

# Washington State Board of Health

MENINGOCOCCAL TECHNICAL ADVISORY GROUP REPORT



## TABLE OF CONTENTS

Introduction .....	1
Acknowledgment .....	2
About the Disease .....	3
About the Vaccine .....	5
Evaluation Criteria .....	6
Bibliography .....	7
Voting Summary .....	9

According to statute (RCW 28A.210.080, 28A.210.100, and 28A.210.140), the Board has the authority to adopt rules on proof of immunizations for school and day care attendance and adopt rules that establish requirements for “full immunization.”

The Board’s rules pertaining to child care and school children’s vaccinations are contained in Chapter 246-105 WAC, Immunization of Child Care and School Children against Certain Vaccine-Preventable Diseases. The immunization rule lists the vaccine preventable diseases children entering child care or school need to be protected against.

## INTRODUCTION

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On June 14, 2006, the Board adopted assumptions, a process, an ethical framework, and criteria to apply to potential vaccine candidates. On August 12, 2015 the Board heard testimony from Lori Buher, Board member of the National Meningitis Association, and mother of a son who contracted meningitis.

Ms. Buher requested that the Board convene a Technical Advisory Group (TAG) to evaluate the meningococcal vaccine for possible inclusion in school immunization requirements. On August 12, 2015, the Board directed staff to convene a meningococcal vaccine TAG.

On December 8, 2015, the TAG met and applied the Board’s immunization criteria to the meningococcal vaccine.

This report is intended to be a summary of the review of the meningococcal vaccine conducted in preparation for the Board’s review in early 2016.

## TECHNICAL ADVISORY GROUP MEMBERSHIP

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The Board convened a technical advisory at the request of Ms. Buher, a member of the National Meningitis Association, to consider adding the meningococcal vaccine for possible inclusion as a school immunization requirement. The committee represented health professionals, public health officials, and tribal health leaders. The Board wishes to acknowledge the members of the group and their work on this project.

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Jeff Duchin, MD	Washington State Association of Local Public Health Officials
Julie Krause Gorom	Parent Representative
Lauren Greenfield BSN, RN	Washington State Association of Local Public Health Officials
Robin Fleming, RN, PhD, NCSN	Office of Superintendent of Public instruction
Lisa Johnson MD	Washington Academy of Family Physicians
Stephen Kutz, MPH	Tribal representative
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Doug Opel, MD, MPH	Seattle Children's Treuman Katz Center for Pediatric Bioethics
Kristi Rice MD	Vaccine Advisory Committee
Michele Roberts, MPH	Department of Health (DOH)
Les Stahlnecker, MS, RN	School Nurse Corps
Diana Yu, MD MSPH	Washington State Board of Health (SBOH)

## ABOUT THE DISEASE

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Meningococcal disease is caused by the bacterium *Neisseria meningitidis*. About 1 out of 10 people have this type of bacteria in the back of their nose and throat with no signs or symptoms of disease; this is called being ‘a carrier’. But sometimes *Neisseria meningitidis* bacteria can invade the body causing certain illnesses, which are known as meningococcal disease.

There are five serogroups (“strains”) of *Neisseria meningitidis*: A, B, C, W, and Y that cause most disease worldwide. Three of these serogroups (B, C, and Y) cause most of the illness seen in the United States.

### **Transmission**

Meningococcal disease is spread from person to person. The bacteria are spread by exchanging respiratory and throat secretions (saliva or spit) during close (for example, coughing or kissing) or lengthy contact, especially if living in the same household. Fortunately, these bacteria are not as contagious as germs that cause the common cold or the flu. The bacteria are not spread by casual contact or by simply breathing the air where a person with meningococcal disease has been.

Sometimes *Neisseria meningitidis* bacteria spread to people who have had close or lengthy contact with a patient with meningococcal disease. People in the same household, roommates, or anyone with direct contact with a patient’s oral secretions, such as a boyfriend or girlfriend, would be considered at increased risk of getting the infection.

### **Risk Factors**

Certain people are at increased risk for meningococcal disease. Some risk factors include:

#### **Age**

- Infants, adolescents or young adults & adults 65 years or older

#### **Environmental Factors**

- Antecedent viral infection
- Household crowding
- Active and passive smoking

#### **Host Factors**

- Persistent complement component deficiency
- Functional or anatomic asplenia

#### **Chronic Underlying Illness**

#### **Occupational (microbiologists)**

#### **First year college students living in residence halls (at higher risk)**

#### **Travel to meningitis belt in sub-Saharan Africa**

### Clinical Features

Incubation period is typically 3-4 days, with a range of 2-10 days.

An abrupt onset of fever, meningial irritation, hypotension, and rash occur. Within hours of the first symptoms, it may cause shock, coma, and death.

The fatality rate is 10-15%, and up to 40% in meningococemia.

Of the people who survive, up to 20% may suffer from serious complications, such as loss of an arm or leg, brain damage, or permanent hearing loss.

