

June 2011

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

**Review of Meningococcal Conjugate Vaccine  
Against Twelve Criteria for  
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 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.

The decision was made by the School/Facility/College Immunization Law Advisory Committee to recommend not requiring meningococcal vaccine for school attendance in Oregon on June 6, 2011.

## The 12 Criteria to Consider in Evaluating Meningococcal Conjugate Vaccine

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.**

ACIP recommends routine vaccination of all persons aged 11-18 years with two doses of meningococcal conjugate vaccine (MCV4). This vaccine is also recommended for college freshmen living in dormitories and residence halls. These students are at a slightly increased risk for meningococcal disease caused by *Neisseria meningitidis* bacteria. MCV4 provides protection from 4 serogroups of bacteria, A, C, Y and W-135.

CDC. *Epidemiology and Prevention of Vaccine-Preventable Diseases*, 11<sup>th</sup> Edition, pages 177-188. Available at <http://www.cdc.gov/vaccines/Pubs/pinkbook/downloads/mening.pdf>

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CDC. Updated Recommendations for Use of Meningococcal Conjugate Vaccines—Advisory Committee on Immunization Practices (ACIP), 2010. *MMWR*. January 28, 2011. 60(03);72-76. (available at <http://www.cdc.gov/mmwr/pdf/wk/mm6003.pdf>)

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

Although invasive meningococcal disease (IMD) is a serious disease, with a case-fatality rate of 8-12% even with appropriate antibiotic therapy, the disease is quite rare. In fact, the incidence rate in Oregon has decreased 75% since 1996. However, Oregon still has a higher rate of meningococcal disease than the U.S. average. The rate of disease in Oregon in 2008 was 1.0 case per 100,000 Oregonians (compared to the national rate of 0.3 per 100,000.) There is no vaccine for serogroup B which is the most common cause of meningococcal disease in Oregon, accounting for about 55% of cases reported during 2004-2008. The overall number of Oregon cases decreased 62% from 1996 to 2004, prior to licensure of MCV4 in 2005. For the fifteen year period, from 1995 through 2009, a total of 176 cases of invasive meningococcal disease were reported among Oregonians 11 to 20 years of age. The annual average is 11.7 cases per year. Of those cases with a serogroup determined, 53 (34%) were due to a serogroup included in MCV4. The occurrence of disease during this time has not been constant and, with the exception of increased activity reported in 2005, has demonstrated a general trend of decreasing incidence over recent years. After licensure of MCV4, from 2006-2009, 18 cases of disease were reported among persons

11-20 years of age in Oregon. Although the highest rates of disease occur among infants, there is no U.S. licensed vaccine for children less than 2 years of age.

Oregon Acute and Communicable Disease Program, 2010.

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

In an article by Ortega-Sanchez et. al., comparing cost-effectiveness studies of vaccines recommended for adolescents, meningococcal vaccines (one dose) were the least cost-effective of all adolescent vaccines. Estimated costs for routine vaccination with MCV4 starting at 11 years of age were \$121,000-205,000 per life-year saved (LYS) and \$88,000-179,000 per quality-adjusted life year (QALY). If MCV4 campaigns were targeted only at counties with high incidence of meningococcal disease, estimated costs were \$38,000 per LYS and \$33,000 per QALY. For college freshmen living in dormitories, one study estimated the cost of vaccinating with MPSV4 to be \$306,000 per LYS (no QALY estimate was provided). The estimated cost of vaccinating with MCV4 compared with MPSV4 would be expected to be lower because of the longer duration of immunity conferred.

At the October 2010 ACIP meeting, mean estimates for QALY saved were as follows: \$281,000 for one dose of meningococcal vaccine given at 11 years of age, \$121,000 for one dose given at 15 years of age, and \$157,000 for two doses given at 11 and 16 years of age. The cost-effectiveness data are based on assumptions lacking biological plausibility, specifically that vaccine effectiveness holds steady at 93% for five years and then wanes to zero immediately at 5 years.

