

# ACIP Recommends Newly Licensed PCV13

BY MIRIAM E. TUCKER

ATLANTA — Recommendations for routine use of the newly licensed 13-valent pneumococcal conjugate vaccine in children should provide a smooth transition from the current 7-valent vaccine.

Licensure of the 13-valent pneumococcal conjugate vaccine (PCV13), Pfizer's Prevnar 13, was announced by a representative from the Food and Drug Administration at a meeting of the Cen-



**'The [committee's] recommendations line up with what we consider appropriate use of the vaccine.'**

DR. BOCCHINI

ters for Disease Control and Prevention's Advisory Committee on Immunization Practices. The vaccine was approved for use in children aged 6 weeks through 5 years of age and is indicated for the prevention of invasive pneumococcal disease caused by all of its 13 serotypes and for prevention of otitis media caused by the serotypes in the 7-valent vaccine, the FDA's Dr. Wellington Sun said.

Following the announcement, the committee then voted on recommendations for routine use of the 13-valent vaccine in previously unvaccinated children aged 2-59 months of age—with the routine primary series given at 2, 4, 6, and 12-15 months of age—and in high-risk children aged 60-71 months, as well as on guidelines for transitioning to PCV13 in children who previously received one or more doses of PCV7.

Children who previously received one or more doses of PCV7 should complete the series with PCV13. Children aged 14-59 months who were completely vaccinated with four doses of PCV7 should receive a single "supplemental" dose of PCV13, but this can occur at the next regularly scheduled office visit, said Dr. Pekka Nuorti of the CDC's respiratory diseases branch.

A supplemental PCV13 dose should also be given to children with underlying medical conditions through 71 months of age, including those who previously received the 23-valent pneumococcal polysaccharide vaccine. Vaccination with a single dose of PCV13 also may be considered for high-risk children aged 6 through 18 years, although such use would be off label, Dr. Nuorti said.

When published in the CDC's Morbidity and Mortality Weekly Report, the

guidelines will contain detailed charts for transitioning children from PCV7 to PCV13 based on age and how many doses of PCV7 they have already received. Dosage intervals also will be included, Dr. Nuorti noted.

Dr. Joseph A. Bocchini, the liaison to ACIP from the American Academy of Pediatrics, said that the academy is likely to support the ACIP recommenda-

tions. "The recommendations line up with what we consider appropriate use of the vaccine. ... I think it will be easy for people to make the [PCV7 to PCV13] transition," Dr. Bocchini of Louisiana State University, Shreveport, said in an interview at the meeting. ■

**Disclosures:** Dr. Nuorti and Dr. Bocchini said they had no conflicts of interest.

## Transition Should be 'Pretty Smooth'

MY TAKE

I don't think the American Academy of Family Physicians will have any trouble with these recommendations, and I don't think family physicians will have any trouble implementing them, because they're already doing pretty well with PCV7 and this is just going to substitute.

It's a good move for Pfizer Inc. to issue credit to providers for unused doses of PCV7. There was a lingering question about what we were going to do with the current PCV7 supplies. If they weren't going to buy them back, the tendency would

be to continue to use them. Now that they're going to buy back, the transition should be pretty smooth.



DOUG CAMPOS-OUTCALT, M.D., is the liaison to ACIP from the American Academy of Family Physicians. He is also associate chair of the Department of Family and Community Medicine at the University of Arizona College of Medicine in Phoenix. He has given vaccine talks for the France Foundation, an independent medical education company that receives grants from various funders.

## Panel Selects Pandemic H1N1 Strain for 2010-11 Flu Vaccine

BY ELIZABETH MEHCATIE

BETHESDA, MD. — The influenza vaccine for the 2010-2011 influenza season in the United States should include a pandemic influenza A(H1N1) strain, instead of one of the two seasonal influenza A strains in the current vaccine, a Food and Drug Administration Advisory Panel recommended.

At a meeting of the FDA's Vaccines and Related Biological Products Advisory Committee last month, the panel unanimously voted that the current influenza A(H1N1) strain included in the 2009-2010 seasonal flu vaccine, an A/Brisbane/59/2007 (H1N1)-like virus, should be replaced with a pandemic A(H1N1) vaccine virus, an A/California/7/2009-like virus, the component of the monovalent pandemic vaccine that has been used this season.

