The success of the rotavirus vaccine

by Donald Murphey, M.D.

At some point in the winter, one of your healthy 6-month-old patients will be rushed to Cook Children's Emergency Department for a new, abrupt illness with symptoms such as:

- Frequent, watery diarrhea
- High fever, up to 40 degrees C
- Persistent irritability
- Lethargy
- Persistent vomiting
- Pallor

They will have poor urine output, tenting of their skin and tacky mucous membranes. The 4-year-old sibling at home, who is in preschool, will be asymptomatic. The infant may recover nicely with diligent oral rehydration, an overnight stop in the short-stay unit or over a couple days of inpatient care with the hospitalists. This child should do well afterward.

A similar infant in North Africa, however, will not survive the same illness. In the United States, infants are at risk of complications of this illness. The cost of evaluating these very ill young infants and lost productivity for their families is significant. All of this is a result of acute rotavirus gastroenteritis. Fortunately, rotavirus is now a vaccine-preventable disease. We have seen sharp declines in this illness in the U.S. with the use of rotavirus vaccine. Efforts by groups like the World Health Organization (WHO), the Gates Foundation and the Global Alliance for Vaccine Immunization (GAVI) are improving access to vaccines for kids in the developing world. Rotavirus, however, still causes more than half a million childhood deaths worldwide each year. It is the No. 1 cause of serious diarrhea in the world.

Rotavirus vaccine has been very successful in improving the health of our kids. There are three rotavirus vaccines that have gone through development, all in the last 20 years. The first was Wyeth's RotaShield® a live, attenuated oral recombinant monkey/human vaccine with four rotavirus strains. In 1996, Cook Children's Medical Center Infectious Disease and primary care pediatric staff in the then fledgling Cook Children's Physician Network teamed up and enrolled 150 infants in the pivotal trial that led to the licensure of this new vaccine. I was the principal investigator. Richard Hochberger, D.O., was one of the key investigators.

We did not see any significant adverse events. Dr. Hochberger observed that the kids who participated avoided marked diarrheal disease over the following winters. This important vaccine was licensed by the FDA, and recommended for use for all infants in the U.S. by the Advisory Committee on Immunization (ACIP) in August 1998. About half a million doses were given over the following year. Extremely rare cases of intussusception were seen, and careful investigation showed that these events were clustered at about one week after the first dose. The vaccine was withdrawn by Merck from the market here in the U.S. Development of the vaccine in the rest of the world stopped as well.

Another rotavirus vaccine was not available in the U.S. for almost 10 years. Merck's RotaTeq® was the next vaccine. It was a live, attenuated oral recombinant human/bovine vaccine that included five strains. It was approved after a trial enrolling 70,000 infants and is given at 2, 4 and 6 months of age, not to be started later than 12 weeks old. It is being used worldwide. The third vaccine is GSK's Rotarix® an oral live, attenuated human vaccine with a single strain that infers cross protection to other strains. This was licensed in Central and South America first, then in the U.S. in 2008, based on studies of 75,000 infants. It is given in two doses starting at 6 weeks of age. Both of these should not be given to children with severe combined immunodeficiency (SCID) or significant immunodeficiency.

The emergence of rotavirus vaccine is demonstration of the beneficial work American pediatricians conduct for the health of kids worldwide. This process has also demonstrated the very robust system here in the U.S. looking for safety issues that on occasion truly are related to childhood vaccines. We can feel comfortable that the process of vaccine development and post licensure safety surveillance in the U.S. provides us with safe vaccines. There is still work to do to protect infants worldwide from vaccine-preventable diseases.

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