

OREGON HEALTH AUTHORITY
IMMUNIZATION PROTOCOL FOR PHARMACISTS
HEPATITIS B VACCINES AND COMBOS:
Recombivax HB^{®1} Engerix-B^{®2} Pediarix^{®3} Twinrix^{®4}

Revisions as of 01-01-2016

- Vaccination age changed to clients ≥ 7 years of age
- Comvax[®] discontinued
- Addition of Healthcare Provider (HCP) postexposure management. See section V table 4 on pages 16–17
- Addition of post-vaccination serology when indicated

NOTE: Please refer clients to their primary care provider or local health department if you suspect the client has been exposed to HBV.

I. OREGON IMMUNIZATION PHARMACY PROTOCOL:

1. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.
2. Screen clients ≥ 7 years of age for contraindications.
3. Provide a current Vaccine Information Statement (VIS) and answer any questions.
4. Record all required data elements in the client's permanent health record.
5. Give hepatitis B vaccine to persons according to risk group, age, type of vaccine and vaccine status.
6. This vaccine may be given with all ACIP–recommended child and adult vaccinations.
7. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.

Note: Give hepatitis B vaccine by IM injection only in the deltoid for adults and children ≥ 36 months of age.

Immunizing Pharmacist Signature

Date

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

Revised: 01-2016

Original: 01-2006



II. A. LICENSED MONOVALENT HEPATITIS B VACCINES*

PRODUCT NAME	VACCINE COMPONENTS	ACCEPTABLE AGE RANGE	THIMEROSAL
Recombivax HB ^{®1}	Hepatitis B	Birth through Adult	No
Engerix-B ^{®2}	Hepatitis B	Birth through Adult	No

*The immune response when doses of hepatitis B vaccine from one manufacturer are followed by subsequent doses from a different manufacturer has been shown to be comparable to the response after a full series using vaccine from a single manufacturer.¹²

II. B. LICENSED COMBINATION HEPATITIS B VACCINE

PRODUCT NAME	VACCINE COMPONENTS	ACCEPTABLE AGE RANGE	THIMEROSAL
Pediarix ^{®3}	DTaP (Infanrix [®]) IPV Hepatitis B (EngerixB [®])	6 weeks to 7 years of age	No
Twinrix ^{®4} *	Hepatitis A (Havrix [®]) and Hepatitis B (EngerixB [®])	≥18 years of age	Trace (< 1 mcg)

* Twinrix[®] is NOT approved for use in persons ≤17 years of age.

III. RECOMMENDATIONS FOR USE:

Pre-exposure Prophylaxis

1. Hepatitis B vaccination is recommended for all infants, children and adolescents ages birth through 18 years regardless of whether the patient has known risk factors for contracting hepatitis B.⁵
2. All unvaccinated adults at risk for hepatitis B virus (HBV) infection and adults seeking protection from HBV infections (e.g., health and public safety workers). Acknowledgment of a specific risk factor is not a requirement for vaccination.⁶
3. All previously unvaccinated diabetics (type 1 or type 2) 19—59 years of age.⁸
4. In the following settings where a high proportion of adults are likely to have risk factors for HBV infection all unvaccinated adults should receive Hepatitis B vaccine:⁷
 - Sexually transmitted disease (STD) treatment facilities,
 - Human immunodeficiency virus (HIV) testing and treatment facilities,
 - Facilities providing drug abuse treatment and prevention,
 - Correctional facilities,
 - College health services,
 - Chronic hemodialysis facilities and end-stage renal disease programs,
 - Institutions and nonresidential daycare facilities for developmentally disabled persons,
 - Health care settings targeting services to injection-drug users and
 - Health care settings targeting services to men who have sex with men.
5. Hepatitis C-positive individuals⁹
6. Immigrants, refugees, or adoptees from countries where HBV infection is endemic, and their household members.^{5, 10}
7. International travelers to areas with intermediate to high rates of HBV infection and who will have close contact with the local population.¹⁰
8. Alaska Natives and Pacific Islanders.⁷
9. Individuals engaged in commercial sex work.

