Rotavirus and Hepatitis A

Pink Book Webinar Series 2017

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Nurse Educator
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

- 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
- 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 Epidemiology

- **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 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
ACIP Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, 2017

Rotavirus Vaccination Schedule

- **2- or 3-dose schedule based on the product:**
  - RV1 (Rotarix): administer 2 oral doses at 2 and 4 months of age
  - RV5 (RotaTeq): administer 3 oral doses at 2, 4, and 6 months of age

- **For both rotavirus vaccines:**
  - May be started as early as 6 weeks of age
  - 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*

*Off-label ACIP recommendation
Rotavirus Vaccination Schedule Considerations

- ACIP did not define a maximum interval between doses
- It is not necessary to restart the series or add doses because of a prolonged interval between doses
- 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

*ACIP off-label recommendation for both vaccine products
Rotavirus Vaccine: Interchangeability of Products

- Complete the series with the same vaccine product whenever possible but if the product previously used is not available or not known, continue or complete the series with the available product*

- If any dose in the series was RV5 (RotaTeq) or the vaccine brand used for any prior dose is not known, administer a total of 3 doses of rotavirus vaccine
  - Separate doses of rotavirus vaccine by at least 4 weeks

*ACIP off-label recommendation
Additional Considerations

- ACIP recommends that providers do not repeat a dose if the infant spits out or regurgitates the vaccine

- Any remaining doses should be administered on schedule
  - Separate doses of rotavirus vaccine by at least 4 weeks

- The infant may eat or drink immediately following vaccine administration
Rotavirus Vaccine Administration

**Preparation:**
- RV5: None
- RV1: Must be reconstituted BEFORE administering

**Route/Site:** Administer ORALLY (PO)

**Administer RV vaccine at the same clinical visit as other needed vaccines**

**Vaccine administration errors:**
- Wrong route: Do NOT inject this vaccine
- Incorrect schedule:
  - 1\textsuperscript{st} dose after 14 weeks 6 days (maximum age)
  - Any dose after 8 months 0 days (maximum age)
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

- 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%
Rotavirus Vaccine Storage and Handling

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

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)
Hepatitis A

- Epidemic jaundice described by Hippocrates
- Differentiated from hepatitis B in 1940s
- Serologic tests developed in 1970s
- Vaccines licensed in 1995 and 1996
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-Containing Vaccines

- Inactivated vaccines

- Single-component HepA vaccine (Havrix and Vaqta)
  - Each product has pediatric and adult formulations
  - Pediatric formulation is approved for children 1 through 18 years of age
  - Adult formulation is approved for persons 19 years of age and older

- Schedule: 2-dose series
  - Separate doses by at least 6 calendar months
Hepatitis A-Containing Vaccines

- HepA-HepB (Twinrix) combination vaccine contains:
  - Hepatitis A 720 ELU (pediatric dose)
  - Hepatitis B 20 mcg (adult dose)

- Approved for persons 18 years of age and older

- Schedules
  - 0, 1, 6 months or
  - 0, 7, 21–30 days and booster dose at 12 months
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.
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 Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, 2017

Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, 2017
Hepatitis A Vaccination of Children

- Routinely recommended for children 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 through 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, 2017

### Table 1: Recommended Immunization Schedule for Adults Aged 19 Years or Older by Age Group, United States, 2017

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>19-21 years</th>
<th>22-26 years</th>
<th>27-59 years</th>
<th>60-64 years</th>
<th>≥ 65 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tdap</td>
<td>1 dose annually</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMR</td>
<td>1 or 2 doses depending on indication</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAP</td>
<td>2 doses</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>HZV</td>
<td>1 dose</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HPV–Female</td>
<td>1 dose</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HPV–Male</td>
<td>1 dose</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>PCV13</td>
<td>1 dose</td>
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</tbody>
</table>

### Table 2: Recommended Immunization Schedule for Adults Aged 19 Years or Older by Medical Condition and Other Indications, United States, 2017

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Pregnancy</th>
<th>Immuno-compromised (including HIV infection)</th>
<th>Mumps–mumps, CMV–CMV</th>
<th>Asplenia, persistent complement deficiencies</th>
<th>Kidney failure, end-stage renal disease, or hemodialysis</th>
<th>Heart or lung disease, chronic obstructive pulmonary disease</th>
<th>Chronic liver disease</th>
<th>Diabetes</th>
<th>Healthcare personnel</th>
<th>Men who have sex with men</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tdap</td>
<td>1 dose annually</td>
<td>Substitute Tdap for Td once, then Td booster every 10 yrs</td>
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<td></td>
<td></td>
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<tr>
<td>MMR</td>
<td>contraindicated</td>
<td>1 or 2 doses depending on indication</td>
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</tr>
<tr>
<td>VAP</td>
<td>contraindicated</td>
<td>2 doses</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HZV</td>
<td>contraindicated</td>
<td>1 dose</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HPV–Female</td>
<td>3 doses through age 26 yrs</td>
<td>3 doses through age 26 yrs</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HPV–Male</td>
<td>3 doses through age 26 yrs</td>
<td>3 doses through age 21 yrs</td>
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<tr>
<td>MenACWY or MPSV4</td>
<td>1 dose</td>
<td>1 dose</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MenB</td>
<td>2 doses</td>
<td>3 doses</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hib</td>
<td>1 dose</td>
<td>3 doses</td>
<td></td>
<td></td>
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</tbody>
</table>

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

**Recommended for adults with additional medical conditions or other indications**

**No recommendation**
Hepatitis A Vaccination for Adults

- International travelers
- Close contacts with an international adoptee from a country of high or intermediate endemicity
- Men who have sex with men
- Persons who use illegal drugs
- Persons who have a clotting-factor disorder
- Persons with occupational risk
- Persons with chronic liver disease, including hepatitis C
Hepatitis A and International Travel

Anti-HAV Prevalence
- High
- High/Intermediate
- Intermediate
- Low
- Very Low
Hepatitis A Vaccination for International Travelers

- The first dose of hepatitis A vaccine should be administered as soon as travel is considered.

- For healthy persons 1 through 40 years of age:
  - 1 dose of single–component vaccine administered at any time before departure.

MMWR 2007;56(No.41):1080-4
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 immune globulin
Hepatitis A Vaccination for Close Contacts of Newly Arriving International Adoptees

- Vaccinate 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 the first dose 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

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

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

- **Vaccine administration errors:**
  - Pediatric formulation administered to an adult (and vice versa)
  - HepB instead of HepA vaccine

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

- Severe allergic reaction to a vaccine component or following a prior dose
- Moderate or severe acute illness
Hepatitis A Vaccine Adverse Reactions

- Local 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 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