# 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.

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| On May 30, 2018, the Immunization School/Facility/College Law Advisory Committee voted to recommend not requiring meningococcal B vaccine for school or college attendance in Oregon. |

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.**

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

https://www.cdc.gov/vaccines/vpd/mening/public/index.html

There are two vaccines that are approved for use in the U.S. for prevention of meningococcal B disease, Bexsero (MenB-4C) and Trumenba (MenB-FHbp).

These vaccines are not currently recommended for universal administration. They 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, made for individual clinical decision making.

"Category A" recommendations are made for all persons in an age- or risk-factor-based group. Meningococcal B vaccines have a Category A recommendation 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, properidin, 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

All students at the OSU Corvallis campus through 25 years of age are currently recommended to receive meningococcal B vaccine because of the ongoing outbreak, and OSU has implemented a requirement that students receive this vaccine.

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

http://studenthealth.oregonstate.edu/general/policies-and-guidelines/immunizations-tb-screening-and-health-history/domestic-student

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

Invasive meningococcal disease (IMD) is a serious disease, with a case-fatality rate of 10-15% even with appropriate antibiotic therapy, but the disease is increasingly rare. In 2015, Oregon had 14 cases of serogroup B disease. In 2016, Oregon had 10 cases of serogroup B disease. University of Oregon had an outbreak of serogroup B disease in 2015-16 with 7 cases including 1 death. Oregon State University is currently experiencing an outbreak, with 6 cases since 2016.

Oregon Acute and Communicable Disease Program, 2018

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

The below table summarizes cost effectiveness estimates. The cost per QALY is estimated to be an order of magnitude higher for the meningococcal B vaccine than the quadrivalent meningococcal vaccine.

**TABLE 2. Potential cases and deaths prevented and cost-effectiveness of different strategies for MenB vaccination of adolescents and young adults, including college students, by age — United States**

| Age at MenB series | Cases prevented | Deaths prevented | NNV* to prevent case | NNV to prevent death | Cost per QALY (million $) |
|---|---|---|---|---|---|
| 11 yrs | 15 | 2 | 203,000 | 1,512,000 | 8.7 |
| 16 yrs | 28 | 5 | 107,000 | 788,000 | 4.1 |
| 18 yrs | 29 | 5 | 102,000 | 638,000 | 3.7 |
| College student | 9 | 1 | 368,000 | 2,297,000 | 9.4 |

**Abbreviations:** MenB = meningococcal B vaccine; NNV = number needed to vaccinate; QALY = quality-adjusted life years.

**Sources:** Unpublished data, ACIP meeting June 2015. Key model assumptions were presented at the June 2015 ACIP meeting. Methods described in Shepard CW, Ortega-Sanchez IR, Scott RD 2nd, Rosenstein NE. Cost-effectiveness of conjugate meningococcal vaccination strategies in the United States. Pediatrics 2005;115:1220–32.

CDC. Use of Serogroup B Meningococcal Vaccines in Adolescents and Young Adults: Recommendations of the Advisory Committee on Immunization Practices, 2015. *MMWR*. October 23, 2015 / 64(41);1171-6. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6441a3.htm

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.**

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. In general, meningococcal vaccines likely provide some short term protection against most strains of serogroup B meningococcal disease, and then wane over time. Below is more detailed information about efficacy and waning.

For MenB-FHbp: "One month following the third dose, 81.0% (95% confidence interval [CI] = 78.0%–83.7%) of subjects in group 1 and 83.9% (CI = 81.1%–86.4%) of subjects in group 2 had a composite response to all four strains tested (2,18)."
"Antibody persistence through 48 months after dose 3 for MenB-FHbp was evaluated in a clinical trial (Pfizer, unpublished data). The data demonstrate an initial rapid decline in antibodies after vaccination followed by a flattening out of the antibody curve at approximately 6 months after the third dose. At 48 months, >50% of vaccinated subjects continued to demonstrate hSBA titers greater than or equal to the lower limit of quantification against three of the four strains tested (Pfizer, unpublished data)."
For MenB-4C: "The immunogenicity and safety of MenB-4C in adolescents and young adults were evaluated in five clinical trials; three randomized controlled trials, one randomized uncontrolled trial, and one immunogenicity extension study (6–10,17,19). In a randomized controlled trial conducted in Chile, persons aged 11–17 years received 2 doses of MenB-4C 1, 2, or 6 months apart. One month following the second dose, 90%–94% of subjects had a composite response to all three strains tested, depending on the vaccination schedule administered; 77%–94% of subjects had an hSBA titer of ≥1:4 against all three strains tested at 18–24 months after the second dose, depending on the vaccination schedule administered (9)."
"In a randomized controlled trial conducted in the United Kingdom, a subset of enrolled subjects (university students aged 18–24 years) received 2 doses of MenB-4C vaccine 1 month apart. One month following the second dose, 88% (CI = 82%–93%) of subjects had a composite response to all three strains tested; 66% (CI = 58%–72%) of the subjects had a composite response to all

