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Details:

(FORM UPDATED: 07/12/2010)

WISCONSIN STATE LEGISLATURE ...
PUBLIC HEARING - COMMITTEE RECORDS

2005-06

(session year)

Assembly

(Assembly, Senate or Joint)

Committee on ... Public Health
(AC-PH)

COMMITTEE NOTICES ...

- *Committee Reports* ... CR
- *Executive Sessions* ... ES
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- *Record of Comm. Proceedings* ... RCP

INFORMATION COLLECTED BY COMMITTEE FOR AND AGAINST PROPOSAL

- *Appointments* ... Appt
- *Clearinghouse Rules* ... CRule
- *Hearing Records* ... bills and resolutions
  (ab = Assembly Bill) (ar = Assembly Resolution) (ajr = Assembly Joint Resolution)
  (sb = Senate Bill) (sr = Senate Resolution) (sjr = Senate Joint Resolution)
- *Miscellaneous* ... Misc

Vote Record
Committee on Public Health

Date: 10/19/05
Moved by: Freese Seconded by: Underheim

AB 589 as amended SB _____ Clearinghouse Rule _____
AJR _____ SJR _____ Appointment _____
AR _____ SR _____ Other _____

A/S Amdt _____
A/S Amdt _____ to A/S Amdt _____
A/S Sub Amdt _____
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Be recommended for:
☒ Passage ☐ Adoption ☐ Confirmation ☐ Concurrence ☐ Indefinite Postponement
☐ Introduction ☐ Rejection ☐ Tabling ☐ Nonconcurrence

Committee Member	Aye	No	Absent	Not Voting
Representative J.A. Hines, Chair	☒	☐	☐	☐
Representative Gregg Underheim	☒	☐	☐	☐
Representative John Townsend	☒	☐	☐	☐
Representative Stephen Freese	☒	☐	☐	☐
Representative Terri McCormick	☒	☐	☐	☐
Representative Sheldon Wasserman	☒	☐	☐	☐
Representative Tamara Grigsby	☒	☐	☐	☐
Representative Charles Benedict	☒	☐	☐	☐
Totals:	8	0	____	____

☐ Motion Carried ☐ Motion Failed

Vote Record
Committee on Public Health

Date: 10/19/05

Moved by: Freese Seconded by: Wasserman

AB 589 SB _____ Clearinghouse Rule _____

AJR _____ SJR _____ Appointment _____

AR _____ SR _____ Other _____

A/S Amdt 1

A/S Amdt _____ to A/S Amdt _____

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Be recommended for:

☐ Passage ☒ Adoption ☐ Confirmation ☐ Concurrence ☐ Indefinite Postponement

☐ Introduction ☐ Rejection ☐ Tabling ☐ Nonconcurrence

Committee Member	Aye	No	Absent	Not Voting
Representative J.A. Hines, Chair	☒	☐	☐	☐
Representative Gregg Underheim	☒	☐	☐	☐
Representative John Townsend	☒	☐	☐	☐
Representative Stephen Freese	☒	☐	☐	☐
Representative Terri McCormick	☒	☐	☐	☐
Representative Sheldon Wasserman	☒	☐	☐	☐
Representative Tamara Grigsby	☒	☐	☐	☐
Representative Charles Benedict	☒	☐	☐	☐
Totals:	8	0	____	____

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Vote Record
Committee on Public Health

Date: 10/19/05

Moved by: Freese Seconded by: Underheim

AB 589 SB _____ Clearinghouse Rule _____

AJR _____ SJR _____ Appointment _____

AR _____ SR _____ Other _____

A/S Amdt 2

A/S Amdt _____ to A/S Amdt _____

A/S Sub Amdt _____

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Be recommended for:

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☐ Introduction ☐ Rejection ☐ Tabling ☐ Nonconcurrence

Committee Member	Aye	No	Absent	Not Voting
Representative J.A. Hines, Chair	☒	☐	☐	☐
Representative Gregg Underheim	☒	☐	☐	☐
Representative John Townsend	☒	☐	☐	☐
Representative Stephen Freese	☒	☐	☐	☐
Representative Terri McCormick	☒	☐	☐	☐
Representative Sheldon Wasserman	☒	☐	☐	☐
Representative Tamara Grigsby	☒	☐	☐	☐
Representative Charles Benedict	☒	☐	☐	☐
Totals:	8	0	____	____

☐ Motion Carried ☐ Motion Failed


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ANDY LAMB
STATE REPRESENTATIVE

September 7, 2005

Dear Chairman Hines and Public Health Committee Members,

Let me begin by apologizing for not being able to testify before the Public Health Committee in person today.

Thank you for your willingness to hear my testimony on Assembly Bill 589 and why it is such an important step in reducing the deaths caused by meningococcal disease. I greatly appreciate the opportunity to explain how we can help more effectively prevent the spread of this dangerous disease by combining technological advances and education.

