Responding to a Meningococcal B Disease Outbreak

A Guide for Community-Based Immunizing Pharmacists

This guide is designed to help community pharmacists respond to outbreaks of serogroup B meningococcal disease (meningococcal serogroup B disease). The contents are intended to help you:

- Understand the disease and its risks.
- Proactively prepare a response strategy.
- Contribute to effective and credible communication efforts.
- Plan or participate in vaccination campaigns.

About Meningococcal Disease

In the United States, 3 serogroups of *Neisseria meningitidis*—serogroups B, C, and Y—cause most cases of invasive meningococcal infection (ie, meningococcal disease).[1] CDC surveillance data from 2014-2016 show that *N. meningitidis* serogroup B is currently the most common cause of meningococcal disease in adolescents and young adults.[2]

Although the majority (97%–98%) of cases of meningococcal disease in the United States are sporadic and uncommon, outbreaks continue to occur in communities, schools, colleges, prisons, and other populations.[3,4] The onset of an outbreak is unpredictable, and the outcomes can be devastating. Each case of meningococcal disease can be life-threatening; the overall fatality rate is 10% to 15%, even with appropriate antibiotic therapy.[5] From 11% to 19% of survivors have permanent, long-term sequelae, including neurologic damage, loss of a limb or digit, and hearing loss.[5,6]

Vaccination is the preferred control measure for meningococcal disease outbreaks.[7] The U.S. Food and Drug Administration has licensed 2 meningococcal serogroup B (MenB) vaccines since 2014.[3]

Once an outbreak is declared, control measures must be implemented as quickly as possible.[8] Community-based immunizing pharmacists can play an important role in ensuring a fast and effective vaccination response.

About Meningococcal B Disease Outbreaks

What Constitutes an Outbreak?

The Centers for Disease Control and Prevention (CDC) classifies meningococcal disease outbreaks as organization-based or community-based.[7] Organization-based outbreaks occur in universities, schools, childcare centers, correctional facilities, or other specific locations. Community-based outbreaks occur in a shared, geographically defined community, such as a neighborhood or town.

Outbreaks are declared on a case-by-case basis by state or local health officials, often working closely with the CDC.[7,9] In general, the threshold for an organization-based outbreak is 2 to 3 cases of meningococcal disease within an organization during a 3-month period.[7] A community-based outbreak is multiple cases of meningococcal disease with an incidence that is above the expected incidence in a community during a 3-month period.[7]

MenB Outbreak

Depending on the population size and specific circumstances, health officials may declare a meningococcal disease outbreak after just 2 to 3 cases.

Since January 2008, there have been at least 12 outbreaks of meningococcal B disease on U.S. college campuses.[7,10] The outbreaks ranged from 2 to 13 cases and lasted from a few days to nearly 3 years.[7] Three students are known to have died.[10,11]

How Do Outbreaks Occur?

N. meningitidis is transmitted via exchange of respiratory and throat secretions during close or lengthy contact, especially in close or crowded living quarters.[1,9,12] ("Close" contact includes behaviors such as kissing, coughing, and sharing eating utensils and drinking glasses.[13]) An estimated 10% of adolescents and adults are asymptomatic transient carriers of *N. meningitidis.*[5]

Outbreaks of meningococcal B disease may be more likely on college campuses because of (1) the increased incidence of disease during adolescence and young adulthood and (2) enhanced person-to-person transmission stemming from close living quarters (eg, residence halls, fraternity and sorority houses) and social behaviors common among students.[8] Data from 4 of the outbreaks between 2013 and 2015 showed a 200-fold to 1,400-fold increase in disease risk during the outbreak period, compared with the general population in the same age group.[3]

College students are at particular risk for meningococcal B disease because of increased disease incidence during adolescence and young adulthood and enhanced person-to-person transmission from close living quarters (eg, residence halls, fraternity and sorority houses) and social behaviors common among students.

What Are the Symptoms of Meningococcal Disease?

Although uncommon, meningococcal disease can progress rapidly and unexpectedly in otherwise healthy individuals.[14] The 2 most common presentations are meningitis and meningococcal sepsis.[5] Less common presentations include pneumonia, septic arthritis, otitis media, and epiglottitis.[5]

The incubation period of meningococcal disease is 3 to 4 days, with a range of 2 to 10 days.[5] It may appear initially as a nonspecific, flu-like illness; however, it can progress quickly to more severe and specific symptoms.[8,15] Typical symptoms of meningitis and meningococcal septicemia are shown in the table.[15]

Typical Symptoms of Meningococcal Disease

Meningitis:

- Fever.
- Headache.
- Stiff neck.
- Nausea.
- Vomiting.
- Photophobia.
- Altered mental status (confusion).

