Immunization Protocol

***Haemophilus influenzae* type b (Hib) Conjugate Vaccines and Combination Vaccines (ActHIB®, PedvaxHIB®, Hiberix®, Pentacel®, Vaxelis®)**	
Last Reviewed	31 August 2023
Last Revised	31 August 2023
This order expires	31 August 2025

Table of contents

1. What's new

Reviewed for updates. No substantive changes.

2. Oregon immunization protocol

A. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.

B. Screen clients for contraindications and precautions.

C. Provide a current Vaccine Information Statement (VIS), answering any questions.

D. Record all required data elements in the client's permanent health record.

E. Verify needle length for intramuscular (IM) injection.

F. Administer a 0.5-mL dose of Hib-containing vaccine IM according to age and vaccine-specific schedule.

G. Hib-containing vaccines can be given with all other routinely recommended vaccines.

H. To avoid injury related to vaccine administration, make sure staff who administer vaccines recognize the anatomic landmarks and use proper IM administration technique.

I. Ask client to remain seated in the clinic for 15 minutes after vaccination to decrease the risk of injury should they faint.

Health Officer Signature Date

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3. Vaccine schedule for *Haemophilus influenzae* type b vaccines[6]

Dose and Route - 0.5 mL, IM			
Dose	**Preferred age**	**Minimum acceptable age**	**Minimum acceptable spacing**
1	2 months	6 weeks	
2	4 months	10 weeks	4 weeks dose 1 to dose 2
3	6 months	14 weeks	4 weeks dose 2 to dose 3
4	15 months	12 months	8 weeks dose 3 to dose 4

4. Licensed *Haemophilus influenzae* type b vaccines[1-5]

Product Name	Vaccine Components	Presentation	Acceptable Age Range	Thimerosal
ActHIB (PRP-T)	Hib	0.5-mL single-dose vials	6 weeks – 5 years	None

Hiberix (PRP-T)	Hib		6 weeks – 4 years	
PedvaxHIB (PRP-OMP)	Hib		6 weeks – 5 years	
Pentacel (PRP-T)	DTaP-IPV-Hib		6 weeks – 4 years	
Vaxelis (PRP-OMP)	DTaP-IPV-Hib-HepB		6 weeks – 4 years	

5. Recommendations for use[6]

Hib (PRP-T), single-antigen (ActHIB, Hiberix) or combination (Pentacel)			
Dose	**Preferred Age**	**Minimum Acceptable Age**	**Minimum Acceptable Spacing**
1	2 months	6 weeks	
2	4 months	10 weeks	4 weeks dose 1 to dose 2
3	6 months	14 weeks	4 weeks dose 2 to dose 3
4	15 months	12 months	8 weeks dose 3 to dose 4
Hib (PRP-OMP),* single-antigen (PedvaxHIB)			
Dose	**Preferred Age**	**Minimum Acceptable Age**	**Minimum Acceptable Spacing**
1	2 months	6 weeks	
2	4 months	10 weeks	4 weeks dose 1 to dose 2
3	15 months	12 months	8 weeks dose 2 to dose 3
Hib (PRP-OMP),* combination (Vaxelis)			
Dose	**Preferred Age**	**Minimum Acceptable Age**	**Minimum Acceptable Spacing**
1	2 months	6 weeks	
2	4 months	10 weeks	4 weeks dose 1 to dose 2
3◊	6 months	6 months	4 weeks dose 2 to dose 3

*PRP-OMP containing vaccines have a protective antibody response after the first dose vaccines and are preferred for Native American/Alaskan Native children to provide early protection due to their higher incidence and earlier onset of disease.[1,9]

◊A total of 4 doses of Hib-containing vaccine are needed if Vaxelis was used for any doses. Any other single-antigen Hib vaccine is acceptable.[9]

Catch-Up for Healthy Children[6]

Hib (ActHIB, Hiberix, Pentacel, Vaxelis, Mixed Brands, or Unknown Product)		
Age at First Dose	**Total Number of Doses**	**Minimum Acceptable Spacing**
<7 months	4	**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

7–11 months	3	**Doses 1 and 2**: 4-week interval **Dose 3**:12–15 months of age and at least 8 weeks after dose
12–14 months	2	**Dose 2**: at least 8 weeks after dose 1
15–59 months	1	**Complete**
Hib (PedvaxHIB)		
Age at First Dose	**Total Number of Doses**	**Minimum Acceptable Spacing**
≤11 months	3	**Doses 1 and 2**: 4-week intervals between each **Dose 3**: 12–15 months of age and at least 8 weeks after dose 2
12–14 months	2	**Dose 2**: at least 8 weeks after dose 1
15–59 months	1	**Complete**

Catch-Up for Children at High-Risk[6]

High-Risk Group	Vaccine Guidance
Patients aged <60 months undergoing chemotherapy or radiation therapy.	If routine Hib doses administered ≥14 days before starting therapy, revaccination not required. If doses administered within 14 days of starting therapy or given during therapy, repeat doses starting at least 3 months following therapy completion.
Patients aged ≥15 months undergoing elective splenectomy	If unimmunized, 1 dose prior to procedure.
Asplenic patients 5 years of age or older	If unimmunized, 1 dose.
HIV-infected children 5-18 years of age	If unimmunized, 1 dose.
HIV-infected persons ≥19 years of age	Hib immunization is not recommended.
Hematopoietic stem cell transplantation (HSCT)	3 doses beginning 6–12 months after HSCT regardless of prior Hib vaccine history

