



## HEALTHCARE PROVIDER FREQUENTLY ASKED QUESTIONS (FAQS) ABOUT RUTGERS UNIVERSITY–NEW BRUNSWICK MENINGOCOCCAL DISEASE OUTBREAK

July 1, 2016

### **What is the current situation regarding meningococcal disease at Rutgers University–New Brunswick?**

Two undergraduate students at Rutgers University–New Brunswick were diagnosed with invasive meningococcal disease caused by *Neisseria meningitidis*, serogroup B in March and April of 2016. Both students had meningitis, and one had bacteremia. Molecular testing performed at the Centers for Disease Control and Prevention (CDC) determined that the 2 isolates from these cases were genetically indistinguishable even though no common link was found between the two students. This suggests that this particular strain is present among the Rutgers University–New Brunswick undergraduate student population and that there is an outbreak.

### **What steps are being taken to address this situation?**

Working with Rutgers University–New Brunswick, the New Jersey Department of Health (NJDOH), in consultation with the Centers for Disease Control and Prevention (CDC), has developed an outbreak response plan. A key component of this plan is a recommendation for individuals at Rutgers University–New Brunswick who are at increased risk for meningococcal disease to be vaccinated with a serogroup B meningococcal (MenB) vaccine.

### **Should any activities on the Rutgers University–New Brunswick campus be canceled because of this situation?**

At this time, there are no recommendations to cancel any activities or scheduled events on the Rutgers University–New Brunswick campus. There are also no recommendations for the surrounding community to avoid casual contact with Rutgers University–New Brunswick students or visiting the Rutgers University–New Brunswick campus. Restricting travel to areas with an outbreak, closing schools or universities, or cancelling sporting or social events are not recommended measures for meningococcal disease outbreak control in the United States. The bacteria that cause meningococcal disease are less infectious than the viruses that cause the flu. The bacteria are spread from person-to-person through the exchange of saliva, coughs, and sneezes. You must be in direct (close) contact with an infected person’s respiratory or oral secretions to be exposed. Meningococcal bacteria also do not live on surfaces for very long.

### **Is this the same strain of bacteria that caused the 2013–2014 outbreak of meningococcal disease associated with Princeton University?**

No, the strains are unrelated.

### **Is invasive meningococcal disease reportable in New Jersey?**

Immediate notification to public health authorities is required for all suspect and confirmed cases of invasive meningococcal disease per N.J.A.C. 8:57. Reporting information is available through the NJDOH website at <http://www.nj.gov/health/cd/reporting.shtml>



## GROUPS RECOMMENDED FOR VACCINATION

### Which groups are being recommended for MenB vaccination?

Three groups are being recommended to receive MenB vaccination due to this outbreak:

- (1) All undergraduate students at Rutgers University–New Brunswick
- (2) Graduate students at Rutgers University–New Brunswick living in undergraduate dormitories
- (3) Any person affiliated with Rutgers University–New Brunswick with certain medical conditions or occupations that put them at increased risk. These include: persistent complement component deficiencies, receipt of the medication eculizumab (Soliris®), anatomic or functional asplenia, and microbiologists who are routinely exposed to *Neisseria meningitidis*.

### What about students at other Rutgers campuses? Should they also receive MenB vaccine?

Persons not affiliated with the Rutgers University–New Brunswick campus are not recommended to receive MenB vaccine specifically in response to this outbreak. However, unrelated to this outbreak, the Advisory Committee on Immunization Practices (ACIP) states that providers should vaccinate persons with high-risk conditions and occupations

(<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6422a3.htm>) and, per a Category B recommendation, may vaccinate any person aged 16–23 years with either MenB vaccine (<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6441a3.htm>).

### Why is everyone at Rutgers University–New Brunswick not being recommended for MenB vaccination?

Meningococcal bacteria are spread from person to person through exchange of respiratory secretions. Because of nasopharyngeal carriage of meningococcal bacteria, this spread can occur through asymptomatic persons. Living in dormitory-style housing and having a high degree of social mixing are considered risk factors for developing meningococcal disease. Therefore, it was determined that the groups listed above are likely to be at increased risk for developing meningococcal disease given the occurrence of two serogroup B meningococcal disease cases among Rutgers University–New Brunswick undergraduate students.

