

From: [Christina Abel](#)
To: [*OAH_RuleComments_OAH](#)
Subject: Immunization Rules docket 0900-30570
Date: Thursday, June 27, 2013 9:49:15 AM
Attachments: [information in the MDH SONAR http.docx](#)

Attachment is my letter

Meningococcal Vaccine

It does not seem reasonable nor is there a need to require the meningococcal vaccine in Minnesota when the vaccine is now already routinely given to adolescents 12 to 18 year of age by enough clinicians resulting in a reduction of reported cases. There has been no reported vaccine preventable case in 2011 -2012. The last 2 of the 3 cases were vaccinated.

- The "requirement" on the school's vaccine form will be for 7th grade, 11-12 years of age. From 2006 through 2012 there have been no reported meningococcal disease cases in Minnesota children, 11-13 years of age.
- The meningococcal vaccine is already on the school immunization form under recommendation, 2 doses (the two doses is off label use, not FDA approved).
- Even though Minnesota statute requires that parents be informed of an exemption option, and that the exemption information must be on the same page as the requirement information, the MDH has put the exemption information on the back side of the form which at times has been omitted when copies (front side) were made for parents.
- Meningococcal disease is rare in the U.S., including Minnesota
- The bacteria is not easily transmittable.
- Vaccinating adolescents does not create herd protection in the community.
- The vaccine does not reduce the seriousness of the disease.
- Routine vaccination of Meningococcal vaccine (MCV4) is not cost-effective.
- Since 2008, 67% of the reported cases were either vaccine failures or were from a non-vaccine strain.
- Meningococcal disease may be a very serious disease but it is also very rare in Minnesota for 11-22 years of age group. There were no vaccine preventable cases in 2011-2012.
- The vaccine may rarely cause adverse effects after vaccination but it still could cause serious health injuries for some adolescents, as found in cases compensated by the [National Vaccine Injury Compensation Program](#). All drugs have side effects.
- A more reasonable approach is to educate parents and students about the disease and vaccine and allow them to make an informed vaccine decision.

This educational approach is already in place for Minnesota postsecondary educational institutions.

The 2003 Minnesota Statute required post-secondary educational institutions to provide information on the risk of meningococcal disease and the availability of an effective vaccine to each individual who is a first-time enrollee and resides in on-campus housing". <http://www.health.state.mn.us/divs/idepc/immunize/laws/history.html>

Thank you,

Christina Abel, RN
3411 Winnetka Ave N
Crystal MN 55427
763-546-1708
[Vaccine Awareness Minnesota](#)

For easy access to links:

National Vaccine Injury Compensation Program

In 2011

[Stipulation; Human Papillomavirus vaccine \(HPV\); Hepatitis A Vaccine; meningococcal vaccine; Guillia-Barre Syndrome \(GBS\)](#) body's immune system attacks your nerves. KAITLYN ANN SMITH, December 29, 2011

[Damages; Decision Based on Proffer Meningococcal; GBS](#)

A lump sum payment of \$1,061,705.70 in the form of a check payable to petitioner, Ashly Whitener, representing compensation for life care expenses expected to be incurred during the first year after judgment

(\$85,191.77), lost earnings (\$713,842.00), pain and suffering (\$229,163.70), and past unreimbursable expenses (\$33,508.23)., Dec 1, 2011

[Stipulation: tetanus-diphtheria-acellular pertussis: meningococcal conjugate; hepatitis A vaccine: brachial neuritis](#)
Carlie Crowell , Nov 22, 2011

[Stipulation: Menactra vaccine; Guillain-Barre Syndrome](#) Jeremy S. Towne received Menactra on August 19, 2008,
07/28/2011

[Damages decision based on Stipulation: HPV Vaccine, Menactra Vaccine, GBS, CIDP.](#) Monica Freese received vaccine May, 2007; 07/08/11

[Stipulation: Influenza vaccine: Menactra; Guillain-Barré Syndrome](#) MALLORY MYERS received vaccine Oct 2008;
06/22/2011

[Damages Decision Based on Stipulation: Menactra, DTaP, Varivax vaccines, Guillain-Barre syndrome](#) W Torres received vaccine Sept 2008; June 14, 2011

[Joint Stipulation on Damages: Meningococcal Vaccine; Conversion Disorder](#) AMANDA FOSTER, June 1, 2011

[Damages Decision based on Stipulation: Meningococcal, HPV Vaccines, acute transverse myelitis](#) SARAH DAVIDSON received the vaccines on June 27, 2007.; April 27, 2011

In 2012:

[Stipulation: human papillomavirus \("HPV"\) vaccine; meningococcal \("Menactra"\) vaccine; gastrointestinal symptoms; muscle weakness; polyneuropathy; Guillain-Barré Syndrome \(GBS\)](#) MADELINE WUNDER, December 10, 2012

[Joint Stipulation on Damages: meningococcal vaccine; atypical fibromyalgia; trigeminal neuralgia.](#) AMY OWENS and RICK OWENS, parents and Natural Guardians of TASHA OWENS, November 21, 2012

[Damages decision based on stipulation: meningococcal vaccine; Hepatitis A vaccine; Varicella vaccine; Human Papillomavirus vaccine; Guillain-Barre syndrome; chronic headache](#) TANYA L. STEWART, as parent and natural guardian of A.A.S., 10/02/2012

[Joint Stipulation on Damages: Human Papillomavirus Vaccine; Meningococcal Vaccine; Varicella Vaccine; Hashimoto's Thyroiditis](#) ALLISON FLOOD 09/20/2012

[Damages: decision based on proffer: varicella, tetanus-diphtheria-acellular pertussis \(Tdap\) vaccine; meningococcal vaccine \(MCV\), hepatitis A.](#) KAITLYN E. AHOLT 06/18/2012 she experienced an episode of [syncope](#) immediately after receiving these vaccinations on July 15, 2012, which caused her to suffer various injuries to her face, jaw and teeth.

[Stipulation: meningococcal vaccine; transverse myelitis; multiple sclerosis](#) ERIN PATRICIA O'NEILL 06/12/2012 TX

[Entitlement; Acute Disseminating Encephalomyelitis; Tdap vaccine; Meningococcal vaccine](#) BRANDON KENNEDY 05/08/2012

A 16-year-old treated in Minnesota won compensation for a 2007, Tdap and/or meningococcal vaccinations, the cause of his Acute Disseminating Encephalomyelitis (ADEM) and related health problems. This was NOT reported to the passive reporting system Vaccine Adverse Event Reporting system even though this adolescent had adverse events after his vaccinations and was compensated for a vaccine injury.

