Immunization Program
Vaccines for Children Program
Haemophilus influenzae type b (Hib) Vaccine Summary
November 2016

Purpose of vaccine summary

- Effective November 14, 2016, Hiberix (*Haemophilus Influenzae* Type b) vaccine, manufactured by GlaxoSmithKline (GSK)is available to order through the Iowa VFC Program.

Haemophilus influenza type b Vaccine Recommendations

Food and Drug Administration (FDA)

- January 14, 2016, the FDA approved expanded use of Hiberix (Haemophilus b Conjugate Vaccine [Tetanus Toxoid Conjugate]) for a 3-dose infant primary vaccination series at ages 2, 4, and 6 months.
- August 19, 2009, the FDA licensed Hiberix conjugate vaccine for use as the booster dose of the Hib vaccine series for children aged 15 months through 4 years who have received previously the primary series of Hib vaccination.

Advisory Committee on Immunization Practices (ACIP)

- Food and Drug Administration Approval for Use of Hiberix as a 3-Dose Primary Haemophilus influenzae Type b (Hib) Vaccination Series; April 29, 2016.
- Prevention and Control of Haemophilus influenzae Type b Disease: Recommendations of the ACIP, 2014; February 28, 2014.

VFC Resolution

The VFC Program follows the ACIP recommendations for the use of *Haemophilus Influenzae* type b (Hib) vaccine for VFC eligible children 6 weeks through 18 years of age.

ACIP Recommended Schedule and Dosage Intervals for Hib Vaccines

The ACIP recommended schedule includes 3 or 4 doses of a Hib-containing vaccine, depending on the specific vaccine, as shown in the table below.

Vaccine Product (Manufacturer)	Trade Name	Components	Primary series	Booster dose
Monovalent vaccines				
PRP-OMP[a,b] (Merck & Co, Inc)	PedvaxHIB	PRP conjugated to OMP	2, 4 months	12 – 15 months
PRP-T (Sanofi Pasteur)	ActHIB	PRP conjugated to tetanus toxoid	2, 4, 6 months	12 – 15 months
PRP-T (GlaxoSmithKline)	Hiberix	PRP conjugated to tetanus toxoid	2, 4, 6 months[d]	12 – 15 months
Combination vaccines				
PRP-OMP-HepB[a,b] (Merck & Co, Inc)	Comvax	PRP-OMP + hepatitis B vaccine	2, 4 months	12 – 15 months
DTaP-IPV/PRP-T (Sanofi Pasteur)	Pentacel	DTaP-IPV + PRP-T	2, 4, 6 months	12 – 15 months
MenCY/PRP-T [c] (GlaxoSmithKline)	MenHibRix	MenCY + PRP-T	2, 4, 6 months	12 – 15 months

a. If a PRP-OMP vaccine is not administered as both doses in the primary series or there is uncertainty about which products were previously administered, a third dose of Hib conjugate vaccine is needed to complete the primary series.
b. Preferred for American Indian/Alaska Native children.
c. HibMenCY is only recommended for routine meningococcal vaccination for infants who are at increased risk for meningococcal disease. These include infants with recognized persistent complement pathway deficiencies and infants who have anatomic or functional asplenia including sickle cell disease. Recommendations for the MenCY component of MenHIbRix can be found at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6203a3.htm.
d. Updated 1/22/16 to include additional indications for Hiberix vaccine effective 1/14/16.

Minimum Age and Intervals

Hib vaccination can begin as early as 6 weeks of age. The recommended interval between primary series doses is 8 weeks, with a minimum interval of 4 weeks. At least 8 weeks should separate the booster dose from the previous (second or third) dose. A booster is recommended at 12-15 months regardless of which vaccine is used for the primary series. Hib vaccines may be given simultaneously with all other vaccines. The ACIP recommends Hib vaccine for all children through 4 years of age.