IV. A. VACCINE SCHEDULE

A. Premature Infant Vaccine Schedule (weight < 2000 grams)				
DOSE 0.5 ml	Born to HBsAg- POSITIVE or UNKNOWN Moms Minimum age	Minimum spacing[*]	Born to HBsAg- NEGATIVE Moms³ Minimum age	Minimum spacing[*]
1	Birth (0-12 hrs.) [◇]		4 weeks [§]	
2	4 weeks [‡]	4 weeks after birth dose #1	8 weeks	4 weeks after dose #1
3 ^{**}	8 weeks	4 weeks after dose #2	24 weeks ^{**}	8 weeks after dose #2 ^{**}
4	24 weeks	8 weeks after dose #3 and 16 weeks after dose #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 age appropriate.¹²

[◇] Premature infants born to HBsAg-Positive mothers and mothers with unknown HBsAg status must receive immunoprophylaxis with hepatitis B vaccine and hepatitis B immunoglobulin (HBIG) within 12 hours after birth. This initial dose of vaccine should not be counted towards completion of the hepatitis B vaccine series. Three (3) additional doses of hepatitis B vaccine should be administered, beginning when the infant is \geq 1 month of age.⁵

[§] The 1st dose of hepatitis B vaccine for premature infants (<2000 grams) born to HBsAg-negative mothers can be given at \geq 1 month of age, including infants who remain in hospital. Preterm infants discharged from hospital before chronological

age of 1 month can also be administered HepB vaccine at discharge, if medically stable and have gained weight consistently.⁵

‡ CHRONOLOGICAL age of 1 month (4 weeks since birth date).

** A 3rd dose will complete the HepB series provided that the 3rd dose is given at ≥ 24 weeks of age, at least 8 weeks after the 2nd dose, and follows the 1st dose by at least 16 weeks. If the 3rd HepB dose is administered before 24 weeks of age, then a 4th dose is required at ≥ 6 months of age to complete the series.⁶

Note: For low-birth-weight infants born to women of unknown status, every effort should be made to determine maternal HBsAg status at the hospital within 12 hours of delivery. If the mother's status remains unknown after 12 hours following delivery, proceed with hepatitis B prophylaxis (vaccine and HBIG)⁶

IV. B. VACCINE SCHEDULE: ≥Full Term⁵

DOSE 0.5 ml	Born to HBsAg- POSITIVE^{§§} or UNKNOWN Moms Minimum age	Minimum spacing[*]	Post vaccine serology testing of HBsAg-POSITIVE Moms only⁶	Born to HBsAg- NEGATIVE Moms³ Minimum age	Minimum spacing[*]
1	Birth (0-12 hrs.) [◇]		Test for HBsAg and antibody to HBsAg 1–2 months after completion of ≥3 doses of a licensed hepatitis B vaccine series. Testing should not be performed before age 9 months nor within 4 weeks of the most recent vaccine dose. ^{◇◇}	4 weeks [§]	
2	4 weeks [‡]	4 weeks after birth dose #1		8 weeks	4 weeks after dose #1
3 ^{**}	8 weeks	4 weeks after dose #2		24 weeks ^{**}	8 weeks after dose #2 ^{**}
4	24 weeks	8 weeks after dose #3 and 16 weeks after dose #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 age appropriate.¹²

◇ Premature infants born to HBsAg-Positive mothers and mothers with unknown HBsAg status must receive immunoprophylaxis with hepatitis B vaccine and hepatitis B immunoglobulin (HBIG) within 12 hours after birth. This initial dose of vaccine should not be counted towards completion of the hepatitis B vaccine series. Three (3) additional doses of hepatitis B vaccine should be administered, beginning when the infant is ≥ 1 month of age.⁵

§ The 1st dose of hepatitis B vaccine for premature infants (<2000 grams) born to HBsAg-negative mothers can be given at ≥ 1 month of age, including infants who remain in hospital. Preterm infants discharged from hospital before chronological age of 1 month can also be administered HepB vaccine at discharge, if medically stable and have gained weight consistently.⁵

‡ CHRONOLOGICAL age of 1 month (4 weeks since birth date).

