Rotavirus and Hepatitis A

Pink Book Webinar Series 2018

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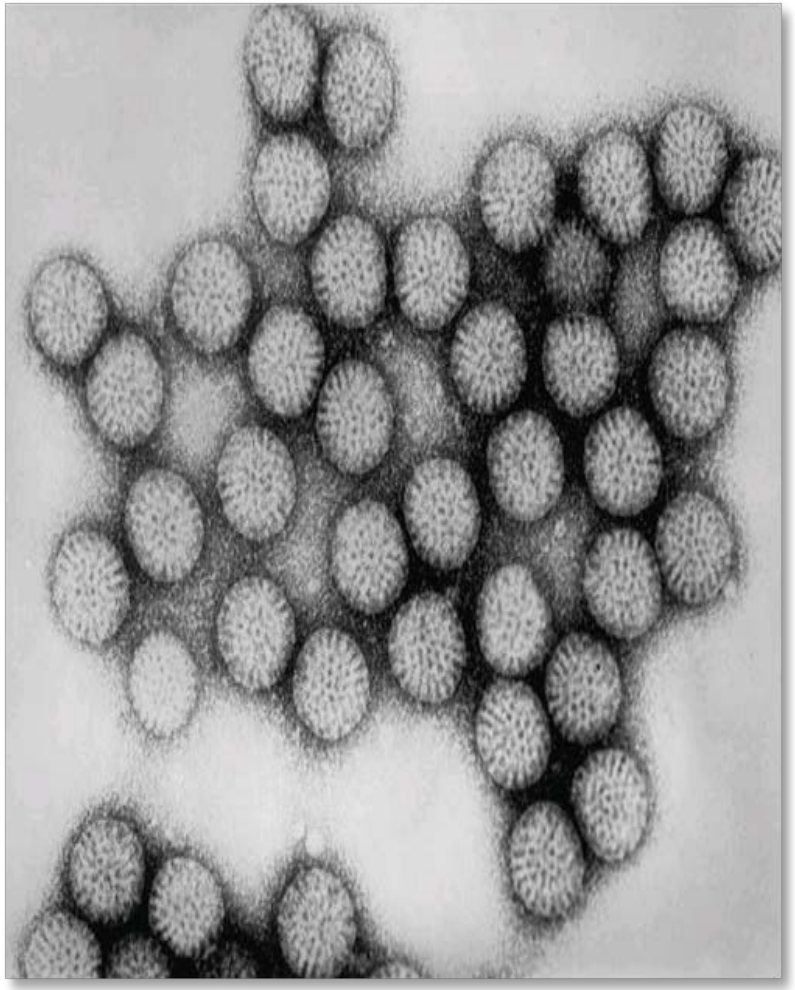
Rotavirus: Disease and Vaccine

Rotavirus

- First identified as a cause of diarrhea in 1973
- Most common cause of severe gastroenteritis in infants and young children
- 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**

Rotavirus: What You Should Know

Q&A

Volume 3, Winter 2012

Rotavirus: What you should know

The Children's Hospital of Philadelphia® | Vaccine Education Center

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.

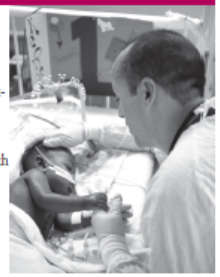
Q. What is my child's risk of getting infected with rotavirus?

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.

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.

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

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.

This information is provided by the Vaccine Education Center at The Children's Hospital of Philadelphia. The Center is an educational resource for parents and healthcare professionals and is composed of scientists, physicians, mothers and fathers who are devoted to the study and prevention of infectious diseases. The Vaccine Education Center is funded by endowed chairs from The Children's Hospital of Philadelphia. The Center does not receive support from pharmaceutical companies.

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Hope lives here.

Children's Hospital of Philadelphia Vaccine Education Center http://media.chop.edu/data/files/pdfs/vaccine-education-center-rotavirus.pdf

