

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

**Criteria for Reviewing Antigens for Potential  
Inclusion in OAR 333-050-0050, 333-050-  
0130 and 333-050-0140  
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 disease they prevent, including transmission within schools, burden of disease, cost-effectiveness, affect 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 criteria are approved with the explanation. Criteria were developed through review of current literature\* and past experience.

- 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.** The vaccine must be universally recommended by the ACIP. The ACIP reviews licensed vaccines and makes recommendations. Its process includes: (1) a

review of the Food and Drug Administration (FDA) labeling/package inserts for each vaccine; (2) is science-based determined through review of the scientific literature (both published and unpublished, when available) on the safety, efficacy, acceptability, and effectiveness of the immunizing agent; (3) an assessment of cost effectiveness; (4) a review of the morbidity and mortality associated with the disease in the population in general and in specific risk groups; (5) a review of the recommendations of other groups; and (6) a consideration of the feasibility of vaccine use in existing child and adult immunization programs. In the clinical development of a vaccine, the efficacy of the vaccine is studied using FDA-approved research protocols that evaluate whether a vaccine protects individuals from contracting the disease in population-based studies. Vaccinations generally have the potential for side effects. The known risks associated with each vaccine (or antigen) must be balanced against the risks of the disease. Vaccines have the potential to reduce, or in some cases even eliminate diseases that can result in serious illness, long-term disability, or death.

2. **The vaccine prevents disease with a significant morbidity and mortality in at least some subset of the Oregon's population.** It is also important to identify any disproportionate impact on any subset of the community i.e. geographically, racially, ethnically.
3. **The vaccine (antigen) is cost-effective from a societal perspective in Oregon.** Immunizations are the most cost-effective clinical preventive service for children but vaccines may be cost effective without being cost savings. In some cases, societal or indirect costs will also need to be considered. Not all vaccines recommended by the ACIP are cost saving or equally effective, so some determination of the vaccine's relative cost-effectiveness may need to be made for comparison purposes when applying the criteria.
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.** The goal is to significantly reduce morbidity and mortality and achieve "herd protection" in specific population groups such as preschoolers, school-age children and college students. The vaccine should also demonstrate a reduction in vaccine-preventable disease in the community after implementation into the immunization schedule over a period of time. Significant changes in frequency of side effects after general use of the vaccine should be considered when adding any vaccine requirement to school law.
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.

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.** If “herd protection” can be achieved, even community members who are not vaccinated (such as newborns and some with chronic illnesses) are offered some protection because the disease has less opportunity to spread within the community. Consideration should be given as to how the disease is transmitted and how contagious the illness is in the school, preschool or college environment.
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. Adding an antigen to the school/facility law with poor provider or public acceptance would be resisted. Postponing the regulation until there is greater usage of the vaccine would assure greater compliance with the requirements and fewer exemptions.
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.
9. **There is a stable and adequate supply of vaccine.** There needs to be sufficient time from the point of introduction of the vaccine to potential implementation of requiring the vaccine for school/facility attendance to ensure that vaccine supplies are being adequately maintained and reduce the chances of vaccine shortages. Shortages add to the work load when changes need to be made in vaccine requirements as well as reduced herd immunity, parent stress and provider confusion.
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.** Many stakeholders and partners are involved in the implementation of new vaccine requirements. Local health departments, schools, certified day cares, preschools, head starts,

computer programmers, medical clinics and health plans are all impacted by school law changes. Each of these key players has issues that affect the feasibility of implementing new immunization requirements. Schools have to contact more families, pay for upgrades for computer software (that in turn must be approved by the state) and educate parents. 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.

**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. What and when vaccines are required will determine whether new rules will add additional provider visits, more medical appointments, time off from work and out of pocket costs.

**12. The vaccine is included in Oregon ALERT IIS for tracking and reporting purposes.** This is to ensure that affected schools/facilities/colleges have the capacity to obtain records for affected children/students when the parents/students can not provide the necessary information. This service greatly enhances school/facility law compliance and reduces the burden on these programs and the families in Oregon.

\*Sources of Information:

AIM (Association of Immunization Managers) Position Statement School and Child Care Immunization Requirements, June 2006.

Washington State Board of Health, Immunization Advisory Committee. Criteria for reviewing antigens for potential inclusion in WAC 246-100-166.

Opel D., Diekema D., Marcuse EK., A Critique of Criteria for Evaluating Vaccines for Inclusion in Mandatory School Immunization Programs. *Pediatrics* August 2008;122 (2) 504-510.