



From the Texas Department of State Health Services Immunization Branch

The goal of the Vaccine Advisory is to disseminate, in a timely manner, practical information related to vaccines, vaccine-preventable diseases, and the vaccine programs managed by the Immunization Branch. The Immunization Branch welcomes readers' input to improve the contents of this document.

To view past issues, go to: www.dshs.state.tx.us/immunize/vacadvise/

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Licensure of a New *Haemophilus Influenzae* Type b (Hib) Vaccine (Hiberix[®]) and Updated Recommendations for Use of Hib Vaccine

On August 19, 2009 a new Hib (*Haemophilus Influenzae* type b) vaccine produced by GlaxoSmithKline, Hiberix[®], was licensed for use as a booster dose in children 15 months through 4 years of age.

This advisory summarizes the indications for Hiberix[®] use and provides guidance from the CDC's Advisory Committee on Immunization Practices (ACIP) on Hib booster dose administration based on increasing vaccine supplies.

This advisory contains:

1. Background information
2. Summary of ACIP's recommendations for use of Hiberix[®] vaccine, and updated recommendations for use of Hib vaccine
3. Texas Vaccines for Children program
4. ImmTrac
5. Texas school and child-care facilities requirements for Hib vaccine
6. Epidemiology and surveillance
7. Reporting vaccine adverse events
8. Resources

1) Background

A nationwide shortage of Hib vaccine started in 2007 when Merck & Co. recalled some lots of Hib vaccine and later suspended production of its Hib-containing vaccine products.

This shortage resulted in a recommendation by CDC to temporarily defer the Hib vaccine booster dose, usually administered at age 12 to 15 months, until supplies could be restored.

This deferral was in effect from December 18, 2007 through June 25, 2009.

Since then, two new Hib vaccine products have been approved: Pentacel[®] for either the primary series in infancy or the booster dose and Hiberix[®], which is only approved for the booster dose up to age 4.

The vaccine supply is now sufficient to reinstate the Hib booster dose and CDC recommends providers begin recalling children in need of the booster dose.

2) Summary of ACIP recommendations

The ACIP recommends Hib booster vaccination for children at age 12 through 15 months; however, because of the recent shortage of Hib vaccines, many children have deferred the booster dose and therefore require catch-up vaccination.

Vaccination recommendations in this report update the previous advisory on Hib booster administration (June 26, 2009) (1), which advised that children with deferred booster doses receive it at the next regularly scheduled visit. Vaccination providers are now recommended to begin recall of children in need of the booster dose when feasible and monovalent Hib vaccine supply in the office is adequate.

The following summary provides ACIP's updated recommendations for Hib booster vaccination and indications for Hiberix[®] use. The complete recommendations can be found at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5836a5.htm>.

- ACIP recommends Hib booster vaccination for children at age 12 through 15 months.
- Hiberix[®] is approved as a booster dose for children 15 months through 4 years of age (prior to fifth birthday) who have received a primary Hib vaccination series of 2 or 3 doses (depending on the formulation of the primary series vaccine).
- Hiberix[®] and other Hib conjugate vaccines can be administered as early as age 12 months for routine and catch-up immunization.
- Hiberix[®] is not licensed for the primary Hib vaccination series.
- Children 12 months through 4 years of age who did not receive a booster dose because of the recent shortage of Hib vaccines should receive a booster dose with any of the available hib-containing vaccines at the earliest opportunity.
- When feasible and when vaccine supply in the office is sufficient, vaccination providers should review medical records to identify and recall children in need of a booster dose.
- If supplies are not adequate, providers should continue to follow previous recommendations to provide the booster dose at the child's next regularly scheduled visit.

3) Texas Vaccines for Children program

On October 1, 2009, the TVFC program added Hiberix[®] to the program for TVFC eligible children. Hiberix[®] should be recorded as Hib on the Monthly Biological Report (EC-33).

Hiberix[®] is supplied in vials containing a sterile, lyophilized powder. The vials will be packaged separately from the prefilled diluent syringes used to reconstitute the vaccine. A video on reconstitution is available at <http://www.hiberix.com/packaging-dosage-administration.html>. For documentation purposes, providers should record the lot number from the vial containing the vaccine (not the diluent). Complete prescribing information for Hiberix[®] is available at http://us.gsk.com/products/assets/us_hiberix.pdf.