It is my sincere hope that this testimony will help you realize how important it is for us to *Educate & Vaccinate.*

For more information on meningococcal disease please visit the Meningitis Foundation of America website at: http://www.musa.org/

Thanks again for hearing my testimony today. Please do not hesitate to contact me with any questions about AB 589 or meningococcal disease.

Sincerely,

Andy Lamb

Representative Andy Lamb
29th Assembly District

Post Office Box 8952 • Madison, WI 53708-8952
(608) 266-7683 • Toll-Free: (888) 529-0029 • Fax: (608) 282-3629 • Rep.Lamb@legis.state.wi.us
29th Assembly District: 1020 Elm Avenue West • Menomonie, WI 54751


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A QUALITY EDUCATION FOR EVERY CHILD

New Wisconsin Promise

State of Wisconsin Department of Public Instruction

Elizabeth Burmaster, State Superintendent

To: Assembly Committee on Public Health
From: Jennifer Kammerud, Legislative Liaison
Date: September 7, 2005
Re: 2005 Assembly Bill 589

The Department of Public Instruction is supportive of raising awareness among parents of meningococcal disease and the efforts to stop the spread of this terrible disease. There are, however, some issues we would like to point out concerning the implementation of Assembly Bill 589.

AB 589 would require the department to distribute information about meningococcal disease to schools in the state. Annually, each school board, private school, and charter school would be required to provide the information to the parents and guardians of students enrolled in grades 6 to 12.

The department is concerned about the practical effects of having schools distribute this type of health information when vaccinations are voluntary, there are questions about supply, and the information could be alarming. Schools, as the source of the information, may be the first place many parents will call for additional information and to share their concerns. Schools do not have the resources to provide this type of follow-up information and will not have the answers parents will be seeking to their health questions. As a result, the department feels other entities, such as local health departments, may be a better source of information as they would have the resources to answer the health questions parents will have.

Furthermore, it is the department's understanding that the meningococcal vaccine will be incorporated into the immunization schedule as a routinely recommended childhood vaccination by at least the 2006 schedule. Given this information, the department feels it would be prudent to provide information on this disease to parents when the vaccinations are part of the immunization schedule. This would allow school districts to treat the meningococcal vaccine in the same fashion as other required vaccinations.

Mailing Address: P.O. Box 7841, Madison, WI 53707-7841 • **Street Address:** 125 South Webster Street, Madison, WI 53702
Telephone: (608) 266-3390 • **Toll Free:** (800) 441-4563 • **FAX:** (608) 267-1052 • **TDD:** (608) 267-2427
Internet Address: www.dpi.state.wi.us


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MENINGOCOCCAL VACCINES

WHAT YOU NEED TO KNOW

1 What is meningococcal disease?

Meningococcal disease is a serious illness, caused by a bacteria. It is a leading cause of bacterial meningitis in children 2-18 years old in the United States.

Meningitis is an infection of fluid surrounding the brain and the spinal cord. Meningococcal disease also causes blood infections.

About 2,600 people get meningococcal disease each year in the U.S. 10-15% of these people die, in spite of treatment with antibiotics. Of those who live, another 11-19% lose their arms or legs, become deaf, have problems with their nervous systems, become mentally retarded, or suffer seizures or strokes.

Anyone can get meningococcal disease. But it is most common in infants less than one year of age and people with certain medical conditions, such as lack of a spleen. College freshmen who live in dormitories have an increased risk of getting meningococcal disease.

Meningococcal infections can be treated with drugs such as penicillin. Still, about 1 out of every ten people who get the disease dies from it, and many others are affected for life. This is why *preventing* the disease through use of meningococcal vaccine is important for people at highest risk.

2 Meningococcal vaccine

Two meningococcal vaccines are available in the U.S.:

- **Meningococcal polysaccharide vaccine (MPSV4)** has been available since the 1970s.
- **Meningococcal conjugate vaccine (MCV4)** was licensed in 2005.

Both vaccines can prevent **4 types** of meningococcal disease, including 2 of the 3 types most common in the United States and a type that causes epidemics in Africa. Meningococcal vaccines cannot prevent all types of the disease. But they do protect many people who might become sick if they didn't get the vaccine.

Both vaccines work well, and protect about 90% of those who get it. MCV4 is expected to give better, longer-lasting protection.

MCV4 should also be better at preventing the disease from spreading from person to person.

3 Who should get meningococcal vaccine and when?

MCV4 is recommended for all children at their routine preadolescent visit (11-12 years of age). For those who have never gotten MCV4 previously, a dose is recommended at high school entry.

Other adolescents who want to decrease their risk of meningococcal disease can also get the vaccine.

Meningococcal vaccine is also recommended for other people at increased risk for meningococcal disease:

- College freshmen living in dormitories.
- Microbiologists who are routinely exposed to meningococcal bacteria.
- U.S. military recruits.
- Anyone traveling to, or living in, a part of the world where meningococcal disease is common, such as parts of Africa.
- Anyone who has a damaged spleen, or whose spleen has been removed.
- Anyone who has terminal complement component deficiency (an immune system disorder).
- People who might have been exposed to meningitis during an outbreak.