** A 3rd dose will complete the HepB series provided that the 3rd dose is given at ≥ 24 weeks of age, at least 8 weeks after the 2nd dose, and follows the 1st dose by at least 16 weeks. If the 3rd HepB dose is administered before 24 weeks of age, then a 4th dose is required at ≥ 6 months of age to complete the series.⁶

◇◇ Response to Revaccination: A study of infants born to HBsAg-positive mothers who did not respond to a primary vaccine series indicated that all those not infected with HBV responded satisfactorily to a repeat 3-dose revaccination series. No data suggest that children who have no detectable antibody after 6 doses of vaccine would benefit from additional doses.⁵

§§ See Section X. Post-vaccine serology, #5 for Hepatitis-E antigen testing.

Note: For low-birth-weight infants born to women of unknown status, every effort should be made to determine maternal HBsAg status at the hospital within 12 hours of delivery. If the mother’s status remains unknown after 12 hours following delivery, proceed with hepatitis B prophylaxis (vaccine and HBIG) ⁵

IV. C. VACCINE SCHEDULE^{1, 2, 3}

B. Routine Infant and Child Vaccine Schedule					
Minimum Age and Dosage Intervals for					
Single and Combination Vaccines ^{* ◊}					
Vaccine 0.5 ml Dose	Minimum age at first dose	Minimum interval from dose 1 to 2	Minimum interval from dose 2 to 3	Minimum interval from dose 1 to 3	Minimum Age at third dose
Infants and children					
Recombivax HB [®] Engerix-B [®]	Birth ^{◊,§,‡}	4 weeks	8 weeks	16 weeks	24 weeks ^{**}
PEDIARIX ^{®◊◊,§§,‡‡}	6 weeks	4 weeks	8 weeks	16 weeks	24 weeks ^{**}

* 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.¹²

◊ All infants should receive the first dose of HepB vaccine soon after birth and before hospital discharge. The 1st dose may be delayed until age 2 months if the infant’s mother is HBsAg-negative.⁵

§ Infants born to HBsAg-positive mothers need 0.5 ml Hep B Immune Globulin (HBIG) administered IM concurrently with hepatitis B vaccine at different sites,

within 12 hours of birth. Efficacy of HBIG given at 12-48 hours is presumed. OHA does not provide HBIG.⁵

‡ Mothers who are HBsAg-unknown should be tested when they arrive for delivery. While test results are pending, newborns should receive the first dose of hepatitis B vaccine. If the mother is found to be HBsAg-positive, the infant should also receive 0.5 ml HBIG as soon as possible but not more than 7 days after birth.⁵

** The last dose of hepatitis B vaccine should not be given to infants before 24 weeks of age. If a 3rd dose is administered before 24 weeks of age, then a 4th dose is required at ≥ 6 months of age to complete the series. Recommended age for receipt of the 3rd dose of hepatitis B vaccine is 6-18 months of age.⁵

◇◇ Three doses of combination vaccines may be given to complete the hepatitis B vaccine series after the preferred dose at birth. Combination vaccines cannot be given before 6 weeks of age. Four doses of a HepB-containing vaccine may be administered when the HepB birth dose is given.⁵

§§ Pediarix[®] is approved by ACIP for use in children born to HBsAg+ and HBsAg unknown women, but not for the HepB birth dose.^{3, 5}

‡‡ The recommended ages for the three dose Pediarix[®] series in infants are; 2 months, 4 months, and ≥ 6 months. However, Pediarix[®] can be used for children behind schedule as long as given for only doses 1, 2 or 3 of HepB, DTaP, and IPV series and child is < 7 years old.³