6. Contraindication[1-5,7]

A. Severe allergic reaction to a previous dose or to a vaccine component.

Components of Hib-Containing Vaccines	
Vaccine[7]	**Vaccine Excipient Summary**
Hib (ActHIB)	Sodium chloride, formaldehyde, sucrose

Hib (Hiberix)	Formaldehyde, sodium chloride, lactose
Hib (PedvaxHIB)	Amorphous aluminum hydroxyphosphate sulfate, sodium chloride
DTaP-IPV/Hib (Pentacel)	Aluminum phosphate, polysorbate 80, sucrose, formaldehyde, glutaraldehyde, bovine serum albumin, 2-phenoxyethanol, neomycin, polymyxin B sulfate
DTaP-IPV-Hib-HepB (Vaxelis)	Polysorbate 80, formaldehyde, glutaraldehyde, bovine serum albumin, neomycin, streptomycin sulfate, polymyxin B sulfate, ammonium thiocyanate, yeast protein, aluminum

7. Warnings and precautions

Pentacel[4], Vaxelis[5]

A. A history of fever ≥40.5°C (104.9°F), hypotonic-hyporesponsive episode, or persistent inconsolable crying lasting ≥3 hours within 48 hours after receipt of a pertussis-containing vaccine.

B. Encephalopathy within 7 days of a previous dose of pertussis-containing vaccine.

C. History of Guillain-Barré syndrome within 6 weeks of a prior vaccine containing tetanus toxoid.

D. For PedvaxHIB, use caution when vaccinating latex-sensitive individuals since the vial stopper contains dry natural latex rubber that may cause allergic reactions.

8. Other considerations

A. The 4th dose in a 4-dose series and the 3rd dose in a 3-dose series are considered booster doses. Any licensed single-antigen Hib vaccine can be given for these doses, regardless of previous brand of Hib received.[6]

B. All monovalent Hib vaccines are interchangeable, but if brands are mixed or unknown, a 4-dose series is recommended.[6]

C. In immunosuppressed persons, including those receiving immunosuppressive therapy, the expected antibody responses may not be obtained.[1-5]

D. 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.[8]

E. Fever-reducing medications like acetaminophen, should not be used before or at the same time as vaccinations. They can be used for fever or discomfort that

develops after vaccination. These medications have not shown to prevent febrile seizures in children with a history of febrile seizures.[8]

9. Side effects and adverse reactions[1-5]

Hib, single-antigen (ActHib, Hiberix, PedvaxHIB)	
Any local reaction—pain, redness, induration or swelling at injection site	Up to 49%
Severe pain, induration or swelling at injection site	Up to 4%
Any systemic reaction—Irritability, drowsiness, loss of appetite, fever.	Up to 70%
Severe (grade 3) systemic reactions—irritability, drowsiness	Up to 6%
Hib, combination (Pentacel, Vaxelis)	
Any local reaction—pain, redness, induration or swelling at injection site	Up to 30%
Any systemic reaction—Irritability, inconsolable crying, loss of appetite, fever.	Up to 50%

10. Storage and handling

All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
All[1-5]	2°– 8°C	Protect from light. Do not freeze.	Hiberix[2] – discard if the diluent has been frozen.

11. Adverse events reporting

Report suspected adverse events to the Vaccine Adverse Events Reporting System (VAERS) online at https://vaers.hhs.gov/reportevent.html. VAERS Reporting Table: https://vaers.hhs.gov/resources/infoproviders.html.

Event and interval from vaccination
A. Shoulder Injury Related to Vaccine Administration (7 days) B. Vasovagal syncope (7 days) C. Any acute complication or sequelae (including death) of above events (interval not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval – see package insert).

12. References

1. ActHIB® package insert. Revised March 2022. Available at www.fda.gov/media/74395/download. Accessed 31 Aug 2023.
2. Hiberix® package insert. April 2018. Available at www.fda.gov/media/77017/download. Accessed 31 Aug 2023.
3. PedvaxHIB® package insert. No date. Available at www.fda.gov/media/80438/download. Accessed 31 Aug 2023.
4. Pentacel® package insert. October 2022. Available at www.fda.gov/media/74385/download. Accessed 31 Aug 2023.
5. Vaxelis® package insert. October 2020. Available at www.fda.gov/media/119465/download. Accessed 31 Aug 2023.
6. Briere EC, Rubin L, Moro P, et al. Prevention and control of *Haemophilus influenzae* type b disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2014; 63(RR-1). Available at: www.cdc.gov/mmwr/PDF/rr/rr6301.pdf. Accessed 31 Aug 2023.
7. CDC. Vaccine Excipient Table. February 2021. Available at: www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf. Accessed 31 Aug 2023.
8. Kroger A, Bahta L, Long S, Sanchez P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html. Accessed 31 Aug 2023.
9. Oliver SE, Moore KL. Licensure of a diphtheria and tetanus toxoids and acellular pertussis, inactivated poliovirus, *Haemophilus influenzae* type b conjugate, and hepatitis B vaccine, and guidance for use in infants. MMWR 2020; 69:136–9. Available at: www.cdc.gov/mmwr/volumes/69/wr/mm6905a5.htm?s_cid=mm6905a5_w. Accessed 31 Aug 2023.

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 standing order is available at: standing orders