Rotavirus Vaccines

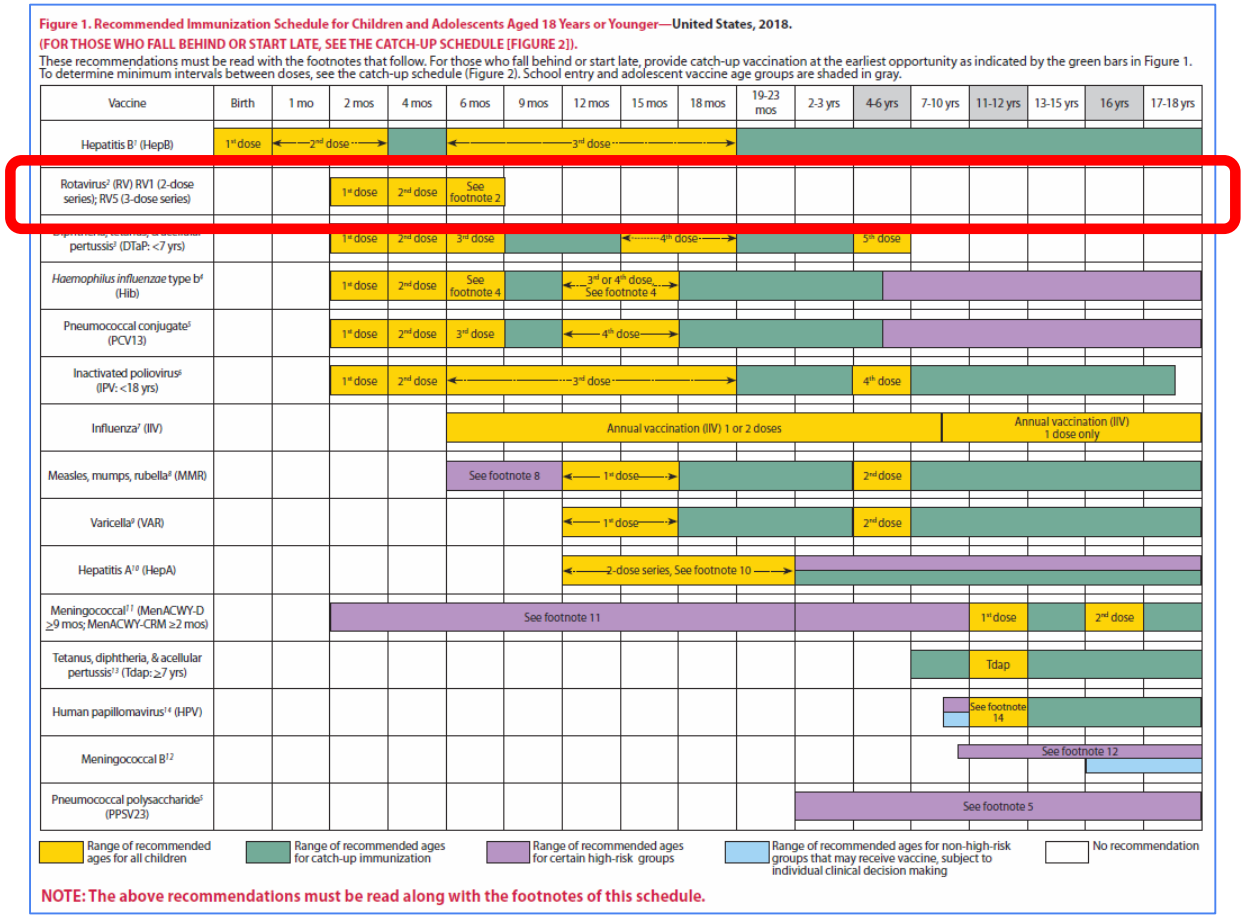
- **RV5 (RotaTeq)**
  - Contains 5 reassortant rotaviruses developed from human and bovine parent rotavirus strains
- **RV1 (Rotarix)**
  - Contains one strain of live, attenuated human rotavirus (type G1PA[8])
- **Both rotavirus vaccines**
  - Live, attenuated
  - Contain no preservatives or thimerosal

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**

Rotavirus Vaccination Schedule

- **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

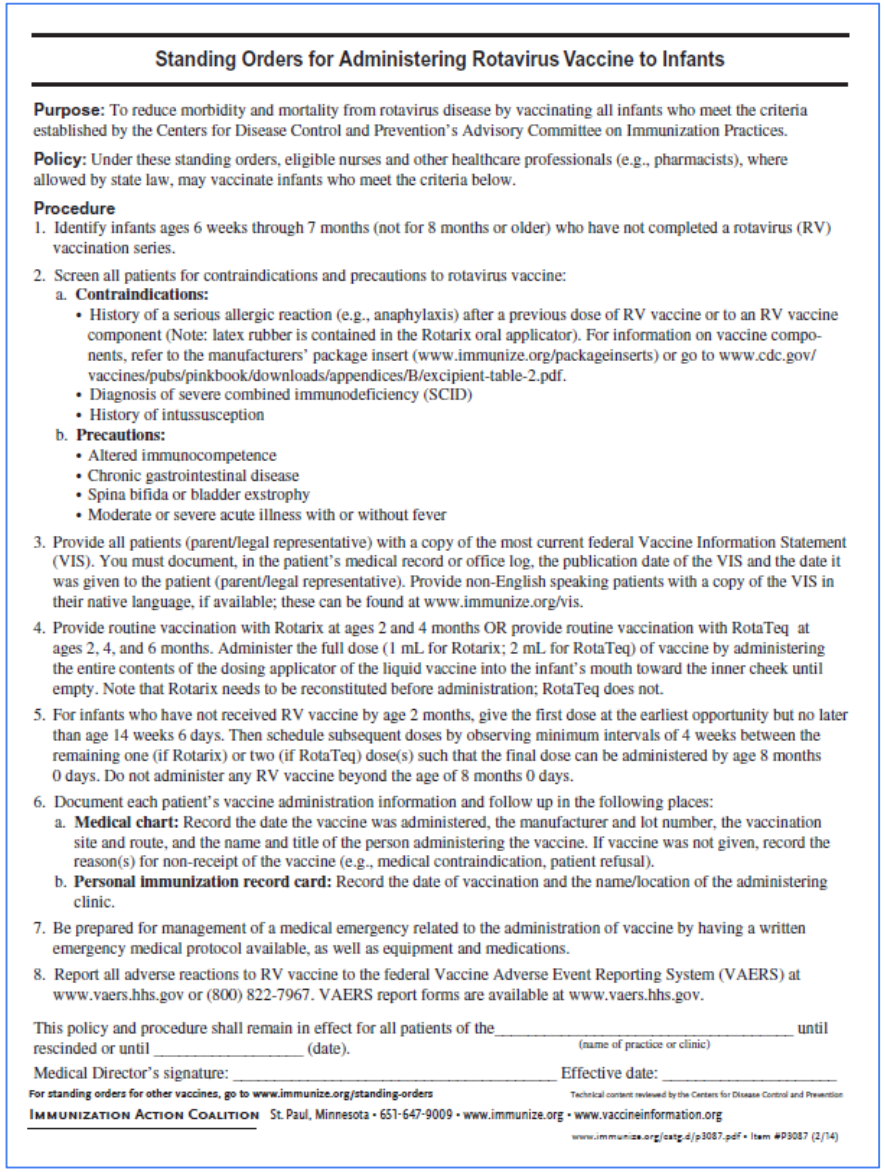
Rotavirus Vaccine Administration

- **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 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 _____ (name of practice or clinic) until rescinded or until _____ (date).

