

Missouri Department of Health and Senior Services

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Peter Lyskowski Acting Director

Jeremiah W. (Jay) Nixon Governor

August 10, 2016

Dear Administrator/Superintendent:

The Missouri Department of Health and Senior Services urges all public and private high schools, colleges and universities in Missouri to provide information to all students and parents about meningococcal disease. Meningitis is a rare but potentially life-threatening disease. Teenagers and young adults are at increased risk of getting meningococcal disease.

Effective beginning the 2016-2017 school year, the following **new** requirement will be implemented for all children enrolled in Missouri public, private, and parochial or parish schools:

• Meningococcal conjugate vaccine will be required for all incoming eighth (8th) grade students. All incoming twelfth (12th) grade students will be required to have two doses of Meningococcal conjugate vaccine, unless the first dose was administered to a student who was 16 years of age or older, in which case only one dose shall be required.

The Bureau of Immunizations has developed an informational fact sheet titled *Meningococcal Disease:* What You Need to Know. The fact sheet provides information regarding the disease, symptoms, treatment, risks, available vaccinations, and CDC recommendations.

Enclosed are the fact sheet and the Vaccine Information Statements offering information on Meningococcal ACWY and Meningococcal B vaccines. The fact sheet is available for ordering or self-printing on the Bureau of Immunizations website at

http://health.mo.gov/living/wellness/immunizations/pdf/MCVFactSheet.pdf.

The Missouri Department of Health and Senior Services' Bureau of Immunizations is committed to working with all public and private high schools, colleges and universities in Missouri to answer any questions or provide additional resources that you can share with students and parents.

For additional information, please contact Lana Hudanick at 314.982.8260 or Lynelle Paro at 573.526.7659.

Sincerely,

Cathy Sullivan, Chief

Enclosures

www.health.mo.gov



VACCINE INFORMATION STATEMENT

Meningococcal ACWY Vaccines—MenACWY and MPSV4: What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de Información Sobre Vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Meningococcal disease is a serious illness caused by a type of bacteria called *Neisseria meningitidis*. It can lead to meningitis (infection of the lining of the brain and spinal cord) and infections of the blood. Meningococcal disease often occurs without warning—even among people who are otherwise healthy.

Meningococcal disease can spread from person to person through close contact (coughing or kissing) or lengthy contact, especially among people living in the same household.

There are at least 12 types of *N. meningitidis*, called "serogroups." Serogroups A, B, C, W, and Y cause most meningococcal disease.

Anyone can get meningococcal disease but certain people are at increased risk, including:

- · Infants younger than one year old
- Adolescents and young adults 16 through 23 years old
- People with certain medical conditions that affect the immune system
- Microbiologists who routinely work with isolates of N. meningitidis
- People at risk because of an outbreak in their community

Even when it is treated, meningococcal disease kills 10 to 15 infected people out of 100. And of those who survive, about 10 to 20 out of every 100 will suffer disabilities such as hearing loss, brain damage, kidney damage, amputations, nervous system problems, or severe scars from skin grafts.

Meningococcal ACWY vaccines can help prevent meningococcal disease caused by serogroups A, C, W, and Y. A different meningococcal vaccine is available to help protect against serogroup B.

Meningococcal ACWY Vaccines

2

There are two kinds of meningococcal vaccines licensed by the Food and Drug Administration (FDA) for protection against serogroups A, C, W, and Y: meningococcal conjugate vaccine (MenACWY) and meningococcal polysaccharide vaccine (MPSV4).

Two doses of MenACWY are routinely recommended for adolescents 11 through 18 years old: the first dose at 11 or 12 years old, with a booster dose at age 16. Some adolescents, including those with HIV, should get additional doses. Ask your health care provider for more information.

In addition to routine vaccination for adolescents, MenACWY vaccine is also recommended for certain groups of people:

- People at risk because of a serogroup A, C, W, or Y meningococcal disease outbreak
- · Anyone whose spleen is damaged or has been removed
- Anyone with a rare immune system condition called "persistent complement component deficiency"
- Anyone taking a drug called eculizumab (also called Soliris®)
- Microbiologists who routinely work with isolates of N. meningitidis
- Anyone traveling to, or living in, a part of the world where meningococcal disease is common, such as parts of Africa
- · College freshmen living in dormitories
- · U.S. military recruits

Children between 2 and 23 months old, and people with certain medical conditions need multiple doses for adequate protection. Ask your health care provider about the number and timing of doses, and the need for booster doses.

MenACWY is the preferred vaccine for people in these groups who are 2 months through 55 years old, have received MenACWY previously, or anticipate requiring multiple doses.

MPSV4 is recommended for adults older than 55 who anticipate requiring only a single dose (travelers, or during community outbreaks).



3

Some people should not get this vaccine

Tell the person who is giving you the vaccine:

· If you have any severe, life-threatening allergies.

If you have ever had a life-threatening allergic reaction after a previous dose of meningococcal ACWY vaccine, or if you have a severe allergy to any part of this vaccine, you should not get this vaccine. Your provider can tell you about the vaccine's ingredients.

