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Oregon School/Facility/College Immunization Advisory Committee:

Review of Rotavirus Vaccine Against Twelve Criteria for School/Facility/College Immunization Requirements

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Process for Reviewing Antigens for Potential Inclusion in OAR 333-050-0050, 333-050-0130 and 333-050-0140.

Request for the inclusion of additional antigens or vaccines can come from the Oregon Immunization Program, IPAT (Immunization Policy Advisory Team), or from the community. Proposed changes to vaccine requirements are discussed with IPAT either in a regularly scheduled meeting or through electronic communication. IPAT will submit their comments and a request for consideration to the Oregon Immunization School Law Advisory Committee.

The Oregon School/Facility Immunization Advisory Committee was established as a part of the school law immunization requirements when the original legislation was passed in 1980. This Committee is composed of immunization stakeholders from the fields of public health, school health, school administration, medicine, day care, child advocacy and consumers (parents). Through consensus, the committee determines what vaccines (antigens) should be included in Oregon school immunization requirements.

Information about new vaccines and the diseases they prevent, including transmission within schools, burden of disease, cost-effectiveness, effect on schools/counties and vaccine availability is presented at a scheduled meeting for committee consideration. The following criteria are an integral part of the discussion and the decision-making process. All 12 criteria must be considered. Members of the Committee are expected to rely on their professional and scientific judgment as well as available data when applying the criteria.

The Committee's recommendation is then submitted to the Oregon Immunization Program for consideration and possible action.

The 12 Criteria to Consider in Evaluating Antigens

The following information is being presented for Committee consideration.
Consideration: Adding rotavirus vaccine to the school law requirements for children's facility attendance.

1. **The vaccine containing this antigen is recommended by ACIP (Advisory Committee on Immunization Practices) and included on its recommended childhood and adolescent immunization schedule**.

   "In February 2006, a live, oral, human-bovine reassortant rotavirus vaccine (RotaTeq® [RV5]) was licensed as a 3-dose series for use among U.S. infants for the prevention of rotavirus gastroenteritis, and the Advisory Committee on Immunization Practices (ACIP) recommended routine use of RV5 among U.S. infants (CDC. Prevention of rotavirus gastroenteritis among infants and children: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 2006;55[No. RR-12]). In April 2008, a live, oral, human attenuated rotavirus vaccine (Rotarix® [RV1]) was licensed as a 2-dose series for use among U.S. infants, and in June 2008, ACIP updated its rotavirus vaccine recommendations to include use of RV1. ACIP recommends routine vaccination of U.S. infants with rotavirus vaccine. RV5 and RV1 differ in composition and schedule of administration. RV5 is to be administered orally in a 3-dose series, with doses administered at ages 2, 4, and 6 months. RV1 is to be administered orally in a 2-dose series, with doses administered at ages 2 and 4 months. ACIP does not express a preference for either RV5 or RV1."

   "The rationale for adopting vaccination of infants as the primary public health measure for prevention of rotavirus disease, especially severe rotavirus disease, in the United States is threefold. First, rates of rotavirus illness among children in industrialized and less developed countries were similar, indicating that clean water supplies and good hygiene have little effect on virus transmission... Second, in the United States, a high level of rotavirus morbidity [e.g., illness requiring a physician treatment, emergency room visit, or hospitalizations] continued in the prevaccine era despite available therapies. For example, the rate of hospitalizations for gastroenteritis in young children declined only modestly during 1979-1995 despite the widespread availability of oral rehydration solutions in the treatment of dehydrating gastroenteritis. Third, studies of natural rotavirus infection indicated that initial infection protects against subsequent severe gastroenteritis, although subsequent asymptomatic infections and mild disease still might occur. Therefore, vaccination early in life, which mimics a child's first natural infection, will not prevent all subsequent disease but should prevent the majority of cases of severe rotavirus disease and their sequelae (e.g., dehydration, physician visits, hospitalizations, and deaths)."