[Reasonable basis: Menactra vaccine; varicella virus vaccine; Tetanus-diphtheria- acellular-pertussis \(Tdap\) vaccine; human papillomavirus \(HPV\) vaccine; herpetic stomatitis](#) inflammation, pain, or swelling in the mouth. KATHERINE McKELLAR January 13, 2012

[Decision by Stipulation: Influenza, Tdap and Meningococcal Vaccines; Transverse Myelitis](#) Peter Cieszewski . January 13, 2012

In 2013:

[Stipulation: Influenza; Meningococcal; Inactivated polio; DTaP; Hepatitis A; Hepatitis B; MMR; Splenic rupture](#) WILLIAM JEFFREY BISHOP 03/27/2013

[Stipulation: Meningococcal Vaccine; Neurological Injury](#) ALYSSA TIERNEY 05/23/2013

[Damages decision based on stipulation: tetanus-diphtheria-acellular pertussis vaccine; varicella vaccine; meningococcal vaccine; acute disseminated encephalomyelitis; Chiari malformation; optic neuritis](#) DOUGLAS FINLAY and CAMMIE FINLAY on behalf of their minor daughter GINA L. FINLAY May 13, 2013

[Stipulation: meningococcal vaccine; Bell's palsy; joint stiffness; myalgia; sensory neuropathy; retinal vasculitis.](#) Eric Hill received the meningococcal vaccine on June 18, 2010,
05/09/2013

[Damages decision based on stipulation; meningococcal vaccine; tetanus- diphtheria-acellular pertussis vaccine; acute disseminated encephalomyelitis](#) STEPHEN J. HUJARSKI May 6, 2013 was reported to VAERS, Ohio

[Decision by Stipulation: Human Papilloma Virus \(HPV\), DTaP and Meningococcal Vaccines; Pancreatitis and Blood Clots](#) SARAH GREGORY 04/16/2013

[Hepatitis A; Gardasil; Menactra; Influenza vaccines; Acute Disseminated Encephalomyelitis; Transverse Myelitis; Decision; Stipulation.](#) TIANA TOCIO March 28, 2013 was reported to VAERS/ Florida

[Stipulation: Influenza; Meningococcal; Inactivated polio; DTaP; Hepatitis A; Hepatitis B; MMR; Splenic rupture](#) WILLIAM JEFFREY BISHOP, March 27, 2013

[Decision by Stipulation: HPV, TDaP and meningococcal conjugate vaccinations; neurological injury... and ataxia](#) LAURIE ROY, parent of Jamie Roy, a minor, January 11, 2013

New published decisions will be added periodically

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guarantee all information is error free or correct. Contact the Clerks Office at (202) 357-6400 for official copies of documents or any other case or court related information.

Vaccine Adverse Reporting System

The Meningococcal vaccine may be given with other vaccines. The adverse event(s) may be coincidental or causal. This is also a passive reporting system. Many serious adverse events, unknown percentage, may not have been reported. An example of possible underreporting is that only two of the five ADEM/meningococcal vaccine cases compensated by the National Vaccine Injury Compensation Program were found on the VAERS web site.

Found 13 ADEM cases that were reported to VAERS after the meningococcal vaccine, in the U.S., 11 to 18 years of age. Were any of the other 11 informed about the vaccine compensation program to rule out possible vaccine injury compensation?

<http://www.medalerts.org/vaersdb/findfield.php?>

[EVENTS=on&PAGENO=2&PERPAGE=10&ESORT=NONE&REVERSEESORT=&VAX=%28MNO%29&SYMPTOMS=%28Acute_disseminated_encephalomyelitis_%2810000709%29%29](http://www.medalerts.org/vaersdb/findfield.php?EVENTS=on&PAGENO=2&PERPAGE=10&ESORT=NONE&REVERSEESORT=&VAX=%28MNO%29&SYMPTOMS=%28Acute_disseminated_encephalomyelitis_%2810000709%29%29)

There were 157 events reported from **Minnesota** and were 11 to 21-years-of-age and received meningococcal vaccine (Menactra)

<http://www.medalerts.org/vaersdb/findfield.php?>

[EVENTS=on&PAGENO=2&PERPAGE=10&ESORT=NONE&REVERSEESORT=&LOWAGE=%2811%29&HIGHAGE=%2822%29&WhichAge=range&STATE=%28MN%29&VAX=%28MNO%29](http://www.medalerts.org/vaersdb/findfield.php?EVENTS=on&PAGENO=2&PERPAGE=10&ESORT=NONE&REVERSEESORT=&LOWAGE=%2811%29&HIGHAGE=%2822%29&WhichAge=range&STATE=%28MN%29&VAX=%28MNO%29)

There were 61 events reported from **Minnesota** and were 11 to 21-years-of-age and received meningococcal vaccine (Menactra) and ER or doctor visit

<http://www.medalerts.org/vaersdb/findfield.php?>

[EVENTS=on&PAGENO=2&PERPAGE=10&ESORT=NONE&REVERSEESORT=&LOWAGE=%2811%29&HIGHAGE=%2822%29&WhichAge=range&STATE=%28MN%29&VAX=%28MNO%29&ER_VISIT=Yes](http://www.medalerts.org/vaersdb/findfield.php?EVENTS=on&PAGENO=2&PERPAGE=10&ESORT=NONE&REVERSEESORT=&LOWAGE=%2811%29&HIGHAGE=%2822%29&WhichAge=range&STATE=%28MN%29&VAX=%28MNO%29&ER_VISIT=Yes)

Meningococcal Vaccine

The proposed rule change to require the meningococcal vaccine for all children in seventh through 12th grade is neither reasonable nor is it necessary.

The meningococcal vaccine is already recommended (2 doses) on the Pupil Immunization Record. <http://www.health.state.mn.us/divs/idepc/immunize/pupilimzrec.pdf>

In Minnesota the vaccine is now already routinely given to adolescents 12 to 18 year of age by enough clinicians resulting in a reduction in the number of vaccine preventable meningococcal disease cases in this age group.

