

**Oregon Immunization School/Children's
Facility/College Law Advisory Committee:**

**Criteria for Reviewing Meningococcal B
vaccine for Potential Inclusion in OAR 333-
050-0050, 333-050-0130 and 333-050-0140
School/Facility/College Immunization
Requirements**

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**Oregon School/Facility Immunization Advisory Committee:
Criteria for Reviewing Meningococcal B vaccine for Potential Inclusion in OAR
333-050-0050, 333-050-0130 and 333-050-0140.**

Process for Reviewing Meningococcal B vaccine 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), Oregon legislature 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/Children's Facility/College Law Advisory Committee.

The Immunization School/Children's Facility/College Law 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.

<p>On September 23, 2015, the Immunization School/Facility/College Law Advisory Committee voted to recommend not requiring meningococcal B vaccine for school or college attendance in Oregon.</p>
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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.

There are two vaccines that are approved for use in the U.S, Bexsero (MenB-4C) and Trumenba (MenB-FHbp), but these vaccines are not currently recommended for universal administration. The vaccines have been recommended for administration for the following individuals ≥ 10 years of age:

- Individuals with functional or anatomic asplenia
- Individuals with sickle cell disease
- Individuals with terminal complement component deficiency (e.g., C5–C9, properdin, factor H, factor D, and patients taking Eculizumab [Soliris®])
- Microbiologists who work routinely with isolates of *Neisseria meningitidis*
- Those at increased risk due to a serogroup B meningococcal disease outbreak

These vaccines are approved for individuals 16–23 years of age with health care provider recommendation to provide short-term protection against most strains of serogroup B meningococcal disease. The preferred age for Meningococcal B vaccination is 16–18 years of age. This is an ACIP “Category B” recommendation: recommendations are made for individual clinical decision making.

(Category “B” means “consider” the vaccine – lower than Category “A,” which basically means “we recommend that you give it.”)

At least through 12/31/2015 we consider the following individuals ≥ 10 years of age “at increased risk due to a serogroup B meningococcal disease outbreak” associated with the University of Oregon:

- Current and incoming University of Oregon undergraduate students
- University of Oregon graduate students, faculty and staff who currently or will be living in campus residence halls, fraternities, or sororities and
- Undergraduate students of any college living in the 13th and Olive apartments (capstone buildings) during winter and spring terms 2015 — including but not limited to undergraduates of University of Oregon, Lane Community College and Northwest Christian University.

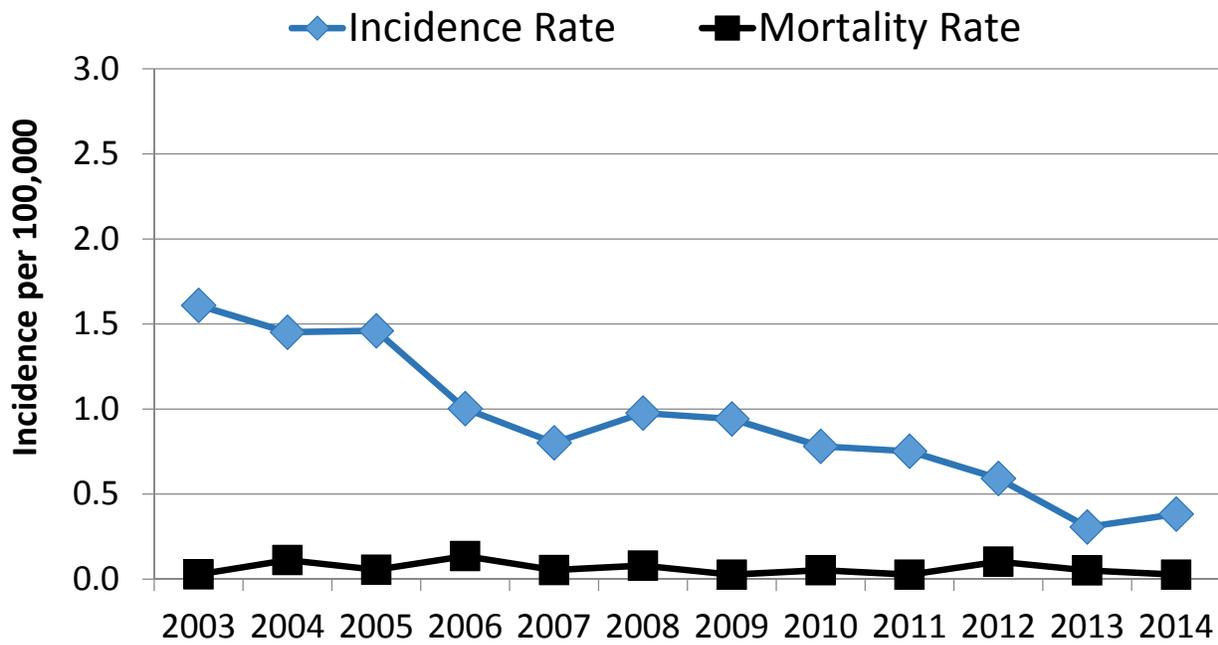
CDC. Use of Serogroup B Meningococcal Vaccines in Persons Aged ≥ 10 Years at Increased Risk for Serogroup B Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices, 2015. *MMWR*. June 12, 2015 / 64(22);608-612

Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6422a3.htm>

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

The incidence of meningococcal disease has in recent years been at or near historic lows in Oregon. In 2014, Oregon had 4 cases of serogroup B disease – an incidence of 1 per million. In 2015, through September 15, there have been 7 cases of serogroup B disease associated with an outbreak at the University of Oregon, including one death.