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/catg.d/p3087.pdf • Item #P3087 (2/14)

Immunization Action Coalition website accessed 4/8/2018

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

Hepatitis A: Disease and Vaccine

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	2 weeks before to 1 week after onset of jaundice

Hepatitis A-Containing Vaccines

- **Inactivated vaccine, 2 single-component products**
  - Haverix (GSK)
  - Vaqta (Merck)
- **Both products have pediatric and adult formulations**
  - Pediatric formulation contains 720 EL.U. per 0.5-mL dose
  - Adult formulation contains 1,440 EL.U. per 1.0-mL dose

Hepatitis A-Containing Vaccines

- **Administer the appropriate formulation based on age**
  - Pediatric formulations: 1 through 18 years of age
  - Adult formulations: 19 years and older

- **Schedule:**
  - 2 doses separated by at least 6 months

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**

CDC website: Current Vaccine Shortages and Delays. Accessed 4/3/2018 https://www.cdc.gov/vaccines/hcp/clinical-resources/shortages.html#note1

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

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 older..
Use the adult formulation of single-component vaccine for persons 19 years of age or older.

A Quick Look at Twinrix Job Aid

MDCH

A Quick Look at Using Hep A/Hep B (Twinrix®)

Indications for Use and Schedule

Approved for:

- Routine schedule of 3 doses; 0, 1, 6 months
- Persons with indications for both hepatitis A and hepatitis B vaccines
- Alternate schedule of 4 doses; 0, 7, 21-30 days and a booster dose 12 months after the first dose

Each dose of Twinrix contains:

- One **adult** dose of hepatitis B vaccine
- One **pediatric** dose of hepatitis A vaccine

Make sure minimum age and minimum intervals are met:

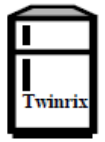
- Minimum age for **any** dose is 18 years
- Minimum intervals for 3-dose schedule:
  - 4 weeks between dose 1 & 2
  - 5 months between dose 2 & 3

Vaccine Administration

- Intramuscular (IM) injection in the deltoid of the arm
- 1-1.5 inch needle; 22-25 gauge
- Professional judgment is appropriate when selecting needle length
- Can be given with other vaccines, at the same visit (use separate sites; space at least 1 inch apart)

Storage and Handling

- Store in the refrigerator between **35°-46° F (2°-8°C)**
- Do NOT freeze
- Keep in the original box
- Shake well before using



CONTRAINDICATIONS

- An anaphylactic reaction to a prior dose of Twinrix, hepatitis A or hepatitis B vaccine
- An anaphylactic reaction to a component of Twinrix (hep A/hep B) including yeast and neomycin

PRECAUTIONS

- Moderate to severe acute illness

FURTHER POINTS

- Because the hepatitis B component of Twinrix® is equivalent to a standard adult dose of hep B vaccine, the schedule is the same whether Twinrix® or single-antigen hep B vaccine is used
- Because the hepatitis A component of Twinrix® is equivalent to a pediatric dose of hep A vaccine, persons 19 years and older who receive only 1 or 2 doses of Twinrix ® will need additional adult doses of single-antigen hep A vaccine

Completing hepatitis A and hepatitis B series with single-antigen hep A, hep B and/or Twinrix®
Any combination of 3 doses of adult hepatitis B or 3 doses of Twinrix = a complete series of hepatitis B
1 dose of Twinrix® + 2 doses of adult hepatitis A = a complete series of hepatitis A
2 doses of Twinrix® + 1 dose of adult hepatitis A = a complete series of hepatitis A

- There is not a separate Vaccine Information Statement (VIS) for Twinrix®. Use the current VISs for hep A and hep B that include information about the Michigan Care Improvement Registry (MCIR).
- VISs with MCIR information are available at www.michigan.gov/immunize or at your local health department.
- Document as "Hep A/Hep B" in MCIR, on the vaccine administration record & immunization record card

Publicly purchased hep A/hep B (Twinrix®) and single-antigen hep A and hep B vaccines are available for persons at high risk for hepatitis A or hepatitis B virus infection when served at local health department or select sites. Eligible adults 19 years and older include those who are uninsured or underinsured. Adults who are Medicaid-eligible and meet high risk criteria for hep A or hep B may receive privately purchased single-antigen vaccines or Twinrix; bill Medicaid for the vaccine & administration fee. Medicare part B & D will cover privately purchased hep A or hep B under certain circumstances—see policies. For persons 18 years and younger, publicly purchased vaccines (excluding Twinrix®) are available in private provider offices under the Vaccines for Children (VFC) program. Eligible children are those with Medicaid, underinsured, uninsured, or Native American or Alaskan Natives. Contact your local health department for more information on these programs.
For additional information, refer to the ACIP Recommendations on the use of Hep A and Hep B vaccines, located at http://www.cdc.gov/vaccines/recs

