CDC Issues Guidelines On Antiviral Use for Flu

BY ROBERT FINN

Children younger than 1 year of age may be given oseltamivir for influenza treatment and prophylaxis despite the expiration of the Food and Drug Administration's emergency authorization allowing use of the drug in that age group, according to new guidelines issued last month by the Centers for Disease Control and Prevention.

In an interview, the CDC's Dr. Tim Uyeki said, "ACIP [the Advisory Committee on Immunization Practices] and CDC are recommending use of oseltamivir for treatment or chemoprophylaxis in children less than 1 year of age with suspected or confirmed influenza, because of the high risk for complications – including serious complications – in children less than 1 year of age, as well as the fact that the 2009 H1N1 virus continues to circulate worldwide including in the U.S."

The FDA issued its emergency use authorization during the 2009-2010 pandemic of influenza A(H1N1). The authorization expired in June 2010.

While encouraging the use of the neuraminidase inhibitors oseltamivir (Tamiflu) and zanamivir (Relenza), the new guidelines emphasize that the antivirals amantadine (Symmetrel) and rimantadine (Flumadine) should not be used for influenza. Those drugs are inactive against influenza B, and the currently circulating strains of influenza A have developed resistance.

In another significant change, the guidelines now emphasize that it's permissible to treat individuals with influenza who are at low risk of complications with oseltamivir and zanamivir.

"We never said, 'Don't treat persons who are not hospitalized and not high risk,' " said Dr. Uyeki, a pediatrician and medical epidemiologist. "The emphasis on high-risk patients and hospitalized patients might have been interpreted as, 'Don't treat persons with mild, uncomplicated illness who were previously healthy.' "

The guidelines encourage physicians to rely on their clinical judgment in making treatment decisions regarding patients with suspected or confirmed influenza. Knowledge of the locally prevalent influenza strains as well as local patterns of antiviral resistance should inform that judgment.

In other influenza news:

► The CDC reports in its latest update that eight children have died from influenza in the United States so far this season. In comparison, there were 282 pediatric deaths during the full 2009-2010 season and 133 during the 2008-2009 season.

The CDC continues to find no evidence of resistance to oseltamivir and zanamivir by any influenza strain currently circulating.

In the week ending Jan. 8, 2011, 11 states were reporting widespread influenza activity (Alabama, Arizona, Connecticut, Kentucky, Louisiana, Maryland, Nevada, New York, North Carolina, Tennessee, and Virginia). Another 17 states were reporting regional influenza activity (Colorado, Florida, Georgia, Illinois, Indiana, Kansas, Maine, Massachusetts, Mississippi, Missouri, New Hampshire, New Jersey, Ohio, Oklahoma, Pennsylvania, South Carolina, and Texas). The remaining states were reporting only local or sporadic influenza activity.

► In its latest influenza update, the World Health Organization reports that influenza cases are continuing to increase in North America, and that the primary strain is influenza A(H3N2). In the United Kingdom, severe and fatal cases of influenza A(H1N1) have increased compared with 2 weeks ago, and 25% of all intensive care beds are occupied by influenza patients. ■

FDA Approves Expanded Age Group for Meningococcal Vaccine

BY ELIZABETH MECHCATIE

The approval of the quadrivalent meningococcal conjugate vaccine manufactured by Novartis has been expanded to include children aged 2-10 years, but does not yet include infants, the company announced last month.

The Food and Drug Administration approved the use of the vaccine for preventing invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y, and W-135 in children aged 2-10 years of age, according to a statement issued by Novartis. The company markets the vaccine (Meningococcal [Groups A, C, Y, and W-135] Oligosaccharide Diphtheria CRM $_{197}$ Conjugate Vaccine) as Menveo. It was approved in 2010 for use in adolescents and adults aged 11-55 years.

Novartis application for approval included children down to age 2 months. But the statement said that the FDA had not included this age group in the approval because of concerns raised that the company believes are of a "procedural nature," and that the company plans to resubmit the application for approval with more clinical data on children 2 months to 2 years within a few months.

Approval for the children aged 2-10 years was based on data in a phase III study of 5,297 children in that age group comparing the safety and immunogenicity against the four serogroups contained in the vaccine with those in the other meningococcal vaccine licensed in the United States, according to Novartis. The statement said that the company has agreed to conduct postmarketing studies.