Incidence and Mortality Rates of Invasive Meningococcal Disease Cases in Oregon



Oregon Acute and Communicable Disease Program, 2015

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

The University of Oregon outbreak demonstrates that (at least for the time being) students there are at much higher risk than others. It is recommended to continue vaccination of University of Oregon undergraduates and other limited groups (see Criteria 1). Although nationally there have been other university-associated clusters, the vast majority of universities haven't not experienced cases of disease, and the background rate of disease is at historic lows. The Meningococcal B vaccines are among the most expensive: >\$300 for a series of either manufacturer's product plus administration costs. With disease rates low

and an expensive vaccine, the cost of saving one year of a young person's life has been estimated at \$3.7-\$9.4 million, depending on when and to whom it's given. The higher figure was the estimate for vaccinating college students. This is orders of magnitude beyond what is typically spent for preventive medicine.

CDC. Considerations for Use of Serogroup B Meningococcal (MenB) Vaccines in Adolescents. Presentation at ACIP, June 24, 2015
Available at <http://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2015-06/mening-03-macneil.pdf>

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.

There is limited experience with Meningococcal B vaccines outside of clinical trials. Because of the low incidence of serogroup B meningococcal disease, vaccine efficacy estimates were based on demonstration of an immune response and not on actual disease prevention. The ACIP workgroup's interpretation of immunogenicity is as follows:

- Immunogenicity suggests but does not prove short-term efficacy
- There is evidence that antibody levels wane during the 6 months after dose 3 of MenB-FHbp, appearing to stabilize at 6-48 months
- Modest waning in antibody was observed through 24 months after dose 2 of MenB-4C

CDC. Considerations for Use of Serogroup B Meningococcal (MenB) Vaccines in Adolescents. Presentation at ACIP, June 24, 2015
Available at <http://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2015-06/mening-03-macneil.pdf>

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.

Meningococcal disease can refer to any illness that is caused by the type of bacteria called *Neisseria meningitidis*, also known as meningococcus. These illnesses are often severe and include infections of the lining of the brain and spinal cord (meningitis) and bloodstream infections (bacteremia or septicemia). Meningococcus bacteria are spread through the exchange of respiratory and throat secretions like spit (e.g., by living in close quarters, kissing).

The communicability of meningococcal disease is generally limited. Recognized environments increasing the risk of meningitis include college freshmen living in dorms and household contacts of persons with meningococcal disease. According to CDC, "In studies of households in which a case of meningococcal disease has occurred, only 3%–4% of households had secondary cases. Most households had only one secondary case. Estimates of the risk of secondary transmission are generally 2–4 cases per 1,000 household members at risk. However, this risk is 500–800 times that in the general population." For this reason, antibiotics are routinely given to household members of persons with meningococcal disease, so as to eradicate the organisms before they can cause invasive disease.

CDC Meningococcal Disease website, accessed 9/16/2015.
Available at <http://www.cdc.gov/meningococcal/index.html>

CDC. *Epidemiology and Prevention of Vaccine-Preventable Diseases*, 13th Edition, pages 231-245.
Available at <http://www.cdc.gov/vaccines/Pubs/pinkbook/downloads/mening.pdf>

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.

Requiring the vaccine for all college students would significantly increase coverage and protection. This vaccine has been recently approved and has not been recommended for universal administration, so coverage is very low.

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

Private providers may purchase the vaccine, and VFC covers the vaccine through VFC providers. Under Oregon's current model standing orders, vaccine may be administered to individuals with specific high-risk conditions and for outbreak control, but administration beyond these circumstances require a specific health care practitioner recommendation.

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.

There is no funding to make this vaccine available on a universal basis, and since ACIP does not recommend general administration of the vaccine, insurance companies may not cover the cost of the vaccine. If one cohort (e.g., all first year college students) were required to have the vaccine, the costs for college students would be approximately \$10,530,000. One cohort at school age (e.g., all 7th graders) would be \$15,180,000. What insurance coverage would be is unknown at this time.

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

Between the two companies making the Meningococcal B vaccine, there appears to be sufficient supply for the current conditions. We do not know what the effect on vaccine supply would be if required Meningococcal B vaccine were required for school or college in Oregon.

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, computer programs, medical clinics and health plans are all impacted by school law changes. Local health departments have to communicate with local providers and students about the new rule changes to ensure that students will not be excluded from school. Oregon law prohibits local health departments from charging parents or students a fee for the vaccine or administration if they are financially unable to pay, and this has a financial impact on the counties. For schools and children's facilities, 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 meningococcal vaccines, so programming changes would be extensive. Exclusion orders and Certificate of Immunization Status forms would also require revision. Meningococcal B vaccine is unique in that the two vaccines are not interchangeable and have different numbers of doses in the series (2 or 3 doses), adding complexity for schools and colleges to track the different schedules for the two different vaccines.

At this time, measles is the only state-mandated vaccine for college students. Many colleges do not have an electronic method for tracking and enforcement of immunization requirements, so the process is time intensive. Additional requirements at the college level would require more staff time. A requirement only for first year students living in dormitories, sororities, fraternities and apartment complexes could pose additional tracking difficulties for colleges.

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

Because of the limited recommendations for the vaccine, little vaccine is currently available in clinics, so accessing the vaccine may be problematic. If college students were required to have the vaccine, these students may come from all areas of the country where the vaccine may not be available in that state. The cost of the series is about \$300 for the vaccine plus costs for administering the vaccine. Insurance may not cover the vaccine or administrative costs outside of the high-risk recommendations and the University of Oregon outbreak.

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

The vaccine is included in ALERT IIS, so schools/facilities/colleges have the capacity to obtain records for children/students. Meningococcal B vaccine, by brand, is forecast only after the first dose of the vaccine has been administered since this is a vaccine currently being used only for specific populations. There are two types of Meningococcal B vaccine, and the brands are not interchangeable.

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?