The most common symptoms include:

- Sudden onset of fever
- Headache
- Stiff neck
- Nausea
- Vomiting
- Light sensitivity
- Confusion

### Incidence by Age Group by Serogroup in the U.S.

Incidence of Meningococcal disease is at an all time low and has been steadily decreasing prior to the use of vaccines.

About 60% of disease among children aged 0 through 59 months was caused by serogroup B.

Serogroups C, W, or Y cause 73% of all cases of meningococcal disease among persons 11 years of age or older.

Peak in disease incidence among people 16-21 years of age persist, even after routine vaccination in 2005.

Outbreaks account for 2-3% of reported cases.

### Reduction in Transmission

Vaccine prevents invasive disease, but no good data on whether the vaccine reduces the carriage or transmission of disease in a group of people.

Most cases (97 or 98 out of 100) appear to be random and are not linked to other cases.

## INCIDENCE IN WASHINGTON

**In 2014** 17 cases were reported of which six (35%) were serogroup B. There was no indication of clustering and none reported to be in school age students. **In 2015** 10 cases were reported of which three (30%) were serogroup B.

## ABOUT THE VACCINE

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### **Meningococcal Conjugate Vaccine**

The TAG focused on currently licensed meningococcal conjugate vaccines (MCV), which covers serogroups A,C,Y, and W. The group did not review meningococcal B conjugate vaccine, which is not currently routinely recommended by the Advisory Committee on Immunization Practices (ACIP).

In 2005, ACIP recommended MCV for all adolescents at 11-12 years of age. A booster dose was recommended in 2010 for 16 year olds due to vaccine waning immunity after 3-5 years.

### **Vaccine Effectiveness**

MCV is about 80-85% effective. MCV is as effective as varicella vaccine after 1 dose, but varicella vaccine is 98% effective after 2 doses. After vaccination, people vaccinated show levels of protective immunity. There is no evidence that vaccine decreases transmission of N. meningitidis because it does not kill bacteria that is present in the nasal passage.

### **Cost Effectiveness**

Routine vaccination with MCV can prevent 270 cases and 36 deaths over 22 years. Vaccination can provide cost savings of \$633,000 per meningococcal case prevented and \$121,000 per life-year saved.

### **Safety and Side Effects**

MCV is a safe vaccine, with the following most frequently reported adverse events:

- Fever
- Headache
- Injection-site reactions
- Dizziness/syncope

### **Vaccine is Acceptable to the Medical Community & Public**

The vaccine is highly acceptable. In 2014, rates of immunization coverage according to the National Immunization Survey is about 79% for one dose of the vaccine in the US and about 82% in Washington State.

Even without a school mandate, coverage rates for meningococcal vaccine are high when compared with Tdap vaccine, which has been required for school entry.

### **Administrative Burden of Delivery and Tracking of Vaccine Are Reasonable**

The number of vaccine doses ordered through the Vaccines for Children Program is similar to Tdap vaccine ordering. Washington State uses a combination of state and federal funds to purchase vaccines for all children, so there is no barrier associated with the cost of the vaccine. The cost of the vaccine is free; however, there may be an administration or office visit fee.

There are other administrative and tracking costs for the provider, school, and parent.

The TAG discussed the burden of implementation for school staff, especially with the second booster dose recommended at age 16.

## EVALUATION CRITERIA

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In June 2006 the Board adopted nine Criteria to Consider in Evaluating Antigens for possible inclusion in the list of immunizations required for child care or school entry.

The development of the criteria was guided by John Stuart Mill whose thesis has become known as the harm principle. Two assumptions were made for establishing the criteria:

- Some kind of process exists to opt out of immunization requirements by children attending either child care centers and school
- That vaccine(s) containing the antigen are accessible and that cost is not a barrier.

### **The nine criteria fall into three areas:**

- Criteria on the effectiveness of the vaccine
- Disease Burden Criteria
- Implementation Criteria

### **The nine criteria are:**

- Recommended by ACIP
- Vaccine Efficacy
- Cost Effectiveness
- Safety and Side Effects
- Disease Prevention
- Reduction in Transmission
- Acceptable to Medical Community & Public
- Delivery and Tracking of Vaccine Are Reasonable
- Burden of Compliance is Reasonable for the Parent/Caregiver

### **Recommendations of the TAG**

The majority of the meningococcal TAG members recommended that the Board not add the Meningococcal vaccine to the rule.

The TAG applied the following ethical framework in its deliberations:

- 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

Only three of the nine criteria - Recommended by ACIP; Safety and Side Effects; and Acceptable to Medical Community and Public - received unanimous support as fully meeting the criteria.

The criteria receiving the least support from the TAG members was reduction in transmission.

### Ethical Framework and Criteria

The Washington State Board of Health Criteria.

