Viral Contaminants Found in RotaTeq Vaccine

BY ELIZABETH MECHCATIE

The use of Rotarix can be resumed and the use of RotaTeq continued because there is no evidence that the porcine virus detected in both rotavirus vaccines poses a safety risk to humans, according to the Food and Drug Administration.

The FDA based its decision on laboratory results from the manufacturers of the two rotavirus vaccines and from FDA laboratories, on a scientific literature review, and on input from scientific and public health experts, according to a statement issued by the agency on May 14. In addition, the agency does not believe a medical follow-up is needed for children who have been vaccinated with these vaccines.

Those experts include the FDA's Vaccines and Related Biological Products Advisory Committee, which met a week before the agency announcement to discuss the recent identification of porcine circovirus (PCV) type 1 DNA in GlaxoSmithKline's rotavirus vaccine, Rotarix, which resulted in the FDA's recommendation to temporarily suspend the use of Rotarix on March 22. At the recent meeting, the FDA announced that PCV has also been detected in Merck & Co.'s rotavirus vaccine, RotaTeq.

In addition, the panel agreed that the benefits of the two rotavirus vaccines greatly outweighed the theoretical risk that the detection of PCV in the vaccines could cause human infection, but recommended more study of this potential risk.

Panelists generally agreed that they were encouraged by the available data that did not indicate that PCV detected in the vaccines caused human infection, but noted that this had not yet been proved. Among the panel's recommendations for further studies were serology studies of children with cystic fibrosis on long-term pancreatic enzyme supplementation to check for evidence of antibodies to PCV. (Pancreatic enzyme supplements are derived from the pancreas of pigs, where PCV is detected.)

'Whether [the virus] can infect humans still remains a question, but it looks like it doesn't cause disease.'

When the temporary suspension of Rotarix use was announced in March, the FDA said that PCV1 DNA had not been found in RotaTeq, but recommended that Merck conduct tests. At the meeting, Dr. Norman Baylor, the director of the FDA's Office of Vaccines Research and Review, told the panel that at the May meeting, Merck had informed the agency that fragments of DNA from PCV type 1 and type 2 have been identified in the vaccine in preliminary studies. But no recommendation to suspend the use of this vaccine was made at that time.

PCV is common among pigs but is not known to cause disease in humans. There is currently no evidence that PCV in rotavirus vaccines licensed in the United States pose a human safety risk, according to Dr. Baylor. In a statement issued late on May 6, Merck said that the levels of PCV DNA detected in RotaTeq were "very low," and that "there is no evidence at this time that DNA from PCV causes any disease in humans."

At the meeting, GSK presented results of studies conducted since PCV DNA was detected in Rotarix, which has not provided any evidence that PCV1 in Rotarix causes infections in humans, according to the presenters. The company tested stool and blood samples taken from vaccine recipients in four Rotarix clinical trials conducted in Africa, Asia, Latin America, and Europe, which included three studies of healthy infants and one of HIV-positive infants. Overall, PCV1 DNA was detected in the stool of four infants, on the third day after vaccination, which the company said was suggestive of "transient passage" of the PCV DNA through the GI tract, but none of these infants or any other infants in the trials had evidence of antibodies to PCV1 in blood samples that had been taken after they received the last vaccine dose, according to GSK.

The FDA and the companies are continuing to conduct studies.

"We have data to suggest this virus is probably not pathogenic in humans," said panelist Dr. José Romero, chief, pediatric infectious diseases, Arkansas Children's Hospital, Little Rock. "Whether it can infect humans still remains a question, but it looks like it doesn't cause disease," added Dr. Romero, who, like other panelists, said that more studies are definitely needed. He and others agreed that this should include more research on PCV2.

PCV2 has been identified as a causal agent of a lethal wasting disease in pigs.

Panelist Dr. Harry Greenberg, the Joseph D. Grant Professor of Medicine and Microbiology and Immunology, Stanford (Calif.) University, said that the vaccine risks "would have to be immense" to outweigh the benefits. But he added that more studies are needed to determine that PCV does not cause human infections and recommended more studies of vaccinees, including serial testing of stool specimens for evidence of viral replication. (He disclosed that he was involved in the development of the first rotavirus vaccine and is a strong proponent of rotavirus vaccination, but has no personal financial relationship to the manufacturers.)

