

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

VACCINES FOR CHILDREN PROGRAM

VACCINES TO PREVENT ROTAVIRUS GASTROENTERITIS

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

Eligible Groups

Infants aged 6 weeks through 32 weeks.

Recommended Schedule for Rotavirus Vaccines

<u>Dose</u>	<u>Age</u>
Primary 1	2 months
Primary 2	4 months
Primary 3	6 months

Dosage Intervals for Rotavirus Vaccines

<u>Age (Dose 1)</u>	<u>Dosing Interval (Dose 1 to 2)</u>	<u>(Dosing Interval Dose 2 to 3)</u>
6 – 12 weeks*	4 – 10 weeks	4 – 10 weeks

* The first dose of rotavirus vaccine should be initiated for infants between 6 and 12 weeks of age because of insufficient data on the safety of the first dose of the vaccine in older infants.

Note: The last dose of rotavirus vaccine should be administered by 32 weeks of age.

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 hypersensitivity or anaphylactic reaction to the vaccine or a constituent of the vaccine or after receiving a previous dose of rotavirus vaccine.

Precautions

The following are precautions to administration of rotavirus vaccine:

a. Acute Gastroenteritis

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 may be substantial and might make the child ineligible to receive vaccine (e.g., older than 12 weeks of age before vaccination is initiated). Rotavirus vaccine has not been studied among infants with concurrent gastroenteritis among whom its immunogenicity and efficacy can theoretically be compromised.

b. Moderate to Severe Illness

Infants with moderate to severe illness should be vaccinated as soon as they have recovered from the acute phase of the illness.

c. Preexisting Chronic Gastrointestinal Disease

Practitioners should consider the potential risks and benefits of administering rotavirus vaccine to infants with preexisting chronic gastrointestinal disease. Infants with preexisting chronic gastrointestinal conditions and not undergoing immunosuppressive therapy should benefit from rotavirus vaccination and the benefits outweigh the theoretical risks. However, the safety and efficacy of rotavirus vaccine have not been established for infants with these preexisting conditions (e.g. congenital malabsorption syndromes, Hirschsprung's disease, short-gut syndrome, or persistent vomiting of unknown cause).

d. Intussusception

Following administration of a previously licensed rotavirus vaccine which is no longer available, an increased risk of intussusception was observed. Available pre-licensure data from a large trial of over 70,000 infants designed to evaluate the risk of intussusception shows no evidence of an association between intussusception and the currently licensed rotavirus vaccine, which is also biologically different (i.e., different rotavirus strain, lower rates of viral shedding, less reactogenicity in terms of fever, vomiting, and diarrhea) than the previous vaccine. However, additional post-licensure surveillance data are required to confirm that the vaccine is not associated with intussusception at a lower rate than would have been detected in pre-licensure trials.

The risks and benefits of vaccination should be considered when vaccinating infants with a previous episode of intussusception. Some data suggest that infants with a history of intussusception may be at higher risk of a repeat episode than other infants. Therefore, until post-licensure data on safety of rotavirus vaccine are available, administration of rotavirus vaccine to infants with a previous episode of intussusception should be withheld.

e. Altered Immunocompetence

Practitioners should consider the potential risks and benefits of administering rotavirus vaccine to infants who are potentially immunocompromised. No safety or efficacy data are available for the administration of rotavirus vaccine to infants who are potentially immunocompromised including:

- *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 with primary and acquired immunodeficiency states, including HIV/AIDS or other clinical manifestations of infection with human immunodeficiency viruses; cellular immune deficiencies, and hypogammaglobulinemic and dysgammaglobulinemic states. There is insufficient data from the clinical trials to support administration of rotavirus vaccine to infants with indeterminant HIV status who are born to mothers with HIV/AIDS.*
- *Infants who have received a blood transfusion or blood products, including immunoglobulins within 42 days.*

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