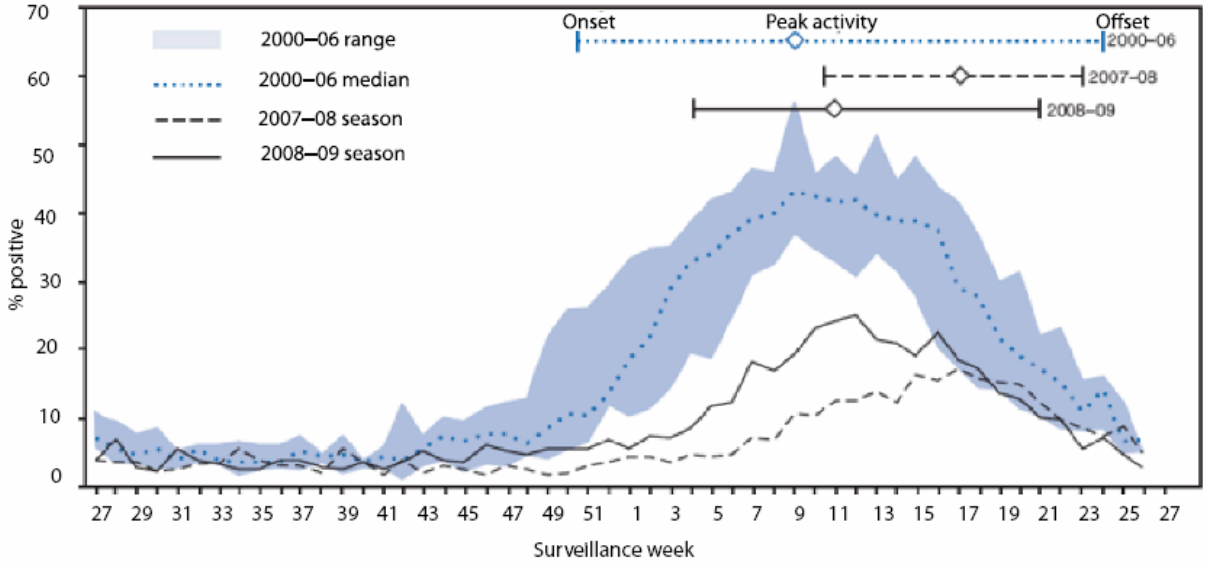
CDC. Prevention of Rotavirus Gastroenteritis Among Infants and Children Recommendations of the Advisory Committee on Immunization Practices (ACIP). *February 6, 2009 / 58(RR02);1-25* (pages 1, 16)
Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5802.pdf

2. **The vaccine prevents disease with a significant morbidity and mortality in at least some subset of the Oregon's population.**

"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.

"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.

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.

"The downward trend in disease, coupled with data from the vaccine trials, suggests that rotavirus vaccination is working, and probably offering some 'herd immunity.'

"We expect that rotavirus disease will decline in Oregon with increasing immunization rates."

Rotavirus, Another Vaccine-Preventable Disease. *CD Summary.* Oregon Department of Human Services, Public Health Division. January 5, 2010. Vol. 59, No. 01
Available at: http://www.oregon.gov/DHS/ph/cdsummary/2010/ohd5901.pdf

3. **The vaccine (antigen) is cost-effective from a societal perspective in Oregon.**

"A routine rotavirus immunization program would prevent 13 deaths, 44,000 hospitalizations, 137,000 emergency department visits, 256,000 office visits, and 1,100,000 episodes requiring only home care for children <5 years of age in the United States. Assuming costs of administration of $10, the break-even price per dose of vaccine was $42 from the societal perspective and $12 from the health care perspective. From the societal perspective, at the manufacturer's price of $62.50 per dose, vaccination would cost $138 per case averted, $3024 per serious case averted, and $197,190 per life-year saved, at a total cost of $515 million to the health care system and $216 million to society. Key variables influencing the results were parental workdays lost, costs of hospitalization, emergency department visits, and child care. Despite a higher burden of serious rotavirus disease than estimated previously, routine rotavirus vaccination would unlikely be cost-saving in the United States at present. Nonetheless, rotavirus vaccination may still be considered a cost-effective intervention."

