

Michelle Davis, Executive Director
Washington State Board of Health
P.O. Box 47990
Olympia, WA 98504-7990

July 20, 2015

Dear Ms. Davis,

I am writing today as the Washington State representative and Executive Board Member for the National Meningitis Association (NMA).

I respectfully request the State Board of Health conduct a meningococcal vaccine review by utilizing the "Criteria for Reviewing Antigens for Potential Inclusion in WAC 246-100-166".

It is my hope and request Washington State will join the many other states such as New York, Louisiana, Delaware, Missouri and Utah who have recently adopted rules or passed legislation requiring meningococcal vaccine(s), or are in the process of doing so.

In my research, I learned that one of the most recent states to adopt such a rule requiring Meningococcal vaccination for school entry was Utah who utilized the same review criteria procedure as Washington State. I have enclosed a copy of the Utah review that was used by their board when they voted to adopt a rule for Meningitis requirements.

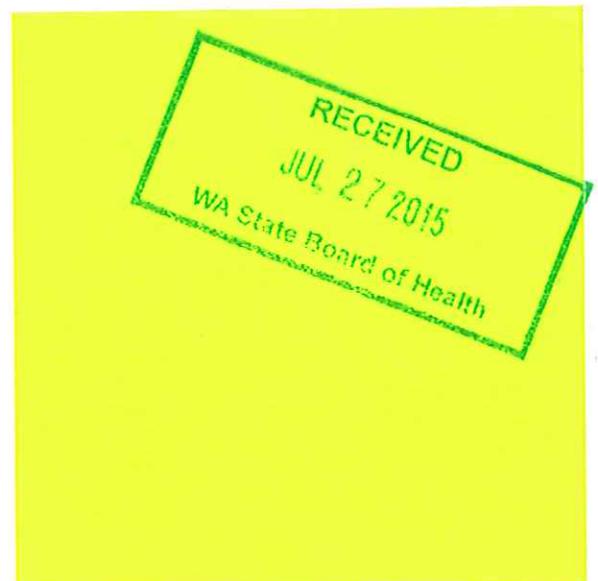
As a Washington State parent of a son who suffered through meningitis, I have personally witnessed the devastating effects of this preventable disease. His ordeal was recently featured in the Seattle Times. I have enclosed a reprint of that story as well and hope that you will consider the great human cost of this disease to Washingtonians as you review WAC 246-100-166.

I urge you to please review this vaccine for inclusion into our state's requirement.

Thank you for your consideration.