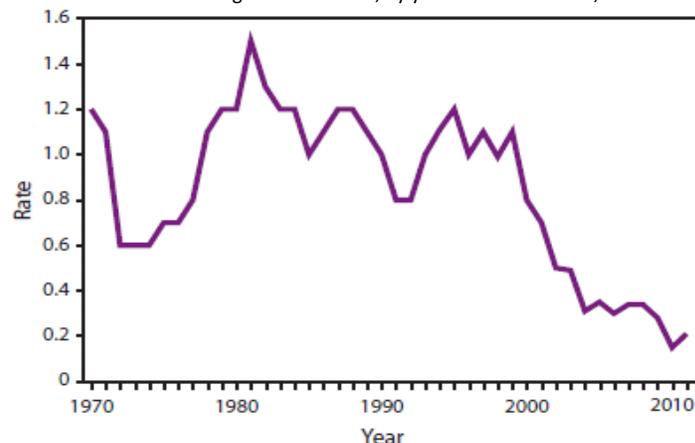
But with any vaccine (drug) there are always possibilities of adverse events after vaccination, either coincidental or causal. There were 157 reported cases from Minnesota to the [Vaccine Adverse Event Reporting System](#) for adolescents, 11-21 year olds, after being vaccinated, which included the meningococcal vaccine.

From the [National Vaccine Injury Compensation Program](#), found 28 persons who were compensated for vaccine injury, which included the meningococcal vaccine, in the years, 2011- 2013.

Below is the Meningococcal information from the Statement of Need and Reasonableness (SONAR) in blue with added information below it: <http://www.health.state.mn.us/divs/idepc/immunize/immrule/sonar.pdf>

P 46 – “About 2,000 to 3,000 people get meningococcal disease each year in the United States” During 2005–2011, an estimated 800–1,200 cases of meningococcal disease occurred annually in the United States, representing an incidence of 0.3 cases per 100,000 population, very rare (CDC, unpublished data, 2012). In the US the incidence has declined since a peak of disease in 1981 ([Figure 1](#)). Even before routine use of a meningococcal conjugate vaccine in adolescents was recommended in 2005 the overall annual incidence of meningococcal disease had decreased 73%, from 1.5 cases per 100,000 population in 1981 to 0.4 cases per 100,000 population in 2005. Since 2005, declines have occurred among all age groups and in all of the serogroups (strains of the bacteria) both vaccine strains and non-vaccine strains.

FIGURE 1. Rate* of meningococcal disease, by year — United States, 1970–2011



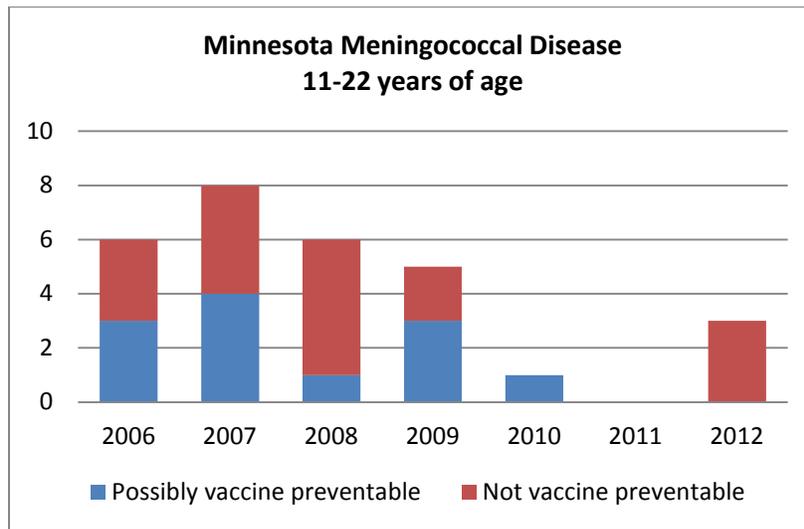
Source: CDC, Unpublished data, National Notifiable Diseases Surveillance System (NNDSS) for 1970–1996 and Active Bacterial Core surveillance (ABCs) system for 1997–2011. * Per 100,000 population. March 22, 2013 / 62(RR02);1-22 Epidemiology of Meningococcal Disease <http://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/min-jun10.pdf>

p-45 “Currently, 22 states require meningococcal vaccination for students in sixth or seventh grade.” Only 16 states have recent requirements for meningococcal vaccination with waivers, of these 5 require education. Another 6 states have education only. Most states do not require this vaccine for Elementary and Secondary Schools.

- 6 - Have education only
- 1 - Education but vaccination only for residential schools, Massachusetts
- 4 - Require education and vaccination
- 11 Vaccination or waiver (VT residential schools only) http://www.immunize.org/laws/menin_sec.asp

p-45 “States with meningococcal vaccination requirements have higher rates of immunization against meningococcal disease: 75 percent vs. 61 percent respectively, according to the National Immunization Survey Minnesota is 63.1 percent, 2011 (11-17 years of age)

Even without requiring meningococcal vaccine for Minnesota’s 7th graders there has been no reported meningococcal disease case in Minnesota children 11-13 years of age from 2006 through 2012. And without a high vaccination level in Minnesota children 11-17 years of age there has been a decline in the number of reported meningococcal disease cases in 11-22 years of age group starting in 2008.



p-8 – “Herd immunity is achieved when the vast majority (90 percent) of the population is immune to a disease because the infectious agent cannot readily spread in a highly immunized community.”

p 48 Transmission

“At any given time, about 10-15 percent of all people are believed to carry *Neisseria meningitidis* bacteria in their throats and nasal passages. This means the bacteria is always present in the **community**, and given the right circumstances, it can cause disease.”

Just vaccinating adolescents will not create herd protection for the community.

“Similarly, some evidence for herd immunity was expected, as had been seen for the conjugate Haemophilus influenzae type-B vaccine and the conjugate pneumococcal vaccine, but that didn't appear to be happening. It appears that the vaccine is protecting only those who are vaccinated and not extending beyond that group.” Dr Offit, Vaccine Education Center, Children's Hospital of Philadelphia, [and] Division of Infectious Disease at Children's [Hospital of Philadelphia]. <http://www.medscape.com/viewarticle/732947>

P 7 “Incidence did not decline in other age groups, suggesting an impact of vaccination (MENINGOCOCCAL) on adolescent disease, but no evidence of herd protection.” ACIP, 2013,

Meningococcal, Recommendations and Reports / Vol. 62 / No. 2 <http://www.cdc.gov/mmwr/PDF/rr/rr6202.pdf>

p-48, “Meningococcal bacteria cannot live for more than a few minutes outside the body, so the disease is not spread as easily as the common cold.” ...“Close contact and secretion exchange are key elements of transmission.”

