INFORMATION PAPER

DHA-IHB
2 December 2015

SUBJECT: Haemophilus influenza type b (Hib)

1. Purpose: To describe Haemophilus influenza type b (Hib) disease and the vaccine to prevent it.

2. Facts.

a. Microbiology. Haempohilus 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. (CDC, Pinkbook)

b. Disease. Hib is transmitted via direct contact with respirator droplets from nasopharyngeal carrier or symptomatic patient. The most common types of disease caused by Haemophilus influenzae type b bacteria includes 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 may also cause invasive disease, such as bacteremia and pneumonia (CDC, Clinician Resource).

c. Epidemiology. Hib disease occurs worldwide. Humans (asymptomatic carriers) are the only know reservoir. Hib does not survive in the environment or on inanimate surfaces (CDC, Pinkbook).

d. Vaccines. There are currently three monovalent purified polyribosylribitol phosphate (PRP) polysaccharide-protein conjugate Hib vaccines licensed by the Federal Drug Administration (FDA) and is available in the United States.

(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.

(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 months. This vaccine contains purified PRP conjugated with tetanus toxoid.

(3) Hiberix® (Hib tetanus toxoid conjugate) is manufactured by GlaxoSmithKline and is licensed by FDA for use as the booster dose (which will be dose 3 or 4, depending on vaccine type used for primary series) of the Hib vaccine series for children aged 15 months through 4 years who have received a Hib primary series. This vaccine contains purified PRP conjugated with tetanus toxoid. (MMWR 2014)

There are three combination vaccines licensed by the FDA that contain Hib conjugate available in the United States.

(4) PRP-OMP/HepB (Comvax®) manufactured by Merck and Co. and licensed by FDA for vaccination against invasive Hib disease and hepatitis B infection in infants at ages 2, 4, and 12 through 15 months. This vaccine includes the antigenic components used in PedvaxHIB (PRP-OMP) and Recombivax HB (hepatitis B surface antigen)

(5) 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 through 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.

(6) MenCY/PRP-T (MenHibRix) manufactured by GlaxoSmithKline and licensed by FDA for vaccination against invasive Hib disease and N. meningitidis serogroups C and Y disease in infants at ages 2, 4, 6, and 12 through 15 months. Infants at increased risk for meningococcal disease should be vaccinated with a 4-dose series of MenCY/PRP-T. Routine meningococcal vaccination is recommended only for infants who are at increased risk for meningococcal disease. MenCY/PRP-T may be used in any infant for routine vaccination against Hib. (MMWR 2014)

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.

ACIP recommends children aged 12–59 months who are at increased risk for Hib disease persons at increased risk for Hib disease (i.e., persons who have early component complement deficiencies, immunoglobulin deficiency, anatomic or functional asplenia, or HIV infection; recipients of hematopoietic stem cell transplant; and recipients of chemotherapy or radiation therapy for malignant neoplasms) receive 2 additional doses of vaccine 8 weeks apart; children who received 2 or more doses of Hib conjugate vaccine before age 12 months should receive 1 additional dose, at least 8 weeks after the last dose.

Hib vaccination during chemotherapy or radiation therapy should be avoided because of possible suboptimal antibody response. Patients vaccinated within 14 days of starting immunosuppressive therapy or while receiving immunosuppressive therapy should be considered unimmunized, and doses should be repeated beginning at least 3 months following completion of chemotherapy. Patients who were vaccinated more than 14 days before chemotherapy do not require revaccination, with the exception of recipients of a hematopoietic stem cell transplant who should be revaccinated with a 3-dose regimen 6–12 months after successful transplant, regardless of vaccination history; at least 4 weeks should separate doses (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 with Comvax is contraindicated in patients with a hypersensitivity to yeast. 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)

g. Adverse Reactions/Events. Redness, warmth, or swelling where the shot was given (up to 1 out of 4 children), and fever over 101°F (up to 1 out of 20 children) are the most common adverse events. The most common non-death serious AE categories were neurologic (37%), other noninfectious (22%) (comprising mainly constitutional signs and symptoms); and gastrointestinal (18%) conditions. Adverse reactions to Hib-containing monovalent vaccines are uncommon, usually mild, and resolve within 12-24 hours. Adverse events occurring after administration of any vaccine should be reported to Vaccine Adverse Events Reporting System (VAERS).

2. References

a. Centers for Disease Control and Prevention, Haemophilus Influenza Disease (including Hib). (n.d.). Retrieved 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 - 13th Edition (2015). (2015, June 1). Retrieved from http://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 1).
Retrieved from http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hib.html

d. Defense Health Agency (DHA) Immunization Healthcare Branch (IHB), Haemophilus influenzae type b (Hib). (n.d.). www.health.mil/hib

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