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Updated Recommendations for Use of Haemophilus influenzae Type b (Hib) Vaccine: Reinstatement of the Booster Dose at Ages 12--15 Months

On December 13, 2007, certain lots of *Haemophilus influenzae* type b (Hib) vaccine marketed as PedvaxHIB (monovalent Hib vaccine) and Comvax (Hib-HepB vaccine), and manufactured by Merck & Co., Inc., were recalled voluntarily, and the company temporarily suspended production of these vaccines. To conserve the limited supply of Hib-containing vaccines, CDC, in consultation with the Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), and the American Academy of Pediatrics (AAP), on December 18, 2007, recommended that vaccination providers temporarily defer the routine Hib vaccine booster dose administered to most healthy children at age 12--15 months (*1*--*5*).

Production of Merck Hib vaccine products is still suspended. However, two other Hib-containing vaccines manufactured by Sanofi Pasteur have been available for use in the United States during this shortage: monovalent Hib vaccine (ActHIB) and DTaP-IPV/Hib (Pentacel). Beginning in July 2009, the manufacturer of these two vaccines will increase the number of doses of these two products available for use in the United States, which will result in the supply being sufficient to reinstate the Hib vaccine booster dose.

Reinstatement of Hib Booster Dose

Effective immediately, CDC, in consultation with ACIP, AAFP, and AAP, is recommending reinstatement of the booster dose of Hib vaccine for children aged 12--15 months who have completed the primary 3-dose series. Infants should continue to receive the primary Hib vaccine series at ages 2, 4, and 6 months. Children aged 12--15 months should receive the booster dose on time. Older children for whom the booster dose was deferred should receive their Hib booster dose at the next routinely scheduled visit or medical encounter. Although supply is sufficient to reinstate the booster dose and begin catch-up vaccination, supply is not yet ample enough to support a mass notification process to contact all children with deferred Hib booster doses.

Sufficient vaccine will be available to administer the primary series at ages 2, 4, and 6 months and a booster dose on time to children aged 12--15 months. As part of delivering the booster dose to those children for whom it was deferred at the next routinely scheduled appointment or medical encounter, practices should discuss with parents the reasons for the change in recommendation and might consider 1) reviewing electronic or paper medical records or immunization information system records to identify children in need of a booster dose before physician encounters, 2) evaluating children's vaccination status during their scheduled visit, and 3) sharing immunization schedules with parents to make them aware of this plan.

Use of Combination Vaccines

During the Hib shortage, children received protection from certain vaccine preventable diseases in their primary vaccination series through various permutations of available combination vaccines (e.g., DTaP-IPV/Hib [Pentacel] and DTaP-IPV-HepB [Pediarix]) and monovalent vaccines (e.g., ActHib, HepB, and IPV). Therefore, a mismatch might exist between patient vaccination needs and the available stock of different vaccine formulations (e.g., combination products versus single-antigen vaccines) in local provider offices. This situation presents a challenge for providers to administer vaccines to ensure appropriate coverage while minimizing extra doses of unneeded vaccine. For example, if a provider is using DTaP-IPV/Hib (Pentacel) vaccine to protect infants against Hib disease, the provider should ensure that adequate stock of monovalent HepB vaccine is available to complete the HepB vaccine series.* Children who need the Hib booster and who already have received 4 doses of DTaP should receive monovalent Hib vaccine (ActHIB) as their Hib booster dose. However, if DTaP-IPV/Hib is the only Hib-containing vaccine available, this combination product can be used to complete the series of Hib vaccination, even if the child already has received all the necessary doses of DTaP and IPV.

Information Regarding ActHIB or Pentacel

Vaccination providers with questions about their supplies of monovalent Hib vaccine (ActHIB) or DTaP-IPV/Hib (Pentacel) purchased with nonpublic funds should contact Sanofi Pasteur's customer service department (telephone, 800-822-2463). Sanofi Pasteur will work directly with physicians to increase allotments of Hib-containing vaccines on the basis of previous purchasing patterns or practice birth cohort and estimates of additional vaccine doses needed. For public vaccine supplies, including Vaccines for Children Program vaccine, providers should contact their state/local immunization program to obtain vaccine.

This recommendation reflects CDC's assessment of the existing national Hib vaccine supply and will be updated if the supply changes. Updated information about the national Hib vaccine supply is available at http://www.cdc.gov/vaccines/vac-gen/shortages/default.htm.

Details about the routine Hib schedule are available at http://www.cdc.gov/vaccines/recs/schedules/default.htm#child. Adverse events following receipt of any vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS) at http://vaers.hhs.gov.

References

1. 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;56:1318--20.
2. CDC. Continued shortage of *Haemophilus influenzae* type b (Hib) conjugate vaccines and potential implications for Hib surveillance---United States, 2008. MMWR 2008;57:1252--5.
3. American Academy of Pediatrics. *Haemophilus influenzae* infections. In: Pickering LK, Baker CJ, Kimberlin CW, Long SS, eds. Red book: 2009 report of the Committee on Infectious Diseases. 28th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2009:314--21.
4. CDC. Invasive *Haemophilus influenzae* type b disease in five young children---Minnesota, 2008. MMWR 2009;58:58--60.
5. CDC health advisory. 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. Available at http://www2a.cdc.gov/han/archivesys/viewmsgv.asp?alertnum=00281.

* Additional information available at http://www.cdc.gov/vaccines/vac-gen/shortages/downloads/eo-hib-hepb-cov.pdf.

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