OREGON HEALTH AUTHORITY
IMMUNIZATION PROGRAM
HEPATITIS B VACCINES AND COMBOS:
Recombivax HB®₁ Engerix-B®₂ Pediarix®₃ Twinrix®₄

Revisions as of 06-01-2017

- Comvax® discontinued
- Addition of pre- and post-vaccination serology when indicated. Section V.B.

I. OREGON IMMUNIZATION MODEL STANDING ORDER:

1. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.
2. Screen clients 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. Babies born to HBsAg-positive mothers need to have post vaccine serology for HBsAg and anti-HBs drawn 1 to 2 months after completing the 3-dose vaccine series, but not before 9 months of age.
7. May be given with all ACIP-recommended child and adult vaccinations.
8. Observe client for 15 minutes after vaccination to decrease the risk for injury should they faint.

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

_______________________________________________________
Signature Health Officer or Medical Provider Date

_______________________________________________________
Signature Health Officer or Medical Provider Date

Revised: 07-2017 Expires July 31, 2018
Original: 01-2006
II. A. LICENSED MONOVALENT HEPATITIS B VACCINES*

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>VACCINE COMPONENTS</th>
<th>ACCEPTABLE AGE RANGE</th>
<th>THIMEROSAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recombivax HB®¹</td>
<td>Hepatitis B</td>
<td>Birth through Adult</td>
<td>No</td>
</tr>
<tr>
<td>Engerix-B®²</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*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.⁵

II. B. LICENSED COMBINATION HEPATITIS B VACCINE

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>VACCINE COMPONENTS</th>
<th>ACCEPTABLE AGE RANGE</th>
<th>THIMEROSAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediarix®³</td>
<td>DTaP (Infanrix®)</td>
<td>6 weeks to 7 years of age</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>IPV Hepatitis B</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(EngerixB®)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Twinrix®⁴ *</td>
<td>Hepatitis A (Havrix®) and Hepatitis B (EngerixB®)</td>
<td>≥18 years of age</td>
<td>Trace (&lt; 1 µg)</td>
</tr>
</tbody>
</table>

* Twinrix® is NOT approved for use in persons <18 years of age.
III. RECOMMENDATIONS FOR USE:

Pre-exposure Prophylaxis

1. All infants, children and adolescents ages birth through 18 years regardless of whether the patient has known risk factors for contracting hepatitis B.6

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.8

3. All previously unvaccinated persons with diabetes mellitus (type 1 or type 2) 19—59 years of age.10

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:9
   - 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. Adults with chronic liver disease, including, but not limited to, Hepatitis C virus infection, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, and an alanine aminotransferase (ALT) or aspartate aminotransferase (AST) level greater than twice the upper limit of normal.11

6. Immigrants, refugees, or adoptees from countries where HBV infection is endemic, and their household members.6,12

7. International travelers to areas with intermediate to high rates of HBV infection and who will have close contact with the local population.12

8. Alaska Natives and Pacific Islanders.9

9. Individuals engaged in commercial sex work.
IV.A. VACCINE SCHEDULE: Premature Infant Vaccine Schedule (weight < 2000 grams)

<table>
<thead>
<tr>
<th>DOSE (0.5 mL)</th>
<th>Born to HBsAg-POSITIVE§§ or UNKNOWN Moms Minimum age</th>
<th>Minimum spacing*</th>
<th>Born to HBsAg-NEGATIVE Moms³ Minimum age</th>
<th>Minimum spacing*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Birth (0–12 hrs.)◊</td>
<td>Within 24 hours of birth§ but no later than age 7 days.⁷</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>4 weeks ‡</td>
<td>4–8 weeks⁷</td>
<td>4 weeks after dose #1</td>
<td></td>
</tr>
<tr>
<td>3 **</td>
<td>8 weeks</td>
<td>4 weeks after dose #2</td>
<td>24 weeks</td>
<td>8 weeks after dose #2</td>
</tr>
<tr>
<td>4</td>
<td>24 weeks</td>
<td>8 weeks after dose #3 and 16 weeks after dose #1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* 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

