GENERAL

Responses By William Schaffner, MD, National Foundation for Infectious Diseases (NFID) medical director and professor of Preventive Medicine and Infectious Diseases at Vanderbilt University School of Medicine

Define “short term protection” for the MenB vaccine.
The duration of protection achieved by either MenB vaccine has not yet been defined. Given this uncertainty, “short term protection” may be interpreted as “several years”, but please note that the actual duration of protection has not been established.

What vaccination is recommended? Quadrivalent AND Serogroup B? One or the other?
Routine vaccination with a quadrivalent vaccine that protects against four major meningococcal serogroups (A, C, W, and Y) is recommended for all adolescents at age 11-12 years with a booster dose at age 16 years.

For adolescents and young adults, CDC recommends that a MenB vaccine series may be administered to people 16 through 23 years of age with a preferred age of vaccination of 16 through 18 years. This recommendation is designed to allow the clinician to make a MenB vaccine recommendation based on the risk and benefit for the individual patient.

Are a student’s close family recognized as at high risk and recommended to receive a MenB shot?
No, unless, of course, some of the family members also are 16 through 18 years of age. Also, we would suggest using care when using the term “high risk”; the absolute risk of MenB disease in adolescent and adult populations in the US is very low. That said, the risk is elevated above this very low baseline in late adolescence and young adulthood.

I have heard that Trumebba can be given as a two vaccine series, instead of three. What do you think about this?
As noted during the webinar, Trumebba now is FDA-approved for a 2-dose series (0, 6 months). The antibody levels achieved by this 2-dose series appear to be somewhat lower than after 3 doses. This might have an influence on duration of protection. The ACIP has not yet commented on the 2-dose series.

Do you recommend Trumebba or Bexsero for MenB? What is the cost per shot? Is the MenB vaccine usually covered by insurance?
Under ordinary circumstances, the CDC has not expressed a preference for either of the meningococcal B vaccines. However, in the case of an outbreak, in some cases, the CDC has been able to conduct lab testing and determined that one of the B vaccines would work better in response to that particular case or outbreak. We recommend you check with individual insurance companies to determine coverage/cost.
Is there a recommendation for students who receive their second (booster dose) prior to turning 16? (For example, we are seeing many students receive their vaccine at their annual physical. Sometimes this may occur one to four months before they turn 16 and they are getting their booster at that visit.) We assume this question refers to the booster dose of MenACWY. Although these intervals should not be a substantial issue, recall that you want the duration of protection to be as long as possible, so we would encourage later immunization if possible.

I am a VFC reviewer. Should I be encouraging providers to give MenB at the same time they are giving the second dose of MenACYW?

Any individual who will be receiving both MenACYW and MenB can get a dose of MenB at the same time they get the second dose of MenACYW. There are no contraindications to receiving MenACYW and MenB at the same visit (in different anatomic sites).

Do you have any recommendation regarding upper age limit for vaccination?

Both the MenB vaccines are FDA-licensed for use in persons 10 through 25 years of age. The ACIP initially recommended that all persons 10 years of age or older who are at increased risk for meningococcal disease should receive MenB vaccine (Category A recommendation). These include:
- Persons with persistent complement component deficiencies.
- Persons with anatomic or functional asplenia.
- Microbiologists routinely exposed to isolates of meningococci.
- Persons exposed because of an outbreak of MenB disease.

Subsequently, the ACIP added a recommendation that the MenB vaccine may be administered to adolescents and young adults (ages 16 through 23 years) on the basis of the healthcare provider’s evaluation and discussion with the patient (Category B recommendation).

I am a community pharmacist and am located very near a college campus. Do all college students fall in the category of being eligible to receive the MenB vaccine even if there is NOT a current outbreak?

Yes, but not just college students; a MenB vaccine series may be administered to people 16 through 23 years of age with a preferred age of vaccination of 16 through 18 years. This recommendation is designed to allow the clinician to make a MenB vaccine recommendation based on the risk and benefit for the individual patient.

How is the vaccine constructed and why did it take so long to develop? The humoral response, as published in the NEJM, was mediocre. Is there an immunity from other sources that might account for the great results seen, for instance, at Princeton?

