OREGON HEALTH AUTHORITY
IMMUNIZATION PROTOCOL FOR PHARMACISTS

Engrerix® Recombivax®
Hepatitis B Vaccines
Pediatric Formulations only

<table>
<thead>
<tr>
<th>Last Reviewed</th>
<th>09 April 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last Revised</td>
<td>10 September 2018</td>
</tr>
<tr>
<td>This order expires</td>
<td>31 July 2020</td>
</tr>
</tbody>
</table>

No change from previous protocol.

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

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 7–18 years of age for contraindications.
3. Provide a current Vaccine Information Statement (VIS) and answer any questions.
4. Verify needle length for IM injection.
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 alternate schedules and footnotes
8. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.

Immunizing Pharmacist Date
## II. A. Table 1. VACCINE SCHEDULE

<table>
<thead>
<tr>
<th>Vaccine &amp; Dose</th>
<th>Dose Volume</th>
<th>Number of doses in series</th>
<th>Preferred age dose 1</th>
<th>Preferred Interval dose 2</th>
<th>Preferred Interval dose 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engerix-B (20 µg/mL)</td>
<td>0.5 mL</td>
<td>3</td>
<td>11 years</td>
<td>1 month</td>
<td>6 months</td>
</tr>
<tr>
<td>Recombivax HB (10 µg/mL)</td>
<td></td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* 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. ³
## II.B Table 2. ALTERNATE SCHEDULES

**Alternate Schedules for Ages 7 through 18 years**

Preferred age and dosage for single antigen hepatitis B vaccines

<table>
<thead>
<tr>
<th>Vaccine &amp; Dose $^\S$</th>
<th>Dose Volume</th>
<th>Number of doses in series</th>
<th>Preferred 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>
</table>
| **Engerix-B $^\Diamond$**  
(20 µg/mL) | 0.5 mL | 4 | 7–10 years | 1 month | 1 month | 2 months | 12 months |
| | | | | | | | |
| | 3 mL | 3 | 7–16 years | 12 months | 12 months | 24 months | |
| | | | | | | | |
| **Recombivax HB:**  
2-dose schedule with adult 1.0 mL dose for 11–15-year olds *  
(10 µg/mL) | 1.0 mL | 2 | 11 years | 4–6 months $^3$ | | | |
If using Recombivax to vaccinate 11–15-year olds, use adult formula and 2 doses.\(^2,^3\)

- If the schedule is started with 1.0 mL of Recombivax HB vaccine, the 2\(^{nd}\) dose must also be 1.0 mL of Recombivax HB\(^\circ\). If Recombivax\(^\circ\) 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\(^\circ\) vaccine. This 2-dose schedule should be completed by 16 years of age.

◊ If using Engerix-B\(^\circ\) 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.\(^1,^3\)

§ The use of a combined vaccine containing hepB is acceptable as long as one antigen is indicated and the other antigen is not contraindicated.\(^3\)
III. LICENSED VACCINES

A. Table 3. 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 mcg HBsAg</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>0.5 mg aluminum</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Engerix-B®2</td>
<td>10 mcg HBsAg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.5mg aluminum</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

B. COMBINATION HEPATITIS B

For Twinrix see adult order.

C. ADJUVANTED HEPATITIS B

For Heplisav-B see adult order.

IV. RECOMMENDATIONS FOR USE³

IV. A. 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. B. POST-EXPOSURE PROPHYLAXIS:

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. C. 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. 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 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 Hypersensitivity to baker’s yeast

VI. PRECAUTIONS

A. RecombivaxHB®¹: Dry natural rubber latex is used in the vial stopper, the syringe plunger stopper and tip cap.

B. Engerix–B®²: Dry natural rubber latex in tip caps may cause allergic reactions in latex-sensitive individuals.

VII. Table 4. SIDE EFFECTS AND ADVERSE EVENTS ¹,²

<table>
<thead>
<tr>
<th>Event</th>
<th>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.⁴

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.³

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.⁴

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.³

   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.³

### IX. Table 5. STORAGE AND HANDLING:¹,²

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>Engerix–B®</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>Recombivax HB®</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
X. Table 6. ADVERSE EVENTS REPORTING

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

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). ^5

Electronic copy of this standing order is available at: 1.usa.gov/PharmacyImmunizationProtocols
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.
REFERENCES


5. Oregon Secretary of the State. Board of Pharmacy, Chapter 855; Division 19; Licensing of Pharmacists. OAR 855-019-0270, 0280, and 0290. Available at: https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=3967. Accessed 09 April 2019.