



Meningococcal B Vaccine

Are you discussing
this with your 16 to 23
year old patients?

Ellen Link, MD

In October 2015, the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices recommended that adolescents and young adults ages 16 to 23 years old might be vaccinated with serogroup B meningococcal vaccine based on individual clinical decision making (Category B recommendation). A recent article published in *Pediatrics* found that during routine visits, 51 percent of pediatricians and 31 percent of family practitioners reported always or often discussing the MenB vaccine with their patients. Among those who discussed the topic often or always, 91 percent recommended the vaccination; among those who never or rarely discussed the vaccine, 11 percent recommended it.¹

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The study was a survey done between October and December 2016 among pediatricians and family physicians who were part of sentinel networks within each specialty. An additional finding was that those somewhat or not at all aware of the MenB vaccine and those practicing in a health maintenance organization were less likely to recommend the vaccine, whereas those aware of disease outbreaks in their state were more likely to discuss MenB vaccine with their patients. The authors concluded that primary care physicians have significant gaps in knowledge about MenB disease and the MenB vaccine, and this appears to be a major driver of the decision not to discuss the vaccine.

Meningococcal disease presents clinically as meningitis (fever, headache, and stiff neck), and sepsis and rash in meningococcemia. *Neisseria meningitidis* serogroups B, C, and Y cause the majority of disease in the United States and serogroup W causes a small portion of disease. Serogroup A causes disease in developing countries. Rates of meningococcal disease have been declining in the United States since the 1990s. Rates of disease are highest in children younger than one year with a second peak in adolescence.²

Significant sequelae are associated with *Neisseria meningitidis* infections. Ten to 15 people out of 100 infected with meningococcal disease will die. About 11 to 19 survivors out of every 100 will have long-term disabilities, including loss of limb, deafness, neurologic problems, or brain damage. The disease is spread by exchanging respiratory and throat secretions during close or lengthy contact, especially if living in the same household.²

In February 2015, the Advisory Committee on Immunization Practices (ACIP) of the CDC recommended the routine use of MenB vaccines in persons 10 years and older at increased risk of the disease (Category A recommendation). In June 2015 the ACIP stated that healthy adolescents and young adults 16 to 23 years of age (preferred ages, 16 to 18) who are not at increased risk of serogroup B meningococcal disease may be considered for vaccination with a MenB vaccine. This provides short-term protection against most strains of serogroup B meningococcal disease (the Category B recommendation), but routine immunization is not recommended.



In September 2016 the American Academy of Pediatrics (AAP) issued a policy statement regarding Meningitis B Vaccine Recommendations.³ They noted that there were two serogroup B meningococcal vaccines available, MenB-FHbp (Trumenba) and MenB-4C (Bexsero). Both are licensed for use in persons 10 to 25 years of age. Trumenba is administered as a 3-dose series for those at increased risk of meningococcal B disease and as a 2-dose series for those not at increased risk. Bexsero is administered as a 2-dose series for all groups. The first dose of Bexsero should be administered at day 0, and the second dose should be administered ≥ 1 month later; the 3-dose series of Trumenba should be administered on a 0-, 1- to 2-, and 6-month schedule. The table below from the policy statement highlights the high-risk recommendations.

TABLE 1**Increased Risk Groups Recommended for the Different Meningococcal Vaccines**

MenACWY	MenB
Complement deficiency ^a	Complement deficiency ^a
Anatomic/functional asplenia ^b	Anatomic/functional asplenia ^b
Outbreak ^c	Outbreak ^c
Microbiologists ^d	Microbiologists ^d
Travelers ^e	
First-year college students ^f	
Military recruits	

↪^a Inherited or chronic deficiencies of C3, C5–C9, properdin, factor D, or factor H or those receiving eculizumab

↪^b Includes sickle cell disease

↪^c The CDC defines outbreaks and those at risk

↪^d Only microbiologists who routinely work with *N meningitidis*

↪^e To areas with hyperendemic or epidemic meningococcal disease

↪^f Unvaccinated or inadequately vaccinated first-year college students who live in residence halls

The policy statement notes that meningococcal disease caused by any serogroup in the U.S. is rare, but can be life threatening. Despite recent outbreaks on college campuses, the incidence of serogroup B meningococcal disease in college students is similar to or lower than the incidence in all 18 to 23 year olds and noncollege students.

Both vaccines appear to provide short-term immunogenicity in healthy individuals. Licensure was based on the ability of the vaccines to elicit detection of bactericidal antibodies that presumably indicate protection. Information regarding antibody persistence is limited. There are theoretical concerns of autoimmune disease after receipt of a vaccine containing FHbp antigen.

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Clinical trials have shown both vaccines to be safe with few serious adverse events, which have all resolved. The table below summarizes these adverse events. Post-marketing studies are being conducted.