IV. D. VACCINE SCHEDULE^{1, 2, 4}

C. Adolescent Vaccine Schedules (11 through 19 years)*

Minimum Age and Dosage Intervals for single and Combination vaccines[§]

Vaccine & Dose	Dose Volume	Number of doses in series	Minimum age at first dose	Minimum interval from dose 1 to 2	Minimum interval from dose 2 to 3 (when applicable)	Minimum interval from dose 1 to 3 (when applicable)
Engerix-B (20mcg/mL) and Recombivax HB (10mcg/mL) with pediatric 0.5mL dose for 11–19 year olds	0.5mL (10mcg/mL)	3	11 years	4 weeks	8 weeks	16 weeks
Recombivax HB: 2-dose schedule with adult 1.0 ml dose for 11–15 yr. Olds ^{°, ‡, **}	1.0mL (10mcg/mL) (adult formula)	2	11 years	16 weeks	N/A	N/A
Engerix-B for 11–19 year olds. (Accelerated) ^{°°}	1.0mL (10mcg/mL)	3	11 years	4 weeks	8 weeks	16 weeks
Twinrix: 3-dose schedule as combined Hep A and Hep B vaccine ^{§§}	1.0mL	3	18 years	4 weeks	20 weeks	6 months
Twinrix 4-dose (Accelerated schedule) ¹⁵	1.0mL	4	18 years	7 days	21–30 days	12 months after dose 1

* If 317- funded adolescents start any HepB series before their 19th birthday, they may complete the series with state-supplied vaccine until they turn 20. Per OIP policy.

◇ If using Recombivax to vaccinate 11–15 year olds, may use adult formula and 2 doses.⁵

§ 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.¹²

‡ This schedule approved only for use with Merck’s Recombivax HB® vaccine. This 2-dose schedule should be completed by 16 years of age.¹³

** If the schedule is started with 1.0 ml of Recombivax HB vaccine, the 2nd dose must also be 1.0 ml of Recombivax HB®. If Recombivax® is not available for dose #2, you must return to a 3-dose schedule and a pediatric dosage to complete the series, regardless of vaccine brand.¹³

◇◇ If using Engerix-B® to vaccinate an 11-19 year old high-risk client (kids born to HBsAg⁺ moms, sexual contacts, travelers to endemic areas, needle-stick victims, etc.) a 1.0 ml dose is recommended.¹¹

§§ The use of a combined vaccine containing hepB is acceptable as long as one antigen is indicated and the other antigen is not contraindicated.^{5, 12, 13, 14}

IV. E. VACCINE SCHEDULE

<p>D. Adult Schedules: ≥19 years of age* Recombivax HB[®] 1 (10mcg/mL), Engerix-B[®] 2 and Twinrix[®]4 (20mcg/mL): Dose Volume for clients ≥20 years of age = 1.0mL Route: IM into the deltoid muscle</p>		
DOSE	MINIMUM SPACING [◇]	MINIMUM AGE
1		20 years
2	4 weeks after dose #1	
3	8 weeks after dose #2 and 16 weeks after dose #1	
Twinrix[®]4		
1		≥18 years of age
2	4 weeks after dose #1	
3	20 weeks after dose #2 and 6 months from dose #1	
Twinrix[®] Accelerated Schedule^{4, 15}		
1		≥18 years of age
2	7 days	
3	21–30 days	
4	12 months from dose 1	

* The usual schedule for adults is two doses separated by no less than 4 weeks, and a third dose 4-6 months after the second dose. If an accelerated schedule is needed, minimum spacing can be used.⁷

◇ 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.¹²

IV. F. VACCINE SCHEDULE

E. Hemodialysis ¹³ and other Immunocompromised Persons Schedule	Single-Antigen Vaccine						Post vaccine serology testing
	Recombivax HB			Engerix-B			
	# of doses [◇]	Dose (mcg)	Volume (ml)	# of doses [§]	Dose (mcg)	Volume (ml)	
<20 years*	3	5	0.5	3	10	0.5 ml	annually [‡]
≥20 years	3	40 [◇]	1.0	4	40 [§]	2.0 ml	

* Higher doses might be more immunogenic, but no specific recommendations have been made.