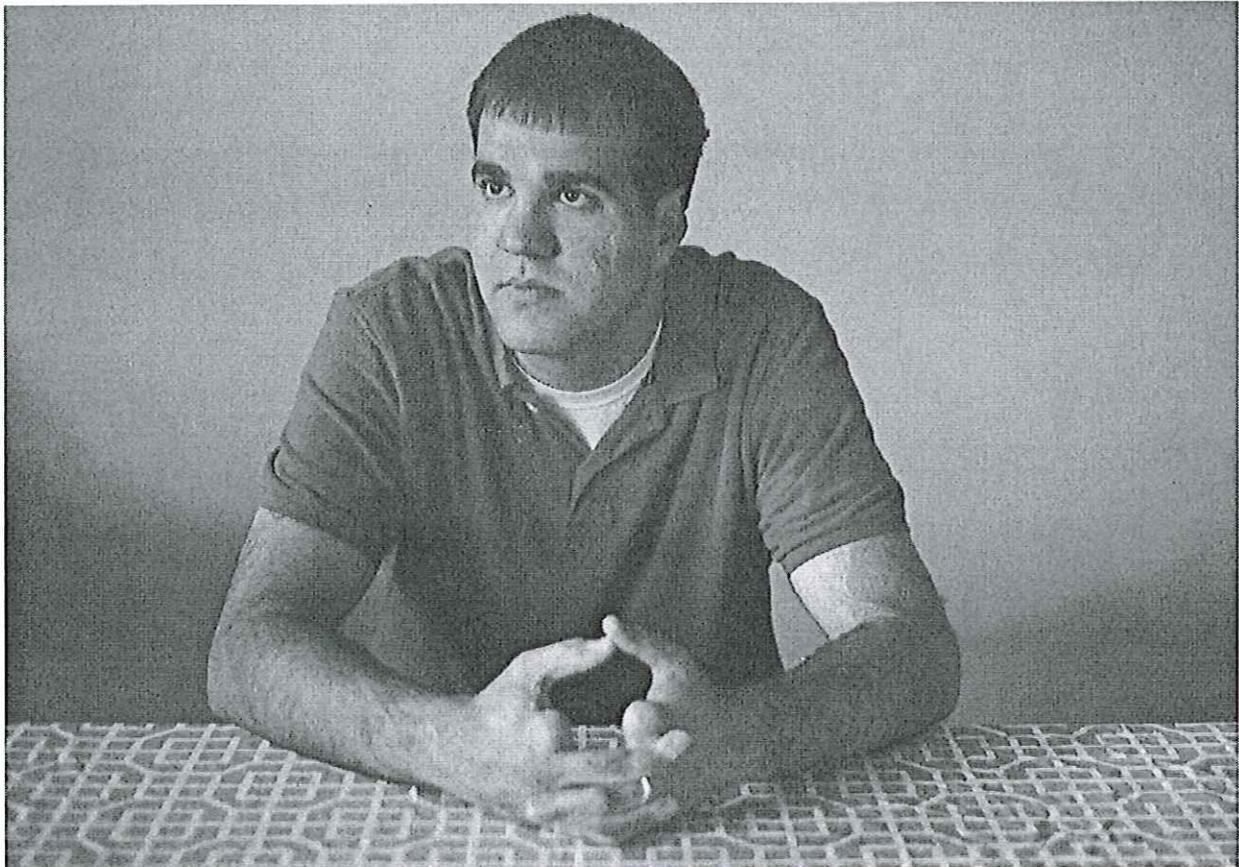


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Menigitis survivor from Seattle urges wider use of lifesaving vaccine

Originally published June 21, 2015 at 8:20 pm Updated June 22, 2015 at 6:28 am



Meningitis B survivor Carl Buher battled a life-threatening infection in 2003, which resulted in the loss of three fingers and his legs below the knee. He recently testified in favor of widespread use of new vaccines to... (Sy Bean/The Seattle Times)

Those who have suffered from meningitis B and loved ones of those who died from the infection hope a federal panel Wednesday will recommend routine use of the shots in older kids and teens, who are at the highest risk.

By JoNel Aleccia
Seattle Times health reporter

Carl Buher was a 14-year-old in Mount Vernon in 2003, when the high-school freshman was hit with a sudden illness: high fever, pounding headache, disorientation and purple splotches over his face and arms.

Within a day, he'd been diagnosed with bacterial meningitis, a rare and fast-moving infection, and flown by helicopter to Seattle Children's for lifesaving antibiotics. Within weeks, he was sent to the intensive-care unit at Harborview Medical Center. Within months, he had lost three fingers and both legs below the knee, amputations forced by the ravages of the disease.

A dozen years later, Buher is a 26-year-old Seattle civil engineer who nimbly navigates despite his missing fingers and prosthetic legs. He's also a vocal advocate for a vaccine that could have prevented his infection in the first place.

"When I got sick, none of us had ever heard of meningitis before," said Buher, who testified this winter before a panel at the Centers for Disease Control and Prevention in Atlanta. "People don't know there's a vaccine and that they should be vaccinating their kids."

On Wednesday, the CDC's Advisory Committee on Immunization Practices (ACIP), which sets U.S. standards, is expected to decide whether a new vaccine to prevent meningitis strain B — the type Buher contracted — should get the nod for widespread use.

The question is whether the meningitis B vaccines used to halt recent college campus outbreaks in New Jersey, California and Oregon will be included among routinely recommended shots — as vaccines that target four other types of meningitis already are.

Bacterial meningitis is an infection that attacks the linings of the brain and spinal cord. It's spread by close contact through respiratory secretions, such as kissing or sharing drinking glasses, which puts teens and young adults particularly at risk.

"We support the most broad-scale recommendations that the committee can do," Buher said.

An estimated 30 to 40 infections and three to four deaths each year could be prevented if the panel were to vote for routine meningitis B vaccinations, surveillance data suggest.

But insiders say concerns about the relatively small number of young people affected by meningitis B infections — 50 to 60 cases a year — as well as questions about the lasting effectiveness of the vaccine, potential problems with delivering it and overall costs — could steer the committee toward a ruling that stops short of a wide advisory.