MCV4 is the preferred vaccine for people 11-55 years of age in these risk groups, but MPSV4 can be used if MCV4 is not available. MPSV4 should be used for children 2-10 years old, and adults over 55, who are at risk.

How Many Doses?

People 2 years of age and older should get 1 dose. (Sometimes an additional dose is recommended for people who remain at high risk. Ask your provider.)

MPSV4 may be recommended for children 3 months to 2 years of age under special circumstances. These children should get 2 doses, 3 months apart.

4 Some people should not get meningococcal vaccine or should wait

- Anyone who has ever had a severe (life-threatening) **allergic reaction to a previous dose** of either meningococcal vaccine should not get another dose.
- Anyone who has a severe (life threatening) **allergy to any vaccine component** should not get the vaccine. Tell your doctor if you have any severe allergies.
- Anyone who is **moderately or severely ill** at the time the shot is scheduled should probably wait until they recover. Ask your doctor or nurse. People with a **mild illness** can usually get the vaccine.
- Meningococcal vaccines may be given to pregnant women. However, MCV4 is a new vaccine and has not been studied in pregnant women as much as MPSV4 has. It should be used only if clearly needed.
- Meningococcal vaccines may be given at the same time as other vaccines.

5 What are the risks from meningococcal vaccines?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of meningococcal vaccine causing serious harm, or death, is extremely small.

Mild problems

Up to about half of people who get meningococcal vaccines have mild side effects, such as redness or pain where the shot was given.

If these problems occur, they usually last for 1 or 2 days. They are more common after MCV4 than after MPSV4.

A small percentage of people who receive the vaccine develop a fever.

Severe problems

Serious allergic reactions, within a few minutes to a few hours of the shot, are very rare.

6 What if there is a moderate or severe reaction?

What should I look for?

- Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

  Or you can file this report through the VAERS web site at www.vaers.org, or by calling 1-800-822-7967.

  VAERS does not provide medical advice.

7 How can I learn more?

- Ask your doctor or nurse. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)**
  - Visit CDC's National Immunization Program website at **www.cdc.gov/nip**
  - Visit CDC's meningococcal disease website at **www.cdc.gov/ncidod/dbmd/diseaseinfo/meningococcal_g.htm**
  - Visit CDC's Travelers' Health website at **www.cdc.gov/travel**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL IMMUNIZATION PROGRAM


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A Look at Each Vaccine: Meningococcus Vaccine

Informaci en Espa...

A new meningococcal vaccine was licensed in early 2005.

Meningococcus is one of the most feared infectious diseases

About one in 20 children with meningitis caused by meningococcus and about one in three children with bloodstream infections (i.e., sepsis) caused by meningococcus will die from the infection. Death from sepsis can occur within 12 hours of the beginning of the illness — it is one of the most rapid and overwhelming infectious diseases known to man!

Learn mc choice to vaccine.

View mor

What is meningococcus?

The bacterium, *Neisseria meningitidis*, primarily targets children under 1 year of age. Because meningococcus is contagious, outbreaks can occur in childcare centers and schools. Cases also occur in high schools and on college campuses.

Meningococcus usually causes meningitis (inflammation of the lining of the brain) or sepsis (an infection of the bloodstream). Symptoms of meningitis include stiff neck, headache, fever and drowsiness. Symptoms of sepsis caused by meningococcus include fever, shock and coma. The disease is so unbelievably rapid, that a child can be perfectly well and, in a matter of only a few hours, be in a coma. For these reasons, meningococcal infections that occur in childcare centers, elementary schools or high schools often cause panic in the community. Every year about 2,500 people in the United States are infected with meningococcus and 300 die. Also, approximately 400 people every year who survive infection have permanent disabilities such as seizures, loss of limbs, kidney disease, deafness or mental retardation.

Consequences of meningococcal infection occur in about 12 percent of infections and include limb amputation, skin grafting, hearing loss, seizures, and mental retardation. About 10 percent of people infected with meningococcus will die from the disease. Immunization is the most effective way to reduce the incidence of death and permanent sequelae caused by meningococcus.

How do you catch meningococcal infection?

Usually meningococcal infection is acquired after intimate contact with an infected person. Intimate contact includes kissing, sharing food or beverages, or staying in the same house or room (including a classroom) for more than four hours a day.

How is the meningococcal vaccine made?

Meningococcus is similar to the pneumococcus and to *Haemophilus influenzae* type b (Hib) in that protection against disease occurs when one develops antibodies to the sugar (or polysaccharide) that coats the bacterium. A meningococcal vaccine, made using only the polysaccharide coating of meningococcus, has been available for several years. Unfortunately, children less than 2 years of age are not very good at making immune responses to the polysaccharide alone.