◇ Dialysis formulation administered on a 3-dose schedule at age 0, 1, and 6 months.

§ Two 1.0 ml doses administered in 1 or 2 injections on a 4-dose schedule at 0, 1, 2, and 6 months

‡ Booster doses should be provided when antibody levels decline below 10 mIU/mL.

V. POST-EXPOSURE PROPHYLAXIS GUIDELINES ¹⁶ See separate HBIG Oregon Model Standing Order.

Table 1. Postexposure prophylaxis for perinatal HBsAg+ source					Post vaccination Serology Testing
HBIG¹⁷			VACCINE		
Exposure	Dose	Recommended timing	Dose	Recommended timing	
Perinatal*	0.5 ml IM	Within 12 hours of birth	0.5 ml IM	Within 12 hours of birth	≥ 3 months and ≤4 weeks after last dose and ≤9 months after series completion

* For premature infants born to positive moms, see Section IV. Table A.

◇ For age-specific dose, see Section IV. Tables B–F.

V. Table 2. Post-exposure prophylaxis for sexual exposures to HBsAg+ source					Post vaccination Serology Testing
HBIG^{16, 17*}			VACCINE		
Exposure	Dose	Recommended timing	Dose	Recommended timing	
Sexual	0.06 ml/kg IM	Single dose ASAP, but not more than 14 days after last sexual contact	Varies [◇]	First dose at same time as HBIG; in different anatomical site	1–2 months after series completion

* See separate Oregon immunization model standing order for hepatitis b immune globulin

◇ For age-specific dose, see Section IV. Tables A–F.

V. Table 3. Postexposure prophylaxis following percutaneous or permucosal exposure¹⁷ *			
Exposed person	Source HBsAg positive	Source HBsAg negative	Source status unknown
Unvaccinated	HBIG x 1 and start HB vaccine	Start vaccine	Start vaccine
Previously Vaccinated			
Documented responder	No treatment	No treatment	No treatment
Documented non-responder to single series	HBIG x1 [◇] plus 1 dose vaccine; test for anti-HBs 4–6 mo. later. If inadequate titer give additional 2 doses of vaccine	No treatment	If known high–risk source, may treat as if HBsAg ⁺
Documented non-responder to ≥4 or more doses	HBIG x2 (1 month apart)	No treatment	If known high-risk source, may treat as if HBsAg ⁺
Response never documented	Test exposed for anti-HBs: if adequate, no treatment; if inadequate, HBIG x 1 plus HB vaccine booster dose; test 4–6 mo. later	No treatment	Test exposed for anti-HBs: if adequate, no treatment; If inadequate, HB vaccine booster dose.

* For Healthcare Providers (HCP) see Section V, Table 4, next page.

[◇]HBIG dose = 0.06mL/kg IM¹⁸

V. Table 4. Postexposure management of healthcare personnel (HCP) after occupational percutaneous and mucosal exposure to blood and body fluids, by HCP hepatitis b vaccination and response status¹⁸

HCP personnel status	Postexposure testing		Postexposure prophylaxis		Postvaccination serologic testing [◊]
	Source patient (HBsAG)	HCP testing (anti-HBs)	HBIG [*]	Vaccination	
Documented responder [§] after complete series (≥3 doses)	No action needed				
Documented nonresponder [‡] after 6 doses	Positive/unknown	**	HBIG x2 separated by a month		No
	Negative	No action needed			
Response unknown after 3 doses	Positive/unknown	≤10mIU/mL ^{**}	HBIG x 1	Initiate revaccination	Yes
	Negative	≤10mIU/mL	None		
	Any result	≥10mIU/mL	No action needed		
Unvaccinated/incompletely vaccinated or vaccine refusers	Positive/unknown	**	HBIG x 1	Complete vaccination	Yes
	Negative		None	Complete vaccination	Yes

* HBIG should be administered intramuscularly as soon as possible after exposure when indicated. The effectiveness of HBIG when administered >7 days after percutaneous, mucosal, or non-intact skin exposures is unknown. HBIG dosage is 0.06 mL/kg. HBIG is administered by intramuscular injection; an appropriate muscle mass (i.e., deltoid or lateral thigh)

should be chosen in which to deliver the large volume of HBIG required and a needle length appropriate for the HCP's size should be used. HBIG can be administered simultaneously with HepB vaccine but at a different injection site.

