Rotavirus and Hepatitis A

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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**

**What is rotavirus?**
A. Rotavirus is a virus that causes the illness 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 illness. In tropical climates, the disease occurs year-round.

**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 causes about 2.7 million children. The virus also caused 200,000 doctor visits, 55,000 to 70,000 hospitalizations, and 20 to 60 deaths. Almost one of every 5 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 yielded from rotavirus. Throughout the world, rotavirus kills about 500,000 children and young people every year; more than any other single vaccine disease. About 1,500 children die every day from rotavirus.

**What is the harm of infection with rotavirus?**
A. Rotavirus causes significant symptoms: high fever, vomiting, and diarrhea. All these symptoms cause children to lose fluids. This in turn is more deadly, even to children who are vomiting, for those who are dehydrated, children are dehydrated and feverish. Vomiting caused by dehydration can be frequent, persistent, and severe. Also, it is very difficult to replace fluids and nutrients in a child who is vomiting. For these reasons, all evaluated vaccine causes children to be dehydrated as quickly or as severely as rotavirus.

**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 that’s not true. About one of every five children in the world are taken to a doctor or a hospital for rotavirus. Some countries with a high level of medical care are more likely to provide the following: supportive medical care for children with rotavirus; and treatment for dehydration. The difference in mortality is explained by very few medical resources.

**Is there a vaccine to prevent rotavirus?**
A. Yes. Two vaccines are available. Each vaccine is given orally. The first vaccine is available by 20 weeks of age and in a combination between 6 weeks and 6 months of age. The second, available by 8 months of age, contains two weakened human rotaviruses.

**Who should get the rotavirus vaccine?**
A. The rotavirus vaccine is given by mouth to children at 2 and 4 months of age or at 5, 6 and 8 months of age, depending on which vaccine is used.

**What is the rotavirus vaccine made of?**
A. Yes. Rotavirus vaccines have been used millions of times without consequence. However, in a very small number of infants (approximately 1 in 100,000) a transient mild diarrhea may occur. Lactose intolerance is a type of intestinal disorder that may cause diarrhea and can also occur. Intestinal infection in much greater approximate 1 in 5,000 people having diarrhea caused by 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.

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

vaccine.chop.edu
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 severe allergic reaction (e.g., anaphylaxis) after a previous dose of RV vaccine or an RV vaccine component. Information on vaccine contraindication is contained in the Rotavirus and packaging insert (www.immunize.org/packaging insert) or go to www.cdc.gov/ vaccinationsafety/pixbook/w coastal/p3ds/vaccsafety-table-2.pdf.
      - Diagnosis of severe combined immunodeficiency (SCID)l
      - History of intussusception
   b. Precautions:
      - Absent immunocompetence
      - Chronic gastrointestinal illness
      - Sputum, trachial or other excretion
      - 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 if the patient was given 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 Rotarix, at ages 2 and 4 months OR provide routine vaccination with Rotarix at ages 2, 4, and 6 months. Administer the first dose (1 mL for Rotarix; 2 mL for Rotarix) of vaccine by administering the entire contents of the single-dose package into the infant's mouth toward the inner cheek until empty. Note that Rotarix needs to be reconstituted before administration; Rotarix does not.
5. If the infant has 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 doses (if Rotarix) or 4 weeks (if Rotarix) after the final dose can be administered by age 8 months 6 days. Do not administer any RV vaccine beyond the age of 8 months 6 days.
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 why, e.g., 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 national 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

Medical Directive's signature: Effective date:

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

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
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.

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

Indications for Use and Schedule

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

Automatic schedule of 4 doses: 0, 1, 2, and 6 months after the first dose

Each dose of Twinrix contains:
- One adult dose of hepatitis A vaccine
- One pediatric dose of hepatitis B 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

Contraindications
- Anaphylactic reaction to a prior dose of Twinrix, hepatitis A or hepatitis B vaccine
- Anaphylactic reaction to a component of Twinrix (HepA-HepB) including yeast and neomycin

Prescriptions
- Moderate to severe acute illness

Further Points
- Because 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-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 Twinrix
  - Hepatitis A and hepatitis B vaccines may be administered at the same visit. A complete series of hepatitis A and hepatitis B vaccines (4 doses) is recommended. A single-antigen vaccine may be used to complete the series. The second dose of hepatitis B vaccine should be administered at least 4 weeks after the first dose of hepatitis A vaccine

- There is 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/library or at your local health department

- Document as “Hep A Hep B” in MCIR, on the vaccine administration record & immunization record card

- Fully vaccinated Hep A (Twinrix) and single-antigen hep A and hep B vaccines are available for seniors at high risk for Hepatitis A or hepatitis B virus infection when served at local health department or sector sites. Epstein-Barr virus (EBV) and childhood vaccination status should be verified when administering Twinrix

- For more information, contact the MCIR knowledgebase on the use of Hep A and Hep B vaccines, located at http://www.mcir.michigan.gov

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
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

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

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

- 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

<table>
<thead>
<tr>
<th>Age</th>
<th>Vaccine Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infants 6 months of age or younger</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>
<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>
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\(^1\)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.
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**
  - 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.
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)

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)