Rotavirus Vaccine Benefit Outweighs Small Risk

BY MIRIAM E. TUCKER

FROM A MEETING OF THE CDC'S ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

ATLANTA – New data on the rotavirus vaccine suggest a slightly increased risk for intussusception following the first dose, but consensus among experts remains that in most cases the vaccine's benefits outweigh the possible risk.

At the meeting , speakers summarized postmarketing surveillance data from Mexico, Brazil, Australia, and the United States for Merck's Rotateq and GlaxoSmithKline's Rotarix. Taken together, the data suggest that the excess risk for intussusception is approximately 1 per 97,000 infants following a first dose of rotavirus vaccine given at 6-14 weeks of age. In contrast, the risk was 1 in 10,000 with Wyeth-Lederle's RotaShield, which was removed from the market in 1999, said Dr. Margaret M. Cortese of the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention.

VITALS

Major Finding: The excess risk for intussusception is approximately 1 per 97,000 infants following a first dose of rotavirus vaccine given at 6-14 weeks of age.

Data Source: Several different sources, including the CDC, Merck, and GlaxoSmithKline.

Disclosures: Dr. Cortese and Dr. Baggs are CDC employees and do not have financial disclosures.

On Sept. 22, 2010, the U.S. Food and Drug Administration approved a label change for Rotarix advising of new data regarding intussusception from an evaluation in Mexico by GSK.

For its part, ACIP will revise the wording of its 2009 rotavirus recommendations only with regard to infants with a previous history of intussusception. Whereas it had previously said that "practitioners should consider the potential risks and benefits of administering rotavirus vaccine" to such infants, the new wording will say that "under usual circumstances in the United States, for infants with a history of intussusception, ACIP considers the possible increased risk of intussusception following rotavirus vaccine to outweigh the benefit of protection against severe rotavirus disease."

However, "providers may administer rotavirus vaccine" to such an infant "if, in a particular circumstance, they believe the benefit to outweigh the possible risk."

Data from the different studies were somewhat conflicting. For Rotateq, the incidence rate ratios for intussusception within 7 days of vaccination were 2.8, compared with infants receiving diphtheria, tetanus, and acellular pertussis (DTaP) vaccine in a surveillance study conducted by Merck and 5.26 compared with historical controls in Australian postlicensure surveillance. However, data from the Vaccine Safety Datalink in the United States showed a reduced rate of intussusception with Rotateq, with a ratio of 0.65 compared with infants who did not receive the vaccine, Dr. James Baggs of the CDC's National Center for Emerging and Zoonotic Infectious Diseases reported.

For Rotarix, the risk ratios were 1.8 within 30 days of vaccination from GSK's self-controlled case series, 4.6 within 7 days of vaccination in Mexico, and 1.1 in Brazil, in self- and case-controlled data collected by the CDC and the Pan American Health Organization, and 3.45 from the Australian study, which was based on just five intussusception cases within 7 days of vaccination.

At the same time, the numbers of hospitalizations for gastroenteritis overall and of gastroenteritis due to rotavirus have been declining, with just 4% of 101 gastroenteritis hospitalizations confirmed as rotavirus so far in 2010, down from 26% of 168 cases in 2009 and 51% of 211 cases in 2006, Dr. Cortese said.

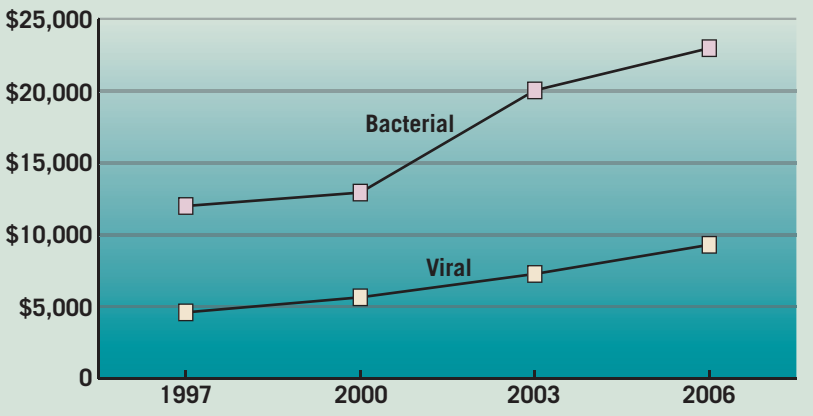
Previous data suggested that the vaccine prevents 88% of rotavirus hospitalizations/deaths, 84% of emergency department visits, and 80% of clinic visits. (The numbers are based on updated inputs to the model published in Pediatrics 2007;119:684-97.) Using those numbers, the CDC estimates that in 2009, rotavirus vaccination prevented 295,822 clinic visits, 169,431 emergency department visits, 52,802 hospitalizations, and 16 deaths. "The vaccine has had a significant impact on rotavirus disease in the United States," Dr. Cortese commented.