Meningococcal Septicemia:

- Fever.
- Fatigue.
- Vomiting.
- Cold hands and feet.
- Chills.
- Severe aches or pain in the muscles, joints, chest, or abdomen.
- Tachypnea.
- Diarrhea.
- Dark purple petechial or purpuric rash (present in later stages).

How Are Outbreaks Controlled?

State and local health departments have primary responsibility for leading outbreak investigations and implementing control measures to reduce the spread of the disease.[9] The primary control measures are vaccination and antimicrobial chemoprophylaxis.[7]

Vaccination. The CDC Advisory Committee on Immunization Practices (ACIP) recommends MenB vaccines in response to outbreaks of meningococcal B disease.[7]

Because the commercially available MenB vaccines consist of novel protein or lipoprotein antigens, they are not interchangeable.[14,15] The same vaccine product must be used for all doses in a series.[16] Although rapid whole genome sequencing of the meningococcal isolates causing an outbreak is possible, the CDC states that vaccine antigen data should not drive the selection of MenB vaccine product.[7]

Antimicrobial Chemoprophylaxis. As stated in CDC guidance, antimicrobial chemoprophylaxis of close contacts of a patient with meningococcal disease is important to prevent secondary cases, regardless of whether a meningococcal outbreak is suspected.[7] Close contacts include[5]:

- Household members.
- Childcare center contacts.
- Anyone directly exposed to the patient's oral secretions (eg, through kissing, mouth-to-mouth resuscitation, endotracheal intubation, or endotracheal tube management) in the 7 days before symptom onset.

Expanded antimicrobial chemoprophylaxis (i.e., administering antibiotics to a wider circle of individuals than those identified as close contacts of a case) usually is not recommended as a standalone measure to control outbreaks of meningococcal disease. The impact of expanded chemoprophylaxis on the course of an outbreak has not been consistently demonstrated.[7]

Antimicrobial chemoprophylaxis should be administered as soon as possible after identification of the index patient, ideally within 24 hours of identification of the index patient.[5] Chemoprophylaxis is considered to be of limited to no value if administered more than 14 days after onset of illness in the index patient.[5] Rifampin, ciprofloxacin, and ceftriaxone are 90%–95% effective in reducing nasopharyngeal carriage of *N. meningitidis* and are considered to be first-line chemoprophylaxis agents.[5]

Be Proactive and Prepared

Once an outbreak of meningococcal B disease is declared, control measures must be implemented as quickly as possible.[8] If a mass vaccination campaign is indicated, it can quickly overwhelm the resources of both the affected organization and local public health departments.[8] As an immunizing pharmacist, you can maximize your contribution by being proactive and prepared.

Consider What You Can Do on Your Own

The simplest level of planning and involvement is considering how you could address a meningococcal B disease outbreak from your practice site. For example, shortly after an outbreak was confirmed at the University of Massachusetts–Amherst in November 2017, a national pharmacy chain issued a press release announcing the availability of MenB vaccine at local stores and encouraging students, faculty, and staff to be vaccinated.[17] Although the university had quickly scheduled 4 large-scale walk-in clinics over 2 weeks, it is conceivable that the times would have been inconvenient for some students or that students might have preferred to get vaccinated in a more private setting.[18] The press release emphasized that doses of vaccine could be ordered on request and available the next day.[17]

Community pharmacies also are a logical and convenient location for people to receive the doses needed to complete the vaccine series.

Establish a Relationship With Your State or Local Health Department

State and local health departments have primary responsibility for leading outbreak investigations and implementing control measures to reduce spread of the disease.[9] Does your health department know that you are able and willing to be recruited as a vaccine provider and source for educating the public in case of an outbreak?

The likely answer is no. The Harvard Opinion Research Program conducted a poll in 2012 that showed among community pharmacy settings, 68% of pharmacists had no contact in the previous year with health department staff.[19]

The Association of Immunization Managers maintains a list with contact information for state/city/territory immunization program managers: **Learn more** →

Participate in State or Local Emergency Preparedness and Response Activities

Does your state or local pharmacy association have a dedicated emergency preparedness coordinator? Or, does the pharmacy association offer training in emergency preparedness? Let the appropriate person know that you are able and willing to serve as a vaccine provider in case of meningococcal B disease outbreaks.

Even if your pharmacy association is not involved in emergency planning, you can seek opportunities to contribute to the development of local operational plans and participate in live emergency drills. You will become familiar with emergency response procedures, and other responders will become familiar with your expertise. Let your local or state health department know of your desire to be involved in emergency preparedness and response.