There are no Oregon-specific cost-effectiveness data.

Widdowson MA, Meltzer MI, Zhang X, Bresee JS, Parashar UD, Glass RI. Cost-effectiveness and potential impact of rotavirus vaccination in the United States. Pediatrics. 2007 Apr;119(4):684-97.
Available at: http://pediatrics.aappublications.org/cgi/reprint/119/4/684

How do the morbidity/mortality statistics and cost-effectiveness estimates support or oppose the addition of this vaccine to school/facility/college requirements?

4. **The vaccine (antigen) has been used in the general population to demonstrate reduction in disease activity with similar level of effectiveness to that demonstrated prior to FDA approval.**

"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."[1]

"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." [1]

"The Food and Drug Administration (FDA), which approves and monitors vaccines to ensure their safety and effectiveness, has found pieces of a non-harmful porcine circovirus (originally found in healthy pigs) called porcine circovirus type 1 (PCV1) in … Rotarix®. PCV1 is not known to cause disease in people or animals." [2]

"The FDA is recommending that healthcare providers temporarily stop using this vaccine in children until further studies are done. There is another brand of rotavirus vaccine called "RotaTeq®." Most children vaccinated in the United States have received RotaTeq®. Experts are looking closely at the RotaTeq® vaccine also, and so far, no porcine circovirus type 1 has been found." [2]

[1]Rotavirus, Another Vaccine-Preventable Disease. *CD Summary.* Oregon Department of Human Services, Public Health Division. January 5, 2010. Vol. 59, No. 01
Available at: http://www.oregon.gov/DHS/ph/cdsummary/2010/ohd5901.pdf

[2]CDC. Q&A on Rotarix® Vaccine for Healthcare Providers and Public Health Professionals.
Available at: http://www.cdc.gov/vaccines/vpd-vac/rotavirus/rotarix-providers.htm

5. The vaccine is necessary to prevent diseases known to be spread in schools or facilities, respectively and will increase safety in the school/facility environment.

"Rotaviruses are shed in high concentration in the stool of infected persons. Transmission is by fecal-oral spread, both through close person-to-person contact and by fomites (such as toys and other environmental surfaces contaminated by stool). Rotaviruses are also probably transmitted by other modes such as fecally contaminated food and water and respiratory droplets.

"Rotavirus is highly communicable, as evidenced by the nearly universal infection of children by age 5 years. Infected persons shed large quantities of virus in their stool beginning 2 days before the onset of diarrhea and for up to 10 days after onset of symptoms. Rotavirus may be detected in the stool of immunodeficient persons for

more than 30 days after infection. Spread within families, institutions, hospitals, and child care settings is common."[1]

OPHD investigated six lab-confirmed rotavirus outbreaks between 2000-2008: four in child care centers, one in a school, and one among restaurant patrons. Four of these outbreaks occurred in the most at risk population of children under 5 years of age. No fatalities occurred, but 13% of outbreak associated cases (7 of 55) were hospitalized. [2]

[1]CDC. *Epidemiology and Prevention of Vaccine-Preventable Diseases*, 11th Edition, page 247. Available at http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/rota.pdf

[2]Oregon Communicable Disease Program, 2010.

Would this vaccine requirement have the potential to reduce the spread of disease in the school/facility/college setting, or is the goal to reduce disease in the community at large? Would this vaccine requirement have the potential to reduce the number of cases of disease, or would it have the potential to prevent outbreaks?

6. Requiring the vaccine for school law will make a significant difference in vaccine coverage in the preschool/school/college populations and vaccinating the infant, child, adolescent or young adult against this disease reduces the risk of person-to-person transmission.