This disease is considered rare and not casually transmitted. This vaccine should not be required because the numbers of cases are very rare and the bacteria is not easily transmitted to others in the community.

p 46 “The disease is very serious. About nine to 12 percent of people with meningococcal disease die ...” **2006 through 2012**, Minnesota had 10 reported deaths from 119 reported meningococcal disease cases in all ages.

- There were 29 (28 persons) reported cases in the 11-22 years of age group with one death, a **3%** death rate. This death was not vaccine preventable. The 2006 death was in a vaccinated 19-year-old student who died from bacteremia attributed to serogroup B, not found in the vaccine. http://www.kare11.com/news/news_article.aspx?storyid=125227
- Of the 9 remaining reported deaths, not in the 11-22 years of age group, the death rate was **10%**.

In Minnesota persons 11-22 years of age have a much lower death rate than the rest of the general population.

p 48 “From **2006-2011**, there were nine deaths due to *Neisseria meningitidis*, four of which were vaccine-preventable serogroups. Two of the vaccine-preventable deaths were in pediatric patients and one was in a young adult.”

2006-2011, none of the nine meningococcal disease deaths were probably vaccine preventable if the ACIP vaccine recommendation guidelines were followed at the time of death. They were either too young or too old, not in the recommended risk group, or contracted the disease with serogroup not found in the vaccine. Only two vaccine preventable deaths were eligible for a licensed vaccine **and** ACIP vaccine recommendations. But neither seem to have risk factors under the ACIP recommendations (high risk: Persons with certain medical conditions such as anatomical or functional asplenia or complement component deficiency) to be vaccinated.

See attachment

p- 50 “Because of the severe nature of the disease ...”

If the vaccine fails to protect it does not diminish the severity of meningococcal disease.

“The case-fatality ratio was similar among persons who had received vaccine compared with those who were unvaccinated (CDC, unpublished data, 2012).” ACIP, *Recommendations and Reports*, March 22, 2013 / 62(RR02);1-22, p 7 <http://www.cdc.gov/mmwr/pdf/rr/rr6202.pdf>

p-50 “The vaccine does not contain the B strain, which is the most common cause of *Neisseria meningitidis* in infants and may cause some cases in adolescents. Because the vaccines do not protect against all strains of meningitis, it is possible that someone could get the vaccine and get meningitis from a meningococcal strain not in the vaccine or from a non-meningococcal infection.”

From 2006 through 2012, 12 (**41%**) of the 29 reported cases (28 persons) 11-22 years of age group, were from serogroups not included in the vaccine. Five were vaccinated, including the only death.

P 50 “In pre-licensure studies, adolescents who received Menactra had a high seroconversion rate, around 98 percent. That means that 98 percent of adolescents who were immunized developed antibodies to the disease and were protected from disease. Since that time, studies have shown a decline in antibodies three to five years after vaccination.”

This was a pre-licensure study. Later the vaccine was found to be less effective.

“With respect to meningococcal conjugate vaccine effectiveness, last June a simulation model was presented to ACIP that modeled breakthrough disease to give a vaccine effectiveness for meningococcal conjugate vaccine. These data suggest the vaccine effectiveness of MenACWY to be 75% to 85%.”

[PDF] [Advisory Committee on Immunization Practices \(ACIP\)](#) DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR DISEASE CONTROL AND PREVENTION Advisory Committee on Immunization Practices (ACIP) Summary Report June 23-24, 2010 P 66 [Advisory Committee on Immunization Practices \(ACIP\)](#) <http://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/min-jun10.pdf>

p-51 “During the 2007 Minnesota legislative session, Senators Tarryl Clark and Sandy Pappas sent a letter to then Commissioner of Health Dianne Mandernach requesting that the Minnesota Immunization Practices Advisory Committee (MIPAC) review the need for meningococcal immunization in high school and college students. The report was completed in November 2007. At that time, the department did not recommend a meningococcal immunization requirement in either high school or college for several reasons: ...” “In the five years since the report, clinicians have incorporated the meningococcal vaccine into their practice and the vaccine is now routinely given to adolescents 12 to 18 year olds.”

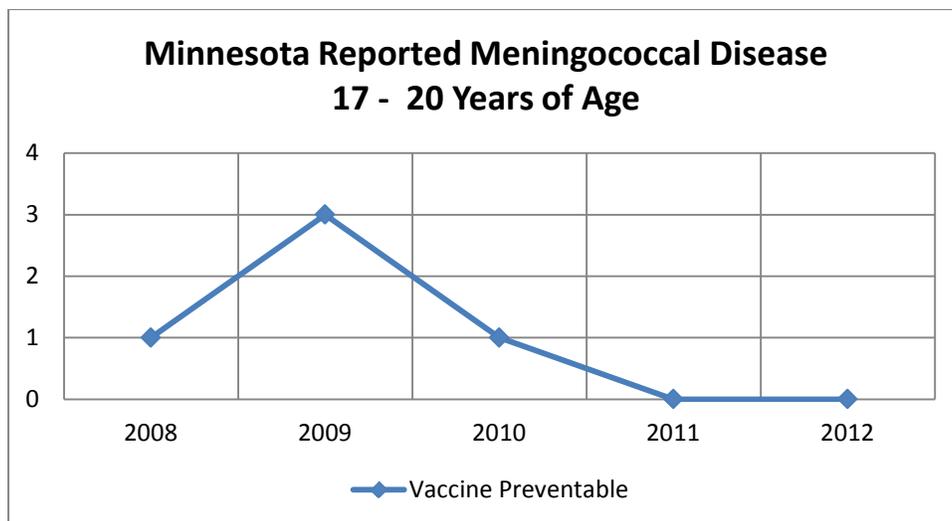
And the ACIP recommendation /By 2008, the goal will be routine vaccination with MCV4 of all adolescents beginning at age 11 years. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5407a1.htm>

Even though the vaccine was not required in 2008 for Minnesota’s 7th graders, Minnesota experienced a decline in the number of reported cases in the 11-22 years of age group. One contributing factor could have been that enough health clinicians incorporated the meningococcal vaccine into their practice and the vaccine is now routinely given to adolescents 12 to 18 year of age.

