



## Complete Summary

---

### GUIDELINE TITLE

Prevention of rotavirus disease: guidelines for use of rotavirus vaccine.

### BIBLIOGRAPHIC SOURCE(S)

American Academy of Pediatrics Committee on Infectious Diseases. Prevention of rotavirus disease: guidelines for use of rotavirus vaccine. *Pediatrics* 2007 Jan;119(1):171-82. [58 references] [PubMed](#)

### GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American Academy of Pediatrics (AAP). Prevention of rotavirus disease: guidelines for use of rotavirus vaccine (RE9840). *American Academy of Pediatrics. Pediatrics* 1998 Dec;102(6):1483-91.

All clinical reports and policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

## \*\* REGULATORY ALERT \*\*

### FDA WARNING/REGULATORY ALERT

**Note from the National Guideline Clearinghouse:** This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [June 15, 2007, RotaTeq \(Rotavirus, Live, Oral, Pentavalent Vaccine\)](#): Changes to the ADVERSE REACTIONS and POST-MARKETING sections of the product's prescribing information. The ADVERSE REACTIONS section was updated to include six cases of Kawasaki disease that were observed during the Phase 3 clinical trial.
- [February 13, 2007, Rotavirus, Live, Oral, Pentavalent Vaccine \[RotaTeq\]](#): FDA Public Health Notification regarding 28 post-marketing reports of intussusception following administration of Rotavirus, Live, Oral, Pentavalent vaccine (RotaTeq).

## COMPLETE SUMMARY CONTENT

\*\* REGULATORY ALERT \*\*

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis

RECOMMENDATIONS  
EVIDENCE SUPPORTING THE RECOMMENDATIONS  
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS  
CONTRAINDICATIONS  
IMPLEMENTATION OF THE GUIDELINE  
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT  
CATEGORIES  
IDENTIFYING INFORMATION AND AVAILABILITY  
DISCLAIMER

## SCOPE

### **DISEASE/CONDITION(S)**

Rotavirus disease

### **GUIDELINE CATEGORY**

Management  
Prevention

### **CLINICAL SPECIALTY**

Family Practice  
Infectious Diseases  
Pediatrics

### **INTENDED USERS**

Physicians

### **GUIDELINE OBJECTIVE(S)**

To provide the rationale and recommendations for use of a bovine-based pentavalent rotavirus vaccine (RotaTeq) in US infants

### **TARGET POPULATION**

Infants 2, 4, and 6 months of age in the United States

### **INTERVENTIONS AND PRACTICES CONSIDERED**

1. Routine immunization with the oral, pentavalent rotavirus vaccine (RotaTeq) for infants at 2, 4, and 6 months of age, including simultaneous administration with other childhood vaccines
2. Consideration of special situations, including
  - Vaccination of preterm infants
  - Vaccination of infants living in households with immunocompromised persons or pregnant women

- Readministration of rotavirus vaccine after regurgitation (not recommended)
  - Hospitalization precautions after rotavirus vaccine administration
3. Reporting of and surveillance for adverse events after rotavirus vaccine administration

### **MAJOR OUTCOMES CONSIDERED**

- Immunogenicity of rotavirus vaccine as measured by serum immunoglobulin A (IgA) titers
- Efficacy of rotavirus vaccine as measured by frequency and severity of diarrheal episodes, frequency of dehydration, and rate of hospitalization/medical visits for diarrhea and vomiting.
- Safety of rotavirus vaccine

## **METHODOLOGY**

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

Searches of Electronic Databases

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

Not stated

### **NUMBER OF SOURCE DOCUMENTS**

Not stated

### **METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE**

Weighting According to a Rating Scheme (Scheme Given)

### **RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE**

#### **Evidence Quality for Grades of Evidence**

- A. Well-designed randomized, controlled trials or diagnostic studies performed on a population similar to the guideline's target population
- B. Randomized, controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies
- C. Observational studies (case-control and cohort design)
- D. Expert opinion, case reports, or reasoning from first principles (bench research or animal studies)

### **METHODS USED TO ANALYZE THE EVIDENCE**

Review

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

### Guideline Definitions for Evidence-Based Statements

**Strong recommendation:** The subcommittee believes that the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B)\*. In some clearly identified circumstances, strong recommendations may be made on the basis of lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms. *Implication:* Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.

