

**OREGON PUBLIC HEALTH DIVISION, DHS,
IMMUNIZATION PROGRAM**

**HAEMOPHILUS INFLUENZAE B (Hib) CONJUGATE VACCINES
AND COMBINATION VACCINES**

**TRIHIBIT®
COMVAX®
PENTACEL®**

Revisions as of 9/08:

- The newly licensed Pentacel® (Hib, DTaP, and IPV) vaccine is being added to this order. (Sections II and III)
- HibTITER® has been removed from this order since it is no longer available in U.S.
- Current ACIP Hib vaccine recommendations pre- and post-splenectomy and hematopoietic stem cell transplant (HSCT) have been added to Section VI, p 9.

I. ORDER

1. Screen for contraindications.
2. Provide the current vaccine information statement (VIS) to the client, answering any questions.
3. Obtain a signed Vaccine Administrative Record (VAR).
4. Give Hib conjugate-containing vaccine (0.5 ml), **intramuscularly** (IM), to infants and children 6 weeks through 4 years of age.
5. Give according to the age and vaccine-specific schedules located in section III.
6. May give Hib conjugate vaccine to previously un-immunized high-risk children and adults 5 years and older with conditions listed in section VI. C and D.
7. Give Hib conjugate vaccine simultaneously with all routine childhood immunizations according to age and immunization status of recipient.
8. Record each dose using the appropriate generic abbreviation.

Signature

Health Officer or Medical Provider

Date

September 2008

II. LICENSED VACCINES

A. Licensed *Haemophilus influenzae b* (Hib) Conjugate Vaccines¹

Product Name	Generic Abbreviation	Acceptable Age Range	Thimerosal
ActHib® (S. Pasteur)	PRP-T	6 weeks–59 months	None
PedvaxHIB® (Merck)	PRP-OMP	6 weeks–59 months	None

B. Licensed COMBINED *Haemophilus influenzae b* (Hib) Vaccines

Product Name	Generic Abbreviation	Acceptable Age Range	Thimerosal
TriHIBit® (ActHib® & Tripedia®) (sanofi pasteur)	PRP-T & DTaP	12–59 months	Trace (Tripedia® component)
COMVAX® (PedvaxHIB® & Recombivax® HepB) (Merck)	PRP-OMP & HepB	6 weeks–59 months	None
Pentacel® (sanofi pasteur)	PRP-T, DTaP, IPV	6 weeks–4 years	None

¹The 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.

III. HIB VACCINE SCHEDULES

III. A 4-dose Schedule Vaccines used: **ActHib®** (PRP-T)¹ and **TriHIBit®** (PRP-T)^{2,3,4,5,6}

Dose/Route: 0.5 mL IM

DOSE	MINIMUM AGE ⁵	MINIMUM SPACING ⁷	RECOMMENDED AGE
1	6 weeks		2 months
2	10 weeks	4 weeks dose 1 to dose 2	4 months
3	14 weeks	4 weeks dose 2 to dose 3	6 months
4 (booster) ⁶	12 months	8 weeks dose 3 to dose 4	15 months

¹Administer ActHib® within 30 minutes of reconstitution.

²TriHIBit® (DTaP and Hib) = ActHib® reconstituted with Tripedia®. Do not give TriHIBit® for the primary Hib series. This vaccine is licensed only for the 4th dose of the DTaP and Hib series.

³TriHIBit may be used as the final dose of the Hib series at ≥12 months of age following any Hib vaccine series as long as it has been ≥8 weeks since the last Hib dose.

⁴Do not use TriHIBit® if no previous Hib doses have been received.

⁵Children 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 VI (p. 9) for ACIP recommendations regarding vaccination of these persons.

⁶Hib 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. Consult the Hib catch-up schedule (p. 7) to determine the doses needed by age if a child is behind.

⁷For 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.