◊ Premature infants born to HBsAg-Pos 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.⁶
§Preterm infants discharged from the hospital before the chronological age of 1 month can be administered Hep B vaccine at discharge, if medically stable and have gained weight consistently.⁶

‡CHRONOLOGICAL age of 1 month (4 weeks since birth date). Monovalent HepB vaccines should be used for doses administered before 6 weeks of age.⁷

**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 at least 16 weeks after the 1st dose. 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.⁸

Administration of a total of 4 doses of HepB vaccine is permitted when a combination vaccine containing HepB is administered after the birth dose.⁷

◊◊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.⁶

§§See Section V. Post-vaccine serology, page 16 for HBeAg, Hepatitis B 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 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. ROUTINE VACCINE SCHEDULE: C. Routine Infant through age 10 years Vaccine Schedule

Minimum Age and Dosage Intervals for Single and Combination Vaccines

<table>
<thead>
<tr>
<th>Vaccine (0.5-mL dose)</th>
<th>Minimum age at first dose</th>
<th>Minimum interval*</th>
<th>Minimum age at third dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>dose 1 to 2</td>
<td>dose 2 to 3</td>
</tr>
<tr>
<td>Recombivax HB®</td>
<td>Birth◊§‡</td>
<td>4 weeks</td>
<td>8 weeks</td>
</tr>
<tr>
<td>Engerix-B®</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PEDIARIX®◊◊‡‡‡</td>
<td>6 weeks</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* 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.  

◊ All infants should receive the first dose of HepB vaccine within 24 hours of birth. The 1st dose may be delayed until age 2 months if the infant’s mother is HBsAg-negative.

§ 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. To request HBIG, see instructions available at: [http://public.health.oregon.gov/DiseasesConditions/CommunicableDisease/ReportingCommunicableDisease/ReportingGuidelines/Documents/state-supplied-prophy.pdf](http://public.health.oregon.gov/DiseasesConditions/CommunicableDisease/ReportingCommunicableDisease/ReportingGuidelines/Documents/state-supplied-prophy.pdf).

‡ 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.⁶

** 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.⁶

◊◊ Pediarix® is approved by ACIP for use in children born to HBsAg+ and HBsAg unknown women, but not for the HepB birth dose.⁶ 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.⁶

‡‡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 in children <7 years old.³
### IV. C. VACCINE SCHEDULE: for Adolescents ages 11 through 18 years*

### Minimum age and dosage intervals for single and combination vaccines§ 1, 2, 4

<table>
<thead>
<tr>
<th>Vaccine &amp; Dose</th>
<th>Dose Volume</th>
<th>Number of doses in series</th>
<th>Minimum age at first dose</th>
<th>Minimum interval from dose 1 to 2</th>
<th>Minimum interval from dose 2 to 3 (when applicable)</th>
<th>Minimum interval from dose 1 to 3 (when applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engerix-B (20 µg/mL) and Recombivax HB (10 µg/mL) with pediatric 0.5-mL dose for 11–19 year olds</td>
<td>0.5 mL (10 µg/mL)</td>
<td>3</td>
<td>11 years</td>
<td>4 weeks</td>
<td>8 weeks</td>
<td>16 weeks</td>
</tr>
<tr>
<td>Recombivax HB: 2-dose schedule with adult 1.0 mL dose for 11–15 year olds◊</td>
<td>1.0 mL (10 µg/mL) (adult formula)</td>
<td>2</td>
<td>11 years</td>
<td>16 weeks</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Engerix-B for 11–19 year olds at high risk.§</td>
<td>1.0 mL (10 µg/mL)</td>
<td>3</td>
<td>11 years</td>
<td>4 weeks</td>
<td>8 weeks</td>
<td>16 weeks</td>
</tr>
<tr>
<td>Twinrix for ≥18 year olds: 3-dose schedule as combined Hep A and Hep B vaccine ‡</td>
<td>1.0 mL</td>
<td>3</td>
<td>18 years</td>
<td>4 weeks</td>
<td>20 weeks</td>
<td>6 months</td>
</tr>
<tr>
<td>Twinrix 4-dose (Accelerated schedule)¹³</td>
<td>1.0 mL</td>
<td>4</td>
<td>18 years</td>
<td>7 days</td>
<td>21–30 days◊</td>
<td>12 months after dose 1</td>
</tr>
</tbody>
</table>
* 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.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

Twinrix® accelerated schedule has a minimum of 11 months between dose 3 and 4.