January 6, 2009

Michigan Department of Health and Human Services http://www.michigan.gov/documents/mdch/QuickLookUsingTwinrix091708_250029_7.pdf

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%

ACIP HepA Vaccine Recommendations: Pediatric

- Routinely vaccinate children at 12 through 23 months of age
- Vaccination should be integrated into the routine vaccination schedule
- Children who are not vaccinated by 2 years of age can be vaccinated at subsequent visits

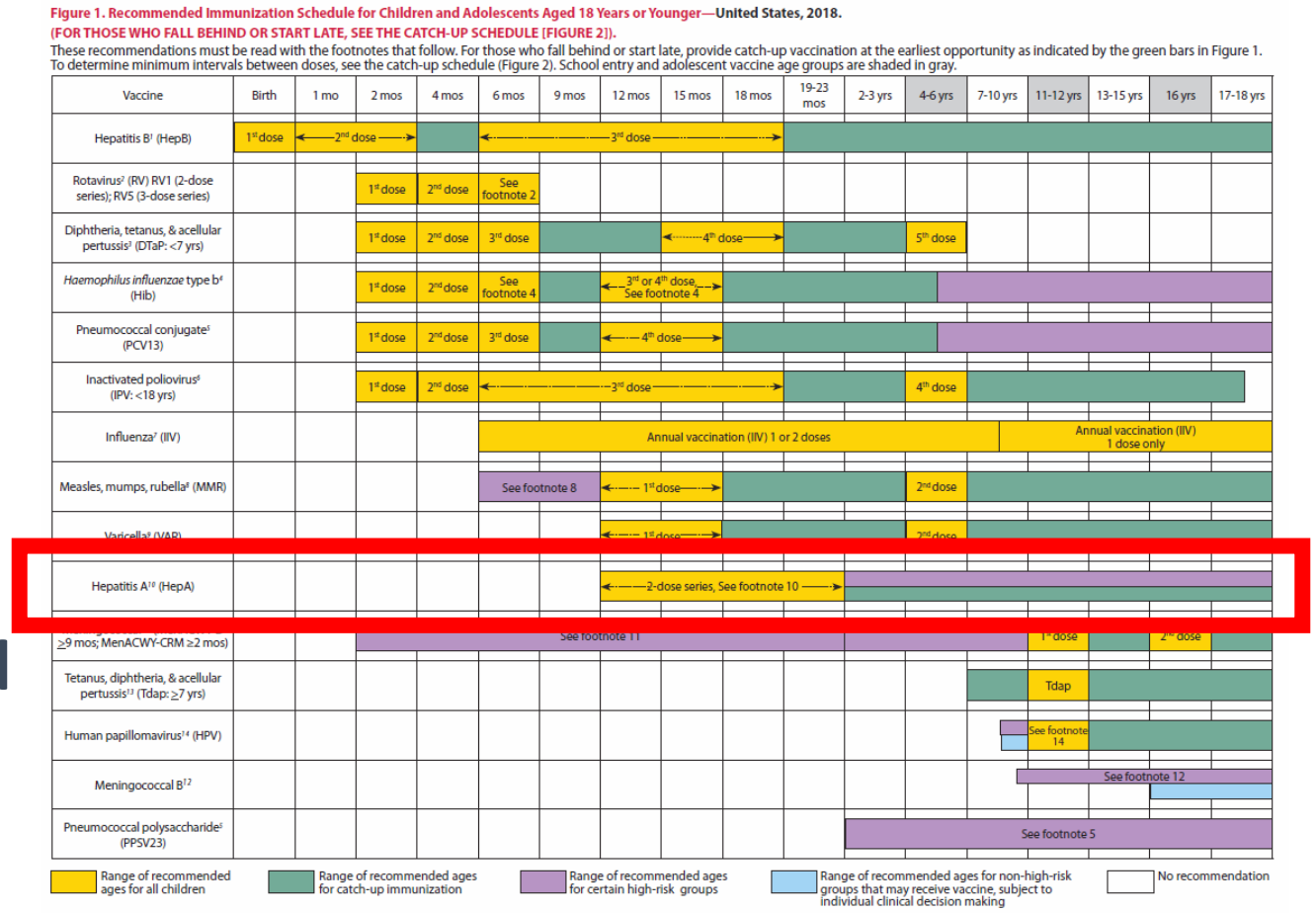


Figure 1. Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger—United States, 2018.

(FOR THOSE WHO FALL BEHIND OR START LATE, SEE THE CATCH-UP SCHEDULE [FIGURE 2]).

These recommendations must be read with the footnotes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Figure 1. To determine minimum intervals between doses, see the catch-up schedule (Figure 2). School entry and adolescent vaccine age groups are shaded in gray.