**Recommendation:** The subcommittee believes that the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade B or C)\*. In some clearly identified circumstances, recommendations may be made on the basis of lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms. *Implication:* Clinicians also should generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.

**Option:** Either the quality of evidence that exists is suspect (grade D)\* or well performed studies (grade A, B, or C)\* show little clear advantage to one approach versus another. *Implication:* Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.

**No recommendation:** There is both a lack of pertinent evidence (grade D)\* and an unclear balance between benefits and harms. *Implication:* Clinicians should feel little constraint in their decision-making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

\* Refer to "Rating Scheme for the Strength of the Evidence" field above for the definitions of evidence grades.

## **COST ANALYSIS**

In a recent analysis that used current estimates of rotavirus disease burden, vaccine efficacy, vaccine coverage rates, and health costs, investigators estimated that a national rotavirus immunization program in which 3 doses of pentavalent rotavirus vaccine are administered at ages 2, 4, and 6 months would result in 255,000 fewer physician visits, 137,000 fewer emergency department visits, 44,000 fewer hospitalizations, and 13 fewer deaths per year in children younger than 5 years. From the health care perspective alone, immunization is likely to be cost-saving at total cost per child (including administration costs) of up to \$66 per child (approximately \$22 per vaccine dose). A higher-priced vaccine would be increasingly unlikely to be cost-saving, and at a cost of more than \$268 per child (approximately \$89 per dose), a rotavirus immunization program would most likely have a net cost to society.

## **METHOD OF GUIDELINE VALIDATION**

External Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Not stated

## **RECOMMENDATIONS**

### **MAJOR RECOMMENDATIONS**

Definitions for the evidence quality (A - D) and evidence-based statements (Strong Recommendation, Recommendation, Option, and No Recommendation) are given at the end of the "Major Recommendations" field.

#### **Routine Immunization With Pentavalent Rotavirus Vaccine**

Infants should receive 3 doses of pentavalent rotavirus vaccine administered orally at 2, 4, and 6 months of age. The first dose should be administered between 6 and 12 weeks of age (i.e., on or before 12 weeks 0 days of age). Subsequent doses should be administered at 4- to 10- week intervals, and all 3 doses of vaccine should be administered by 32 weeks of age (i.e., on or before 32 weeks 0 days) (strong recommendation; evidence grade A; well-designed randomized, controlled trials).

Immunization should not be initiated for infants older than 12 weeks because of insufficient data on safety of the first dose of pentavalent rotavirus vaccine in older infants (recommendation; evidence grade D; expert opinion).

Vaccine should not be administered after 32 weeks of age because of insufficient data on the safety and efficacy of pentavalent rotavirus vaccine in infants after this age (recommendation; evidence grade D; expert opinion). Adverse events, such as fever, were substantially higher in children who initiated or completed the rotavirus reassortant-tetravalent (RRV-TV) vaccine series after 6 months of age

(Joensuu, Koskenniemi, & Vesikari, 1998; Vesikari et al., 1991; Vesikari et al., 1986).

For infants in whom the first dose of pentavalent rotavirus vaccine is inadvertently administered off label at 13 weeks of age or older, the rest of the rotavirus immunization series should be completed per the schedule defined above, because timing of the first dose should not affect the safety and efficacy of the second and third dose (recommendation; evidence grade D; expert opinion).

Infants documented to have had rotavirus gastroenteritis before receiving the full course of rotavirus immunizations should still initiate or complete the 3-dose schedule because the initial infection frequently provides only partial immunity (recommendation; evidence grade D; expert opinion).

Infants who are being breastfed can receive pentavalent rotavirus vaccine. The efficacy of pentavalent rotavirus vaccine is similar among breastfed and nonbreastfed infants (strong recommendation; evidence grade A; well-designed randomized, controlled trials).

