Fact Sheet

Rotavirus

1. **What is FDA announcing?**

   FDA is announcing the approval of RotaTeq™, a new vaccine for the prevention of rotavirus gastroenteritis in infants. RotaTeq™ is the only US licensed vaccine that effectively prevents a viral infection, called rotavirus that may cause diarrhea, vomiting, fever and dehydration.

2. **What is rotavirus and how commonly does it occur?**

   Infection with rotavirus is a leading cause of severe diarrhea in infants and young children in the United States and worldwide. In the United States, the disease occurs more often during the winter, with the most activity occurring from November to May. Most children, whether in the US or elsewhere, are infected with rotavirus before they are two years old.

   Sometimes diarrhea and vomiting due to rotavirus infection can lead to the loss of body fluids (dehydration), which in some instances may be severe enough to require hospitalization. In the United States, rotavirus infection causes an estimated 55,000 hospitalizations a year of infants and young children, although death due to rotavirus infection is rare. However, in developing countries, rotavirus gastroenteritis is a major cause of childhood death and is estimated to cause several hundred thousand deaths annually.

   Once an infant has been exposed to rotavirus, it takes approximately 2 days for symptoms to appear. Infants and children develop vomiting and watery diarrhea that may last 3-8 days, and fever and abdominal pain occur frequently. A child may have rotavirus gastroenteritis more than once, because there are many different rotavirus types, but repeat infections tend to be less severe than the original infection.

3. **How is rotavirus gastroenteritis treated?**

   Treatment is supportive and includes replacement of fluids (rehydration), by mouth, with products that contain water with sugar and certain minerals. Such treatment is usually effective; however, severe cases may require a visit to the emergency room or hospitalization so that lost body fluids can be replaced with fluids given directly through the veins using an intravenous (i.v.) line.

4. **How is rotavirus spread?**

   Rotavirus is contagious and the infection is usually spread from person to person, through the fecal-oral route. Fecal–oral transmission occurs when bacteria or viruses found in the stool of one child are swallowed by another child. This can occur when

small amounts of fecal matter may be found on surfaces such as toys, books, clothing, etc. and on the hands of parents or child-care providers; but are usually invisible. Rotavirus may also be transmitted through intake of fecally-contaminated water or food or by respiratory droplets that people sneeze, cough, drip, or exhale. Rates of the illness among children in developed and less developed countries are similar.

5. **How is rotavirus vaccine given?**

   The vaccine is a liquid given by mouth with the first dose given between 6-12 weeks of age and two additional doses administered at 4- to 10-week intervals. All three doses should be completed before a child reaches 32-weeks of age. RotaTeq™ may be given to pre-term infants according to their age in weeks since birth.

6. **Can toddlers or older children be vaccinated with the new vaccine?**

   No, the vaccine should be given to infants with the first dose at 6-12 weeks of age and according to the recommended schedule of age as described in question 5.

7. **How well does rotavirus vaccine work to prevent rotavirus gastroenteritis?**

   Overall, approximately 72,000 healthy infants were studied worldwide in randomized placebo-controlled studies to look at both the safety of RotaTeq™ and how well it works. The data showing how well RotaTeq™ prevents rotavirus gastroenteritis comes from almost 7,000 of these infants from the United States and Finland. In these studies, RotaTeq™ prevented 74% of all rotavirus gastroenteritis cases and 98% of the severe cases.

   In addition, RotaTeq™ reduced the need for hospitalization for gastroenteritis due to rotavirus by 96%.

8. **Are there are any possible side effects associated with the use of rotavirus vaccine?**

   During the studies, rates of serious adverse events were similar in infants receiving RotaTeq™ compared to those infants who did not receive the vaccine.

   The following were reported more often in infants who received RotaTeq™, when compared to those who received placebo; diarrhea (24.1% in vaccine recipients vs 21.3% in those receiving placebo), vomiting (15.2% in vaccine recipients vs 13.6% in those receiving placebo), ear infection (14.5% in vaccine recipients vs 13.0% in those receiving placebo), runny nose and sore throat (6.9% in vaccine recipients vs 5.8% in those receiving placebo), wheezing and coughing (1.1% in vaccine recipients vs 0.7% in those receiving placebo).

