OREGON STATE PUBLIC HEALTH DIVISION, DHS
IMMUNIZATION PROGRAM

HEPATITIS A VACCINE
Inactivated Virus Vaccine

Revisions as of 01/08

- ACIP has new recommendations on post-exposure prophylaxis (Section IV, p. 4).
- Hep A vaccine is preferred over IG for healthy contacts 12 months–40 years of age.
- IG should be used for contacts <12 months or >40 years of age, are immunocompromised, or have chronic liver disease; and for contacts for whom vaccine is contraindicated.

I. ORDER:

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

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Signature Health Officer or Medical Provider Date

II. A. LICENSED MONOVALENT HEPATITIS A VACCINES[1]			
Product name	**Vaccine component(s)**	**Acceptable age range**	**Thimerosal**
Havrix®	Hepatitis A	≥ 1year	None
Vaqta®	Hepatitis A	≥ 1year	None
B. LICENSED COMBINATION HEPATITIS A VACCINE			
TWINRIX®[2,3]	Hepatitis A (Havrix®) Hepatitis B (Engerix-B®)	≥ 18 years	Trace

[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.

[2] Schedules using combinations 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.

[3]Twinrix® is not approved for use in persons less than 18 years of age.

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 1–18 years in the United States. **State-funded vaccine (VFC and 317) may be used for all children 1–18 years of age.**
2. Vaccine is recommended for Oregon 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. All susceptible persons traveling to or working in countries that have high or intermediate hepatitis A endemicity should be vaccinated or receive IG before departure. Hepatitis A vaccination at the age-appropriate dose***** is preferred to IG.
2. For optimal protection, IG can be considered in addition to vaccine for older adults, immunocompromised persons, and persons with chronic liver disease or other chronic medical conditions who are traveling to an area within 2 weeks.
3. Travelers who elect not to receive vaccine, are <12 months of age, or are allergic to a vaccine component should receive a single dose of IG (0.02 ml/kg) which provides protection for up to 3 months. Travelers whose travel period will be ⩾2 months should receive IG at 0.06 ml/kg; administration must be repeated if the travel period is >5 months.

*Age 1–18 years: 0.5 ml; age ≥19 years: 1.0 ml.

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

Post-exposure Prophylaxis

A**.** Persons who have been exposed to hepatitis A within the past 14 days and who have never received hepatitis A vaccine should be administered a single dose of vaccine or IG (0.02 ml/kg) as soon as possible.[1]

- For healthy persons **12 months–40 years of age, single-antigen hepatitis A vaccine at the age-appropriate dose is preferred to IG** because vaccine provides longer-lasting immunity and is easier to administer.
- **For persons >40 years of age, IG is preferred** because hepatitis A is more severe, and the vaccine has not been shown to work following exposure for persons in this age group. If IG cannot be obtained, vaccine should be given.
- **IG should be used for children aged <12 months, immunocompromised persons, persons with chronic liver disease, and persons for whom vaccine is contraindicated.**

B. Prophylaxis should be administered according to the criteria above to unvaccinated persons in the following situations:

- **Close personal contacts:** administer to all household, sexual, and illicit drug contacts of persons with serologically confirmed HAV infection.
- **Child care centers:** administer to all previously unvaccinated staff and attendees of child care centers or homes if
  - a. One or more cases of hepatitis A are recognized in children or employees or
  - b. Cases are recognized in two or more households of center attendees. In centers that do not provide care to children who wear diapers, prophylaxis should be given only to classroom contacts of an index case.
  - c. When an outbreak occurs in a center, (i.e., HAV cases in 3 or more families), prophylaxis should also be given to unvaccinated household contacts of children in diapers who attend the center.

Post-exposure Prophylaxis (cont.)

C. The confirmation of HAV infection in the index patient by IgM anti-HAV testing is recommended prior to providing post-exposure prophylaxis to contacts. Contacts need **not** be serologically screened for immunity before giving IG or vaccine.
D. Persons who have received 1 dose of hepatitis A vaccine at least 1 month prior to exposure should receive their 2nd dose of the series six months after dose #1.
E. Should cost constraints require a choice between IG, and vaccine for post-exposure prophylaxis, IG should be offered.
F. Food Handlers**:** In the event that a food handler contracts hepatitis A, they may be at increased risk of transmitting their infection to others because of their occupation. Be alert to identify any co-worker who has been exposed to HAV by the index case. Should there be evidence of a risk of transmission of hepatitis A from an infected food handler to other co-workers who handle food, only then should the local health jurisdiction consider offering prophylaxis to other food handlers at the site. Per State Epidemiologist.
G. **Common-source exposure:** Because common-source transmission to patrons at a food establishment is unlikely, prophylaxis of patrons usually is not recommended but may be considered if the following is true:
   - During the time when the food handler was likely to be infectious, the food handler both directly handled uncooked foods, or foods after cooking and had diarrhea or poor hygienic practices, **and**
   - Patrons can be identified and treated within 2 weeks of exposure**.**
H. In settings where repeated exposures to HAV may have occurred (e.g., institutional cafeterias), stronger consideration of vaccine may be warranted.
I. Other facilities where transmission has been known to occur are schools, hospitals, and other work settings where epidemiologic investigation indicates that transmission has occurred inside the facility.

