Rotavirus and Hepatitis A

Pink Book Webinar Series 2019

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Veterinary Medical Officer
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

Q&A

What is rotavirus?

A. Rotavirus is a virus that infects the lining of the intestines. Typically, the virus infects children between the ages of 6 months and 2 years. In severe cases, infants and young children may become very sick. These illnesses occur during the winter in the United States and lead 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.

What is rotavirus like?

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 more than 2.7 million illnesses. The virus also caused 308,000 doctor visits, 55,000 to 78,000 hospitalizations, and 21 to 61 deaths. Almost all of the babies born in the U.S. were hospitalized with dehydration caused by rotavirus. Since the rotavirus vaccine became widely used, at least 90 percent fewer children have suffered from rotavirus throughout the world. Rotavirus kills about 500,000 children and young children every year, more than any other single infectious disease. About 1,500 children die every day from rotavirus.

How are people infected with rotavirus?

A. Rotavirus causes severe symptoms: high fever, vomiting, and diarrhea. All three symptoms cause children to lose fluids. Too much fluid loss can cause dehydration, which can be dangerous for young children. Vomiting caused by rotavirus can be frequent, persistent, and severe. Also, it is very difficult to replace fluids and electrolytes in children who are vomiting. For this reason, it is extremely common for children to be dehydrated as quickly or as severely as a rotavirus infection.

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

A. Most people think rotavirus infections are not severe in developing countries, but that’s not true. About one of every five children who get sick with rotavirus disease in developing countries are children with severe disease. Throughout the world, rotavirus kills about 500,000 children and young children every year, more than any other single infectious disease. About 1,500 children die every day from rotavirus.

What should children do when they are sick with rotavirus?

A. A 2-year-old girl woke up with high fever and vomiting. The mother called the nurse who performed her fast, fever, and vomiting. Rotavirus caused by rotavirus can be frequent, persistent, and severe. Also, it is very difficult to replace fluids and electrolytes in children who are vomiting. For this reason, it is extremely common for children to be dehydrated as quickly as or as severely as a rotavirus infection. Throughout the world, rotavirus kills about 500,000 children and young children every year, more than any other single infectious disease. About 1,500 children die every day from rotavirus.

2

Rotavirus Vaccine
## Rotavirus Vaccines

<table>
<thead>
<tr>
<th>Vaccine product</th>
<th>Age indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single-component vaccines</td>
<td></td>
</tr>
<tr>
<td>RotaTeq (RV5)</td>
<td>6 weeks to 32 weeks of age</td>
</tr>
<tr>
<td>Rotarix (RV1)</td>
<td>6 weeks to 24 weeks of age</td>
</tr>
</tbody>
</table>
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 Clinical Considerations
### Rotavirus Vaccination Schedule

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

- **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)
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
Rotavirus
Resources
- Ask the Experts–Rotavirus FAQs: [www.immunize.org/askexperts/experts_rota.asp](http://www.immunize.org/askexperts/experts_rota.asp)
- CDC Rotavirus Disease and Vaccination: [www.cdc.gov/rotavirus/index.html](http://www.cdc.gov/rotavirus/index.html)
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 severe 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 Rotales oral applicator. For information on vaccine components, refer to the manufacturer’s package insert [www.immunize.org/packaging.htm] or go to www.cdc.gov/vaccinesafety/data/sheets
   - History of severe combined immunodeficiency (SCID)
   - History of intussusception
   b. Precautions:
      - Advanced prematurity
      - Chronic gastrointestinal disease
      - Sepsis or biliary atresia
      - 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.
4. Provide routine vaccination with Rotales 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 Rotales; 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 Rotales 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 4 weeks old. Then schedule subsequent doses by observing minimal intervals of 4 weeks between the remaining one (if Rotales) or two (if RotaTeq does) such that the final dose can be administered by age 8 months old. Do not administer any RV vaccine beyond the age of 8 months old.
6. Document each patient’s vaccine administration information and follow up in the following phases:
   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.

This policy and procedure shall remain in effect for all patients of the

Medical Director’s signature: __________________________
Effective date: __________________________

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

Immunization Action Coalition
3604 40th Street, Minneapolis, MN 55403 | 612-347-8000 | www.immunize.org | www.vacconf.org

www.immunize.org                                                                         866-366-7005 (Toll Free) 800-638-3926 (Ohio)
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

<table>
<thead>
<tr>
<th>Reservoir</th>
<th>Human</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transmission</td>
<td>Fecal–oral</td>
</tr>
<tr>
<td>Temporal pattern</td>
<td>None</td>
</tr>
<tr>
<td>Communicability</td>
<td>2 weeks before to 1 week after onset of jaundice</td>
</tr>
</tbody>
</table>
Hepatitis A outbreaks in 10 states have occurred primarily among persons who:

• Use injection and noninjection drugs
• Are homeless
• Are their close, direct contacts