Like other childhood vaccines, pentavalent rotavirus vaccine can be administered to infants with transient, mild illnesses, with or without low-grade fever (Atkinson et al., 2002) (recommendation; evidence grade D; expert opinion).

### **Simultaneous Administration With Other Childhood Vaccines**

Pentavalent rotavirus vaccine can be administered together with diphtheria tetanus-acellular pertussis (DTaP), *Haemophilus influenzae* type b (Hib), inactivated poliovirus (IPV), hepatitis B, and pneumococcal conjugate vaccines. Available evidence suggests that the vaccine does not interfere with the immune response to the Hib, IPV, hepatitis B, and pneumococcal conjugate vaccines and the diphtheria and tetanus antigens in DTaP vaccine (strong recommendation; evidence grade A; well-designed randomized, controlled trials). Because validation of the pertussis assays is still under review, insufficient immunogenicity data are available to confirm lack of interference of immune responses when pentavalent rotavirus vaccine is administered concomitantly with childhood vaccines to prevent pertussis (recommendation; evidence grade D; expert opinion).

### **Special Situations**

#### **Preterm Infants (Those Born at Less Than 37 Weeks' Gestation)**

Practitioners should consider the potential benefits and risks of immunizing preterm infants against rotavirus. Limited data suggest that preterm infants are at increased risk of hospitalization from viral gastroenteritis during their first year of life (Newman et al., 1999). In clinical trials, the safety and efficacy of pentavalent rotavirus vaccine seem to be similar for preterm and term infants, although a relatively small number of preterm infants have been evaluated. The lower concentration of maternal antibody to rotaviruses in very low birth weight, preterm infants theoretically could increase the risk of adverse reactions from pentavalent rotavirus vaccine. The American Academy of Pediatrics (AAP) supports immunization of preterm infants under the following conditions: the

infant is at least 6 weeks of age, the infant is clinically stable, and the first dose of vaccine is given at the time of discharge or after the infant has been discharged from the hospital nursery. Until further data are available, the AAP considers the benefits of pentavalent rotavirus vaccine immunization of preterm infants to outweigh the theoretical risks (recommendation; evidence grade B; randomized, controlled trials with minor limitations).

### **Exposure of Immunocompromised Persons to Immunized Infants**

Infants living in households with persons who have or are suspected of having an immunodeficiency disorder or impaired immune status can be immunized (recommendation; evidence grade D; expert opinion). Most experts believe that the protection of the immunocompromised household member afforded by immunization of young children in the household outweighs the small risk of transmitting vaccine virus to the immunocompromised household member and any subsequent theoretical risk of vaccine virus–associated disease. To minimize potential virus transmission, persons having contact with the feces of the immunized infant (e.g., after changing a diaper) should use measures such as good hand-washing for at least 1 week after the first dose of pentavalent rotavirus vaccine.

### **Exposure of Pregnant Women to Immunized Infants**

Infants living in households with pregnant women can be immunized (recommendation; evidence grade D; expert opinion). Most women of childbearing age would have preexisting immunity to rotavirus, so the risk of infection and disease from potential exposure to the attenuated vaccine virus strain is very low. In addition, immunization of young children would decrease potential exposure of the pregnant women to wild virus if the unimmunized infant suffers from rotavirus gastroenteritis.

### **Regurgitation of Vaccine**

The practitioner should not readminister a dose of pentavalent rotavirus vaccine to an infant who regurgitates, spits out, or vomits during or after administration of vaccine (recommendation; evidence grade D; expert opinion). The infant can receive the remaining recommended doses of pentavalent rotavirus vaccine at the appropriate intervals. Data are limited regarding the safety of administering a dose of pentavalent rotavirus vaccine higher than the recommended dose and on the efficacy of administering a partial dose. Additional data on safety and efficacy are needed to evaluate the benefits and risks of readministration.

