

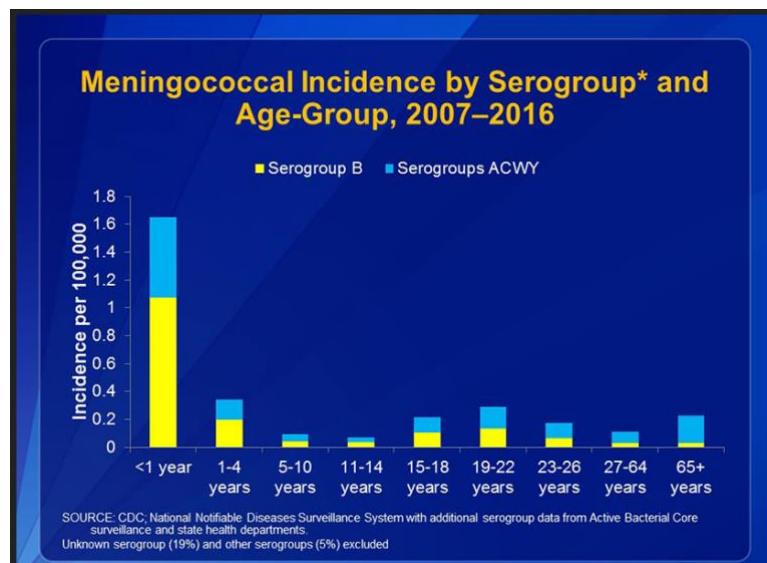
Mark Jenkins, MD  
Executive Director, Hall Health Center  
4060 E. Stevens Way NE  
Seattle, WA 98195

June 3, 2019

Dear Dr. Jenkins,

Informed Choice Washington (ICWA) is a nonprofit with a mission to protect the rights of vaccine consumers and to advocate for scientific integrity in vaccine policies such that they reflect the actual capabilities, limitations, risks, and unintended consequences of the vaccine products on the market.

We are concerned that the University of Washington (UW) has added a new requirement for the MenACWY vaccine as a condition for University entry starting in 2019.<sup>i</sup> We are aware that the Immunization Policy & Procedures task force was convened that led to the adoption of this new requirement; however, to ensure that the UW vaccine policy serves the best interest of your student population, we hope you will understand the need to reconsider this requirement. We respectfully request that, as Chair of the Advisory Committee on Communicable Diseases, you provide answers to the questions below (in bold) along with evidence to substantiate your answers. This letter and your response (or lack of substantive response) will become public record available to WA State and nationwide stakeholders, including current and prospective UW students.

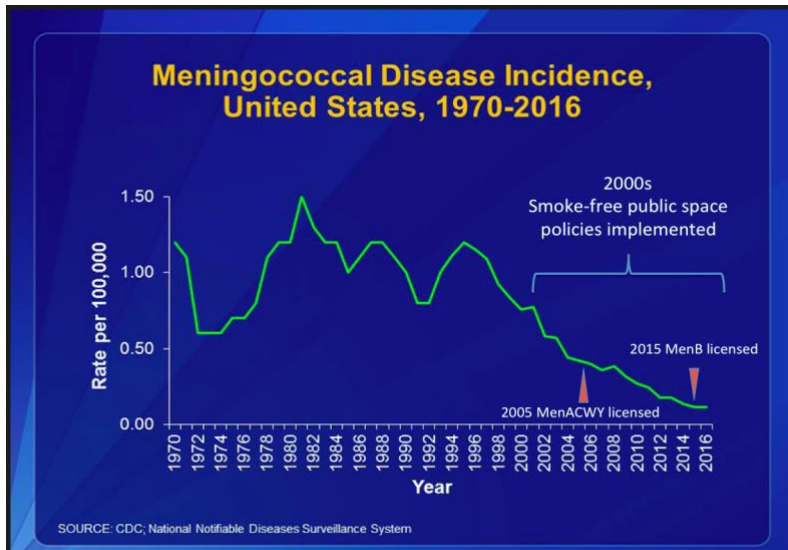


First, per the WA DOH 2017 Communicable Disease Report, the rate of meningococcal disease in Washington State is currently 2 per million (0.2 per 100,000).<sup>ii</sup> Given that the predominant serogroup causing invasive meningococcal disease in WA State and nationwide is serogroup B, the MenACWY vaccine theoretically targets only about half of invasive meningococcal infections. Hence, mass vaccination of students with the MenACWY vaccine can at most attempt to prevent an event that occurs at a frequency of 1 per million.

Graph source: A CDC slide on the overall incidence of meningococcal disease by age.

Cumulative incidence rate from serogroups A, C, W, and Y in the college-age group (19-22 years) is about 1 per million.

<https://www.cdc.gov/meningococcal/surveillance/index.html>



Graph source: A CDC slide on meningococcal disease incidence, modified to indicate the years of the MenACWY and MenB vaccine licensures and the implementation of more stringent smoke-free public health policies.

