WASHINGTON STATE BOARD OF HEALTH

Immunization Advisory Committee:
Criteria for Reviewing Antigens for Potential Inclusion in WAC 246-105-030

Updated November 8, 2017

The Washington State Board of Health (Board) has authority under RCW 28A.210.140 to adopt rules establishing the immunization requirements for child care or school entry.[1] WAC 246-105-030 outlines the antigens that children must be protected against for child care or school entry. The Board faces complex decisions about which antigens to include in the rules. As new vaccines are developed, some may be added to the Advisory Committee on Immunization Practices (ACIP) Recommended Childhood and Adolescent Immunization Schedule. In addition, antigens not already required for school and child care may be reviewed for potential inclusion in the immunization rule.

The Board considers factors other than those considered by the ACIP to address the unique needs of our state. The Board believes that approaching these decisions using Board developed rationale and criteria is the best method for protecting children and the community at large while balancing the interests of parents and families in Washington State.

In order to develop (and revise as needed) the criteria to guide this decision-making, the Board has engaged immunization stakeholders from public health, schools, child care, medicine, epidemiology, child advocacy, and medical ethics as well as consumers (parents). The Board established the Immunization Advisory Committee (IAC) in December 2005 to recommend criteria that a Technical Advisory Group (TAG) could use to evaluate which antigens to include in WAC 246-105-030 (Immunization of child care and school children against certain vaccine preventable diseases).

The original IAC met three times to develop the criteria and recommendations described in this report. In addition, between the second and third meeting of the IAC a TAG further refined the criteria and tested them against the pertussis antigen. The IAC reviewed and further refined the TAG's work at its final meeting in March 2006. These criteria were presented to the Board at the April 12, 2006 meeting.
The Board adopted the report as an interim report and asked that the TAG further refine the criteria and test them against three antigens (pertussis, tetanus, and diphtheria).

The TAG met on May 17, 2006. The results of the TAG deliberations were presented to and adopted by the Board on June 14, 2006. On July 11, 2017 the Board and Department of Health (Department) convened a separate TAG to evaluate the criteria and make recommendations to the Board regarding what updates should be made to the criteria. Board and Department staff presented the TAGs recommendations to the Board on November 9, 2017 and the Board adopted the recommended changes.

[1] Antigen means a substance, foreign to the body, which stimulates the production of antibodies by the immune system. Antigens include foreign proteins, bacteria, viruses, pollen and other materials.

FRAMEWORK

John Stuart Mill in On Liberty wrote, "The only purpose for which power can rightfully be exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant." This thesis has become known as the harm principle. The IAC endorsed the harm principle and interpreted it to mean that vaccine requirements for children entering child care and/or school are justifiable when without them:

- The state's obligation to protect the public's health and safety would be compromised.
- An individual's decision could place others' health in jeopardy;
- The state's economic interests could be threatened by the costs of care for vaccine preventable illness, related disability, or death, and by the cost of managing vaccine preventable disease outbreaks;
- The state's duty to educate children could be compromised.

ASSUMPTIONS

The IAC made two assumptions while drafting the criteria: (1) a process exists to opt out of immunization requirements by children attending either child care or school; and (2) vaccine(s) containing the antigen are accessible and that cost is not a barrier under the current system of universal purchasing, this would mean that the state purchases and distributes the vaccine.

PROCESS FOR REVIEWING ANTIGENS FOR POTENTIAL INCLUSION IN WAC 246-105-030

1. The Board reviews the proposed antigen to determine whether the two assumptions listed above have been met; whether there is adequate information specific to Washington State with which to evaluate the antigen against the nine criteria below; and whether there is some likelihood, based on a preliminary review, that the antigen might meet those criteria. Generally speaking the Board will wait until the Department of Health has made the vaccine containing the antigen(s) available to providers in Washington State.

2. If the Board determines that the assumptions above have been met, the Board will establish a TAG to review the antigen against the nine criteria below. For antigens that are part of a combination vaccine, each antigen will be considered separately against the criteria. The TAG must include representatives from the fields of public health, primary care, epidemiology, medical ethics, and representatives of diverse communities in Washington State. At the discretion of the Board sponsor, the TAG can also include consumers (parents); community members with diverse perspectives on immunizations; and representatives from the fields of school health, school administration, child care, child advocacy, immunization administration, and others important to the discussion and review. In addition to providing the TAG with current literature and other relevant information such as survey data, the Board will ask the Department of Health to supply current information about the antigen that is specific to Washington State.