The other meningococcal conjugate vaccine approved in the United States is Menactra, manufactured by Sanofi Pasteur, which is also approved for immunizing people aged 2-55 years against invasive meningococcal disease caused by the four serogroups contained in the vaccine, the same included in Menveo. ■

Herpes Zoster Vaccine Effective in Real Practice

BY MARY ANN MOON

FROM JAMA

The herpes zoster vaccine reduced the incidence of the disease by 55% in real-world clinical practice, according to a report in the Jan. 12 issue of the journal.

This finding, from a retrospective cohort study involving more than 303,000 healthy, community-dwelling adults aged 60 and older from diverse backgrounds, confirms and extends the results of clinical trials that found the vaccine effective under idealized conditions. In addition, the cohort study found further benefits that had not been shown before: The herpes zoster vaccine also decreased the rate of ophthalmic herpes, and it was effective in patients with underlying chronic diseases that were feared to interfere with their immune function.

Thus, the benefits of the herpes zoster vaccine extend to the ophthalmic manifestation of the disease, to all races, both genders, and all ages over 60, as well as to patients with chronic illness, said Hung Fu Tseng, Ph.D., of Southern California Kaiser Permanente, Pasadena, and associates.

These results are particularly important given that the public's acceptance of the vaccine has been slow and it is not yet in widespread use. "This vaccine has the potential to annually prevent tens of thousands of cases of herpes zoster and postherpetic neuralgia nationally. To date, herpes zoster vaccine uptake has been poor due to weaknesses in the adult vaccine infrastructure and also due to serious barriers to the vaccine among clinicians and patients.

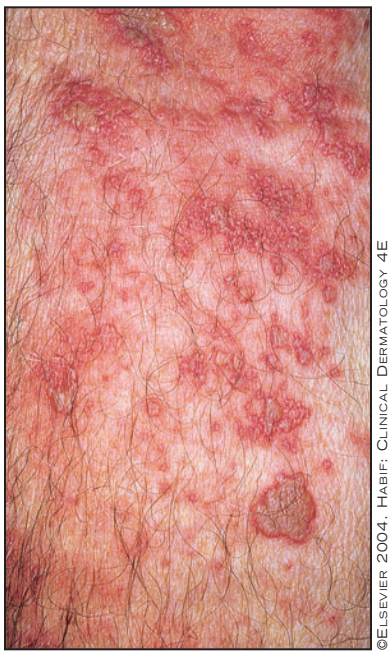
"Solutions to these challenges need to be found so that individuals seeking to receive herpes zoster vaccine will be able to reduce their risk of experiencing this serious condition," Dr. Tseng and his colleagues wrote.

They assessed the vaccine's effectiveness in 75,761 California patients in the managed care plan who were immunized in 2007-2009, comparing outcomes with those of 227,283 age-matched control subjects who were not vaccinated. A total of 5,434 cases of herpes zoster developed during an average follow-up of 1-2 years.

The incidence of herpes zoster was 6.4 per 1,000 person-years in the vaccinated group, compared with 13 per 1,000 patient-years in the control group. This reflects a 55% reduction in incidence with the vaccine, the investigators wrote (JAMA 2011;305:160-6).

This result indicates that "1 episode of herpes zoster would be averted for every 71 patients receiving the vaccine," they wrote.

The vaccine benefit persisted across all subgroups of patients, particularly in the oldest subjects. "Our results support recommendations to offer herpes zoster vaccine to eligible patients of all ages, including the oldest population," Dr. Tseng and his associates wrote.



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The vaccine benefit persisted, particularly in the oldest patients.

"For the oldest group, this could translate into a very large absolute reduction in disease because they bear the greatest burden of herpes zoster and postherpetic neuralgia and are also especially vulnerable to these disabling conditions," the researchers added.

The vaccine's effectiveness against ophthalmic herpes is an important finding not reported previously. Ophthalmic involvement is common and can lead to serious vision-threatening sequelae, they noted.

The finding that the vaccine also was effective in patients with chronic underlying disease was "reassuring," because "these diseases might have interfered with functional immunity and vaccine effectiveness. Control of pain from herpes zoster and postherpetic neuralgia is complicated in these patients because of their underlying conditions and the medications they must take," Dr. Tseng and his colleagues said.

The study was limited in that it involved only fully insured patients in a single region of the country. In addition, with its short follow-up, the study "was not designed to capture any decline in protection that is likely to occur with time," they added.

Dr. Tseng and three associates reported receiving research funding from Merck for other vaccine studies. ■