

Health Advisory:

Invasive *Haemophilus influenzae* Type B Disease in Young Children and Importance for All Young Children to Receive the 3 Dose Primary Series with Available Hib-containing Vaccine

March 25, 2009

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Health Alerts convey information of the highest level of importance which warrants immediate action or attention from Missouri health providers, emergency responders, public health agencies, and/or the public.

Health Advisories provide important information for a specific incident or situation, including that impacting neighboring states; may not require immediate action.

Health Guidances contain comprehensive information pertaining to a particular disease or condition, and include recommendations, guidelines, etc. endorsed by DHSS.

Health Updates provide new or updated information on an incident or situation; can also provide information to update a previously sent Health Alert, Health Advisory, or Health Guidance; unlikely to require immediate action.

Health Advisory
March 25, 2009

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DIRECTOR

SUBJECT: Invasive *Haemophilus influenzae* Type B Disease in Young Children and Importance for All Young Children to Receive the 3 Dose Primary Series with Available Hib-containing Vaccine

In an effort to minimize invasive Hib (*Haemophilus influenzae* type b) disease during the current Hib vaccine shortage, health care providers must be vigilant about ensuring that all young children are appropriately vaccinated with the 3 dose primary series of Hib vaccine.

A nationwide shortage of Hib vaccine began in December 2007, and is ongoing. The shortage resulted in a recommendation by the Centers for Disease Control and Prevention (CDC) to temporarily defer the Hib vaccine booster dose (routinely recommended at 12 through 15 months) for children who are NOT at high risk of Hib infection, until supplies are restored. This recommendation is still in effect. There are indications that the challenge associated with the temporary deferral of the booster dose has led to lower completion rates of the primary Hib series.

In addition, temporary deferral of the booster dose at 12 through 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 5 months through 3 years were reported with invasive Hib disease (the highest number since 1992); one of the children died. Three of the five children had received no vaccinations because of parent or guardian deferral or refusal. The fourth child, aged 5 months, had received 2 doses of vaccine in accordance with the primary series schedule. The fifth child had a high risk condition but did not receive the recommended booster dose.

There is enough available Hib-containing vaccine for all U.S. children to receive the three dose primary series. All children should complete the primary series by 7 months of age; high risk children should continue to receive the full primary series and the booster dose.

The potential for an increase in the incidence of invasive Hib disease also serves as a reminder of the importance of reporting all persons with known or suspected *Haemophilus influenzae* invasive disease, and obtaining laboratory confirmation that the causative organism is Hib. Known or suspected cases of *Haemophilus influenzae* invasive disease should be reported to your local public health agency, or to the Missouri Department of Health and Senior Services (DHSS): during business hours at 573-751-6113, after hours and on weekends at 800-392-0272, or by fax at 573-526-0235. *Haemophilus influenzae* isolates cultured from normally sterile sites (e.g., blood, cerebrospinal fluid) should be submitted to the Missouri State Public Health Laboratory for confirmatory testing and serotype identification.

Additional information on the issues regarding Hib vaccine is contained in a Health Advisory issued by CDC on March 18, 2009. This document is reproduced below, starting on the following page.

Questions should be directed to DHSS' Bureau of Immunization Assessment and Assurance at (573) 751-6124 or (800) 219-3224.

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Invasive *Haemophilus influenzae* Type B Disease in Young Children and Importance for All Young Children to Receive 3 Dose Primary Series with Available Hib-containing Vaccine

Centers for Disease Control and Prevention (CDC)

March 18, 2009

<http://www2a.cdc.gov/HAN/ArchiveSys/ViewMsgV.asp?AlertNum=00281>

Background of the Hib Vaccine Shortage

Health care providers must be vigilant about ensuring that all young children are appropriately vaccinated with the 3 dose primary series of Hib (*Haemophilus influenzae* type b) vaccine. 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 only one manufacturer of Hib vaccine in the United States (sanofi pasteur). The shortage resulted in a recommendation by CDC to defer the Hib booster (routinely recommended at 12 through 15 months) for children who are NOT at high risk of Hib infection temporarily, until supplies are restored. This recommendation is still in effect.