Instead, the group could recommend a "permissive" vaccination, said Dr. Paul Offit, a vaccine expert and the chief of the division of infectious diseases at Children's Hospital of Philadelphia. That would allow doctors to deliver it and insurance companies to pay for it, but wouldn't place it on the list of must-have shots on which parents rely.

"That's my sense," Offit said.

The shots — which run \$130 apiece and require two or three doses — would be included in the federal Vaccines for Children program, which provides vaccines at no cost to children whose families can't afford to pay for them.

“I think the advocates would be happy that this is a very good start,” said Offit.

But to Buher and others, including the National Meningitis Association, it's far less than they've been demanding.

Lynn Bozof, president of the association, lost her 20-year-old son, Evan, to meningitis in 1998. At that time, a vaccine to prevent the infection was used to protect U.S. military recruits, but wasn't approved in the wider population.

“There was a vaccine available, and we didn't know about it,” the Georgia mother said. “This will be the same thing: Why didn't someone tell me? Why didn't I know?”

Bozof said she fears that only motivated parents with well-informed doctors will understand the benefits of the vaccine — until it's too late.

“For the average person, it is not going to be on their radar to be looking out for that vaccine,” she said.

Linda Dahlstrom Anderson, a Seattle mother whose 7-month-old son, Phoenix, died nearly a decade ago after a meningitis B infection, said such a lack of knowledge leaves an entire community at risk.

“They're not statistics, they're children,” said Dahlstrom Anderson, who also has an 8-year-old son she plans to protect against the disease. “Each one represents a whole universe of people. With Phoenix, it's hundreds of people.”

The fight for wider use caps a long and contentious effort to make a meningitis B vaccine available in the U.S.

Since 2005, vaccines have been licensed in the U.S. to protect against four strains of meningitis: A, C, W-135 and Y. Since 2011, ACIP has recommended the routine use of the shots in kids ages 11 to 18, with booster doses at 16.

But until last year, no vaccine was licensed in the U.S. to prevent infections caused by strain B, the type linked to outbreaks that caused 13 infections, including a death, at Princeton University and the University of California, Santa Barbara in 2013 and 2014. This year, seven people have been sickened by meningitis B at the University of Oregon, including one student who died.

Now, however, there are two vaccines approved by the Food and Drug Administration that target strain B: Trumenba, made by Pfizer, and Bexsero, by Novartis. The ACIP currently recommends them for people aged 10 to 25 with underlying illness and during outbreaks — but not for the broader adolescent and young adult population.

Offit and Dr. William Schaffner, a Vanderbilt University infectious-disease expert, were both part of the CDC's work group that studied the meningitis B vaccines.

"The work group has been remarkably studious and thorough," Schaffner said. "They've looked rigorously at the morbidity and the mortality of the disease."

The group has noted that all meningitis infections in the U.S. are at historic lows, with about 550 cases in 2013, down from a peak of about 3,800 cases in the late 1990s. Although individual illnesses and outbreaks are rare, they're devastating to the communities — and the families — they strike.

The infections are caused by *Neisseria meningitidis* bacteria. When the bacteria infect the lining of the brain and spinal cord, it's called meningitis. When the infection remains in the blood, it's called meningococemia. About 10 percent of people infected with the bacteria die, and an additional 20 percent are left disfigured, disabled or deaf, the CDC notes.

"For me, vaccination is not theoretical. It's intensely personal," Dahlstrom Anderson said. "When I think about vaccination, it comes down to that one little, sweet face."

Neither Offit nor Schaffner could say for sure how the panel will vote, or even whether the scheduled vote was certain to occur. The group could decide to postpone a decision.

Officials at Washington state colleges have been awaiting the ACIP recommendation to decide whether to add information about the meningitis B vaccine to required education materials. Twenty-one states require proof of meningitis vaccination or a waiver for college enrollment; Washington isn't among them.

Although meningitis B vaccines have been approved for months, Bozof said she's heard from parents who can't find them. She recommends contacting travel clinics, which may be more likely to stock the shots.

In the meantime, Seattle advocates like Buher and Dahlstrom Anderson said they hope the advisory group will vote on the recommendation now — and include a full analysis of the true cost of the disease for victims and families.

"Even if I find a house, I'm going to have to modify it," Buher said. "There's the cost of getting new wheelchairs, of getting cars modified. The cost of survival is high for me."