Contact Local Colleges and High Schools

If a meningococcal B disease outbreak occurred at a large university, a vaccination campaign likely would be coordinated by the student health service. But what about smaller colleges or high schools that lack these resources? They may welcome the services of an immunizing pharmacist with experience in conducting immunization clinics.

Make an appointment to speak with someone in the administrative offices. It may be possible to develop a formalized memorandum of understanding or other pre-outbreak plan that could be implemented quickly when needed.

The American Pharmacists Association webpage "Pharmacy and Public Health Collaboration: Pandemic Planning Resource Center" includes a Memorandum of Understanding (MOU) Toolkit for Public Health and Pharmacies and an MOU template: **Learn more**

Address Administrative Requirements

Every state has its own statutes and regulations about who has authority to *prescribe* vaccines and who has authority to *administer* vaccines.

Be sure to find out if your state requires a population-applicable vaccine protocol or standing order (or both) for MenB vaccine. It is imperative that the protocol or standing order be in place *before* it is needed in response to a meningococcal B disease outbreak. The protocol or standing order should cover off-site immunizations. (A standing order template and emergency medical protocols for adults and children and teens from the Immunization Action Coalition are provided with this guide.)

Although pharmacists are authorized to administer MenB vaccines in most states, many states impose age-related limitations (especially for patients younger than 18 years of age). These restrictions may be lifted if a public health emergency is declared. Consider how state laws and regulations might affect your ability to respond effectively to an outbreak; try to address possible limitations explicitly in emergency plans.

It also is important to ensure the operational status and access to the local immunization information system. You need to check this to determine who is eligible to receive MenB vaccine as well as to report administered vaccinations.

Consult with a professional to determine if your liability insurance covers off-site immunizations and what appropriate coverage levels would be. Individual policies for pharmacists may be advisable in addition to a company policy.

Consider How You Will Obtain and Cover the Costs of Vaccine and Other Supplies During an Outbreak

In the event of a meningococcal B disease outbreak, a large number of at-risk individuals may need to be vaccinated in a relatively short period of time. When an outbreak occurred at the University of Wisconsin–Madison in 2016, mass clinics vaccinated 12,000 students on campus within the first week.[20]

Part of being proactive is considering the answers to questions such as:

- How would it be possible to obtain the necessary amount of vaccine to cover the local at-risk population (eg, student body of local college)?
- Would vaccine be provided by the CDC or local health department, or would it have to be obtained commercially?
- How will the documentation and billing of vaccinations be handled?
- Would it be possible to provide vaccine at no cost to at-risk persons? If so, how would vaccine administration costs (eg, staff time, cost of non–vaccine-related supplies) be covered?
- Would it be possible to provide the entire vaccine series at no cost, or just the initial dose?

ACIP recommends MenB vaccines in response to outbreaks of serogroup B meningococcal disease.[7] In accordance with this recommendation, most private insurers would cover vaccination with no out-of-pocket costs. However, because plan policies vary, patients would need to check with their insurance provider to determine whether they would incur any cost or whether prior authorization would be required.[21]

Determine How Follow-Up Will Take Place

Recall that both commercially available MenB vaccines are licensed as a series. Even if mass vaccination clinics are scheduled, plans will be needed to ensure that at-risk individuals receive the subsequent dose(s). For example, will additional clinics be scheduled at the appropriate time interval(s)? Will individuals be encouraged to follow up on their own?

As mentioned earlier, community pharmacies are a convenient and accessible location for people to receive subsequent doses in the vaccine series. **Because the same vaccine product must be used for all doses in a series**, pharmacists would need to access the immunization information system to verify previous dose(s).

Provide Education

Students, parents, community members, and other affected persons all need credible and reliable information during an outbreak of meningococcal B disease. Education efforts should be initiated as soon as an outbreak is suspected.[7] As an immunizing pharmacist, you can contribute to effective communication and education about meningococcal disease and MenB vaccine. Be sure to coordinate the content of your messages with information disseminated by local, state, and federal public health officials, university communications offices, etc.—consistency is crucial for credibility!

Important Points to Communicate

Persons at risk due to an outbreak of meningococcal B disease are most likely to receive MenB vaccine if they consider meningococcal disease to be serious, if they view immunization as the best way to protect themselves, and if they receive a recommendation from their parents.[22] Education strategies should focus on the following key messages to parents[23]:

- Although uncommon, meningococcal disease (meningitis) is a serious bacterial infection that can lead to lifelong complications and even death. Possible complications include neurologic damage, amputation, and hearing loss.[5]
- Adolescents and young adults are at increased risk of meningococcal disease, especially if they live in close quarters.[23]
- Meningococcal disease is vaccine-preventable; however, vaccination may not protect all recipients.[23,24]