In order for young children to make an immune response, the polysaccharide must first be attached to a harmless protein. (see How Are Vaccines Made?). The new meningococcal vaccine licensed in early 2005 is made from these complex sugars. Polysaccharides have been stripped from the surface of four of the five different types of meningococcal bacteria that cause disease and each is linked (conjugated) to a harmless protein. The four conjugated polysaccharides are combined into a single shot.

Hib and pneumococcal vaccines have been easier to make than the meningococcal vaccine. The Hib vaccine was easier to make because there is only one type of *Haemophilus influenzae* that commonly causes severe disease in children (type b). The pneumococcal vaccine was easier to make than the meningococcal vaccine because, although there are about 90 different types of pneumococcus, most of the disease in children is caused by seven types. Therefore, the pneumococcal vaccine contains these seven different types of polysaccharides — each linked to a protein.

The problem with making a vaccine to protect against meningococcus is that, although there are only five different types of meningococcus that commonly cause disease (types A, B, C, Y and W-135), it has been very difficult to make a vaccine that includes type B and meningococcus type B accounts for a two-thirds of meningococcal infections in infants and one-third of meningococcal infections in adolescents and adults.

Who should get the meningococcal vaccine?

The meningococcal vaccine is recommended for:

- Adolescents entering middle school (11-12 year olds) or high school (15 years old)
    - Children and adults without a spleen
    - Children and adults who lack a particular group of serum proteins that help the body fight infection (called complement proteins)
    - College freshmen living in dormitories
    - People exposed to someone infected with meningococcus during an outbreak if the type of meningococcus is one contained in the vaccine (types A, C, Y or W-135)
    - Children and adults who will be travelling to sub-Saharan Africa between December and June

However, because everyone between 12 and 19 years of age is at risk for meningococcal disease, any teenager or young adult could reasonably choose to get the vaccine.

Does the meningococcal vaccine have side effects?

The current meningococcal vaccine may cause pain or tenderness where the shot is given. The vaccine does not have any serious side effects.

Should college students get the meningococcal vaccine?

The risk of meningococcal infection is highest in those less than 1 year of age,

and much lower in those between 4 and 15 years of age. At around 15 years of age the incidence of meningococcal disease again rises, although not nearly to the level that occurs in young children. So there is again an increased risk of meningococcal infection in adolescents and young adults. College freshmen that live in dormitories are five times more likely to get a meningococcal infection as compared with those who live off campus or don't attend college. Therefore, the new meningococcal vaccine is likely to be recommended for all college freshmen living in dormitories. Although adolescents and young adults are less likely than infants to be infected, they are more likely to die from disease.

One of the children in my child's school got meningitis. Should my child get the meningococcal vaccine, take antibiotics, or do neither?

First, try to find out what bacteria caused the meningitis. This usually takes about 48 hours from the time that the diagnosis was first made. Remember, bacteria such as pneumococcus and *Haemophilus influenzae* type b (Hib) can also cause meningitis. If the bacterium was meningococcus, find out from public health officials whether it really was an outbreak of meningococcus and whether the outbreak was caused by one of the types contained in the vaccine (specifically, types A, C, Y or W-135). If so, your child should receive the meningococcal vaccine.

In addition, antibiotics (such as rifampin, ceftriaxone or ciprofloxacin) should be used for all children who have come in close contact with someone who was infected. Close contact is defined as sharing a classroom for more than four hours a day, kissing or sharing food or beverages. Close contact in the week prior to the outbreak of meningococcus puts one at greatest risk of infection.

Do the benefits of the meningococcal vaccine outweigh its risks?

Each year about 2,600 people in the United States are infected with meningococcus and 300 die. About 400 survivors suffer permanent disabilities such as seizures, loss of limbs, kidney disease, deafness, or mental retardation. The meningococcus vaccine does not cause any severe reactions. Therefore, the benfits of this vaccine ourtweigh its risks.

COMMONWEALTH OF VIRGINIA
DEPARTMENT OF EDUCATION
P.O. BOX 2120
RICHMOND, VIRGINIA 23218-2120

SUPTS. MEMO NO. 47
August 12, 2005

Administrative

TO: Division Superintendents

FROM: Jo Lynne DeMary
Superintendent of Public Instruction

SUBJECT: Dissemination of Information Regarding Meningococcal Meningitis

Meningococcal disease is a rare, but potentially fatal, bacterial infection that can cause meningitis, a severe swelling of the brain and spinal cord or meningococcemia, a severe blood infection. Meningococcal disease is spread through air droplets and by direct contact with an infected person. Early symptoms may resemble the flu, making diagnosis difficult. The disease can progress very quickly, killing an otherwise healthy young person in 48 hours or less. More than 50 percent of meningococcal disease in the U. S. occurs in persons 11 years of age or older.