TABLE 2

Local and Systemic Adverse Events Reported in Clinical Trials for MenB-4C and MenB-FHbp

Adverse Event	MenB-4C (Bexsero), %	MenB-FHbp (Trumenba), %
Severe pain at injection site	20–29	5–8
Fever ≥ 38 C	1–5	2–8
Headache (severe)	4–6	1
Fatigue (severe)	4–6	1–4
Muscle pain (severe)	12–13	1–3
Joint pain (severe)	2	1
Use of antipyretic medication	NA	17–28

The AAP policy statement on serogroup B Meningococcal Vaccine made the following summary recommendations: Persons 10 years and older at increased risk of meningococcal disease should receive a MenB vaccine routinely (Category A recommendation for all three of the following groups):

- (a) persons with persistent complement component deficiencies, including inherited or chronic deficiencies in C3, C5–C9, properdin, factor D, or factor H or those receiving eculizumab;
- (b) persons with anatomic or functional asplenia, including sickle cell disease; and
- (c) healthy persons identified to be at increased risk because of a serogroup B meningococcal disease outbreak (defined by local health departments on the basis of CDC criteria); these persons should receive a MenB vaccine series if their treating health care providers, in consultation with their local health or state departments, determine they are appropriate candidates on the basis of CDC criteria.

A MenB vaccine series is not routinely recommended, but it may be administered to adolescents and young adults 16 to 23 years of age to provide short-term protection against diverse strains of serogroup B meningococcal disease (Category B recommendation). If a MenB vaccine is administered, the preferred age for MenB vaccination is between 16 to 18 years old. This age preference is based on limited data on antibody persistence and the peak ages of invasive serogroup B meningococcal disease. Primary care providers should discuss the availability of the MenB vaccine with their adolescent patients, ideally at 16 to 18 years of age. This should include the low incidence but severity of the disease, as well as the unknown efficacy of the vaccine. Discussion also should include that both vaccines have been shown safe with few serious side effects in clinical trials and that ongoing data collection is occurring. Benefits, risks, and costs should be discussed with patients and their families to determine if the vaccine is appropriate for them. Additional details regarding the vaccines can be found in the package inserts and in the following resources.

Resources

1. Kempe A, Allison MA, MacNeil JR, et al. Adoption of serogroup B meningococcal vaccine recommendations. *Pediatrics*. 2018;142(3):e20180344.
2. Centers for Disease Control and Prevention (CDC). Meningococcal Disease: Technical and Clinical Information. Available at <https://www.cdc.gov/meningococcal/clinical-info.html> Accessed September 26, 2018.
3. AAP Committee on Infectious Diseases. Recommendations for Serogroup B Meningococcal Vaccine for Persons 10 Years and Older. *Pediatrics*. 2016;138(3).



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

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.

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

2 Serogroup B Meningococcal Vaccines

Two serogroup B meningococcal vaccines—Bexsero® and Trumenba®—have been licensed by the Food and Drug Administration (FDA).

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 isolates of *N. meningitidis*

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.

For best protection, more than 1 dose of a serogroup B meningococcal vaccine is needed. The same vaccine must be used for all doses. Ask your health care provider about the number and timing of 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 health care 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 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.



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4 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

Other problems that could happen after these vaccines:

- 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 provider if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get shoulder pain that can be more severe and longer-lasting than the more routine soreness that can follow injections. 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. These would usually start 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 clinic.

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.

7 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 Serogroup B Meningococcal Vaccine

08/09/2016

42 U.S.C. § 300aa-26

Office Use Only



Recommended Immunization Schedule for Children and Adolescents Aged 18 Months to 18 Years

Vaccines	18 mos	19-23 mos	2-3 yrs	4-6 yrs	7-10 yrs	11-12 yrs	13-15 yrs	16 yrs	17-18 yrs
Hepatitis B ¹ (HepB)	←*3 rd dose→	§							
Rotavirus ² (RV) RV1 (2-dose series); RV5 (3-dose series)	•	•	•	•	•	•	•	•	•
Diphtheria, tetanus, & acellular pertussis ³ (DTaP: <7 yrs)	←*4 th dose→	§		*5 th dose	•	•	•	•	•
Haemophilus influenzae type b ⁴ (Hib)		§							→
Pneumococcal conjugate ⁵ (PCV13)		§							→
Inactivated poliovirus ⁶ (IPV;<18 yrs)	←*3 rd dose→	§	§	*4 th dose		§		§	•
Influenza ⁷ (IIV)	* Annual vaccination (IIV) 1 or 2 doses				* Annual vaccination (IIV) 1 dose only				
Measles, mumps, rubella ⁸ (MMR)	§			*2 nd dose			§		
Varicella ⁹ (VAR)	§			*2 nd dose			§		
Hepatitis A ¹⁰ (HepA)	←*2 nd dose series, See footnote 10→				§				
Meningococcal ¹¹ MenACWY-D ≥9 mos; MenACWY-CRM ≥2 mos)	→ See footnote 11			→			*1 st dose	§	*2 nd dose §
Tetanus, diphtheria, & acellular pertussis ¹³ (Tdap: ≥7 yrs)	•	•	•	•	§		*Tdap		§
Human papillomavirus ¹⁴ (HPV)	•	•	•	•	•	±	*See footnote 14	§	
Meningococcal B ¹²	•	•	•	•	•	→	→ See footnote 12		±
Pneumococcal polysaccharide ⁵ (PPSV23)	•	•					→ See footnote 5		

* = Range of recommended ages for all children § = Range of recommended ages for certain high-risk groups ± = Range of recommended ages for non-high-risk groups that may receive vaccine, subject to individual clinical decision making • = No recommendation

Note: The above recommendations must be read along with the footnotes for this schedule. The full recommendations including footnotes are available at: <https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>



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