Immunization Protocol

Hepatitis A Vaccines (HAVRIX®, VAQTA®, TWINRIX®)

<table>
<thead>
<tr>
<th>Last Reviewed</th>
<th>6 October 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last Revised</td>
<td>6 October 2021</td>
</tr>
<tr>
<td>This order expires</td>
<td>31 October 2023</td>
</tr>
</tbody>
</table>

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1. What’s new
Updated formatting.

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.
F. Administer an IM dose of hepatitis A vaccine appropriate for the patient’s age and the formulation being used.

G. May be given with all routinely recommended vaccines.

H. Ask client to remain seated in the clinic for 15 minutes after vaccination to reduce the risk of injury should they faint.

### 3. Vaccine schedule for Hepatitis A

#### Pediatric Hepatitis A Vaccine

<table>
<thead>
<tr>
<th>Dose</th>
<th>Preferred age</th>
<th>Minimum acceptable age</th>
<th>Minimum acceptable spacing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>12 months</td>
<td>12 months</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>18 months</td>
<td>18 months</td>
<td>6 months</td>
</tr>
</tbody>
</table>

#### Adult Hepatitis A Vaccine

<table>
<thead>
<tr>
<th>Dose</th>
<th>Preferred age</th>
<th>Minimum acceptable age</th>
<th>Minimum acceptable spacing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>19 years</td>
<td>19 years</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td>6 months</td>
</tr>
</tbody>
</table>

#### Adult Hepatitis A – Hepatitis B Combination Vaccine

<table>
<thead>
<tr>
<th>Dose</th>
<th>Preferred age</th>
<th>Minimum acceptable age</th>
<th>Minimum acceptable spacing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>18 years</td>
<td>18 years</td>
<td>1 month</td>
</tr>
<tr>
<td>2</td>
<td>18 years</td>
<td></td>
<td>6 months</td>
</tr>
</tbody>
</table>

#### Hepatitis A-Hepatitis B Accelerated Schedule

<table>
<thead>
<tr>
<th>Dose</th>
<th>Preferred age</th>
<th>Minimum acceptable age</th>
<th>Minimum acceptable spacing</th>
</tr>
</thead>
</table>
18 years | 18 years
---|---
7 days | 21 days
12 months | 

4. Licensed Hepatitis A Vaccine

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Vaccine Components</th>
<th>Presentation</th>
<th>Acceptable Age Range</th>
<th>Thimerosal</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAVRIX&lt;sup&gt;1&lt;/sup&gt; pediatric</td>
<td>Hepatitis A 720 ELISA units</td>
<td>0.5-mL single-dose vials and prefilled syringes</td>
<td>1-18 years</td>
<td>None</td>
</tr>
<tr>
<td>HAVRIX&lt;sup&gt;1&lt;/sup&gt; adult</td>
<td>Hepatitis A 1440 ELISA units</td>
<td>1.0-mL single-dose vials and prefilled syringes</td>
<td>≥19 years</td>
<td>None</td>
</tr>
<tr>
<td>VAQTA&lt;sup&gt;2&lt;/sup&gt; pediatric</td>
<td>Hepatitis A 25 units</td>
<td>0.5-mL single-dose vials and prefilled syringes</td>
<td>1-18 years</td>
<td>None</td>
</tr>
<tr>
<td>VAQTA&lt;sup&gt;2&lt;/sup&gt; adult</td>
<td>Hepatitis A 50 units</td>
<td>1.0-mL single-dose vials and prefilled syringes</td>
<td>≥19 years</td>
<td>None</td>
</tr>
<tr>
<td>TWINRIX&lt;sup&gt;3&lt;/sup&gt;</td>
<td>Hepatitis A 720 ELISA units, Hepatitis B 20 micrograms</td>
<td>1.0-mL prefilled syringes</td>
<td>≥18 years</td>
<td>None</td>
</tr>
</tbody>
</table>

5. Recommendations for use

A. All children should routinely receive hepatitis A vaccine, beginning at 12 months of age.

B. Persons at increased risk for hepatitis A virus (HAV) infection should be routinely vaccinated, including:
   a. Travelers to countries with high or intermediate hepatitis A endemicity.
      • Infants aged 6-11 months should receive hepatitis A vaccine before international travel. Doses administered before 1 year of age do not count towards the two-dose series.
      • Infants under 6 months, persons traveling in less than 2 weeks, and other travelers who choose not to be vaccinated should receive
immune globulin before travel. See the immunization protocol for immune globulin for more information.

b. Men who have sex with men,

c. Persons who use illegal drugs,

d. Persons in group settings for persons with developmental disabilities,

e. Persons who work with HAV-infected non-human primates or with clinical or nonclinical material containing HAV in a research laboratory,

f. Persons who anticipate close personal contact with an international adoptee from a high or intermediate endemicity country during the first 60 days after arrival of the adoptee in the U.S.,

g. Persons experiencing homelessness,

h. Persons in correctional facilities during outbreaks.