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 B[1] (HepB)	1st dose	← 2nd dose →			← 3rd dose →												
Rotavirus[2] (RV) RV1 (2-dose series); RV5 (3-dose series)			1st dose	2nd dose	See footnote 2												
Diphtheria, tetanus, & acellular pertussis[3] (DTaP: <7 yrs)			1st dose	2nd dose	3rd dose			← 4th dose →				5th dose					
Haemophilus influenzae type b[4] (Hib)			1st dose	2nd dose	See footnote 4		← 3rd or 4th dose, See footnote 4 →										
Pneumococcal conjugate[5] (PCV13)			1st dose	2nd dose	3rd dose		← 4th dose →										
Inactivated poliovirus[6] (IPV: <18 yrs)			1st dose	2nd dose	← 3rd dose →							4th dose					
Influenza[7] (IIV)					Annual vaccination (IIV) 1 or 2 doses									Annual vaccination (IIV) 1 dose only			
Measles, mumps, rubella[8] (MMR)					See footnote 8		← 1st dose →					2nd dose					
Varicella[9] (VAR)							← 1st dose →					2nd dose					
Hepatitis A[10] (HepA)							← 2-dose series, See footnote 10 →										
≥9 mos; MenACWY-CRM ≥2 mos)			See footnote 11											1st dose		2nd dose	
Tetanus, diphtheria, & acellular pertussis[13] (Tdap: ≥7 yrs)														Tdap			
Human papillomavirus[14] (HPV)														See footnote 14			
Meningococcal B[12]																See footnote 12	
Pneumococcal polysaccharide[5] (PPSV23)																	See footnote 5

Range of recommended ages for all children

Range of recommended ages for catch-up immunization

Range of recommended ages for certain high-risk groups

Range of recommended ages for non-high-risk groups that may receive vaccine, subject to individual clinical decision making

No recommendation

Hepatitis A Vaccination of Children

- Existing hepatitis A vaccination programs for children 2–18 years of age should be maintained
- New efforts for routine vaccination of children 12 months of age should enhance, not replace, ongoing vaccination programs for older children
- Areas without an existing hepatitis A vaccination program can consider catch-up vaccination for unvaccinated children 2-18 years of age

ACIP Recommended Immunization Schedule for Adults 19 Years of Age and Older, 2018

Figure 1. Recommended immunization schedule for adults aged 19 years or older by age group, United States, 2018

This figure should be reviewed with the accompanying footnotes. This figure and the footnotes describe indications for which vaccines, if not previously administered, should be administered unless noted otherwise.

Vaccine	19–21 years	22–26 years	27–49 years	50–64 years	≥65 years
Influenza[1]	1 dose annually				
Tdap[2] or Td[2]	1 dose Tdap, then Td booster every 10 yrs				
MMR[3]	1 or 2 doses depending on indication (if born in 1957 or later)				
VAR[4]	2 doses				
RZV[5] (preferred)				2 doses RZV (preferred)	
or				or	
ZVL[5]					1 dose ZVL
HPV–Female[6]	2 or 3 doses depending on age at series initiation				
HPV–Male[6]	2 or 3 doses depending on age at series initiation				
PCV13[7]	1 dose				
PPSV23[7]	1 or 2 doses depending on indication				1 dose
HepA[8]	2 or 3 doses depending on vaccine				
HepB[9]	3 doses				
MenACWY[10]	1 or 2 doses depending on indication, then booster every 5 yrs if risk remains				
MenB[10]	2 or 3 doses depending on vaccine				
Hib[11]	1 or 3 doses depending on indication				

Recommended for adults who meet the age requirement, lack documentation of vaccination, or lack evidence of past infection

Recommended for adults with other indications

No recommendation

Figure 2. Recommended immunization schedule for adults aged 19 years or older by medical condition and other indications, United States, 2018

This figure should be reviewed with the accompanying footnotes. This figure and the footnotes describe indications for which vaccines, if not previously administered, should be administered unless noted otherwise.

Vaccine	Pregnancy[1-6]	Immuno-compromised (excluding HIV infection)[3-7,11]	HIV infection CD4+ count (cells/μL)[3-7,9-10]		Asplenia, complement deficiencies[7,10,11]	End-stage renal disease, on hemodialysis[7,9]	Heart or lung disease, alcoholism[7]	Chronic liver disease[7-9]	Diabetes[7,9]	Health care personnel[3,4,9]	Men who have sex with men[6,8,9]
			<200	≥200							
Influenza[1]	1 dose annually										
Tdap[2] or Td[2]	1 dose Tdap each pregnancy	1 dose Tdap, then Td booster every 10 yrs									
MMR[3]	contraindicated			1 or 2 doses depending on indication							
VAR[4]	contraindicated			2 doses							
RZV[5] (preferred)				2 doses RZV at age ≥50 yrs (preferred)							
or				or							
ZVL[5]	contraindicated			1 dose ZVL at age ≥60 yrs							
HPV–Female[6]		3 doses through age 26 yrs		2 or 3 doses through age 26 yrs							
HPV–Male[6]		3 doses through age 26 yrs		2 or 3 doses through age 21 yrs							2 or 3 doses through age 26 yrs
PCV13[7]		1 dose									
PPSV23[7]		1 or 2 doses depending on indication									
HepA[8]		2 or 3 doses depending on vaccine									
HepB[9]		3 doses									
MenACWY[10]		1 or 2 doses depending on indication , then booster every 5 yrs if risk remains									
MenB[10]		2 or 3 doses depending on vaccine									
Hib[11]		3 doses HSCT recipients only		1 dose							

Recommended for adults who meet the age requirement, lack documentation of vaccination, or lack evidence of past infection