· If you are pregnant or breastfeeding.

There is not very much information about the potential risks of this vaccine for a pregnant woman or breastfeeding mother. It should be used during pregnancy only if clearly needed.

If you have a mild illness, such as a cold, you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.

4

Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own within a few days, but serious reactions are also possible.

As many as half of the people who get meningococcal ACWY vaccine have **mild problems** following vaccination, such as redness or soreness where the shot was given. If these problems occur, they usually last for 1 or 2 days. They are more common after MenACWY than after MPSV4.

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

Problems that could happen after any injected vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction.
 Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

5

What if there is a serious reaction?

What should I look for?

 Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness—usually within a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 and get to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the "Vaccine Adverse Event Reporting System" (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not give medical advice.

6

The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

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How can I learn more?

- Ask your health care provider. He or she 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) or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement Meningococcal ACWY Vaccines

03/31/2016

42 U.S.C. § 300aa-26



VACCINE INFORMATION STATEMENT

Serogroup B Meningococcal Vaccine (MenB): What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

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1 Why get vaccinated?

Meningococcal disease is a serious illness caused by a type of bacteria called *Neisseria meningitidis*. It can lead to meningitis (infection of the lining of the brain and spinal cord) and bacteremia or septicemia (infections of the blood). Meningococcal disease often strikes without warning—even people who are otherwise healthy.

Meningococcal disease can spread from person to person through close contact (coughing or kissing) or lengthy contact, especially among people living in the same household.

There are at least 12 types of *Neisseria meningitidis*, called "serogroups." Serogroups A, B, C, W, and Y cause most meningococcal disease.

Anyone can get meningococcal disease but certain people are at increased risk, including:

· Infants less than one year old

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- · Adolescents and young adults 16 through 23 years old
- People with certain medical conditions that affect the immune system
- Microbiologists who routinely work with isolates of N. meningitidis
- People at risk because of an outbreak in their community

Even when it is treated, meningococcal disease kills 10 to 15 infected people out of 100. And of those who survive, about 10 to 20 out of every 100 will suffer disabilities such as hearing loss, brain damage, amputations, nervous system problems, or severe scars from skin grafts.

Serogroup B meningococcal (MenB) vaccine can help prevent meningococcal disease caused by serogroup B. Other meningococcal vaccines are recommended to help protect against serogroups A, C, W, and Y.

Serogroup B Meningococcal Vaccines

Two serogroup B meningococcal vaccines have been licensed by the Food and Drug Administration.

These vaccines are recommended routinely for people 10 years or older who are at increased risk for serogroup B meningococcal infections, including:

 People at risk because of a serogroup B meningococcal disease outbreak

- · Anyone whose spleen is damaged or has been removed
- Anyone with a rare immune system condition called "persistent complement component deficiency"
- Anyone taking a drug called eculizumab (also called Soliris®)
- Microbiologists who routinely work with N. meningitidis isolates

These vaccines may also be given to anyone 16 through 23 years old to provide short term protection against most strains of serogroup B meningococcal disease; 16 through 18 years are the preferred ages for vaccination.

The recommended schedule depends on which vaccine you get:

- Bexsero® is given as 2 doses, at least 1 month apart.
 or
- Trumenba® is given as 3 doses, with the second dose 2 months after the first and the third dose 6 months after the first.

The same vaccine must be used for all doses.

3 Some people should not get these vaccines

Tell the person who is giving you the vaccine:

- If you have any severe, life-threatening allergies. If you have ever had a life-threatening allergic reaction after a previous dose of serogroup B meningococcal vaccine, or if you have a severe allergy to any part of this vaccine, you should not get the vaccine. Tell your healthcare provider if you have any severe allergies that you know of, including a severe allergy to latex. He or she can tell you about the vaccine's ingredients.
- If you are pregnant or breastfeeding.

 There is not very much information about the potential risks of this vaccine for a pregnant woman or breastfeeding mother. It should be used during pregnancy only if clearly needed.
- If you are not feeling well.
 It is usually okay to get this vaccine when you have a mild illness, but you might be advised to come back when you feel better.



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Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of reactions. These are usually mild and go away on their own within a few days, but serious reactions are also possible.

More than half of the people who get serogroup B meningococcal vaccine have **mild problems** following vaccination. These reactions can last up to 3 to 7 days, and include:

- Soreness, redness, or swelling where the shot was given
- · Tiredness or fatigue
- · Headache
- Muscle or joint pain
- · Fever or chills
- · Nausea or diarrhea

Problems that could happen after any injected vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
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What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 and get to the nearest hospital. Otherwise, call your doctor.
- Reactions should be reported to the "Vaccine Adverse Event Reporting System" (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

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7 How can I learn more?

- Ask your healthcare provider. He or she 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) or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement (Interim)
Serogroup B Meningococcal Vaccine

08/14/2015

42 U.S.C. § 300aa-26





What is meningococcal disease?