Ten to 14 percent of cases are fatal; however, among adolescents it can be as high as 22 percent. One in five of those who survive the disease will suffer a permanent disability that could include brain damage, limb amputations, or hearing loss. However, up to 83 percent of meningococcal infections among the ages of 15 and 24 are potentially vaccine-preventable.

In February 2005, the Centers for Disease Control (CDC) and Prevention's Advisory Committee on Immunization Practices (ACIP) issued new recommendations stating that children at pre-adolescence (11- to 12-year olds), adolescents entering high schools, and college freshmen living in dormitories should be immunized against meningococcal disease. In addition, ACIP's recommendations state that all other adolescents who wish to decrease their risk of meningococcal disease may elect to receive the vaccine.

School divisions are an important source of health information for parents and students. CDC has developed fact sheets on meningococcal disease and the vaccine, as well as a sample letter to parents, all of which are attached to this Superintendents' Memorandum. The Department of Education and the Department of Health highly recommend that this information be provided to all parents with the first day of school packets. For more information about meningococcal disease and immunization, visit the following Web sites:

www.cdc.gov/nip/vaccine/mening/mcv4/mcv4_acip.htm
www.meningococcaldisease.com
www.nmaus.org
www.sanofipasteur.us
www.nfid.org/ncai

Should you have questions, please contact Gwen P. Smith, school health specialist, in the Department of Education at 804-786-8671 or email at gwen.smith@doe.virginia.gov, or James Farrell, director of immunization at 804-864-8055 or email at james.farrell@vdh.virginia.gov.

JLD/gps

Attachments


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Meningococcal Disease Information

Q. What is meningococcal disease?

A. Meningococcal disease is caused by bacteria. Meningococcal disease can cause an infection of the covering of the brain and spinal cord (meningitis) or the blood. The bacteria can live in the membranes of the nose and throat, usually with no symptoms. In a small number of people, the bacteria pass to the blood, causing either a serious infection of the blood or meningitis.

Q. How is this germ spread?

A. The bacteria are spread from person to person by direct contact with an infected person's nose or throat secretions.

Q. What are the signs of being sick with this germ?

A. Illness often starts with a sudden fever, headache, stiff neck, a rash, and possibly nausea and vomiting. An infected person may be very sick within a few hours and should seek medical care immediately.

Q. Who is at highest risk for getting the disease?

A. Babies, children and young adults are most likely to get the disease. People living in crowded places are at higher risk for infection. Outbreaks usually do not occur in school or workplace settings.

Q. Can meningococcal disease be prevented?

A. Yes, the disease can be prevented by good hygiene. Cover nose and mouth when sneezing or coughing, throw used tissues away and wash hands often.

Q. What vaccines may prevent a child from getting this germ?

A. Two vaccines are available to prevent this infection:

Meningococcal Conjugate Vaccine (MCV4), which is *Menactra*

This vaccine is licensed in the U.S. for persons 11-55 years of age. It is likely that this vaccine or a similar vaccine will be licensed for younger age groups in the future. This vaccine is recommended for:

- Young adolescents at the pre-adolescent visit (11-12 years old)
- Adolescents at high school entry (about 15 years old)
- Groups that have a higher risk of meningococcal disease, such as students that will be college freshmen living in dormitories.

Meningococcal Polysaccharide Vaccine (MPSV4), which is *Menomune*

This vaccine is recommended for people who have an increased risk of disease due to certain medical conditions who are age 2-10 years and over 55 years. People at high risk need revaccination every 3-5 years.

For questions about meningococcal disease or vaccines to prevent meningococcal disease, please contact your physician or your local health department.

