

OREGON HEALTH AUTHORITY

IMMUNIZATION PROTOCOL FOR PHARMACISTS

HAEMOPHILUS INFLUENZAE B (Hib) CONJUGATE VACCINES^{1, 2, 3}

01-01-2016:

- Updates to format
- Addition of high-risk table
- Vaccination age changed to clients ≥ 7 years of age

I. OREGON IMMUNIZATION MODEL STANDING ORDER:

1. Check the ALERT Immunization Information System to determine whether the patient needs this vaccine and any other vaccines.
2. Screen clients ≥ 7 years of age for contraindications.
3. Provide the current vaccine information statement (VIS) to the client, answering any questions.
4. Record all required data elements in the client's permanent health record, including indication of which Hib vaccine was used.
5. Give Hib conjugate-containing vaccine (0.5 ml), **intramuscularly** (IM), to high-risk persons according to the high-risk table, Section III C on page 3.
6. May be given with all ACIP-recommended child and adult vaccinations.
7. Observe client for 15 minutes after vaccination to decrease the risk for injury should they faint.

Immunizing Pharmacist Signature

Date

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

Revised 01-01-2016

II. LICENSED VACCINES

A. Licensed <i>Haemophilus influenzae</i> b (Hib) Conjugate Vaccines*			
Product Name[◇]	Generic Abbreviation	Acceptable Age Range	Thimerosal
ActHib ^{® 1} (sanofi pasteur)	PRP-T	≥7 years	None
PedvaxHIB ^{®2} (Merck)	PRP-OMP	≥7 years	None
Hiberix ^{® 3} (GSK)	PRP-T	≥7 years	None

* The Hib vaccines are considered interchangeable. Any brand of licensed vaccine may be used for the booster dose, regardless of what was received in the primary series. If it is necessary to change the vaccine brand mid-series, 4 doses of any combination are required to complete the (primary and booster) series.⁵

[◇]See section III C page 3 for immunocompromised children and adults.

III. HIB VACCINE SCHEDULES

III. A. 4-dose Schedule Vaccines used: ActHib[®] (PRP-T)^{1 * ◇ §}

Dose/Route: 0.5 mL IM			
DOSE	MINIMUM AGE	MINIMUM SPACING	RECOMMENDED AGE
1	≥7 years		2 months
2	≥7 years	4 weeks dose 1 to dose 2	4 months
3	≥7 years	4 weeks dose 2 to dose 3	6 months
4 (booster)	≥7 years	8 weeks dose 3 to dose 4	15 months

* If you cannot give ActHib[®] immediately after reconstitution, discard at end of

clinic day.⁵

◊ Hib vaccines are considered interchangeable. Any brand of licensed vaccine may be used for the booster dose, regardless of what was received in the primary series. If it is necessary to change the vaccine brand mid-series, 4 doses of any combination are required to complete the primary and booster series.⁶

§ For retrospective checking, doses that violate the minimum spacing or age by 4 or fewer days do not need to be repeated. Doses administered 5 days or earlier than the minimum interval or age should be repeated as age appropriate.⁵

III.B. RECOMMENDATIONS AND SCHEDULE

Dose & Route ^{2,3}	Minimum Age	Booster ⁴
0.5mL IM	≥7 years of age	No

¹In 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:

III. C. HIGH-RISK SCHEDULE FOR HIB-CONTAINING VACCINES⁷

High-risk group*	Hib vaccine guidance
Patients aged ≥7 years undergoing elective splenectomy	If unimmunized: [§] 1 dose prior to procedure ^{‡1, and ‡2}
Asplenic patients aged ≥7 years and adults	If unimmunized: [§] 1 dose
HIV-infected children ≥7 years –18 years ¹⁵	If unimmunized: [§] 1 dose
HIV-infected adults	Hib vaccination is not recommended
HSCT	3 doses at least 1 month apart, beginning 6–12 months after HSCT, regardless of prior Hib vaccine history ⁸

* 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.

‡¹. 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 Adobe PDF file [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.)

‡². 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).

