Protocol for Hepatitis A Containing Vaccines
(HAVRIX®, VAQTA®, TWINRIX®)

1. What's New

A. Warnings and Precautions-Latex (Removed for Twinrix®)

2. Immunization Protocol

A. Administer an IM dose of Hepatitis A vaccine appropriate for the person's age and the formulation being used.

B. Hepatitis A vaccines may be given with all routinely recommended vaccines.

3. Vaccine Schedule

Pediatric Hepatitis A Vaccine[1,2] (HAVRIX®, VAQTA®) Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	7-18 years	
2		6 months

Adult Hepatitis A Vaccine[1,2] (HAVRIX®, VAQTA®) Dose and Route – 1.0-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥19 years	
2		6 months

Adult Hepatitis A – Hepatitis B Combination Vaccine[3] (TWINRIX®) Dose and Route – 1.0-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥18 years	
2		4 weeks
3		6 months

Adult Hepatitis A – Hepatitis B Combination Vaccine[3] (TWINRIX®) Dose and Route – 1.0-mL, IM		
Accelerated Schedule		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥18 years	
2		7 days
3		21 days
4		12 months

4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved 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 mcg	1.0-mL prefilled syringes	≥18 years	

5. Recommendations for Use[4]

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.
        i. 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 (MSM)
    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
E. Any person who requests vaccination

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.[1-3]

Protocol for Hepatitis A Containing Vaccines (HAVRIX®, VAQTA®, TWINRIX®)

Vaccine	Contains
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[1-3]

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, 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[4]

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[1-3]

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

A. Upon storage, a fine white deposit with a clear colorless layer above may be present. Shake well before use to obtain a slightly opaque, white suspension.
B. Store medications according to OAR 855-041-1036.
C. 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° to 8°C (36° to 46° F)	Do not use if vaccine has been frozen.	

11. References

1. HAVRIX®. [Package insert]. September 2022. Available at: https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Havrix/pdf/HAVRIX.PDF. Accessed 11 July 2023.
2. VAQTA®. [Package insert]. April 2023. Available at: https://www.merck.com/product/usa/pi_circulars/v/vaqta/vaqta_pi.pdf. Accessed 11 July 2023.
3. TWINRIX® [Package insert]. April 2023. Available at: https://www.fda.gov/media/119351/download. Accessed 11 July 2023.
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 11 July 2023.

12. Appendix

A. N/A