

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

**Criteria for Reviewing Quadrivalent
Meningococcal Conjugate 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:
Review of Quadrivalent Meningococcal Conjugate Vaccine (MCV4) Against
Twelve Criteria for School/Facility/College Immunization Requirements**

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), 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 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.

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

The 12 Criteria to Consider in Evaluating Quadrivalent Meningococcal Conjugate Vaccine

1. **The vaccine containing these antigens 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>

ACIP recommends routine vaccination of all persons aged 11-18 years with two doses of quadrivalent meningococcal conjugate vaccine (MCV4). One dose is also recommended for unvaccinated first year college students up through age 21 living in residential housing. These students are at a small increased risk for meningococcal disease caused by *Neisseria meningitidis* bacteria. MCV4 provides protection from 4 serogroups of bacteria, A, C, Y and W-135. Vaccination is also recommended for certain high-risk individuals in other age groups.

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>

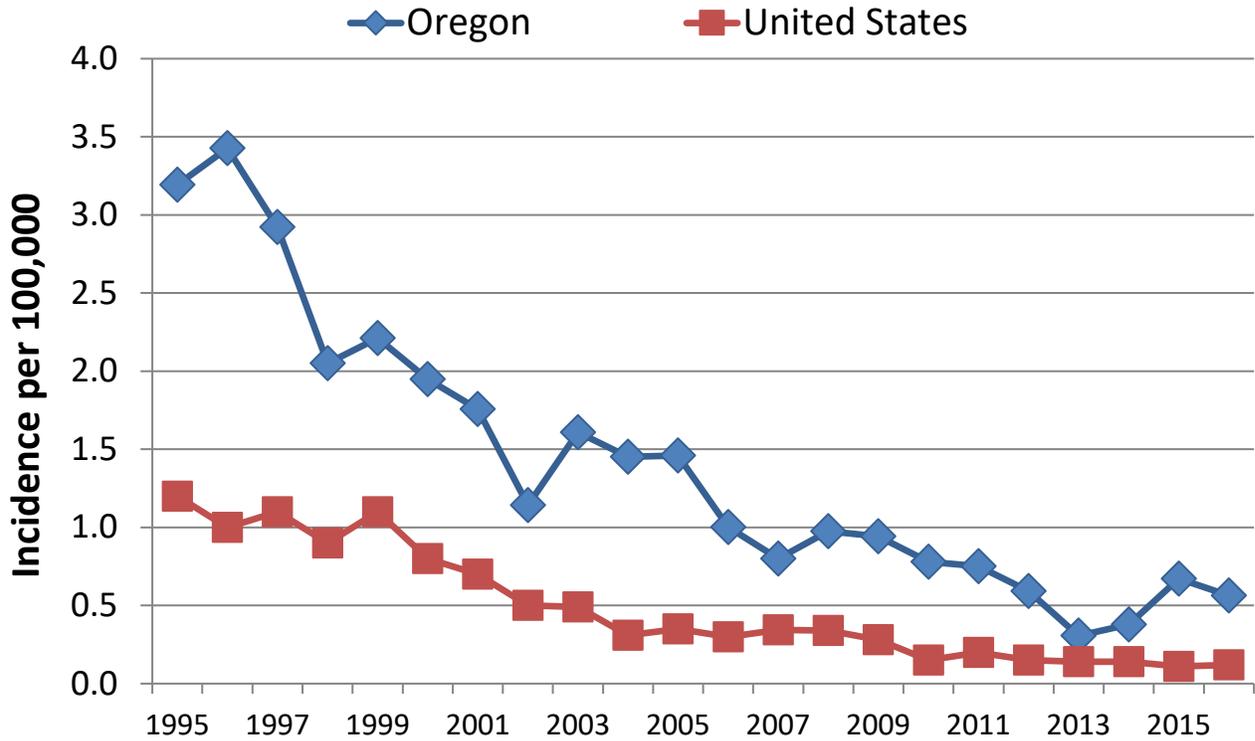
CDC. Prevention and Control of Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. March 22, 2013 / 62(RR02);1-22. Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm>

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 Oregon, the incidence has decreased 79% since 1996. However, Oregon still has a higher rate of meningococcal disease than the U.S. average (see chart below). The overall number of Oregon cases decreased 52% from 1996 to 2004, prior to licensure of MCV4 in 2005. During this nine-year period, Oregon reported an average of 69 cases a year. After vaccine licensure, from 2006 through 2016, Oregon reported an average of 27 cases per year. From 2006 through 2016, 31 cases were reported in ages 5-17

years, for an average of 3 cases per year in this age group. From 2006 through 2016, 46 cases were reported in ages 18-24 years, for an average of 6 cases per year in this age group. From 2010 through 2016, 50% in ages 5-17 years and 43% in ages 18-24 years were due to a serogroup included in quadrivalent meningococcal conjugate vaccine. The occurrence of disease during this time has not been constant and has demonstrated a general trend of decreasing incidence. The highest rates of disease occur among infants, but the vaccine is recommended only for infants at high risk; there is no universal recommendation for infants to receive meningococcal vaccine.

Incidence of IMD Cases



Oregon Acute and Communicable Disease Program, 2010, 2018.

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>

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

The following table summarizes cost-effectiveness estimates for different strategies of MCV4 vaccination in adolescents. A two dose schedule at 11 and 16 years is estimated

to prevent the highest number of cases and deaths, and to be the most cost effective; this is the recommendation adopted from ACIP.

