Pharmacy Protocol

Hepatitis A Vaccines (HAVRIX®, VAQTA®, TWINRIX®)	
Last Reviewed	6 October 2021
Last Revised	6 October 2021
This order expires	31 October 2023

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1. What's new

Updated formatting.

2. Immunization pharmacy 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.

I have read, understand, and agree to participate by the terms of this protocol.

Immunizing Pharmacist Signature Date

3. Vaccine schedule for Hepatitis A

Pediatric Hepatitis A Vaccine[4]			
Dose and Route – 0.5-mL, IM			
Dose	**Preferred age**	**Minimum acceptable age**	**Minimum acceptable spacing**
1	7 years	7 years	
2			6 months

Adult Hepatitis A Vaccine[4]			
Dose and Route – 1.0-mL, IM			
Dose	**Preferred age**	**Minimum acceptable age**	**Minimum acceptable spacing**
1	19 years	19 years	
2			6 months

Adult Hepatitis A – Hepatitis B Combination Vaccine[3]			
Dose and Route – 1.0-mL, IM			
Dose	**Preferred age**	**Minimum acceptable age**	**Minimum acceptable spacing**
1	18 years	18 years	
2			1 month
3			6 months
Hepatitis A-Hepatitis B Accelerated Schedule[3]			
Dose	**Preferred age**	**Minimum acceptable age**	**Minimum acceptable spacing**
1	18 years	18 years	

2			7 days
3			21 days
4			12 months

4. Licensed Hepatitis A Vaccine

Product Name	Vaccine Components	Presentation	Acceptable Age Range	Thimerosal
HAVRIX[1] pediatric	Hepatitis A 720 ELISA units	0.5-mL single-dose vials and prefilled syringes	1-18 years	None
HAVRIX[1] adult	Hepatitis A 1440 ELISA units	1.0-mL single-dose vials and prefilled syringes	≥19 years	
VAQTA[2] pediatric	Hepatitis A 25 units	0.5-mL single-dose vials and prefilled syringes	1-18 years	
VAQTA[2] adult	Hepatitis A 50 units	1.0-mL single-dose vials and prefilled syringes	≥19 years	
TWINRIX[3]	Hepatitis A 720 ELISA units Hepatitis B 20 micrograms	1.0-mL prefilled syringes	≥18 years	

5. Recommendations for use

A. All children should routinely receive hepatitis A vaccine.

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.

      - 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.

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 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 ≥7 years 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

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 971-673-4VFC (4823).

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)

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

1. HAVRIX package insert. Current as of October 2019. Available at: https://www.fda.gov/media/119388/download. Accessed 28 September 2021.
2. VAQTA package insert. Current as of October 2020. Available at:

https://www.fda.gov/media/74519/download. Accessed 28 September 2021.

3. TWINRIX package insert. Current as of October 2019. Available at: https://www.fda.gov/media/119351/download. Accessed 28 September 2021.
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 28 September 2021.
5. Kroger AT, Duchin J, Vázquez M. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). www.cdc.gov/vaccines/hcp/aciprecs/general-recs/downloads/general-recs.pdf. Accessed 28 September 2021.
6. CDC. Vaccine Excipient Summary. February 2020. Available at: www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table2.pdf. Accessed 28 September 2021.

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