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OREGON PUBLIC HEALTH DIVISION • DEPARTMENT OF HUMAN SERVICES

ROTAVIRUS: ANOTHER VACCINE-PREVENTABLE DISEASE

Worldwide, rotavirus is the leading cause of severe acute diarrhea in children aged <5 years.[1, 2] The disease is characterized by vomiting and watery diarrhea for 3–8 days, while fever and abdominal pain occur frequently. Rotavirus is transmitted by the fecal-oral route, and by the age of five nearly every child in the world has been infected with rotavirus at least once.[3] Before rotavirus vaccine was available in the United States, rotavirus caused an estimated 20 to 60 deaths, 55,000 to 70,000 hospitalizations, 205,000 to 272,000 emergency department visits, and 410,000 outpatient visits annually.[4] Rotaviral disease has typically had a winter-spring seasonality with west-to-east geographic progression in the United States; it generally begins in the West during December–January and flows thence across the country, ending in the Northeast during May–June.[5, 6] This issue of the *CD Summary* reviews rotavirus vaccines and the effect that they have apparently exerted on the incidence of rotavirus disease in the United States.

VACCINE #1: SWING AND A MISS

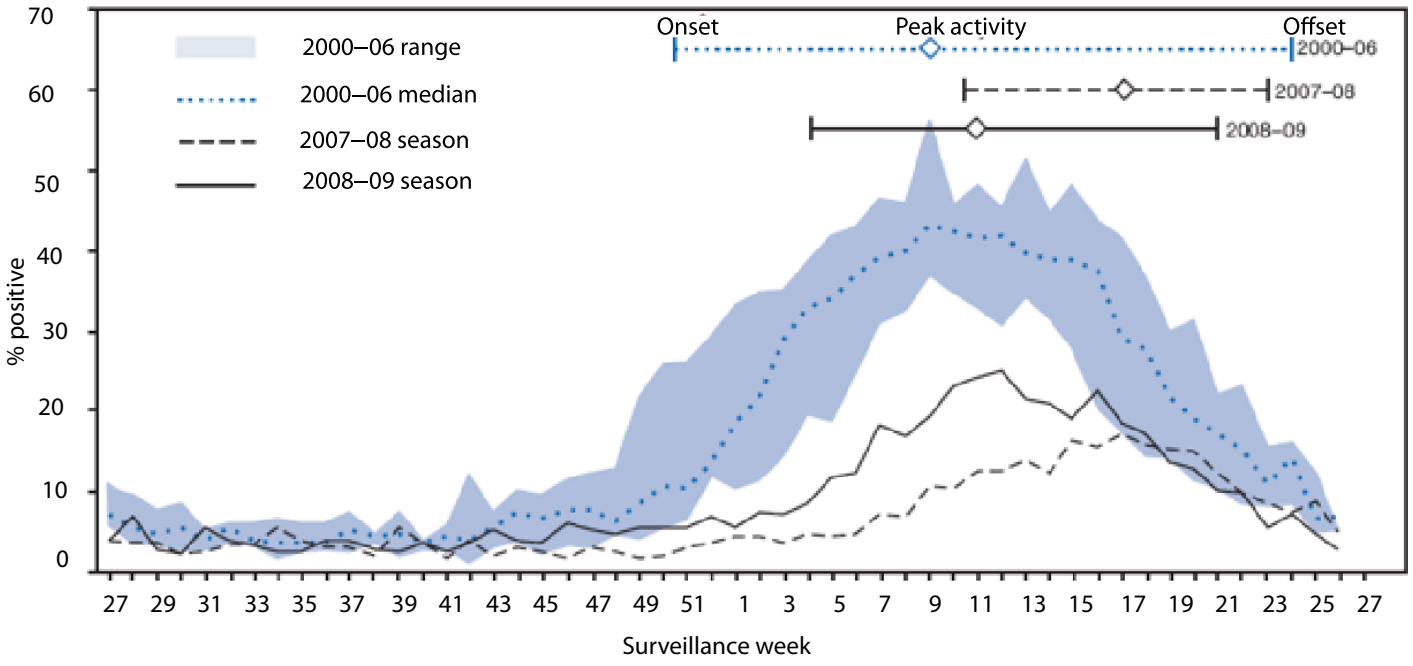
The first rotavirus vaccine licensed in the U.S. was RotaShield™, an oral formulation of live, rhesus-human reassortant rotaviruses. It was approved by FDA in August 1998 and recommended for universal use in children in October of that year. However, by July 1999 the national Vaccine Adverse Events Reporting System had picked up 15 reports of intussusception in vaccinees. The manufacturer withdrew the product in October 1999, and subsequent investigation associated RotaShield™ with an excess risk of intussusception of about 1 case per 11,000 vaccinees. The vast majority of such cases occurred within 3–7 days following receipt of the vaccine.[7, 8]

VACCINES #2 & 3: STAND-UP DOUBLE?