three strains tested at 11 months after the second dose (8). In a randomized uncontrolled trial conducted in Australia and Canada, persons aged 11–17 years received 2 doses of MenB-4C 1 month apart. One month following the second dose, 63% (CI = 57%–68%) of subjects had a composite response to all three strains tested (7,19)."
https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6441a3.htm

In 2016, ACIP recommended that a 2 dose series of Trumenba may be given to individuals not at increased risk of meningococcal B disease, based on persistence of antibody response that was not significantly different for the 3 dose series vs. a 2 dose series given with 6 month spacing between the doses.
https://www.cdc.gov/mmwr/volumes/66/wr/mm6619a6.htm?s_cid=mm6619a6_e#F1_down

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.**

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 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 5/7/2018.
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 students would significantly increase coverage and protection. This vaccine has not been recommended for universal administration, so coverage is low. At least one college (Oregon State University) currently requires meningococcal B vaccine for attendance. Two universities (Oregon State University and University of Oregon) have vaccinated thousands of students in response to outbreaks.

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. Administration beyond these circumstances require a specific health care provider 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. |
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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 should 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 cost per dose of meningococcal B vaccine ranges from $119-$136. Eligible children are covered for meningococcal B vaccine through the Vaccines for Children through 18 years of age. Private insurance should cover meningococcal B vaccine; however, it is unknown what insurance barriers may exist. For example, for some college students who had no in-network providers where they went to school, insurance

would not cover out-of-network meningococcal B vaccine. Clinics receiving state-supplied vaccine cannot charge 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 and clinics participating in the Vaccines for Children's program. Additional burden would be placed on the local health departments and public clinics as they are required to vaccinate all people that need vaccines for school.

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

Between the two companies making the Meningococcal B vaccines, there is sufficient supply 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.**

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 must be approved by the state. Many computer programs used by schools, child care facilities and local health authorities for data collection and reporting are not currently designed to accept meningococcal vaccines, so programming changes would be extensive. Exclusion orders and Certificate of Immunization Status forms would require revision. Local health departments would 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. Adding more vaccines when still phasing in other vaccines can then lead confusion and frustration that can potentially overwhelm the partners in the process which may weaken the effectiveness of school law enforcement. The phasing in of Hepatitis A for students through grade 12 will be complete in 2021. Meningococcal B vaccine is unique in that the two vaccines are not interchangeable and have different schedules, 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. Some 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 college housing could pose additional tracking difficulties for colleges. Some colleges currently require meningococcal vaccines.

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

For adolescents, the first dose of meningococcal B vaccine could be administered at age 16 with the second dose of meningococcal ACWY vaccine; the second dose would likely necessitate one additional clinic visit. ORS 433.269 states, "Local health departments shall make immunizations available for administration under the direction of a local health officer in convenient areas and at convenient times. A local health department may not refuse to administer an immunization to a person because the person is unable to pay for the immunization." Local health departments can request an administrative fee, although the student must be able to receive the vaccine at no cost. The cost a dose of vaccine ranges from $119-$136 for the vaccine plus costs for administering the vaccine. Insurance should cover Category B recommendations, although reimbursement can be difficult, as noted during outbreaks.

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

Schools/colleges may obtain records for Meningococcal B vaccine in ALERT IIS. Meningococcal B vaccine is forecast in ALERT IIS only after the first dose of the vaccine has been administered, since this is a vaccine currently being used only for specific populations. ALERT IIS will forecast for additional dose(s) of the specific brand received, as 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?