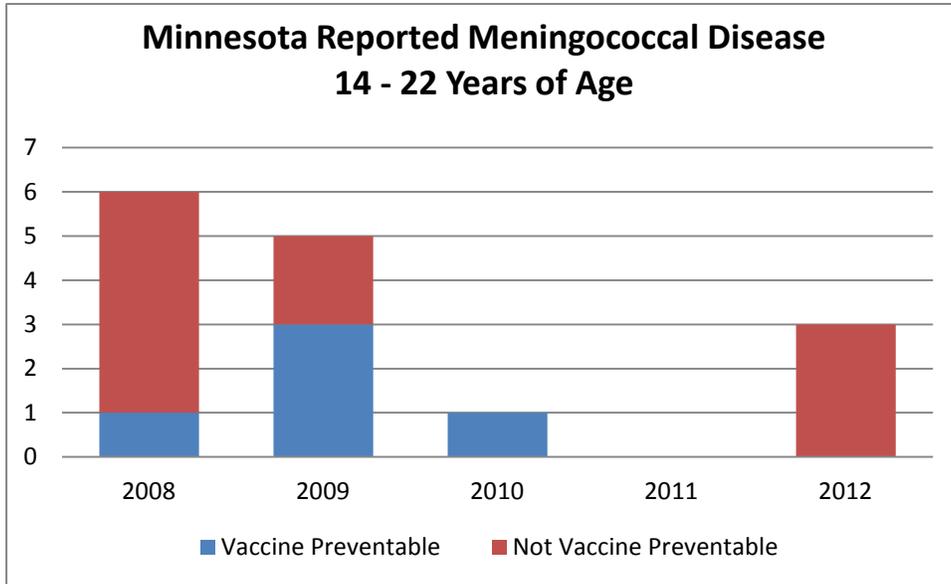
The meningococcal vaccine is already recommended (2 doses) on the Pupil Immunization Record.

<http://www.health.state.mn.us/divs/idepc/immunize/pupilimzrec.pdf>

The recommendation seems to be working; therefore there is no need to make the vaccine a requirement.

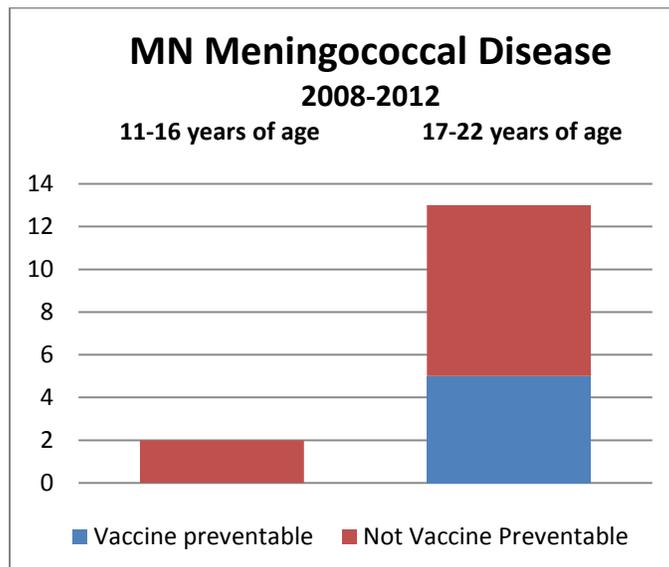


There were a total of 15 reported meningococcal disease cases in person 14 to 22 years of age from 2008 to 2012. Ten (68%) were not vaccine preventable because they were either vaccinated or a strain not found in vaccine. Requiring the meningococcal vaccine will not reduce the number of non-vaccine preventable cases but education could.



p-50 “2005, the ACIP determined that the benefit of meningococcal vaccination was worth the cost and recommended MCV4 in adolescents.” “A study conducted at the time of licensure in 2005 found that, considering only direct medical costs, routine vaccination of MCV4 was not cost-effective.” “...studies have shown a decline in antibodies three to five years after vaccination.”

If 7th graders were required to be vaccinated at 11-12 years of age they will need a booster dose at 16 years as recommended by the ACIP. The reason is that immunity from the required 11-12 year old vaccination has waned putting them in a theoretically higher risk group, 16-21 years of age. But in Minnesota, from 2008-2012, there has been no reported vaccine preventable meningococcal disease in children, 11-16 years of age.



The recommendation for two doses (off-label use/not approved by the FDA) was passed by the ACIP by one vote, 6 to 5 in favor of the booster. *"The reason for the no vote was "Do we really have enough money in the system to pay for that extra dose?" Dr Offit* Vaccine Education Center, Children's Hospital of Philadelphia <http://www.medscape.com/viewarticle/732947>

Federal and State taxes (Minnesota Vaccines for Children Program (MnVFC) - Minnesota Dept) or health insurance pays for children's vaccines. <http://www.health.state.mn.us/divs/idepc/immunize/mnvfc/index.html>

Insurance companies do not benefit if the vaccine is not cost effective for medical care.

Budgeting Tax money:

"COL Cieslak , DoD always follows ACIP recommendations. He expressed concern with this vaccine because it already is one of the more expensive vaccines. The last data he recalled was well in excess of \$30 million per death prevented. They could easily be talking about doubling that cost by adding the booster dose. Obviously, this would be a major cost to the taxpayer if they had to foot the bill for the entire DoD." ACIP Meeting June 2010

<http://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/min-jun10.pdf> p 72

P 46 *"Although adolescents are less likely to be infected than infants, disease incidence increases beginning around age 11 and reaches a secondary peak around age 19"*

Back in 2000, the risk of meningococcal disease in college students who lived in on-campus housing was three times higher than students who lived off campus and about twice as high as the general population of the same age. (*JAMA* 1999; 281:1906-10)

In 2003 Minnesota only required education about the disease and vaccine for post secondary education. Education seemed to be reasonable and necessary back then as it does today.

The 2003 Minnesota Statute required post-secondary educational institutions to provide information on the risk of meningococcal disease and the availability of an effective vaccine to each individual who is a first-time enrollee and resides in on-campus housing".

<http://www.health.state.mn.us/divs/idepc/immunize/laws/history.html>

"Summary – Meningococcal Vaccine

Since the rates of meningococcal disease, which can cause serious disability and death, rise among adolescents, and the meningococcal vaccine is highly effective in preventing the three strains of the disease that cause the most disease, the department believes requiring the meningococcal vaccine for all children in seventh through 12th grade is both reasonable and necessary."

2006-2012, Minnesota had no reported death that was vaccine preventable in **11-2 2 years of age group**.

Data presented to the ACIP suggested the vaccine effectiveness of meningococcal vaccine/ACWY to be 75% to 85%. The vaccine starts waning within 2-5 years.

2008-2012, two "vaccine" type strains did cause 8 of the 15 cases. But three (38%) of the 8 cases were vaccinated.

2008-2012, Only 5 (33%) of the 15 meningococcal disease cases in this age group were considered vaccine preventable.

