OREGON HEALTH AUTHORITY

IMMUNIZATION PROTOCOL FOR PHARMACISTS

HAEMOPHILUS INFLUENZAE b (Hib) CONJUGATE VACCINE

Revisions as of 12-2011

- Removal of TriHibit® from protocol. Section II p.2.
- Updated recommendations from the Advisory Committee on Immunization Practices (ACIP) for administering Hib vaccines to persons undergoing splenectomies or Hematopoietic stem cell transplants (HSCT) section III p.3.

I. Order:

1. Check the ALERT Immunization Information System to determine whether the patient needs this vaccine and any other vaccines.
2. Screen clients ≥11 years of age for contraindications.
3. Provide an Adolescent Well Visit Flyer to those 11—18 years of age.
4. Provide a current Vaccine Information Sheet (VIS) answering any questions.
5. Obtain a signed Vaccination Administration Record (VAR)
6. Give Hib conjugate vaccine (0.5mL) intramuscularly (IM) to high-risk persons ≥11 years of age noted in section III, pg. 3.
7. May give Hib conjugate vaccine simultaneously with all routine adolescent and adult immunizations.
8. Record dose using the appropriate generic abbreviation.

Immunizing Pharmacist Signature

For multiple signatures see: http://1.usa.gov/PharmacyImmunizationProtocols

Revised: 12-2011
Reviewed: 12-2013
Original: 06-2005
II. LICENSED HIB VACCINES

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>GENERIC ABBREVIATION</th>
<th>ACCEPTABLE AGE RANGE</th>
<th>THIMEROSAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>PedvaxHIB® (Merck)</td>
<td>PRP-OMP</td>
<td>≥11 years of age</td>
<td>No</td>
</tr>
<tr>
<td>ActHib® (Aventis Pasteur)</td>
<td>PRP-T</td>
<td>≥11 years of age</td>
<td>No</td>
</tr>
<tr>
<td>Hiberix® (GSK)</td>
<td>PRP-T</td>
<td>≥11 years of age</td>
<td>No</td>
</tr>
</tbody>
</table>

1Children and adults with sickle cell disease, leukemia, functional or anatomic asplenia, immunosuppression from cancer chemotherapy, HIV infection, and hematopoietic stem cell transplants (HSCT) are at increased risk for invasive Hib disease, and Hib vaccine is immunogenic in these high-risk persons. See Section III (p. 3) for ACIP recommendations regarding vaccination of these persons.

2The Hib vaccines are considered interchangeable. Any brand licensed for the primary vaccination series may be used. Conjugate vaccines approved for high risk individuals ≥5 years of age.

3Hiberix® will be in a limited supply in US. Once the 4.3 million doses are purchased the supply will end.

4Hiberix is to be used only as a booster dose in children who have received a primary series with a Haemophilus b Conjugate Vaccine that is licensed for primary immunization.

5Hiberix® needs to be reconstituted only with accompanying saline diluent and must be administered promptly or stored refrigerated between 2° and 8°C and administered within 24 hours. Discard any unused reconstituted vaccine.

6Administer ActHib® with saline diluent within 24 hours of reconstitution.
III. RECOMMENDATIONS & SCHEDULING

<table>
<thead>
<tr>
<th>Dose &amp; Route</th>
<th>Minimum Age</th>
<th>Booster</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5mL IM</td>
<td>≥11 years of age</td>
<td>No</td>
</tr>
</tbody>
</table>

In general, Hib vaccination of children older than 59 months of age is not recommended. However, some older children and adults, with the following conditions, are at increased risk for invasive Hib disease and may be vaccinated:

A. Functional or anatomic asplenia (e.g., sickle cell disease, post splenectomy)
   - Splenectomy.
   - If splenectomy is planned: give one 0.5ml dose at least 14 days before surgery.
   - If splenectomy has already taken place give 0.5ml dose as soon as patient’s condition is stable in children, adolescents, and adults.


B. Immunodeficiency (in particular, persons with IgG2 subclass deficiency)
C. Immunosuppression from cancer chemotherapy
D. HIV infection
E. Hematopoietic stem cell transplant (HSCT) recipients and Hib vaccine: ACIP recommends a 3-dose Hib regimen starting at 6 months post-HSCT for all ages. At least 1 month should separate the doses.

2 Previously unvaccinated persons ≥11 years of age with one of the above high-risk conditions should be given one pediatric dose (0.5 ml) of Hib conjugate vaccine.

3 Hematopoietic stem cell transplant (HSCT) recipients and Hib vaccine: ACIP and AAP recommend a 3-dose Hib regimen at 12, 14, and 24 months post-HSCT for all ages (2009 Red Book, p.80).

4 Revaccination with Hib for the above high-risk conditions is not recommended. (MMWR 2006; 55(RR-15):26).
IV. CONTRAINDICATIONS

1. Anaphylactic reaction to the vaccine or any component of the vaccine.
2. Moderate or severe illness with or without fever: delay immunization until illness has resolved.
3. Contraindications and precautions for combined vaccines are the same as those for each individual component. (See DTaP, Hep B and IPV standing orders).

V. PRECAUTIONS

VI. SIDE EFFECTS AND ADVERSE REACTIONS

<table>
<thead>
<tr>
<th>Event</th>
<th>Frequency/Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Pain, redness, swelling at injection site</td>
<td>5–30%. Usually resolves in 24 hours.</td>
</tr>
<tr>
<td>2. Fever, irritability</td>
<td>Infrequent</td>
</tr>
</tbody>
</table>

1 Side effects for combination vaccines (i.e. Comvax®, TriHIBit® and Pentacel®) are similar to those for individual vaccine components (see side effects and adverse reactions for HepB, DTaP and IPV vaccine).

VII. OTHER CONSIDERATIONS

For someone with a history of fainting with injections, a 15-minute observational period is recommended post-immunization.
VIII. STORAGE AND HANDLING

Store at 2-8°C (36-46°F) Do not freeze.

Does not use after expiration date.

IX. ADVERSE EVENTS REPORTING

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS) at 1-800-822-7967. Forms and procedures can be found at the VAERS website: [www.vaers.hhs.gov](http://www.vaers.hhs.gov). In addition, a copy of the reporting form should be reported to the patient’s primary provider, per Oregon Revised Statute (ORS) 855-019-0280(4).

X. Table 1. Events Reportable to VAERS

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Illness, disability, injury or condition</th>
<th>Time period until first symptom</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccines containing Hib-antigen</td>
<td>1. Early onset Hib disease</td>
<td>7 days</td>
</tr>
<tr>
<td></td>
<td>2. Any acute complication sequelae (including death)</td>
<td>Any time</td>
</tr>
</tbody>
</table>

REFERENCES


3. CDC. Licensure of a *Haemophilus influenzae* Type b (Hib) vaccine (Hiberix®) and updated recommendations for use of Hib vaccine. MMWR 2009; 58 (36): 1008-1009. Available at: [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5836a5.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5836a5.htm)

4. CDC. General Recommendations on Immunization. MMWR 2006; 55(RR15):1-48. Available at: [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5515a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5515a1.htm)


9. CDC. Licensure of a diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus, and *Haemophilus* b conjugate vaccine and guidance for use in infants and children. MMWR 2008; 57 (39): 1079–80. Available at [www.cdc.gov/mmwr/preview/mmwrhtml/mm5739a5.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5739a5.htm).
To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971.673.0300. For other questions, consult with the vaccine recipient’s primary health care provider or a consulting physician.

Electronic copy of this protocol available at:

http://1.usa.gov/PharmacyImmunizationProtocols

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