Two new live, oral rotavirus vaccines have since come onto the scene. The first, a pentavalent human-bovine reassortant, was christened RotaTeq®. In a randomized, double-blind, placebo-controlled trial (RDBPCT) involving 68,000 infants, a three-dose series of this vaccine was found to be 98% efficacious against "severe" rotavirus disease—that measured by emergency department visits or hospitalizations. It was approved by FDA in 2006.

Rotarix®, featuring a live, attenuated human strain, was approved by FDA in 2008; its two-dose series was tested in a RDBPCT involving 63,225 infants and found to be 85% efficacious against severe rotavirus disease. Expect some arguing by the manufacturers about type-specific differences in efficacy; but ACIP considered the two vaccines pretty much equivalent and recommended that all children be vaccinated with one or the other.[4]

Figure 1. Percentage of rotavirus tests with positive results, by surveillance week — participating laboratories, National Respiratory and Enteric Virus Surveillance System, United States, July 2000–June 2009*[1]



* A median of 67 laboratories (range: 62--72) contributed rotavirus testing data to NREVSS during July 2000--June 2009.

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What about intussusception? Tight age restrictions (first dose to be given no later than 14 weeks 6 days of age and the last dose no later than 8 months 0 days of age) in the recommendations were intended to avoid the peak risk period for naturally occurring intussusception—thereby avoiding spurious associations with the vaccine. It seems to have worked, as no evidence of elevated risk has surfaced either in clinical trials or in post-licensure surveillance for each of the two vaccines.[9]

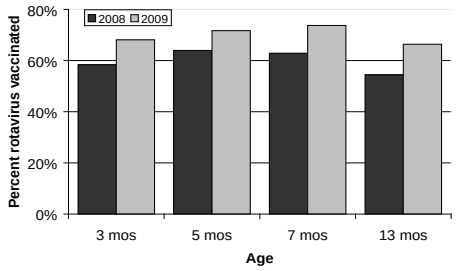
DISEASE PLUMMETING

To characterize trends, CDC analyzed data from its National Respiratory and Enteric Viruses Surveillance System in which laboratories from around the U.S. submit weekly reports on rotavirus test results. In an analysis of results from the 29 laboratories that consistently reported ≥30 weeks of data per season, positive tests for rotavirus were lower in the 2007–08 and 2008–09 seasons than in the previous six seasons (Figure 1). This pattern was reflected in each of the four US regions analyzed. Moreover, the latter two seasons were each shorter in length and later in onset than the median timeframes during 2000–2006.[1]

OREGON DATA

Rotavirus is not reportable in Oregon. The most recent year for which we have statewide hospital discharge data is 2007; during 2000–2007, 18% of acute gastroenteritis-related hospital discharges of patients <5 years of age were coded as rotavirus—an average of 149 per year, with an overall peak during March.

Figure 2. Rotavirus immunization uptake by age, Portland-metro area, 2008–09



We expect that rotavirus disease will decline in Oregon with increasing immunization rates. Sentinel immunization providers in Washington and Multnomah Counties reported that during 2009, about 68% of 3-month-old infants had their first dose of rotavirus vaccine—up from ~58% during 2008 (Figure 2).

In 2010 Oregon's Emerging Infections Program will commence participation in a study of rotavirus vaccine effectiveness. We will link routinely collected rotavirus laboratory testing data with immunization data from Oregon's statewide immunization registry to see whether declining disease incidence has anything to do with vaccination. Watch this space.

SUMMARY

Even without the results of a more in-depth rotavirus vaccination effectiveness study, at least two recommendations can be made based on available data. First, vaccinate infants. The downward trend in disease, coupled with data from the vaccine trials, suggests that rotavirus vaccination is working, and probably offering some "herd immunity" in addition to protecting the children to whom the vaccine is given. Next (and last), we feel obligated to point out that, as with most diarrheal diseases, spread of rotavirus infection may also be prevented with diligent hand hygiene and keeping kids with diarrhea away from child care and other settings that present opportunities for transmission.

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