Temporary deferral of the booster dose at 12 through 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 5 months through 3 years were reported with invasive Hib disease; one died. Three patients had received no vaccinations because of parent or guardian deferral or refusal. One child was aged 5 months and had received 2 doses of Hib PRP-TT vaccine in accordance with the primary series schedule. Another child had received 2 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 in 2008 were the most reported for 1 year from Minnesota since 1992, when 10 cases were reported.

There is enough Hib-containing vaccine for all U.S. children to receive the primary series. All children should complete the primary series by 7 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 3 doses of Hib-containing vaccine (2, 4, and 6 months). Although there is enough Hib-containing vaccine nationally to support these recommendations, there may be times when practitioners do not have an adequate supply of vaccine to meet local demand. If Hib vaccine is not available in the office at the time of a 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.

In addition, using available Hib-containing vaccines has presented challenges associated with switching from the Merck to sanofi products for some providers.

There are indications that these challenges have led to lower completion of the primary series. Preliminary information comes from sentinel immunization information systems (registries) in select states, which 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. In the scenario of booster dose deferral, it is even more important that all infants receive the complete primary series.

Specifically, some of the 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, and provider and parent concerns about over vaccination resulting from switching to the sanofi pasteur Hib-containing vaccine. Despite these challenges, health care 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 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 vaccine as outlined below:

- If the child is at least 6 weeks but less than 12 months of age and has received zero, one, or two doses of Hib vaccine, schedule him/her for the first or next dose(s) immediately with 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 vaccine, schedule appointments for two doses, eight weeks apart.
- If the child is between 12 and 14 months of age and has received Hib vaccine but did not complete the primary series before they turned 1 year old (i.e., had 1 dose of the Merck product OR 1-2 doses of the sanofi product), schedule an appointment for 1 additional dose, a minimum of eight weeks from the last dose.
- If the child is at least 15 months of age but less than 5 years of age and has not received any doses of Hib vaccine OR has not completed the primary series (i.e., had 1 dose of the Merck product OR 1-2 doses of the sanofi product), schedule an appointment for one dose.
- If the child is 5 years old or older and hasn't received any Hib 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 certain other immunodeficiency syndromes, and malignant neoplasms. CDC recommends that providers continue to vaccinate these children with available Hib conjugate vaccines according to the routinely recommended schedules, including the 12 through 15 month booster dose. Providers who serve predominantly American Indian/Alaska Native (AI/AN) children living in AI/AN communities should continue to stock and use PRP-OMP– containing Hib vaccines (Merck product) and vaccinate according to the routinely recommended schedule, which includes the 2-dose primary series (ages 2 and 4 months) and a 12 through 15 month booster dose. This product is available from the VFC Pediatric Vaccine Stockpile, through their state immunization programs.

For more information about Hib disease and vaccination contact your state or local public health official or CDC at 1-800-232-4636/1-800-CDC-INFO or by email at www.cdc.gov/vaccines/about/contact/nipinfo_contact_form.htm. Information about current vaccine shortages and delays can be found at <http://www.cdc.gov/vaccines/vac-gen/shortages/default.htm>.

Additional Sources of Information

CDC. Invasive *Haemophilus influenzae* Type B Disease in Five Young Children – Minnesota, 2008. *MMWR* 2009;58(3):58-60.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5803a4.htm>

CDC. Continued shortage of *Haemophilus influenzae* Type B (Hib) Conjugate Vaccines and Potential Implications for Hib Surveillance – United States, 2008. *MMWR* 2008;57(46):1252-1255.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5746a2.htm>

CDC. Interim recommendations for the Use of *Haemophilus influenzae* Type B (Hib) Conjugate Vaccines Related to the Recall of Certain Lots of Hib-containing Vaccines (PedvaxHIB and Comvax). *MMWR* 2007; 56(50):1318-1320.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5650a4.htm>