It is not reasonable to require this vaccine in Minnesota because the number of reported cases is extremely small (none in the last two years) without any vaccine requirement.

Meningococcal Vaccine Injury

The proposed rule change to require the meningococcal vaccine for all children in seventh through 12th grade is not reasonable and it is not necessary.

Meningococcal disease may be a very serious disease but it is also rare in Minnesota for persons 11-22 years of age.

The vaccine can cause rare adverse effects after vaccination including very serious injuries.

The recommendation of this vaccine has resulted in a reduction of disease in this age group. But since the vaccine can cause permanent neurological injury, first do no harm, requiring the vaccine does not seem reasonable or needed.

National Vaccine Injury Compensation Program

Some of the National Vaccine Injury Compensation Program rulings include “Respondent (the government) denies injury/death was caused-in-fact by vaccination, Nonetheless, the parties agreed informally to resolve this matter ... usually when other causes were also ruled out.

Settlement dates, 2011-2013, National Vaccine Injury Compensation Program included persons who received vaccines, including meningococcal vaccine, and were compensated.

Vaccine Adverse Event Reporting System

The adverse events after Meningococcal vaccine may also include other vaccines. The adverse event may be coincidental or causal.

Found 157 events from Minnesota who were 11 to 21-years-of-age and received meningococcal vaccine (Menactra)

Found 61 events from Minnesota who were 11 to 21-years-of-age and received meningococcal vaccine (Menactra) and included ER or doctor office visits.

Found 7 events reported from Minnesota and were 11 to 21-years-of-age and received meningococcal vaccine (Menactra) and was hospitalized. Links and reports included on following pages

National Vaccine Injury Compensation Program

Many of the rulings include “Respondent (the government) denies injury/death was caused-in-fact by vaccination, Nonetheless, the parties agreed informally to resolve this matter ... usually when other causes were also ruled out.

Most of the cases were given multiple vaccines making it difficult to know which one or is it the combination of vaccines that contributed to the injuries.

Highlighted the diagnosed injuries in [green](#).

Definitions:

[Acute Disseminated Encephalomyelitis \(ADEM\)](#) is a rare inflammatory demyelinating disease of the central nervous system. ADEM is thought to be an autoimmune disorder in which the body's immune system mistakenly attacks its own brain tissue, triggered by an environmental stimulus in genetically susceptible individuals.

[brachial neuritis](#) sudden onset of shoulder weakness and pain, thought to be due to inflammation of the nerve roots in the cervical spine.

[CIDP](#) Chronic inflammatory demyelinating polyneuropathy, immune-mediated inflammatory disorder of the peripheral nervous system.

[acute transverse myelitis](#) inflammation of the spinal cord

[Hashimoto's Thyroiditis](#) immune system attacks thyroid gland resulting inflammation often leads to an underactive thyroid gland (hypothyroidism)

[Bell's palsy](#) sudden weakness in your facial muscles

[retinal vasculitis](#) Inflammation of the tiny blood vessels of the retina

[opsoclonus myoclonus](#) rare neurological disorder characterized by an unsteady, trembling gait, myoclonus (brief, shock-like muscle spasms), and opsoclonus (irregular, rapid eye movements). Other symptoms may include difficulty speaking, poorly articulated speech, or an inability to speak. A decrease in muscle tone, lethargy, irritability, and malaise (a vague feeling of bodily discomfort) may also be present.

[Guillain-Barre Syndrome](#) disorder in which your body's immune system attacks your nerves.

In 2011

[Stipulation; Human Papillomavirus vaccine \(HPV\); Hepatitis A Vaccine; meningococcal vaccine; Guillain-Barre Syndrome \(GBS\)](#) body's immune system attacks your nerves. KAITLYN ANN SMITH, December 29, 2011

[Damages; Decision Based on Proffer Meningococcal; GBS](#)

A lump sum payment of \$1,061,705.70 in the form of a check payable to petitioner, Ashly Whitener, representing compensation for life care expenses expected to be incurred during the first year after judgment (\$85,191.77), lost earnings (\$713,842.00), pain and suffering (\$229,163.70), and past unreimbursable expenses (\$33,508.23)., Dec 1, 2011

[Stipulation; tetanus-diphtheria-acellular pertussis; meningococcal conjugate; hepatitis A vaccine; brachial neuritis](#) Carlie Crowell , Nov 22, 2011

[Stipulation; Menactra vaccine; Guillain-Barre Syndrome](#) Jeremy S. Towne received Menactra on August 19, 2008, 07/28/2011

[Damages decision based on Stipulation; HPV Vaccine, Menactra Vaccine, GBS, CIDP.](#) Monica Freese received vaccine May, 2007; 07/08/11

[Stipulation; Influenza vaccine; Menactra; Guillain-Barré Syndrome](#) MALLORY MYERS received vaccine Oct 2008; 06/22/2011

[Damages Decision Based on Stipulation; Menactra, DTaP, Varivax vaccines, Guillain-Barre syndrome](#) W Torres received vaccine Sept 2008; June 14, 2011

[Joint Stipulation on Damages; Meningococcal Vaccine; Conversion Disorder](#) AMANDA FOSTER, June 1, 2011

[Damages Decision based on Stipulation; Meningococcal, HPV Vaccines, acute transverse myelitis](#) SARAH DAVIDSON received the vaccines on June 27, 2007.; April 27, 2011

In 2012:

[Stipulation; human papillomavirus \("HPV"\) vaccine; meningococcal \("Menactra"\) vaccine; gastrointestinal symptoms; muscle weakness; polyneuropathy; Guillain-Barré Syndrome \(GBS\)](#) MADELINE WUNDER, December 10, 2012

[Joint Stipulation on Damages; meningococcal vaccine; atypical fibromyalgia; trigeminal neuralgia.](#) AMY OWENS and RICK OWENS, parents and Natural Guardians of TASHA OWENS, November 21, 2012

[Damages decision based on stipulation; meningococcal vaccine; Hepatitis A vaccine; Varicella vaccine; Human Papillomavirus vaccine; Guillain-Barre syndrome; chronic headache](#) TANYA L. STEWART, as parent and natural guardian of A.A.S., 10/02/2012

[Joint Stipulation on Damages; Human Papillomavirus Vaccine; Meningococcal Vaccine; Varicella Vaccine; Hashimoto's Thyroiditis](#) ALLISON FLOOD 09/20/2012

[Damages; decision based on proffer; varicella, tetanus-diphtheria-acellular pertussis \(Tdap\) vaccine; meningococcal vaccine \(MCV\), hepatitis A.](#) KAITLYN E. AHOLT 06/18/2012 she experienced an episode of [syncope](#) immediately after receiving these vaccinations on July 15, 2012, which caused her to suffer various injuries to her face, jaw and teeth.