◇ Should be performed 1–2 months after the last dose of the HepB vaccine series (and 4–6 months after administration of HBIG to avoid detection of passively administered anti-HBs) using a quantitative method that allows detection of the protective concentration of anti-HBs (≥ 10 mIU/mL).

§ A responder is defined as a person with anti-HBs ≥ 10 mIU/mL after ≥ 3 doses of HepB vaccine.

‡ A nonresponder is defined as a person with anti-HBs < 10 mIU/mL after ≥ 6 doses of HepB vaccine.

** HCP who have anti-HBs < 10 mIU/mL, or who are unvaccinated or incompletely vaccinated, and sustain an exposure to a source patient who is HBsAg-positive or has unknown HBsAg status, should undergo baseline testing for HBV infection as soon as possible after exposure, and follow-up testing approximately 6 months later. Initial baseline tests consist of total anti-HBc; testing at approximately 6 months consists of HBsAg and total anti-HBc.

VI. CONTRAINDICATIONS

A. Pediarix^{®3} RecombivaxHB^{®1} Engerix-B^{®2} Twinrix^{®4}:

Hypersensitivity to baker's yeast, neomycin, the preservative thimerosal, or any other component of the vaccine.

Severe allergic reaction or anaphylactic response after a previous dose.

Moderate or severe acute illness with or without fever should be deferred until illness resolves.

B. Pediarix[®] pertussis and tetanus components³:

Encephalopathy within 7 days of administration of a previous dose of a pertussis-containing vaccine that is not attributable to another identifiable cause is a contraindication to administration of any pertussis-containing vaccine, including Pediarix[®].

C. Progressive Neurologic Disorder, including infantile spasms, uncontrolled epilepsy, or progressive encephalopathy is a contraindication to administration of any pertussis-containing vaccine.

D. Guillian-Barré Syndrome (GBS): If GBS occurs within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, careful consideration of the potential benefits and risks should be evaluated.

VII. PRECAUTIONS

A. Pediarix^{®3} RecombivaxHB^{®1} Engerix-B^{®2}:

Fever in infants was associated with higher rates relative to separately administered vaccines.³

Apnea following IM vaccination has been observed in some infants born prematurely.

B. RecombivaxHB^{®1}: Dry natural rubber latex **is used** in the vial stopper, the **syringe plunger stopper and tip cap**.

C. Pediarix^{®3} Engerix-B^{®2} Twinrix^{®4}:

Dry latex rubber in tip caps may cause allergic reactions in latex-sensitive individuals.

VIII. SIDE EFFECTS AND ADVERSE EVENTS²¹

Event	Adults	Infants and children
Pain at injection site	13% - 29%	3% - 9%
Mild systemic complaints (fatigue, headache)	11% - 17%	0 –20%
Temperature up to 37.7 C (≤99.9°F)	1%	0.4% -6%
Severe systemic reactions	Rare	Rare

IX. OTHER CONSIDERATIONS

- 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.¹²
- Lactation:** Breast feeding is not a contraindication to vaccination for mother or infant. HBsAg-positive women should be encouraged to breast feed; breast-feeding does not pose any additional risk of exposure to the infant.¹⁹
- DO NOT RESTART A SERIES.** Count the number of doses the recipient has had and give the next dose due, observing client age and minimum spacing.^{5, 7}
- Pregnancy:** Hepatitis B vaccine is approved for use in pregnancy and should be given to pregnant women.¹³
- Hemodialysis** patients require special formulation and/or dosage. See Section IV. C, page 6.⁵

