OREGON HEALTH AUTHORITY
IMMUNIZING PHARMACIST PROTOCOL

HEPATITIS A VACCINES: **Havrix ® Vaqta® Twinrix®**	
Last Reviewed	15 April 2019
Last Revised	06 August 2018
This order expires	31 July 2021

April 2, 2019

Additional language and tables regarding the recommendations of the Advisory Committee on Immunization Practices (ACIP) for the use of hepatitis A vaccine for postexposure prophylaxis and for preexposure prophylaxis for international travel.[4] MMWR 2018;67:1216–1220.

Postexposure Prophylaxis (PEP) against Hepatitis A Virus (HAV) Infection:

1. Initiate HAV PEP as soon as possible, within 2 weeks of exposure.
2. Give HepA vaccine to all persons aged >7 years of age regardless of risk group, with co-administration of immune globulin (IG) when indicated.
3. See table 4 in section IV D for risk assessment details.

I. OREGON IMMUNIZATION PHARMACY PROTOCOL:

1. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.
2. Screen clients >7 years of age for contraindications.
3. Provide a current Vaccine Information Statement (VIS) and answer any questions.
4. Verify needle length for IM injection into the vastus lateralis or deltoid muscles.
5. Both client and vaccinator must be seated for vaccine administration. Administer hepatitis A vaccine IM.[6] Avoid injecting into the upper third of deltoid muscle.[5]
6. Record all required data elements in the client's permanent health record.
7. This vaccine may be given with all ACIP–recommended child and adult vaccinations.
8. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.

Immunizing Pharmacist Date

II. Table 1. HEPATITIS A VACCINE SCHEDULE

Preferred dosages and schedules of hepatitis A vaccines					
Vaccine	**Age group**	**Dose**	**Volume**	**# Doses in series**	**Schedule**
Havrix[1] (GlaxoSmithKline [GSK])	7–18 years	720 El.U.*	0.5 mL	2	0, 6–12 mos.
	≥19 years	1440 El.U.*	1.0 mL	2	0, 6–12 mos.
Vaqta[2] (Merck & Co.)	7–18 years	25 U**	0.5 mL	2	0, 6–18 mos.
	≥19 years	50 U**	1.0 mL	2	0, 6–18 mos.

*El.U. = Elisa Units **U = Units

Combination vaccine using hepatitis A and hepatitis B vaccines					
Vaccine	**Age group**	**Antigens used**	**Volume**	**# Doses in series**	**Schedule**
Twinrix[3] (GlaxoSmithKline [GSK])	18 years and older	Havrix (720 El.U.) combined with Engerix-B (20 mcg)	1.0 mL	3	0, 1, 6 mos.
				4	0, 7, 21–30 days, 12 months

Adapted from http://www.immunize.org/askexperts/experts_hepa.asp on 04-10-2018.

Administering 2-doses of 25 U VAQTA® or 2-doses of 720 EL.U. HAVRIX® to persons aged >18 years in place of one adult dose is not an ACIP recommendation and is not included as a method for dosage and administration in the manufacturers' package inserts. Hepatitis A vaccines should be administered in the age-appropriate doses.[10]

III. LICENSED VACCINES*

Product name	Vaccine component(s)	Minimum Acceptable age range	Latex	Thimerosal
LICENSED MONOVALENT HEPAITITS A				
Havrix® [1]	Hepatitis A	≥ 7 years	Tip caps **may** contain natural rubber latex	None
Vaqta® [2]	Hepatitis A	≥ 7 years	Vial stopper, syringe plunger stopper, and tip caps **contain** natural rubber latex	None
LICENSED COMBINATION HEPATITIS A and B				
Twinrix® [3] ◊	Hepatitis A (Havrix®) Hepatitis B (Engerix-B®)	≥ 18 years	Tip caps **may** contain natural rubber latex	Trace

*Limited data suggest 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.[5]

◊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 Table 6, Vaccine Interchangeability table.[11]

IV. RECOMMENDATIONS FOR USE

A. Post-Exposure and Risk Assessment Table regardless of risk group, with co-administration of IG when indicated. See table IV. A. 4.

1. HepA vaccine should be administered to all persons aged ≥7 years of age regardless of risk group, with co-administration of IG when indicated. See table IV. A. 4.

2. Immunocompetent persons aged >7 years of age who have not completed the 2-dose series should receive a single dose of HepA vaccine. In addition to vaccine, IG may be administered to adults >40 years depending on providers' risk assessment. See next page:

A. 4. Table 3: Categories of persons with increased risk for hepatitis A virus (HAV) infection or increased risk for complications in the event of exposure to HAV[4]

Type of risk	Risk Category	Example
Increased risk for HAV infection	Close contacts of persons with HAV infection*	Household contacts
		Caretakers
		Sexual Contacts
	Occupational risk	Persons working with non-human primates
		Persons working with HAV in a research laboratory
Increased risk for HAV-associated complications	Immunocompromised persons	Congenital or acquired immunodeficiency
		HIV infection
		Chronic renal failure/Undergoing dialysis
		Solid organ, bone marrow, or stem cell transplant recipients
		Persons with diseases requiring treatment with immunosuppressive drugs/biologics (e.g., tumor necrosis alpha inhibitors), long-term systemic corticosteroids, radiation therapy
	Chronic liver disease	Hepatitis B infection
		Hepatitis C infection
		Cirrhosis (any etiology)
		Fatty liver disease (hepatic steatosis)
		Alcoholic liver disease
		Autoimmune hepatitis
	*Excludes health care personnel using appropriate personal protective equipment	Alanine aminotransferase (ALT) or aspartate amino transferase (AST) level more than twice the upper limit of normal or persistently elevated for 6 months

5. Immunocompromised persons aged >7 years of age or have chronic liver disease should receive IG and HepA vaccine simultaneously in a different anatomic site as soon as possible after exposure particularly those with special risk factors for either HAV infection or increased risk for complications in the event of an exposure to HAV.
6. The second dose of HepA vaccine is not necessary for PEP. To complete the series, a second dose should not be administered any sooner than 6 months after the first dose.
7. 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.

IV. B. RECOMMENDATIONS FOR USE Cont.

1. **<u>Pre-exposure</u>** Prophylaxis—General

    a) Hepatitis A vaccination is recommended by the ACIP for all children and adolescents aged ≥7 years of age.[6]

2. Vaccine is recommended for adults greater than 18 years of age at increased risk of infection, including[6,9]:

    a) Persons traveling to or working in countries that have a high or intermediate endemicity of infection, including persons with travel related to international adoption.
    b) Household members and other close personal contacts (e.g., regular babysitters) of adopted children newly arriving from countries with high or intermediate hepatitis A endemicity.
    c) Persons with direct contact with persons who have hepatitis A. 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.[6 pg 17]

d) Men who have sex with men.
e) People experiencing homelessness.
f) People who use illicit drugs (whether by injection or non-injection)
g) Persons with occupational risk for infection, working with non-human primates or with hepatitis A virus (HAV) in a research laboratory.
h) Persons who have chronic liver disease, Hepatitis B virus or Hepatitis C virus infections, or have received or are waiting for a liver transplant.
i) Persons who have clotting factor disorders (e.g., hemophilia).
j) All clients seen in STD clinics.
k) IG should be used for infants <12 months, those who are immunocompromised, or have chronic liver disease; and for contacts for whom vaccine is contraindicated.[7]

3. Any person wishing to obtain immunity.

Table 4: Recommendations for postexposure prophylaxis and preexposure protection, by age group and risk category			
Indication/Age group	Risk category/Health status	Hepatitis A vaccine	Immune globulin
Postexposure prophylaxis			
<12 mos	Healthy	No	0.1 mL/kg*
12 mos–40 yrs	Healthy	1 dose◊	None
>40 yrs	Healthy	1 dose◊	0.1 mL/kg§
≥12 mos	Immunocompromised or chronic liver disease	1 dose	0.1 mL/kg‡
≥12 mos	Vaccine contraindicated**	no	0.1 mL/kg
Preexposure protection◊◊			
<6 mos	Healthy	No	0.1–0.2 mL/kg§§
6–11 mos	Healthy	1 dose‡‡	None
12 mos–40 yrs	Healthy	1 dose***	None
>40 yrs	Healthy	1 dose***	0.1–0.2 mL/kg§§,◊◊◊
All ages	Immunocompromised or chronic liver disease	1 dose***	0.1–0.2 mL/kg§§,◊◊◊
>6 mos	Persons who elect not to receive vaccine or for whom vaccine is contraindicated	No	0.1–0.2 mL/kg§§

*Measles, mumps, and rubella vaccine should not be administered for at least 3 months after receipt of IG.

◊ A second dose is not required for postexposure prophylaxis; however, for long-term immunity, the hepatitis A vaccination series should be completed with a second dose at least 6 months after the first dose.

§ The provider's risk assessment should determine the need for immune globulin administration. If the provider's risk assessment determines that both vaccine and immune globulin are warranted, HepA vaccine and immune globulin should be administered simultaneously at different anatomic sites

‡ Vaccine and immune globulin should be administered simultaneously at different anatomic sites.

** Life-threatening allergic reaction to a previous dose of hepatitis A vaccine, or allergy to any vaccine component.

◊◊ IG should be considered before travel for persons with special risk factors for either HAV infection or increased risk for complications in the event of exposure to HAV.

§§ 0.1 mL/kg for travel up to 1 month; 0.2 mL/kg for travel up to 2 months, 0.2mL/kg every 2 months for travel of ≥2 months' duration.

‡‡ This dose should not be counted toward the routine 2-dose series, which should be initiated at age 12 months.

*** For persons not previously vaccinated with HepA vaccine, administer dose as soon as travel is considered, and complete series according to routine schedule.

◊◊◊ May be administered, based on providers' risk assessment.

IV. C. Pre-exposure Prophylaxis—Foreign Travel

1. **Healthy persons age 7 years–40 years** who are planning travel to an area with high or intermediate HAV endemicity and have not received HepA vaccine should receive a single dose of HepA vaccine as soon as travel is considered and should complete the 2-dose series according to the routine schedule.
2. **Person aged >40 years, immunocompromised persons, and persons with chronic liver disease** planning departure <2 weeks should receive the initial dose of HepA vaccine, and simultaneously may be administered IG as a separate anatomic injection site.
3. **In addition to HepA vaccine, IG should be considered** before travel for persons with special risk factors for either HAV infection or increased risk for complications in the event of an exposure to HAV.

Table 5: Hepatitis A Immune Globulin (IG) Prophylaxis

Product Name	Vaccine Components	Duration of Travel[12, 13, 14]	Dose
GamaSTAN® S/D[12]	Human Plasma	Up to 1 month	0.1 mL/kg (0.05 mL/lb) **IM**
		Up to 2 months	0.2 mL/kg (0.1 mL/lb) **IM**
		≥2 months	Repeat 0.2 mL/kg every 2 months **IM**
		Exposure of Contacts	0.1 mL/kg (0.05 mL/lb) **IM**

IV. D. Pre-exposure Prophylaxis—Food Handlers[6, 10]

1. **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 IV-A. General Pre-Exposure Prophylaxis-B), and should be immunized for their own protection.

2. **Food Handlers and common-source exposure**: Hepatitis A is reportable, and the need for immunization of food-service co-workers or customers must be determined through investigation by local public health officials. Per OIP Medical Director.

IV. E. VACCINE INTERCHANGEABILITY:

Although studies show that adults immunized with different formulations of the same monovalent vaccine respond similarly, ACIP recommends completion of any vaccination regimen with the same product whenever possible. However, if the originally used product is not available or known, vaccination with another monovalent product or with a combined vaccine is acceptable.[5] The recommended intervals between doses for the hepatitis A, hepatitis B, and Twinrix® vaccines differ from each other and must still be observed. Twinrix is approved for persons 18 years of age and older, and can be administered to persons in this age group for whom either hepatitis A and hepatitis B vaccines is recommended. Because the hepatitis B component of Twinrix is equivalent to a standard adult dose of hepatitis B vaccine, the schedule is the same whether Twinrix or single-antigen hepatitis B vaccine is used. Single-antigen hepatitis A pediatric dose in Twinrix or single antigen adult hepatitis A vaccine can be used to complete a series begun with Twinrix or vice versa.[11] See the table below:

Table 6: Single-Antigen Hepatitis A (HA) 1.0 mL and Twinrix® schedule integrated for persons ≥18 years of age

	Dose 1	**Dose 2:** separated by ≥4 weeks from 1st dose of Twinrix® or HepA vaccine	**Dose 3:** separated by ≥5 months from 2nd dose of Twinrix® or HepA vaccine **and** ≥6 months from 1st dose of Twinrix® or HepA Vaccine
Vaccine Given	Adult HA Vaccine	Twinrix®	Twinrix®
	Twinrix®	Adult HA	Adult HA
	Twinrix®	Twinrix®	Adult HA

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.

V. CONTRAINDICATIONS

Havrix® and **Vaqta®**: A history of immediate and or severe allergic or hypersensitivity reactions (e.g., anaphylaxis) after a previous dose of any hepatitis A vaccine or with an anaphylactic reaction to neomycin.[1,2]

Twinrix®: Severe allergic reaction (e.g., anaphylaxis) after a previous dose of any hepatitis A-containing or hepatitis B-containing vaccine, or to any component of TWINRIX, including yeast and neomycin.[3]

VI. PRECAUTIONS

Havrix® and **Twinrix®**: Dry latex rubber in the tip cap may cause allergic reactions in latex-sensitive individuals.[1,3]

Vaqta®: Dry natural rubber latex **is used** in the vial stopper, the syringe plunger stopper and tip cap.[2]

Havrix®, Vaqta® and Twinrix®: Vaccination should be deferred during a moderate or severe acute illness until symptoms have resolved.[5]

No special precautions need to be taken when vaccinating immunocompromised persons.[6]

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. The titers for hepatitis A following concomitant administration of VAQTA®, yellow fever and typhoid vaccines were adequate. Once the booster dose of VAQTA® was administered, the titers for hepatitis A between these two groups were comparable.[2]

VII. OTHER CONSIDERATIONS

1. **Adverse Events**: epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case of anaphylactic or acute hypersensitivity reaction.[5]
2. **Immunocompromised**: Immunocompromised persons may have a diminished immune response to all Hepatitis A vaccines including individuals receiving immunosuppressant therapy.[1,2,3]
3. **Lactation:** It is not known whether Hepatitis A vaccines are excreted in human milk. Use with caution in nursing mothers. [1,2,3]

4. **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.[6]

VIII. Table 7. SIDE EFFECTS AND ADVERSE EVENTS[1]:

Havrix® Number followed for Safety	Havrix® 2–3 Doses N =12,274 Adverse Reaction %	
Age in **Years**	Adults and children ≥2 years	
	Adult	Child
Local Reaction, Injection site pain and tenderness	56	21
Headache	14	9
Section 6.1 package insert, page 4		

VIII. Table 8. SIDE EFFECTS AND ADVERSE EVENTS[2]:

Vaqta® Number followed for Safety	Vaqta® Dose 1 N=515 Adverse Reaction %	Vaqta® Booster N=475 Adverse Reaction %
Age in **Years**	Healthy Children and Adolescents **≤18 years**	Healthy Children and Adolescents **≤18 years**
Local Reaction, Injection site		
Pain	6.4	3.4
Tenderness	4.9	1.7
Redness	1.9	0.8
Swelling	1.7	1.5
Warmth	1.7	0.6
Systemic Complaints		
Abdominal pain	1.2	1.1
Pharyngitis	1.2	0
Headache	0.4	0.8
Table 5 page 7[2]		

VIII. Table 9. SIDE EFFECTS AND ADVERSE EVENTS[3]:

Twinrix® Number followed for Safety	Twinrix® N=385 Adverse Reaction %	Twinrix® N=382 Adverse Reaction %	Twinrix® N=374 Adverse Reaction %
Age in **Years**	18–70 years	18–70 years	18–70 years
Local Reaction, Injection site			
Pain	37	35	41
Redness	8	9	11
Swelling	4	4	6
Systemic Complaints			
Headache	22	15	13
Fatigue	14	13	11
Diarrhea	5	4	6
Nausea	4	3	2
Vomiting	1	1	0
Fever	4	3	2
Table 1 page 4[3]			

1. Data from 11 clinical trials of 17–70 -year-olds indicated that 1 month after completion of the three dose Twinrix® series, seroconversion for antibodies against hepatitis A virus was 99.9%; after two doses the seroconversion rate was 98.8% and after one dose, 93.8%.[3]

2. Data from a randomized comparative study of 496 healthy adults ≥18 years of age showed that individuals who completed the 4-dose series of Twinrix® on the accelerated dosing schedule had an immune response comparable to those who received complete vaccination with separately administered hepatitis A and hepatitis B vaccines.[3]

IX. Table 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	Latex	Temp	Storage Issues	Notes
Havrix® 1	Yes: syringe	Store at 2°–8°C	Do not use if vaccine has been frozen.	Do not dilute to administer
Vaqta® 2	Yes: syringe			
Twinrix® 3	Yes: syringe			

X. ADVERSE EVENTS REPORTING

Private providers are to report events directly to VAERS and can read about options on how to do so at https://vaers.hhs.gov/reportevent.html

A pharmacist who administers any vaccine must report the following elements 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)(3).[15]

Electronic copy of this standing order is available at:
1.usa.gov/PharmacyImmunizationProtocols

Table 11. VAERS Reporting Table*:
https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

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)

Effective date: March 21, 2017. The Reportable Events Table (RET) reflects what is reportable by law (42 USC 300aa-25) to the Vaccine Adverse Event Reporting System (VAERS) including conditions found in the manufacturer package insert. In addition, healthcare professionals are encouraged to report any clinically significant or unexpected events (even if not certain the vaccine caused the event) for any vaccine, whether or not it is listed on the RET.

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