ACIP Presents PCV13 Draft Recommendations

BY HEIDI SPLETE

ATLANTA — If it is approved for use in the United States, a 13-valent pneumococcal conjugate vaccine in children would have recommendations mirroring those already in place for the 7-valent vaccine. Draft guidelines on PCV13 were presented at a meeting of the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Committee member Dr. Michael Marcy introduced the discussion of the 13-valent pneumococcal conjugate vaccine (PCV13) and cited recent data from the CDC's Morbidity and Mortality Weekly Report that showed a significant association between bacterial coinfections and severe cases of the pandemic influenza A(H1N1) virus.

The timing of the licensure may allow for the use of PCV13 during the 2009/2010 flu season, noted Dr. Pekka Nuorti of the CDC, who presented the draft recommendations. The Food and Drug Administration's review of the vaccine is ongoing, and a decision is expected this month, said Dr. Peter Paradiso of Wyeth Pharmaceuticals, which makes PCV13.

The vaccine is designed to protect infants and young children against the pneumococcal diseases caused by the seven serotypes in the PCV7 vaccine, plus six additional serotypes: 1, 3, 5, 6A, 7F, and 19A. PCV13 is currently licensed in Chile and Mexico, Dr. Paradiso said.

To expedite a potential transition to PCV13, the CDC said provisions are in place for voting on vaccine recommendations in advance of the next scheduled ACIP meeting in February.

The draft recommendations involve four groups: unvaccinated infants and children, children who have started their PCV vaccine schedules with PCV7, children who have completed the PCV7 schedule, and immunocompromised children or children with chronic illness.

For unvaccinated infants and children, the recommendations are the same as for PCV7, with PCV13 replacing PCV7 for all doses, said Dr. Nuorti.

The draft recommendations also state that children who began their vaccination series with PCV7 can complete the series with PCV13 at any point in the schedule, and children who have completed the primary infant series with PCV7 should receive a single PCV13 dose during the second year of life to provide protection against the six additional serotypes.

Dr. Nuorti added that the proposed recommendations for the 23-valent pneumococcal polysaccharide vaccine (PPSV23) after PCV13 for individuals aged 2 years and older with underlying medical conditions are the same as those currently recommended for the use of PPSV23 after PCV7, although no safety and immunogenicity data are yet available for this vaccine sequence.

Dr. Paradiso of Wyeth reviewed safety and immunogenicity data presented at an ACIP meeting earlier this year, including comparison data from a study including 125 children aged 15 months to 2 years, and 182 children aged 2 years to 5 years. The studies suggest that the safety profiles and immune responses were similar to those seen with PCV7. ■

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Children who began their vaccination series with PCV7 can complete the series with PCV13 at any point in the schedule, said Dr. Pekka Nuorti of the CDC.