavitt.

CCHIT was launched in 2004 by the American Health Information Management Association, the Healthcare Information and Management Systems Society, and the National Alliance for Health Information Technology to establish baseline criteria for EHR products and provide a seal of approval to products that meet those standards. CCHIT received a 3-year grant from the Department of Health and Human Services in September 2005.

In this first round of applications, CCHIT is evaluating products from across the spectrum, including EHR systems for the small office to those for large clinics, Dr. Leavitt said at a meeting of the American Health Information Community. This group advises HHS on health IT interoperability issues.

The more than two dozen applications received represent only a small fraction of the 200 or so vendors who have products available commercially, but it is about double what CCHIT officials had expected in the first round, Dr. Leavitt said.

Physicians have been heavily involved in the evaluation of products, Dr. Leavitt said. Of the 175 people who volunteered to evaluate products during 8-hour demonstration sessions, about 80% were practicing physicians. "I think the providers are interested in this," he said.

"Plug and play" systems that will not require a practice to spend $50,000 on an interface compose one CCHIT goal, Dr. Leavitt said at Toward an Electronic Patient Record, an annual conference sponsored by the Medical Records Institute.

CCHIT plans to review and certify EHR products for the ambulatory setting on a quarterly basis. In 2007, the group will begin certification of EHR products for the inpatient setting, and CCHIT will tackle certification of EHR networks in the spring of 2008. ■

Nancy Nickell, associate editor for Practice Trends, contributed to this report.

Concurrent FluMist, MMR, Varicella Vaccines Effective

BY JANE SALODOF MACNEIL
Southwest Bureau

SAN FRANCISCO — Physicians can administer the live attenuated influenza vaccine marketed as FluMist during the same healthy infant visit in which they administer the measles-mumps-rubella and varicella vaccines, 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.

'There's no interference [by FluMist] with the antibody response to the other vaccines given at the same time.'

DR. NOLAN

"There's no interference with the antibody response to the other vaccines given at the same time," Dr. Terry Nolan said in an interview alongside a poster describing outcomes for 1,245 infants aged 12-15 months in the prospective, placebo-controlled trial.

The study randomized healthy infants at 44 sites in the United States during the months from May to October in 2001 and 2002. Infants also were randomized from November to May in 2001 and 2002 at three additional sites in Australia, where Dr. Nolan is the head of the school of population health at the University of Melbourne.

Investigators used the formulation of FluMist 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 FluMist, has announced that it will seek approval of a newer formulation 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 FluMist formulations are delivered as an intranasal spray. This gives FluMist an advantage over the trivalent inactivated influenza (TIV) vaccine that is already approved for inoculation of healthy infants, according to Dr. Nolan.

"The vaccine [FluMist] is easier to give to babies because it is not an injection. They don't cry. They love it," he said. "And it appears to be as effective, if not more effective, than the injected 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 FluMist on the second and third visits.
- In Group 2, 422 infants received MMR-II, Varivax, and FluMist on their first visit. They were given FluMist on the second visit, and a placebo on the third visit.
- In Group 3, the remaining 412 infants received FluMist 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 FluMist with the other vaccines did not alter seroresponse rates or geometric mean titers to MMR II and Varivax vaccines. Similarly, there was no change in the strain-specific seroconversion rates or geometric mean titers for each of the three vaccine strains in the FluMist 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 reactogenicity events were not statistically significant at 42 days.

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

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

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

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