The FDA Clears Influenza A(H1N1) Test for Marketing

BY ELIZABETH MECHCATIE

A test for the 2009 H1N1 influenza A virus that has been available under an emergency use provision since last summer has been cleared for use by the Food and Drug Administration, the agency announced.

This test was made available in July 2009 through an Emergency Use Authorization (EUA), which allows the FDA to authorize the use of unapproved medical products when a public health emergency has been declared. The first wave of the 2009 influenza virus A outbreaks in the spring of 2009 was the basis of the public health emergency declared in April 2009, and tests for the virus were subsequently made available under the EUA.

'With this clearance, the availability of Simplexa H1N1 test will not be affected when the public health emergency expires.'

The test cleared by the FDA is the Simplexa Influenza A H1N1 (2009), which is manufactured by Focus Diagnostics Inc. This was the first test to be made available commercially through the EUA, according to a statement from the company.

"With this clearance, the availability of Simplexa H1N1 test will not be affected when the public health emergency expires," Dr. Jeffrey Shuren, director of the FDA's Center for Devices and Radiological Health, said in the FDA statement announcing clearance of the test.

The test uses specimens from nasal swabs or aspirates; a positive test indicates infection with the 2009 H1N1 influenza virus, but a negative test result "does not preclude influenza virus infection," according to the FDA statement. ■

The FDA's information on 2009 H1N1 influenza is available at www.fda.gov/NewsEvents/PublicHealthFocus/ucm150305.htm#tests.

Study Supports Alternating, Combining Antipyretics

BY PATRICE WENDLING

FROM THE ANNUAL MEETING OF THE PEDIATRIC ACADEMIC SOCIETIES

VANCOUVER, B.C. — Combined and alternating doses of ibuprofen and acetaminophen provided greater antipyresis than ibuprofen alone in a randomized trial involving 60 febrile children.

Although combining and alternating doses of these agents is common, there are limited data to support this practice with standard U.S. doses.

In 2001 the American Academy of Pediatrics stated that "alternating doses every 6 hours might be used so that one drug or the other is administered every 3 hours," but urged clinicians to "exercise discretion when considering this therapy" (Pediatrics 2001;108:1020-4). The current study evenly randomized children, aged 6 months to 7 years (mean, 3.4 years), with temporal artery temperatures of at least 38° C (mean, 38.7°) to ibuprofen alone, ibuprofen combined with acetaminophen, or ibuprofen followed by acetaminophen 3 hours later. Ibuprofen was dosed at 10 mg/kg and acetaminophen at 15 mg/kg.

At baseline, there was no significant difference in the children's temperatures, but at hour 4 there was a statistically significant increase in the ibuprofen-alone group that was maintained at hours 5 and 6, Dr. Deepa Sekhar reported on behalf of principal investigator Dr. Ian M. Paul and their colleagues at Pennsylvania State University in Hershey.

At hour 6, 50% of the ibuprofen-alone children were febrile (mean, 38.5° C), whereas in both of the combined groups, all of the children were afebrile, except one in the ibuprofen plus acetaminophen group.

The findings at hours 4, 5, and 6 for the combined arm are highly relevant to parents who give medications to their children prior to day care, school, or sleep, Dr. Sekhar said at the meeting.

"Right or wrong, fever phobia is widespread among parents and caregivers alike," she commented.

One attendee questioned whether using two medications reinforces this phobia. Dr. Sekhar agreed, but said that many parents she sees are already using two and that now she can tell them these regimens work and are safe.

The regimen of ibuprofen followed by acetaminophen 3 hours later was chosen because health care providers tend to prefer ibuprofen first for higher fevers, Dr. Paul said in an interview.

A previous survey of 161 pediatric providers found that 50% advise parents to alternate acetaminophen and ibuprofen for febrile illnesses, and that 57% use ibuprofen for temperatures of 102° F or higher (Pediatrics 2000;105:1009-12).

Another attendee questioned whether fever should be fought as it is, observing that several infectious disease colleagues favor fever and feel it is associated with a number of immunologic changes that could be beneficial for fighting infection.

Again Dr. Chakar agreed, and to a round of laughter added, "But school nurses are powerful people."