For other questions or information, please contact your health service region, or TVFC consultant.

4) ImmTrac

ImmTrac users can record the administration of Hiberix[®] vaccine using the ImmTrac short description “Hib, PRP-T or CPT Code 90648.” The ImmTrac immunization scheduler will generate recommendations for the next Hib vaccine, but will not specifically recommend it as being the “booster” (final) dose in the Hib series. Providers should review the child’s vaccination history and consult ACIP recommendations to determine if administration of Hiberix[®] vaccine is appropriate.

For more information about ImmTrac, please visit www.ImmTrac.com.

5) Texas school and child-care facilities requirement for Hib vaccine

The immunization requirement for school and child-care facilities remains the same.

The current requirement for Hib vaccine consists of a primary series of two doses at 2 and 4 months of age or three doses at age 2, 4, and 6 months (depending on the vaccine formulation) and a booster dose at age 12-15 months.

In January of 2008, the Texas Department of State Health Services (DSHS) sent a letter to schools and child-care facilities indicating that due to the Hib shortage, compliance with the routine Hib vaccine booster would not be enforced. Although Hib vaccine supply has improved, until DSHS gives further guidance, compliance with the Hib vaccine booster will continue to be waived.

6) Epidemiology and surveillance

Before the availability of Hib vaccines, Hib disease was the leading cause of bacterial meningitis among children under 5 years old in the United States. Meningitis is an infection of the tissue covering the brain and spinal cord, which can lead to lasting brain damage and deafness. Hib disease can also cause pneumonia, severe swelling in the throat, infections of the blood, joints, bones, and tissue covering of the heart, as well as death. Hib disease is spread through the air by coughing and sneezing.

Prior to the introduction of a Hib vaccine, approximately 20,000 cases of Hib disease occurred each year in the United States. Hib meningitis is fatal in one of 20 children and can cause permanent brain damage in 10-30% of survivors. Since the introduction of Hib vaccine, the incidence of invasive Hib has decreased over 99%. Hib disease is age-dependent and it is very uncommon in people over 5 years old. In the pre-vaccine era, children between the ages of 6 and 12 months were the most commonly affected.

Hib is a reportable condition in Texas.

7) Reporting adverse vaccine events

Clinically significant adverse events following vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).

Adverse events from privately purchased vaccine may be reported directly to VAERS at <http://vaers.hhs.gov/>. Secure web-based reporting is available on the VAERS website. Contact 800-822-7967 for forms and information.

In Texas, reports of events following vaccination at public health clinics or with vaccine provided through public funding such as the Texas Vaccines for Children (TVFC) program should be reported through the Texas Department of State Health Services, Immunization Branch (MC 1946), P.O. Box 149347, Austin, TX 78714-9347. The pre-addressed and postage-paid VAERS form with this address can be obtained by calling the Immunization Branch. A copy of the form is also available in the TVFC toolkit. For more information about VAERS, please contact DSHS at 800- 252-9152.

8) Resources

- Hiberix® package insert:
<http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm179530.pdf>
- CDC. Updated recommendations for use of *Haemophilus influenzae* type b (Hib) vaccine: reinstatement of the booster dose at ages 12--15 months:
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5824a5.htm>
- CDC. Recommendations for use of *Haemophilus b* conjugate vaccines and a combined diphtheria, tetanus, pertussis, and *Haemophilus b* vaccine. Recommendations of the Advisory Committee on Immunization Practices (ACIP):
<http://www.cdc.gov/mmwr/preview/mmwrhtml/00023705.htm>
- Provider answers on return to Hib booster:
<http://www.cdc.gov/vaccines/vpd-vac/hib/faqs-return-to-booster-hcp.htm>
- Hib Vaccine Information Statement:
<http://cdc.gov/vaccines/pubs/vis/downloads/vis-hib.pdf>
- The DSHS Addendum to Hib VIS is available at:
<http://www.dshs.state.tx.us/immunize/vis/ec-111.pdf>

We hope you generously forward this advisory to others who may benefit from this information.

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