Assuming a relative risk of 4.6 for excess intussusception cases for one vaccinated birth cohort through 5 years of age, the vaccine prevents 1,100 hospitalizations and 80 deaths for every one case of intussusception, she said.

In a statement posted online after the ACIP meeting, the CDC said, "Considering that the data currently available suggest a small risk of intussusception caused by rotavirus vaccine is possible and considering that the benefits of rotavirus vaccination are great, the CDC continues to recommend both Rotarix and RotaTeq to prevent severe rotavirus disease in U.S. infants and children. The CDC will continue to monitor additional data on intussusception as they become available." ■

DATA WATCH

Cost of Hospital Stay Up 102% for Viral Infections, 91% for Bacterial Infections



Note: Based on weighted national estimates for children 0-17 years old.
Source: Agency for Healthcare Research and Quality

ELSEVIER GLOBAL MEDICAL NEWS

CDC: Adult Tdap Rates Lag as Pertussis Spikes

BY JANUARY W. PAYNE

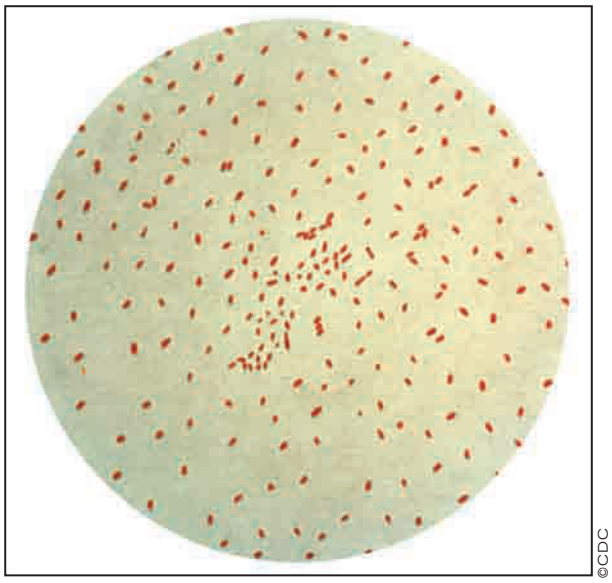
FROM MORBIDITY AND MORTALITY WEEKLY REPORT

Despite 2005 recommendations that people aged 10-64 years receive the tetanus, diphtheria, and acellular pertussis (Tdap) vaccine every 10 years, vaccination rates remain suboptimal, according to researchers from the Centers for Disease Control and Prevention.

In 2008, just 5.9% of adults aged 18-64 years were estimated to have received the Tdap vaccine. Tdap vaccination rates were higher for health care personnel – 15.9% – than for adults who have contact with infants – 5.0%. And for adults in this age range for whom Tdap vaccination history could be determined, 36.5% were overdue for a tetanus booster shot, which the Tdap vaccine would now replace.

These findings are especially alarming given the recent spike in the number of pertussis cases across the United States, and they underscore the need for more aggressive vaccination efforts, the researchers reported.

The analysis of data from the National Health Interview Survey showed that about 62% of adults aged 18-64 years reported having been vaccinated against tetanus in the previous 10 years in 2008, and 60% reported having updated vaccinations in 1999 (MMWR 2010;59:1302-6).



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Vaccine-preventable *Haemophilus pertussis* infection is on the rise.

The Advisory Committee on Immunization Practices that made the 2005 Tdap recommendations suggested that the vaccine may be used to provide protection against infection with pertussis.

It is particularly important for health care personnel and adults who have contact with infants to be vaccinated against pertussis, because they are at higher risk for transmitting the illness to susceptible groups.

While tetanus infections are rare in the United States, pertussis is considered a common illness, according to the CDC. In 2008, 13,278 cases of pertussis were reported in the United States, although that is likely to be an underestimate given that the illness typically has nonspecific symptoms and often isn't properly diagnosed. Infants less than age 6 months who are too young to have completed pertussis vaccinations themselves are at risk of contracting the infection from their adult caretakers.

To improve Tdap vaccination rates, the CDC advises health care providers to recommend the Tdap vaccination to adults aged 18-64 years whose last tetanus shot was more than 10 years ago. For health care providers and adults who have contact with infants younger than age 1 year, the interval between the last tetanus shot and a new Tdap vaccine can be as little as 2 years. ■