

**Draft—3/11/10**

**Oregon School/Facility Immunization Advisory  
Committee:**

**Review of Pneumococcal Conjugate Vaccine  
Against Twelve Criteria for  
Children’s Facility Immunization  
Requirements**

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**Oregon School/Facility Immunization Advisory Committee:  
Review of Pneumococcal Conjugate 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 pneumococcal conjugate 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.**

From:

CDC. *Epidemiology and Prevention of Vaccine-Preventable Diseases*, 11<sup>th</sup> Edition, pages 217-230. Available at

<http://www.cdc.gov/vaccines/Pubs/pinkbook/downloads/pneumo.pdf>

"The first pneumococcal conjugate vaccine (PCV7) was licensed in the United States in 2000. It [provides protection against] seven serotypes of *S. pneumoniae* (4, 9V, 14, 19F, 23F, 18C and 6B)... The serotypes included in PCV7 accounted for 86% of bacteremia, 83% of meningitis, and 65% of acute otitis media among children younger than 6 years of age in the United States during 1978-1994."

All children younger than 5 years of age are recommended to be routinely vaccinated with PCV.

"The primary series beginning in infancy consists of three doses routinely given at 2, 4, and 6 months of age. A fourth (booster) dose is recommended at 12-15 months of age... Unvaccinated children aged 7 through 11 months should receive two doses of vaccine at least 4 weeks apart, followed by a booster dose at age 12 through 15 months. Unvaccinated children aged 12 through 23 months should receive two doses of vaccine, at least 8 weeks apart. Previously unvaccinated healthy children 24 through 59 months of age should receive a single dose of PCV7. Unvaccinated children 24 through 59 months of age with sickle cell disease, asplenia, HIV infection, chronic illness, cochlear implant, or immunocompromising conditions should receive two doses of PCV7 separated by at least 8 weeks."

The recently licensed PCV13 provides protection against 13 serotypes including the 7 serotypes in PCV7. When PCV13 becomes available, this vaccine will replace PCV7. At the February 2010 meeting, ACIP voted to recommend that children under 5 years of age who have completed their PCV7 series receive one dose of PCV13.

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

Invasive pneumococcal disease rates decreased dramatically in children less than 5 years of age after the introduction of the vaccine. In the Clackamas/Multnomah/Washington Tri-County area, where surveillance data are

obtained, there have been no reported deaths from invasive pneumococcal disease caused by the strains listed in the vaccine in children under the age of five since 2002. In 2007, there were 2 cases of invasive pneumococcal disease caused by serotypes in the vaccine.

Following PCV7 introduction, overall national rates of invasive pneumococcal disease (IPD) have declined by 80 percent in children less than 5 years of age. In 2009, there were zero cases of invasive pneumococcal disease caused by serotypes in PCV7 and seven cases of IPD caused by serotypes in the newly approved PCV13.

Oregon Acute and Communicable Disease Program, 2010.

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

In a study published in 2000 by Lieu et al., with the disease rates prevalent at the time and a vaccine cost of \$58 per dose, the estimated cost per year of life saved was \$80,000. Since then, the vaccine has come into widespread use, and pneumococcal disease rates declined among both children and adults, possibly from a “herd immunity” effect. An analysis by Ray et al., published in 2006, in which declines in disease among adults were attributed to vaccination of children, estimated a cost of only \$7,500 per year of life saved. On the other hand, after these benefits have been reaped (i.e., with current vaccination rates), it is not clear how much additional benefit would be gained by additional vaccination. The last reported death from invasive pneumococcal disease in a child <5 years of age in our surveillance area in the Tri-County area around Portland was in 2001. If there are few deaths left to be prevented, the cost per year of life saved would be very high.

In a presentation to ACIP, PCV13 was reported to be cost-saving compared to PCV7 for routine use. “Catch up immunization with one dose of PCV13 among children 12-59 months old who have been fully vaccinated with PCV7 may not be cost-saving when indirect effects are not considered but still appears to be comparable in cost-effectiveness to other accepted interventions.”

Lieu TA, Ray GT, Black SB, Butler JC, Klein JO, Breiman RF, Miller MA, Shinefield HR. Projected cost-effectiveness of pneumococcal conjugate vaccination of healthy infants and young children. *JAMA*. 2000 Mar 15;283(11):1460-8.

Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/10732936>

Ray GT, Whitney CG, Fireman BH, Ciuryla V, Black SB. Cost-effectiveness of pneumococcal conjugate vaccine: evidence from the first 5 years of use in the United States incorporating herd effects. *Pediatr Infect Dis J*. 2006 Jun;25(6):494-501.

Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/16732146>

Messonnier ML, et al. Cost-Effectiveness of Using 13-valent Pneumococcal Conjugate Vaccine in Infants and Young Children to Prevent Pneumococcal Disease in the United States. Presentation to ACIP, October 2009. Available at <http://www.cdc.gov/vaccines/recs/acip/downloads/mtg-slides-oct09/11-1-PCV13.pdf>

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

The vaccine has demonstrated a reduction in vaccine-preventable disease in the community after implementation into the immunization schedule.