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.14

This schedule approved only for use with Merck’s Recombivax HB® vaccine. This 2-dose schedule should be completed by 16 years of age.14

§ 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.15

‡ The use of a combined vaccine containing hepB is acceptable as long as one antigen is indicated and the other antigen is not contraindicated.6
IV. D. VACCINE SCHEDULE: E. Adult Schedules: ≥19 years of age*

Recombivax HB® Engerix–B® and Twinrix® Dose Volume for clients ≥20 years of age = 1.0 mL

Route: IM into the deltoid muscle

<table>
<thead>
<tr>
<th>Recombivax HB 1(10mcg/mL)</th>
<th>Engerix-B 2(20mcg/mL)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DOSE</strong></td>
<td><strong>MINIMUM SPACING 0</strong></td>
<td><strong>MINIMUM AGE</strong></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>20 years</td>
</tr>
<tr>
<td>2</td>
<td>4 weeks after dose #1</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>8 weeks after dose #2 and 16 weeks after dose #1</td>
<td></td>
</tr>
</tbody>
</table>

Twinrix® Usual Schedule 4, 14(20mcg/mL)

| 1 |  | ≥18 years of age |
| 2 | 4 weeks after dose #1 | |
| 3 | 20 weeks after dose #2 and 6 months after dose #1 | |

Twinrix® Accelerated Schedule 4, 13(20mcg/mL)

| 1 |  | ≥18 years of age |
| 2 | 7 days | |
| 3 | 21–30 days | |
| 4 | 11 months after dose 3 and 12 months after 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. 9
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. 

E. VACCINE INTERCHANGEABILITY:
Although studies show that adults immunized with different formulations of the same monovalent vaccine respond similarly, ACIP recommends completion of any vaccination regimen with the same product whenever possible. However, if the originally used product is not available or known, vaccination with another monovalent product or with a combined vaccine is acceptable. The recommended intervals between doses for the hepatitis A, hepatitis B, and Twinrix® vaccines differ from each other and must still be observed. Prior to switching an individual from Twinrix® to a single-antigen vaccine or vice-versa, please review the following table:

<table>
<thead>
<tr>
<th>Vaccine Given</th>
<th>Dose 1</th>
<th>Dose 2: separated by ≥ 4 weeks from 1st dose of Twinrix® or HepA vaccine</th>
<th>Dose 3: separated by ≥ 5 months from 2nd dose of Twinrix® or HepA vaccine and ≥6 months from 1st dose of Twinrix® or HepA Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult HA Vaccine</td>
<td>Twinrix</td>
<td>Twinrix</td>
<td>Adult HA</td>
</tr>
<tr>
<td>Twinrix</td>
<td>Adult HA</td>
<td>Twinrix</td>
<td>Adult HA</td>
</tr>
<tr>
<td>Twinrix</td>
<td>Twinrix</td>
<td>Twinrix</td>
<td>Adult HA</td>
</tr>
</tbody>
</table>
Twinrix® is not recommended for post exposure prophylaxis.\textsuperscript{9}

**Note:** At this time it has been demonstrated that healthy children and adolescents who have received two doses of VAQTA\textsuperscript{®} can expect their hepatitis A antibody response to persist for at least five years. Healthy adults receiving two doses of VAQTA\textsuperscript{®} were shown to have their hepatitis A antibody response last at least four years.
IV. E. VACCINE SCHEDULE: for Patients on Hemodialysis\textsuperscript{14A, 14B} and other Immunocompromised Persons

<table>
<thead>
<tr>
<th>Age</th>
<th>Single-Antigen Vaccine</th>
<th>Post vaccine serology testing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Recombivax HB\textsuperscript{1}</td>
<td></td>
</tr>
<tr>
<td></td>
<td># of doses\textsuperscript{0}</td>
<td>Dose (µg)</td>
</tr>
<tr>
<td>&lt;20 years*</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>≥20 years</td>
<td>3</td>
<td>40\textsuperscript{◊}</td>
</tr>
</tbody>
</table>

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

\textsuperscript{0} Dialysis formulation administered on a 3-dose schedule at 0, 1, and 6 months.

