

IMMUNIZATION PROTOCOL FOR PHARMACISTS

HEPATITIS A VACCINE Inactivated Virus Vaccine

Revisions as of 1/06:

- ACIP has expanded the hepatitis A vaccine recommendation for children to a national recommendation and has lowered the minimum age to 1 year. (II-A)
- Hepatitis C+ individuals and STD clients have been added to pre-exposure prophylaxis recommendations for adults. (III-A).

I. ORDER:

1. Screen for contraindications.
2. Provide the current Vaccine Information Statement (VIS), answering any questions.
3. Obtain a signed Vaccine Administration Record (VAR).
4. Give hepatitis A vaccine **intramuscularly** into the deltoid muscle.
 - a. Use formulation and dosage according to age and vaccine.
 - b. May give simultaneously with all other vaccines, including travel vaccines and immune globulin, according to previous vaccine status of recipient.

Pharmacist Signature

Date

Electronic copy of this protocol available at:
<http://www.oregon.gov/dhs/ph/imm/provider/pharmpro.shtml>
**To request this material in an alternate format (e.g., Braille),
please call (971) 673-0300.**

| II. A. LICENSED MONOVALENT HEPATITIS A VACCINES¹ | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|-----------------------------|-------------------|
| Product name | Vaccine component(s) | Acceptable age range | Thimerosal |
| Havrix® | Hepatitis A | ≥ 1 years | None |
| Vaqta® | Hepatitis A | ≥ 1 years | None |
| B. LICENSED COMBINATION HEPATITIS A | | | |
| TWINRIX® ^{2,3} | Hepatitis A (Havrix®) Hepatitis B (Engerix-B®) | ≥ 18 years | Trace |
| <p>¹ Limited data indicate that vaccines from different manufacturers are interchangeable. Completion of the hepatitis A vaccination series with vaccine from the same manufacturer is preferable, but if the initial vaccine product is unknown or unavailable, vaccination with either product is acceptable.</p> <p>² Schedules using a combination of Twinrix® and single-antigen hepatitis A vaccines have not been studied. Guidelines for use of Twinrix® to complete a hepatitis A vaccine series begun with monovalent vaccine and for use of monovalent vaccine to complete a series begun with Twinrix® have been provided by the Advisory Committee on Immunization Practices (ACIP). See schedules in Twinrix Standing order.</p> <p>³ Twinrix® is not approved for use in persons less than 18 years of age.</p> | | | |

III. PRE-EXPOSURE RECOMMENDATIONS FOR USE

A. Pre-exposure Prophylaxis – General

1. Hepatitis A vaccination is recommended by the ACIP for all children and adolescents aged 1 through 18 years in the United States.
2. Vaccine is recommended for adults greater than 18 years of age at increased risk of infection, including:
 - Persons traveling to or working in countries that have high or intermediate endemicity of infection.
 - Men who have sex with men.
 - Injection drug users.
 - Persons working with non-human primates or with hepatitis A virus (HAV) in a research laboratory.
 - Persons who have chronic liver disease, Hepatitis B virus or Hepatitis C virus infections, or have received or are waiting for a liver transplant.
 - Persons who have clotting factor disorders (e.g., hemophilia).
 - All clients seen in STD clinics.

B. Pre-exposure Prophylaxis - Foreign Travel

1. Primary immunization should be initiated at least 4 weeks prior to expected exposure to HAV. Persons can be assumed to be protected 4 weeks after receiving the first dose of vaccine, although the second dose 6-12 months later is needed for long-term protection.
2. If immunization is given less than 4 weeks before expected exposure, IG (0.02 ml/kg) should also be given at a separate injection site. If vaccination is contraindicated, a single dose of IG (0.02 ml/kg) will confer short-term (1-2 months) protection. If long-term protection is needed, a larger single dose of IG (0.06 ml/kg) will confer 3-5 months of protection. The long-term dose may be repeated every five months.

C. Pre-exposure of Food Handlers

In general, persons working as food handlers in Oregon are not at increased risk for hepatitis A infection when compared to the general public. Therefore, it is not currently recommended that food handlers get immunized because of their occupation. Some food handlers however, do have other risks for hepatitis A (i.e. listed under III-A. General Pre-Exposure Prophylaxis-B), and should be immunized for their own protection.

IV. POST-EXPOSURE RECOMMENDATIONS FOR USE

Please refer all persons needing post-exposure prophylaxis to their primary health care provider or the local health department.

Typically, post-exposure prophylaxis includes:

- A single IM dose of IG (0.02 ml/kg) and
- The first dose of hepatitis A vaccine (two-dose series).

V. VACCINE SCHEDULE:

| A. <u>HAVRIX</u>^R (GlaxoSmithKline) | | | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|---------------|----------------------------------|------------------------------------------------|
| <u>AGE</u> | <u>DOSE</u> (EL.U) | <u>VOLUME</u> | <u>NUMBER</u> <u>OF DOSES</u> | <u>MINIMUM</u> <u>INTERVAL</u> ¹ |
| 18 years ² | 720 EL.U | 0.5 ml | 2 | 6 months |
| ≥19 years* | 1440 EL.U | 1.0 ml | 2 | 6 months** |
| ¹ For retrospective checking, doses that violate the minimum interval (to next dose) by 4 or fewer days do not need to be repeated. | | | | |
| ² GlaxoSmithKline has manufactured two pediatric formulations. For the 18 year old, check that the correct formulation is used for the appropriate dosage and schedule. | | | | |
| B. <u>VAQTA</u>^R (Merck)¹ | | | | |
| <u>AGE</u> | <u>DOSE (U)</u> | <u>VOLUME</u> | <u>NUMBER</u> <u>OF DOSES</u> | <u>MINIMUM</u> <u>INTERVAL</u> ¹ |
| 18 years | 25 U | 0.5 ml | 2 | 6 months |
| ≥19 years* | 50 U | 1.0 ml | 2 | 6 months** |
| * The adult formulation of either vaccine must be used for persons 19 years of age and older; do not double the pediatric formulation to create an adult dose of vaccine. | | | | |
| ** The adult booster should be administered between 6 to 12 months from the first dose. | | | | |

