

CDC Calls for Suspension of Childhood Rotavirus Vaccine

"NO ONE SHOULD NOW BE GIVING ROTAVIRUS VACCINE TO ANYONE."

Editorial Staff

Earlier this year, concerned parents and health care groups nationwide began voicing their opposition to the continued use of the hepatitis B vaccine after a report showed more than 24,000 adverse events - including 439 deaths - that were allegedly linked to the vaccine between 1990 and 1998.*

Now, another childhood vaccination is raising similar concerns. Less than a year after going on the market, the Centers for Disease Control has recommended that administration of the oral rotavirus vaccine for infants be postponed until at least November, 1999 pending an ongoing investigation.

The decision to pull the vaccine comes after the CDC's Vaccine Adverse Event Reporting System received as many as two dozen reports in the past year of a painful and life-threatening bowel obstruction that occurred in some infants shortly after ingesting the vaccine.

The decision has also prompted at least one national physician organization, the Association of American Physicians and Surgeons, to question the safety of an immunization system that dictates that children born in the U.S. receive an average of 21 separate vaccinations before age five, three of which are for rotavirus.

Rotavirus Vaccine Was Never Fully Effective

Rotavirus is the most common cause of diarrhea in infants and young children in the U.S. The virus is responsible for approximately 30 deaths each year. Virtually all children will have one or more rotavirus infections in the first five years of life, but children between six and 24 months of age have the highest risk of infection.

Research to develop a rotavirus vaccine began with tests on animals in the mid-1970s, culminating with a live oral vaccine that combines human rotavirus strains with rotavirus taken from rhesus monkeys.

The vaccine was approved by the CDC's Advisory Committee on Immunization Practices in March 1998 and was licensed for approval by the Food and Drug Administration on August 31 of last year. But despite more than two decades of research to create an effective form of immunization, CDC documents reveal that receiving the rotavirus vaccine could be less effective than natural immunity.

In a report issued on March 19th of this year, the CDC stated that although children can be infected with rotavirus several times during their lives, after one natural infection, 75% are protected against diarrhea from a subsequent rotavirus infection, and 88% are protected against cases of severe diarrhea from rotavirus.

Studies of a series of four efficacy trials completed in the U.S. and Finland showed that the vaccine

demonstrated no more than 68% efficacy against any rotavirus diarrhea, and as little as 69% efficacy against severe rotavirus diarrhea.

The CDC also admitted in an October 1998 fact sheet that the rotavirus vaccine was far from being a panacea. "Although rotavirus vaccine is highly effective against severe rotavirus disease, a large number of milder cases of rotavirus diarrhea will still occur and ... parents will need to be educated that this vaccine does not prevent all childhood diarrhea," the report said.

Problems from the Start

Even before gaining final approval, preliminary reports appeared to link the rotavirus vaccine with an increased incidence of intussusception, a rare intestinal condition that causes infolding of one segment of the intestine within another in children between the ages of five and nine months. Accompanying symptoms may include persistent vomiting, black or bloody stools, irritability or lethargy. Without proper treatment, which may include surgery, the condition can be fatal.

According to government studies, the normal background incidence of intussusception is approximately 51 per 100,000 infant years, or one case per 100,000 infant weeks. A review of prelicensure trials conducted in Finland and the United States, however, show a intussusception rate much higher than normal in infants who have received the vaccine.

Out of 10,054 children inoculated with rotavirus, a total of five cases of intussusception were reported - three within a week of receiving the vaccine. Extrapolation of the three cases would equate to roughly 30 cases per 100,000 infant weeks, nearly 30 times the normal background rate of intussusception.

Reports also show that vaccinated children from the Finland trial had more than five times the incidence of high-grade fever and twice the rate of diarrhea compared to children given a placebo.

Coming to a Head

Despite the apparent warning signs, the rotavirus vaccine gained approval from the Food and Drug Administration on August 31, 1998. Just over two months later, the American Academy of Pediatrics issued guidelines recommending the vaccine be administered to all children at two, four and six months.

By early 1999, the rotavirus vaccine had been added to the CDC's list of recommended vaccines for infants and was on its way to being added to the list of mandatory vaccines.

As more children and infants began receiving the vaccine, however, The Vaccine Adverse Events Reporting System (VAERS) began receiving reported cases of intussusception associated with children who had been given the vaccine.

According to the CDC, the first substantial evidence appeared in June, when an epidemiologist noticed an unusual number of intussusception cases in children who had received the vaccine in seven states. Results of postlicensure trials being conducted in Minnesota and northern California also suggested increased cases of bowel obstructions at six times the expected rate.

By the first week of July, at least 23 separate accounts of intussusception in children who had taken the rotavirus vaccine had been reported to VAERS. Eight infants required surgery to correct bowel obstructions, with one child losing seven inches of intestine in the process. Faced with mounting evidence, on July 15, the Centers for Disease Control issued a statement recommending that use of the vaccine be postponed until November of this year so that the health

risks and costs associated with rotavirus could be studied further. Barbara Reynolds, a spokeswoman for the centers, told the *New York Times* that "no one should now be giving rotavirus vaccine to anyone."

A day after the CDC issued its statement, the American Academy of Pediatrics did an about-face and pulled its support. Ten months after recommending delivery of the rotavirus vaccine, the AAP issued a new set of guidelines and recommended that doctors should temporarily "suspend administration of rotavirus vaccine to unimmunized and partially immunized children, pending collection and evaluation of additional information."

Physician Group Speaks Out

Riding on the heels of the CDC's decision, the Association of American Physicians and Surgeons urged Congress to review the process by which vaccines are tested and approved for use in the United States.

In a press release issued last month, AAPS Executive Director Dr. Jane Orient questioned the actions of the CDC and FDA regarding implementation the rotavirus vaccine. "The situation with the rotavirus vaccine may be a clue to a far more serious problem with the vaccine's approval," wrote Dr. Orient. "The Surgeon General and CDC claim the vaccine's withdrawal was prompted by the VAERS reports received through July 1999. But why was the vaccine approved in the first place, when the incidence of the serious complication of intussusception was far higher in prelicensure trials than in the VAERS reports?"

"We must ask, what did they know and when (did) they know it? AAPS has been studying the reports and has concluded that the FDA and CDC may have ignored or concealed data that showed the problems from the outset.

"As increasing numbers of vaccines are being mandated, one has to inquire whether the rotavirus story is the tip of the iceberg," Dr. Orient continued. "Just how rigorous is the process of safety testing? What are the guarantees of the integrity of the process? We believe the process may be tainted by conflicts of interest.

"The tragedy of the rotavirus vaccine might never have happened if the public had access to the data used by the FDA and CDC in recommending the vaccine.

"Decisions about vaccines given to children should be made by parents in a consultation with the child's attending physician, not mandated by a small group of 'experts' with minimal accountability," concluded Dr. Orient. "While vaccines have been a very effective weapon against certain infectious diseases, this is no reason to relax safety standards or to override informed consent."

* See "Hepatitis B Vaccine Comes under Fire" in the August 23, 1999 issue (<http://www.chiroweb.com/archives/17/18/07.html>).

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