There were several scientific challenges to creating MenB vaccines. Prominent among them was that the MenB serogroup is antigenically diverse. This is in contrast to the A, C, W, and Y serogroups which are antigenically stable. The two vaccines are constructed differently. In brief, Trumemba consists of two recombinant antigens; Bexsero is composed of three recombinant proteins and outer membrane vesicles containing an outer membrane protein. The vaccine used in the Princeton outbreak was Bexsero. Although not a perfect match with the outbreak strain, two of the vaccine antigens were expressed in the outbreak strain. Two months after the second dose of vaccine, 66% of recipients had measurable serum bactericidal activity against the outbreak strain, a traditional surrogate measure of protection. However, responses to two reference meningococcal strains were excellent (87% to 100%). The outbreak ceased; whether the vaccination campaign played a role (minor or major) remains provocatively unknown.
Further Detail Provided by Susan Even, MD, executive director of the University of Missouri Student Health Center, Chair of the ACHA Vaccine Preventable Disease Advisory Committee

The two MenB vaccines were developed using different procedures and the complexity is such that I don’t think one could adequately explain the process. The capsule of meningococcal B bacteria makes it much harder to devise a vaccine against it. Humoral measures of antibody response are only representations of the actual human immune response, which is not measurable. Strains of Men B in different locations are antigenically and genetically diverse. MMWR October 23, 2015/64(41);1171-6 gives a complete explanation of the two B vaccines (MenB-FHbp and MenB-4C) in the section titled "MenB Vaccine Immunogenicity and Safety"

**CAMPUS-RELATED QUESTIONS**

Responses by Susan Even, MD, executive director of the University of Missouri Student Health Center, Chair of the ACHA Vaccine Preventable Disease Advisory Committee

**What is the final recommendation for student nurses working in acute care areas and also living in dorms?**

There are no specific recommendations regarding Meningitis B (or any meningococcal vaccines) for healthcare professionals or healthcare professional students. If a nursing student lives in a dorm and the campus follows the CDC recommendations for meningococcal vaccine, that student should have the booster MCV4 vaccine (at age 16 or later) and should be given the option to obtain one of the 2 MenB vaccine series.

**Campuses with previous outbreaks (or considered to still be in an outbreak status) are promoting universal immunization for MenB. Given the current ACIP/CDC guidelines, how do these impact campuses that have not experienced a case of meningococcal disease? How do you know when you are no longer in an "outbreak" status?**

First, if a campus is not in "outbreak status," there are no specific recommendations regarding universal immunization of students for MenB. Campuses should enforce the recommendation for booster of the quadrivalent MCV4 at age 16 or later and may offer the option of a MenB vaccine series, with the caveat that in the event of a future MenB outbreak, there may be additional or different MenB vaccine recommendations based on the genetics pattern.

To my knowledge, there is no guideline that outlines when a campus is no longer in outbreak status. At this time, that decision would be made in coordination with local, state and CDC officials. There may be more definitive guidance in the future through ACIP deliberations.

**Would you recommend a booster for a 25-year-old going back to graduate school but living in their own apartment and not the dorms?**

A 25 year old grad student living off campus is not considered at increased risk for meningococcal disease, so I would not recommend a meningococcal vaccine (either the quadrivalent MCV4 or MenB series.) However, if an outbreak of MenB occurred on that campus, there would be a determination regarding the population at risk which could possibly include the 25-year old grad student.

**Do you know of any schools requiring MenB for incoming first year students residing on campus?**

Other than schools that are in "outbreak status," I am not aware of any requiring MenB for first year students living on campus. That said, there is no database that I am aware of that outlines the immunization requirements of institutions of higher education in the US.

Updated September 2016
Are there any serological tests available to evaluate post vaccine immunity?
The serologic tests that have been used by the pharmaceutical companies to evaluate post-vaccine antibody levels are not available commercially as far as I know.

OUTBREAK RESPONSES-RELATED QUESTIONS

Responses Provided by Jonathan Pletcher, MD, director, Medical Services Princeton University

Were there any reports of vaccine failures? (i.e. students who completed the two- or three-dose series who became infected with a "vaccine homologous" strain)
After our immunization clinics were implemented, there were no new cases among Princeton students, although a student from another school was exposed to the same strain from a Princeton student.

Were there any issues around parental consent for vaccines if student was not yet 18 years old?
I am not aware of any problems with parental consent - by mid-year we have extremely few students under 18

Any insight on how to successfully lobby a Board of Regents, legislators, or other governing bodies to make the MenACWY vaccine a hard requirement for immunization compliance?
Men ACYW is a hard requirement to register for classes, and there is a NJ law requiring universities to report on vaccine compliance.

For additional information on Meningococcal disease, visit www.nfid.org/meningococcal. For resources to use on college campuses, visit www.nfid.org/meningitis-toolkit.