IV. CONTRAINDICATIONS

1. Anaphylactic reaction to the vaccine or any component of the vaccine.^{1, 2, 3}
2. Moderate or severe illness with or without fever: delay immunization until illness has resolved.²
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 AND WARNINGS

1. If Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the decision to give any tetanus toxoid-containing vaccine should be based on careful consideration of the potential benefits and possible risks.^{1, 2, 3}
2. Dry latex rubber in the diluent stopper cap may cause allergic reactions in latex-sensitive individuals.^{1, 2, 3}

VI. OTHER CONSIDERATIONS

1. **Adverse Events:** epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case of anaphylactic or acute hypersensitivity reaction.⁵
2. **Immunocompromised:** individuals with altered immunocompetence may have reduced immune responses.^{1, 2, 3}
3. **Children with history of Haemophilus influenzae** type b disease at >2 years of age or older are considered immune.⁷
4. **Children who contract Hib disease < 2 years of age** should be considered unimmunized and receive Hib vaccine as recommended in the Hib vaccine schedule. Immunization should begin as soon as possible during the convalescent phase of the illness and be completed as needed for the child's age.⁷
5. **Vaccination of internationally adopted children:** Because the number of vaccinations needed for protection decreases with age and adverse events are rare, age-appropriate vaccination should be provided. Hib vaccination is not recommended routinely for children ≥5 years of age.⁵
6. **Hib case reporting:** Refer to the Oregon Acute and Communicable Diseases Investigative Guidelines available at:
<http://public.health.oregon.gov/DiseasesConditions/CommunicableDisease/ReportingCommunicableDisease/ReportingGuidelines/Documents/hflu.pdf>
for controlling the spread of an outbreak, antibiotic prophylaxis, and the protection of contacts.

VII. SIDE EFFECTS AND ADVERSE REACTIONS

Number followed for Safety	1. Pedvax HIB ^{®2} 6 hours Post dose 1 Adverse Reaction % 2–6 months		2. Hiberix ^{®3} Within 4 days of vaccination Adverse Reaction % Mean age: 16 months
Age in Years			
Local Reaction, Injection site	N =222	N = 674	N=371
Pain	Yes	Yes	20.5
Redness		2.2	24.5
Swelling		2.5	14.8
Rash	Yes	Yes	
Systemic Complaints			
Irritability	Yes	Yes	25.9
Fever ≥38.5° C (≥101°F)	18.1		34.8
Alteration in appetite	Yes	Yes	22.9
Alteration in sleep	Yes	Yes	19.9
Crying >4 hours	Yes	Yes	
Diarrhea	Yes	Yes	14.6
Vomiting			4.9
Pedvax HIB [®] has Table 5 on page 7 ²			
Hiberix [®] Table 1 page 6 ³			

1. Fever or local reactions in subjects first vaccinated at 2 to 6 months of age with liquid Pedvax HIB^{®2} along with OPV and DTP.
2. Hiberix^{®3} coadministered with DTaP-HBV-IPV³

VIII. STORAGE AND HANDLING

All clinics and pharmacies enrolled with the VFC program must **immediately** report any storage and handling deviations to their Oregon Immunization Program health educator. The health educator assignment map is located at: http://bit.ly/HE_Map

Vaccine	Temp	Storage Issues	Notes
ActHib^{® 1}	Store at 2°–8°C (36°F–46°F)	Do not freeze either lyophilized vaccine or diluent. If not administered immediately, administer within 24 hours of reconstitution. After reconstitution, store refrigerated between 2° and 8°C (36° and 46°F). Discard the reconstituted vaccine if not used within 24 hours.	Dry natural latex rubber in diluent stopper
Pedvax HIB^{® 2}	Store at 2°–8°C (36°F–46°F)	Do not use if vaccine has been frozen. Report to health educator.	Dry natural latex rubber in vial stopper.
Hiberix^{®3}	Store <i>Diluent</i> at 2°–8°C (36°F–46°F) or room temperature	Administer within 24 hours of reconstitution. After reconstitution, store refrigerated between 2° and 8°C (36° and 46°F). Discard the reconstituted vaccine if not used within 24 hours.	Dry natural latex rubber in tip caps of prefilled syringes. No latex in the plungers of the prefilled syringes. No latex in single-dose vial stoppers.

IX.ADVVERSE EVENTS REPORTING

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS). The VAERS online report form is available at <https://vaers.hhs.gov/esub/step1>.