3. At the TAG meeting(s) the Board sponsor is responsible for assuring (1) that each TAG member is provided with the opportunity to review and comment on if the antigen under consideration meets the framework and criteria and (2) that decisions about adding or removing antigens from the rule are based on the best available scientific evidence with

the understanding that the science will continue to evolve. Following this discussion each TAG member will be asked to provide their vote on whether or not they recommend that the Board add the antigen by initiating formal rule making. In addition to providing their vote, each TAG member will have an opportunity to provide comments about the antigen and how it does or does not meet the assumptions and criteria.

4. Board staff will provide the Board with the final vote tally, TAG Member ballot comments, and a brief summary of the TAG's deliberations on each of the nine criteria for consideration and possible action.

THE THREE CATEGORIES OF CRITERIA

The IAC grouped criteria into three categories: vaccine effectiveness, disease burden, and implementation.

NINE CRITERIA TO CONSIDER IN EVALUATING ANTIGENS

I. Criteria on the effectiveness of the vaccine

1. A vaccine containing this antigen is recommended by the Advisory Committee on Immunization Practices and included on its Recommended Childhood & Adolescent Immunization Schedule.
2. The vaccine containing this antigen is effective as measured by immunogenicity[2] and population-based prevention data in Washington State, as available.
3. The vaccine containing this antigen is cost effective from a societal perspective.
4. Experience to date with the vaccine containing this antigen demonstrates that it is safe and has an acceptable level of side effects

II. Disease Burden Criteria

5. The vaccine containing this antigen prevents disease(s) that has significant morbidity and/or mortality in at least some sub-set of the population.
6. Vaccinating against this disease reduces the risk of person-to-person transmission, with transmission in a school or child care setting or activity being given the highest priority.

III. Implementation of the Criteria

7. The vaccine containing this antigen is acceptable to the medical community and the public.
8. The administrative burdens of delivery and tracking of vaccine containing this antigen are reasonable.
9. The burden of compliance for the vaccine containing this antigen is reasonable for the parent/caregiver.

EXPLANATIONS FOR THE NINE CRITERIA

I. Criteria on the effectiveness of the vaccine

- A vaccine containing this antigen is recommended by the Advisory Committee on Immunization Practices (ACIP) and included on its recommended childhood and adolescent immunization schedule.

  The vaccine must be recommended by the ACIP. The ACIP reviews licensed vaccines. It makes recommendations for newly licensed vaccines and regularly updates its recommendations. Its process includes: (1) a review of the Food and Drug Administration (FDA) labeling/package inserts for each vaccine; (2) a thorough review of the scientific literature (both published and unpublished, when available) on the safety, efficacy, acceptability, and effectiveness of the immunizing agent, with consideration of the relevance, quality, and quantity of published and unpublished data; (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

[2] Immunogenicity means the ability of an antigen or vaccine to stimulate the body to produce an immune response. Vaccines often include antigens that stimulate an immune response to a particular disease but are not necessarily the same as the organism that would cause the disease.

immunization programs. Feasibility issues include (but are not limited to) acceptability to the community, parents, and patients; vaccine distribution and storage; access to vaccine and vaccine administration; impact on the various health care delivery systems; population distribution effects; and social, legal, and ethical concerns.

- The antigen is effective as measured by immunogenicity and population based prevention data in Washington State, as available.

  In the clinical development of a vaccine, the effectiveness 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 or generates an immunologic response (immunogenicity) comparable to vaccines that have been shown to be effective in preventing disease. More information about its population-based effectiveness is gained from large trials and community-based analyses after FDA approval. There may or may not be effectiveness data from Washington State, but the disease prevalence and incidence in the state should be sought and reviewed.

- The vaccine containing this antigen is cost effective from a societal perspective.