[1]Persons administered IG for whom hepatitis A vaccine is also recommended for other reasons should receive a dose of vaccine simultaneously with IG. The second dose of vaccine should be administered ≥6 months after the first dose to complete the series.

V. VACCINE SCHEDULE

A. HAVRIX®[1,2] (GlaxoSmithKline) Route: IM

AGE	DOSE (EL.U)	VOLUME	NUMBER OF DOSES	MINIMUM SPACING[3,]
1-18 years	720 EL.U	0.5 ml	2	6 months
≥19 years[4]	1440 EL.U	1.0 ml	2	6 months[5]

[1] Children whose first hepatitis A vaccine was Havrix® 360 EL.U (discontinued 9/98) should receive two additional doses of any currently licensed pediatric Hep A vaccine.

[2] GlaxoSmithKline has manufactured two pediatric formulations. Check that the correct formulation is being used for the appropriate dosage and schedule.

[3] 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.

[4]The adult formulation of this vaccine must be used for persons ≥19 years of age. Do not double the pediatric formulation to create an adult dose of vaccine.

[5] The adult booster should be administered 6 to 12 months after the first dose.

B. VAQTA® (Merck) Route: IM

AGE	DOSE (U)	VOLUME	NUMBER OF DOSES	MINIMUM SPACING[1]
1-18 years	25 U	0.5 ml	2	6 months
≥19 years[2]	50 U	1.0 ml	2	6 months[3]

[1] For retrospective checking, doses that violate the minimum spacing or age by 4 or fewer days do not need to be repeated.

[2]The adult formulation of this vaccine must be used for persons ≥ 19 years of age. Do not double the pediatric formulation to create an adult dose of vaccine.

[3]The adult booster should be administered 6 to 12 months after the first dose.

Note: At this time it has been demonstrated that healthy children and adolescents who have received two doses of VAQTA® can expect their hepatitis A antibody response to persist for at least five years. Healthy adults receiving two doses of VAQTA® were shown to have their hepatitis A antibody response last at least four years.

VI. CONTRAINDICATIONS

A. Do Not Give Hepatitis A vaccine to persons with a history of:
   - Hypersensitivity to alum, preservative 2-phenoxy ethanol (Havrix® only), or any component of the vaccine
   - Anaphylaxis (hives, swelling of the mouth and throat, difficulty breathing, hypotension, or shock) to a previous vaccination.

B. Vaccination should be deferred during a moderate or severe acute illness until symptoms have resolved.

VII. PRECAUTIONS

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.

B. Immunocompromised: No special precautions need to be taken when vaccinating immunocompromised persons.

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.

VIII. SIDE EFFECTS AND ADVERSE REACTIONS

HAVRIX® (GlaxoSmithKline)	**VAQTA®** (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
Children: 15% Soreness at injection site 8% Feeding problems 4% Headache 4% Induration at injection site	**Children:** 19% Pain 17% Tenderness 9% Warmth at injection site

- 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:
   1. Children – Pre-vaccination testing of children is not indicated because of expected low prevalence of infection.
   2. 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 (e.g. American Indians, Alaskan Natives, and Hispanics) the prevalence may be high enough to warrant pre-vaccination testing.

B. POST-VACCINATION TESTING:
   Post-vaccination testing is not indicated because of the high proportion of both adults and children who respond to the vaccine.

C. 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 should be reported by public providers to the Immunization Program, Health Services, using a Vaccine Adverse Events Reporting System (VAERS) form, according to state guidelines. Private providers report all adverse events directly to VAERS at 800-822-7967, or via the website at www.vaers.org.

XI. REFERENCES

1. CDC. Update: Prevention of hepatitis A after exposure to hepatitis A virus and in international travelers: updated recommendations of the Advisory Committee on Immunization Practices. MMWR 2007; 56(41).
2. Hepatitis A vaccine versus immune globulin for post-exposure prophylaxis. N Engl J Med 357; 17:1685–94.
3. CDC Prevention of hepatitis A through active or passive immunization. MMWR 2006; 55(RR-7).
4. CDC Sexually transmitted diseases treatment guidelines 2002. MMWR 2002; 51(RR-6); 60–1.
5. Hepatitis A. In: *Epidemiology and Prevention of Vaccine-Preventable Diseases* ("Pink Book"). Atkinson W, Hamborsky J, Wolfe S, eds.10th ed. Washington, DC: Public Health Foundation, 2007:197-89. Available at: http://www.cdc.gov/nip/publications/pink/hepa.pdf.
6. Hepatitis A. In: *Pickering LK, ed. Red Book: 2006 Report of the committee on Infectious Diseases*. 27th ed. Elk Grove Village, IL: American Academy of Pediatrics: 2006: 326–35.
7. 2005 vaccine package inserts for Havrix® and Vaqta®.

For more information or to clarify any part of the above order, consult with your health officer or contact the DHS Immunization Program at 971-673-0300.

For a copy of this order visit our website at
http://oregon.gov/DHS/ph/imm/provider/stdgordr.shtml.
To request this material in an alternate format (e.g., braille),
please call 971-673-0300.