



ACIP Recommendation: U.S. Rotavirus Vaccine

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The Advisory Committee on Immunization Practices (ACIP) recommended today that Rotashield, the only U.S.-licensed rotavirus vaccine, no longer be recommended for infants in the United States. Today's action is based on the results of an expedited review of scientific data presented to the ACIP by CDC in cooperation with the FDA, NIH, and Public Health Service officials, along with Wyeth-Lederle. Data from the review indicate a strong association between Rotashield and intussusception (bowel obstruction) among some infants during the first 1-2 weeks following vaccination. Use of the vaccine was suspended in July pending the data review by the ACIP. Parents should be reassured that their children who received rotavirus vaccine before July and remain well are not at increased risk for intussusception now.

Rotavirus and other causes of severe diarrhea remain a serious health concern for young children in the United States. In the U.S., rotavirus disease has been associated with approximately 50,000 hospitalizations and at least 20 deaths per year.

CDC announced today the start of a national education program to help parents manage severe diarrhea in children, the most serious complication of rotavirus illness. Education efforts will include outreach to parents through their health care providers and directly to parents through popular media such as parent magazines and radio public service announcements, in English and Spanish. Parents are urged to learn steps to relieve diarrhea symptoms in their children. Most importantly, parents are urged to learn the signs that their child may be suffering from severe dehydration from diarrhea and needs immediate medical care. Signs of severe dehydration in children include crying without tears, sunken eyes, unusual drowsiness or fussiness and dry, sticky mouth.

In July, the Public Health Service recommended to parents and health care providers that they postpone use of Rotashield as a precautionary measure following reports, from its early alert system, of intussusception among some infants following rotavirus vaccination. Also at that time, the manufacturer in consultation with the FDA voluntarily ceased distribution of the vaccine and, last week, withdrew the vaccine from the U.S. market. Experts agree that continued research is needed to clarify the relationship between intussusception and this rotavirus vaccine and to develop new vaccines against this disease.

Most importantly, health care providers should reassure parents that continued immunization of children against other life-threatening diseases is critical to prevent illness and disease outbreaks. Overall, vaccines are one of the safest and most effective medical interventions of our time, and the decision to immunize children against diseases like polio, whooping cough, bacterial meningitis and diphtheria is a sound one. For more information about vaccines, contact CDC's National Immunization Information Hotline at 1-800-232-2522 (English) or 1-800-232-0233 (Spanish). For more information about managing diarrhea in children, visit CDC's website at www.cdc.gov