

DPHHS HAN

From: DPHHS HAN
Sent: Tuesday, May 18, 2010 8:49 AM
Subject: DPHHS HAN ADVISORY 2010 - 16: FDA Revises Recommendations for Rotavirus Vaccines
Attachments: ApprovedProd.pdf

State of Montana DPHHS HAN ADVISORY

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DPHHS Recommendations:

FDA Revises Recommendations for Rotavirus Vaccines

The U.S. Food and Drug Administration today revised its recommendations for rotavirus vaccines for the prevention of the disease in infants and has determined that it is appropriate for clinicians and health care professionals to resume the use of Rotarix and to continue the use of RotaTeq.

The agency reached its decision based on a careful evaluation of information from laboratory results from the manufacturers and the FDA's own laboratories, a thorough review of the scientific literature, and input from scientific and public health experts, including members of the FDA's Vaccines and Related Biological Products Advisory Committee that convened on May 7, 2010 to discuss these vaccines.

The FDA also considered the following in its decision:

- Both vaccines have strong safety records, including clinical trials involving tens of thousands of patients as well as clinical experience with millions of vaccine recipients.
- The FDA has no evidence that PCV1 or PCV2 pose a safety risk in humans, and neither is known to cause infection or illness in humans.
- The benefits of the vaccines are substantial, and include prevention of death in some parts of the world and hospitalization for severe rotavirus disease in the United States. These benefits outweigh the risk, which is theoretical.

Information for parents and caregivers is available on the web at:

<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205547.htm>

Information for health care providers is available on the web at:

<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205548.htm>

DPHHS Subject Matter Expert (SME) Contact:

For additional information, please contact the DPHHS Immunization Program at 406-444-5580.

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Categories of Health Alert Messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for a specific incident or situation; may not require immediate action.

Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

Vaccines, Blood & Biologics

Update on Recommendations for the Use of Rotavirus Vaccines

May 14, 2010

Summary

FDA is updating its recommendations on both Rotarix and RotaTeq, vaccines for the prevention of rotavirus disease in infants. Based on careful evaluation of a variety of scientific information, 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.

Background

On [March 22, 2010](#)¹, FDA provided an early communication regarding Rotarix, manufactured by GlaxoSmithKline Biologicals (GSK). At that time, FDA recommended that clinicians and public health professionals in the United States temporarily suspend the use of Rotarix while the agency and manufacturer investigated the finding of DNA from porcine circovirus type 1 (PCV1) in the vaccine. Since that time, both FDA and GSK have confirmed the presence of PCV1 in the vaccine.

On [May 6, 2010](#)², FDA provided information about RotaTeq, manufactured by Merck & Co, Inc. FDA indicated that preliminary studies conducted by Merck identified fragments of DNA from PCV1 and from a related porcine circovirus type 2 (PCV2) in RotaTeq. FDA noted that it would seek input from its Vaccines and Related Biological Products Advisory Committee (VRBPAC) and provide updates in the near future.

Updated Recommendations

FDA has evaluated laboratory results from the manufacturers and its own laboratories. In addition, FDA's VRBPAC convened on [May 7, 2010](#)³ to discuss the findings of PCV and PCV DNA in rotavirus vaccines. Based on a careful evaluation of this information, a thorough review of the scientific literature, and input from scientific and public health experts, the Agency is revising its recommendation to temporarily suspend use of the Rotarix vaccine. 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.

FDA considered the following information in its decision:

- Both vaccines have strong safety records, including clinical trials involving tens of thousands of patients as well as clinical experience with millions of recipients. FDA has no evidence that either PCV1 or PCV2 poses a safety risk in humans, and notes that neither is known to cause infection or illness in humans.
- The benefits of the vaccines are substantial, and include prevention of hospitalization for severe rotavirus disease in the U.S. and of death in other parts of the world. The benefits of the vaccines, which are known, outweigh the risk, which is theoretical.

Next Steps

FDA is working with each of the manufacturers (GSK and Merck) to update the labeling for both Rotarix and RotaTeq vaccines to include information about the presence of PCV1 (Rotarix) and DNA from PCV1 and PCV2 (RotaTeq) in the vaccines.

FDA is working with each of the manufacturers to plan the appropriate follow up studies, taking into account the input received from members of the VRBPAC on May 7, 2010.

FDA and the manufacturers will continue to investigate the findings of PCV in rotavirus vaccines, and will evaluate information from ongoing testing by FDA and the manufacturers. As noted by the firm during the May 7, 2010, VRBPAC meeting, GSK plans to rederive its vaccine, in consultation with FDA. Merck is in the early stages of its investigation, and has not yet determined next steps in this regard.

Updated Information for Clinicians and Public Health Professionals

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. 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.

The benefits of vaccination against rotavirus disease are substantial, both in the United States and the developing world and far outweigh any theoretical risk posed by PCV types 1 and 2. The safety record of both rotavirus vaccines is excellent.

FDA will keep the public and clinical community updated through www.fda.gov⁴ and other communications.

Links on this page:

1. <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205540.htm>
2. <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm211101.htm>
3. <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/VaccinesandRelatedBiologicalProductsAdvisoryCommittee/ucm197728.htm>
4. <http://www.fda.gov/>