### **Hospitalization After Immunization**

If a recently immunized child is hospitalized for any reason, no precautions other than standard precautions need be taken to prevent the spread of vaccine virus in the hospital setting (recommendation; evidence grade D; expert opinion).

### **Reporting Adverse Events**

Any clinically significant or unexpected adverse events that occur after administration of rotavirus vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS). The National Childhood Vaccine Injury Act requires health care professionals to report to VAERS any event listed (1) by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine or (2) in the table of reportable events following vaccination (see <http://vaers.hhs.gov/reportable.htm>) that occurs within the specified time period after immunization. Pentavalent rotavirus vaccine is covered under the general category of rotavirus vaccines in the table of reportable events, and no specific conditions are listed for reporting. VAERS reporting forms and information can be requested 24 hours a day by calling 800-822-7967 or by accessing the VAERS Web site at <http://vaers.hhs.gov>.

### **Enhanced Postlicensure Surveillance for Adverse Events**

In prelicensure clinical trials, pentavalent rotavirus vaccine has not been associated with any serious adverse events, including intussusception. Nevertheless, continued monitoring for adverse events after introduction of pentavalent rotavirus vaccine into routine immunization programs is important, particularly in light of the previous experience with RRV-TV vaccine. In addition to manufacturer-sponsored phase IV studies, postlicensure monitoring will include enhanced review of adverse events reported to VAERS. The Vaccine Safety Datalink (VSD) will also be used to monitor intussusception risk associated with pentavalent rotavirus vaccine and to evaluate any other possible associations that may be identified through VAERS or in phase IV studies. The VSD project includes information on persons enrolled in 8 large health maintenance organizations, with an annual birth cohort of more than 90 000 infants. Data on all vaccines administered within the study population are recorded and linked with diagnoses from medical encounters to determine rates of potential adverse events that result from immunization. Recently developed rapid-analysis methods allow the VSD to conduct near "real-time" monitoring for vaccine adverse events.

Given the background rate of natural intussusception among US infants (25–38 cases per 100 000 infants) and the large number of children who potentially are eligible for immunization, some intussusceptions are expected to occur in the 2-week period after immunization by chance alone that will be unrelated to the vaccine. Consequently, intensive postlicensure surveillance will be necessary to assess the safety of pentavalent rotavirus vaccine against this rare event.

### **Contraindications and Precautions**

#### **Contraindications**

*Serious Allergic Reaction to a Vaccine Component or a Previous Vaccine Dose*

Pentavalent rotavirus vaccine should not be administered to infants who have severe hypersensitivity to any component of the vaccine or who have experienced a serious allergic reaction to a previous dose of pentavalent rotavirus vaccine (recommendation; evidence grade D; expert opinion).

#### **Precautions**

### *Altered Immunocompetence*

Practitioners should consider the potential risks and benefits of administering rotavirus vaccine to infants with known or suspected altered immunocompetence (recommendation; evidence grade D; expert opinion). Children and adults who are immunocompromised because of congenital immunodeficiency, bone marrow 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 blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms that affect the bone marrow or lymphatic system
- On immunosuppressive therapy (including high-dose systemic corticosteroids)
- With primary and acquired immunodeficiency states, including human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS) or other clinical manifestations of infection with HIV, cellular immune deficiencies, and hypogammaglobulinemic and dysgammaglobulinemic states (data from clinical trials are insufficient to support administration of rotavirus vaccine to infants with indeterminate HIV status who are born to mothers with HIV or AIDS)
- Who have received a blood transfusion or blood products, including immune globulins, within 42 days (in general, rotavirus vaccine should be deferred for 42 days after receipt of an antibody-containing product if possible; however, if the 42-day deferral would cause the first dose of rotavirus vaccine to be scheduled for  $\geq 13$  weeks of age, a shorter deferral interval should be used to ensure that the first dose is administered before 13 weeks of age)

### *Moderate-to-Severe Acute Gastroenteritis*

In usual circumstances, pentavalent rotavirus vaccine should not be administered to infants with acute, moderate- to-severe gastroenteritis until the condition improves (recommendation; evidence grade D; expert opinion). However, infants with mild acute gastroenteritis can be immunized, particularly if the delay in immunization may be substantial and might make the child ineligible to receive vaccine (e.g., older than 12 weeks of age before immunization is initiated). Pentavalent rotavirus vaccine has not been studied among infants with concurrent acute gastroenteritis, among whom its immunogenicity and efficacy theoretically can be compromised. For example, infants who received oral poliovirus vaccine during an episode of acute gastroenteritis, in some instances, had diminished poliovirus antibody responses to oral poliovirus.

