

## INFORMATION PAPER

DHA-IHD  
13 July 2024

SUBJECT: Haemophilus influenzae type b (Hib)

1. Purpose. To describe Haemophilus influenzae type b (Hib) disease and vaccines to prevent it.
2. Facts.
  - a. Microbiology. Haemophilus influenzae is a pleomorphic gram-negative coccobacillus. H. influenzae may be either encapsulated (typeable) or unencapsulated (nontypeable). There are six encapsulated serotypes (designated a–f) that have distinct capsular polysaccharides. Hib is typeable serotype b of Haemophilus influenzae. (CDC, Pinkbook 2021)
  - b. Disease. Haemophilus influenzae type b bacteria is transmitted via direct contact with respirator droplets from nasopharyngeal carrier or symptomatic patient. The most common types of disease caused by Hib bacteria include pneumonia, bacteremia, meningitis, epiglottitis, septic arthritis, cellulitis, otitis media, and purulent pericarditis. Other less common infections include endocarditis and osteomyelitis. Non-b Haemophilus influenzae bacteria can cause disease similar to Hib infections. Nontypeable Haemophilus influenzae bacteria commonly causes ear infections in children and bronchitis in adults but can also cause invasive disease. (CDC, Clinician Resource).
  - c. Epidemiology. Hib disease occurs worldwide. Humans (asymptomatic carriers) are the only known reservoir. Transmission is person to person, either by droplet inhalation or direct contact with secretions. Hib does not survive in the environment or on inanimate surfaces. The pattern is bimodal with peaks in Sep-Dec and Mar-May. (CDC, Pinkbook 2021).
  - d. Vaccines. There are currently three monovalent polysaccharide-protein conjugate Hib vaccines licensed by the Federal Drug Administration (FDA) and is available in the United States. There are also two combination vaccines licensed by the FDA that contain Hib conjugate available in the United States. Hib-only conjugate vaccines should be used for certain high risk older children, adolescents and adults.
    - (1) PedvaxHIB® (Hib meningococcal protein conjugate) PRP-OMP vaccine manufactured by Merck and Co. and licensed by FDA as a 2-dose primary series for infants at ages 2 and 4 months, with a booster dose (dose 3) at age 12 months. PRP-OMP contains purified PRP conjugated with an outer membrane protein complex (OMPC) of Neisseria meningitidis. Approved for use in children 2 months through 71 months of age.
    - (2) ActHIB® (Hib tetanus toxoid conjugate) vaccine manufactured by Sanofi Pasteur and licensed by FDA as a 3-dose primary series for infants at ages 2, 4, and 6 months, with a booster dose (dose 4) at age 15-18 months. This vaccine contains purified PRP conjugated with tetanus toxoid. Approved for use in children 2 months through 5 years of age.
    - (3) Hiberix® (Hib tetanus toxoid conjugate) is manufactured by GlaxoSmithKline and is licensed by FDA for use as a 3-dose primary series for infants at ages 2, 4, and 6

months, with a booster dose (dose 4) at age 15-18 months. To facilitate timely booster vaccination, Hiberix® can be administered as early as age 12 months. This vaccine contains purified PRP conjugated with tetanus toxoid. (MMWR 2016) Approved for use in children 6 weeks through 4 years of age (prior to 5th birthday).

- (4) DTaP/IPV/PRP-T (Pentacel®) manufactured by Sanofi Pasteur and licensed by FDA for vaccination against invasive Hib disease, diphtheria, tetanus, pertussis, and poliomyelitis in infants at ages 2, 4, 6, and 15-18 months. It is not indicated for the DTaP/IPV booster dose at age 4 through 6 years. The vaccine includes the antigenic components used in ActHIB (PRP-T) and Poliovax. Approved for use in children 6 weeks through 4 years of age (prior to 5th birthday).
- (5) DTaP-IPV-Hib-HepB (Vaxelis®) manufactured by Merk & Co. and Sanofi Pasteur (MSP) and licensed by FDA for vaccination against invasive Hib disease and diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B in infants at ages 2, 4, and 6 months. It is not recommended for the booster dose at age 12-15 months, use a different Hib-containing vaccine. It only counts for the first three doses of DTaP and IPV. It is acceptable for any Hep B dose except the birth dose. Approved for use in children 6 weeks through 4 years of age (prior to 5th birthday).

e. Clinical Guidance. The Hib vaccine is a routine childhood immunization in the United States. Hib vaccines are administered intramuscularly in individual doses of 0.5 mL. Advisory Committee for Immunization Practices (ACIP) recommends routine vaccination with a licensed conjugate Hib vaccine for infants aged 2 through 6 months (2 or 3 doses, depending on vaccine product) with a booster dose at age 12 through 15 months. Guidance for high-risk groups is in the table below:

