



Vaccine Advisory

From the Texas 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.

To view past issues, go to: www.dshs.state.tx.us/immunize/vacadvise/

Advisory No. 19

January 4, 2012

Updated Contraindications for Rotavirus Vaccine

The Centers for Disease Control and Prevention (CDC) has updated its contraindications for rotavirus vaccine. CDC now recommends that a history of intussusception be a contraindication to rotavirus vaccination, and not just a precaution.

This advisory summarizes the new recommendation published in the October 21, 2011 issue of the *Morbidity and Mortality Weekly Report* (MMWR). To read the full report, visit: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6041a5.htm>.

This advisory contains:

1. Background information
2. Summary of ACIP's recommendations for rotavirus vaccine
3. Texas Vaccines for Children program (TVFC)
4. ImmTrac
5. Texas school and child-care facilities requirements for rotavirus vaccine
6. Epidemiology and surveillance
7. Reporting vaccine adverse events
8. Resources

1) Background

The Food and Drug Administration (FDA) licensed RotaTeq[®] (Merck & Co., Inc.) in February 2006 and Rotarix[®] (GlaxoSmithKline Biologicals) in April 2008 for routine use in U.S. infants to

prevent severe rotavirus disease in infants and children. These are the only vaccines licensed in the United States to prevent severe rotavirus disease.

The FDA has approved revised prescribing information and patient labeling from GlaxoSmithKline Biologicals for the monovalent rotavirus vaccine (RV1, marketed as Rotarix®) and revised prescribing information and patient labeling from Merck & Co. for the pentavalent rotavirus vaccine (RV5, marketed as RotaTeq®) to include history of intussusception as a contraindication. The FDA approved the revisions for RV1 in February 2011 and for RV5 in July 2011.

CDC continues to recommend both Rotarix® and RotaTeq® to prevent severe rotavirus disease in U.S. infants and children.

2) Summary of ACIP Recommendations

In its rotavirus vaccination recommendations, CDC is updating the contraindications for rotavirus vaccine (RV1 and RV5) to include history of intussusception. Previously, CDC had considered history of intussusception a precaution but not a contraindication.

Rotavirus vaccination is now contraindicated for:

- infants with a history of severe allergic reaction (eg., anaphylaxis) after a previous dose of rotavirus vaccine or exposure to a vaccine component,
- infants diagnosed with severe combined immunodeficiency (SCID), and
- Infants with a history of intussusception.

3) Texas Vaccines for Children program

Eligible groups for rotavirus vaccine include infants 6 weeks to 8 months of age.

Recommended Schedule for Rotavirus Vaccines

<u>Dose</u>	<u>Rotateq®</u> <u>Age</u>	<u>Rotarix®</u> <u>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	

For other questions or information, please contact your health service region, or TVFC consultant.

4) ImmTrac

ImmTrac users can report Rotarix[®] vaccine administered using CPT code 90681 or RotaTeq[®] using the ImmTrac code 90680.

For more information about ImmTrac, please refer to: www.ImmTrac.com.

5) Texas school and child-care facilities requirement for rotavirus vaccine

Rotavirus vaccine is not required for child-care entrance.

Current requirements for child-care facilities in Texas can be viewed at <http://www.dshs.state.tx.us/immunize/docs/school/6-15.pdf>.

6) Epidemiology and surveillance

Rotavirus is a virus that causes severe diarrhea, often accompanied by vomiting, fever, and dehydration, mostly in babies and young children. Rotavirus is mainly transmitted from person to person via the fecal-oral route. It is the leading cause of diarrhea in infants and young children, accounting for an estimated 527,000 deaths annually worldwide among children less than 5 years of age. Adults can also be infected, though the disease tends to be mild. The incubation period for rotavirus disease is approximately 2 days.

Rotavirus is not the only cause of severe diarrhea, but it is one of the most serious. Before rotavirus vaccine was licensed for use, rotavirus was responsible for more than 400,000 doctor visits, more than 200,000 emergency room visits, 55,000 to 70,000 hospitalizations, and 20-60 deaths in the United States each year. Children are most likely to get rotavirus diarrhea between November and May, depending on the part of the country they live in.

Rotavirus is not a reportable condition in Texas.

7) Reporting Vaccine Adverse Events

An adverse event is a health problem that is reported after someone gets a vaccine or medicine. Note that persons may experience adverse events shortly after vaccination which may or may not be caused by the vaccine. Adverse events following vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS). While VAERS is an important system for helping to find potential signs, VAERS is primarily used to detect signals that may require further investigation, but is not able to determine if an adverse event was caused by vaccination.

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. You may also contact VAERS at (800)-822-7967 for forms and information.

In Texas, reports of adverse events following vaccination at public health clinics or with vaccine provided through public funding such as the Texas Vaccines for Children (TVFC) program should be reported through the Texas Department of State Health Services, Immunization Branch via fax or mail.

- Fax a completed VAERS Form to: (866) 624-0180 (toll-free)
- Mail a completed VAERS form to DSHS, Immunization Branch, MC-1946, P.O. Box 149347, Austin, TX 78714-9347

A copy of the form is also available in the TVFC Toolkit. For more information about VAERS or for a pre-addressed postage-paid VAERS form, you can contact DSHS at (800) 252-9152.

8) Resources

- FDA product approval information-licensing action (Rotarix[®] package insert):
<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm245491.htm>
- FDA product approval information-licensing action (RotaTeq[®] package insert):
<http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142288.pdf>
- CDC statement regarding Rotarix[®] and RotaTeq[®] vaccines and intussusception:
<http://www.cdc.gov/vaccines/vpd-vac/rotavirus/intussusception-studies-acip.htm>
- Rotavirus Vaccine Information Statement (VIS):
<http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-rotavirus.pdf>
- The DSHS Addendum to the Rotavirus VIS is available at:
<http://www.dshs.state.tx.us/immunize/literature/litlist.shtm> (Scroll down to number 17)

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

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