Catch-up Vaccination

Age at first vaccination	Primary series	Booster
7-11 months	2 doses, at least 4 weeks apart	Age 12-15 months at least 8 weeks after the second dose*
12-14 months	2 doses, at least 8 weeks apart	N/A
15-59 months	1 dose	N/A

* A booster dose at 12 - 15 months of age is only necessary if 2 or 3 primary doses (depending on vaccine type used) were administered before age 12 months.

Hib Vaccination in High-Risk Groups

High-risk group*	Hib Vaccine Guidance
Patient <12 months of age	Follow routine Hib vaccination recommendations
Patients 12 - 59 months of age	If unimmunized or received 0 or 1 dose before age 12 months: 2 doses 2 months apart If received 2 or more doses before age 12 months: 1 dose If completed a primary series and received a booster dose at age 12 months or older: no additional doses
Patients undergoing chemotherapy or radiation therapy, age <59 months†	If routine Hib doses given 14 or more days before starting therapy: revaccination not required If dose given within 14 days of starting therapy or given during therapy: repeat doses starting at least 3 months following therapy completion
Patients undergoing elective splenectomy, >15 months-18 years	If unimmunized§: 1 dose prior to procedure ‡
Asplenic patients >59 months -18 years	If unimmunized§: 1 dose
HIV-infected patients >59 months – 18 years	If unimmunized§: 1 dose
Recipients of hematopoietic stem cell transplant, through 18 years	Regardless of Hib vaccination history: 3 doses (at least 1 month apart) beginning 6-12 months after transplant

* Patients with functional or anatomic asplenia, HIV infection, immunoglobulin deficiency including Immunoglobulin G2 subclass deficiency, or early component complement deficiency, recipients of a hematopoietic stem cell transplant (HSCT), and those receiving chemotherapy for malignant neoplasms.

† Some experts suggest conducting serologic testing for these patients.

‡ Some experts suggest vaccination at least 14 days before the procedure; some experts suggest administering a dose prior to elective splenectomy regardless of prior vaccination history.

§ Patients who have received a primary series and booster dose or at least 1 dose of Hib vaccine after 14 months of age are considered immunized.

Recommended Dosage

Refer to product package inserts. Recommended dosage is 0.5mL given intramuscularly (IM) at ages 2, 4, 6 months and 12-15 months. PRP-OMP (Pedvax Hib) is recommended to be given at 2, 4 and 12-15 months of age.

Vaccine Storage and Handling

- Store refrigerated at 2 - 8° C, 36 - 46° F.
- Do not freeze.
- After reconstitution, Hiberix should be administered promptly or stored refrigerated and administered within 24 hours. Discard vaccine if not used within 24 hours of reconstitution.
- Lyophilized vaccine vials – store refrigerated at 2 - 8° C, 36 - 46° F; protect from light.
- Diluent - store refrigerated between 2 - 8° C, 36 - 46° F or at a controlled room temperature (68 - 77° F). Do not freeze.

Hiberix is supplied as a lypholized powder that is reconstituted with saline diluent (provided in a syringe). Hiberix does not contain a preservative (thimerosal) and neither the vial stopper nor the pre-filled diluent syringe contains latex.

Precautions

Adverse reactions following Hib conjugate vaccines are not common. Less than one third of the people who get Hib vaccine have mild problems following vaccination.

- Swelling, redness, or pain can occur and usually resolve within 12-24 hours
- Systemic reactions are infrequent
- Serious adverse reactions are rare

Contraindications

- Severe allergic reaction to vaccine component or following a prior dose
- Moderate or severe acute illness
- Age younger than 6 weeks

Additional precaution and contraindication information can be found in the package inserts available at:
http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM093833

IDPH/Immunization Program Recommendations

The IDPH, Immunization Program routinely follows and promotes the ACIP Recommended Immunization Schedule. The Immunization Program is implementing Hiberix vaccine in accordance with the ACIP recommendations and the VFC resolution.