

VACCINE ADVISORY

From the Department of State Health Services Immunization Branch

The goal of the Vaccine Advisory is to disseminate, in a timely manner, practical information related to vaccines, vaccine-preventable diseases, and the vaccine programs managed by the Immunization Branch. The Immunization Branch welcomes readers' input to improve the contents of this document.

November 29, 2006

Advisory No. 5. The Rotavirus Vaccine

This advisory presents the Advisory Committee on Immunization Practices (ACIP) recommendations on use of the oral rotavirus vaccine that was licensed in February 2006 by the Food and Drug Administration (FDA).

This advisory contains:

1. Background information
2. Summary of ACIP's final recommendations
3. Texas Vaccines for Children Program
4. ImmTrac
5. Texas school and day-care facilities requirements
6. Epidemiology and surveillance
7. Reporting adverse vaccine effects
8. Resources (Vaccine)
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1) Background information

Rotavirus is a viral infection that can cause severe diarrhea, vomiting, fever and dehydration in infants and young children. Although common – most children get rotavirus at least once – rotavirus infection can have serious consequences. In the United States, rotavirus is responsible for approximately 400,000 physician office visits, 200,000 emergency room visits, 55,000 – 70,000 hospitalizations; and 20 – 60 deaths each year. Rotavirus is responsible for an estimated 4% to 5% of all childhood hospitalizations.

In February 2006, the FDA licensed an oral rotavirus vaccine, RotaTeq™, manufactured by Merck & Co., Inc. The ACIP voted to recommend the new vaccine for routine use among infants and to incorporate it into the Vaccines for Children (VFC) Program.

2) Summary of recommendations

The ACIP recommends routine vaccination of infants with three doses of rotavirus vaccine administered orally at ages 2, 4, and 6 months. Children should receive the first dose between ages six to 12 weeks, subsequent doses at intervals of four to 10 weeks, and all three doses of vaccine should be administered by age 32 weeks. There is insufficient data on safety and efficacy outside of these age ranges to make a broader recommendation.

In 1998, the FDA briefly licensed a different vaccine against rotavirus that was later withdrawn from the market because of its association with an increased risk of intussusception, a rare type of blockage or twisting of the intestine. The safety profile of the new vaccine, RotaTeq™, was evaluated in a large study that evaluated over 70,000 children. The study did not find an increased risk of intussusception or any other serious adverse event with the new vaccine.

Merck is conducting a post-licensure study of approximately 44,000 children and the Centers for Disease Control and Prevention (CDC) is conducting a separate large study through its Vaccine Safety Datalink Program, which evaluates vaccine safety in approximately 80,000 U.S. infants every year.

The ACIP's complete recommendations for the rotavirus vaccine have been published in the *Morbidity and Mortality Weekly Report* and can be found at www.cdc.gov/mmwr/preview/mmwrhtml/rr5512a1.htm?s_cid=rr5512a1_e.

3) Texas Vaccines for Children (TVFC) program

In June 2006, the TVFC Program added the rotavirus vaccine, RotaTeq® to the program for TVFC-eligible infants. This vaccine is not two-tiered, meaning that it may be administered to underinsured children at any TVFC-enrolled clinic site. The vaccination series consists of three doses administered orally from ready-to-use vials and the vaccine is stored in the refrigerator.

Incomplete doses may occur if an infant spits or regurgitates the vaccine. If for any reason an incomplete dose of this vaccine is administered, a replacement dose is not recommended. Additional information regarding RotaTeq®, including contraindications and warnings, may be found in the product package insert or at the following website:

http://www.merck.com/product/usa/pi_circulars/r/rotateq/rotateq_pi.pdf

The Medicaid billing CPT code for rotavirus vaccine is 90680.

If you have additional questions regarding TVFC information, please contact your Health Service Region or TVFC consultant.

4) ImmTrac

ImmTrac users can report pentavalent rotavirus vaccines administered using the ImmTrac code: "ROTAV-Pent". Although ImmTrac can record rotavirus vaccine doses administered, and doses will be reflected on the client immunization history, the ImmTrac immunization scheduler will not generate recommendations for rotavirus vaccine at this time. Providers

should consult ACIP recommendations to determine when the rotavirus vaccine should be administered. For more information about ImmTrac, go to: www.ImmTrac.com.

5) Texas school and day-care daily requirements for the rotavirus vaccine

There are no requirements for school or daycare attendance.

6) Epidemiology and surveillance

Rotavirus is the most common cause of severe diarrhea among children, resulting in the hospitalization of approximately 55,000 children each year in the United States and the death of over 600,000 children annually worldwide. The incubation period for rotavirus disease is approximately two days. The disease is characterized by vomiting and watery diarrhea for three to eight days, and fever and abdominal pain occur frequently. Immunity after infection is incomplete, but repeat infections tend to be less severe than the original infection. The primary mode of transmission is fecal-oral, although some have reported low titers of virus in respiratory tract secretions and other body fluids. Because the virus is stable in the environment, transmission can occur through ingestion of contaminated water or food and contact with contaminated surfaces. In the United States and other countries with a temperate climate, the disease has a winter seasonal pattern, with annual epidemics occurring from November to April. The highest rates of illness occur among infants and young children, and most children in the United States are infected by 2 years of age. Adults can also be infected, though disease tends to be mild.

Rotavirus is not a reportable condition in Texas.

7) Reporting vaccine adverse events

Clinically significant adverse events following vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).

Adverse events from privately purchased vaccine may be reported directly to VAERS at <http://vaers.hhs.gov/>. Secure web-based reporting is available on the VAERS website. Contact 800-VAC-RXNS for forms and information.

A copy of the VAERS form is also available in the TVFC toolkit. To request a VAERS form or additional information, call the VAERS contact in your area:

- **In Texas:** 800.252.9152
- **For Bexar County:** 210.207.2087
- **For City of Houston:** 713.558.3518

8) Resources (Vaccine)

The American Academy of Pediatrics:

- Policy statement: *Prevention of Rotavirus Disease: Guidelines for Use of Rotavirus Vaccine*. November 2, 2006

- Rotavirus V Implementation Guidance:

http://www.cispimmunize.org/pro/pro_main.html?http&&www.cispimmunize.org/pro/rotavirus.htm

The *New England Journal of Medicine* article: Safety and Efficacy of an Attenuated Vaccine against Severe Rotavirus Gastroenteritis:

<http://content.nejm.org/cgi/content/full/354/1/11>

National Center for Immunization and Respiratory Diseases:

<http://www.cdc.gov/nip/menus/vaccines.htm#rotavirus>

RotaTeq® Package insert (pdf file):

www.merck.com/product/usa/pi_circulars/r/rotateq/rotateq_pi.pdf

Varicella Vaccine Information Statement:

www.immunize.org/vis/rota_06.pdf

Immunization Branch addendum to VIS:

<http://www.dshs.state.tx.us/immunize/vischart.shtm> (Scroll down to number 18)

The Rotavirus Vaccine Program:

<http://www.rotavirusvaccine.org/>

9) Resources (Disease)

CDC Respiratory and Enteric Viruses Branch rotavirus webpage:

<http://www.cdc.gov/ncidod/dvrd/revb/nrevss/rotfeat.htm>

Medline Plus:

<http://www.nlm.nih.gov/medlineplus/rotavirusinfections.html>

We hope you generously forward this advisory to others who may benefit from this information.

The Vaccine Advisory is now available online. To see previous issues, go to:

www.dshs.state.tx.us/immunize/vacadvise/

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