UTAH SCIENTIFIC VACCINE ADVISORY COMMITTEE
CRITERIA FOR REQUIRED VACCINES
FOR CHILDCARE CENTER AND/OR SCHOOL ENTRY

Nine Criteria (and Associated Scoring) to Use as a Tool in Evaluating Antigens

I. Criteria on the effectiveness of the Meningococcal vaccine

1. A vaccine containing this antigen is recommended by the Advisory Committee on Immunization Practices and included on their recommended childhood immunization schedule.

- Yes, this criteria is met
 No, this criteria is not met

Comments:

ACIP recommends routine administration of a MenACWY vaccine for all persons aged 11 through 18 years. A single dose of vaccine should be administered at age 11 or 12 years, and a booster dose should be administered at age 16 years. Adolescents who receive their first dose at age 13 through 15 years should receive a booster dose at age 16 through 18 years. The minimum interval between doses of MenACWY is 8 weeks. Adolescents who receive a first dose after their 16th birthday do not need a booster dose unless they become at increased risk for meningococcal disease. Persons aged 19 through 21 years are not recommended routinely to receive MenACWY. MenACWY may be administered up to age 21 years as catch-up vaccination for those who have not received a dose after their 16th birthday. Persons at increased risk for meningococcal disease also are recommended for routine meningococcal vaccination.

Source

1. CDC. MMWR, March 22, 2013 / 62(RR02);1-22.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm>

2. The antigen is effective (in terms of immunogenicity and population based prevention).

- Extremely Effective
 Effective
 Somewhat Effective
 Marginally Effective
 Not Effective

Comments:

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. The expected number of breakthrough cases was calculated from available vaccine coverage and disease incidence data, and estimates of expected vaccine effectiveness were based on prelicensure serologic evidence of immune response. 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%. Of the 13 reports of breakthrough disease for which data on underlying conditions were available, four persons had underlying conditions or behaviors associated with an increased risk for bacterial infections, including 1) Type 1 diabetes mellitus; 2) current smoking; 3) history of bacterial meningitis and recurrent infections; and 4) aplastic anemia, paroxysmal nocturnal hemoglobinuria, and receipt of eculizumab (which blocks complement protein C5).

A case-control study evaluating the vaccine effectiveness of meningococcal conjugate vaccine in adolescents began in January 2006. Because MenACWY-D was the only licensed conjugate vaccine until February 2010, the preliminary results provided in this report are estimates for MenACWY-D only. As of August 29, 2012, a total of 157 case-patients and 180 controls were enrolled in the effectiveness study. The overall estimate of vaccine effectiveness in adolescents vaccinated 0 through 6 years earlier was 69% (95% confidence interval [CI] = 50%–81%). Vaccine effectiveness was 82% (CI = 54%–93%) for adolescents vaccinated <1 year earlier, 80% (CI = 52%–92%) for adolescents vaccinated 1–<2 years earlier, 71% (CI = 34%–87%) for adolescents vaccinated 2–<3 years earlier, and 59% (CI = 5%–83%) for adolescents vaccinated 3–<6 years earlier. Although CIs around the point estimates are wide, these results suggest that vaccine effectiveness wanes over time.

Source

1. CDC. MMWR, March 22, 2013 / 62(RR02);1-22.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm>

3. The vaccine containing this antigen is cost effective (from a societal perspective).

- Extremely Cost Effective
- Cost Effective
- Somewhat Cost Effective
- Marginally Cost Effective
- Not Cost Effective

Comments:

As part of the evaluation of the adolescent vaccination program, a cost-effectiveness analysis was performed to compare the cost-effectiveness of the following three vaccination strategies: 1) a single dose at age 11 years, 2) a single dose at age 15 years, and 3) a dose at age 11 years with a booster dose at age 16 years. The economic costs and benefits of these meningococcal vaccination strategies in adolescents were assessed from a societal perspective. A multivariable analysis was performed with a Monte Carlo simulation in which multiple parameters were varied simultaneously over specified probability distributions. These parameters included disease incidence (46%–120% of the 10-year average), case-fatality ratio (34%–131% of the 10-year average), rates of long-term sequelae, acute meningococcal disease costs (i.e., inpatient care, parents' work loss, public health response, and premature mortality costs), lifetime direct and indirect costs of meningococcal disease sequelae (i.e., long-term special education and reduced productivity), and cost of vaccine and vaccine administration (range: \$64–\$114). Vaccination coverage (37%–90%) and initial vaccine efficacy (39%–99%) also were varied for evaluation purposes. The vaccine was assumed to be 93% effective in the first year, and then waning immunity was modeled as a linear decline over the next 9 years unless a booster dose was administered. The vaccine effectiveness of the second dose was assumed to be higher with a slower rate of waning immunity. The results of the cost-effectiveness analysis indicate that a 2-dose series at ages 11 years and 16 years has a similar cost-effectiveness compared with moving the single dose to age 15 years or maintaining the single dose at 11 years. However, the number of cases and deaths prevented is substantially higher with the 2-dose strategy.