## VACCINATION INFORMATION

### What are the ACIP recommendations for MenB vaccine?

ACIP recommends MenB vaccination for people 10 years and older at increased risk for meningococcal disease per a Category A recommendation. Groups considered to be at increased risk for meningococcal disease are:

- People with functional and anatomic asplenia (including sickle cell disease);
- People with persistent complement component deficiencies (C3, C5-C9, properdin, factor H, factor D), and taking Soliris® for treatment of atypical hemolytic uremic syndrome (aHUS) or paroxysmal nocturnal hemoglobinuria (PNH);
- Microbiologists who are regularly exposed to *Neisseria meningitidis*; or
- **People at increased risk because of an outbreak of serogroup B meningococcal disease**



ACIP also states that patients and clinicians may consider MenB vaccination for all people 16 through 23 years old. The ACIP recommendation states, "A serogroup B meningococcal (MenB) vaccine series may be administered to adolescents and young adults 16 through 23 years of age to provide short-term protection against most strains of serogroup B meningococcal disease. The preferred age for MenB vaccination is 16 through 18 years of age." This recommendation is labeled "Category B," meaning that individual clinical decision making is recommended.

#### **Which MenB vaccine should be used?**

Two MenB vaccines, Trumenba<sup>®</sup> and Bexsero<sup>®</sup>, are licensed for use in the United States. **Based upon laboratory testing of the specific outbreak strain at RU-NB, the best protection is expected with the full 3-dose series of Trumenba<sup>®</sup>.** Therefore, the NJDOH and Rutgers University recommend, with support from the CDC, that Trumenba<sup>®</sup> be administered to help protect against the particular strain present on the RU-NB campus. While one or two doses of Bexsero<sup>®</sup> or Trumenba<sup>®</sup> will provide some short-term protection against the specific outbreak strain at RU-NB, the best protection is expected to require completion of the **full three-dose series of Trumenba<sup>®</sup> with the second dose given 1–2 months after the first and the third dose 6 months after the first.**

#### **What is the MenB vaccine schedule?**

For Trumenba<sup>®</sup>, the vaccine schedule is:

- Dose 1: 0 months
- Dose 2: 1–2 months after Dose 1
- Dose 3: 6 months after Dose 1

***NOTE:** The 2-dose Trumenba<sup>®</sup> vaccine schedule is not recommended in an outbreak setting.*

#### **When should Trumenba<sup>®</sup> be administered?**

NJDOH and Rutgers University–New Brunswick, with the support of CDC, are encouraging people who are recommended for MenB vaccination to receive 2 of the 3 doses of Trumenba<sup>®</sup> before arriving on campus for the start of the 2016–2017 academic year. Importantly, the best protection against serogroup B meningococcal disease is expected with the full 3-dose series of Trumenba<sup>®</sup>.

#### **What should be done if someone previously received the 2-dose schedule of Trumenba<sup>®</sup> at 0 and 6 months?**

If someone received 2 doses of Trumenba<sup>®</sup> at least 6 months apart, he/she does not need additional doses of MenB vaccine.

#### **What should be done if a Rutgers University–New Brunswick student who is recommended for vaccination has already received 1 or 2 doses of Bexsero<sup>®</sup>?**

If someone has received 1 dose of Bexsero<sup>®</sup>, it is recommended that you administer another dose of Bexsero<sup>®</sup> at least 1 month after the first dose. If someone has received 2 doses of Bexsero<sup>®</sup> at least 1 month apart, no further doses of MenB vaccine are recommended.

#### **If someone received 1 dose of Bexsero<sup>®</sup>, can they finish the series with Trumenba<sup>®</sup>?**

No. Trumenba<sup>®</sup> and Bexsero<sup>®</sup> are not interchangeable. If there is a reason to switch from Bexsero<sup>®</sup> to Trumenba<sup>®</sup>, it is recommended to wait at least 1 month between products and then administer the full 3-dose series of Trumenba<sup>®</sup>.



**I know the recommended 3-dose schedule for Trumenba® is 0, 1-2, and 6 months. What are the MINIMUM acceptable intervals between doses of Trumenba®? I have a student who got a dose on June 4 and then another on October 4. When should I administer the 3<sup>rd</sup> dose?**

Neither ACIP nor the CDC meningococcal subject matter experts have addressed this issue. Given the lack of guidance, we must assume that the routine intervals are also the minimum intervals for Trumenba, 4 – 8 weeks between doses 1 and 2, 4 months between doses 2 and 3, and 6 months between doses 1 and 3. It is important to use these intervals when scheduling doses. However, if these intervals are violated, the doses still count and do not need to be repeated. In light of this outbreak, we are trying to get members of the RU-NB community who are recommended to receive Trumenba® vaccinated as soon as possible so that they have time to develop the optimal antibody response. Thus, if possible, it is best not to extend the series beyond the recommended 6 months. In the situation above, it would probably be best to administer the 3<sup>rd</sup> dose in December – 6 months from the 1<sup>st</sup> dose. There is no data from the trials on doses of vaccine administered less than one month apart. You should always use your clinical judgement when making such decisions based on all the available information.

