

Hib Return to Booster Q & A – for Providers

1. Is there any guidance about completing the HepB vaccine series in settings where Pentacel (DTaP-IPV-Hib) is being used for the Hib series?
 - A. Providers who are using Pentacel for the Hib series should use monovalent HepB vaccine to complete the HepB vaccine series. This will minimize extra-immunization. Providers will need to plan ahead to ensure they have adequate doses of HepB vaccine on hand. For more guidance about completing the HepB vaccine series, taking into account the mother's hepatitis B surface antigen status (HBsAg) and vaccine availability, please refer to <http://www.cdc.gov/vaccines/vac-gen/shortages/downloads/eo-hib-hepb-cov.pdf>.

2. What are the different Hib vaccine products currently available and for what ages are they recommended for use?
 - A. Hib vaccines products that are available include sanofi's monovalent Hib vaccine (ActHib) and the combination product DTaP-IPV/Hib (Pentacel). These two products are recommended for ages 2 months, 4 months, 6 months, and 12-15 months.

Note that for providers who serve predominantly American Indian/Alaska Native (AI/AN) children living in AI/AN communities, the Merck monovalent Hib vaccine, PedvaxHib, has been available through the states' immunization programs from the VFC Pediatric Vaccine Stockpile. These providers should continue to stock and use PRP-OMP – containing Hib vaccines (PedvaxHib and Comvax) and vaccinate according to the routinely recommended schedule.

3. Can the Hib “booster” dose refer to either the third or the fourth dose of Hib-containing vaccine?
 - A. Yes. If for a given child a provider has used a sanofi product (either monovalent ActHib or combination vaccine Pentacel) for any of the doses in the series at the recommended ages, a total of 4 doses is needed (3 primary doses in the first year of life and 1 booster dose in the second year of life) If for a given child the provider has restricted use to Merck's monovalent Hib product (PedvaxHib) or the combination product HepB-Hib (Comvax) for age appropriate doses, the total number of doses in this series is three (2 primary doses and 1 booster dose). If a child has fallen behind in the series of Hib vaccine, fewer doses are required to complete the series regardless of the previous brand used. See Table 1 catch up at:

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5751a5.htm?s_cid=mm5751a5_e

4. What is the current recommendation for children at increased risk for Hib disease, and has this recommendation changed?
 - A. There has been no change in the recommendation for children at increased risk for Hib disease. Throughout the shortage—during which deferral of the booster dose was recommended for most children, those children at increased risk for Hib disease have specifically been recommended to continue to receive the complete series of Hib vaccine (including the primary series and booster). Children at increased risk for Hib disease include those with asplenia, sickle cell disease, and human immunodeficiency virus infection and certain other immunodeficiency syndromes, and malignant neoplasms. In addition, some groups at particular risk of invasive Hib disease (i.e., American Indians/Alaska Natives) have been recommended to receive remaining doses of Merck’s Hib vaccine, which is available from the VFC Pediatric Vaccine Stockpile. This recommendation has not changed.

5. Is it anticipated that supplies of Hib-containing vaccine will be sufficient in the near future to allow for active recall of children for whom the booster dose was deferred?
 - A. CDC does not recommend active recall for children for whom the booster dose was deferred until supplies of Hib vaccine improve. CDC recommends that children older than age 15 months for whom the booster dose was deferred receive the booster dose when they are next seen in the office for a routinely scheduled or sick visit. If additional Hib-containing vaccine becomes available to support active recall, CDC will communicate this information broadly with partners and providers.

6. If a Hib-containing combination vaccine is the only product available to a practice to bring a child up-to-date for Hib, but the child is already up-to-date for the other vaccines in the combination, is it safe to administer the combination vaccine?
 - A. Providers should plan ahead so that adequate supplies of the appropriate products are available at the time of the child’s visit and that extra-immunization is minimized. However, if Pentacel (that is, the sanofi combination product DTaP-IPV/Hib) is the only Hib-containing vaccine available, this product should be used to complete the Hib vaccination series, even if the child has already received all the necessary doses of DTaP and IPV. Studies suggest that extra DTaP can lead to an increase in local reactogenicity (e.g., sore arm).

Hib Return to Booster Q & A - for Parents:

1. What are a “primary vaccination” and a “booster dose”?

A. For most vaccines, more than one dose is needed for full protection. Each of the first doses, called “primary vaccination” or “the primary series” provides some protection. They also “prime” or prepare the immune system to develop stronger and stronger immunity as each dose of vaccine is received. The final dose, given several months after the primary series is called the “booster” because it is needed to boost protection to a high, long-lasting level.

For Hib, depending on which brand of vaccine your doctor uses, the primary doses are given at 2 and 4 months of age or at 2, 4 and 6 months of age. For Hib vaccine, by age 12 through 15 months, it's time for a booster dose.

2. I heard about some Hib cases that were very serious. So why is it OK to wait until the next time I take my baby/child in for some other reason to get the Hib booster? Shouldn't I make an appointment right away?

A. Even though supplies are increasing, there's still not enough vaccine right now for every child who needs a booster dose. If your child already received the "primary series" of Hib vaccine as an infant, then he/she already has a level of protection, but this level could fade over time. The booster dose is needed to make sure that your child has the highest possible level of protection.

3. Why was there a shortage of Hib vaccine and why is the shortage getting better?

A. The shortage occurred because one of the two manufacturers temporarily could not make Hib vaccine. This left only one manufacturer of the vaccine. This one manufacturer is now making more Hib vaccine, allowing children to receive the booster dose at 12 through 15 months of age.

4. Is the Hib vaccine safe?

A. Yes. The Hib vaccine used today is technically known as Hib conjugate vaccine, and it is a very safe vaccine, as are all vaccines recommended to be given to children in this country. To make sure that vaccines are safe, they first need to be licensed by the FDA. The FDA only licenses vaccines after studies show that they are safe. After vaccines are licensed, FDA and CDC monitor their use, including any reports of side effect. Hib conjugate vaccines have been used extensively in this country and around the world for more than 10 years, and during this time, the vaccine has proven to be

as safe as the first testing indicated that it would be. The vaccine has been given to millions of children.

Reactions following Hib conjugate vaccines are uncommon. Local swelling, redness, or pain at the site of injection have been reported in 5%-30% of children receiving Hib vaccine. Serious adverse reactions are extremely rare.

5. What is Hib disease?

A. Hib disease is a serious infection caused by a bacteria (*Haemophilus influenzae* type b). Before Hib vaccine, Hib disease was the leading cause of bacterial meningitis among children under 5 years old. Meningitis is an infection of the brain and spinal cord coverings which can lead to lasting brain damage and deafness. Hib disease can also cause pneumonia, severe swelling of the throat, infection of the blood, joints, bones, and covering of the heart, and can lead to death. Hib vaccine can prevent Hib disease.