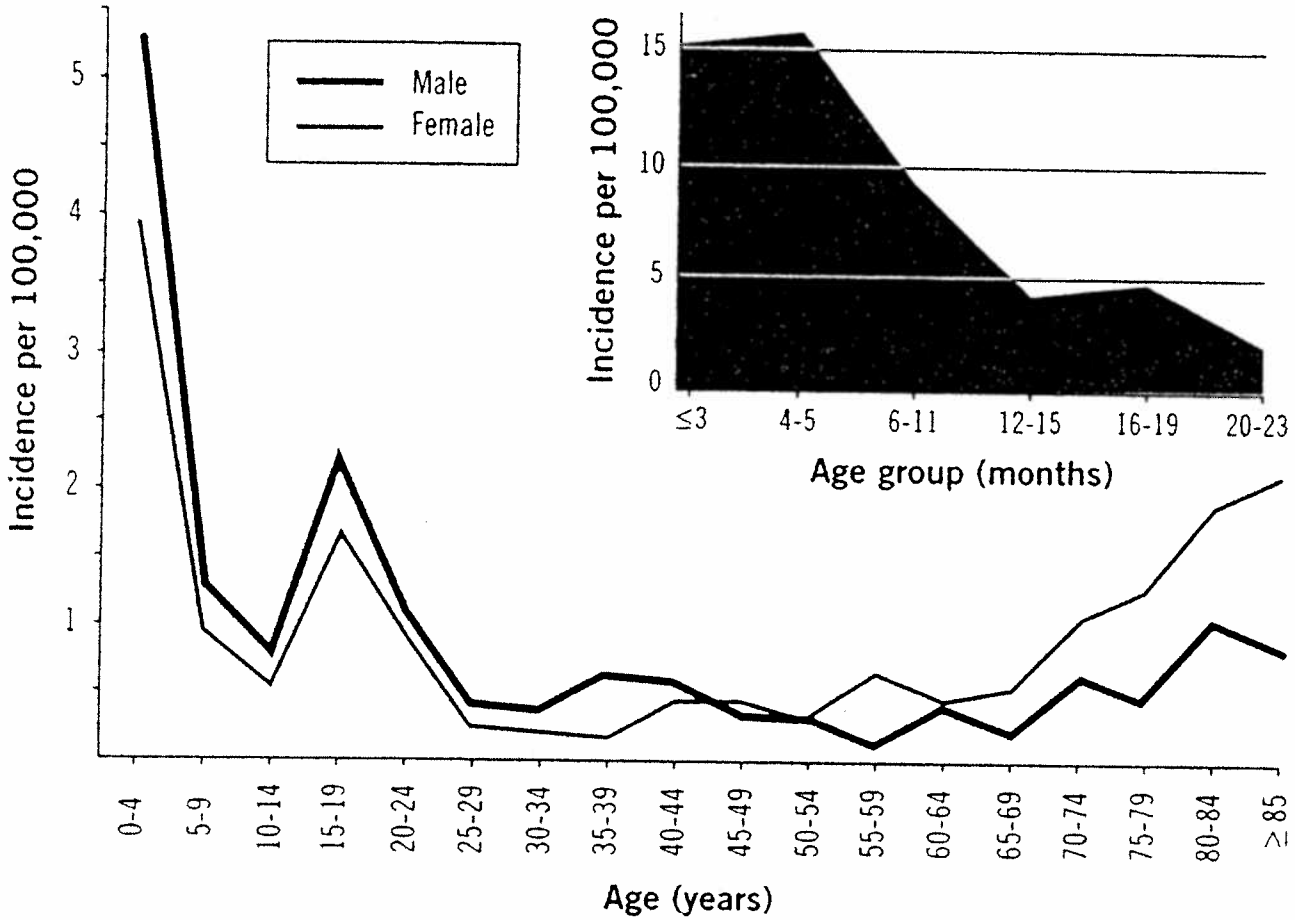
Additional information may be found at the following websites:

- http://www.in.gov/isdh/healthinfo/meningococcal%20disease.htm
- http://www.cdc.gov/nip/vaccine/mening/mening_fs.htm

Information supplied by the Indiana State Department of Health – SEA 326 - 2005
7/12/2005

Figure 1:

Invasive Meningococcal Disease by Age and Sex in the U.S., 1992-1996



Rates of meningococcal disease were adjusted for race.

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Source: Rosenstein[5]


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years indicate a background annual incidence of 1–2 cases per 100,000 person-years (CDC; Healthcare Utilization Project Nationwide Inpatient Sample; Agency for Healthcare Research and Quality, unpublished data, 1989–2001). This finding suggests that the rate of GBS based on the number of cases reported within 6 weeks of administration of MCV4 is similar to what might have been expected to occur by chance alone. However, the timing of the onset of neurologic symptoms (i.e., within 2–5 weeks of vaccination) is of concern. In addition, the extent of underreporting of GBS to VAERS is unknown; therefore, additional cases might be unreported (*5,6*).

Prelicensure studies conducted by Sanofi Pasteur of approximately 7,000 recipients of MCV4 revealed no GBS cases (*7*). CDC has conducted a rapid survey by using available VSD and other health-care–organization databases. No cases of GBS have been detected among nearly 110,000 MCV4 recipients represented in these databases. Data from two VSD sites indicated that 86%–97% of vaccine recipients had 6 weeks of follow-up via automated data collection. These data do not rule out an association between MCV4 and GBS.

During 1999–2005, a total of 30 million doses of three different meningococcal C conjugate vaccines (MenC), with either diphtheria CRM (nontoxic variant of diphtheria toxin) or tetanus toxoid as carrier proteins, have been used in the United Kingdom (UK) for persons aged <18 years. Five cases of GBS were reported in the UK after administration of MenC vaccines (UK Department of Health, unpublished data, 2005). This reported number of cases is lower than would have been expected to occur by chance in a population this age.

To date, evidence is insufficient to conclude that MCV4 causes GBS. An ongoing known risk for serious meningococcal disease exists. Therefore, CDC is recommending continuation of current vaccination strategies. Whether receipt of MCV4 vaccine might increase the risk for recurrence of GBS is unknown; avoiding vaccinating persons who are not at high risk for meningococcal disease and who are known to have experienced GBS previously is prudent.