Recommended for adults with other indications

Contraindicated

No recommendation

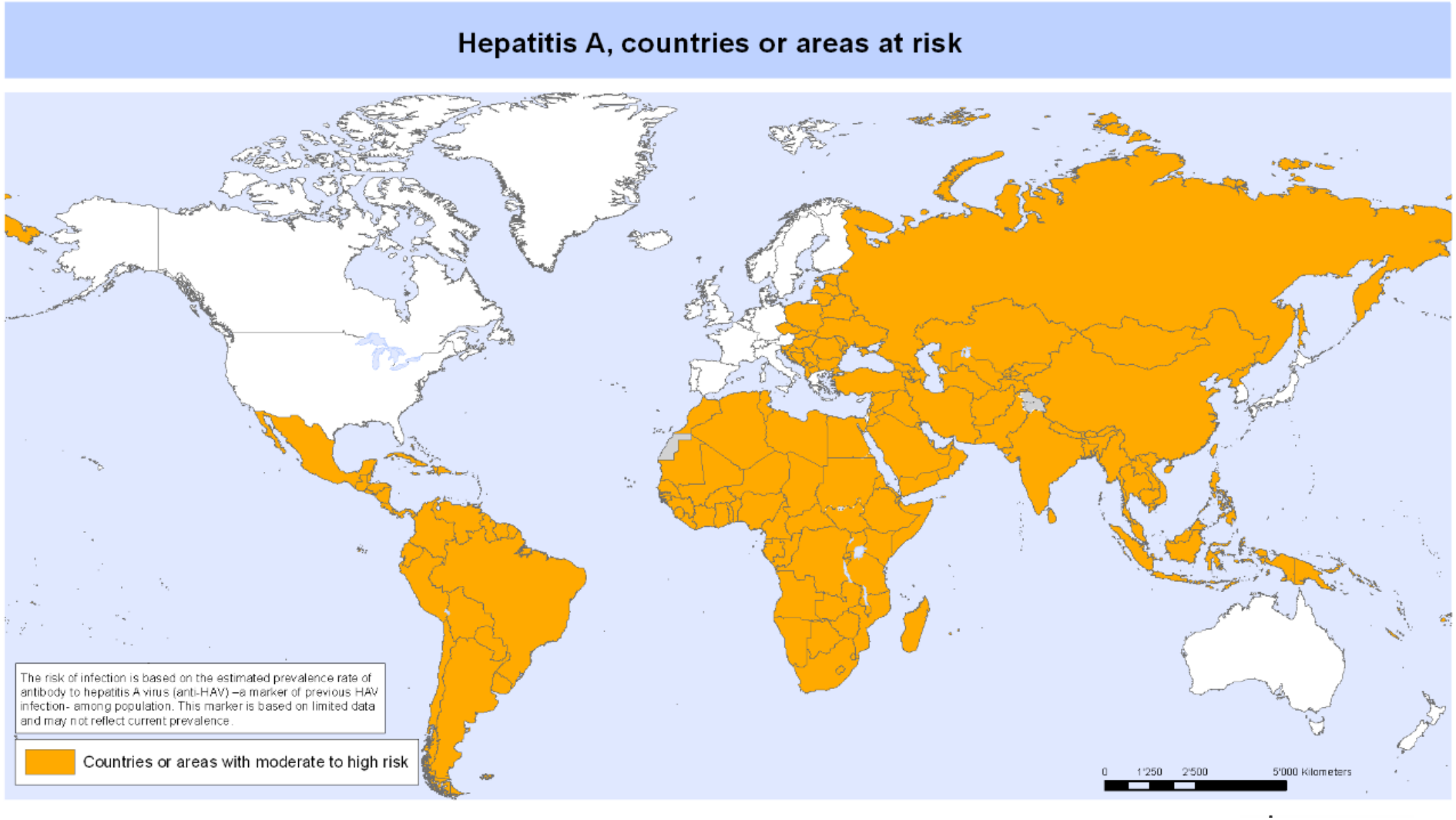
Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States 2018

https://www.cdc.gov/vaccines/schedules/hcp/adult.html

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 an international adoptee from an area with high or intermediate endemicity
  - Men who have sex with men
  - Injection or non-injection drug use
  - Clotting factor disorders
  - Work with nonhuman primates or in a hepatitis A research laboratory setting
  - Chronic liver disease
  - Healthy adults who have recently been exposed to hepatitis A

Hepatitis A and International Travel



World Health Organization map of countries of area of risk for hepatitis A. Accessed 4/3/2018. http://gamapserver.who.int/mapLibrary/Files/Maps/Global_HepA_ITHRiskMap.png?ua=1.

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 life-long protection–even if the trip is over
  - Post-vaccination testing is not recommended