[Stipulation; meningococcal vaccine; transverse myelitis; multiple sclerosis](#) ERIN PATRICIA O'NEILL 06/12/2012 TX

Entitlement; [Acute Disseminating Encephalomyelitis; Tdap vaccine; Meningococcal vaccine](#) BRANDON KENNEDY 05/08/2012

A 16-year-old treated in Minnesota won compensation for a 2007, Tdap and/or meningococcal vaccinations, the cause of his Acute Disseminating Encephalomyelitis (ADEM) and related health problems. This was NOT reported to the passive reporting system Vaccine Adverse Event Reporting system even though this adolescent had adverse events after his vaccinations and was compensated for a vaccine injury.

[Reasonable basis; Menactra vaccine; varicella virus vaccine; Tetanus-diphtheria- acellular-pertussis \(Tdap\) vaccine; human papillomavirus \(HPV\) vaccine; herpetic stomatitis](#) inflammation, pain, or swelling in the mouth. KATHERINE McKELLAR January 13, 2012

[Decision by Stipulation; Influenza, Tdap and Meningococcal Vaccines; Transverse Myelitis](#) Peter Cieszewski . January 13, 2012

In 2013:

[Stipulation; Influenza; Meningococcal; Inactivated polio; DTaP; Hepatitis A; Hepatitis B; MMR; Splenic rupture](#) WILLIAM JEFFREY BISHOP 03/27/2013

[Stipulation; Meningococcal Vaccine; Neurological Injury](#) ALYSSA TIERNEY 05/23/2013

[Damages decision based on stipulation; tetanus-diphtheria-acellular pertussis vaccine; varicella vaccine; meningococcal vaccine; acute disseminated encephalomyelitis; Chiari malformation; optic neuritis](#) DOUGLAS FINLAY and CAMMIE FINLAY on behalf of their minor daughter GINA L. FINLAY May 13, 2013

[Stipulation; meningococcal vaccine; Bell's palsy; joint stiffness; myalgia; sensory neuropathy; retinal vasculitis.](#) Eric Hill received the meningococcal vaccine on June 18, 2010, 05/09/2013

[Damages decision based on stipulation; meningococcal vaccine; tetanus- diphtheria-acellular pertussis vaccine; acute disseminated encephalomyelitis](#) STEPHEN J. HUJARSKI May 6, 2013 was reported to VAERS, Ohio

[Decision by Stipulation; Human Papilloma Virus \(HPV\), DTaP and Meningococcal Vaccines; Pancreatitis and Blood Clots](#) SARAH GREGORY 04/16/2013

[Hepatitis A; Gardasil; Menactra; Influenza vaccines; Acute Disseminated Encephalomyelitis, Transverse Myelitis; Decision; Stipulation.](#) TIANA TOCIO March 28, 2013 was reported to VAERS/ Florida

[Stipulation; Influenza; Meningococcal; Inactivated polio; DTaP; Hepatitis A; Hepatitis B; MMR; Splenic rupture](#) WILLIAM JEFFREY BISHOP, March 27, 2013

[Decision by Stipulation; HPV, TDaP and meningococcal conjugate vaccinations; neurological injury, , and ataxia](#) LAURIE ROY, parent of Jamie Roy, a minor, January 11, 2013

New published decisions will be added periodically

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Vaccine Adverse Reporting System

The Meningococcal vaccine may be given with other vaccines. The adverse event(s) may be coincidental or causal. This is also a passive reporting system. Many serious adverse events, unknown percentage, may not have been reported. An example of possible underreporting is that only two of the five ADEM/meningococcal vaccine cases compensated by the National Vaccine Injury Compensation Program were found on the VAERS web site.

Found 13 ADEM cases that were reported to VAERS after the meningococcal vaccine, in the U.S., 11 to 18 years of age. Were any of the other 11 informed about the vaccine compensation program to rule out possible vaccine injury compensation?

<http://www.medalerts.org/vaersdb/findfield.php?EVENTS=on&PAGENO=2&PERPAGE=10&ESORT=NONE&REVERSE SORT=&VAX=%28MNQ%29&SYMPTOMS=%28Acute disseminated encephalomyelitis %2810000709%29%29>

There were 157 events reported from **Minnesota** and were 11 to 21-years-of-age and received meningococcal vaccine (Menactra)

<http://www.medalerts.org/vaersdb/findfield.php?EVENTS=on&PAGENO=2&PERPAGE=10&ESORT=NONE&REVERSESORT=&LOWAGE=%2811%29&HIGHAGE=%2822%29&WhichAge=range&STATE=%28MN%29&VAX=%28MNQ%29>

There were 61 events reported from **Minnesota** and were 11 to 21-years-of-age and received meningococcal vaccine (Menactra) and ER or doctor visit

http://www.medalerts.org/vaersdb/findfield.php?EVENTS=on&PAGENO=2&PERPAGE=10&ESORT=NONE&REVERSESORT=&LOWAGE=%2811%29&HIGHAGE=%2822%29&WhichAge=range&STATE=%28MN%29&VAX=%28MNQ%29&ER_VISIT=Yes

There were 7 events reported from **Minnesota** and were 11 to 21-years-of-age and received meningococcal vaccine (Menactra) and was hospitalized.

5 of the 7 reported cases:

12 yrs, 14 days after meningococcal vaccine - Write-up: Pt has developed encephalitis, based on MRI / clinical findings. He presented with changes in Mental Status, including seizure activity ~ 2 weeks after vaccine administration. Currently recovering in high dose Solumedrol and anti-epileptic meds (remain hospitalized).

18 yrs, 40 days after meningococcal vaccine -Write-up: Transferred to 2nd Hospital, from 1st hospital on 9/2/2011 with 3 day history of double vision, facial weakness, and paresthesias in right hand and both feet. She was admitted and continued to have progression of symptoms with difficulty walking and dysphagia and continuation of initial symptoms. She did not develop respiratory problems. At both hospitals studies were negative, but at 2nd she was treated with plasmapheresis and her symptoms improved. She was discharged 9/10/2011. She received PT here and at this time she has made remarkable progress. PT expects to discontinue therapy next week. She is able to run on a treadmill and lift weights, though her strength. (possible Guillain-Barre syndrome within 6 weeks)

18 yrs, 1 day after hep B, meningococcal and pneumonia vaccines - Write-up: Patient received Pneumovax at the clinic on 5/31/06. Developed redness and swelling at the injection site. Emergency room visits x 4 (given Rocephin x 2, Rx for Keflex and later Augmentin). Admitted to hospital on 6/4/06 for IV antibiotics, started on Clindamycin and Zosyn. Later Zosyn discontinued and Vancomycin initiated.