III. B. 3-dose Schedule: Vaccines used: **PedvaxHIB®** (PRP-OMP)¹ or **COMVAX®** (PRP-OMP & Hep B)^{2,3}

Dose/Route: 0.5 ml IM

DOSE	MINIMUM AGE⁴	MINIMUM SPACING⁴	RECOMMENDED AGE
1	6 weeks ^{2,3}		2 months
2	10 weeks	4 weeks after dose #1	4 months
3 (booster)	12 months	8 weeks after dose #2	15 months

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 VI (p. 9) for ACIP recommendations regarding vaccination of these persons.

²COMVAX® is approved by ACIP for use in children born to HBsAg-positive and HBsAg-unknown women. COMVAX® may be used whenever administration of any components of the combination is indicated and other components are not contraindicated.

³Do not give COMVAX® or any Hib conjugate vaccine to infants younger than 6 weeks of age. A dose given before 6 weeks of age may reduce the response to subsequent Hib vaccine doses.

⁴For 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 appropriate for age.

III. C. 4-Dose Schedule for PENTACEL® (DTaP, IPV, ActHIB®)^{1,2}**Dose/Route: 0.5 ml IM**

DOSE	MINIMUM AGE	MINIMUM SPACING	RECOMMENDED AGE
1	6 weeks		2 months
2	10 weeks	4 weeks dose 1 to dose 2	4 months
3	14 weeks	4 weeks dose 2 to dose 3	6 months
4 (booster)	12 months ³	6 months ⁴ dose 3 to dose 4	15 months

¹Hib 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. Consult the Hib catch-up schedule (p. 7) to determine the doses needed by age if a child is behind.

²For 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 appropriate for age.

³This minimum age is determined by the DTaP and Hib components of Pentacel®.

⁴This minimum interval is determined by the DTaP component in Pentacel®.

III. D. Schedules for specific Hib vaccines			
VACCINE	AGE AT 1ST DOSE²	SERIES³	MINIMUM SPACING²
ActHIB® (PRP-T) ¹	<7 months	4 doses	Doses 1, 2 and 3: 4-week intervals between each Dose 4: 12–15 months of age and at least 8 weeks after dose 3
PedvaxHIB® ⁴ (PRP-OMP)	<7 months	3 doses	Doses 1 and 2: 4-week interval Dose 3: 12–15 months of age and at least 8 weeks after dose 2
All vaccines	7–11 months	3 doses	Doses 1 and 2: 4 week interval Dose 3: 12–15 months of age and at least 8 weeks after dose 2
All vaccines	12–14 months	2 doses	Dose 2: at least 8 weeks after dose 1
All vaccines	15–59 months	1 dose	None
<p>¹ If the child has received at least one dose of ActHIB® or the previously received brand is unknown, the four-dose schedule should be used.</p> <p>² For retrospective checking, doses that violate the minimum spacing or age by 4 or fewer days do not have to be repeated.</p> <p>³ When an incorrect Hib dose is given (violating the minimum spacing or age), forecast the next dose due by calculating the correct spacing from the date of the incorrect dose, but no sooner than the correct minimum age.</p> <p>⁴ If PedvaxHIB® #3 is given when the child is at least 14 weeks of age but less than 12 months, a 4th dose of any licensed Hib vaccine is required at 12–15 months of age.</p>			

III. E. Hib Vaccine Catch-up Schedule		
CURRENT AGE	NUMBER OF PREVIOUS DOSES	RECOMMENDED REGIMEN¹
7–11 months	1 dose of any Hib vaccine	1 dose now (at 7–11 months), and a booster ≥ 8 weeks later at 12–15 months of age (3 doses total)
7–11 months	2 doses of ActHIB®(PRP-T)	1 dose now (at 7–11 months), and a booster ≥ 8 weeks later at 12–15 months of age (4 doses total)
12–14 months	2 doses before 12 months of age	1 dose of any licensed conjugate vaccine ≥ 8 weeks after last dose (3 doses total)
12–14 months	1 dose before 12 months of age	2 doses of any licensed conjugate vaccine, separated by ≥ 8 weeks (3 doses total)
15–59 months	Any incomplete schedule ²	1 dose only of any licensed conjugate vaccine ≥ 8 weeks after last dose
<p>¹ 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 appropriate for age.</p> <p>² If a 3rd dose of any Hib vaccine is given at ≥ 12 months of age, a 4th dose is not needed; the series is considered complete.</p> <p>Note: Above schedule adapted from AAP Red Book, 25th Edition, 2000)</p>		

IV. CONTRAINDICATIONS AND PRECAUTIONS

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

V. SIDE EFFECTS AND ADVERSE REACTIONS¹

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

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).