TABLE 5. Summary of cost-effectiveness analyses of different strategies for adolescent vaccination — United States

Dosage	Cases averted		Deaths averted		QALY saved		Cost per QALY saved (\$)	
	No.	(Range)	No.	(Range)	No.	(Range)	No.	(Range)
1 dose at 11 yrs	94	(43–165)	11	(5–20)	736	(330–1,130)	256,000	(84,000–650,000)
1 dose at 15 yrs	115	(51–205)	14	(6–25)	850	(390–1,380)	219,000	(63,000–600,000)
1 dose at 11 yrs with booster dose at 16 yrs	184	(92–308)	22	(11–40)	1,442	(610–2,130)	212,000	(67,000–535,000)

Abbreviation: QALY = quality-adjusted life years.

Source: Unpublished data with updated estimates, Advisory Committee on Immunization Practices (ACIP) meeting, October 2010. 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. Prevention and Control of Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. March 22, 2013 / 62(RR02);1-22
 Available at: <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm#Tab5>

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.

“Today, meningococcal disease is at a historic low in the United States. Rates of meningococcal disease have been declining in the United States since the 1990s, with much of the decline seen before the routine use of meningococcal conjugate vaccines. Among 11 through 19 year olds the rate of meningococcal disease caused by serogroups C, Y, and W has decreased (80%) since preteens and teens were first recommended to get a meningococcal conjugate vaccine. Similar declines were not seen in age groups not routinely getting conjugate vaccines. These data suggest

meningococcal conjugate vaccines provide protection to those vaccinated, but do not provide protection to the larger, unvaccinated community through herd immunity.”

With an uncommon disease like meningococcal disease, a lot of people need to get a vaccine before its effectiveness can be measured on a large scale. “Available data suggest that protection from meningococcal conjugate vaccines decreases in many teens within 5 years, which highlights the importance of the 16-year-old booster dose so that teens maintain protection during the ages when they are most at risk for meningococcal disease.”

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

“To assess vaccine effectiveness among adolescents, CDC carried out a simulation study of breakthrough disease (i.e., cases that occur among vaccine recipients) and a case-control study. The first estimate of vaccine effectiveness was based on a simulation approach that calculated the expected number of cases in vaccinated persons... When the number of expected cases was compared with the observed number of breakthrough cases, vaccine effectiveness during 2005–2008 was estimated to be 80%–85%.”

“A case-control study evaluating the vaccine effectiveness of meningococcal conjugate vaccine in adolescents began in January 2006.” The below table summarizes the results.

Years vaccinated prior to study	Vaccine Effectiveness	Confidence Interval
<1	82%	54%–93%
1–<2	80%	52%–92%
2–<3	71%	34%–87%
3–<6	59%	5%–83%
Overall estimate 0-6 years	69%	50%–81%

“Although CIs around the point estimates are wide, these results suggest that vaccine effectiveness wanes over time.”

CDC. Prevention and Control of Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. March 22, 2013 / 62(RR02);1-22.
Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm>

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.

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 would have a significant impact on vaccine coverage for adolescents. As of May 2018, 77% of adolescents ages 13-17 had at least one dose of MCV4, up from 70% in 2015; 63% were up-to-date with the recommended number of doses (1 or 2) based on age and previous vaccination history (i.e., one dose for ages 13-15, one dose at age 16-17 (one or two doses total), or one dose within the past three years for ages 16-17 (one or two doses total)) National Immunization Survey – Teen 2016 estimates one dose MCV4 coverage for 13-17 year olds in Oregon at 70.5% (± 6.0) compared to 82.2% (± 1.0) for the U.S.

Oregon ALERT Immunization Information System, 2018.

CDC. National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13–17 Years — United States, 2016. *MMWR*. 2017 / 66:874–882

Available at: <https://www.cdc.gov/mmwr/volumes/66/wr/mm6633a2.htm>

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

Uptake of MCV4 has been increasing in Oregon, demonstrating acceptance from the medical community and general public.

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.

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. A single dose of MCV4 vaccine current costs the state \$101-109 depending on the product. Most children are covered for MCV4, through the Vaccines for Children program or private insurance. College students who are 18 years or younger may also be eligible for the Vaccines for Children program. It is unknown how many college students in Oregon are uninsured or underinsured. Additional factors that would need to be considered in making an estimation of cost for college students would include the number of first year college students living in residential housing, the uptake of vaccine in first year college students, the proportion with insurance covering MCV4, the number of students coming from other states and the number of freshmen over 18 years of age as these students would not be eligible for the VFC program. 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.

317 Funded Vaccine—Effective February 1, 2018. Oregon Health Authority, Public Health Division, Immunization Program.

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

There is a stable and adequate supply of vaccine at this time. Menactra (sanofi pasteur) was licensed in 2005, and a second quadrivalent meningococcal conjugate vaccine, Menveo (Novartis) was licensed in 2010.

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. MCV4 is recommended at 11-12 years and 16 years of age, so the grades for the requirements to start would likely be 7th and 11th grades. A new requirement has never been implemented in a high school grade. It is unknown the effect this may have on high school drop out rates.

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, MCV4 can be administered with other recommended immunizations, including Tdap. Tdap is currently required for 7th grade students, so one additional clinic visit would be necessary to receive the second dose of vaccine if a two-dose requirement was implemented. 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.

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

Meningococcal quadrivalent vaccine doses are documented for all ages submitted to ALERT IIS and forecast for 11 through 18 years of age.

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?