**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.**

Whether the school/facility environment poses a safety risk to its children by virtue of the presence of a disease should remain a factor when considering a school/facility requirement for that vaccine or antigen. Five to seventy percent of healthy adults carry the bacteria that cause pneumococcal disease, and 27-58% children in schools are carriers. "Attendance at a child care center has also been shown to increase the risk of invasive pneumococcal disease and acute otitis media 2–3-fold among children younger than 59 months of age." Community acquired pneumococcal disease outbreaks are not common and generally occur in crowded environments including jails and nursing homes, and in persons with underlying illness.

CDC. *Epidemiology and Prevention of Vaccine-Preventable Diseases*, 11<sup>th</sup> Edition, pages 217-230. Available at <http://www.cdc.gov/vaccines/Pubs/pinkbook/downloads/pneumo.pdf>

**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 across racial and ethnic groups.**

Adding a requirement for PCV for children's facilities may not significantly increase the uptake of PCV. Uptake of 4 doses of PCV7 in the Sentinel region is 65% for children 19-35 months of age. Sentinel data also indicate that children are receiving the PCV7 dose 4 at almost the same rate as DTaP dose 4, a vaccine that is required for children's facility attendance (DTaP 4 rates ranged from 1.2% to 2.2% higher than PCV7 dose 4

rates from 2008 Quarter 2 to 2009 Quarter 4). Data from the National Immunization Survey estimate that 79.4% of 19-35 month old in Oregon have 4 doses of PCV7 and 79.7% of the same group have 4 doses of DTaP. Children's facilities (certified childcare, Head Start, and preschool) report that 94% of children are up-to-date for DTaP dose 4. Children attending children's facilities represent approximately one-third of the children in their age group. The percentage of children attending a registered child care setting is unknown. Registered facilities are asked to have immunization records available on children in their care but there is no enforcement element to this requirement. Therefore, approximately two-thirds of children under 5 years of age do not attend a facility where a PCV requirement would be enforced.

4<sup>th</sup> Quarter Sentinel Report, 2009. Oregon Immunization Program  
National Immunization Survey, Quarter 1-4, 2008. Available at: [http://www.cdc.gov/vaccines/stats-surv/nis/tables/08/tab03\\_antigen\\_state.xls](http://www.cdc.gov/vaccines/stats-surv/nis/tables/08/tab03_antigen_state.xls)  
Childcare Coverage Assessment Survey, 2009. Oregon Immunization Program

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

It would appear from the above data, PCV is generally acceptable to the public and being administered by the medical community.

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

A vaccine cannot be added to school law requirements unless it is assured that every child has access to the vaccine and that it is affordable. Estimates for the need for general fund dollars range from \$144,173 to \$703,556 per year, depending on the number of doses needed for each child. These estimates do not include the cost if an additional dose of PCV13 is needed for children.

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 is a stable and adequate supply of PCV7 at this time. The supply of PCV13 is unknown at this time.

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

Whenever new immunization requirements are added, schools have to contact more families about needed vaccines and spend time educating parents. Computer software upgrades must be made and paid for, and in turn must be approved by the state. Computer programs are not currently designed to accept pneumococcal vaccines, so programming changes would be extensive for those programs that evaluate at the pre-kindergarten level. Most certified day care programs do not use computers to evaluate immunization records; a very complicated schedule such as PCV, where children can be required to have one or up to four doses (or five with PCV13) of the vaccine depending on their age, would be a challenge. Hib has been required since 1991 and most errors and confusion from exclusion orders issued were Hib related (before the vaccine shortage).

Exclusion orders and Certificate of Immunization Status forms also require revision when additional vaccines are added to school/children's facility immunization requirements. Local health departments have to prepare and mail more exclusion orders, provide more community clinics and communicate with local providers and parents about the new rule changes to ensure that children will not be excluded from school. Health plans need to cover the costs of the vaccines when feasible to improve access. Oregon law prohibits local health departments from charging an administrative fee if parents are financially unable to pay, and this has a financial impact on the counties. Adding more vaccines when still phasing in other vaccines complicates the entire process that can then lead to errors, confusion, and frustration that can potentially overwhelm the partners in the process which may weaken the effectiveness of school law enforcement. However, there are no other vaccines currently being phased-in at the children's facility level at this time.

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

The majority of providers give pneumococcal conjugate vaccine doses to their clients with other recommended vaccines. During a potential catch-up period, there may be additional visits required. In addition, the new recommendation for a dose of PCV13 to be given to children under 5 years of age who have completed the PCV7 series may necessitate an additional clinic visit.

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

Pneumococcal vaccine doses are documented in ALERT. Pneumococcal conjugate vaccine is forecast through age 4 years.