

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

VACCINES FOR CHILDREN PROGRAM

VACCINES TO PREVENT ROTAVIRUS GASTROENTERITIS

The purpose of this resolution is to add a newly licensed rotavirus vaccine to the Vaccines for Children Program.

VFC resolution 2/06-2 is repealed and replaced by the following:

Eligible Groups

Infants aged 6 weeks to 8 months.

Recommended Schedule for Rotavirus Vaccines

| <u>Dose</u> | <u>Rotateq[®] Age</u> | <u>Rotarix[®] Age</u> |
|-------------|------------------------------------|------------------------------------|
| Primary 1 | 2 months | 2 months |
| Primary 2 | 4 months | 4 months |
| Primary 3 | 6 months | ----- |

Dosage Intervals and Ages for Rotavirus Vaccines

| | RV5 (RotaTeq [®] ; Merck) | RV1 (Rotarix [®] ; GSK) |
|----------------------------|------------------------------------|----------------------------------|
| Number of doses in series | 3 | 2 |
| Recommended ages for doses | 2, 4, and 6 months | 2 and 4 months |
| Minimum age for first dose | 6 weeks | |
| Maximum age for first dose | 14 weeks 6 days | |
| Interval between doses | 4 weeks or more | |
| Maximum age for last dose | 8 months 0 days | |

Recommended Dosages

Refer to product package inserts.

Contraindications

The following conditions are contraindications to administration of rotavirus vaccine:

a. Serious Allergic Reaction to Vaccine Components

Severe allergic reaction (e.g., anaphylaxis) after a previous dose of rotavirus vaccine or to a vaccine component. Latex rubber is contained in the Rotarix[®] oral applicator, so infants with a severe (anaphylactic) allergy to latex should not receive Rotarix[®]. The Rotateq[®] dosing tube is latex-free.

Precautions

The following are precautions to administration of rotavirus vaccine:

a. Altered Immunocompetence

Practitioners should consider the potential risks and benefits of administering rotavirus vaccine to infants with known or suspected altered immunocompetence; consultation with an immunologist or infectious diseases specialist is advised. Children and adults who are immunocompromised because of congenital immunodeficiency, hematopoietic transplantation, or solid organ transplantation sometimes experience severe, prolonged and even fatal rotavirus gastroenteritis. However, no safety or efficacy data are available for the administration of rotavirus vaccine to infants who are potentially immunocompromised, including

- Infants with primary and acquired immunodeficiency states, including cellular immunodeficiencies; and hypogammaglobulinemic and dysgammaglobulinemic states.
- Infants with blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic system
- Infants on immunosuppressive therapy (including high dose systemic corticosteroids);
- Infants who are HIV-exposed or infected. However, the following considerations support vaccination of HIV-exposed or infected infants:
 - the HIV diagnosis may not be established in infants born to HIV-infected mothers before the age of the first rotavirus vaccine dose; only 1.5%-3% of HIV-exposed infants in the US will be determined to be HIV-infected, and
 - Vaccine strains of rotavirus are considerably attenuated

b. Acute Gastroenteritis

In usual circumstances, rotavirus vaccine should not be administered to infants with acute, moderate to severe gastroenteritis until the condition improves. However, infants with mild acute gastroenteritis can be vaccinated, particularly if the delay in vaccination might be substantial and might make the child ineligible to receive vaccine (e.g., aged ≥ 15 weeks 0 days before the vaccine series is started). Rotavirus vaccine has not been studied among infants with concurrent acute gastroenteritis. In these infants, the immunogenicity and efficacy of rotavirus vaccine can theoretically be compromised. For example, infants who receive oral poliovirus vaccine (OPV) during an episode of acute gastroenteritis in some circumstances have diminished poliovirus antibody responses.

c. Moderate to Severe Illness

As with all other vaccines, the presence of a moderate or severe acute illness with or without fever is a precaution to administration of rotavirus vaccine. Infants with a moderate to severe acute illness should be vaccinated as soon as they have recovered from the acute phase of the illness. This precaution avoids superimposing any potential adverse effects of the vaccine on the underlying illness or mistakenly attributing a manifestation of the underlying illness to the vaccine. Vaccination should not be delayed because of the presence of mild respiratory tract illness or other mild acute illness with or without fever.

d. Preexisting Chronic Gastrointestinal Disease

Infants with preexisting gastrointestinal conditions (e.g., congenital malabsorption syndromes, Hirschsprung's disease, short-gut syndrome) who are not undergoing immunosuppressive therapy should benefit from rotavirus vaccine vaccination, and ACIP considers the benefits to outweigh the theoretical risks. However, no data are available on the safety and efficacy of rotavirus vaccine for infants with preexisting chronic gastrointestinal disease.

e. Previous History of Intussusception

Practitioners should consider the potential risks and benefits of administering rotavirus vaccine to infants with a previous history of intussusception. Available data do not indicate that RV5 or RV1 are associated with intussusception. A previously licensed rotavirus vaccine that is no longer available in the United States, Rotashield® (Wyeth-Lederle Vaccines and Pediatrics), was associated with an increased risk for intussusception. Compared to infants who have never had intussusception, infants with a history of intussusception are at higher risk for a repeat episode of intussusception.

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