Immunization Protocol

Pediatric Hepatitis B Vaccines and Combos: Engerix B®; Recombivax HB®; Pediarix®, VAXELIS™	
Last Reviewed	22 July 2021
Last Revised	22 July 2021
This order expires	31 August 2023

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1. What's new

Combined previously separate "Infants with birth weight <2000 grams" (2019) and "Hepatitis B vaccine pediatric formulations" (2019) into one standing order.

Added new, hexavalent, DTaP, IPV, Hib and Hep. B combination vaccine, VAXELIS.

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 into the vastus lateralis or deltoid muscles.

F. To avoid shoulder injury related to vaccine administration, make sure staff who administer vaccines recognize the anatomic landmarks for identifying the deltoid and vastus lateralis muscles and use proper intramuscular administration technique.

G. Give hepatitis B vaccine to persons according to risk group, age, type of vaccine and vaccine status. See section 3 for schedule.

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

I. May be given with all ACIP-recommended child and adult vaccinations.

J. 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 Hepatitis B[5]

Dose and Route: 0.5 mL IM			
Dose	**Preferred age**	**Minimum acceptable age**	**Minimum acceptable spacing**
1	Birth	Birth	
2	2 months	4 weeks	4 weeks dose 1 to 2
3	6 months	6 months	8 weeks dose 2 to 3 **and** 16 weeks dose 1 to 3

4. Licensed Hepatitis B vaccines

Product Name	Vaccine Components	Presentation	Acceptable Age Range	Thimerosal
ENGERIX-B, pediatric formulation[1]	Hepatitis B	0.5-mL single-dose vials and prefilled syringes	Birth – 19 years*	None
Pediarix[3]	DTaP-IPV-Hep.B,	0.5-mL prefilled syringes	6 weeks – 6 years	
RECOMBIVAX HB, pediatric formulation[2]	Hepatitis B	0.5-mL single-dose vials and prefilled syringes	Birth – 19 years*	
VAXELIS[4]	DTaP-IPV-Hib-Hep. B.	0.5-mL single-dose vials and prefilled syringes	6 weeks – 4 years	

*Use adult formulation for persons ≥20 years of age[1,2].

5. Recommendations for use

Routine Pediatric Hepatitis B Vaccine Schedule[5]			
Dose	**Preferred Age**	**Minimum Acceptable Age**	**Minimum Acceptable Spacing**
1	Birth*	Birth	
2	2 months	4 weeks	4 weeks after dose 1
3	6 months	6 months	8 weeks after dose 2 **and** 16 weeks after dose 1

*Infants weighing <2000 grams born to HBsAg-negative mothers should receive the first dose of hepatitis B vaccine at hospital discharge or 1 month of age and will need a total of four doses for full protection (see schedule below).

DTaP-IPV-Hep. B (Pediarix)[3]			
Dose	**Preferred age**	**Minimum acceptable age**	**Minimum acceptable spacing**
1	2 months	6 weeks	
2	4 months	10 weeks	4 weeks dose 1 to 2
3	6 months	6 months	8 weeks dose 2 to 3

DTaP-IPV-Hep. B-Hib (VAXELIS)[4]			
Dose	**Preferred age**	**Minimum acceptable age**	**Minimum acceptable spacing**
1	2 months	6 weeks	
2	4 months	10 weeks	4 weeks dose 1 to 2
3	6 months	6 months	8 weeks after dose 2 **and** 16 weeks after dose 1

Hepatitis B Vaccine Schedule for Infants <2000 grams (HBsAg+ or HBsAg Unknown Mothers)[5]		
Dose	**Minimum Age**	**Minimum Acceptable Spacing**
1	Birth*	
2	1 month	4 weeks after birth dose
3	2–3 months	4 weeks after dose 2
4	6 months	8 weeks after dose 3 **and** 16 weeks after dose 1

Catch-up Hepatitis B Vaccine Schedule[5]		
Dose	**Preferred Spacing**	**Minimum Acceptable Spacing**
1	Anytime	
2	2 months after dose 1	4 weeks after dose 1
3	4 months after dose 2 **and** 6 months after dose 1	8 weeks after dose 2 **and** 16 weeks after dose 1

Alternative Hepatitis B Vaccine Schedules							
Vaccine and Formulation	Dose Volume	Number of Doses in Series	Age at First Dose	Minimum Acceptable Spacing			
				From dose 1 to 2	From dose 2 to 3	From dose 1 to 3	From dose 1 to 4
ENGERIX-B[1] (20 µg/mL)	0.5 mL	4	1–10 years	1 month	1 month	2 months	12 months
		3	11–16 years	12 months	12 months	24 months	
	1.0 mL*	4	11–18 years	1 month	1 month	2 months	12 months
		3		1 month	2 months	6 months	
RECOMBIVAX HB[2] (10 µg/mL)	1.0 mL	2	11–15 years◊	4 to 6 months			

* 1.0-mL dose recommended for persons who travel to endemic areas, sexual contacts and children born to HBsAg+ mothers.

◊ Both doses must be 1.0 mL of Recombivax HB®. Series must be completed prior to 16th birthday or an additional dose is required.

