

## **Study shows updated rotavirus vaccine not linked to increase in bowel obstruction**

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The rotovirus vaccine was pulled from the marketplace in 1999 after being associated with painful gastrointestinal complications, however, the updated rotavirus vaccines do not appear to increase the occurrence of these potentially fatal side effects, according to a new study by child health experts at C.S. Mott Children's Hospital.

The two updated versions of the vaccine, re-introduced in 2006 and 2008, prevent infection by rotavirus, which causes vomiting, <u>abdominal</u> <u>pain</u>, severe diarrhea and frequently requires hospitalization for young infants and children. Rotavirus was once the leading cause of <u>gastrointestinal illness</u> among children in the U.S.

The new study, published in this week's *Archives of Pediatric* Adolescent <u>Medicine</u>, shows the re-introduction of the vaccine has not caused an increase in a severe bowel obstruction called intussusception, the side effect that led to the original vaccine's withdrawal.

"We always need to carefully weigh the risks and benefits of <u>childhood</u> <u>vaccines</u>. Fortunately, our results suggest that rotavirus vaccines have not increased the rate of intussusception in the U.S.," says <u>pediatrician</u> Joe Zickafoose, M.D., M.S., a research fellow with the Child <u>Health</u> <u>Evaluation</u> and Research Unit.

Recent international studies have shown that, among vaccinated infants, the two latest rotavirus vaccines may be associated with a small increase in cases of intussusception.



However, the re-introduction of rotavirus vaccines in the United States did not appear to increase the rate of hospitalizations for intussusception.

More than 70 percent of infants in the U.S. have been vaccinated against rotavirus. The re-introduction of rotavirus vaccines is credited with reducing the number of diarrhea-related outpatient visits, emergency department visits, and hospitalizations among children.

Data used in the study came from the Healthcare Cost and Utlization Project's Kids' Inpatient Database, which is a sample of 80 percent of national pediatric discharges. The study focused on children younger than 1-year-old based on previous data which showed the most cases on intussusception occur within weeks of the vaccine being administered at ages 2-months, 4-months and 6-months old.

The investigators examined data trends from the decade prior to vaccine re-introduction, 1997-2006, and then made comparisons to data after vaccine re-introduction.

When comparing data, investigators expected to see 36 intussusceptionrelated hospitalizations per 100,000 children under 1-year-old by 2009.

Despite the re-introduction of the vaccines, there were only 33.3 hospitalizations per 100,000 children in 2009, making it very unlikely that the vaccines led to additional cases.

The latest versions of the rotavirus vaccine were licensed following studies in over 70,000 children, which showed no increased risk for intussusception among those vaccinated. However, there has been lingering concern that a small amount of risk may have been missed in these studies.

"We hope that our study provides information that will continue to



reassure parents that the benefits of rotavirus vaccine outweigh the risks," says Zickafoose, lead author of the study.

**More information:** Zickafoose JS, Benneyworth BD, Riebschleger MP, Espinosa CM, Davis MM. Intussusception hospitalizations before and after the reintroduction of rotavirus vaccine in the United States. *Arch Pediatr Adolesc Med.* Epub Jan. 2, 2012.

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