C. Persons at increased risk for severe disease from HAV infection, including:

a. Persons with immunocompromising conditions or chronic liver disease,

b. Persons who are HIV positive.

D. Other persons recommended for vaccination:

a. Pregnant women at risk for HAV infection,

b. Persons at risk during outbreaks,

c. Any person who requests vaccination.

6. Contraindications:

Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Vaccine Excipient Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAVRIX</td>
<td>MRC-5 cellular proteins, formalin, aluminum hydroxide, amino acid supplement, phosphate-buffered saline solution, polysorbate 20, neomycin sulfate, aminoglycoside antibiotic</td>
</tr>
<tr>
<td>VAQTA</td>
<td>Amorphous aluminum hydroxyphosphate sulfate, non-viral protein, DNA, bovine albumin, formaldehyde, neomycin, sodium borate, sodium chloride, other process chemical residuals</td>
</tr>
<tr>
<td>TWINRIX</td>
<td>MRC-5 cellular proteins, formalin, aluminum phosphate, aluminum hydroxide, amino acids, sodium chloride,</td>
</tr>
</tbody>
</table>
7. Warnings and precautions:

A. **Hypersensitivity to latex**: HAVRIX and TWINRIX - tip caps of prefilled syringes contain latex. VAQTA – vial stopper and the syringe plunger stopper and tip cap contain latex.

B. **Altered immunocompetence**: Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished immune response.

C. **Limitation of vaccine effectiveness**: Hepatitis A virus has a relatively long incubation period, 20-50 days. Hepatitis A vaccine may not prevent hepatitis A infection in individuals who have an unrecognized hepatitis A infection at the time of vaccination.

D. **Syncope**: Fainting can occur after vaccination.

8. Other considerations

A. **Post-exposure prophylaxis**: People ≥1 year of age who have been exposed to HAV should receive single-antigen hepatitis A vaccine within 2 weeks of exposure. Persons should complete the two-dose series for long-term protection. Immune globulin may also be indicated for some persons. See the immunization protocol for immune globulin.

B. **Serologic testing**: Postvaccination serologic testing for immunity is not necessary after routine vaccination. Testing for the presence of anti-HAV antibody at least one month after vaccination is recommended for persons whose subsequent clinical management depends on knowledge of their immune status and persons for whom revaccination might be indicated, such as persons with HIV infection and other immunocompromised persons (e.g., HCT and solid organ transplant recipients and persons receiving chemotherapy).

C. **Revaccination**: Revaccination is not necessary for healthy persons. Revaccination may be considered for immunosuppressed persons who fail to demonstrate an adequate immune response after the initial vaccination series.

9. Side effects and adverse reactions

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single-antigen hepatitis A vaccine</td>
<td>Up to 67% adults, 37% children</td>
</tr>
<tr>
<td>Local reactions: soreness, redness, swelling</td>
<td>Up to 67% adults, 37% children</td>
</tr>
</tbody>
</table>
### 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).

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Temp</th>
<th>Storage Issues</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>Store at 2°-8°C</td>
<td>Do not use if vaccine has been frozen.</td>
<td></td>
</tr>
</tbody>
</table>

### 11. Adverse events reporting

Report adverse events online to the Vaccine Adverse Events Reporting System (VAERS) at [https://vaers.hhs.gov/reportevent.html](https://vaers.hhs.gov/reportevent.html).

VAERS Reporting Table: [https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf](https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf)

**Event and interval from vaccination**

- A. Shoulder Injury Related to Vaccine Administration (7 days)
- B. Vasovagal syncope (7 days)
- C. Any acute complication or sequelae (including death) of above events (interval - not applicable)
- D. 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 (available at link below) 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).
12. References


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