  This analysis should consider both the costs of the immunization (e.g. antigen, storage, administration, medical and societal costs of adverse reactions to the immunization, etc.) and the benefits of the immunization (e.g. lives saved, medical and societal benefits of preventing adverse reactions from vaccine-preventable disease, etc.). This process may include consultation with an economist as resources allow. Vaccines may be cost effective without being cost saving. In other words, the direct costs of some vaccines (e.g. antigen, storage, administration) balanced against direct savings (e.g. medical care, disability, death) may not result in net savings. Societal or indirect costs (e.g. lost productivity of care takers of ill children) will also need to be taken into consideration. These costs are much harder to quantify. 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.

- Experience to date with the vaccine containing this antigen indicates that it is safe and has an acceptable level of side effects.

  Vaccinations are not without side effects. The known risks associated with each vaccine (or antigen) must be balanced against the risks of the disease. Vaccine safety will be evaluated using research and reports from: pre-licensure, the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD) project, and other reliable sources.

II. Disease Burden Criteria

- The vaccine containing this antigen prevents diseases with significant morbidity and/or mortality implications in at least some sub-set of the population.

  Vaccines have the potential to reduce, or in some cases even eliminate, diseases that can result in serious illness, long-term disability, or death. For example, before the measles immunization was available, nearly everyone in the United States contracted measles and an average of 450 measles-associated deaths were reported each year between 1953 and 1963. The morbidity/mortality burden of measles was not equal for all members of the population. Examples of significant morbidity measures include rates of hospitalizations, long-term disability, disease incidence, and disproportionate impact.

- Vaccinating against this disease reduces the risk of person-to-person transmission, with transmission in a school or child care setting or activity being given the highest priority.

  Having a large proportion of the population vaccinated with the antigen helps to stem person to person transmission of the disease (i.e., herd immunity). Even community members who are not vaccinated (such as newborns and those with chronic illnesses) are offered some protection because the high immunization rate results in the disease having less opportunity to spread within the community. Vaccinating children in school and/or child care can increase the percentage of children in these groups who are immune and thus reduce the risk of outbreaks of the disease in these groups and in the community at large. Special consideration of disease transmission in a school or child care setting or activity should be given the highest priority. For the purpose of this criterion, "activity" refers to school or child care extracurricular activities including, but not limited to, field trips, sports events, or other activities held on or off campus.

III.Implementation Criteria

- The vaccine is acceptable to the medical community and the public

  It is possible to gauge the level of provider acceptance of a vaccine by querying state professional societies such as the Washington Academy of Family Physicians and the Washington State Chapter of the American Academy of Pediatrics. Vaccine uptake data are also available from the Department of Health to determine provider use of the vaccine. While there is generally a good correlation between the levels of physicians' and the general publics' acceptance of particular vaccines, the TAG should consider additional ways of accurately gauging public acceptance of the particular vaccine. Adding an antigen to WAC 246-105-030 related to a vaccine with poor provider or public acceptance would likely be resisted. Postponing the regulation until there is greater approval of the vaccine would assure more effective policy.

- The administrative burdens of delivery and tracking of vaccines containing this (these) antigen(s) are reasonable.

  Many institutions and individuals are involved in implementation of the rule when the Board adds a new vaccine to WAC 246-105-030. These include: the Department of Health, the Department of Social and Health Services, the Office of Superintendent of Public Instruction (OSPI), local health jurisdictions, schools, child care, health plans, health care providers, and families. For each of these key players, there are issues that affect the feasibility of implementing an immunization recommendation. For example, introduction of a new vaccine can result in schools conducting more parental follow-up and making changes to record and information systems—this in turn can impact school staff workload. Assuring that a reasonable burden of work is present will enhance the effectiveness of the policy. The TAG includes representatives from affected parties such as OSPI, schools, and child care when assessing an antigen against this criterion.

- The burden of compliance for the vaccine containing this antigen is reasonable for the parent/caregiver.

  Parents and caregivers are often involved in obtaining vaccines for children. This can include: transporting children to medical appointments, taking time off of work for medical appointments, maintaining the child's immunization records, etc. When a vaccine is required for child care and/or school entry it affects the health decisions that parents make on their child's behalf because parents must, at the very least, take the required vaccine into account.

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