Source

1. CDC. MMWR, March 22, 2013 / 62(RR02);1-22.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm>

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

- Safe
- Somewhat Safe
- Marginally Safe
- Not Safe

Comments:

As many as half the people who get meningococcal vaccines have mild side effects, such as redness or pain where the shot was given. A small percentage of people who receive the vaccine develop a mild fever. Serious allergic reactions, within a few minutes to a few hours of the shot, are very rare.

Adverse Events Reported after Receipt of Meningococcal Conjugate Vaccine

MenACWY-D

From licensure of MenACWY-D in January 14, 2005, through September 30, 2011, VAERS received 8,592 reports involving receipt of MenACWY-D in the United States; 89.0% reports involved persons aged 11 through 19 years. MenACWY-D was administered alone in 22.5% of case reports. The median time from vaccination to onset of an adverse event was 1 day. Males accounted for 40.6% of the reported events. The most frequently reported adverse events were fever 16.8%, headache 16.0%, injection site erythema 14.6%, and dizziness 13.4%. Syncope previously has been identified as an adverse event following any vaccination, with a higher proportion of syncope events reported to VAERS having occurred in adolescents compared with other age groups (89). Syncope was reported in 10.0% of reports involving MenACWY-D. Among all MenACWY-D reports, 563 (6.6%) were coded as serious (i.e., resulted in death, life-threatening illness, hospitalization, prolongation of hospitalization, or permanent disability).

Among those reports coded as serious, the most frequent adverse events reported included headache (37.5%), fever (32.5%), vomiting (23.6%), and nausea (22.2%). Cases of Guillain-Barré Syndrome (GBS) were recorded in 86 (15.3%) reports coded as serious, although the diagnosis has not been validated by medical records for all reports. A total of 24 (0.3%) deaths were reported, each of which was documented by autopsy report or other medical records and occurred in persons aged 10 through 23 years.

Among the 24 reports of death, 11 (45.8%) indicated that the cause of death was meningococcal infection (nine with a serogroup included in the vaccine and two with a nonvaccine serogroup). Among the other 13 (54.2%) reports of death, which occurred from the day of vaccination to 127 days following vaccination, stated causes of death were cardiac (five), neurologic (two), infectious (two), behavioral (i.e., suicide) (two), rheumatologic (one), and unexplained (one). There was no pattern among these reports. Except for the finding of GBS, which was further evaluated and is discussed below, no signals were identified in VAERS after MenACWY-D vaccination.

MenACWY-CRM

During February 19, 2010–September 30, 2011, VAERS received 284 reports of adverse events following receipt of MenACWY-CRM in the United States. Approximately three fourths (78.9%) of the reported events concerned persons aged 11 through 19 years. Males were the subject of 44.0% of reports; 45.4% of reports involved other vaccines administered at the same time, and 4.2% of reports were coded as serious. One death was reported, with the cause of death stated as unexplained. The median time from vaccination to adverse event onset was 0 days (the day of vaccination). The most common adverse event reported was injection-site erythema (19.7%) followed by injection-site swelling (13.7%). Syncope was reported in 8.8% of reports. No cases of GBS were reported. Administration errors (e.g., wrong diluent used or subcutaneous injection) without adverse events were described in 15.5% of reports involving MenACWY-CRM.

