State of Alaska Epidemiology **Bulletin**

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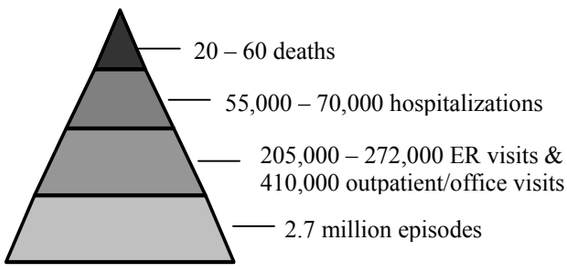
Rotavirus Vaccine Now Available from Alaska Immunization Program

Background

Rotavirus is the most common cause of severe gastroenteritis in infants and young children worldwide, resulting in ~500,000 deaths/year among children aged <5 years in developing countries.[1] Although rotavirus infections results in relatively few childhood deaths in the United States, nearly every child in the country is infected with rotavirus by age 5 years (Figure 1).

Figure 1. Estimated Number of Annual Deaths, Hospitalizations, Emergency Department Visits, and Episodes of Rotavirus Gastroenteritis among Children Aged <5 Years, United States[1]



The spectrum of rotavirus illness ranges from mild, watery diarrhea of limited duration to severe diarrhea with vomiting and fever that can result in dehydration with electrolyte imbalance, shock, and death. Following an incubation period of 1–3 days, the illness can begin abruptly, and vomiting often precedes the onset of diarrhea. Up to one third of patients have a temperature of >102° F. Gastrointestinal symptoms generally resolve in 3–7 days. Children aged 3–35 months are at increased risk for severe disease.[1]

Rotaviruses are transmitted primarily by the fecal-oral route, both through close person-to-person contact and through fomites. In the United States, rotaviruses cause winter seasonal peaks of gastroenteritis. In Alaska, the peak incidence typically occurs from February through late spring.[2]

Vaccine Administration and Storage

RotaTeq® (Merck), is a live, oral vaccine that contains five reassortant rotaviruses developed from human and bovine strains. RotaTeq® was licensed for use in the United States in 2006. It is provided in a squeezable plastic dosing tube with a twist-off cap designed to allow the vaccine to be administered directly to infants by mouth. Each tube contains a single 2-mL dose of liquid buffer-stabilized solution that is pale yellow in color (sometimes with a pink tint). This formulation protects the vaccine from gastric acid and stabilizes the product, allowing for storage at refrigerator temperatures (36° – 46° F [2° – 8° C]) for up to 24 months. The vaccine should be administered as soon as possible after being removed from refrigeration. RotaTeq® contains no preservatives or thimerosal.

Routine Administration

Infants should receive three (3) doses of RotaTeq® orally at ages 2, 4 and 6 months. Dose #1 may be administered between ages 6–12 weeks. Subsequent doses should be administered at 4–10 week intervals, and all 3 doses of vaccine should be administered by age 32 weeks. Vaccination should not be initiated for infants age >12 weeks due to insufficient data on safety of the first dose in older infants. Vaccine should not be administered after age 32 weeks because of insufficient data on the safety and efficacy of rotavirus vaccine in infants after this age. Infants who have had rotavirus gastroenteritis before receiving the full course of rotavirus vaccinations should still initiate or complete the 3-dose schedule as outlined above because prior infection often provides only partial immunity.

RotaTeq® Fast Facts	
# Doses in Series	3
Method of Administration	Oral
Recommended Schedule	Ages 2, 4, and 6 months
Interval Between Doses	4 – 10 weeks
Special Timing Considerations	
Dose #1	Must be administered between ages 6 – 12 wks → Do not begin series if aged ≥13 weeks
Dose #3	Must be administered by 32 weeks old → Do not continue series if aged ≥33 weeks

Contraindications and Precautions

Rotavirus vaccine should not be administered to infants with severe hypersensitivity to any vaccine component or who have experienced a serious allergic reaction to a prior dose. The decision to vaccinate if a precaution is present should be made on a case-by-case basis. This becomes particularly relevant if a delay in vaccination might be substantial, potentially making the child ineligible to receive vaccine (e.g., age ≥13 weeks). Precautions in vaccine administration, requiring consideration of potential risks and benefits, exist for children with:

- Altered immunocompetence;
- Acute, moderate-to-severe gastroenteritis (infants with mild acute gastroenteritis can be vaccinated.);
- Pre-existing chronic gastrointestinal conditions; and
- A history of intussusception (see below).

Special Situations

- Infants who are born prematurely but who are at least age 6 weeks and clinically stable may be vaccinated.
- Infants living in households with persons who are immunocompromised or pregnant may be vaccinated.
- A RotaTeq® dose need not be readminister to an infant who regurgitates, spits out, or vomits during or after vaccine administration. Remaining recommended doses should be administered as scheduled.

Rotavirus Vaccine and Intussusception

Intussusception is a condition that occurs when one portion of the intestine telescopes into a nearby portion, resulting in a bowel obstruction. Because a previously licensed formulation of rotavirus vaccine (RotaShield®,Wyeth-Ayerst)was associated with increased risk of intussusception among vaccinees,[3] federal health officials are carefully monitoring of the incidence of intussusception following RotaTeq® administration. The number of such cases reported to date is consistent with the number expected in unvaccinated children. Recently the U.S. Food and Drug Administration issued a statement encouraging reporting of any possible additional cases;[4] however, this was not a vaccine warning, and no changes have been made to vaccine recommendations. Additional information is available on the Centers for Disease Control and Prevention website.[5]

References:

1. Prevention of Rotavirus Gastroenteritis Among Infants and Children. Centers for Disease Control and Prevention, *MMWR Recommendations and Reports*, August 11, 2006/ 55(RR-12). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5512.pdf.
2. Personal communication. Rosalyn Singleton, MD, Alaska Native Tribal Health Consortium.
3. Withdrawal of Rotavirus Vaccine Recommendation. Centers for Disease Control and Prevention. *MMWR*, November 5, 1999/ 48 (42). Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4843a5.htm.
4. Information on RotaTeq® and Intussusception. Food and Drug Administration, FDA Public Health Notification, February 13, 2007. Available at: http://www.fda.gov/cber/safety/phnrota021307.htm.
5. Intussusception and RotaTeq® Vaccine. Centers for Disease Control and Prevention. Available at: http://www.cdc.gov/od/science/iso/concerns/rotavirus.htm.

(Contributed by Laurel Wood, MPA, Immunization Program Manager, Section of Epidemiology.)