**What meningococcal vaccines are available for adults in the United States?**

Since 2005, 2 types of meningococcal vaccines have been available in the United States that protect against meningococcal serogroups A, C, W, and Y: 1) meningococcal polysaccharide vaccine (MPSV4; Menomune, Sanofi Pasteur), which is made up of polysaccharide (sugar molecules) from the surface of the meningococcal bacteria; and 2) meningococcal conjugate vaccines (MCV4; Menactra, Sanofi Pasteur; Menveo, GSK) in which the polysaccharide is chemically bonded ("conjugated") to a protein to produce better protection. MCV4 is more effective in young children than the original polysaccharide vaccine.

More recently, vaccines have become available that offer protection from meningococcal serogroup B. These vaccines are composed of proteins also found on the surface of the bacteria. Neither type of vaccine contains live meningococcal bacteria.

MPSV4 and MCV4 provide no protection against serogroup B disease, and meningococcal serogroup B vaccines (MenB) provide no protection against serogroup A, C, W, or Y disease. For protection against all 5 serogroups of meningococcus, it is necessary to receive MCV4 or MPSV4 and MenB.

Trade Name	Type of Vaccine	Serogroups Included	Year Licensed	Approved Ages
Menomune	Polysaccharide	A, C, W, Y	1981	2 years and older
Menactra	Conjugate	A, C, W, Y	2005	9 months–55 years*
Menveo	Conjugate	A, C, W, Y	2010	2 months–55 years*
Trumenba	Protein	B	2014	10–25 years+
Bexsero	Protein	B	2015	10–25 years+

\*May be given to people age 56 years or older (consult ACIP recommendations at [www.cdc.gov/mmwr/pdf/rr/rr6202.pdf](http://www.cdc.gov/mmwr/pdf/rr/rr6202.pdf)).

+May be given to people age 26 years or older (consult ACIP recommendations at [www.cdc.gov/mmwr/pdf/wk/mm6422.pdf](http://www.cdc.gov/mmwr/pdf/wk/mm6422.pdf)).



**College students typically receive a meningococcal vaccine prior to starting college. Why is another meningococcal vaccine being recommended for this outbreak?**

The meningococcal conjugate vaccine (MenACWY) routinely given to adolescents prior to college entry protects against 4 serogroups of meningococcal bacteria: A, C, W, and Y. It does not protect against serogroup B, which is the serogroup that has caused the two recent cases at Rutgers University–New Brunswick.

**Can MenB vaccine be given with other vaccines?**

Yes, it is safe to give MenB vaccine with the meningococcal conjugate vaccine, MenACWY, or with any other vaccine.

**Will receiving the MenB vaccine fulfill the N.J.A.C. 8:57 – 6, Higher Education Immunization rules, requirement for students attending four year colleges and residing in campus dormitories?**

No. Students must receive the MenACWY vaccine to fulfill this requirement.

**If I am administering MenB vaccine to someone who is not in a group recommended to receive MenB vaccine at RU-NB, does it matter if I administer Bexero® or Trumenba®? If I have someone attending another college/university within NJ, is there a brand preference?**

No. The preference for Trumenba® is specific to this situation and for the groups recommended to be vaccinated in response to the outbreak associated with the RU-NB campus. Based upon laboratory testing of the specific outbreak strain at RU-NB, the best protection is expected with the full 3-dose series of Trumenba®. In other situations, Bexero® or Trumenba® may be administered.

**We anticipate that parents will be seeking serology to prove immunity to meningococcal disease in lieu of vaccination. Would a positive meningococcal titer (serology) be accepted as evidence of immunity?**

According to the meningococcal subject matter experts at CDC the only test for which there is a correlate of immunity is a serum bactericidal assay (SBA). This test is mostly used for research and is not likely to be commercially available. An IgG EIA that might be available at a commercial laboratory is not useful for determining immunity. So there is no practical serologic test for determining immunity to meningococcus. Serologic testing is not recommended except perhaps in a research setting.