A pharmacist who administers any vaccine must report the following elements to the OHA ALERT Immunization Information System in a manner prescribed by OHA within 15 days of administration. This replaces the former requirement to notify the primary health care provider. A pharmacist is not required to notify the primary health care provider. Oregon Administrative Rule 855-019-0290-(2)(3).^{14, 15}

VAERS Reporting Table* :

<p><i>Hemophilus influenzae</i> type b in any combination (conjugate)- Hib, Hib-HepB, DTP-Hib, DTaPIPV/ Hib</p>	<p>Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval - see package insert)</p>
---	--

* Effective date: November 10, 2008. The Reportable Events Table (RET) reflects what is reportable by law (42 USC 300aa-25) to the Vaccine Adverse Event Reporting System (VAERS) including conditions found in the manufacturers package insert.

In addition, healthcare professionals are encouraged to report any clinically significant or unexpected events (even if you are not certain the vaccine caused the event) for any vaccine, whether or not it is listed on the RET.

Manufacturers are also required by regulation (21CFR 600.80) to report to the VAERS program all adverse events made known to them for any vaccine. Available at: [https://vaers.hhs.gov/resources/VAERS Table of Reportable Events Following Vaccination.pdf](https://vaers.hhs.gov/resources/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf) Accessed 10 November 2015.

REFERENCES

1. ActHIB[®] 2014 package insert. Available at: www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM109841.pdf . Accessed 18, September 2015
2. PedvaxHIB[®] 2011 package insert. Available at: www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM253652.pdf . Accessed 18, September 2015
3. Hiberix[®] 2012 package insert. Available at: www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM179530.pdf . Accessed 18, September 2015
4. CDC. Use of MenACWY-CRM vaccine in children aged 2 through 23 months at increased risk for meningococcal disease: Recommendations of the Advisory Committee on Immunization Practices, 2013. MMWR 2014;63(24); 527–30. Available at: www.cdc.gov/mmwr/preview/mmwrhtml/mm6324a2.htm Accessed 1 October 2015.
5. CDC. General recommendations on immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2011;60(2);1–64. Available at: www.cdc.gov/mmwr/pdf/rr/rr6002.pdf Accessed 18, September 2015
6. *Haemophilus influenzae* type b. In: *Epidemiology and Prevention of Vaccine-Preventable Diseases* (“Pink Book”). Atkinson W, Hamborsky J, Wolfe S, eds. Updated 13th ed. Washington, DC: Public Health Foundation, 2015:119–133. Available at: www.cdc.gov/vaccines/pubs/pinkbook/downloads/hib.pdf .
7. CDC. Prevention and control of haemophilus influenza type b disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2014; 63(RR01);1–14. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6301a1.htm> . Accessed 1 October 2015.
8. Rubin LG, et al: 2013 IDSA clinical practice guideline for vaccination of the

- immunocompromised host. *Clinical Infectious Diseases* Advance Access: 2013. 1–57. Available at:
cid.oxfordjournals.org/content/early/2013/11/26/cid.cit684.full
Accessed 28 December 2015.
9. CDC. Haemophilus b conjugate vaccines for prevention of Haemophilus influenza type b disease among infants and children two months of age and older. Recommendations of the ACIP. *MMWR* 1991;40(RR01);1–7. Available at:
<http://www.cdc.gov/mmwr/preview/mmwrhtml/00041736.htm> .
Accessed 1 October 2015.
 10. 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. Accessed 1 October 2015.
 11. Immunization Action Coalition (IAC). *Vaccines with Diluents: How to Use Them*. 2015. Available at: www.immunize.org/catg.d/p3040.pdf
Accessed 1 October 2015.
 12. CDC. Prevention and control of meningococcal disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). 2013. *MMWR* 2013; 62(RR02);1–22. Available at:
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm> .
Accessed 1 October 2015.
 13. CDC. Recommended immunization schedule for persons aged 0 through 18 years. 2015. Footnote 13. Available at:
<http://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent-shell.html> . Accessed 1 October 2015.
 14. State of Oregon, Administration of Vaccines by Pharmacists: 855–019–270. Available at:
www.oregon.gov/pharmacy/Imports/Rules/December10/855-019_Perm.pdf Accessed 11 August 2015.

15. Oregon Administrative Rule. Board of Pharmacy. Division 19. Licensing of pharmacists: 855-019-0290 (2). Available at:
http://www.oregon.gov/pharmacy/Imports/Rules/December10/855-019_Perm.pdf Accessed 11 September 2015.

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 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

Electronic copy of this protocol available at:
1.usa.gov/PharmacyImmunizationProtocols