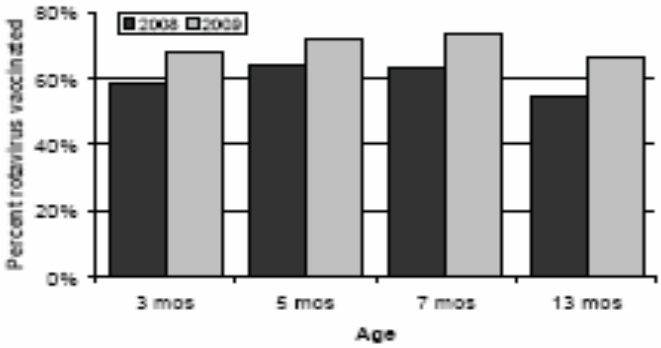
A very small number of children attend certified daycares under the age of 8 months when the vaccine should be administered. The data from the 2010 children's facility Immunization Primary Review Summary reports show that there were 60,543 children attending certified child cares/preschools/Head Start programs and only 3,672 children 18 months of age and younger (the number of children younger than 8 months of age attending these facilities cannot be ascertained with current data available). This number represents 6.1% of the children attending these facilities and represents only about 5% of the population in the 0-18 month age group; the percentage would be even smaller for children 0-8 months. Registered child cares serve additional children in this age range. Although registered child care providers are required to obtain an up-to-date immunization record on each child, there is no enforcement system in place to significantly increase the number of children receiving rotavirus vaccine through school law requirements for registered child cares.

Oregon Immunization Program. Immunization Assessment for Children's Facilities, 2010.

7. The vaccine is acceptable to the Oregon medical community and the general public.

Public acceptance of specific vaccines needs to be considered. Uptake of new vaccines is monitored through reporting by Oregon ALERT IIS, which tracks vaccines being administered in the public and private health care community. The chart below indicates the uptake of the vaccine in the Portland Metro area.

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



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.

Rotavirus, Another Vaccine-Preventable Disease. *CD Summary.* Oregon Department of Human Services, Public Health Division. January 5, 2010. Vol. 59, No. 01
Available at: http://www.oregon.gov/DHS/ph/cdsummary/2010/ohd5901.pdf

What level of provider/public acceptance and vaccine uptake are necessary so that addition of this vaccine to school/facility/college law would be most effective? If uptake and acceptance are very high, the requirement would have little impact, and if very low, the requirement would face a lot of resistance.

8. Ensure that sufficient funding is available on a state level to purchase vaccines for children who would need to meet the new law requirements.

A vaccine can not be added to school law requirements unless it is assured that every child has access to the vaccine and that it is affordable. If the cost of the vaccine exceeds the funding available through federal programs, it will be necessary

for the state to set aside funds to purchase the proposed required vaccine. The targeted population for rotavirus is relatively small – 260 children needing general fund purchased vaccine – for an annual cost of approximately $42,842.

Cost estimate to state general fund prepared by the Oregon Immunization Program in response to Senate Joint Resolution 1, Legislative Session 2009

9. There is a stable and adequate supply of vaccine.

There appears to be sufficient vaccine available, though the impact of having one of the rotavirus vaccines removed from the inventory has not been thoroughly evaluated at this time.

10. The administrative burdens of delivery and tracking of vaccine and Oregon school/facility rule implementation is reasonable in light of any other vaccines currently being phased in to law.

There are very few school/childcare computer tracking systems available for programs serving children under the age of five. The rotavirus vaccine has a complex schedule (2 or 3 doses depending on the brand given) and has a brief period of time for the child to receive the vaccine since it should not be administered after 8 months of age. Children who have not started the series by 16 weeks of age would not be able to receive the vaccine. Unless facilities were to enforce the requirements on a monthly basis, there would be very few children subject to exclusion each year. Expecting day care directors to understand and enforce the requirement could be problematic.

11. The burden of compliance for the vaccine is reasonable for the parent/caregiver.

Parents and caregivers are often involved in obtaining vaccines for their children. The rotavirus vaccine is routinely given to children who are receiving their vaccines on schedule, and during the same clinic visits in which other vaccines are received.

12. The vaccine is included in Oregon ALERT IIS for tracking and reporting purposes.

Rotavirus vaccine doses are documented for all ages submitted to ALERT and forecast as age appropriate.

What is a reasonable administrative burden for the school/facility/college, and would a new requirement for this vaccine create an acceptable or unacceptable burden on schools/facilities/colleges? What is a reasonable burden for the parent/caregiver?