Ismael R. Ortega-Sanchez, Grace M. Lee, R. Jake Jacobs, Lisa A. Prosser, Noelle-Angelique Molinari, Xinzhi Zhang, William B. Baine, Mary M. McCauley, Ted Miller for the Working Group on Leading Economic Issues for New Vaccine for Adolescents. Projected Cost-effectiveness of New Vaccines for Adolescents in the United States. *Pediatrics*, Jan 2008; 121: S63 - S78.

Available at [http://pediatrics.aappublications.org/cgi/content/abstract/121/Supplement\\_1/S63?eaf](http://pediatrics.aappublications.org/cgi/content/abstract/121/Supplement_1/S63?eaf)  
CDC. Cost-Effectiveness of Meningococcal Vaccination Strategies for Adolescents in the United States. Presentation at ACIP, October 27, 2010.

Available at <http://www.cdc.gov/vaccines/recs/acip/downloads/mtg-slides-oct10/02-3-mening-CostEffect.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.**

Nationally, incidence of invasive meningococcal disease has been decreasing since 1996. The vaccine is estimated to be 80-90% effective against the serogroups contained in the vaccine for at least three years.

CDC. Summary of Notifiable Diseases --- United States, 2007. *MMWR*. July 9, 2009: 56(53);1-94.

Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5653a1.htm>

CDC. Estimate of Effectiveness of Meningococcal Conjugate Vaccine (MCV4). Presentation at ACIP, June 24, 2009.

Available at <http://www.cdc.gov/vaccines/recs/acip/downloads/mtg-slides-jun09/07-3-menin.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.**

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." The rate of meningococcal disease in freshmen living in dormitories was 5.1/100,000 compared with a rate of 1.9/100,000 for freshmen not living in dormitories and 1.4/100,000 for all 18-23 year olds (data from 1998-1999).

CDC. *Epidemiology and Prevention of Vaccine-Preventable Diseases*, 11<sup>th</sup> Edition, pages 179-180.

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 school age children. Uptake of MCV4 for 11-12 year olds in Oregon is currently at 20.4%. Although revaccination with MCV4 is recommended for some high risk groups and duration of immunity for this vaccine is unclear, college freshmen living in dormitories who received a previous adolescent dose of MCV4 are not recommended to be revaccinated.

4<sup>th</sup> Quarter Sentinel Report, 2010. Oregon Immunization Program

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

Uptake of MCV4 is low at this point, but has increased in 11-12 year olds from 16.6% in 2008 quarter 2 to 20.4% in 2010 quarter 4, and increased in 13-17 year olds from 21.6% in 2008 quarter 2 to 41.5% in 2010 quarter 4.

2<sup>nd</sup> Quarter Sentinel Report, 2008. Oregon Immunization Program

4<sup>th</sup> Quarter Sentinel Report, 2010. Oregon Immunization Program

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 cannot 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. Based on projections developed during the spring of 2009 for SJR1 legislation, the biennial costs for providing MCV4 would be about \$566,101 for one school-aged cohort per year for a requirement for only one dose of vaccine. For two doses of vaccine or for college students, no estimate has been prepared. Factors that would need to be considered in making an estimation would include the number of college freshmen living in dormitories, the uptake of vaccine in college freshmen, the proportion with insurance covering MCV4, and the number of freshmen over 18 years of age as these students would not be eligible for the VFC program. Currently, the booster dose of the vaccine is not covered under 317 funding in Oregon for healthy adolescents unless they are in a specified high risk group.

Cost estimate to state general fund prepared by the Oregon Immunization Program in response to Senate Joint Resolution 1, Legislative Session 2009

317 Funded Vaccine—Effective June 1, 2011. Oregon Health Authority, Office of Family Health, Immunization Program.

Available at

<http://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/Documents/317chart.pdf>

**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 quadravalent 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 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. 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. 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.

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 freshmen living in dormitories potentially could pose additional tracking difficulties for colleges.

**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 7<sup>th</sup> 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 that if a vaccine is required for school attendance, local health departments must provide vaccines in convenient areas and at convenient times and “no person shall be refused service because of inability to pay.” However, providers do request an administrative fee. Although the amount of money requested is modest and the student must be able to receive the vaccine at no cost, some parents feel responsible to pay fees they may not be able to afford.

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

Meningococcal vaccine doses are documented for all ages submitted to ALERT and forecast 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?