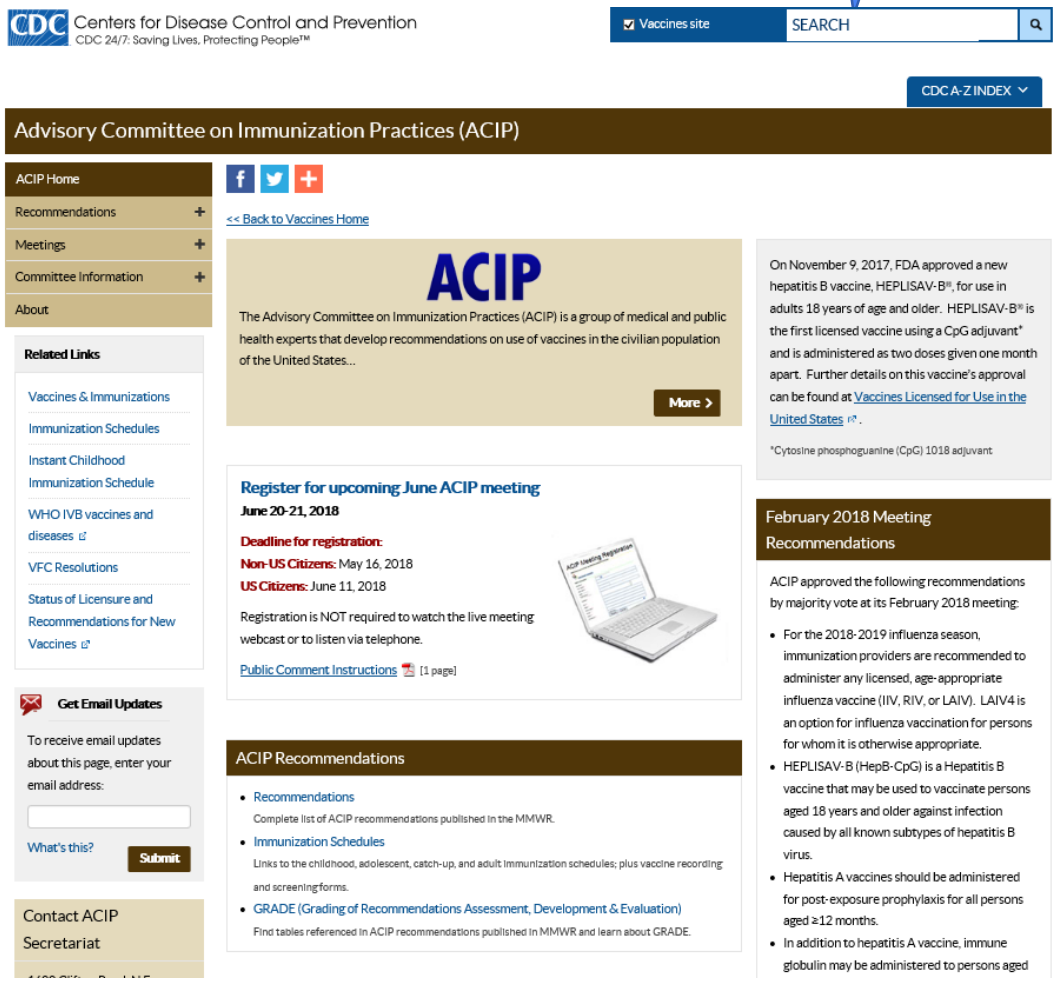
MMWR 2007;56(No.41):1080-4

Hepatitis A Vaccine for International Travelers: Infants

New!

- 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



This recommendation has been adopted by the CDC Director and will become official once published in *MMWR*

CDC website: Advisory Committee on Immunization Practices (ACIP) accessed on 4/3/2018 https://www.cdc.gov/vaccines/acip/index.html

Summary: Hepatitis A Vaccine Recommendations and International Travel

Infants 6 months of age or younger	Immunoglobulin (IG)
Infants 6 through 11 months of age	Vaccine[1] (or IG[2])
Healthy persons 1 year of age or older	Vaccine
Persons with a vaccine contraindication	IG
Immunocompromised persons	Vaccine with addition of IG[3]
Persons with chronic liver disease	Vaccine
Pregnant women	Vaccine

[1]This recommendation has been adopted by the CDC Director and will become official once published in *MMWR*

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

[3]If measles is not endemic in the region

Hepatitis A Vaccination for International Travelers

- Persons at risk of severe disease from hepatitis A planning to travel in 2 weeks or sooner should receive the first dose of vaccine and also can receive immunoglobulin

MMWR 2007;56(No.41):1080-4

Vaccination for Close Contacts of Newly Arriving International Adoptees

- Hepatitis A vaccination for unvaccinated persons who anticipate close personal contact during the first 60 days after arrival of an international adoptee from a country of high or intermediate endemicity
- Administer dose 1 as soon as adoption is planned–ideally 2 or more weeks before the arrival of the adoptee

MMWR 2009;58(No.36):1006-7

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**
  - Not indicated for children
  - May be considered for some adults and older adolescents
- **Postvaccination**
  - Not indicated

Hepatitis A Vaccine Administration

- **Follow proper injection practices**
  - Use aseptic technique
  - Use a new needle and syringe for each injection
- **Route: IM injection**
  - Needle gauge: 22 – 25 gauge
  - Needle length*: 1 – 1.5 inch depending on the patient's age and/or weight

