Data Are Preliminary

Febrile Seizures *from page 1*

of Family Physicians, Dr. Douglas Campos-Outcalt, said in an interview that "it's a pretty small risk. It certainly was an increased risk, but the absolute risk wasn't very high. You have to put the whole thing in context. Febrile seizures are a concern to parents, but they aren't life-threatening events. I think it's worth counseling parents, but vaccine risks are pretty low."

Dr. David Kimberlin, co-liaison to ACIP from the American Academy of Pediatrics, said that "the data are extremely preliminary. Until we know more, there should be no changes to the use of influenza vaccine in pediatrics in the United States."

Concern about Fluzone – the only influenza vaccine recommended for use for the 2010-2011 flu season in infants and children 6-23 months of age – arose from a data mining signal from the passive Vaccine Adverse Events Reporting System. Prior to that, a report from Australia suggested a statistically increased risk for febrile seizures within a day of receipt of another brand of flu vaccine that has since been pulled from the market worldwide.

The VSD will continue to monitor this until the end of the influenza season and will also look for possible roles of other concomitant vaccines. An ACIP working group will consider additional information on febrile seizures following vaccination, said Dr. Frank DeStefano of the CDC's Immunization Safety Office.

In a statement, Pfizer spokesman Curtis Allen said, "In addition to Pfizer's routine safety surveillance, we have conducted a comprehensive evaluation of our Prevnar 13 safety data, including results from clinical trials and our post-marketing safety database and, at this time, we have not observed a change in the safety profile with respect to febrile seizures. Our safety evaluation is ongoing and we will continue to work closely with the CDC and FDA to evaluate the CDC data, which are preliminary and require further investigation." ■

VITALS

Major Finding: Preliminary data suggest one excess febrile seizure for every 1,640 vaccinees aged 12-23 months who receive Fluzone and Prevnar vaccines simultaneously.

Data Source: Real-time analysis of data from a large managed care database that includes 2.2 million children.

Disclosures: Dr. Lee and Dr. Marcy stated that they have no relevant financial disclosures. Dr. Campos-Outcalt has no personal disclosures, but the AAFP sponsors two vaccine fellowships funded by Merck. Dr. Kimberlin has no personal disclosures, but his institution is a study site for nonvaccine trials sponsored by GlaxoSmithKline, Cubist, and Cellex. Dr. DeStefano is a CDC employee and has no relevant financial disclosures.

VERBATIM

'While ill adults were more likely than children to have visited Asia, more ill children presented after travel to Europe and the Middle East/North Africa.'

Dr. Bonnie M. Word, page 12

AAP: With Fever, Don't Focus on Temperature

BY ESTHER FRENCH

FROM PEDIATRICS

Communicate to parents that their goal is to alleviate a child's discomfort and monitor for signs of serious illness rather than simply lowering their child's temperature, an American Academy of Pediatrics report.

Although fever is normal and often beneficial to the immune system, "fever phobia" remains prevalent, and pediatricians must redirect overblown parental concerns about their child's fever, reported Dr. Janice E. Sullivan of the University of Louisville (Ky.) and Dr. Henry C. Farrar of Arkansas Children's Hospital, coauthors of the report with the AAP section on clinical pharmacology and therapeutics and the committee on drugs (Pediatrics 2011;127:580-7).

Fever is a sign of illness, but "our focus on gathering that information gives the message to parents that fever is bad," Dr. Sullivan said in an interview.

If the focus is solely on the fever, she added, lowering that fever may reassure the parent that the child is stable when really that parent should be watching for signs of serious illness. These worrisome signs include dehydration, a fever of at least 103° F, or a fever that persists. Encourage parents to treat fever in exceptional populations, such as patients with cardiomyopathy.

Encourage proper hydration and think carefully before recommending the use of antipyretics such as acetaminophen and ibuprofen, the report urged. The most important goal should be "to improve the child's overall comfort," not to lower temperature, and the report cited the lack of evidence that "reducing fever reduces morbidity or mortality from a febrile illness." Although alternating or combining antipyretics is common, "questions remain regarding the safety of this practice as well as the effectiveness in treating discomfort, which is the primary end point," according to the report.

"If we're treating discomfort, one agent should be adequate," Dr. Sullivan said.

The report urged pediatricians to "advocate for a limited number of formulations of acetaminophen and ibuprofen." Dr. Sullivan added that the availability of two different concentrations of acetaminophen and the lack of appropriate measuring devices may account for the high percentage of incorrect dosages.

Dr. Sullivan reported no relevant financial disclosures. ■

Guanfacine Is Approved to Use as An ADHD Adjunct Treatment

Guanfacine has been approved by the Food and Drug Administration as an adjunct to stimulant medications for the treatment of attention-deficit/hyperactivity disorder in children and adolescents aged 6-17, the manufacturer announced in a statement.

The extended-release form of the drug, a selective alpha-2A adrenergic receptor agonist, previously had been approved as monotherapy for treating ADHD. The adjunctive therapy indication was based on a 9-week study of children and adolescents, according to the prescribing information for guanfacine, marketed as Intuniv by Shire PLC. The 9-week study included 455 patients with ADHD who had a suboptimal response to stimulant treatment.

Patients were randomized to receive a dose of guanfacine or placebo in the morning or evening or placebo in combination with the stimulant they had been receiving, with the dose of guanfacine starting at 1 mg titrated weekly over a 5-week period to a maximum of 4 mg/day, based on tolerability and clinical response.

At the end of 9 weeks, the mean reductions in total scores on the ADHD rating scale (ADHD-RS-IV) were significantly greater among those who received the combination than among those who continued on the psychostimulant alone.

The prescribing information states that it is indicated "as an integral part of a total treatment program for ADHD that may include other measures (psychological, educational, and social) for patients with this syndrome."

–Elizabeth Mechcatie