6. Contraindications[1-4]

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

B. Hypersensitivity to yeast.

Vaccine[8]	Vaccine Excipient Summary
ENGERIX-B	aluminum hydroxide, yeast protein, sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate
Pediarix	formaldehyde, aluminum hydroxide, aluminum phosphate, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B, yeast protein
RECOMBIVAX HB	formaldehyde, potassium aluminum sulfate, amorphous aluminum hydroxyphosphate sulfate, yeast protein
VAXELIS	polysorbate 80, formaldehyde, glutaraldehyde, bovine serum albumin, neomycin, streptomycin sulfate, polymyxin B sulfate, ammonium thiocyanate, yeast protein, aluminum

C. Pediarix and VAXELIS: Encephalopathy within 7 days of a pertussis-containing vaccine not attributable to another cause.

D. VAXELIS: history of progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized.

7. Warnings and precautions[1-4]

A. Apnea following IM vaccination has been observed in premature and low-birth-weight (<2000 grams) babies.

B. Higher rates of fever in infants was associated with administration of Pediarix compared to infants that received all components separately.

C. In clinical trials, VAXELIS was associated with higher rates of fever, relative to vaccination with Pentacel. Rates of fever-related medical events were similar between the two groups.

D. Guillain-Barré Syndrome (GBS) occurring within 6 weeks of a vaccine containing tetanus toxoid is a precaution for Pediarix.

E. Engerix B, Recombivax HB, and Pediarix: Dry natural rubber latex is used in the vial stopper, the syringe plunger stopper and tip cap.

8. Other considerations[5]

A. Infants born to HBsAg+ or HBsAg unknown mothers need to receive HBIG and hepatitis B vaccine within 12 hours of birth. Affected infants weighing <2000 g should receive the same treatment, but the first dose does not count towards series completion.

B. Babies born to HBsAg-positive mothers need to have post-vaccine serology for HBsAg and Hepatitis B surface antibody (anti-HBs) drawn 1 to 2 months after completing the 3-dose vaccine series, but not before 9 months of age. For more information, see the hepatitis B immune globulin order.

C. Infants that receive a birth dose of hepatitis B vaccine followed by 3 doses of a combination vaccine containing hepatitis B antigen will end up receiving 4 doses of hepatitis B vaccine. ACIP has specifically stated that this is acceptable.

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

as age-appropriate.

E. Being breast fed is not a contraindication to vaccination.

F. Adoptees born in Asia, the Pacific Islands, Africa, and other regions of high or intermediate hepatitis B endemicity should undergo serologic testing for HBsAg regardless of vaccination status. Adoptees born in countries other than those mentioned above whose records indicate receipt of ≥3 doses of vaccine can be considered protected if ≥1 dose was administered at age ≥6 months.

9. Side effects and adverse reactions[1-4]

Adverse Event	Infants and Children
ENGERIX-B[1], RECOMBIVAX HB[2], Pediarix[3]	
Pain at the injection site	Up to 9%
Fatigue, headache, other mild systemic symptoms	Up to 20%
Temperature up to 37.7 C (≤99.9°F)	Up to 6%
Any severe reaction	Less than 1%
VAXELIS[4]	
Pain at the injection site	Up to 44%
Irritability, crying, somnolence	Up to 55%
Temperature up to 38 C (100.4°F)	Up to 19%
Redness, swelling, decreased appetite, vomiting	Up to 25%

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[1-4]	Temp	Storage Issues
Engerix B, Pediarix, Recombivax HB, Vaxelis	Store at 2°–8° C	Do not use if vaccine 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

VAERS Reporting Table: https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

Event and interval from vaccination
A. Anaphylaxis or anaphylactic shock (7 days)
B. Brachial neuritis (28 days)
C. Shoulder injury related to vaccine administration (7 days)
D. Vasovagal syncope (7 days)
E. Any acute complications or sequelae (including death) of the above event (interval not applicable)
F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval: see package insert.

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).[6]

12. References

1. ENGERIX-B® package insert. 2019. Available at: www.fda.gov/media/119403/download. Accessed 14 July 2021.
2. RECOMBIVAX HB® package insert. 2018. Available at: www.fda.gov/media/74274/download. Accessed 14 July 2021.
3. Pediarix® package insert. 2019. Available at: www.fda.gov/media/79830/download. Accessed 14 July 2021.
4. VAXELIS™ package insert. October 2020. Available at: www.fda.gov/media/119465/download. Accessed 14 July 2021.
5. Schillie S, Vellozzi C, Reingold A, et al. Prevention of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices. MMWR 2018; 67(RR-1):1–31. Available at www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm?s_cid=rr6701a1_w. Accessed 24 July 2020.
6. 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 24 July 2020.

7. Ezeanolue E, Harriman K, Hunter P, Kroger A, Pellegrini C. General Best Practice Guidelines for Immunization. 2017. Available at: www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html. Accessed 24 July 2020.
8. Centers for Disease Control and Prevention. Vaccine Excipient Summary. Available at: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf. Accessed 10 July 2020

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

Electronic copy of this pharmacy protocol is available at: protocols