### *Moderate-to-Severe Febrile Illness*

Infants with moderate-to-severe illness should be immunized as soon as they have recovered from the acute phase of the illness (recommendation; evidence grade D; expert opinion). This precaution avoids superimposing adverse effects of the vaccine on the underlying illness or mistakenly attributing a manifestation of the underlying illness to the vaccine.

### *Preexisting Chronic Gastrointestinal Disease*

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

#### Previous History of Intussusception

After administration of a previously licensed rotavirus vaccine (RRV-TV), an increased risk of intussusception was observed. Available prelicensure data from a large trial of 70,000 infants show no evidence of an association between intussusception and pentavalent rotavirus vaccine. However, additional postlicensure surveillance data are required to confirm that the vaccine is not associated with intussusception at a lower rate than the rate that would have been detected in prelicensure trials. In addition, some data suggest that infants with a history of intussusception may be at higher risk of a repeat episode than other infants. Therefore, until postlicensure data on safety of rotavirus vaccine are available, the risks and benefits of immunization should be considered when immunizing infants with a previous episode of intussusception (recommendation; evidence grade D; expert opinion).

#### **Definitions:**

##### **Evidence Quality for Grades of Evidence**

- A. Well-designed randomized, controlled trials or diagnostic studies performed on a population similar to the guideline's target population
- B. Randomized, controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies
- C. Observational studies (case-control and cohort design)
- D. Expert opinion, case reports, or reasoning from first principles (bench research or animal studies)

##### **Definitions for Evidence-Based Statements**

**Strong recommendation:** The subcommittee believes that the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B). In some clearly identified circumstances, strong recommendations may be made on the basis of lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms. *Implication:* Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.

**Recommendation:** The subcommittee believes that the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative

recommendation), but the quality of evidence is not as strong (grade B or C). In some clearly identified circumstances, recommendations may be made on the basis of lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms. *Implication*: Clinicians also should generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.

**Option**: Either the quality of evidence that exists is suspect (grade D) or well performed studies (grade A, B, or C) show little clear advantage to one approach versus another. *Implication*: Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set boundaries on alternatives; patient preference should have a substantial influencing role.

**No recommendation**: There is both a lack of pertinent evidence (grade D) and an unclear balance between benefits and harms. *Implication*: Clinicians should feel little constraint in their decision-making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

### **CLINICAL ALGORITHM(S)**

None provided

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

### **REFERENCES SUPPORTING THE RECOMMENDATIONS**

[References open in a new window](#)

### **TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS**

The type of supporting evidence is identified and graded for selected recommendations (See the "Major Recommendations" field).

## **BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS**

### **POTENTIAL BENEFITS**

Appropriate use of rotavirus vaccine to prevent rotavirus disease

### **POTENTIAL HARMS**

In prelicensure clinical trials, pentavalent rotavirus vaccine has not been associated with any serious adverse events, including intussusception. Refer to the section on "Safety" in the original guideline document for additional information on intussusception and other adverse events among pentavalent rotavirus vaccine recipients.

See the "Major Recommendations" field for additional precautions.

## CONTRAINDICATIONS

### CONTRAINDICATIONS

Pentavalent rotavirus vaccine is contraindicated for infants with a serious allergic reaction to any vaccine component or to a previous dose of vaccine.