#### 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***

###### Source

- CDC. Prevention and control of meningococcal disease: Recommendations of the ACIP. MMWR 2005; 54(No. RR07): 1-21. [www.cdc.gov/mmwr/preview/mmwrhtml/rr5407a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5407a1.htm)
- Recommended Childhood and Adolescent Immunization Schedule – US, 2006: [www.cdc.gov/mmwr/preview/mmwrhtml/mm5451-Immunization1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5451-Immunization1.htm)
- CDC. Updated recommendations for use of meningococcal conjugate vaccines: Advisory Committee on Immunization Practices. MMWR 2010; 60(No. RR03): 72-76. [www.cdc.gov/mmwr/preview/mmwrhtml/mm6003a3.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6003a3.htm)
- Recommended Immunization Schedules for Persons Aged 0 Through 18 Years – US, 2011: [www.cdc.gov/mmwr/preview/mmwrhtml/mm6005a6.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6005a6.htm)

##### ***2) The antigen is effective as measured by immunogenicity and population-based prevention***

###### Source

- CDC. Prevention and control of meningococcal disease: Recommendations of the ACIP. MMWR 2013; 62(No. RR02): 1-22. [www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm)
- Baxter, R, Reisinger, K, Block SL, Percell, S, Odrljin T, Dull PM, and

Smolenov I. Antibody persistence after primary and booster doses of a quadrivalent meningococcal conjugate vaccine in adolescents. *Pediatric Infectious Disease Journal*; 33:11169-1176

- CDC. Epidemiology and Prevention of Vaccine-Preventable Diseases. 13th edition, 2015. [www.cdc.gov/vaccines/pubs/pinkbook/downloads/mening.pdf](http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/mening.pdf)

##### ***3) The vaccine containing this antigen is as cost effective from a societal perspective as other vaccines used to prevent the diseases included in WAC 246-105-030***

###### Source

- CDC. Prevention and control of meningococcal disease: Recommendations of the ACIP. MMWR 2013; 62(No. RR02): 1-22. [www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm)
- 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.

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

**Source**

- CDC. Meningococcal Vaccine Information Statement (VIS): [www.immunize.org/vis/meningococcal.pdf](http://www.immunize.org/vis/meningococcal.pdf)
- CDC. Prevention and control of meningococcal disease: Recommendations of the ACIP. MMWR 2013; 62(No. RR02): 1-22. [www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm)
- Jackson L, Jacobson, R, Reisinger, K, Anemona, A, Danzig, L, and Dull, P. A randomized trial to determine the tolerability and immunogenicity of a quadrivalent meningococcal glycoconjugate vaccine in healthy adolescents. *The Pediatric Infectious Disease Journal* 2009;28:86-91.

**II. DISEASE BURDEN CRITERIA**

**5) The vaccine containing this antigen prevents disease(s) with significant morbidity and/or mortality in at least some sub-set of the population**

**Source**

- CDC. Prevention and control of meningococcal disease: Recommendations of the ACIP. MMWR 2013; 62(No. RR02): 1-22. [www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm)
- 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. Vaccine Preventable Disease Surveillance Manual, 5th ed. 2011. Meningococcal Disease: Chapter 8-1. [www.cdc.gov/vaccines/pubs/surv-manual/chpt08-mening.pdf](http://www.cdc.gov/vaccines/pubs/surv-manual/chpt08-mening.pdf)

**6) Vaccinating the infant, child, or adolescent against this disease reduces the risk of person-to-person transmission.**

**Source**

- CDC meningococcal information: [www.cdc.gov/features/meningococcal/](http://www.cdc.gov/features/meningococcal/)

**III. IMPLEMENTATION CRITERIA**

**7) The vaccine is acceptable to the medical community and the public**

**Source**

- CDC. Meningococcal Conjugate Vaccines Policy Update: Booster Dose Recommendations <http://pediatrics.aappublications.org/content/128/6/1213.full>
- Simpson JE, Hills RA, Allwes D, Rasmussen L. Uptake of meningococcal vaccine in Arizona schoolchildren after implementation of school-entry immunization requirements. *Public Health Reports* 2013;128:36-45.

**8) The administrative burdens of delivery and tracking of vaccine containing this (these) antigen(s) are reasonable.**

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

**Source**

- National Immunization Survey: [www.cdc.gov/mmwr/preview/mmwrhtml/mm6429a3.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6429a3.htm)

## VOTING SUMMARY

### Technical Advisory Group: Recommendation Ballot

	YES	NO	UNSURE	COMMENTS
Recommended by ACIP	13			
Vaccine Efficacy	9		4	
Cost Effectiveness	7	4	2	
Safety & Side Effects	13			
Disease Prevention	8	2	3	
Reduction in Transmission	5	6	2	
Acceptable to Medical Community & Public	13			
Delivery & Tracking of Vaccine	7	3	3	
Burden of Compliance is Reasonable for the Parent/Caregiver	10	1	2	
<b>I Recommend That The Board Add Meningococcal Vaccine to the Rule</b>	2	8	3	



# WASHINGTON STATE BOARD OF HEALTH

Working for a safer and healthier Washington since 1889

The Board provides leadership in developing and promoting policies that prevent disease, and improve and protect health for all people in Washington

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