Guillain-Barré Syndrome and Meningococcal Conjugate Vaccine

In 2005, shortly after licensure of MenACWY-D, several cases of Guillain-Barré Syndrome (GBS) were reported to VAERS. Symptom onset clustered approximately 14 days after vaccination with MenACWY-D. No deaths were reported, and most persons recovered

increased risk for GBS post-MenACWY-D vaccination was outweighed by the protection that the vaccine offers against meningococcal disease. However, because the risk for recurrence of GBS after meningococcal vaccination was unknown, FDA considered previous history of GBS a contraindication for use of this vaccine. A large retrospective cohort study of adolescents aged 11 through 21 years that was conducted during 2005–2008 included approximately 1.4 million persons vaccinated with MenACWY-D. In an analysis that took into account the missing data, estimates of the attributable risk for GBS ranged from zero to 1.5 additional cases of GBS per 1 million vaccines within the 6-week period following vaccination.

VSD conducts near-real time surveillance for adverse events and tests vaccine safety hypotheses. The system collects medical care and vaccination information on approximately 9 million members. VSD uses Rapid Cycle Analysis to monitor vaccine safety in near real-time. Each week, the number of outcomes in vaccinated persons is compared with the expected number of outcomes in the comparison group using maximized sequential probability ratio testing. No cases of GBS were identified within 1–42 days following 889,684 vaccine doses of MenACWY-D administered during January 2005–March 2010.

In June 2010, after reviewing the two safety studies, ACIP voted to remove the precaution for persons with a history of GBS because the benefits of meningococcal vaccination outweigh the risk for recurrent GBS in these persons. A history of GBS continues to be listed as a precaution in the package inserts for MenACWY-D and MenACWY-CRM. Since the June 2010 ACIP meeting, no specific concerns have been raised about the risk for GBS in persons who both have a history of this condition and have been vaccinated with meningococcal conjugate vaccine.

Postlicensure Safety of Coadministration with Tdap

Two postlicensure studies have evaluated use of Tdap when administered simultaneously or sequentially with MenACWY. In a clinical trial to evaluate administration of one Tdap product (Boostrix, GSK) and MenACWY-D, immune responses to the meningococcal serogroups and to pertussis, diphtheria, and tetanus were similar regardless of whether the two vaccines were administered simultaneously or separated by 30 days. There were no differences in the safety evaluation in either of the groups. In a postlicensure surveillance study using VSD data, the risk for medically attended adverse events was low (0–2.6 per 10,000 vaccinations) and similar regardless of whether persons received Tdap and MenACWY simultaneously or sequentially.

Source

1. CDC. Meningococcal Vaccine Information Sheet (VIS).
<http://www.cdc.gov/vaccines/hcp/vis/vis-statements/mening.pdf>
2. CDC. MMWR, March 22, 2013 / 62(RR02);1-22.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm>