FDA and CDC are alerting health-care providers to this preliminary information and are actively investigating the situation because of its potentially serious nature. The manufacturer has sent letters to health-care providers and is updating the package insert to reflect that GBS has been reported in association with the vaccine. CDC recommends that adolescents and their caregivers be informed of this ongoing investigation as part of the consent process for vaccination with Menactra.

FDA and CDC are requesting that providers or other persons with knowledge of possible cases of GBS (or other clinically significant adverse events) occurring after vaccination with MCV4 report them to VAERS. Reports of GBS should be submitted to VAERS at http://www.vaers.hhs.gov or by telephone at 800-822-7967. CDC further requests that health-care providers report other cases of GBS that occur among persons aged 11–19 years to state health departments in accordance with state or local disease-reporting guidelines. CDC suggests that state health departments consider enhancing surveillance for GBS in adolescents to assist in answering these critical questions. Cases of meningococcal disease should be reported to state health departments and, if available, information on vaccination status should be provided; isolates should be saved and sent to state health departments for serogroup identification.

References

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Guillain-Barré Syndrome Among Recipients of Menactra® Meningococcal Conjugate Vaccine — United States, June–July 2005

On January 14, 2005, a quadrivalent (A, C, Y, and W135) meningococcal conjugate vaccine (Meningococcal Polysaccharide Diphtheria Toxoid Conjugate Vaccine, Menactra®, Sanofi-Pasteur, Swiftwater, Pennsylvania) (MCV4) was licensed in the United States. MCV4 is a tetravalent vaccine; each 0.5-mL dose contains 4 μg each of capsular polysaccharide from *Neisseria meningitidis* serogroups A, C, Y, and W-135 conjugated to 48 μg of diphtheria toxoid. In February 2005, the Advisory Committee on Immunization Practices (ACIP) recommended routine vaccination of adolescents at the preadolescent health-care visit (at ages 11–12 years) (*1*). For persons who have not been vaccinated previously, ACIP recommended vaccination before high-school entry (at approximately age 15 years). Routine vaccination also is indicated for first-year college students living in dormitories and for other persons at increased risk.*

As of October 4, 2005,† the Vaccine Adverse Event Reporting System (VAERS) received five reports of Guillain-Barré syndrome (GBS) in persons after receipt of MCV4 vaccination. VAERS, operated by CDC and the Food and Drug Administration (FDA), is a national passive surveillance system that monitors the safety of vaccines (*2*). Health-care providers, state and local health departments, consumers, and vaccine manufacturers are encouraged to report adverse events involving all U.S.-licensed vaccines. All five persons had been vaccinated during June 10–July 25. This report describes the clinical and epidemiologic features of these five cases and summarizes preliminary data from ongoing studies.

Case Reports

Case 1. A male aged 18 years was vaccinated with MCV4; 15 days later, he experienced tingling in his feet and hands. He had no history of major underlying illness; his mother had had GBS 5 years earlier. He reported no history of respiratory or gastrointestinal illnesses during the 6 weeks before onset of symptoms. Sixteen days after vaccination, he was hospitalized, and nerve conduction studies (NCS) of upper and lower extremities, 2 days after onset of symptoms, were consistent with GBS. He was observed for 3 days, discharged, and then readmitted 2 days later with bilateral facial weakness and increasing lower extremity weakness. Patellar, triceps, and biceps deep tendon reflexes (DTRs) were absent. NCS performed 4 days after the previous examination revealed worsening motor nerve conduction velocities consistent with GBS. Tests for mononucleosis and Lyme disease were negative. During hospitalization, he was treated with plasmapheresis. His facial palsy and gait improved, and his reflexes returned. He was discharged home.

Case 2. A male aged 17 years was vaccinated with MCV4; approximately 25 days later, he had difficulty walking, followed by difficulty moving from a standing to a seated position. Medical history included attention deficit hyperactivity disorder and Asperger syndrome; he had been taking multiple psychotropic medications. He did not report recent respiratory or gastrointestinal illness. Thirty-two days after vaccination, he was hospitalized with bilateral muscle weakness of upper and lower extremities with absent DTRs. NCS was consistent with GBS. Cerebrospinal fluid (CSF) analysis revealed 2 white blood cells (WBC)/mm^3 with protein of 60 mg/dL; bacterial cultures were negative. DNA polymerase chain reaction (PCR) for adenovirus, herpes simplex virus types 1 and 2, varicella zoster virus, cytomegalovirus (CMV), and Epstein-Barr virus (EBV), and RNA PCR for West Nile virus, eastern equine encephalitis virus, St. Louis encephalitis virus, enterovirus, and California group and Cache Valley viruses, were all negative. During hospitalization, he was treated with intravenous immunoglobulin (IVIG). On discharge, his motor strength and gait were improved.

