



Charlie Crist
Governor

Ana M. Viamonte Ros, M.D., M.P.H.
State Surgeon General

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Dear Vaccines for Children (VFC) Program Participants:

The Centers for Disease Control and Prevention (CDC) Health Advisory Regarding *Haemophilus influenzae* Type b (Hib) Disease in Young Children and Importance for All Young Children to Receive Three-Dose Primary Series with Available Hib-Containing Vaccine

The Florida Department of Health (DOH), Bureau of Immunization is providing the following information regarding invasive *Haemophilus influenzae* Type b (Hib) disease in young children and the importance for all young children to receive the three-dose primary series with available Hib-containing vaccine. The information was published on March 18, 2009 by the CDC Health Advisory and distributed via the Health Alert Network.

Background of the Hib Vaccine Shortage

A nationwide shortage of Hib vaccine began in December 2007, and is ongoing. The recall of certain lots of the two Hib-containing vaccines produced by *Merck & Co, Inc.*, and cessation of production of both vaccines, has left *Sanofi Pasteur* as the only manufacturer of Hib vaccine in the United States. The shortage resulted in a recommendation by the CDC to temporarily defer the Hib booster dose (routinely recommended in children 12 to 15 months of age) for children who are not at high risk of Hib infection until supplies are restored. This recommendation is still in effect.

Potential Increase in Cases of Hib Disease

Temporary deferral of the booster dose in children 12 to 15 months of age for non-high-risk children may have resulted in increased Hib carriage and transmission in non-symptomatic children. There is potential to see increases in cases of Hib disease at the local level. During 2008 in Minnesota, five children, aged five months through three years, were reported with invasive Hib disease; one died. Three of the children had received no vaccinations because of parent or guardian deferral or refusal. One child was five months of age and had received two doses of Hib PRP-OMP vaccine, but no booster dose, per CDC recommendations during the shortage. Subsequent to Hib infection, this child was diagnosed with hypogammaglobulinemia. The five cases reported in 2008 were the most reported for one year from Minnesota since 1992, when 10 cases were reported.

Importance for All Young Children to Receive Three-Dose Primary Series

There is enough Hib-containing vaccine for all children in the United States to receive the primary series. All children should complete the primary series by seven months of age; high-risk children should continue to receive the full primary series and the booster dose.

Completion of the primary series with currently available vaccine products (manufactured by *Sanofi Pasteur*) requires a total of three doses of Hib-containing vaccine at two, four, and six months of age. Although there is enough Hib-containing vaccine nationally to support these recommendations, there may be times when practitioners do not have an adequate supply to meet local demand. If Hib vaccine is not available in the office at the time of the visit, children who are unable to receive one of the primary series doses should be tracked and recalled to schedule an appointment to receive their dose as soon as vaccine becomes available in the office.

Some challenges in using the currently available Hib-containing vaccines have included provider reluctance to switch inventory and schedules, misunderstanding regarding what constitutes primary versus booster doses, determining a catch-up schedule in the setting of the deferred booster, challenges associated with switching from *Merck & Co.* to *Sanofi Pasteur* products, and provider and parent concerns about over-vaccination resulting from switching to the *Sanofi Pasteur* Hib-containing vaccines.

There are indications that these challenges have led to lower completion of the primary series. Preliminary information from sentinel information systems (registries) in select states have indicated up to 10% lower coverage with the third Hib dose in the primary series compared to other vaccines (DTaP, PCV7) commonly administered at the same visit.

Despite these challenges, healthcare providers need to ensure that all children are appropriately vaccinated with the primary series. For example, if Pentacel® (DTaP-IPV/Hib) is the only Hib-containing vaccine available, this combination product should be used to complete the primary series, even if doing so results in receipt of additional doses of other antigens (e.g., DTaP, IPV). The Hib-containing vaccine products that are available may not be what providers used previously in their practice; however, the potential for increased transmission of Hib disease makes it more important than ever that every child is adequately protected.

Recommendations

The following non-high-risk children should be scheduled to receive the primary series of Hib-containing vaccine:

- If the child is at least six weeks of age, but less than 12 months of age, and has received zero, one, or two doses of Hib-containing vaccine, schedule the child for the first or next dose(s) immediately within a minimum of four weeks between the doses. These children will need one booster dose when the Hib vaccine shortage is over.
- If the child is between 12 and 14 months of age, and has not had any doses of Hib-containing vaccine, schedule appointments for two doses, eight weeks apart.
- If the child is between 12 and 14 months of age, and has received Hib-containing vaccine, but did not complete the primary series before turning one year of age (i.e., had one dose of the *Merck & Co.* product or one to two doses of the *Sanofi Pasteur*

product), schedule an appointment for one additional dose, a minimum of eight weeks apart.

- If the child is at least 15 months of age, but less than five years of age, and has not received any doses of Hib-containing vaccine, or has not completed the primary series (i.e., had one dose of the *Merck & Co.* product or one to two doses of the *Sanofi Pasteur* product), schedule an appointment for one dose.
- If the child is five years of age or older, and has not received any Hib-containing vaccine, Hib vaccine is not necessary.

Certain children are at increased risk for Hib disease, including children with asplenia, sickle cell disease, human immunodeficiency virus infection and other certain immunodeficiency syndromes, and malignant neoplasms. The CDC recommends that providers continue to vaccinate these children with available Hib conjugate vaccines according to routinely recommended schedules, including the booster dose at 12 to 15 months of age. Providers who serve predominately American Indian/Alaskan Native (AI/AN) children living in AI/AN communities should continue to stock and use PRP-OMP-containing Hib vaccines (*Merck & Co.* product) and vaccinate according to the routinely recommended schedule, which includes the two-dose primary series (two and four months of age) and a booster dose at 12 to 15 months of age. This product is available to providers from the VFC Pediatric Vaccine Stockpile, through their state immunization programs.

The bureau asks that you provide this information to colleagues, members, coalitions, and partners with an interest in the provision of Hib-containing vaccine. If you have any questions regarding the use of Hib-containing vaccines, please contact Phyllis Yambor, R.N., Bureau of Immunization, at (850) 245-4342. Please contact Robert Griffin, VFC Program Coordinator, at (800) 483-2543, if you have any questions regarding the VFC Program's vaccine supply.

Sincerely,

Signature on file

Charles H. Alexander, Chief
Bureau of Immunization
Division of Disease Control
Florida Department of Health

CHA/rg/sdh

cc: Phyllis Yambor, R.N., Executive Community Health Nursing Director,
Bureau of Immunization
Robert Griffin, VFC Program Coordinator
Bureau of Immunization
Bureau of Immunization Field Staff