• universal hepatitis B (HepB) vaccination within 24 hours of birth for medically stable infants weighing ≥2,000 grams;
• postvaccination serologic testing for infants whose mother’s Hepatitis B surface antigen status (HBsAg) remains unknown indefinitely (e.g., when a parent or person with lawful custody surrenders an infant confidentially shortly after birth);
• single-dose revaccination for infants born to HBsAg positive women not responding to the initial vaccine series;
• removal of permissive language for delaying the birth dose until after hospital discharge.

Note: Pregnant women, Heplisav–B™ and Twinrix® are under the Adult Hepatitis B order.

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. Verify needle length for IM injection for either the vastus lateralis or the deltoid muscles. See section II for schedules.
5. Avoid injecting in the upper third of the deltoid muscle.
6. Both client and vaccinator must be seated for vaccine administration.
7. Give Hepatitis B vaccine to persons according to risk group, age, type of vaccine and vaccine status. See section II for schedules.

8. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.

<table>
<thead>
<tr>
<th>Signature</th>
<th>Health Officer or Medical Provider</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

II. A. VACCINE SCHEDULE

<table>
<thead>
<tr>
<th>Routine Schedule: Pediatric Formulations: Prior to 19th birthday</th>
<th>Preferred age for single and combination vaccines 1, 2, 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine</td>
<td>Dose Vol</td>
</tr>
<tr>
<td>-------------------</td>
<td>----------</td>
</tr>
<tr>
<td>Engerix-B (20 µg/mL)</td>
<td>0.5 mL</td>
</tr>
<tr>
<td>Recombivax HB (10 µg/mL)</td>
<td>0.5 mL</td>
</tr>
<tr>
<td>Pediarix</td>
<td>0.5 mL</td>
</tr>
</tbody>
</table>
II. FOOTNOTES

*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.4

◊ All infants should receive the first dose of HepB vaccine within 24 hours of birth.

§ 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.4 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.

‡ 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.4

** 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. Preferred age for receipt of the 3rd dose of hepatitis B vaccine is 6–12 months of age, although 18 months of age is acceptable.5

◊◊ Pediarix® is approved by ACIP for use in children born to HBsAg+ and HBsAg unknown women, but not for the HepB birth dose.4 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.⁴

††The preferred 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
### II.B ALTERNATE SCHEDULES

<table>
<thead>
<tr>
<th>Vaccine &amp; Dose§</th>
<th>Dose Volume</th>
<th>Number of doses in series</th>
<th>Age at first dose</th>
<th>Preferred interval from dose 1 to 2</th>
<th>Preferred interval from dose 2 to 3</th>
<th>Preferred interval from dose 1 to 3</th>
<th>Preferred interval from dose 1 to 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engerix-B◊ (20 µg/mL)</td>
<td>0.5 mL</td>
<td>4</td>
<td>1–10 years</td>
<td>1 month</td>
<td>1 month</td>
<td>2 months</td>
<td>12 months</td>
</tr>
<tr>
<td></td>
<td>1.0 mL</td>
<td>3</td>
<td>5–16 years</td>
<td>12 months</td>
<td>12 months</td>
<td>24 months</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.0 mL</td>
<td>4</td>
<td>11–18 years</td>
<td>1 month</td>
<td>1 month</td>
<td>2 months</td>
<td>12 months</td>
</tr>
<tr>
<td></td>
<td>1.0 mL</td>
<td>3</td>
<td>11–18 years</td>
<td>1 month</td>
<td>2 months</td>
<td>6 months</td>
<td></td>
</tr>
<tr>
<td>Recombivax HB: 2-dose schedule with adult 1.0 mL dose for 11–15-year-olds * (10 µg/mL)</td>
<td>1.0 mL</td>
<td>2</td>
<td>11 years</td>
<td>4–6 months⁴</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.0 mL</td>
<td>2</td>
<td>11 years</td>
<td>4–6 months⁴</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Preferred interval from dose 1 to 2: 1 month
* Preferred interval from dose 2 to 3: 1 month
* Preferred interval from dose 1 to 3: 2 months
* Preferred interval from dose 1 to 4: 12 months

◊ Engerix-B

§ Dose refers to the amount of antigen administered per dose.
*If using Recombivax to vaccinate 11–15-year-olds, use adult formula and 2 doses.  

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

◊ 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.

§ The use of a combined vaccine containing hepB is acceptable as long as one antigen is indicated and the other antigen is not contraindicated.
III. LICENSED VACCINES

A. SINGLE-ANTIGEN HEPATITIS B

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>VACCINE COMPONENTS</th>
<th>LATEX</th>
<th>THIMEROSAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recombivax HB®¹</td>
<td>5 µg HBsAg 0.5 mg aluminum</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Engerix-B®²</td>
<td>10 µg HBsAg 0.5 mg aluminum</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

B. COMBINATION HEPATITIS B

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>VACCINE COMPONENTS</th>
<th>LATEX</th>
<th>THIMEROSAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediarix®³</td>
<td>10 µg of HBsAg 25 Lf of diphtheria toxoid 10 Lf of tetanus toxoid 25 µg of inactivated pertussis toxin 25 µg of filamentous hemagglutinin 8 µg of pertactin 40 D-antigen Units (DU) of type 1 poliovirus 8 DU of type 2 poliovirus 32 DU of type 3 poliovirus</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

IV. RECOMMENDATIONS FOR USE

IV. A. Universal Vaccination of Infants

- All infants should receive the HepB vaccine series as part of the recommended childhood immunization schedule, beginning at birth as a safety net.
- For all medically stable infants weighing ≥2,000 grams at birth and born to HBsAg-negative mothers, the first dose of vaccine should be
administered within 24 hours of birth (new recommendation). Only single-antigen HepB vaccine should be used for the birth dose.