**If someone had meningococcal disease, is vaccination still recommended?**

Yes. Disease may not confer protection against future episodes of meningococcal disease.

**Is Trumenba® safe, and what side effects are common?**

Available data suggest that Trumenba® is safe. Safety will continue to be monitored. More than half of the people who get Trumenba® have mild problems following vaccination:

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



These reactions usually get better on their own within three to seven days, but serious reactions are possible. Trumenba<sup>®</sup> is more likely to produce common or expected short-term side effects (especially pain where the shot was given) than other adolescent vaccines (e.g., HPV, quadrivalent meningococcal conjugate, and Tdap vaccines). For further information about specific vaccines, please see the Vaccine Information Statements (VIS) at: <http://www.cdc.gov/vaccines/hcp/vis/index.html>.

**Where do I report vaccine adverse events?**

The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program run by CDC and the Food and Drug Administration (FDA). VAERS serves as an early warning system to detect possible safety issues with U.S. vaccines by collecting information about adverse events that occur after vaccination. Information about reporting is available through the CDC website at <http://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/>.

**Are there any contraindications to receiving MenB vaccine?**

Hypersensitivity to any component of Trumenba<sup>®</sup> is the only medical contraindication to vaccination.

**Will the MenB vaccine be covered by insurance?**

If you have questions regarding health insurance coverage, you should check with the specific insurance plan. In general, insurance companies will provide coverage for vaccines if they are given in accordance with Category A recommendations of ACIP.

## OCCUPATIONAL HEALTH

**Are healthcare providers caring for ill persons at risk of developing meningococcal disease?**

Because meningococcal bacteria are spread from person to person through respiratory secretions, healthcare providers are not considered to be at increased risk for meningococcal disease unless they have had contact with respiratory secretions without the appropriate use of personal protective equipment. This would include unprotected mouth-to-mouth resuscitation, suctioning, or intubation before, or less than 24 hours after, appropriate antimicrobial therapy was initiated.

**Should healthcare providers receive MenB vaccine?**

There is no recommendation for healthcare providers to receive MenB vaccine unless they have a high-risk medical condition or occupation as outlined above or are in one of the groups recommended to receive the vaccine as part of the outbreak response.

**When should healthcare providers receive antimicrobial chemoprophylaxis?**

Healthcare providers who have had direct contact with the respiratory secretions of a patient with suspected or confirmed meningococcal disease without the appropriate use of personal protective equipment should receive antimicrobial chemoprophylaxis. This would include unprotected mouth-to-mouth resuscitation, suctioning, or intubation before, or less than 24 hours after, appropriate antimicrobial therapy was initiated.

Being in the same room as a patient with meningococcal disease or performing a routine history or physical exam would not place a healthcare provider at increased risk for meningococcal disease.

**If caring for an ill individual, what kind of infection control should be used?**

If meningococcal disease is suspected or confirmed, immediate institution of standard and droplet precautions should be employed. Droplet precautions can be discontinued after the person has been on appropriate antimicrobial therapy for greater than 24 hours.

## ANTIMICROBIAL CHEMOPROPHYLAXIS

**How do I identify close contacts of cases who require antimicrobial chemoprophylaxis?**

Following immediate notification, the local health department, in consultation with NJDOH, will conduct an investigation into a case of meningococcal disease to identify close contacts and make recommendations regarding antimicrobial chemoprophylaxis. Healthcare providers can assist public health authorities by getting as much information as possible regarding exposures during the 10 days prior to symptom onset. Because the rate of secondary disease for close contacts is highest immediately after onset of disease in the index patient, antimicrobial chemoprophylaxis should be administered as soon as possible (ideally <24 hours after identification of the index patient). Conversely, chemoprophylaxis administered >14 days after exposure to the index patient is probably of limited or no value.

**What is the definition of a close contact?**

A close contact is defined as follows:

- All members of the patient's household, especially young children
- Healthcare and emergency medical workers who may have been exposed to the patient's oral/nasal secretions through unprotected mouth-to-mouth resuscitation, intubation, or suctioning
- Childcare or nursery school attendees who were in the classroom with the patient in the 10 days before onset
- Persons who may have had contact with the patient's oral secretions through kissing or sharing food, drink, or eating utensils in the 10 days before onset
- Persons who ate or slept in the same dwelling as the patient in the 10 days before onset
- Persons sitting next to someone with meningococcal disease on a flight  $\geq$  8 hours

Additional information on antimicrobial chemoprophylaxis may be found in Appendix A of the 2013 *Morbidity and Mortality Weekly Report (MMWR)* article summarizing ACIP recommendations for prevention and control of meningococcal disease (<http://www.cdc.gov/mmwr/pdf/rr/rr6202.pdf>).