6. **Internationally adopted children.** Adoptees born in Asia, the Pacific Islands, Africa, and other regions of high or intermediate HepB endemicity should undergo serological testing for hepatitis B surface antigen (HBsAg) regardless of vaccination status. If positive they should be monitored for development of liver disease. Household members of HBsAg-positive children should be vaccinated. 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. Those not known to be vaccinated for hepB or who have received < 3 doses should receive age-appropriate doses to complete their series.¹²
7. **Immune response** when one or two doses of vaccine from manufacturer are followed by subsequent doses from a different manufacturer has been shown to be comparable to a full course of vaccination with a single vaccine.¹¹
8. **Booster doses:** When anti-HBs levels decline to ≤ 10 mIU/mL per annual antibody testing, booster doses should be considered for those with an ongoing risk for exposure:
 - a. **Hemodialysis patients**
 - b. **For other immunocompromised persons:** (e.g., HIV-infected persons, hematopoietic stem-cell transplant recipients, and persons receiving chemotherapy), the need for booster doses has not been determined.
 - c. For **children and adults with normal immune status**, a booster dose is not recommended, nor is serologic testing to assess antibody levels.²⁰

X. POST-VACCINATION SEROLOGY¹³

1. Post-vaccination testing includes serological screening for two different markers, each for a specific reason:
 - a. **HBsAg:** to determine whether they have become infected with the hepatitis B virus; **AND**
 - b. **HBsAb (Anti-HBs):** to determine whether the vaccine was effective in mounting an immune response in the recipient.
2. Vaccine recipients who do not develop a serum antibody response (a HBsAb titer of ≥ 10 mIU/ml or “positive” result) after the primary series should be revaccinated with a complete series prior to re-testing.

3. No cost testing is available to local health departments through the Oregon State Public Health Laboratory. This will be maintained as long as funding is available to support this testing. There is a charge for testing ordered by private providers. For information about sample collection, storage, and transport, refer to the OSPHL Lab Test Menu at www.healthoregon.org/labtests.
4. The OSPHL offers serologic testing for HBsAg, anti-HBs, and anti-HBc (IgM and total). **E antigen testing is not routinely available, but may be arranged under special circumstances;** consult with the Acute and Communicable Disease Program (ACDP) at 971-673-1111. For more information, refer to the OSPHL Lab Test Menu at www.healthoregon.org/labtests. The OSPHL does not perform PCR testing for hepatitis B virus. *

* **HBeAg** (Hepatitis B e-antigen): This is a viral protein that is secreted by hepatitis B infected cells. It is associated with chronic hepatitis B infections and is used as a marker of active viral disease and a patient's degree of infectiousness.

A **positive result** indicates the person has high levels of virus and greater infectiousness.

A **negative result** indicates low to zero levels of virus in the blood and a person is considered less infectious.²³

XI. 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

Hepatitis B vaccines^{1, 2, 3, 4}

Vaccine	Temp	Storage Issues	Notes
Pediarix [®]	Store at 2°–8°C	Do not use if vaccine has been frozen.	Report to health educator
Engerix–B [®]	Store at 2°–8°C	Do not use if vaccine has been frozen. Do not dilute to administer	Report to health educator
Recombivax HB [®]	Store at 2°–8°C	Do not use if vaccine has been frozen.	Report to health educator
Twinrix [®]	Store at 2°–8°C	Do not use if vaccine has been frozen.	Report to health educator

XII. ADVERSE 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).
24, 25

TABLE C. Events Reportable to VAERS²²

Vaccine	Event and interval from vaccination
Vaccines containing Hepatitis B	<ol style="list-style-type: none"> 1. Anaphylaxis or anaphylactic shock (7 days). 2. Any acute complications or sequelae (including death) of the above event (interval not applicable). 3. Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval—see package insert).

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>

REFERENCES

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