- For infants transferred to a different facility after birth (e.g., a hospital with a higher level of neonatal care), staff at the transferring and receiving facilities should communicate regarding the infant’s HepB vaccination and HBIG receipt status to ensure prophylaxis is administered in a timely manner (new recommendation).
- The final dose in the vaccine series should not be administered before age 24 weeks (164 days).
- In populations with currently or previously high rates of childhood HBV infection (e.g., Alaska Natives; Pacific Islanders; and immigrant families from Asia, Africa, and countries with intermediate or high endemic rates of infection), the first dose of HepB vaccine should be administered at birth and the final dose at age 6–12 months.

IV. B. Vaccination of Children and Adolescents

- HepB vaccination is recommended for all unvaccinated children and adolescents aged <19 years.
- Children and adolescents who have not previously received HepB vaccine should be vaccinated routinely at any age (i.e., children and adolescents are recommended for catch-up vaccination).

IV. C. POST-EXPOSURE PROPHYLAXIS: 4

1. Non-occupational Settings

HBsAg-Positive Source

For the management of persons who are exposed to HBV through a distinct, identifiable exposure to blood or body fluids that contain blood, in non-occupational settings. The exposed person does not need to undergo
post-vaccination serologic testing following vaccination based solely on being exposed.

- Exposed persons who have written documentation of a complete HepB vaccine series and who did not receive post-vaccination testing should receive a single dose of HepB vaccine.

- Exposed persons who are in the process of being vaccinated but who have not completed the vaccine series should receive a dose of HBIG and complete the HepB vaccine series (it is not necessary to restart the HepB vaccine series). HepB vaccine may be administered simultaneously with HBIG at a separate anatomical injection site (e.g., separate limb).

- Exposed unvaccinated persons should receive both HBIG and HepB vaccine as soon as possible after exposure (preferably within 24 hours). HepB vaccine may be administered simultaneously with HBIG at a separate anatomical injection site (e.g., separate limbs). Studies are limited on the maximum interval after exposure during which postexposure prophylaxis is effective, but the interval is unlikely to exceed 7 days for percutaneous exposure and 14 days for sexual exposures. The HepB vaccine series should be completed according to the vaccination schedule.

2. HBsAg-Unknown Source

Exposed persons with written documentation of a complete HepB vaccine series require no further treatment.

Exposed persons who are in the process of being vaccinated but who are not fully vaccinated should complete the HepB vaccine series (it is not necessary to restart the vaccination series).

Exposed unvaccinated persons should receive the HepB vaccine series with the first dose administered as soon as possible after exposure, preferably within 24 hours. Studies are limited on the maximum interval after exposure during which postexposure prophylaxis is effective, but the interval is unlikely to exceed 7 days for percutaneous exposure and 14
days for sexual exposures. The vaccine series should be completed according to the vaccination schedule.

IV. D. 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. Hepatitis B 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 proper specimen submission, refer to the Lab Test Menu at 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) is a viral protein 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 elevated 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.

V. CONTRAINDICATIONS

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

B. Pediarix ®3: Hypersensitivity to neomycin, polymyxin B, or yeast

C. Pediarix®3 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

**VI. PRECAUTIONS**

A. RecombivaxHB®, Engerix–B®, Pediarix®: Apnea following IM vaccination has been observed in some infants born prematurely.

B. Pediarix®: Higher rates of fever in infants were associated with receipt of Pediarix® than with separately administered vaccines.3

**Guillain-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®: Dry natural rubber latex is used in the vial stopper, the syringe plunger stopper and tip cap.

D. Engerix-B® Pediarix®: Dry natural rubber latex in tip caps may cause allergic reactions in latex-sensitive individuals.

**VII. SIDE EFFECTS AND ADVERSE EVENTS**

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

2. **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 acceptable spacing.4

3. **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.6

4. **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.4
   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.4
IX. STORAGE AND HANDLING: \(^1, 2, 3\)

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).

<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>Do not dilute</td>
</tr>
<tr>
<td>Engerix–B®</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recombivax HB®</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

X. ADVERSE EVENTS REPORTING

Public providers are to complete the Vaccine Adverse Events Reporting System (VAERS) report online at [https://vaers.hhs.gov/esub/step1](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](http://vaers.hhs.gov/index).
TABLE C. EVENTS REPORTABLE TO VAERS

<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