The panel's consumer representative, Vicky Debold, director of patient safety at the National Vaccine Information Center, Vienna, Va., said that the available evidence was "colored by a great deal of uncertainty." ■

More information for clinicians is available at www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205548.htm.

Nasal Screening for MRSA in NICU Significantly Cuts Infection Rate

BY MIRIAM E. TUCKER

BETHESDA, MD. — Nasal screening for methicillin-resistant *Staphylococcus aureus* significantly reduced the infection rate in a neonatal intensive care unit, in a retrospective study of 5,893 infants seen over two 42-month periods.

VITALS

Major Finding: A total of 5 infants (0.15%) became infected in the NICU during the screening period, versus 29 (1.11%) during the period when screening was not performed.

Data Source: A retrospective study of 5,893 infants seen over two 42-month periods.

Disclosures: None was reported.

Some U.S. states have enacted legislation for mandatory screening for nasal colonization with methicillin-resistant *Staphylococcus aureus* (MRSA) among inpatients in high-risk inpatient units, but there is still ongoing debate about the value of such screening, Dr. Jeremias L. Murillo said in a poster presented at the annual conference on antimicrobial resistance sponsored by the National Foundation for Infectious Diseases.

Records from January 2006 to June 2009, when all patients admitted to the NICU were screened for nasal carriage of MRSA, were compared with those from an equivalent 42-month period from July 2002 to December 2005, when no nasal screenings were performed. All MRSA infections were identified from a microbiology database and confirmed by chart review.

Nasal screenings were performed via rapid polymerase chain reaction testing, and infants found positive were decolonized with topical mupirocin, with contact isolation maintained until decolonization was completed.

There were no significant differences in birth weight or gestational age between the 3,269 infants who were screened and the 2,624 who were not.

A total of 5 infants (0.15%) became infected in the NICU during the screening period, compared with 29 (1.11%) during the period when screening was not performed, Dr. Murillo of Children's Hospital of New Jersey and Beth Israel Medical Center, Newark, reported.

In an interview, Dr. Murillo noted that in 2002 it took an average of 72 days from the time of admission before the infants became infected, compared with only 14 days in 2005, just before his hospital began screening.

"We felt that the shortened time frame was because the babies were coming into the NICU already colonized with MRSA and were therefore getting infected earlier," he commented. ■

Parents' Attitudes Towards HPV Vaccination of Boys,

BY ROXANNA GUILFORD-BLAKE

ATLANTA — Although most parents in a national survey say that they believe the male HPV vaccine is important, only about half said they would have their own sons vaccinated.

Of the 1,178 parents of boys aged 18 years and younger who responded, 90% said they believed the male HPV vaccination was important in general, Dr. Amanda Dempsey of the University of Michigan, Ann Arbor, reported in a poster at the National Immunization Conference sponsored by the Centers for Disease Control and Prevention. However, only 52% of parents of boys aged 9-17 years indicated that they would have their own son vaccinated in the near future, and only 48% of the parents of boys aged 8 years and younger said they would do so when their son was older.

Parents appeared to be more motivated by the possibility of transmission rather than disease protection, even though there's no evidence the vaccine protects against transmission, Dr. Dempsey noted in an interview.

In data not reported on the poster, 100% of parents cited decreased transmission as a reason to get the vaccine—more than those who cited preventing male cancers (93%) or genital warts (91%). Perceived benefits to vaccination had the largest impact on parental vaccination intention; perceived susceptibility—but not perceived severity—was also a factor. Parents having less than a high school education were associated with decreased vaccination intention for older, but not younger, boys.

The study was conducted before the vaccine was licensed for males, and that may have had an impact on parental decisions, they noted. The research is a starting point; it may help identify key messages that resonate with parents. Intervention studies are underway to explore ways to tailor effective messages. ■

Disclosures: *Dr. Dempsey serves on an advisory board for Merck & Co.*