C. VACCINE INTERCHANGEABILITY:

Data on the ability to interchange vaccines from different manufacturers are not available. Completion of the regimen with the same product is preferable. However, if the originally used product is not available or not known, vaccination with either product is acceptable. Adolescents (18 years old) whose first dose was the discontinued Havrix™ 360 EL.U or unknown should receive two additional doses of any hepatitis A vaccine formulation.

| VI. CONTRAINDICATIONS | VII. PRECAUTIONS |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p data-bbox="188 281 760 1050">A. Do Not Give Hepatitis A vaccine to persons with a history of:</p> <ul data-bbox="261 415 760 835" style="list-style-type: none"><li data-bbox="261 415 760 617">• Hypersensitivity to alum, preservative 2-phenoxy ethanol (Havrix® only), or any component of the vaccine<li data-bbox="261 632 760 835">• Anaphylaxis (hives, swelling of the mouth and throat, difficulty breathing, hypotension, or shock) to a previous vaccination. <p data-bbox="188 884 760 1050">B. Vaccination should be deferred during a moderate or severe acute illness until symptoms have resolved.</p> | <p data-bbox="854 281 1446 747">A. Pregnancy: Since vaccine is produced from inactivated hepatitis A virus, the theoretical risk to the developing fetus is expected to be low when the vaccine is administered to a pregnant woman. The risk of vaccination should be weighed against the risk for hepatitis A in women who may be at high risk for exposure to hepatitis A virus.</p> <p data-bbox="854 795 1466 961">B. Immunocompromised: No special precautions need to be taken when vaccinating immunocompromised persons.</p> <p data-bbox="854 1010 1461 1824">C. Concomitant use with yellow fever and typhoid vaccines: The rate of seroconversion for hepatitis A antibodies following the first dose of VAQTA® or the concomitant administration of the first dose of VAQTA® with the yellow fever and typhoid vaccines is similar. However, the titers for hepatitis A were reduced following concomitant administration of VAQTA®, yellow fever and typhoid vaccines versus VAQTA® alone. Once the booster dose of VAQTA® was administered, the titers for hepatitis A between these two groups were comparable.</p> |

VIII. SIDE EFFECTS and ADVERSE REACTIONS:

| <u>HAVRIX^R</u> (GlaxoSmithKline) | <u>VAQTA^R</u> (Merck) |
|-----------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| Adults: 56% Soreness at injection site 14% Headache 7% Malaise <10% Swelling <10% Erythema | Adults: 53% Tenderness 51% Pain 17% Warmth at injection site 16% Headache |

- When compared to hepatitis B vaccine, the incidence of side effects has been similar.
- No serious adverse events have been attributed definitively to hepatitis A vaccine.
- Vaccination of a person who is immune because of prior infection does not increase the risk for adverse events.

IX. OTHER CONSIDERATIONS:**A. PRE-VACCINATION TESTING:**

Adults - The decision about whether to test should be based on cost of vaccination compared with the cost of the testing and whether testing is likely to interfere with initiating vaccination. In adults more than 40 years of age and certain populations (i.e. American Indians, Alaskan Natives, and Hispanics) the prevalence may be high enough to warrant pre-vaccination testing.

B. POST-VACCINATION TESTING:

C. Post-vaccination testing is not indicated because of the high rate of immune response to the vaccine.

D. For someone with a history of fainting with injections, a 15 minute observational period is recommended post immunization.

X. ADVERSE EVENT REPORTING:

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS) at 1-800-822-7967. Forms and procedures can be found at the VAERS website: www.vaers.org. In addition, a copy of the completed VAERS form should be sent to the patient's primary provider, per ORS 855-041-0510.

XI. REFERENCES:

1. ACIP Provisional Recommendations for Hepatitis A Vaccination of Children; October 2005. Available at: www.cdc.gov/nip/recs/provisional_rec/hepA_child.pdf.
2. CDC's Advisory Committee on Immunization Practices Expands Hepatitis A Vaccination for Children; 10/28/05 Press Release. Available at: www.cdc.gov/od/oc/media/pressrel/r051028.htm.
3. CDC Sexually Transmitted Diseases Treatment Guidelines 2002. MMWR, 2002; 51 (RR-6); 60-1.
4. Hepatitis A. In: *Epidemiology and Prevention of Vaccine-Preventable Diseases* ("Pink Book"). Atkinson W, Hamborsky J, Wolfe S, eds. 8th ed. Washington, DC: Public Health Foundation, 2004: 177-89. Available at: <http://www.cdc.gov/nip/publications/pink/hepa.pdf>.
5. CDC Prevention of Hepatitis A Through Active or Passive Immunization: Recommendations of ACIP. MMWR 1999; 48 (RR-12).
6. 2005 vaccine package inserts for Havrix® and Vaqta®.

For more information or to clarify any part of the above order, consult with the vaccine recipient's primary health care provider, or contact the Health Services, Immunization Program at (971) 673-0300.