<https://www.cdc.gov/meningococcal/surveillance/index.html>

Second, the CDC states the following: “Today, meningococcal disease is at a historic low in the United States. Incidence of meningococcal disease has been declining in the United States since the 1990s, with much of the decline seen prior to routine use of meningococcal conjugate vaccines. In addition, serogroup B meningococcal disease has continued to decline even though vaccines were not available to help protect against it until the end of 2014.”<sup>iii</sup> This begs the question: what factors are the real reason behind the decline in meningococcal disease, for which the vaccines have taken undue credit?

While the vast majority of meningococcal infections do not result in meningitis, exposure to second-hand smoke in children<sup>iv</sup> and marijuana use/ nightclub attendance by

students<sup>v</sup> are among well-established risk factors for invasive meningococcal disease in these at-risk age groups. Nationwide public health policies have successfully discouraged smoking and reduced exposure to second-hand smoke in public spaces, including college campuses, workplaces, restaurants and bars. Hence, the observed trend in invasive meningococcal disease reduction is likely due to the implementation of these measures.

Furthermore, a new law to take effect in January of 2020, which raises the legal age to purchase tobacco and vaping products from 18 to 21 in Washington State,<sup>vi</sup> is likely to facilitate the downward trend in meningococcal disease in the college-age group even further. We commend the UW on implementing any measures that reduce exposure to smoke on its campuses, thereby improving public health outcomes. In contrast, vaccination carries risks, and this new requirement will bar admission to students who object to receiving the MenACWY vaccine.

Considering how rare meningococcal disease is in the population targeted by the new MenACWY vaccine requirement, please explain how the task force determined that the requirement would substantially improve public health without putting the personal health of any MenACWY recipient at risk of vaccine injury.

**Please describe and attach evidence the task force relied upon:**

- a) to ascertain that the rate of serious vaccine-related adverse events resulting in hospitalization, permanent damage or death of MenACWY vaccine recipients would not exceed 1 per million (i.e., that it would not exceed the rate of the target meningococcal disease in the student population);
- b) to assess how thoroughly the evidence on the rate of serious vaccine-related adverse events was collected.
  - i) Was a saline placebo used in any randomized controlled trial?
  - ii) If so, was the sample size of the study sufficient to capture any adverse event that may happen at a rate of about 1 per million in a randomized controlled trial or other setting that statistically distinguishes between a vaccine-related and a coincidental event?

- iii) Was the duration of the follow-up in such vaccine safety study long enough to capture the onset and rate of vaccine-related autoimmune or chronic health conditions in vaccine recipients relative to saline placebo recipients?
- c) to determine that the MenACWY vaccine is not just immunogenic (i.e., capable of stimulating anti-capsular meningococcal antibodies) but is actually effective in preventing invasive meningococcal disease.
  - i) Does the evidence of clinical efficacy exist?
  - ii) If so, what is the rate of the MenACWY vaccine failure in preventing invasive meningococcal disease from target strains?
  - iii) What is the number needed to vaccinate (NNV) to prevent one case of meningococcal meningitis given the vaccine failure rate?
- d) to estimate how many cases of serious vaccine-related adverse events will be incurred to prevent one case of meningococcal meningitis.

When answering our questions, please be advised that because the downward trend in meningococcal disease incidence preceded the introduction of the currently available meningococcal vaccines and is confounded by the introduction of laws and policies affecting meningococcal disease risk factors (e.g. exposure to second-hand smoke), the disease reduction trend in and of itself does not constitute evidence that these vaccines are effective in meningococcal disease prevention.

Lastly, in order to protect the right to informed consent of prospective and current UW students, we respectfully request that you:

- a) change the MenACWY vaccine requirement into a voluntary vaccination option available to students and inform UW students of their right to opt out;
- b) inform UW students that per the CDC data the cumulative rate of meningococcal disease from serogroups A, C, W, and Y is 1 per million in their age group;
- c) educate UW students about meningococcal disease risk factors (such as second-hand smoke and social mixing) so that they can better protect their own health from a very rare chance of contracting meningococcal meningitis; and
- d) ensure that UW students are informed about the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Injury Compensation Program (VICP) when offered vaccination.

We are looking forward to your response and a UW vaccine policy change with respect to the MenACWY vaccine requirement.

Sincerely,

Bernadette Pajer  
 co-president, Informed Choice Washington  
 bernadette@informedchoicewa.org

<sup>i</sup> <http://depts.washington.edu/hhpcweb/requirement-for-students-entering-fall-2019-and-later/>

<sup>ii</sup> <https://www.doh.wa.gov/Portals/1/Documents/5100/420-004-CDAnnualReport2017.pdf>

<sup>iii</sup> <https://www.cdc.gov/vaccines/vpd/mening/hcp/about-vaccine.html>

<sup>iv</sup> <https://www.ncbi.nlm.nih.gov/pubmed/21151890>

<sup>v</sup> <https://www.ncbi.nlm.nih.gov/pubmed/18277925>

<sup>vi</sup> <http://lawfilesexternal.wa.gov/biennium/2019-20/Pdf/Bills/Session%20Laws/House/1074.SL.pdf>