13 yrs, 1 day after hep B, meningococcal, and Tdap vaccines - Write-up: Pt developed severe headache w/ neck stiffness about one day after receiving vaccine--suspicious for meningitis, so hospitalized for one day (but with negative workup).

11 yrs, same day after meningococcal, Tdap, and pneumonia vaccines - Write-up: Pt developed shortness of breath, wheezing & flushing within minutes. He received EPIPEN, Prednisone, Albuterol & BENADRYL & was transported by ambulance to the ED. He developed petechiae on upper body.

Summary:

It does not seem reasonable nor is there a need to require the meningococcal vaccine in Minnesota when the vaccine is now already routinely given to adolescents 12 to 18 year of age by enough clinicians resulting in a reduction of reported cases. There has been no reported vaccine preventable case in 2011-2012. The last 2 of the 3 cases were vaccinated.

- The "requirement" on the school's vaccine form will be for 7th grade, 11-12 years of age. From 2006 through 2012 there have been no reported meningococcal disease cases in Minnesota children, 11-13 years of age.
- The meningococcal vaccine is already on the school immunization form under recommendation, 2 doses (the two doses is off label use, not FDA approved).
- Even though Minnesota statute requires that parents be informed of an exemption option, and that the exemption information must be on the same page as the requirement information, the MDH has put the exemption information on the back side of the form which at times has been omitted when copies (front side) were made for parents.
- Meningococcal disease is rare in the U.S., including Minnesota
- The bacteria is not easily transmittable.
- Vaccinating adolescents does not create herd protection in the community.
- The vaccine does not reduce the seriousness of the disease.
- Routine vaccination of Meningococcal vaccine (MCV4) is not cost-effective.
- Since 2008, 67% of the reported cases were either vaccine failures or were from a non-vaccine strain.
- Meningococcal disease may be a very serious disease but it is also very rare in Minnesota for 11-22 years of age group. There were no vaccine preventable cases in 2011-2012.
- The vaccine may rarely cause adverse effects after vaccination but it still could cause serious health injuries for some adolescents, as found in cases compensated by the [National Vaccine Injury Compensation Program](#). All drugs have side effects.
- A more reasonable approach is to educate parents and students about the disease and vaccine and allow them to make an informed vaccine decision.

This educational approach is already in place for Minnesota postsecondary educational institutions.

The 2003 Minnesota Statute required post-secondary educational institutions to provide information on the risk of meningococcal disease and the availability of an effective vaccine to each individual who is a first-time enrollee and resides in on-campus housing".

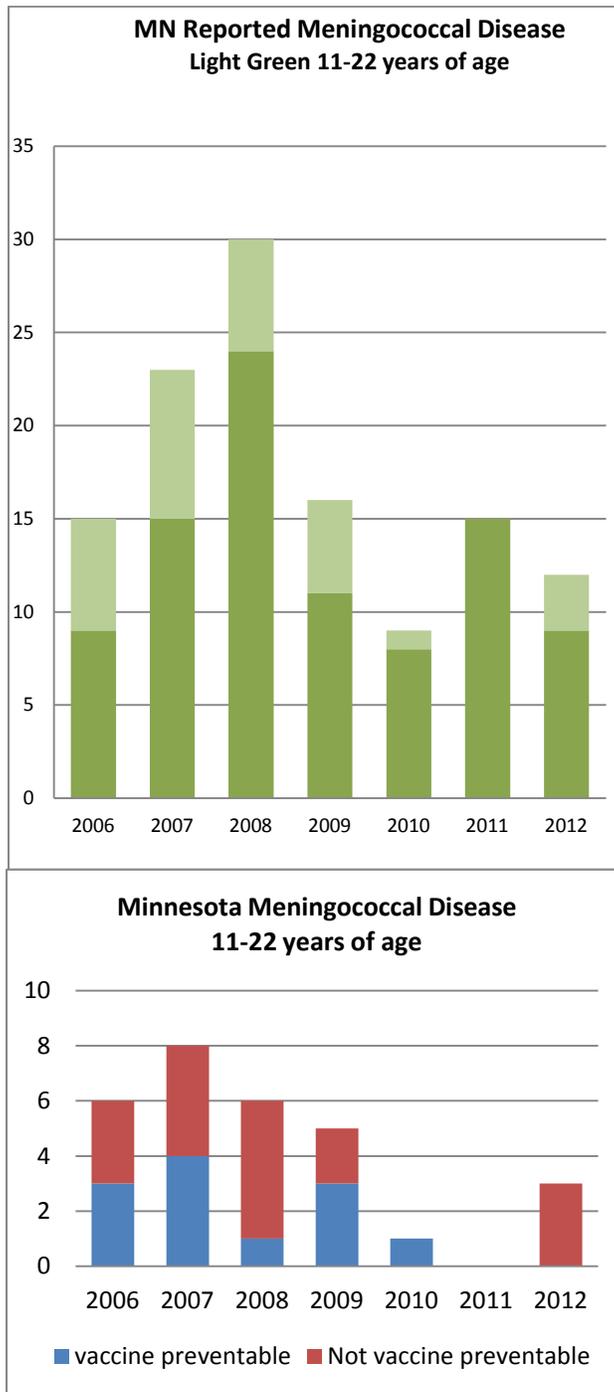
<http://www.health.state.mn.us/divs/idepc/immunize/laws/history.html>

Thank you,

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[Vaccine Awareness Minnesota](#)

FYI



Vaccine strains included C and Y and non-vaccine strain B.

2008 4- B(22,18,18, 14 yrs), 2- C/ 18 and 16 yrs (vaccinated) 13-17 years 38.9% vaccinated
 2009 1- B (22 yrs), 2-Y/both 17 yrs, 2-C/20 and 18 yrs (vaccinated) 13-17 years 43% vaccinated
 2010 1-Y/20 yrs 13-17 years 57% vaccinated
 2011 0 13-17 years 63% vaccinated
 2012 2-B/21(vaccinated) and 22-year-old, 1- Y/17yrs (vaccinated)