



Oklahoma State
Department of Health

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DISEASE and PREVENTION SERVICES
IMMUNIZATION SERVICE

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Single Antigen Hib Vaccine Supply Not Adequate Pentacel® Must Be Used for the Primary Series of Hib Vaccine

Merck, Inc. has announced that they have recently identified the need for an additional manufacturing change that will delay the return of their Hib-containing vaccines PedvaxHIB® and Comvax® (HepB/Hib combined) to the U.S. market. Merck does not expect to be able to provide PedvaxHIB or Comvax until mid-2009.

This means that Sanofi Pasteur remains the only Hib producer and their ActHIB® supplies are decreasing while their Pentacel® (DTaP-IPV/Hib combined vaccine) supplies are increasing. Until the single antigen Hib vaccine shortage is resolved, vaccine providers must use Pentacel even if they are not enthusiastic about it. Choice of Hib vaccine product is not an option at this time.

Clinicians may refer to the *OK BY ONE Schedule During the Hib Vaccine Shortage* for help in incorporating Pentacel into the childhood immunization schedule. This schedule and others may be found on the Immunization Service webpage at <http://imm.health.ok.gov>.

Pentacel vaccine must be used as intended. Removing the ActHIB vaccine from Pentacel and administering it separately is not an acceptable practice. The ActHIB component should be reconstituted with the DTaP/IPV portion and the entire vaccine administered as it is packaged. Pentacel was not licensed for use with any other diluent.

The recommendation to **defer the booster dose** of Hib vaccine has not changed. Vaccine providers should temporarily defer the routine Hib booster dose given at 12-15 months of age **except for specific high-risk groups**, who should continue to receive the full series and the booster dose. Children at high-risk from Hib disease include: children with sickle cell disease, asplenia, leukemia, malignant neoplasms, HIV

infection and certain other immunocompromising conditions, and American Indian and Alaska Native children.

American Indian and Alaska Native children should continue to receive PedvaxHIB, which is available from the Centers for Disease Control and Prevention (CDC) stockpile; 2 primary doses are advised at 2 and 4 months of age and a booster dose at 12-15 months of age. Other children at high-risk may receive PedvaxHIB or ActHIB. **All other children should receive the full primary series of 3 doses of ActHIB/Pentacel at 2, 4, and 6 months of age.**

Infants who have not received the full primary series of 3 doses of ActHIB, or 2 doses of PedvaxHIB during the first 12 months of life will be at greatest risk of infection and serious disease if prevalence of Hib increases in the population during this time of vaccine shortage. Data from Hib vaccine clinical trials showed that a reduced primary series will not accomplish adequate protection from *H. influenzae* type B infection through the at-risk period. Because the booster dose is further needed to reduce carriage of the bacterium, the accumulation of toddlers without this protection from carriage means there is increased potential for resurgence of Hib transmission and disease.

The United Kingdom experience illustrates the importance of the booster dose in reducing carriage. Hib vaccination in the UK started with the primary series only. Unlike the U.S., they had continued transmission of Hib, which prompted them to institute a booster dose, after which their rates of invasive Hib disease declined. Because we currently do not have enough vaccine for a booster dose, we must protect infants with the primary series. Fortunately we have not seen an increase in invasive Hib disease in the U.S.

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