\textsuperscript{§} Two 1.0-mL doses administered in 1 or 2 injections on a 4-dose schedule at 0, 1, 2, and 6 months

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

V. A. POST-EXPOSURE PROPHYLAXIS GUIDELINES: See separate Hepatitis B Immune Globulin (HBIG) Oregon Model Standing Order.
V. B. INDICATIONS FOR PRE- AND POST-EXPOSURE SEROLOGY

Pre-exposure assessment of current or past anti-HBs (HBsAb) results upon hire, followed by one or more additional doses of HepB vaccine for health-care personnel (HCP) with anti-HBs antibody levels <10 mIU/mL helps to ensure protection if they have an exposure to HBV-containing blood or body fluids. Because vaccine-induced anti-HBs wanes over time, testing HCP for anti-HBs years after vaccination might not distinguish vaccine nonresponders from responders.

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 induced a protective immune response in the recipient.

HCP with documentation of a complete ≥3-dose HepB vaccine series but no documentation of anti-HBs ≥10 mIU/mL and who are at risk for occupational blood or body fluid exposure might undergo anti-HBs testing upon hire or matriculation.

Alternatively, it might be more practical for very recently vaccinated HCP with anti-HBs <10 mIU/mL to receive 3 consecutive additional doses of HepB vaccine (usually 6 doses total), followed by anti-HBs testing 1–2 months after the last dose.

Incompletely vaccinated HCP (including those who refuse vaccination) should receive additional dose(s) of vaccine to complete the series. HCP lacking documentation of HepB vaccination should be considered unvaccinated (when documentation for HepB vaccine doses is lacking) or incompletely vaccinated (when documentation for some HepB vaccine doses is lacking) and should receive additional doses to complete a documented HepB series. Testing unvaccinated or incompletely vaccinated HCP for anti-HBs is not necessary and is potentially misleading, because anti-HBs ≥10 mIU/mL as a correlate of vaccine-induced protection has only been determined for persons who have completed an approved vaccination series.

Post-vaccination serologic testing for anti-HBs is recommended 1–2 months after the last vaccine dose for HCP at risk for occupational percutaneous or mucosal exposures.
To assess vaccine response in remotely vaccinated HCP (e.g., those who received HepB vaccination as part of routine infant [1991] or catch-up adolescent [1995] vaccination), a challenge dose of HepB vaccine can be used to determine the presence of vaccine-induced immunologic memory through generation of an anamnestic response. HCP with an anti-HBs antibody level ≥10 mIU/mL following a challenge dose are considered protected, regardless of whether this level subsequently declines.

**Services Available at the Oregon State Public Health Laboratory (OSPHL)**

OSPHL offers serologic testing for HBsAg, anti-HBs, hepatitis B core antibody (anti-HBc), and IgM anti-HBc. E antigen testing is not routinely available, but may be arranged under special circumstances. Consult with the Acute and Communicable Disease Prevention section at 971-673-1111. For more information regarding properly specimen submission, refer to the Lab Test Menu at [www.healthoregon.org/labtests](http://www.healthoregon.org/labtests). As of January 2017, OSPHL does not provide PCR testing for hepatitis B virus.*

*Note: As of January 2017, testing is available to LHDs through the Oregon State Public Health Laboratory at no charge. This will be maintained as long as funding is available to support this testing. There is a charge for testing ordered by private providers.

**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 that the person has high levels of virus and greater infectiousness.