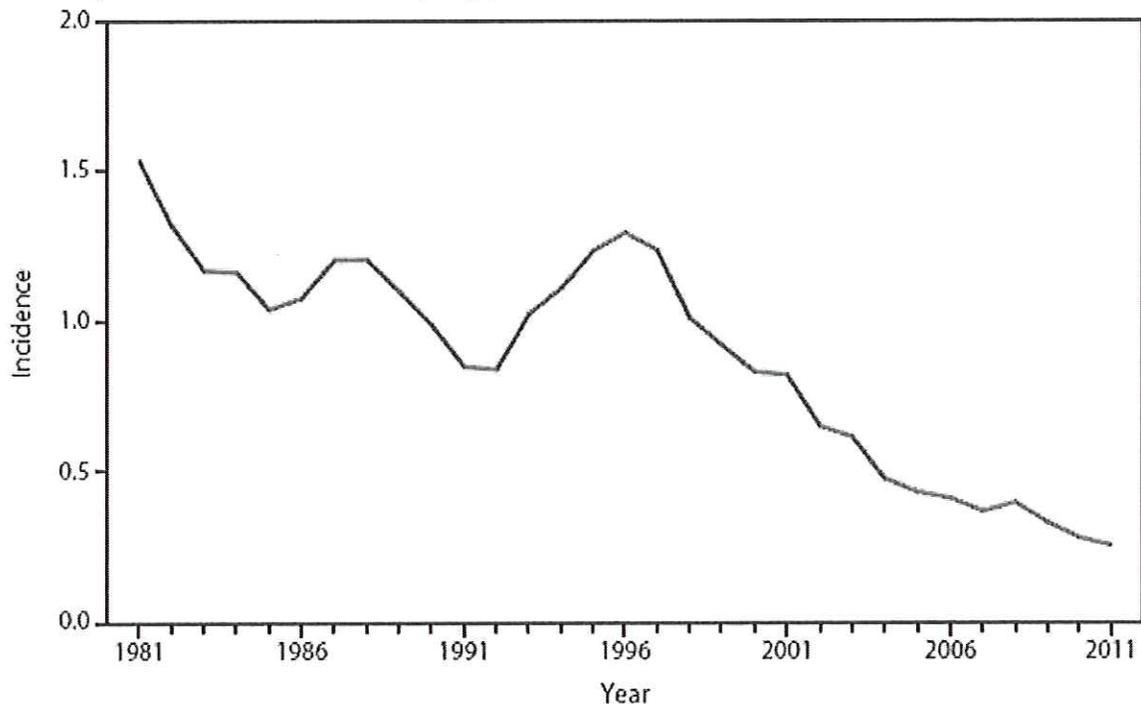
II. Disease Burden Criteria

5. The vaccine containing this antigen prevents diseases with significant morbidity and/or mortality implications (in some sub-set of the population).

- Extremely Significant Morbidity and/or Mortality
- Significant Morbidity and/or Mortality
- Somewhat Significant Morbidity and/or Mortality
- Marginally Significant Morbidity and/or Mortality
- Not Significant Morbidity and/or Mortality

Comments:

Meningococcal Disease. Incidence,* by year — United States, 1981–2011



* Per 100,000 population.

*Meningococcal disease describes the spectrum of infections caused by *Neisseria meningitidis*, including meningitis, bacteremia, and bacteremic pneumonia. Meningococcal disease develops rapidly, typically among previously healthy children and adolescents, and results in high morbidity and mortality. Meningococcal disease incidence remained low in 2011, but it continues to cause significant morbidity and mortality in the United States.*

Additional Meningococcal disease data:

- 2011 Data, US: <http://www.cdc.gov/mmwr/PDF/wk/mm6053.pdf>
- All Data Years, US: http://www.cdc.gov/mmwr/mmwr_nd/
- 2012 Data, Utah: http://health.utah.gov/epi/anrpt/anrpt12/2012_CD_Annual_Rpt.pdf

Source

1. CDC. MMWR July 5, 2013 / 60(53);1-117. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6053a1.htm>

6. Vaccinating the child with this antigen reduces the risk of person-to-person transmission.

- Yes, this criteria is met
 No, this criteria is not met

Comments:

Meningococcal disease can be spread from person to person. Many people carry the bacteria in their throats without getting meningococcal disease. Since so many people carry the bacteria, most cases of meningococcal disease appear to be random and aren't linked to other cases. Although anyone can get meningococcal disease, adolescents are at an increased risk. The vaccine helps prevent meningococcal disease and it can prevent two of the three most common disease-causing strains.

Source

<http://www.cdc.gov/features/meningococcal/>

III. Implementation Criteria

7. The vaccine containing this antigen is acceptable to the medical community and enjoys a high degree of public trust.

- Extremely Acceptable
- Acceptable
- Somewhat Acceptable
- Marginally Acceptable
- Not Acceptable

Comments:

The American Academy of Pediatrics (AAP) approved updated ACIP recommendations for the use of quadravalent meningococcal conjugate vaccines in adolescents and in people at persistent high risk of meningococcal disease.

Source

Meningococcal Conjugate Vaccines Policy Update: Booster Dose Recommendations.
<http://pediatrics.aappublications.org/content/128/6/1213.full>

8. The administrative burdens of delivery and tracking of vaccines containing this antigen are reasonable.

- Extremely Reasonable
- Reasonable
- Somewhat Reasonable
- Marginally Reasonable
- Not Reasonable

Comments:

Meningococcal vaccine is a ACIP recommended and VFC approved vaccine and since 2005 it has been available through our Utah VFC program. It has been our experience over the past years that there is no undue burden in the delivery or the tracking of this vaccine.

9. The burden of compliance for the vaccine containing this antigen is reasonable for the parent/care giver.

- Extremely Reasonable
- Reasonable
- Somewhat Reasonable
- Marginally Reasonable
- Not Reasonable

Comments:

Evidence from current National Immunization Survey (NIS) indicates that Utah adolescents (aged 13-17 years) are near the national average with 56.5% having received a Meningococcal vaccine in the past year. The national average is 53.8% for the vaccine. This indicates that parents and caregivers are not over burdened with compliance issues concerning this vaccine.