



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. 16

September 2, 2010

Revised Recommendations for Rotavirus Vaccines

This report presents updated recommendations for the use of rotavirus vaccines (Rotarix[®] and RotaTeq[®]).

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1) Background

On March 22, 2010, the FDA called for a temporary halt to the use of Rotarix[®] vaccine after DNA from porcine circovirus type 1 (PCV1) was found in the vaccine, which is manufactured by Glaxo SmithKline.

On May 6, 2010, the FDA indicated that preliminary studies showed the RotaTeq[®] vaccine, manufactured by Merck & Co, Inc., contained fragments of DNA from PCV1 and from a related porcine circovirus type 2 (PCV2).

On May 7, 2010, the FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) met to discuss these vaccines. The advisory committee recommended resuming the use of Rotarix[®] and not taking any action with RotaTeq[®].

2) Summary

On May 14, 2010, the FDA announced an update to its recommendations for rotavirus vaccines for the prevention of the disease in infants. Based on careful evaluation of a variety of scientific information, the FDA has determined it is appropriate for clinicians and health care professionals to resume the use of Rotarix[®] and to continue the use of RotaTeq[®].

This recommendation supersedes the FDA's previous recommendation from March 22, 2010, which called for health care providers to suspend use of Rotarix[®].

The FDA also recommends that clinicians and public health professionals inform parents of the findings of PCV DNA or PCV in rotavirus vaccines, and that there is no evidence that these findings pose a safety risk in humans. Both the prescribing information and patient labeling will be revised to include this information.

Details of the updated FDA recommendations can be found at:

<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm212140.htm>

3) TVFC

Beginning September 1, 2010, the Texas Vaccines for Children program will fulfill orders for both Rotarix[®] and RotaTeq[®] according to provider choices selected earlier in the year. If a provider failed to choose vaccines by the July 31, 2010 deadline, RotaTeq[®] will be sent as the state's default vaccine.

For questions related to the TVFC program, please contact your local health department or health service region representative.

4) ImmTrac

ImmTrac users can report Rotarix[®] vaccine administered using the ImmTrac code "ROTAV-Mono" and RotaTeq[®] using the ImmTrac code "ROTAV-Pent".

5) Texas school and child-care requirements

Currently, rotavirus vaccine is not required for school or child-care attendance.

6) Reporting adverse vaccine events

An adverse event is a health problem that is reported after someone gets a vaccine or medicine.

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: 1-866-624-0180 (toll-free)
- Mail a completed VAERS form to DSHS, Immunization Branch, MC-1946, P.O. Box 149347, Austin, TX 78714-9347

A pre-addressed and postage-paid VAERS form can be obtained by calling the Immunization Branch. A copy of the form is also available in the TVFC Toolkit. For more information about VAERS, you can contact DSHS at 800- 252-9152.

7) Resources

- New Rotavirus Interim VIS:
<http://www.cdc.gov/vaccines/pubs/VIS/downloads/vis-rotavirus.pdf>
- Information for Parents and Caregivers:
<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205547.htm>
- Information for Health Care Providers:
<http://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm205548.htm>

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

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