



Immunization Management Consultancy
3851 Rosecrans Street, MS P573
San Diego, CA 92110-3115
Phone: 619-692-8661
Fax: 619-692-5677

IMMUNIZATION BULLETIN

FDA OK's Resumption of Rotarix® Use

Background: The US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) have lifted the recommended to temporarily suspend use of Rotarix® vaccine. The suspension was rescinded after the FDA conducted an extensive review of the vaccine's safety records as well as discussions with scientists and public health officials. The suspension was originally ordered after DNA fragments from Porcine Circovirus (PCV) were found in GSK's Rotarix® vaccine by an independent researcher using new technology to detect viral genetic material. Some genetic material for PCV was also found in RotaTeq® the Rotavirus vaccine made by Merck. PCV is a virus that infects swine but is not known to cause disease or be harmful to humans.

Rotavirus is one of the most common infections for children world-wide. The World Health Organization estimates that all most all children globally contract Rotavirus infection by age 5. Rotavirus most often infects infants and young children (ages 3 months to 2 years) and is the leading cause of severe, dehydrating diarrhea in this age group. More than 2 million children are hospitalized every year by Rotavirus and about 500,000 die every year from this disease. Dehydrating diarrhea from Rotavirus remains one of the most common causes for hospitalization for children under 5 in the United States.

The vaccines have a strong safety record involving millions of recipients. They have been very effective in reducing hospitalization rates of children under 5 from dehydrating diarrhea.

FDA Recommendations

The FDA and ACIP recommended reinstating administration of Rotarix® and continuing to give RotaTeq® vaccines to children. There is no evidence of a safety risk for either vaccine. The benefit of preventing a potentially severe infection from Rotavirus that can cause hospitalization due to dehydrating diarrhea outweighs any potential harm since there is no evidence that PCV causes disease in humans.

Additional Information

An updated VIS for both brands of Rotavirus vaccines includes information about PCV. The updated VIS can be downloaded at: http://www.immunize.org/vis/rota_06.pdf. Translations of the revised VIS for Rotavirus are pending. Parents should be counseled that the Rotavirus vaccine is safe, effective and drastically reduces the chance that their child will be hospitalized with severe dehydration due to diarrhea from Rotavirus infection.

Please contact SDIB's Immunization Management Consultancy Team with questions or to request consultancy services:

Jennifer Sterling: jennifer.sterling@sdcounty.ca.gov, (619) 692-8366

Daniel Wurm: daniel.wurm@sdcounty.ca.gov, (619) 692-5730

Everardo Aguilar: everardo.aguilar@sdcounty.ca.gov (619) 692-5599

Visit our website at WWW.SDIZ.ORG