CDC Reinstates Hib Booster at Routine Visits

BY MIRIAM E. TUCKER

ATLANTA — Physicians should resume giving booster vaccinations for Haemophilus influenzae type b (Hib) vaccine to children aged 12-15 months at routine visits, the Centers for Disease Control and Prevention recommended.

The Hib vaccine supplies were severely reduced almost 2 years ago when Merck & Co. voluntarily recalled certain lots of its PedvacHib (monovalent Hib vaccine) and Comvax (Hib-HepB) vaccines; production of those vaccines has not resumed. Because of the resulting shortage, the CDC recommended at that time (December 2007) that physicians defer the 12- to 15-month Hib booster dose for healthy children (MMWR 2009;24:673-4).

Beginning July 1, 2009, Sanofi Pasteur, manufacturer of ActHib (monovalent Hib vaccine) and Pentacel (DTaP-IPV/Hib vaccine), aimed to ramp up production of those vaccines, allowing enough supply to resume the 12- to 15-month booster dose, Dr. Abigail Shefer said at a meeting of the CDC's Advisory Committee on Immunization Practices.

However, vaccine supply still will be insufficient to support a mass notification process in which all children whose booster dose was deferred.

CDC's Dr. Michael L. Jackson. Between May 2008 and April 2009, a total of 43 cases were identified, compared with an annual average of 31.4 cases prior to the shortage.

Moreover, 32 states reported several Hib cases at or below baseline and just 20 states were over baseline. No differences were seen in characteristics of the Hib cases during the shortage compared with prior cases in either the mean age (10.9 months during the shortage vs. 13.7 months before the shortage) or percentage of unvaccinated cases or under-vaccinated cases (66% vs. 54%), said Dr. Jackson of the CDC's meningitis and vaccine preventable diseases branch.

Another Hib vaccine, GlaxoSmithKline's Hiberix, is forthcoming. The company submitted a biologic license application for Hiberix with the proposed indication as a booster dose at 15 months to less than 5 years of age for the prevention of invasive disease. Data submitted to the Food and Drug Administration come from seven studies (including six that assess immunogenicity) with "core" data involving a total of 1,008 subjects, and two studies with a total of 1,396 subjects providing "supportive" data, GSK's Dr. Remon Abu-Elyazeed said at the meeting.

Those studies show that a booster dose of Hiberix provides immune responses in children who were previously primed with Hib vaccine, and is immunogenic when coadministered with other pediatric vaccines, said Dr. Abu-Elyazeed, head of GSK's pediatric vaccines division.

Denise Fulton contributed to this report.