High-risk group*	Hib vaccine guidance
Patients aged <12 mos	Follow routine Hib vaccination recommendations
Patients aged 12–59 mos	If unimmunized or received 0 or 1 dose before age 12 mos: 2 doses, 8 wks apart If received ≥2 doses before age 12 mos: 1 dose 8 wks after last dose If completed a primary series and received a booster dose at age ≥12 mos: no additional doses
Patients aged <60 months undergoing chemotherapy or radiation therapy†	If routine Hib doses administered ≥14 days before starting therapy: revaccination not required If dose administered within 14 days of starting therapy or given during therapy: repeat doses starting at least 3 mos following therapy completion
Patients aged ≥15 mos undergoing elective splenectomy	If unimmunized:‡ 1 dose prior to procedure§
Asplenic patients aged >59 mos and adults	If unimmunized:‡ 1 dose
HIV-infected children aged ≥60 mos	If unimmunized:‡ 1 dose
HIV-infected adults	Hib vaccination is not recommended
Recipients of hematopoietic stem cell transplant, all ages	Regardless of Hib vaccination history: 3 doses (at least 4 wks apart) beginning 6–12 mos after transplant

\* Persons 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, and those receiving chemotherapy or radiation therapy for malignant neoplasms.

† Some experts suggest conducting serologic testing for these patients (Source: Rubin LG, Levin MJ, Ljungman P, et al. 2013 IDSA clinical practice guideline for vaccination of the immunocompromised host. Clin Infect Dis 2013;[Epub ahead of print] doi: 10.1093/cid/cit684).

‡ Patients who have not received a primary series and booster dose or at least 1 dose of Hib vaccine after 14 months are considered unimmunized.

§ Some experts suggest vaccination at least 14 days before the procedure (Sources: CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 2011;60[No. RR-2]; CDC. Recommendations of the Advisory Committee on Immunization Practices (ACIP): use of vaccines and immune globulins in persons with altered immunocompetence. MMWR 1993;42 [No. RR-4]; Rubin LG, Levin MJ, Ljungman P, et al. 2013 IDSA clinical practice guideline for vaccination of the immunocompromised host. Clin Infect Dis 2013;[Epub ahead of print] doi: 10.1093/cid/cit684.) Some experts suggest administering a dose prior to elective splenectomy regardless of prior vaccination history (Source: American Academy of Pediatrics. Haemophilus influenzae infections. In: Pickering L, Baker C, Kimberlin D, Long S, eds. Red book: 2012 report of the Committee on Infectious Diseases. Elk Grove Village, IL: American Academy of Pediatrics; 2012:345–52).

(MMWR 2014)

f. Precautions and Contraindications. Vaccination with a Hib-containing vaccine is contraindicated in infants aged <6 weeks because of the potential for development of immunologic tolerance. Vaccination with a Hib-containing vaccine is contraindicated among

persons known to have a severe allergic reaction to any component of the vaccine. Vaccination should be delayed for children with moderate or severe acute illnesses. Minor illnesses (e.g., mild upper respiratory infection) are not contraindications to vaccination. (CDC, Pinkbook 2021)

- g. Adverse Reactions/Events. Adverse Reactions following Hib conjugate vaccines are not common. Swelling, redness, or pain have been reported in 5% to 30% of recipients and usually resolve within 12 to 24 hours. Systemic reactions such as fever and irritability are infrequent. Among reports to the Vaccine Adverse Event Reporting System (VAERS) following Hib vaccination, the most frequently reported adverse events were fever (31%), crying (11%), injection site erythema (11%), irritability (10%), and rash (9%). The median time from vaccination to onset of an adverse event was 1 day. Adverse events occurring after administration of any vaccine should be reported to Vaccine Adverse Events Reporting System (VAERS).
- h. DoD Policy. The DoD follows the Advisory Committee for Immunization Practices (ACIP) for routine, age, or condition-specific vaccine recommendations.

### 3. References

- a. Centers for Disease Control and Prevention (CDC), Haemophilus Influenza Disease (including Hib). (n.d.). Retrieved February 21, 2024 from <http://www.cdc.gov/hi-disease/clinicians.html>
- b. Centers for Disease Control and Prevention, Haemophilus influenzae type b, The Pink Book: Course Textbook - 14th Edition (2021, August). Retrieved from <https://www.cdc.gov/vaccines/pubs/pinkbook/hib.html#haemo>
- c. Centers for Disease Control and Prevention, 2014, Morbidity and Mortality Weekly Report (MMWR), Haemophilus influenzae Type b Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP) (2014, February 28) Retrieved from <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hib.html>
- d. Centers for Disease Control and Prevention 2016, Morbidity and Mortality Weekly (MMWR), Food and Drug Administration Approval for Use of Hiberix as a 3-Dose Primary Haemophilus influenzae Type b (Hib) Vaccination Series: Recommendations of the Advisory Committee on Immunization Practices (ACIP) (2016, April 29) Retrieved from <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hib.html>
- e. Centers for Control and Prevention, Vaccines and Preventable Diseases, Haemophilus Influenza type b Vaccination. (n.d.). Retrieved from <https://www.cdc.gov/vaccines/vpd/hib/index.html>

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