VI. OTHER CONSIDERATIONS

- A. Children with history of *Haemophilus influenzae* type b disease at 2 years of age or older are considered immune.
- B. Children who contract Hib disease before 2 years of age should be considered un-immunized 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.
- C. Hematopoietic stem cell transplant (HSCT) recipients and Hib vaccine: ACIP and AAP recommend a 3-dose Hib regimen at 12, 14, and 24 months after HSCT for all ages (2006 Red Book, p.79).
- D. Splenectomy and Hib vaccine: one 0.5-ml dose of any Hib vaccine is recommended 2 weeks before or 2 weeks after splenectomy in children, adolescents, and adults if Hib vaccine was not given in infancy. No revaccination of Hib is currently recommended by ACIP (MMWR 2006; 55.(RR-15):26).
- E. For someone with a history of fainting with injections, a 15-minute observational period is recommended post-immunization.
- F. 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.
- G. **Hib case reporting:** Refer to the Oregon DHS *Investigative Guidelines* (www.dhs.state.or.us/publichealth/odpe/guideln/hflu/pdf) for controlling the spread of an outbreak, antibiotic prophylaxis, and the protection of contacts

VII. ADVERSE EVENT REPORTING

The adverse events listed below, following immunization, should be reported by public providers to the Immunization Program, Health Services, using a Vaccine Adverse Events Reporting System form (VAERS), according to state guidelines. Private providers report all adverse events directly to VAERS.

VAERS phone number: 800-822-7967, and the website address is <http://vaers.hhs.gov>

Table 1. Events Reportable to VAERS

Vaccine	Illness, disability, injury or condition	Time period until first symptom
Vaccines containing Hib antigen	1. Early-onset Hib disease	7 days
	2. Any acute complication (including death)	Any time

VIII. REFERENCES

1. *Haemophilus b* conjugate vaccines for prevention of *Haemophilus influenzae* type b disease among infants and children two months of age and older: recommendations of the ACIP. MMWR 1991; 40 (RR-1). Available at www.cdc.gov/mmwr/preview/mmwrhtml/00041736.htm.
2. *Haemophilus influenzae* infections. In: Pickering LK, ed. *Red Book: 2006 Report of the Committee on Infectious Diseases*. 27th ed. Elk Grove Village, IL: American Academy of Pediatrics: 2006: 310-8.
3. *Haemophilus influenzae* type b. In: *Epidemiology and Prevention of Vaccine-Preventable Diseases* (“Pink Book”). Atkinson W, Hamborsky J, Wolfe S, eds. Updated 10th ed., 2nd Printing. Washington, DC: Public Health Foundation, 2008:115–27. Available at: www.cdc.gov/vaccines/pubs/pinkbook/downloads/hib.pdf.
4. Recommendations for use of *Haemophilus b* conjugate vaccine and a combined diphtheria, tetanus, pertussis, and *Haemophilus b* vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1993; 42 (RR-13). Available at www.cdc.gov/mmwr/PDF/rr/rr4213.pdf.
5. Pentacel® 2008 package insert. Available at

- www.fda.gov/CbER/label/pentacellB.pdf,
6. Comvax® 2004 package insert. Available at www.merck.com/product/usa/pi_circulars/c/comvax/comvax_pi.pdf.
7. ActHIB® 2005 package insert. Available at <http://vaers.hhs.gov/pdf/ActHIB.pdf>
8. PedvaxHIB® package insert.

For more information or to clarify any part of the above order, consult with your health officer or the Oregon State Public Health Division Immunization Program at 971-673-0300.

**To download a copy visit our website at
<http://oregon.gov/dhs/ph/imm/provider/stdgordr.shtml>
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please call 971-673-0300.**