# Hepatitis A-Containing Vaccines

<table>
<thead>
<tr>
<th>Vaccine product</th>
<th>Age indications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Havrix</strong></td>
<td></td>
</tr>
<tr>
<td>Pediatric formulation</td>
<td>Birth – 18 years</td>
</tr>
<tr>
<td>Adult formulation</td>
<td>19 years and older</td>
</tr>
<tr>
<td><strong>Vaqta</strong></td>
<td></td>
</tr>
<tr>
<td>Pediatric formulation</td>
<td>Birth – 18 years</td>
</tr>
<tr>
<td>Adult formulation</td>
<td>19 years and older</td>
</tr>
<tr>
<td><strong>Twinrix</strong></td>
<td></td>
</tr>
<tr>
<td>Adult formulation</td>
<td>18 years and older</td>
</tr>
</tbody>
</table>

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
  - 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%
Hepatitis A Clinical Considerations
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 HIV infection*

*Newly voted on recommendations by ACIP. New recommendations will be published soon in MMWR once approved by CDC director
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 Hepatitis A Vaccine Recommendations: Adult

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>19–21 years</th>
<th>22–26 years</th>
<th>27–49 years</th>
<th>50–64 years</th>
<th>≥65 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis A (HepA)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2 or 3 doses depending on vaccine</td>
</tr>
</tbody>
</table>
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 noninjection drug use
- Clotting factor disorders
- 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*

* Newly voted on recommendations by ACIP. New recommendations will be published soon in MMWR once approved by CDC director.
Hepatitis A and International Travel

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

https://www.cdc.gov/mmwr/volumes/67/wr/mm6743a5.htm
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

<table>
<thead>
<tr>
<th>Age</th>
<th>Vaccine/IG Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infants less than 6 months of age</td>
<td>Immunoglobulin (IG)</td>
</tr>
<tr>
<td>Infants 6 through 11 months of age</td>
<td>Vaccine(^1) (or IG(^2))</td>
</tr>
<tr>
<td>Healthy persons 1 year of age or older</td>
<td>Vaccine</td>
</tr>
</tbody>
</table>

**Special Populations**

<table>
<thead>
<tr>
<th>Special Population</th>
<th>Vaccine/IG Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persons with a vaccine contraindication</td>
<td>IG</td>
</tr>
<tr>
<td>Immunocompromised persons</td>
<td>Vaccine with addition of IG(^3)</td>
</tr>
<tr>
<td>Persons with chronic liver disease</td>
<td>Vaccine</td>
</tr>
<tr>
<td>Pregnant women</td>
<td>Vaccine</td>
</tr>
</tbody>
</table>

\(^1\) [https://www.cdc.gov/mmwr/volumes/67/wr/mm6743a5.htm](https://www.cdc.gov/mmwr/volumes/67/wr/mm6743a5.htm)

\(^2\) If measles is not endemic in the region

\(^3\) Based on provider guidance risk assessment and availability of vaccine or IG
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.
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
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***:
  - 1-3 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 Administration Errors

<table>
<thead>
<tr>
<th>We administered:</th>
<th>Now:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult formulation to a child</td>
<td>Dose counts, revaccination is not indicated*</td>
</tr>
<tr>
<td>HepB, Hib, or HPV instead of HepA vaccine</td>
<td>Dose does not count toward completion of the HepA series</td>
</tr>
</tbody>
</table>

*If meets minimum age and interval (if applicable)
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

Vaccine storage label example
Available at [www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf](http://www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf)
General Recommendations for Persons Vaccinated Outside the U.S.

- Vaccines administered outside the U.S. can be accepted as valid if the schedule is similar to U.S. recommendations.

- With the exception of influenza and PPSV23 vaccines, only written documentation should be accepted as evidence of previous vaccination.

Determining What to Do Next

- **Questions? Health care providers may:**
  - Repeat the vaccinations—safe and prevents the need for serologic testing
  - Use serologic testing judiciously—may avoid unnecessary injections
    - But for most vaccines, many serologic tests cannot document protection against infection
    - Cost can be a factor

ACIP General Best Practice Guidelines on Immunizations [https://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf](https://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf)
Child Resources

- Ask the Experts–Hepatitis A FAQs: [www.immunize.org/askexperts/experts_hepa.asp](http://www.immunize.org/askexperts/experts_hepa.asp)
- CDC Hepatitis A Disease: [www.cdc.gov/hepatitis/hav/index.htm](http://www.cdc.gov/hepatitis/hav/index.htm)
- CDC Hepatitis A Vaccination: [www.cdc.gov/vaccines/vpd/hepa/hcp/index.html](http://www.cdc.gov/vaccines/vpd/hepa/hcp/index.html)
Foreign Language Terms Job Aids

2018 Binational Immunization Resource Tool for Children from Birth through 18 Years

Appender B: Foreign Language Terms: Aids to translating foreign immunization records

Quick Chart of Vaccine-Preventable Disease Terms in Multiple Languages


IAC: Quick Chart of Vaccine-Preventable Disease Terms in Multiple Languages http://www.immunize.org/catg.d/p5122.pdf
Adult Resources

- Ask the Experts–Hepatitis A FAQs:  
  [www.immunize.org/askexperts/experts_hepa.asp](http://www.immunize.org/askexperts/experts_hepa.asp)

