Immunization Protocol

Hepatitis A Vaccines (Havrix®, Vaqta®, Twinrix®)	
Last Reviewed	4 April 2024
Last Revised	4 April 2024
This order expires	31 October 2025

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1. What's new

Correction: Clarification of spacing between doses for the TWINRIX Accelerated Schedule for adults. The accelerated schedule includes four doses with 7 days between doses 1 and 2, 14 days between doses 2 and 3, and the fourth dose needs to be at least 12 months after the first dose and 11 months after dose 3.

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. Ensure epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment are available for immediate use in case of anaphylactic or acute hypersensitivity reaction.

G. Administer an IM dose of hepatitis A (HepA) vaccine appropriate for the patient's age and the formulation being used.

H. May be given with all routinely recommended vaccines.

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

Health Officer Signature Date

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3. Vaccine schedule for Hepatitis A

Pediatric Dose and Route: 0.5 mL IM		
Dose	**Minimum acceptable age**	**Minimum acceptable spacing**
1	12 months	
2		6 months dose 1 to 2

Adult Dose and Route: 0.5 mL IM		
Dose	**Minimum acceptable age**	**Minimum acceptable spacing**
1	19 years	
2		6 months dose 1 to 2

Hepatitis A – Hepatitis B Combination Vaccine (Twinrix[3]) Dose and Route: 1 mL, IM		
Dose	**Minimum acceptable age**	**Minimum acceptable spacing**

1	≥18 years	
2		1 month
3		5 months

Accelerated Schedule Hepatitis A – Hepatitis B Combination Vaccine (Twinrix[3]) Dose and Route: 1 mL, IM		
Dose	**Minimum acceptable age**	**Minimum acceptable spacing**
1	≥18 years	
2		7 days dose 1 to 2
3		14 days dose 2 to 3
4		11 months dose 3 to 4 and 12 months after dose 1

4. Licensed Hepatitis A Vaccine

Trade Name	Presentation	Acceptable Age Range
Havrix[1] or Vaqta[2] pediatric	0.5-mL single-dose vials and prefilled syringes	1-18 years
Havrix[1] or Vaqta[2] adult	1.0-mL single-dose vials and prefilled syringes	≥19 years
Twinrix[3]	1.0-mL prefilled syringes	≥18 years

5. Recommendations for use

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

B. Persons at increased risk for hepatitis A virus infection should be routinely vaccinated, including:

   a. Travelers to countries with high or intermediate hepatitis A endemicity.

      - Infants aged 6-11 months should receive HepA vaccine before international travel. Doses administered before 1 year of age do not count towards the two-dose series.
      - Infants less than 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 Immune Globulin, Hepatitis A and Measles protocol for immune globulin 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,
b. Persons with chronic liver disease, including persons with hepatitis B infection, hepatitis C infection, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, or an alanine aminotransferase (ALT) or aspartate aminotransferase (AST) level persistently greater than twice the upper limit of normal.
c. 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.

Vaccine	Vaccine Excipient Summary[7]
Havrix	MRC-5 cellular proteins, formalin, aluminum hydroxide, amino acid supplement, phosphate-buffered saline solution, polysorbate 20, neomycin sulfate, aminoglycoside antibiotic
Vaqta	Amorphous aluminum hydroxyphosphate sulfate, non-viral protein, DNA, bovine albumin, formaldehyde, neomycin, sodium borate, sodium chloride, other process chemical residuals

Twinrix	MRC-5 cellular proteins, formalin, aluminum phosphate, aluminum hydroxide, amino acids, sodium chloride, phosphate buffer, polysorbate 20, neomycin sulfate, yeast protein

7. Warnings and precautions:

A. **Hypersensitivity to latex**: Havrix- 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, 15-50 days (average of 28 days). Hepatitis A vaccine may not prevent hepatitis A infection in individuals who have an unrecognized hepatitis A infection at the time of 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.

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

Adverse Event	Frequency
Single-antigen hepatitis A vaccine	
Local reactions: soreness, redness, swelling	Up to 67% adults, 37% children
Systemic reactions: fever, headache, irritability, loss of appetite	Up to 14% adults, 9% children
Hepatitis A-Hepatitis B vaccine	

Local reactions: soreness and redness	Up to 41%
Systemic reactions: headache and fatigue	Up to 22%

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 800-980-9431.

Vaccine	Temp	Storage Issues	Notes
All	Store at 2°-8°C	Do not use if vaccine has been frozen.	

11. Adverse events reporting

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

VAERS Reporting Table:
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)

12. References

1. Havrix package insert. Current as of October 2019. Available at: https://www.fda.gov/media/119388/download. Accessed 4 April 2024.
2. Vaqta package insert. Current as of October 2020. Available at: https://www.fda.gov/media/74519/download. Accessed 4 April 2024.
3. Twinrix package insert. Current as of April 2023. Available at: https://www.fda.gov/media/119351/download. Accessed 4 April 2024.
4. Nelson NP, Weng MK, Hofmeister MG, et al. Prevention of hepatitis A infection in the United States: Recommendations of the ACIP. MMWR 2020;69(5);1-42. Available at: https://www.cdc.gov/mmwr/volumes/69/rr/pdfs/rr6905a1-H.pdf.

Accessed 4 October 2024.

5. Kroger A, Bahta L, Long S, Sanchez P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP), updated August 1, 2023. Available at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html. Accessed 4 April 2024.
6. CDC. Vaccine Excipient Summary. Nov 2021. Available at: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf. Accessed 4 April 2024.

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: https://www.oregon.gov/oha/ph/preventionwellness/vaccinesimmunization/immunizationproviderresources/pages/stdgordr.aspx