Also included in the vaccine should be an A/Perth/16/2009 (H3N2)-like virus and a B/Brisbane/60/2008-like virus (B/Victoria lineage), the panel said.

The panel's recommendation is based on the finding that the vast majority of influenza A(H1N1) viruses circulating worldwide have been the pandemic strain. At the meeting, Nancy Cox, Ph.D., director of the influenza division at the Centers for Disease Control and Prevention, Atlanta, told the panel that there has been very little evidence of circulating

seasonal A(H1N1) influenza viruses.

The panel meets every year at this time to make preliminary recommendations on the components of the trivalent vaccine for the forthcoming influenza season in the northern hemisphere. It considered information on the strains circulating worldwide as well as recommendations announced by the World Health Organization for the 2010-2011 influenza vaccine to be used in the northern hemisphere.

The panel voted to replace the influenza A(H3N2) strain included in the current vaccine, with a southern hemisphere vaccine virus A/Perth/16/2009 (H3N2)-like virus. Dr. Cox said that activity of seasonal A(H3N2) viruses has been "relatively low" worldwide, compared with previous years, and what has been circulating antigenically is closely related to the A/Perth/16/2009 virus.

The panel voted to retain the influenza B component that is in the current vaccine, a B/Brisbane/60/2008-like virus (B/Victoria lineage). Influenza B viruses have been circulating at low levels in many countries, but Victoria lineage viruses continue to predominate, Dr. Cox said.

The panel's recommendations were the same as the WHO recommendations for the three components of the influenza vaccine for the forthcoming season in the northern hemisphere. ■

## High-Dose Influenza Vaccine Helpful for Older Adults

BY MIRIAM E. TUCKER

ATLANTA — Fluzone High-Dose vaccine was significantly more immunogenic than standard-dose influenza vaccine in a study of 3,876 individuals aged 65 years or older.

Sanofi-Pasteur's Fluzone High-Dose was licensed last December for use in that age group. In the phase III, multicenter, double-blind study, participants were randomized to receive either high-dose (HD) vaccine containing 60 mcg hemagglutinin per strain or standard dose (SD) with 15 mcg hemagglutinin per strain. Blood specimens were obtained before vaccination and on day 28 for evaluation of influenza antibodies. Safety data were collected for up to 6 months after vaccination, Dr. David Greenberg said at a meeting of the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Reported injection site reactions within 7 days of vaccination were more common with HD. Pain was reported by 36% of the 2,573 participants who were assessed after receiving the HD vaccine and in 24% of the 1,260 in the SD group. Grade III pain was uncommon in both groups (0.3% with HD and 0.2% with SD). Erythema occurred in 15% with HD and 11% with SD, and swelling in 9% and 6%, respectively.

Grade III erythema and swelling occurred in less than 2% of both groups. Most injection site reactions were mild to moderate and resolved within 3 days, said Dr. Greenberg, Sanofi-Pasteur's senior director of scientific and medical affairs.

Rates of systemic reactions were similar between the HD and SD groups, including myalgia (21% HD, 18% SD), malaise (18%, 14%), headache (17%, 14%), and fever (0%, 0.1%). Adverse events in the 30 minutes following vaccination were comparable (about 0.3% in both groups), as were rates of unsolicited adverse events within 28 days post vaccination (22% of both groups) (J. Infect. Dis. 2009;200:172-80).

Only two serious adverse events were reported by investigators as being vaccine-related: an exacerbation of Crohn's disease 2 days after receipt of HD vaccine, and a new diagnosis of myasthenia gravis 1 month after SD vaccination.

To satisfy requirements of the Food and Drug Administration, Fluzone was required to demonstrate superiority to SD vaccine for at least two of the three vaccine influenza strains, without inferiority for any strain. Fluzone achieved superiority—as determined by significantly greater geometric mean antibody titers—for the H1N1 and H3N2 strains and noninferiority for the B strain, Dr. Greenberg reported. ■