**Which antibiotics are recommended for antimicrobial chemoprophylaxis?**

**TABLE. Recommended chemoprophylaxis regimens for protection against meningococcal disease — Advisory Committee on Immunization Practices (ACIP), United States, 2012**

Drug	Age group	Dosage	Duration and route of administration*
Rifampin <sup>†</sup>	Children aged <1 mo	5 mg/kg every 12 hrs	2 days
	Children aged ≥1 mo	10 mg/kg every 12 hrs	2 days
Ciprofloxacin <sup>§</sup>	Adults	600 mg every 12 hrs	2 days
	Adults	500 mg	Single dose
Ceftriaxone	Children age <15 yrs	125 mg	Single IM dose
Ceftriaxone	Adults	250 mg	Single IM dose

**Abbreviation:** IM = intramuscular.

\* Oral administration unless indicated otherwise.

<sup>†</sup> Rifampin is not recommended for pregnant women because the drug is teratogenic in laboratory animals. Because the reliability of oral contraceptives might be affected by rifampin therapy, consideration should be given to using alternative contraceptive measures while rifampin is being administered.

<sup>§</sup> Ciprofloxacin is not generally recommended for persons aged <18 years or for pregnant and lactating women because the drug causes cartilage damage for immature laboratory animals. However, ciprofloxacin may be used for chemoprophylaxis of children when no acceptable alternative therapy is available. A recent review identified no reports of irreversible cartilage toxicity or age-associated adverse events in children and adolescents (Source: Burstein GR, Berman SM, Blumer JL, Moran JS. Ciprofloxacin for the treatment of uncomplicated gonorrhea infection in adolescents: does the benefit outweigh the risk? Clin Infect Dis 2002;35:S191–9).

Reference: <http://www.cdc.gov/mmwr/pdf/rr/rr6202.pdf>

**What is the purpose of giving antimicrobial chemoprophylaxis to close contacts of meningococcal cases?**

The purpose of antimicrobial chemoprophylaxis is to eradicate nasopharyngeal carriage of *Neisseria meningitidis* and thus prevent disease in close contacts of patients with invasive meningococcal disease. Antimicrobial chemoprophylaxis of close contacts is important to prevent secondary cases.

**Why don't we give antimicrobial chemoprophylaxis to more people on campus?**

Expanding chemoprophylaxis beyond close contacts of cases (mass chemoprophylaxis) is not routinely recommended to control outbreaks of meningococcal disease.

**ADDITIONAL INFORMATION**

**What are some relevant CPT and ICD-10 codes for meningococcal visits/vaccination?**

This list is not all-inclusive and is meant as a guide. Please confirm all codes prior to use.

90620	Meningococcal recombinant protein and outer membrane vesicle vaccine, serogroup B, 2 dose schedule, for intramuscular use
90621	Meningococcal recombinant lipoprotein vaccine, serogroup B, 3 dose schedule, for intramuscular use
90733	Meningococcal polysaccharide vaccine, serogroups A, C, Y, W-135, quadrivalent (MPSV4), for subcutaneous use
90734	Meningococcal conjugate vaccine, serogroups A, C, Y and W-135, quadrivalent (MenACWY), for intramuscular use
90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid)

D57.00- D57.819	Sickle-cell disorders
D84.1	Defects in the complement system
D89.89	Other specific disorders involving the immune, mechanism, not elsewhere classified
Q89.01	Asplenia (congenital)
Z20.811	Contact with and (suspected) exposure to meningococcus
Z23	Encounter for immunization
Z59.3	Problems related to living in residential institution
Z79.81/Z90.81	Acquired absence of spleen

**Where can I find more information about clinical management of symptomatic and asymptomatic persons?**

Please see accompanying document ***“Guidance for Clinicians Caring for Patients in the Context of the Meningococcal Disease Outbreak at Rutgers University–New Brunswick”***.

Also see the ACIP recommendations for *Prevention and Control of Meningococcal Disease* (2013) at: <http://www.cdc.gov/mmwr/pdf/rr/rr6202.pdf>