- CDC Hepatitis A Disease:  
  [www.cdc.gov/hepatitis/hav/index.htm](http://www.cdc.gov/hepatitis/hav/index.htm)

- CDC Hepatitis A Vaccination:  
  [www.cdc.gov/vaccines/vpd/hepa/hcp/index.html](http://www.cdc.gov/vaccines/vpd/hepa/hcp/index.html)

- Standing Orders for Administering Hepatitis A Vaccine: Adults:  
A Quick Look at Twinrix Job Aid

Indications for Use and Schedule

Approved for:
- Routine schedule of 3 doses: 0, 1, 6 months
- Immunization for both hepatitis A and hepatitis B vaccines

Schedule of 4 doses: 0, 1, 2, 21-30 days and a booster dose 12 months after the 2nd dose

Each dose of Twinrix contains:
- 1 adult dose of hepatitis B vaccine
- 1 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 doses 1 & 2
  - 6 months between doses 2 & 3

Contraindications
- An anaphylactic reaction to a prior dose of Twinrix, hepatitis A or hepatitis B vaccine
- An anaphylactic reaction to a component of Twinrix (HepA or Hep B) including yeast and thimerosal

Precautions
- Moderate to severe acute illness

Facts to Know
- The hepatitis D component of Twinrix is equivalent to a standard adult dose of hep D vaccine, the schedule is the same whether Twinrix or single-dose hep B vaccine is used
- 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

Table of Hepatitis A and hepatitis B series with single-antigen hep A, hep B and/or Twinrix

- 1 dose of Twinrix + 3 doses of adult hepatitis B = a complete series of hepatitis B
- 2 doses of Twinrix + 1 dose of adult hepatitis A = a complete series of hepatitis A

- There is no 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/myvaccine or at your local health department.
- Document as "Hep A/B " in MCIR, on the vaccine administration record & immunization record card

100% orthoformaldehyde (DF) and single-dose hep A and hep B vaccines are available for persons at high risk for hepatitis A or hepatitis B virus infection who served in the military or local health department or similar work. Effective before 19 years and older includes those who are unvaccinated or under-vaccinated. Adults also have the influenza vaccine and may get high risk orders to hep A to hep B if they receive primary or booster doses.

For additional information, contact your local health department or visit:
- http://www.michigan.gov/myvaccine
- http://www.michigan.gov/vaccineinformation

January 5, 2010

Michigan Department of Health and Human Services
Hepatitis A Vaccine Standing Orders for Children and Adults

### 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 order 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 2 months and older with antigenic exposure to a country where immunization is high for hepatitis A (e.g., all except Canada, Japan, Australia, New Zealand, and Western Europe)
   - Anticipated close personal contact with child from a country with high or intermediate endemicity during the first 60 days after the adoption of the vaccine in the United States
   - A child who has seen with other travelers
   - Uses of street drugs (injecting and non-injecting)
   - Diagnosis of typhoid fever, including hepatitis B and C
   - Diagnosis of a clotting factor disorder, such as hemophilia
   - Engagement in a research laboratory requiring work with sera or plasma
   - 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 immunoglobulin [IG] instead of vaccine)
   - Any other child or teen who wants to be protected from Hepatitis A

2. **Screen for contraindications and precautions**
   - Note: 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 any of its components. For information on vaccine components, refer to the manufacturer’s package insert, or go to www.immunize.org/patients/pubs/local/learnloads/appendix6/1/recipientrule2.pdf.
   - Sensitivity: Moderately or severe acute illnesses with or without fever

3. **Provide Vaccine Information Statements**
   - Provide all patients (or, in the case of minors, their parents or legal representatives) 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. A Spanish and Hindi version of the VIS can be found at www.immunize.org. For information about how to document that the VIS was given, see section 6 titled “Document Vaccinations.”

### 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 (e.g., all except Canada, Japan, Australia, New Zealand, and Western Europe)
   - A child who has seen with other travelers
   - Uses of street drugs (injecting and non-injecting)
   - Diagnosis of typhoid fever, including hepatitis B and C
   - Diagnosis of a clotting factor disorder, such as hemophilia
   - Anticipated close personal contact with a child from a country with high or intermediate endemicity during the first 60 days after the adoption of the vaccine in the United States
   - Engagement in a research laboratory requiring work with sera or plasma
   - 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 immunoglobulin [IG] instead of vaccine)
   - Any other adult who wants to be protected from Hepatitis A

2. **Screen for contraindications and precautions**
   - Note: Do not give HepA to adults who have experienced a serious reaction (e.g., anaphylaxis) to a prior dose of the vaccine or any of its components. For information on vaccine components, refer to the manufacturer’s package insert, or go to www.immunize.org/patients/pubs/local/learnloads/appendix6/1/recipientrule2.pdf.
   - Sensitivity: Moderately or severe acute illnesses 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. A Spanish and Hindi version of the VIS can be found at www.immunize.org. For information about how to document that the VIS was given, see section 6 titled “Document Vaccinations.”