Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases

Rotavirus

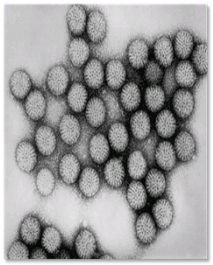
September 2018

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

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

Rotavirus Vaccines

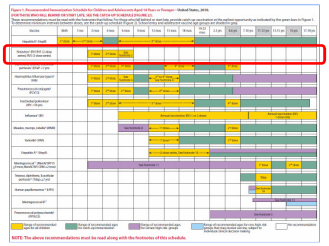
- **RV5 (RotaTeq)**
  - Contains 5 reassortant rotaviruses developed from human and bovine parent rotavirus strains
- **RV1 (Rotarix)**
  - Contains one strain of live, attenuated human rotavirus (type G1PA[8])
- **Both rotavirus vaccines**
  - Live, attenuated
  - Contain no preservatives or thimerosal

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

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

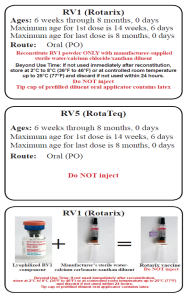
- **Intussusception**
  - RV1 postlicensure evaluation–1 to 3 excess cases per 100,000 first doses, possible risk for RV5 cases too small to confirm
  - Vaccine Adverse Event Reporting System (VAERS) reports show event clusters in 3–6 days following RV5
  - Vaccine Safety Datalink (VSD) shows no increased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



Questions?