See the "Major Recommendations" field for further information concerning precautions and contraindications.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Staying Healthy

### IOM DOMAIN

Effectiveness  
Timeliness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

American Academy of Pediatrics Committee on Infectious Diseases. Prevention of rotavirus disease: guidelines for use of rotavirus vaccine. Pediatrics 2007 Jan;119(1):171-82. [58 references] [PubMed](#)

### ADAPTATION

Not applicable: Guideline was not adapted from another source.

### DATE RELEASED

1998 Dec (revised 2007 Jan)

### GUIDELINE DEVELOPER(S)

American Academy of Pediatrics - Medical Specialty Society

## **GUIDELINE DEVELOPER COMMENT**

This American Academy of Pediatrics (AAP) policy statement was prepared in parallel with Center for Disease Control and Prevention (CDC) recommendations and reports, including the NGC Summary of the CDC guideline [Prevention of Rotavirus Gastroenteritis Among Infants and Children: Recommendations of the Advisory Committee on Immunization Practices](#).

Much of the background presented in this AAP statement is based on the literature review, analyses of unpublished data, and deliberations of CDC staff in collaboration with the Advisory Committee on Immunization Practices Rotavirus Vaccine Work Group (with liaison from the AAP).

## **SOURCE(S) OF FUNDING**

American Academy of Pediatrics

## **GUIDELINE COMMITTEE**

Committee on Infectious Diseases

## **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

*Committee on Infectious Diseases, 2006-2007:* Joseph A. Bocchini, Jr, MD, *Chairperson*; Robert S. Baltimore, MD; Henry H. Bernstein, DO; John S. Bradley, MD; Michael T. Brady, MD; Penelope H. Dennehy, MD; Margaret C. Fisher, MD; Robert W. Frenck, Jr, MD; David W. Kimberlin, MD; Sarah S. Long, MD; Julia A. McMillan, MD; Lorry G. Rubin, MD

*Liaisons:* Richard D. Clover, MD, American Academy of Family Physicians; Marc A. Fischer, MD, Centers for Disease Control and Prevention; Richard L. Gorman, MD, National Institutes of Health; Douglas R. Pratt, MD, Food and Drug Administration; Anne Schuchat, MD, Centers for Disease Control and Prevention; Benjamin Schwartz, MD, National Vaccine Program Office; Jeffrey R. Starke, MD, American Thoracic Society; Jack Swanson, MD, Practice Action Group

*Ex Officio:* Larry K. Pickering, MD, Red Book Editor

*Consultant:* Edgar O. Ledbetter, MD

*Staff:* Alison Siwek, MPH

## **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

Not stated

## **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: American Academy of Pediatrics (AAP). Prevention of rotavirus disease: guidelines for use of rotavirus vaccine (RE9840). American Academy of Pediatrics. Pediatrics 1998 Dec;102(6):1483-91.

All clinical reports and policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

#### **GUIDELINE AVAILABILITY**

Electronic copies: Available from the [American Academy of Pediatrics \(AAP\) Policy Web site](#).

Print copies: Available from American Academy of Pediatrics, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

#### **AVAILABILITY OF COMPANION DOCUMENTS**

None available

#### **PATIENT RESOURCES**

Not stated

#### **NGC STATUS**

This summary was completed by ECRI on March 20, 1999. The information was verified by the guideline developer on April 30, 1999. This summary was updated on July 19, 1999, with information regarding AAP's interim recommendations. This NGC summary was updated by ECRI on April 2, 2007. The updated information was verified by the guideline developer on April 9, 2007. This summary was updated by ECRI Institute on July 9, 2007 following the FDA advisory on RotaTeq (Rotavirus, Live, Oral, Pentavalent) vaccine.

#### **COPYRIGHT STATEMENT**

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions. Please contact the Permissions Editor, American Academy of Pediatrics (AAP), 141 Northwest Point Blvd, Elk Grove Village, IL 60007.

### **DISCLAIMER**

#### **NGC DISCLAIMER**

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public

or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at <http://www.guideline.gov/about/inclusion.aspx> .

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

© 1998-2008 National Guideline Clearinghouse

Date Modified: 9/22/2008