Dr. Paul told this news organization: "Day cares and schools are more concerned with a number on the thermometer rather than what should or shouldn't be fought or even the activity/functioning of the child. They have firm rules as to who gets sent home and who doesn't based on this number. This has a trickle-down effect to parents and health care providers." ■

VITALS

Major Finding: Six hours after administration, 50% of children treated with ibuprofen alone were febrile versus all but one child treated with combined or alternating doses of ibuprofen and acetaminophen.

Data Source: Randomized trial in 60 febrile children.

Disclosures: The research was supported by grants from the George L. Laverty Foundation, the National Institutes of Health, and the Penn State General Clinical Research Center. Dr. Paul disclosed serving as a consultant for Novartis, Procter & Gamble, and the Consumer Healthcare Products Association. Dr. Sekhar reported no conflicts.

Concomitant Use of PCV13, TIV Is Safe, Effective in Adults

BY ROXANNA GUILFORD-BLAKE

FROM THE NATIONAL IMMUNIZATION CONFERENCE

ATLANTA — In healthy adults, the 13-valent pneumococcal conjugate vaccine can be safely administered at the same time as trivalent inactivated influenza vaccine without compromising immunogenicity, reported Dr. Robert W. Frenck Jr. of Cincinnati Children's Hospital Medical Center and colleagues.

PCV13 is not approved for use in adults, but "likely will be in the not-too-distant future, and this study will help clinicians decide how to administer the vaccine," Dr. Frenck said.

The findings from randomized, double blind, phase III clinical trials were presented in a poster at the conference, sponsored by the Centers for Disease Control and Prevention.

For the study, 1,116 healthy adults aged 50-59 years were randomized to receive either PCV13 and TIV (PCV13+TIV) followed by placebo 1 month later, or TIV and placebo (TIV+placebo) followed by PCV13 1 month later.

"Noninferiority of PCV13+TIV to TIV+placebo was demonstrated for all virus subtypes," investigators reported. The PCV13+TIV and TIV+placebo groups each had similar proportions of responders with a fourfold increase in TIV antibody titer (see chart).

Similarly, for the PCV13, investigators reported that the noninferiority criterion was met for all serotypes.

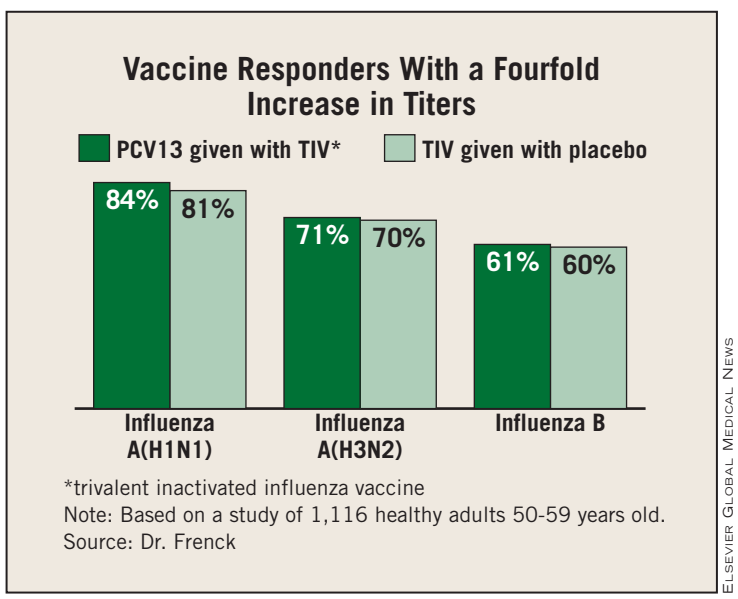
Most adverse events were mild; none was serious. Local reactions occurred in 89% of PCV13+TIV recipients vs. 39% in recipients of TIV+placebo and 85% of those receiving PCV13 alone. Systemic events occurred in 86% of PCV13+TIV recipients, 76% of recipients of TIV+placebo, and 77% of those receiving PCV13 alone. ■

VITALS

Major Finding: Healthy adults had immunogenic responses of 84% to influenza A(H1N1), 71% to influenza A(H3N2), and 61% to influenza B when the pneumococcal vaccine and the trivalent influenza vaccine were given together.

Data Source: Randomized, double blind, phase III clinical trials in over 1,000 healthy adults.

Disclosures: The study was funded by Pfizer Inc. Dr. Frenck said he had no other conflict to declare. Several of the coauthors are Pfizer employees.



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