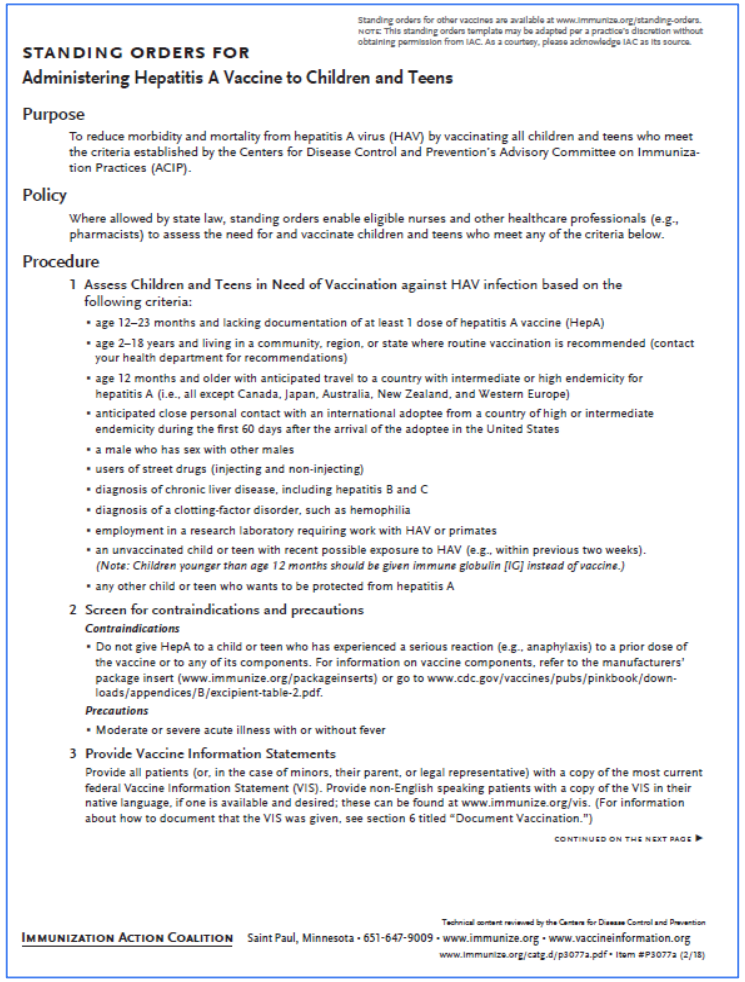
*Professional judgement should be used to determine the proper needle length and site. Influencing factors include injection technique, local reaction, number of vaccines to be administered, patient age, size and muscle mass

Vaccine Administration

- **Site*:**
  - 1–3 years: Vastus lateralis muscle is preferred; deltoid muscle may be used if the muscle mass is adequate
  - 4 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 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

1 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

2 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

3 Provide Vaccine Information Statements

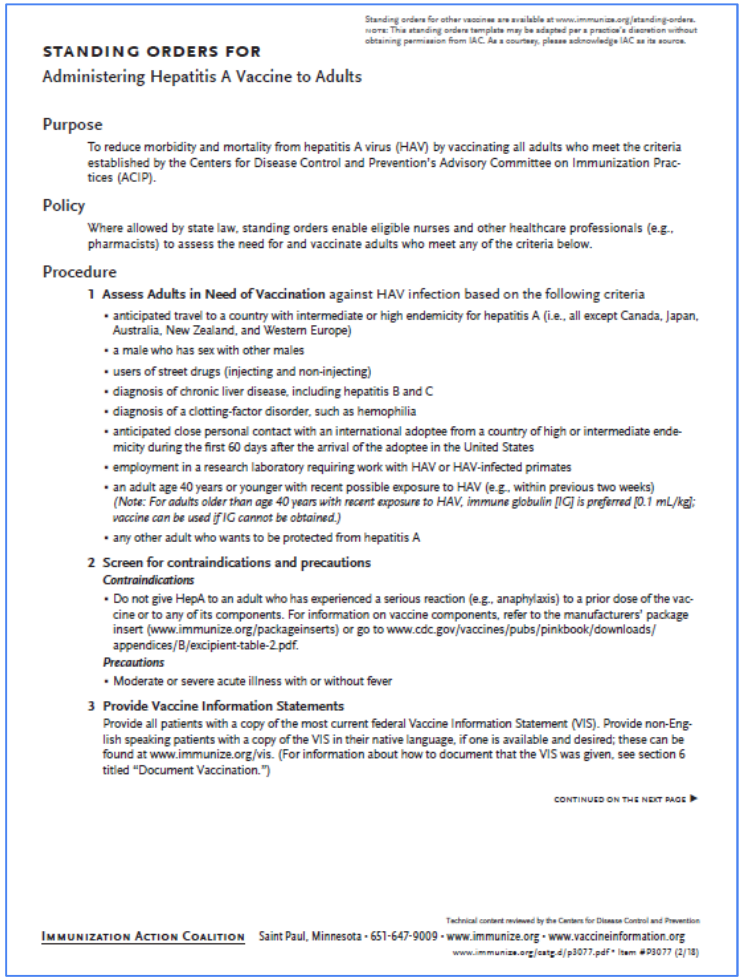
Provide all patients (or, in the case of minors, their parent, or legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available and desired; these can be found 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 ▶

Technical content reviewed by the Centers for Disease Control and Prevention

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)



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

1 **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

2 **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

3 **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.")

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www.immunize.org/catg.d/p3077.pdf • Item #P3077 (2/18)

Immunization Action Coalition website accessed 4/8/2018 children http://www.immunize.org/catg.d/p3077a.pdf adult http://www.immunize.org/catg.d/p3077.pd

Vaccine Administration Errors

- **Adult formulation administered to a child**
  - MORE antigen than the recommended dose was administered
  - If the dose meets minimum age and interval, it may be counted
- **Pediatric formulation administered to an adult**
  - LESS antigen than the recommended dose was administered
  - The dose does not count and should be repeated ASAP
    - There is no time/spacing interval that must be met
- **HepB instead of HepA vaccine**

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 reactions 20–50%
- Systemic reactions (malaise, fatigue) less than 10%
- No serious adverse reactions reported

Hepatitis A Vaccine Storage and Handling

- Store hepatitis A vaccine 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
- Store pediatric and adult formulations separately, away from each other and other look or sound-alike vaccines (e.g., HepB, Hib)

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 (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 stopper and tip cap contain 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)-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

Vaccine storage label example
Available at www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf