



EpiVac Pink Book Web-on-Demand Series

Rotavirus and Hepatitis A–2020

Immunization Services Division

National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

Atlanta, GA

Learning Objectives

- For each vaccine-preventable disease, identify those for whom routine immunization is recommended.
- For each vaccine-preventable disease, describe characteristics of the vaccine used to prevent the disease.
- Describe an emerging immunization issue.
- Locate current immunization resources to increase knowledge of team's role in program implementation for improved team performance.
- Implement disease detection and prevention health care services (e.g., smoking cessation, weight reduction, diabetes screening, blood pressure screening, immunization services) to prevent health problems and maintain health.

Today's Agenda

**EpiVac Pink Book Web-on-Demand Series: Rotavirus and Hepatitis A–
2020**

Andrew Kroger, MD, MPH, Medical Officer, CDC/NCIRD

Continuing Education Information

- CE credit, go to: www.cdc.gov/GetCE
- Search course number: WD4344-081220
- CE credit expires: July 1, 2022
- CE instructions are available on the EpiVac Pink Book Web-on-Demand Series web page
- Questions and additional help with the online CE system, e-mail CE@cdc.gov

The screenshot shows the TCEO website interface. At the top, there is a blue header with the text "Training and Continuing Education Online (TCEO)". Below this is the TCEO logo, which consists of the letters "TCEO" in a bold, blue font with a green leaf-like shape above the "O". Underneath the logo, it says "TRAINING AND CONTINUING EDUCATION ONLINE".

On the left side, there is a vertical navigation menu with the following items: "TCEO Home", "Search Courses", "Create Account", "9 Simple Steps to Earn CE", "Frequently Asked Questions", and "Contact TCEO".

The main content area on the right has a blue header with the text "New to TCEO?". Below this, there are three sections of text:

- Visit Create Account.** Once your account has been created, you will be able to search for courses and complete requirements to receive CE.
- Already have a TCEO account from the previous system?** To move your account to the new system please sign in above using your existing TCEO username and password. Once signed in, follow the prompts to verify and update your account. After your account is updated, forward you will use this email address and password to sign in.
- Not sure how to get started?** Follow these 9 Simple Steps to earn continuing education for the courses you have taken or conferences you have attended!

Below the text, there is a row of four small images: a woman smiling at a child, a man in a suit looking at a screen, a doctor in a white coat holding a dog, and a woman sitting at a computer desk.

At the bottom of the page, there is a "Welcome to TCEO" message and a line of small text: "Training and Continuing Education Online (TCEO) is a system that provides access to CDC educational activities for continuing education (CE). Use TCEO to search for CE opportunities, complete course e..."

Disclosure Statements

In compliance with continuing education requirements, all presenters must disclose any financial or other associations with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters, as well as any use of unlabeled product(s) or product(s) under investigational use.

CDC, our planners, content experts, and their spouses/partners wish to disclose they have no financial interests in or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters.

Planners have reviewed content to ensure there is no bias.

Disclosure Statements

Content will not include any discussion of the unlabeled use of a product or a product under investigational use with the exception of Dr. Kroger's discussion of rotavirus and hepatitis A vaccines in a manner recommended by the Advisory Committee on Immunization Practices, but not approved by the Food and Drug Administration.

CDC does not accept any commercial support.



Rotavirus and Hepatitis A

Pink Book Web-on-Demand Series 2020

Andrew Kroger, MD, MPH

Medical Officer/Medical Health Educator

1

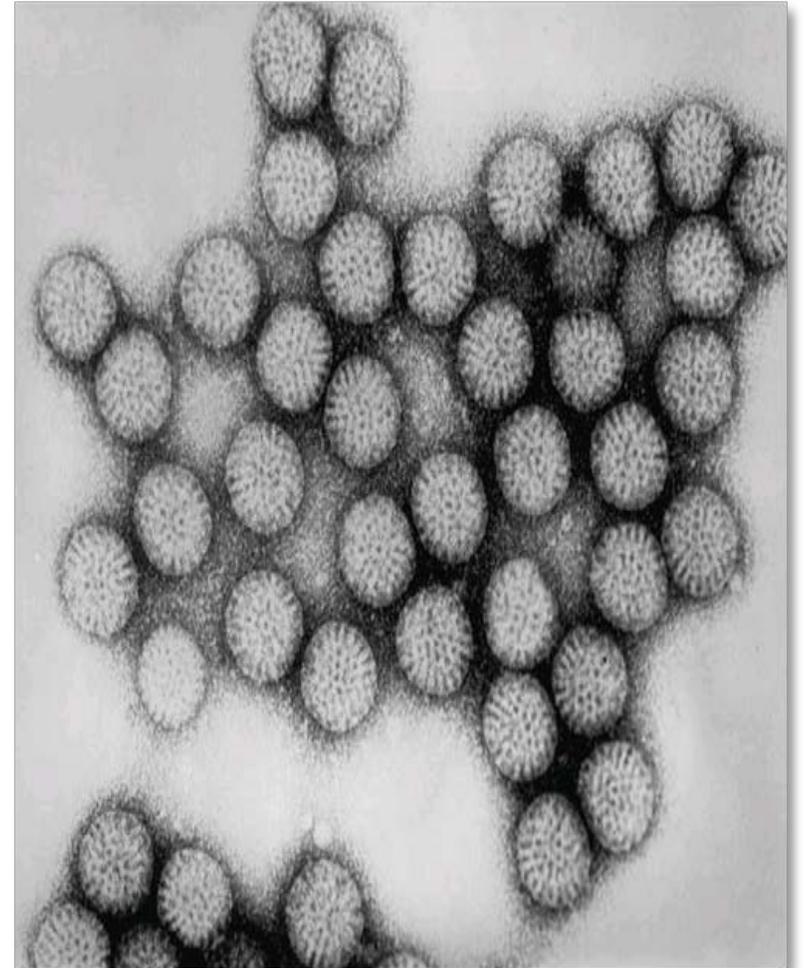
**Rotavirus
Disease**

Rotavirus

- **First identified as a cause of diarrhea in 1973**
- **Leading cause of severe gastroenteritis among U.S. children before introduction of vaccine in 2006**
- **Nearly universal infection by age 5 years**
- **Responsible for up to 500,000 diarrheal deaths each year worldwide**

Rotavirus

- Two important outer shell proteins—VP7, or G-protein, and VP4, or P-protein define the serotype of the virus
- From 1996–2005, five predominate strains in the U.S. (G1–G4, G9) accounted for 90% of the isolates
- G1 strain accounts for 75% of infections
- Very stable and may remain viable for weeks or months if not disinfected



Rotavirus Immunity

- **Antibody against VP7 and VP4 probably important for protection**
 - Cell-mediated immunity probably plays a role in recovery and immunity
- **First infection usually does not lead to permanent immunity**
- **Reinfection can occur at any age**
- **Subsequent infections generally less severe**

Rotavirus Clinical Features

- Short incubation period
- First infection after 3 months of age generally most severe
- May be asymptomatic or result in severe, dehydrating diarrhea with fever and vomiting
- Gastrointestinal symptoms generally resolve in 3–7 days

Rotavirus Complications

- Infection can lead to severe diarrhea, dehydration, electrolyte imbalance, and metabolic acidosis
- Immunocompromised children may experience severe prolonged gastroenteritis
- May have abnormalities in multiple organ systems, especially the kidney and liver

Rotavirus Epidemiology

- **World-wide distribution**
 - Similar in developed and developing countries
- **Reservoir**
 - Human–GI tract and stool
- **Transmission**
 - Fecal–oral, fomites
- **Temporal pattern**
 - Fall and winter (temperate areas)
- **Communicability**
 - 2 days before to 10 days after onset of symptoms

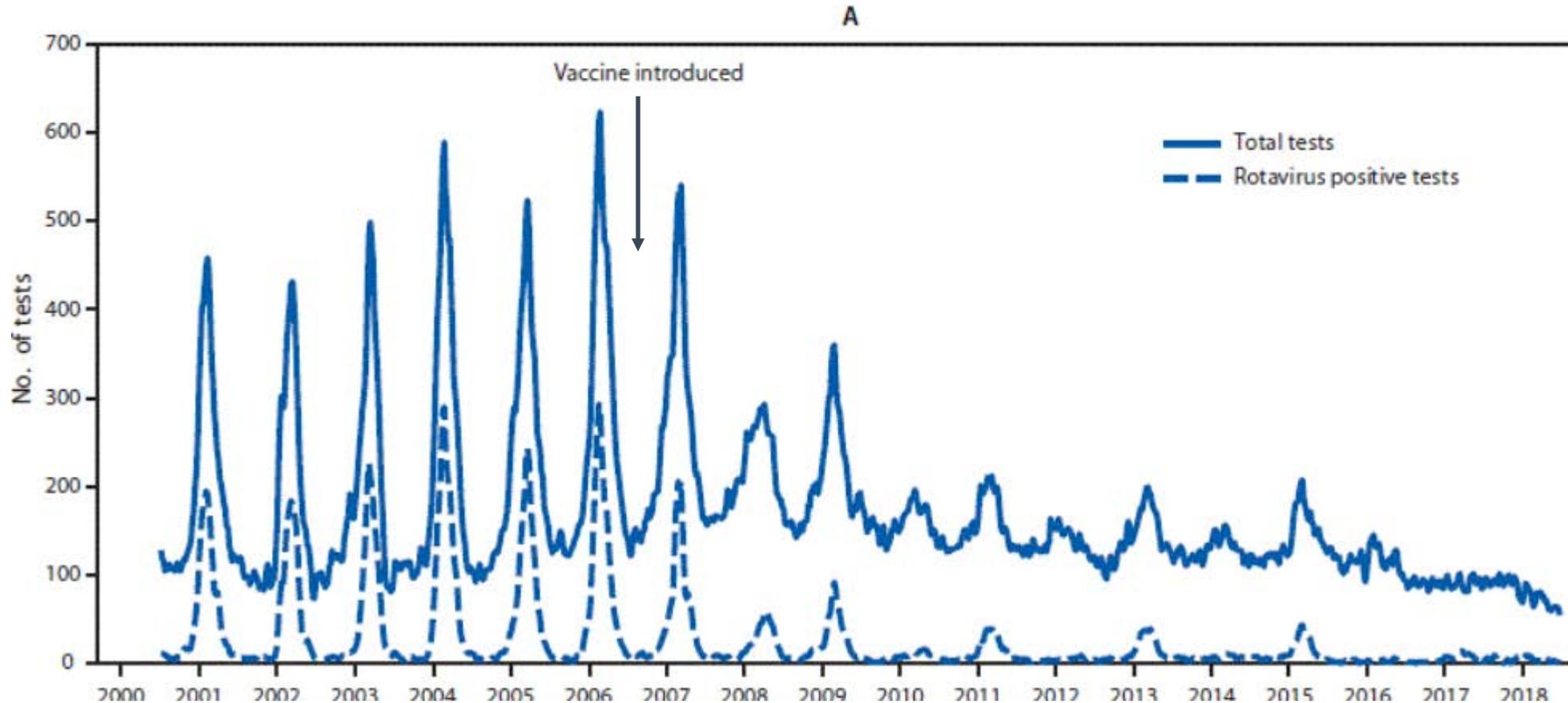
Rotavirus Disease in the United States Prevaccine Era

- **Annually responsible for:**
 - 3 million infections
 - More than 400,000 physician visits
 - 200,000 emergency dept. visits
 - 55,000–70,000 hospitalizations
 - 20–60 deaths
- **\$1 billion in direct and indirect costs**



Impact of Rotavirus Vaccine Introduction

FIGURE 1. Total number of rotavirus tests and positive rotavirus tests (A) and percent positivity (B) among the 23 continuously reporting National Respiratory and Enteric Virus Surveillance System (NREVSS) laboratories* — NREVSS, United States, 2000–2018



Rotavirus: What You Should Know



VOLUME 3, WINTER 2012

Rotavirus: What you should know

The Children's Hospital of Philadelphia



Before a rotavirus vaccine was available, each year in the United States almost 3 million children experienced high fevers, persistent vomiting and diarrhea as a result of rotavirus infections. These illnesses occurred during the winter in the United States and led to hundreds of thousands of doctor visits, tens of thousands of hospitalizations, and a small number of deaths. In other parts of the world where vaccines and medical access are limited, rotavirus still claims the lives of more than 1,000 children every day.

Q. What is rotavirus?

A. Rotavirus is a virus that infects the lining of the intestines. Typically, the virus infects children between 6 and 24 months of age. In temperate climates, such as the United States, rotavirus is a winter disease. In tropical climates, the disease occurs year-round.

Q. What is my child's risk of getting infected with rotavirus?

A. Almost everyone in the world is infected with rotavirus by 5 years of age. Before the vaccine, every year in the United States, rotavirus caused illness in 2.7 million children. The virus also caused 500,000 doctor visits, 55,000 to 70,000 hospitalizations and 20 to 60 deaths. About one of every 65 children born in the U.S. was hospitalized with dehydration caused by rotavirus. Since the rotavirus vaccine became widely used, at least 50 percent fewer children have suffered from rotavirus. Throughout the world, rotavirus kills about 500,000 infants and young children every year, more than any other single infectious disease. About 1,400 children die every day from rotavirus.

Q. What is the harm of infection with rotavirus?

A. Rotavirus causes three significant symptoms: high fever, vomiting and diarrhea. All three symptoms cause children to lose fluids. But none is more troublesome than vomiting. Vomiting caused by rotavirus can be frequent, persistent and severe. Also, it's very difficult to replace fluids and minerals in children who are vomiting. For this reason, no intestinal virus causes children to be dehydrated as quickly or as severely as rotavirus.

For the latest information on all vaccines, visit our Web site at

Q. Why do so many children in the developing world die from rotavirus?

A. Most people think rotavirus infections are more severe in developing countries, but they're not. About one of every five first-time rotavirus infections is moderate to severe, both in developed and developing countries. But countries with a high level of medical care are more likely to provide the lifesaving, supportive treatment children with rotavirus need. This difference is illustrated by a true story:



A 2-year-old girl wakes up with high fever and vomiting. The mother calls a nurse who instructs her to give the child frequent sips of Pedialyte®, but the child simply can't hold anything down. By the next morning, the mother is concerned about dehydration and takes the child to the doctor's office, where her fears are confirmed. The doctor examines the child and finds that when she cries she doesn't make tears and that she hasn't urinated in 10 hours: he tells the mother that her child is severely dehydrated and calls an ambulance. By the time the child arrives at the hospital, she is listless. Doctors in the emergency department try to give her intravenous fluids but, because she is so dehydrated, they can't find a vein in her arms or legs. The doctors call in a surgeon to put an intravenous line into her neck, allowing them to give the child much-needed fluids and saving her life.

In countries with limited medical resources, this child would have died from dehydration.

vaccine.chop.edu

Rotavirus: What you should know

Q. Is there a vaccine to prevent rotavirus?

A. Yes. Two vaccines are available. Both vaccines are given orally. The first became available in 2006 and is a combination between a cow rotavirus and human rotaviruses. The second, available in 2008, contains a weakened human rotavirus.

Q. Who should get the rotavirus vaccine?

A. The rotavirus vaccine is given by mouth to children at either 2 and 4 months of age or at 2, 4 and 6 months of age, depending upon which vaccine is used.

Q. Is the rotavirus vaccine safe?

A. Yes. Rotavirus vaccines have been given to millions of babies without consequence. However, in a very small number of infants (approximately 1 in 100,000) a condition called intussusception may occur. Intussusception is a type of intestinal blockage that may require surgery. Because the chance of being hospitalized with a rotavirus infection is much greater (approximately 1 in 65), the benefits of receiving the vaccine are far greater than the risks.



Throughout the world, rotavirus kills about 500,000 infants and young children every year, more than any other single infectious disease. About 1,400 children die every day from rotavirus.

Q. Does the rotavirus vaccine work?

A. Yes. About 98 of every 100 children who receive the rotavirus vaccine are protected against severe rotavirus disease. In clinical trials, none of the children who got the vaccine were hospitalized for rotavirus and there was a 96 percent decrease in doctor visits due to rotavirus.

Since the vaccine has become available, the United States has seen about half as many cases of rotavirus in young children as well as a decrease in hospitalization for dehydration caused by this disease.

The Children's Hospital of Philadelphia



vaccine.chop.edu

The Children's Hospital of Philadelphia

Hope lives here.

The Children's Hospital of Philadelphia, the nation's first pediatric hospital, is a world leader in patient care, pioneering research, education and advocacy.
©2012 by The Children's Hospital of Philadelphia. All Rights Reserved. • 501/597-12

2

**Rotavirus
Vaccine**

Rotavirus Vaccines

Vaccine product	Age indications
Single-component vaccines	
RotaTeq (RV5)	6 weeks to 32 weeks of age
Rotarix (RV1)	6 weeks to 24 weeks of age

Rotavirus Vaccine Efficacy

- **Any rotavirus gastroenteritis**
 - 74—87%
- **Severe gastroenteritis**
 - 85—98%
- **Both vaccines have significantly reduced physician visits for diarrhea and reduced rotavirus-related hospitalizations**
- **No ACIP preference for one product (RV5 vs. RV1) over the other**

3

**Rotavirus
Clinical
Considerations**

Rotavirus Vaccination Schedule

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19-23 mos	2-3 yrs	4-6 yrs	7-10 yrs	11-12 yrs	13-15 yrs	16 yrs	17-18 yrs
Rotavirus (RV) RV1 (2-dose series); RV5 (3-dose series)			1 st dose	2 nd dose	See Notes												

- **2 RV1 or 3 RV5 oral doses beginning at 2 months of age**
 - May be started as early as 6 weeks of age
- **For both rotavirus vaccines:**
 - Maximum age for first dose is 14 weeks, 6 days*
 - Minimum interval between doses is 4 weeks
 - Maximum age for any dose is 8 months, 0 days

*ACIP off-label recommendation for both vaccines because the labeled maximum age for the first dose of RV5 is 12 weeks

Rotavirus Vaccination Schedule

- ACIP did not define a maximum interval between doses
- Doses of rotavirus vaccine should be separated by at least 4 weeks
- No rotavirus vaccine should be administered to infants older than 8 months, 0 days*
- It is not necessary to restart the series or add doses because of a prolonged interval between doses

*ACIP off-label recommendation for both vaccine products because the labeled maximum age for RV1 is 24 weeks, and the labeled maximum age for RV5 is 32 weeks

Rotavirus Vaccine Recommendations

- **ACIP recommends that providers do not repeat the dose if the infant spits out or regurgitates the vaccine**
- **Any remaining doses should be administered on schedule**
 - Doses of rotavirus vaccine should be separated by at least 4 weeks
- **Complete the series with the same vaccine product whenever possible**

Rotavirus Vaccine Recommendations

- If product used for a prior dose or doses is not available or not known, continue or complete the series with the product that is available
- If any dose in the series was RV5 (RotaTeq) or the vaccine brand used for any prior dose is not known, a total of 3 doses of rotavirus vaccine should be administered
- Infants documented to have had rotavirus gastroenteritis before receiving the full course of rotavirus vaccinations should still begin or complete the 2- or 3-dose schedule

Rotavirus Vaccine Administration

- **Preparation:**
 - RV5: None
 - RV1: Must be reconstituted BEFORE administering
- **Route/Site: Administer ORALLY (PO)**
 - The infant may eat or drink immediately following vaccine administration
- **May be administered during the same clinical visit as other vaccines**

Vaccine Administration Errors

■ Route:

- RV1 inadvertently injected
 - The dose does NOT count. Re-administer the vaccine ORALLY ASAP

■ Schedule errors:

- 1st dose was inadvertently given after 14 weeks, 6 days (maximum age)
 - The dose counts
 - Administer the remaining doses of the series at the routinely recommended intervals
 - Timing of the first dose should not affect the safety and efficacy of the remaining doses
- Any dose after 8 months, 0 days (maximum age)
 - Rotavirus vaccine should not be given after age 8 months, 0 days even if the series is incomplete

Rotavirus Vaccine Contraindications

- **Severe allergic reaction to a vaccine component (including latex) or following a prior dose of vaccine**
 - RV1 (Rotarix) oral applicator contains latex rubber
- **History of intussusception**
- **Severe combined immunodeficiency (SCID)**

Rotavirus Vaccine Precautions*

- **Altered immunocompetence (except SCID, which is a contraindication)**
 - Limited data do not indicate a different safety profile in HIV-infected versus HIV-uninfected infants
 - HIV diagnosis not established in infants due for rotavirus vaccine
 - Vaccine strains of rotavirus are attenuated
 - These considerations support rotavirus vaccination of HIV-exposed or infected infants

*The decision to vaccinate if a precaution is present should be made on a case-by-case risk and benefit basis.

Rotavirus Vaccine Precautions

- **Acute, moderate, or severe gastroenteritis or other acute illness**
- **The decision to vaccinate if a precaution is present should be made on a case-by-case risk and benefit basis**

Rotavirus Vaccine Adverse Events

■ Intussusception

- RV1 postlicensure evaluation—1 to 3 excess cases per 100,000 first doses, possible risk for RV5 cases too small to confirm
- Vaccine Adverse Event Reporting System (VAERS) reports show event clusters in 3–6 days following RV5
- Vaccine Safety Datalink (VSD) shows no increased risk of intussusception (unable to assess RV1)

Rotavirus Vaccine Adverse Reactions

■ RV5 (RotaTeq)

- Diarrhea 18.1%
- Vomiting 11.6%
- Also greater rates of otitis media, nasopharyngitis, and bronchospasm

■ RV1 (Rotarix)

- Irritability 11.4%
- Cough or runny nose 3.6%
- Flatulence 2.2%

Vaccine Storage and Handling

- Store rotavirus vaccines in a refrigerator between 2°C–8°C (36°F–46°F)
- Store in the original packaging with the lids closed in a clearly labeled bin and/or area of the storage unit
 - Protect the vaccine from light
- Store RV1 (Rotarix) diluent in the refrigerator with the vaccine or at room temperature up to 25°C (77°F)
- Do not freeze vaccine or diluent

RV1 (Rotarix)

Ages: 6 weeks through 8 months, 0 days
Maximum age for 1st dose is 14 weeks, 6 days
Maximum age for last dose is 8 months, 0 days

Route: Oral (PO)

Reconstitute RV1 powder ONLY with manufacturer-supplied sterile water/calcium chloride/xanthan diluent

Beyond Use Time: If not used immediately after reconstitution, store at 2°C to 8°C (36°F to 46°F) or at controlled room temperature up to 25°C (77°F) and discard if not used within 24 hours.

Do NOT inject

Tip cap of prefilled diluent oral applicator contains latex

RV5 (RotaTeq)

Ages: 6 weeks through 8 months, 0 days
Maximum age for 1st dose is 14 weeks, 6 days
Maximum age for last dose is 8 months, 0 days

Route: Oral (PO)

Do NOT inject

RV1 (Rotarix)



Lyophilized RV1 component

+



Manufacturer's sterile water-calcium carbonate-xanthan diluent

=



Rotarix vaccine
Do NOT inject

Beyond Use Time: If not used immediately after reconstitution, store at 2°C to 8°C (36°F to 46°F) or at controlled room temperature up to 25°C (77°F) and discard if not used within 24 hours.
Tip cap of prefilled diluent oral applicator contains latex

Knowledge Check

True or false: if a child is older than 14 weeks, 6 days, and has never received a dose of rotavirus vaccine, they should not receive vaccine

A) True

B) False



Answer

- A) True



4

**Rotavirus
Resources**

- Ask the Experts–Rotavirus FAQs:
www.immunize.org/askexperts/experts_rota.asp
- CDC Rotavirus Disease and Vaccination:
www.cdc.gov/rotavirus/index.html
- Questions and Answers–Rotavirus What You Should Know:
<https://media.chop.edu/data/files/pdfs/vaccine-education-center-rotavirus.pdf>
- Standing Orders for Administering Rotavirus Vaccine:
www.immunize.org/catg.d/p3087.pdf

Rotavirus Vaccine Standing Orders

Standing Orders for Administering Rotavirus Vaccine to Infants

Purpose: To reduce morbidity and mortality from rotavirus disease by vaccinating all infants who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate infants who meet the criteria below.

Procedure

1. Identify infants ages 6 weeks through 7 months (not for 8 months or older) who have not completed a rotavirus (RV) vaccination series.
2. Screen all patients for contraindications and precautions to rotavirus vaccine:
 - a. **Contraindications:**
 - History of a serious allergic reaction (e.g., anaphylaxis) after a previous dose of RV vaccine or to an RV vaccine component (Note: latex rubber is contained in the Rotarix oral applicator). For information on vaccine components, refer to the manufacturers' package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
 - Diagnosis of severe combined immunodeficiency (SCID)
 - History of intussusception
 - b. **Precautions:**
 - Altered immunocompetence
 - Chronic gastrointestinal disease
 - Spina bifida or bladder exstrophy
 - Moderate or severe acute illness with or without fever
3. Provide all patients (parent/legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
4. Provide routine vaccination with Rotarix at ages 2 and 4 months OR provide routine vaccination with RotaTeq at ages 2, 4, and 6 months. Administer the full dose (1 mL for Rotarix; 2 mL for RotaTeq) of vaccine by administering the entire contents of the dosing applicator of the liquid vaccine into the infant's mouth toward the inner cheek until empty. Note that Rotarix needs to be reconstituted before administration; RotaTeq does not.
5. For infants who have not received RV vaccine by age 2 months, give the first dose at the earliest opportunity but no later than age 14 weeks 6 days. Then schedule subsequent doses by observing minimum intervals of 4 weeks between the remaining one (if Rotarix) or two (if RotaTeq) dose(s) such that the final dose can be administered by age 8 months 0 days. Do not administer any RV vaccine beyond the age of 8 months 0 days.
6. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to RV vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date). (name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

For standing orders for other vaccines, go to www.immunize.org/standing-orders

Technical content reviewed by the Centers for Disease Control and Prevention

IMMUNIZATION ACTION COALITION St. Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org

www.immunize.org/astg_d/p3087.pdf • Item #P3087 (2/14)

1

**Hepatitis
A
Disease**

Hepatitis A

- Epidemic jaundice described by Hippocrates
- Differentiated from hepatitis B in 1940s
- Serologic tests developed in 1970s
- Vaccines licensed in 1995 and 1996
- Until 2004, hepatitis A was the most frequently reported type of hepatitis in the U.S.

Hepatitis A Clinical Features

- Incubation period 28 days (range 15–50 days)
- Illness not specific for hepatitis A
- Likelihood of symptomatic illness directly related to age
- Children generally asymptomatic, adults symptomatic

Hepatitis A Epidemiology

Reservoir

Human

Transmission

Fecal–oral

Temporal pattern

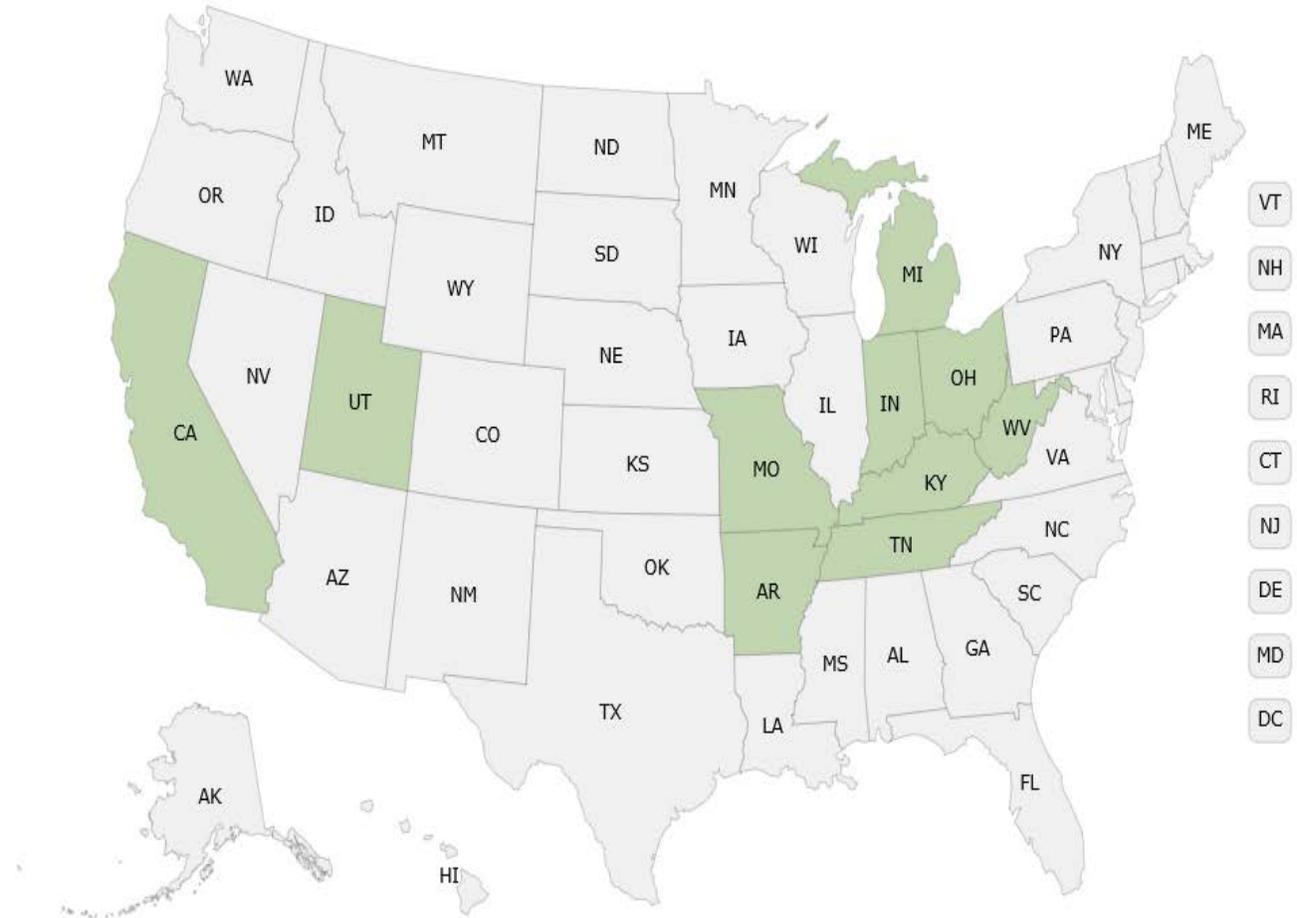
None

Communicability

1 to 2 weeks before to 1 week
after onset of jaundice

Hepatitis A Outbreak 2017-2019

- Hepatitis A outbreaks in 10 states have occurred primarily among persons who:
 - Use injection and noninjection drugs
 - Are homeless
 - Are their close, direct contacts



2

**Hepatitis
A
Vaccine**

Hepatitis A-Containing Vaccines

Vaccine product	Age indications
Havrix	
Pediatric formulation	Birth – 18 years
Adult formulation	19 years and older
Vaqta	
Pediatric formulation	Birth – 18 years
Adult formulation	19 years and older
Twinrix	
Adult formulation	18 years and older

Administer the appropriate formulation based on the patient's age

Hepatitis A-Containing Vaccines

- **Twinrix (HepA-HepB) combination vaccine contains:**
 - Hepatitis A 720 EL.U. (pediatric dose)
 - Hepatitis B 20 mcg (adult dose)
- **Approved for persons 18 years of age and older**
- **Schedules**
 - 3-dose: 0, 1, 6 months
 - or
 - 4-dose: 0, 7, 21–30 days and booster dose at 12 months after first dose

Vaccine Supply

- **Large outbreaks of Hepatitis A among adults in several US cities resulted in increased demand for vaccine and constrained vaccine supply**
- **In response, CDC has**
 - Collaborated with manufacturers to understand options for managing supplies in the public and private sector and increasing national supply
 - Increased vaccine availability on CDC's adult vaccine contracts
- **Available vaccine supplies have increased and progress has been made regarding ongoing outbreaks**
- **Manufacturers have supply to meet current demand**
- **CDC and vaccine manufacturers are monitoring the demand and need for adult Hepatitis A vaccine**
- **Note, supply constraints do not apply to the pediatric Hepatitis A vaccine supply**

Hepatitis A Vaccine Efficacy

- **HAVRIX (GSK)**
 - 40,000 Thai children 1 to 16 years of age
 - Vaccine efficacy 94%
- **VAQTA (Merck)**
 - 1,000 New York children 2 to 16 years of age
 - Vaccine efficacy 100%
- **Twinrix (GSK)**
 - 1,551 healthy adults 17 to 70 years of age
 - Vaccine efficacy HepA 99.9% and HepB 98.5%

3

**Hepatitis A
Clinical
Considerations**

ACIP Hepatitis A Vaccine Recommendations: Pediatric

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19-23 mos	2-3 yrs	4-6 yrs	7-10 yrs	11-12 yrs	13-15 yrs	16 yrs	17-18 yrs
Hepatitis A (HepA)					See Notes		2-dose series, See Notes										

- All children should receive vaccine at 12 through 23 months of age
- Vaccination should be integrated into the routine vaccination schedule
- Catch-up all unvaccinated children between 2 and 18 years
- Vaccination of all children 12 months and older with a high-risk condition

*Newly voted on recommendations by ACIP. New recommendations will be published soon in MMWR once approved by CDC director

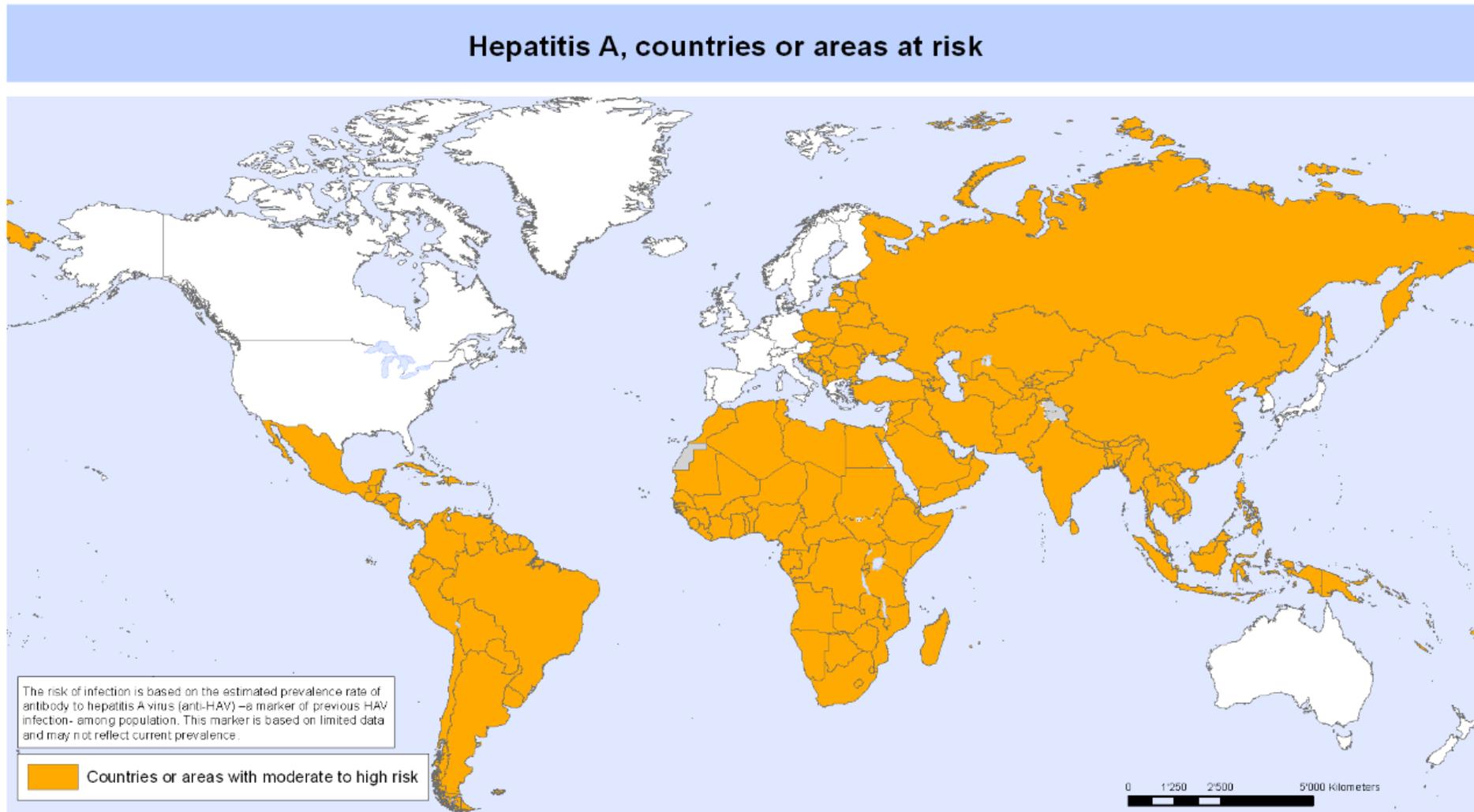
ACIP Hepatitis A Vaccine Recommendations: Adult

Vaccine	19–21 years	22–26 years	27–49 years	50–64 years	≥65 years
Hepatitis A (HepA)	2 or 3 doses depending on vaccine				

ACIP HepA Vaccine Recommendations: Adult

- **Administer vaccine to adults at increased risk, including:**
 - Travel to or work in areas with high or intermediate endemicity
 - Close, personal contact with international adoptee (e.g., household or regular babysitting) in first 60 days after arrival from country with high or intermediate endemic hepatitis A (administer dose 1 as soon as adoption is planned, at least 2 weeks before adoptee's arrival)
 - Men who have sex with men
 - Injection or noninjection drug use
 - Work with nonhuman primates or in a hepatitis A research laboratory setting
 - Chronic liver disease
 - Adults who report homelessness
 - Healthy adults who have recently been exposed to hepatitis A
 - Persons living with HIV
 - Persons in settings for exposure, including health care settings targeting services to injection or noninjection drug users or group homes and nonresidential day care facilities for developmentally disabled persons (individual risk factor screening not required)

Hepatitis A and International Travel



World Health Organization map of countries of area of risk for hepatitis A. Accessed 7/23/2019.
http://gamapserver.who.int/mapLibrary/Files/Maps/Global_HepA_ITHRiskMap.png?ua=1.

Hepatitis A Vaccine for International Travelers: Infants

- Administer a single dose of HepA vaccine to infants 6–11 months of age*
- Infants should restart the 2-dose series of HepA vaccine at 12 months of age or older as recommended

 Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

[A-Z Index](#)

Search



Morbidity and Mortality Weekly Report (MMWR)

CDC



Update: Recommendations of the Advisory Committee on Immunization Practices for Use of Hepatitis A Vaccine for Postexposure Prophylaxis and for Preexposure Prophylaxis for International Travel

Weekly / November 2, 2018 / 67(43);1216-1220

[Subscribe to MMWR](#)

Please note: An erratum has been published for this report. To view the erratum, please click [here](#).

Noele P. Nelson, MD, PhD¹; Ruth Link-Gelles, PhD¹; Megan G. Hofmeister, MD¹; José R. Romero, MD²; Kelly L. Moore, MD³; John W. Ward, MD¹; Sarah F. Schillie, MD¹ ([View author affiliations](#))

Hepatitis A Vaccination for International Travelers: Children and Adults

- **One dose of a monovalent hepatitis A vaccine protects most healthy people 1–40 years of age**
- **Administer HepA vaccine to persons 1 year of age and older**
 - Start the series as soon as travel is being considered to an area outside the U.S. where protection against hepatitis A is recommended
 - The series should be completed for lifelong protection – even if the trip is over
 - Postvaccination testing is not recommended

Summary: Hepatitis A Vaccine Recommendations and International Travel

Age	
Infants less than 6 months of age	Immunoglobulin (IG)
Infants 6 through 11 months of age	Vaccine ¹
Healthy persons 1 year of age or older	Vaccine
Special Populations	
Persons with a vaccine contraindication	IG
Immunocompromised persons	Vaccine with addition of IG ²
Persons with chronic liver disease	Vaccine
Pregnant women	Vaccine

¹The does does not count toward the routine series.

²Based on provider guidance risk assessment and availability of vaccine or IG

Knowledge Check

Which is NOT a risk factor for Hepatitis A?

- A) Clotting Factor Disorders
- B) Close, personal contact with an international adoptee (e.g., household or regular babysitting) in first 60 days after arrival from a country with high or intermediate endemic hepatitis A (administer dose 1 as soon as adoption is planned, at least 2 weeks before adoptee's arrival)
- C) Work with nonhuman primates or in a research laboratory setting
- D) Chronic liver disease
- E) Men who have sex with men



Answer

- A) Clotting factor disorders



Twinrix and Single-Component Hepatitis A Vaccine

- **Adult formulation hepatitis A vaccine may be used to complete a schedule begun with Twinrix and vice versa***
- **Acceptable schedules**
 - 2 Twinrix and 1 hepatitis A (adult formulation)
 - 1 Twinrix and 2 hepatitis A (adult formulation)
- **Maintain spacing recommended for Twinrix**

*Use the pediatric formulation of single-component vaccine for persons 18 years of age and younger.
Use the adult formulation of single-component vaccine for persons 19 years of age or older.

Hepatitis A Vaccination Additional Recommendations

- **Not routinely recommended for:**
 - Health care personnel
 - Child care center staff
 - Sewer workers or plumbers
- **Food handlers may be considered based on local circumstances**

Hepatitis A Serologic Testing

- **Prevaccination serologic testing is not indicated for children**
 - Older adolescents: Testing may be cost-effective for certain populations
- **Postvaccination**
 - Not indicated

Hepatitis A Vaccine Administration

■ Route: IM injection

- Needle gauge: 22 – 25 gauge
- Needle length*: 1 – 1.5 inch depending on the patient's age and/or weight

■ Site*:

- 1-2 years: Vastus lateralis muscle is preferred; deltoid muscle may be used if the muscle mass is adequate
- 3 years and older: Deltoid muscle is preferred; vastus lateralis muscle may be used

*Professional judgement should be used to determine the proper needle length and site. Influencing factors include injection technique, local reaction, number of vaccines to be administered, patient age, size and muscle mass

Hepatitis A Vaccine

Contraindications and Precautions

- Severe allergic reaction to a vaccine component or following a prior dose
- Moderate or severe acute illness

Hepatitis A Vaccine Adverse Reactions

- Local reaction **20% - 50%**
- Systemic reactions
(malaise, fatigue) **Less than 10%**
- No serious adverse reactions reported

Vaccine Storage and Handling

- Store hepatitis A vaccine in a refrigerator between 2°C-8°C (36°F-46°F)
- Store pediatric and adult formulations:
 - In the original packaging with the lids closed
 - In a clearly labeled bin and/or area of the storage unit-not next to each other

HepA (Havrix)-Pediatric Formulation

Ages: 12 months through 18 years
Use for: Any dose in the series
Route: Intramuscular (IM) injection

Read the package insert that accompanies the product to check for the presence of natural rubber or latex.

HepA (Havrix)-Adult Formulation

Ages: 19 years and older
Use for: Any dose in the series
Route: Intramuscular (IM) injection

Read the package insert that accompanies the product to check for the presence of natural rubber or latex.

HepA (Vaqta)-Pediatric Formulation

Ages: 12 months through 18 years
Use for: Any dose in the series
Route: Intramuscular (IM) injection

Vial stopper and syringe plunger contain latex

HepA (Vaqta)-Adult Formulation

Ages: 19 years and older
Use for: Any dose in the series
Route: Intramuscular (IM) injection

Vial stopper and syringe plunger stopper and tip cap contain latex

4

**Hepatitis
A
Resources**

Child Resources

- Ask the Experts—Hepatitis A FAQs: www.immunize.org/askexperts/experts_hepa.asp
- CDC Hepatitis A Disease: www.cdc.gov/hepatitis/hav/index.htm
- CDC Hepatitis A Vaccination: www.cdc.gov/vaccines/vpd/hepa/hcp/index.html
- Standing Orders for Administering Hepatitis A Vaccine: Children and Teens: www.immunize.org/catg.d/p3077a.pdf

Hepatitis A Vaccine Standing Orders for Children and Adults

Standing orders for other vaccines are available at www.immunize.org/standing-orders.
NOTE: This standing orders template may be adapted per a practice's discretion without obtaining permission from IAC. As a courtesy, please acknowledge IAC as its source.

STANDING ORDERS FOR Administering Hepatitis A Vaccine to Children and Teens

Purpose
To reduce morbidity and mortality from hepatitis A virus (HAV) by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy
Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate children and teens who meet any of the criteria below.

Procedure

- Assess Children and Teens in Need of Vaccination** against HAV infection based on the following criteria:
 - age 12–23 months and lacking documentation of at least 1 dose of hepatitis A vaccine (HepA)
 - age 2–18 years and living in a community, region, or state where routine vaccination is recommended (contact your health department for recommendations)
 - age 12 months and older with anticipated travel to a country with intermediate or high endemicity for hepatitis A (i.e., all except Canada, Japan, Australia, New Zealand, and Western Europe)
 - anticipated close personal contact with an international adoptee from a country of high or intermediate endemicity during the first 60 days after the arrival of the adoptee in the United States
 - a male who has sex with other males
 - users of street drugs (injecting and non-injecting)
 - diagnosis of chronic liver disease, including hepatitis B and C
 - diagnosis of a clotting-factor disorder, such as hemophilia
 - employment in a research laboratory requiring work with HAV or primates
 - an unvaccinated child or teen with recent possible exposure to HAV (e.g., within previous two weeks).
(Note: Children younger than age 12 months should be given immune globulin [IG] instead of vaccine.)
 - any other child or teen who wants to be protected from hepatitis A
- Screen for contraindications and precautions**

Contraindications

 - Do not give HepA to a child or teen who has experienced a serious reaction (e.g., anaphylaxis) to a prior dose of the vaccine or to any of its components. For information on vaccine components, refer to the manufacturers' package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.

Precautions

 - Moderate or severe acute illness with or without fever
- Provide Vaccine Information Statements**
Provide all patients (or, in the case of minors, their parent, or legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available and desired; these can be found at www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

CONTINUED ON THE NEXT PAGE ►

IMMUNIZATION ACTION COALITION Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org
www.immunize.org/catg.d/p3077a.pdf • Item #P3077a (2/18)

Technical content reviewed by the Centers for Disease Control and Prevention

Standing orders for other vaccines are available at www.immunize.org/standing-orders.
NOTE: This standing orders template may be adapted per a practice's discretion without obtaining permission from IAC. As a courtesy, please acknowledge IAC as its source.

STANDING ORDERS FOR Administering Hepatitis A Vaccine to Adults

Purpose
To reduce morbidity and mortality from hepatitis A virus (HAV) by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy
Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate adults who meet any of the criteria below.

Procedure

- Assess Adults in Need of Vaccination** against HAV infection based on the following criteria:
 - anticipated travel to a country with intermediate or high endemicity for hepatitis A (i.e., all except Canada, Japan, Australia, New Zealand, and Western Europe)
 - a male who has sex with other males
 - users of street drugs (injecting and non-injecting)
 - diagnosis of chronic liver disease, including hepatitis B and C
 - diagnosis of a clotting-factor disorder, such as hemophilia
 - anticipated close personal contact with an international adoptee from a country of high or intermediate endemicity during the first 60 days after the arrival of the adoptee in the United States
 - employment in a research laboratory requiring work with HAV or HAV-infected primates
 - an adult age 40 years or younger with recent possible exposure to HAV (e.g., within previous two weeks)
(Note: For adults older than age 40 years with recent exposure to HAV, immune globulin [IG] is preferred [0.1 mL/kg]; vaccine can be used if IG cannot be obtained.)
 - any other adult who wants to be protected from hepatitis A
- Screen for contraindications and precautions**

Contraindications

 - Do not give HepA to an adult who has experienced a serious reaction (e.g., anaphylaxis) to a prior dose of the vaccine or to any of its components. For information on vaccine components, refer to the manufacturers' package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.

Precautions

 - Moderate or severe acute illness with or without fever
- Provide Vaccine Information Statements**
Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available and desired; these can be found at www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

CONTINUED ON THE NEXT PAGE ►

IMMUNIZATION ACTION COALITION Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org
www.immunize.org/catg.d/p3077.pdf • Item #P3077 (2/18)

Technical content reviewed by the Centers for Disease Control and Prevention

Continuing Education Information

- CE credit, go to: www.cdc.gov/GetCE
- Search course number: WD4344-081220
- CE credit expires: July 1, 2022
- CE instructions are available on the EpiVac Pink Book Web-on-Demand Series web page
- Questions and additional help with the online CE system, e-mail CE@cdc.gov

The screenshot shows the TCEO website interface. At the top, there is a blue header with the text "Training and Continuing Education Online (TCEO)". Below this is the TCEO logo, which consists of the letters "TCEO" in a bold, blue font with a green leaf-like shape above the "O". Underneath the logo, the text "TRAINING AND CONTINUING EDUCATION ONLINE" is displayed in a smaller, blue font.

On the left side, there is a vertical navigation menu with several blue buttons: "TCEO Home", "Search Courses", "Create Account", "9 Simple Steps to Earn CE", "Frequently Asked Questions", and "Contact TCEO".

The main content area on the right has a white background. It starts with a section titled "New to TCEO?" in bold. Below this, there are two paragraphs of text. The first paragraph says "Visit [Create Account](#). Once your account has been created, you will be able to search for courses and complete requirements to receive CE." The second paragraph says "Already have a TCEO account from the previous system? To move your account to the new system please sign in above using your existing TCEO username and password. Once signed in, follow the prompts to verify and update your account. After your account is updated you will use this email address and password to sign in." Below this is another section titled "Not sure how to get started?" with a paragraph that says "Follow these 9 Simple Steps to earn continuing education for the courses you have taken or conferences you have attended!"

At the bottom of the main content area, there is a row of four small images: a woman smiling at a child, a man in a suit looking thoughtful, a doctor in a white coat holding a small dog, and a woman sitting at a desk with a computer monitor.

Below the images, the text "Welcome to TCEO" is displayed. At the very bottom, there is a small line of text: "Training and Continuing Education Online (TCEO) is a system that provides access to CDC educational activities for continuing education (CE). Use TCEO to search for CE opportunities, complete course en..."

E-mail Your Immunization Questions to Us

NIPINFO@cdc.gov

Write “Web-on-Demand–Rota-HepA”
in the subject line



EpiVac Pink Book Web-on-Demand Resources

- Comprehensive list of resources for ALL sessions
- Located on the web page for this web-on-demand session at www.cdc.gov/vaccines/ed/webinar-epv/index.html
- Additional materials located on this webpage include:
 - Principles of Vaccination slide set
 - Web-on-demand questions and answers
 - Transcript of this session
 - Continuing education instructions

COURSE RESOURCES

Epidemiology and Prevention of Vaccine-Preventable Diseases

- ▶ Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book) Supplement: www.cdc.gov/vaccines/pubs/pinkbook/supplement.html

Overall Resources

- ▶ Current childhood and adult immunization schedules: www.cdc.gov/vaccines/schedules/index.html
- ▶ CDC Vaccine Schedules App for Health Care Providers: www.cdc.gov/vaccines/schedules/hcp/schedule-app.html
- ▶ Advisory Committee on Immunization Practices (ACIP) recommendations: www.cdc.gov/vaccines/hcp/acip-recs/index.html
- ▶ CDC General Best Practice Guidelines for Immunization: www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- ▶ CDC Continuing Education Information: www.cdc.gov/vaccines/ed/ce-credit-how-to.html
- ▶ Health Care Personnel Vaccination Recommendations: www.immunize.org/catg.d/p2017.pdf
- ▶ Pink Book Webinar Series: www.cdc.gov/vaccines/ed/webinar-epv/index.html
- ▶ Vaccines Licensed for Use in the United States Package Inserts: www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm
- ▶ You Call the Shots: www.cdc.gov/vaccines/ed/youcalltheshots.html

Course Intro and Objectives

- ▶ What is the Advisory Committee on Immunization Practices (ACIP)?: www.cdc.gov/vaccines/hcp/conversations/downloads/vacsafe-acip-color-office.pdf
- ▶ CDC Immunization Resources for You and Your Patients: www.cdc.gov/vaccines/hcp/admin/downloads/Resource-Booklet.pdf
- ▶ Parents' Guide to Childhood Immunizations: www.cdc.gov/vaccines/parents/tools/parents-guide/index.html
- ▶ Order Information for Free CDC Immunization Materials for Providers and Patients: www.cdc.gov/pubs/CDCInfoOnDemand.aspx

Principles of Vaccination

- ▶ Immune System Research: www.niaid.nih.gov/research/immune-system-research
- ▶ What is the Immune System?: www.vaccines.gov/basics/work/prevention
- ▶ Understanding How Vaccines Work: www.cdc.gov/vaccines/hcp/conversations/downloads/vacsafe-understand-color-office.pdf
- ▶ Vaccines Work: www.vaccines.gov/basics/work/index.html
- ▶ Vaccine Basics: How Vaccines Work: www.vaccineinformation.org/how-vaccines-work/
- ▶ The History of Vaccines: How Vaccines Work: www.historyofvaccines.org/content/how-vaccines-work

General Best Practice Guidelines

- ▶ Ask the Experts-Scheduling Vaccines FAQs: www.immunize.org/askexperts/scheduling-vaccines.asp
- ▶ Ask the Experts-Combination Vaccines FAQs: www.immunize.org/askexperts/experts_combo.asp
- ▶ Ask the Experts-Precautions and Contraindications FAQs: www.immunize.org/askexperts/precautions-contraindications.asp
- ▶ Foreign Language Vaccine-Preventable Disease Terms: www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/foreign-products-tables.pdf
- ▶ Guide to Contraindications and Precautions to Commonly Used Vaccines: www.immunize.org/catg.d/p3072a.pdf
- ▶ Guidelines for Vaccinating Pregnant Women: www.cdc.gov/vaccines/pregnancy/hcp/guidelines.html
- ▶ IDSA 2013 Clinical Practice Guideline for Vaccination of the Immunocompromised Host: www.idsociety.org/Guidelines/Patient_Care/IDSA_Practice_Guidelines/Vaccination_of_the_Immunocompromised_Host/
- ▶ Interval Between Antibody-Containing Products and Measles- and Varicella-Containing Vaccines: www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/a/mmr_ig.pdf



Thank You From Atlanta!