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Some confusion arises from the difference between the routinely recommended quadrivalent meningitis vaccine (MenACWY vaccine) and MenB vaccine. MenACWY vaccine protects against *N. meningitidis* serogroups A, C, W, and Y; it is administered to adolescents 11 to 12 years of age.[25] Vaccines to protect against serogroup B—one of the most common causes of meningococcal disease—only first became available in the United States in 2014.[3] They are recommended for certain high-risk groups and may be considered for individuals 16 to 23 years of age.[25]

Include Parents of At-Risk Adolescents and Young Adults

Education about meningococcal B disease needs to target parents as well as at-risk adolescents and young adults. In one survey conducted at a university following an outbreak, students cited "My parents told me I should get vaccinated" as a strong motivator for receiving MenB vaccine.[22]

Many parents may believe that their child is protected against meningococcal disease because the child received the routine MenACWY vaccine. Parents especially need to be educated that this vaccine does not protect against meningococcal B disease.

Parents need to be educated that the routinely recommended quadrivalent meningitis vaccine (MenACWY vaccine) does not protect against meningococcal B disease.

Take Advantage of Existing Materials

Education campaigns employ a variety of channels, such as emails, posters, flyers, newspaper articles and advertisements, and social media.[22] Fortunately, a number of ready-made public education and awareness materials are available and can be customized easily.

The CDC maintains a webpage of feature stories, podcasts, videos, and print materials related to meningococcal disease and vaccination at https://www.cdc.gov/meningococcal/pubs-tools/multimedia.html#materials. (A copy of the fact sheet "Serogroup B Meningococcal Disease: What You Need to Know" is included with this guide.)

The National Foundation for Infectious Diseases offers a "Meningococcal Disease College Toolkit" at http://www.nfid.org/meningitis-toolkit.

Components of the "Meningococcal Disease College Toolkit" include an infographic, awareness poster, educational flyer, and frequently asked questions document, as well as a public service announcement and sample social media posts.

The National Meningitis Association has several videos featuring parents whose children died from meningococcal B disease. They are available at http://www.nmaus.org/educational-resources/psas/.

Immunize At-Risk Individuals

A major role for immunizing pharmacists is, of course, to actually administer the MenB vaccine. Ideally, the vaccination campaign begins as soon as possible after the meningococcal B disease outbreak is declared. At one university that scheduled a vaccine clinic shortly after cases of meningococcal disease were confirmed, vaccination rates exceeded 90% of the targeted 9,000 students.[8] At another university that had a 3-month gap between confirmed cases of disease and the first vaccine clinic, the vaccination rate was 51% of the targeted 19,000 students.[8]

As with all immunizations, you should follow best practices for vaccine delivery.

1. **Check your statewide or local immunization reporting system to see if it provides information on whether patients need a MenB vaccine.**

2. **Screen for contraindications.**
   Refer to the vaccine Prescribing Information for contraindications. A general screening checklist for adults and a targeted checklist for teens—both from the Immunization Action Coalition—are included with this guide. Both checklists are available in multiple languages on the Immunization Action Coalition website at http://www.immunize.org/handouts/screening-vaccines.asp.

3. **Provide a current Vaccine Information Statement (VIS) and answer any questions.**
   The current VIS for MenB vaccine is available on the CDC website at https://www.cdc.gov/vaccines/hcp/vis/current-vis.html. You must ensure that you have the most recent version. (The VIS current as of August 9, 2016, is included with this guide.)

   The Immunization Action Coalition provides up-to-date translations of the VIS in multiple languages at http://www.immunize.org/vis/vis_meningococcal_b.asp.

4. **Record all required data elements in the patient's permanent health record.**

   - Patient name.
   - Vaccine type.
   - Vaccine expiration date.
   - Vaccine manufacturer and lot number.
   - Date vaccine administered.
   - Name, address, and title of person administering the vaccine.
   - Date printed on the VIS.
   - Date the VIS is given to the vaccine recipient or that person's legal representative.

   It also is helpful to record the route and site of vaccine administration.

5. **Administer a single 0.5-mL intramuscular dose of meningococcal B vaccine.**

6. **Ask the patient to remain seated and on the premises for 15 minutes after vaccination.**

   This decreases the risk of injury in case of fainting.

7. **Update the patient's vaccination record in your state or local immunization information system.**

8. **Notify the patient's primary care provider, if known, regarding administration of the vaccine.**

9. **Arrange for subsequent dose(s).**

   Patients should not leave the vaccination area without a clear understanding of when and how they should receive subsequent dose(s) of MenB vaccine. Plan to collect email addresses and other contact information to facilitate follow-up. The state or local immunization information system may offer reminder capabilities.

10. **Provide the patient with documentation of the vaccination.**

    Be sure to indicate which specific MenB vaccine.

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