* Military recruits, travelers to areas in which meningococcal disease is hyperendemic or epidemic, microbiologists who are routinely exposed to isolates of *N. meningitidis*, patients with anatomic or functional asplenia, and patients with terminal complement deficiency

† A sixth report of a possible case was received on October 4 and is currently being investigated.

Case 3. A female aged 17 years was vaccinated with MCV4. She had a previous history of GBS at ages 2 and 5 years, both beginning 14 days after vaccination with childhood vaccines. She had not been previously vaccinated with meningococcal vaccine. Both episodes of GBS were characterized by muscle weakness, decreased reflexes, and difficulty walking. During both episodes, she was treated with intravenous immunoglobulin and completely recovered. Fourteen days after vaccination with MCV4, she reported numbness of toes and tongue and had a lump in her throat. These symptoms were followed by numbness of thighs and fingertips, arm weakness, inability to run, difficulty walking, and falling. Sixteen days after vaccination, she was hospitalized, and neurologic examination revealed decreased tone and weakness of both arms and legs and reflexes reduced or absent in ankles, knees, and arms. CSF results revealed 0 WBC/mm^3 and protein 26 mg/dL. She was treated with IVIG, recovered, and discharged home.

Case 4. A female aged 18 years was vaccinated with MCV4. Six days after vaccination, she had a sore throat that lasted for 6 days, and 29 days after vaccination she reported a severe headache and was evaluated in an emergency department (ED), where she had a normal computerized tomography (CT) scan, was treated with ketorolac, and discharged on oral ibuprofen. Thirty-one days after vaccination, the patient reported numbness of legs and had trouble standing on her toes. The next morning she could not stand. The patient was admitted to the hospital, and physical examination revealed decreased muscle strength in ankles and wrists bilaterally and reduced biceps, knee, and ankle DTRs. Previous medical history included mild ulcerative colitis that had been asymptomatic off medications; she did not report having diarrhea during the 6 weeks before onset of muscle weakness. Her only outpatient medications were oral contraceptives. CSF analysis revealed 1 WBC/mm^3 and a protein concentration of 30 mg/dL. NCS was consistent with GBS. She was treated with IVIG. After a 7-day hospitalization, her motor strength had improved, and she was discharged home with outpatient physical therapy. Three weeks after discharge, her weakness and gait were improved.

Case 5. A female aged 18 years was vaccinated with MCV4; 14 days later, she experienced heaviness in her legs when walking upstairs. During the next 8 days, her difficulty walking continued, and she had bilateral leg pain. Subsequently, she reported headache, back and neck pain, vomiting, and tingling in both hands. She became unable to walk and was evaluated in an ED, where an initial diagnosis of viral meningitis was made. Two days later, she was hospitalized for progressive weakness and inability to walk. Neurologic examination revealed bilateral acute flaccid weakness with decreased DTRs.

The woman had traveled to Portugal during the week before onset of symptoms and had a history of seasonal allergies and sinusitis, but she reported no history of respiratory, gastrointestinal, or other febrile illnesses during the 3 months before onset. CSF examination revealed 5 WBC/mm^3 and protein concentration of 177 mg/dL. Viral and bacterial cultures of CSF were negative. EBV IgM, CMV IgM, ELISA serology for Lyme disease, and serologic testing for syphilis were all negative. Electrodiagnostic studies were consistent with GBS. Treatment included plasmapheresis and IVIG. Weakness progressed to include paralysis of arms, difficulty swallowing, and respiratory compromise. She required intubation for 1 week. She was discharged to a rehabilitation facility, and 53 days after onset, she had recovered the ability to talk, feed herself, sit, and stand.

Case Summary

All reported GBS cases occurred among persons aged 17–18 years who were vaccinated during June 10–July 25 and had symptom onset 14–31 days after MCV4 vaccination. On the basis of information obtained to date, one patient reported another acute illness before onset of neurologic symptoms. The five patients described in this report received vaccine from four different lots. These cases were reported from Pennsylvania (two), New York, Ohio, and New Jersey (one case each).

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Editorial Note: GBS is a serious neurologic disorder involving inflammatory demyelination of peripheral nerves (*3*). It can occur spontaneously or after certain antecedent events such as infections. Illness is typically characterized by the subacute onset of progressive, symmetrical weakness in the legs and arms, with loss of reflexes. Sensory abnormalities, involvement of cranial nerves, and paralysis of respiratory muscles also can occur. A small proportion of patients die, and 20% of hospitalized patients can have prolonged disability. *Campylobacter jejuni*, which causes bacterial gastroenteritis, especially in young adults and during the summer months, is one identified precipitating factor for GBS.

Approximately 2.5 million doses of MCV4 have been distributed nationally since March 2005 (Sanofi-Pasteur, unpublished data, 2005). The number of exact vaccine doses administered is unknown. The precise rate of GBS also is unknown. Data from the Vaccine Safety Datalink (VSD), a collaborative project between CDC and eight managed care organizations in the United States (*4*), and the Health Care Utilization Project on GBS incidence in persons aged 11–19