9. **Another vaccine for rotavirus was withdrawn in 1999 because of cases of intussusception associated with the administration of that particular vaccine. Was the risk of intussusception evaluated for RotaTeq™?**

Yes, a large study of over 70,000 children designed specifically to assess a risk of intussusception similar to what was found for the previous rotavirus vaccine was conducted before licensure of RotaTeq™. The results of this study did not show an increased risk of intussusception for RotaTeq™ when compared to those infants who received placebo. In order to further observe RotaTeq™ for the potential that it could be associated with increased rates of intussusception or other serious adverse events, the manufacturer, Merck and Co., Inc., has committed to conducting another study after licensure of approximately 44,000 children, and CDC will also conduct a large study in its Vaccine Safety Datalink Program (VSD), which evaluates vaccine safety among approximately 80,000 US infants every year. In addition, for the first three years of licensure the manufacturer will report cases of intussusception to FDA within 15 days of receiving them, and all other serious side effects on a monthly basis. FDA and CDC will be closely monitoring the Vaccine Adverse Event Reporting System (VAERS) for any reports of intussusception. Although there is no evidence to date that RotaTeq™ causes intussusception, this aggressive post-licensure monitoring should enhance our ability to detect this risk.

10. **What is intussusception?**

Intussusception is a rare blockage or twisting of the intestine, which can be life-threatening. One portion of the intestine telescopes into a nearby portion, causing the intestinal obstruction. The most common site is where the small intestine joins the large intestine. Because the two walls of the intestines press against each other, this causes inflammation, swelling, and eventually decreased blood flow. If it is not detected early, internal bleeding, a hole in the intestines and infection in the abdomen may occur because the intestinal tissue has died from the decreased blood flow. With prompt detection and treatment, almost all patients fully recover. Although persons of any age can get intussusception, it is most common among infants in the first year of life and occurs spontaneously in approximately 1 in 2,000 healthy young infants and children per year.

11. **Who should not be immunized with rotavirus vaccine?**

Infants who are allergic to any of the ingredients of the vaccine and infants who have an allergic reaction after getting a dose of the vaccine should not be immunized with RotaTeq™.

RotaTeq™ is a live virus vaccine that should not be given to infants with known or suspected weakened immune systems caused by treatments that they are taking such as radiation, a class of drugs called corticosteroids, or due to conditions such as HIV, cancer, blood disorders (e.g., leukemia, and see the approved labeling for additional information), and kidney or other organ transplant. Infants born to mothers with HIV should not receive this vaccine unless it has been established that the infant is not infected with HIV.

At this time, there is not enough information to support the use of RotaTeq™ in infants with any of the following:

-temperature greater than or equal to 100.5^{o}F (38.1^{o}C)
-previous history of rotavirus infection

-active, short-term, gastrointestinal illness
-repeated gastrointestinal problems, such as frequent diarrhea and failure to thrive
-history of stomach disorders that have been present since birth
-history of intussusception
-history of abdominal surgery
-who have received a blood transfusion or blood products, including immunoglobulins within 42 days
-live in a household with persons whose immune systems are weakened and therefore cannot fight off infections as well.

Each time before your child receives a dose of RotaTeq™, discuss with your healthcare provider any health problems that your child may have and any medications that your child is currently taking or has been prescribed.

12. **Does rotavirus vaccine contain thimerosal?**

    No. RotaTeq™ does not contain thimerosal or any other preservatives.

13. **Can rotavirus vaccine be administered with other vaccines?**

    In the studies, RotaTeq™ was administered with diphtheria and tetanus toxoids, acellular pertussis (DTaP), inactivated poliovirus vaccine (IPV), haemophilus influenzae type b conjugate vaccine, hepatitis B vaccine, and pneumococcal conjugate vaccine. However, not enough data are available to confirm that RotaTeq™ does not interfere with childhood vaccines that prevent pertussis when they are given at the same time. Additional studies will be conducted to address this question.

14. **Has the Advisory Committee on Immunization Practices (ACIP) made a recommendation on RotaTeq™?**

    The ACIP does not make a recommendation until FDA has licensed a vaccine. Now that RotaTeq™ has received approval, it is anticipated that the ACIP will convene soon to discuss RotaTeq™.

15. **How can I report a serious side effect with RotaTeq™, or other vaccines, to FDA?**

    Adverse reactions and other problems related to vaccines should be reported to the Vaccine Adverse Event Reporting System, which is maintained by FDA and the Centers for Disease Control and Prevention. For a copy of the vaccine reporting form, call 1-800-822-7967 or report on line to www.vaers.hhs.gov

Connecticut Department of Public Health
410 Capitol Avenue
P.O. Box 340308
Hartford, CT 06134-0308
Phone: (860) 509-7929
FAX: (860) 509-7945
www.dph.state.ct.us