A **negative result** indicates low to zero levels of virus in the blood and that the person is less infectious to others. ⁹
VI. CONTRAINDICATIONS

A. **RecombivaxHB**®¹ **Engerix–B**®² **Pediarix**®³ **Twinrix**®⁴:
   Hypersensitivity to baker’s yeast

B. **Pediarix**®³: Hypersensitivity to neomycin, polymyxin B, yeast
   **Twinrix**®⁴: Hypersensitivity to neomycin, polysorbate 80, polymyxin B
   **Severe allergic reaction** or anaphylactic response after a previous dose.
   **Moderate or severe acute illness** with or without fever: defer vaccination until illness resolves.

C. **RecombivaxHB**®¹: Allergy to soy peptones.

D. **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®.
   **Progressive Neurologic Disorder**, including infantile spasms, uncontrolled epilepsy, or progressive encephalopathy is a contraindication to administration of any pertussis-containing vaccine.³

VII. PRECAUTIONS

A. **RecombivaxHB**®¹ **Engerix–B**®² **Pediarix**®³ **Twinrix**®⁴: **Apnea** following IM vaccination has been observed in some infants born prematurely.

B. **Pediarix**®³: **Fever** in infants was associated with higher rates relative to separately administered vaccines.³

   **Guillian-Barré Syndrome (GBS)**: If GBS occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the potential benefits and risks should be carefully considered.
C. RecombivaxHB®¹: Dry natural rubber latex is used in the vial stopper, the syringe plunger stopper and tip cap.

Engerix–B®² Pediarix®³ Twinrix®⁴:

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

VIII. SIDE EFFECTS AND ADVERSE EVENTS⁴

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

IX. 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. **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.¹⁷

3. **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.⁶, ⁹

4. **Pregnancy**: Hepatitis B vaccine is approved for use in pregnancy and should be given to pregnant women when indicated.¹⁴
5. **Hemodialysis** patients require special formulation and dosage. See Section IV. C, page 6.  

6. **Internationally adopted children.** Adoptees born in Asia, the Pacific Islands, Africa, and other regions of high or intermediate hepatitis B endemicity should undergo serological testing for 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.  

7. **Booster doses:** For hemodialysis patients, the need for booster doses should be assessed by annual testing of vaccinees for antibody levels, and booster doses should be provided when antibody levels decline below 10 mIU/mL.  
   a. **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.
X. 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).

**Hepatitis B vaccines**

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Temp</th>
<th>Storage Issues</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediarix®</td>
<td>Store at 2°–8°C</td>
<td>Do not use if vaccine has been frozen</td>
<td></td>
</tr>
<tr>
<td>Engerix–B®</td>
<td></td>
<td>Do not dilute</td>
<td></td>
</tr>
<tr>
<td>Recombivax HB®</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Twinrix®</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
XII. ADVERSE EVENTS REPORTING

Public providers are to complete the Vaccine Adverse Events Reporting System (VAERS) report online at https://vaers.hhs.gov/esub/step1.

1. Save a copy of the report number for your records.
2. Send copies of the report and VAERS ID number to the Oregon Immunization Program Vaccine Safety Coordinator via confidential email at ORVAERS.Reports@state.or.us or fax (971-673-0278).

Private providers are to report events directly to VAERS and can read about options on how to do so at http://vaers.hhs.gov/index.

TABLE C. Events Reportable to VAERS 19

<table>
<thead>
<tr>
<th>Event and interval from vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Anaphylaxis or anaphylactic shock (7 days)</td>
</tr>
<tr>
<td>B. Shoulder Injury Related to Vaccine Administration (7 days)</td>
</tr>
<tr>
<td>C. Vasovagal syncope (7 days)</td>
</tr>
<tr>
<td>D. Any acute complications or sequelae (including death) of the above event (interval - not applicable)</td>
</tr>
<tr>
<td>E. Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval - see package insert)</td>
</tr>
</tbody>
</table>

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: http://1.usa.gov/OregonStandingOrders
REFERENCES

1. Recombivax® HB package insert (nd) available at:

2. Energex B® package insert (nd). Available at:

3. Pediarex® package insert (nd). Available at:

4. Twinrix® package insert (nd) available at:


