CDC Says to Defer Most Hib Vaccine Boosters

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The Centers for Disease Control and Prevention has recommended that providers temporarily defer administration of the routine *Haemophilus influenzae* type b (Hib) vaccine booster dose at age 12-15 months except to children in specific groups at high risk.

These groups include children with asplenia, sickle cell disease, HIV infection and certain other immunodeficiency syndromes, and malignant neoplasms.

American Indian/Alaska Native children also are at special risk and should continue to receive the booster (MMWR Dispatch 2007;56:1-2).

The CDC made its decision in consultation with its Advisory Committee on Immunization Practices, the American Academy of Family Physicians, and the American Academy of Pediatrics.

Merck & Company announced a voluntary recall last month of 13 lots of Hib vaccine because of potential contamination at its Pennsylvania manufacturing plant.

Those lots include about 1 million doses of vaccine distributed beginning in April 2007 that are currently in doctors' offices.

In routine testing, the company identified the potential for microorganisms to survive a sterilization step during the manufacturing process.

No actual contamination has been found, and the Centers for Disease Control and Prevention and the Food and Drug Administration have seen no evidence of any adverse events.

The most likely type of adverse event would involve bumps or abscesses at the injection site appearing about 1 week following the immunization.

"This is not an immediate health threat," Dr. Julie L. Gerberding, CDC director, said at a news conference.

"But we do need to do everything we can to restore effective vaccine coverage in the long run, because children are at risk for *Haemophilus influenzae* disease if we don't solve this problem over the next several months," she said.

Two vaccine products are affected. Merck is recalling 11 lots of PedvaxHIB and 2 lots of COMVAX. COMVAX combines the Hib vaccine with a vaccine for hepatitis B.

The lot numbers that are being recalled can be located at www.cdc.gov/vaccines/recs/recalls/hib-recall-faqs-12-12-07.htm.

Dr. Gerberding emphasized that the potency of the vaccine in the recalled lots was unaffected, so children who already have received doses from those lots will not need to be reimmunized.

Merck supplies about 50% of the 14 million doses of Hib vaccine used annually in the United States, with Sanofi Aventis providing the other 50%.

It's unknown how soon Merck will be able to resume full production, but Dr. Anne Schuchat, director of the CDC National Center for Immunization and Respiratory Diseases, said that she anticipates supply problems.

"This is not a health threat, but it's certainly an inconvenience," Dr. Schuchat said.

"It certainly poses some challenges for parents and for doctors. We are working closely together with Merck and with Sanofi. …We're also working closely with public health and providers to decrease the interruptions in practice that might occur because of this recall."

Prior to the introduction of the vaccine, there were 20,000 cases of *H. influenzae* disease in the United States annually, 1,000 of which ended in death. In recent years, however, there have been fewer than 100 documented cases annually.

"I think we have a nice cushion of protection in this country, because 94% of toddlers are up to date on their Hib vaccine, and there's very little of this bacteria spreading around in our community," Dr. Schuchat said.

The CDC and the FDA have initiated discussions with Sanofi-Aventis to determine whether that company might be able to increase its supply of vaccine.

The CDC maintains a stockpile of approximately 750,000 doses of Pediavax-HIB, and will be releasing some of those doses, but this will not fully address the shortage.

The CDC will be releasing these stockpiled doses to the private sector through Merck and to the public sector through the Vaccines for Children (VFC) program. ■