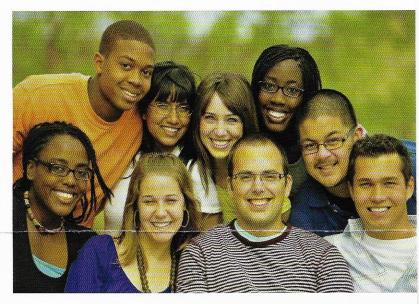
Meningococcal disease is an infection caused by the bacterium *Neisseria meningitidis* that can affect the blood stream, brain and spinal cord. There are thirteen different serogroups of *Neisseria meningitidis* that can cause disease, five of which cause the most disease in the United States. Meningococcal disease is the leading cause of bacterial meningitis in the United States.

About 1,000 people get meningococcal disease each year in the United States. Although meningococcal disease is somewhat rare, 10 to 14 percent of infected people die from the disease. In instances where it is not fatal, it can lead to permanent brain damage, loss of hearing, loss of arms and legs and potentially lifelong disability.

Although anyone can contract meningococcal disease, it is most common in infants less than one year of age, in adolescents 16 to 21 years of age and in people with certain medical conditions, such as the lack of a spleen. Adolescents and young adults have an increased incidence of disease, accounting for nearly 15 percent of all United States cases. College students are susceptible to meningococcal disease because they live in close quarters and often share food, drink and cosmetics.

What are the symptoms of meningococcal disease?

The symptoms of meningococcal disease may include high fever, chills, nausea, exhaustion and a rash. Early symptoms of meningococcal disease can be mistaken for influenza. An infected person may become seriously ill very quickly. If any of these symptoms are unusually sudden or severe, seek medical attention immediately.



How is meningococcal disease diagnosed?

Meningococcal disease is diagnosed by taking blood and spinal fluid samples from a person who is possibly infected. The medical laboratory will grow and identify the bacteria in culture to give a confirming diagnosis.

Antibiotics can be used to treat meningococcal infections and reduce the risk of death, but sometimes the infection has caused too much damage to the body for antibiotics to prevent death or serious long-term disabilities.

How does meningococcal disease spread?

Meningococcal disease is spread person-to-person through exchange of respiratory and throat secretions. Kissing, sharing drinking glasses, food or eating utensils, sharing a cigarette or lipstick, coughing and having close social contact (living in the same household) are examples of how this disease spreads.

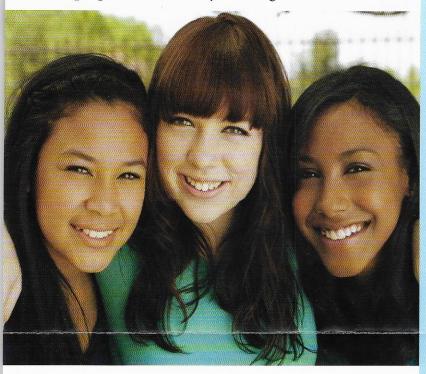
How can you reduce the risk for getting meningococcal disease?

The best way to reduce the risk of getting meningococcal disease is through immunization. Other ways to reduce the risk of meningococcal disease are to avoid sharing items that have touched someone's mouth such as cups, bottles, food, cosmetics and smoking materials.

What is the meningococcal vaccine?

There are three kinds of meningococcal vaccine available in the United States:

- Meningococcal conjugate vaccine (MCV4)
 protects against A, C, Y and W-135 serogroups
 and is the preferred vaccine for people 9 months
 through 55 years of age.
- Meningococcal Serogroup B vaccine (MenB)
 protects against serogroup B and is for people
 without high risk conditions 16 through 23 years
 of age.
- Meningococcal polysaccharide vaccine (MPSV4)
 protects against serogroup A, C, Y and W and
 is the only meningococcal vaccine licensed for
 people older than 55 years of age.



Who should get the meningococcal vaccine?

The Centers for Disease Control and Prevention (CDC) recommends two doses of MCV4 for adolescents.

- The first dose at 11 or 12 years old, with a booster dose at 16.
- For those who receive the first dose at 13 through 15 years of age, a booster dose is recommended at 16 through 18.
- For those who receive the first dose after 16, no booster dose is needed.

CDC recommends MCV4 or MPSV4 for:

- Individuals who have a damaged spleen, whose spleen has been removed or who have sickle cell disease.
- Individuals who are traveling to countries in which meningococcal disease is epidemic.
- Individuals who are at an increased risk of a meningococcal A, C, Y and W-135 disease due to an outbreak.

CDC recommends MenB vaccine for:

- Individuals who are at an increased risk because of a meningococcal serogroup B disease outbreak.
- Individuals who have a damaged spleen, whose spleen has been removed or who have sickle cell disease.
- Individuals who are 16 through 23 years without high risk conditions.

How effective is the recommended meningococcal vaccine?

MCV4 vaccines are 85 percent effective in protecting against four of the five major strains of the bacteria responsible for meningococcal disease.

HAVE QUESTIONS?

Individuals who have questions or concerns about meningococcal disease should contact their health care provider.

Children may be eligible to receive free vaccines through the Vaccines for Children program before their 19th birthday. Contact the Missouri Department of Health and Senior Services or your local public health agency to find out if your child is eligible.

