# ACIP weighs in on meningococcal B vaccines

## Although not recommended for routine vaccination, either of the 2 approved MenB vaccines may be considered by individuals 16 to 23 years of age, and would be indicated for those ≥10 years at high risk for meningococcal infection.

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The Advisory Committee on Immunization Practices (ACIP) voted at its June 2015 meeting to make a "B" recommendation for the use of meningococcal B vaccine for individuals 16 through 23 years of age. The Committee felt that the vaccine can be used if one desires it, but at this time it should not be included in the category of a routinely recommended vaccine.

Meningococcal meningitis caused by serogroup B is a serious disease, but it is rare. From 2009 to 2013, the annual number of meningococcal B cases in individuals ages 11 to 24 years ranged from 54 to 67, with 5 to 10 deaths and 5 to 13 serious sequelae.[1] Since 2009, there have been outbreaks on 7 university campuses with cases-per-outbreak numbering 2 to 13.[1] These well publicized outbreaks created much disruption and an impression of increased risk among college students. But the surveillance system of the Centers for Disease Control and Prevention (CDC) demonstrates that the rate of infection among college students is actually lower than it is among individuals the same age who are not in college (**TABLE 1**).[1]

The combined incidence of 0.14/100,000 means that to prevent one case, 714,000 individuals need to be vaccinated; 5 million need to be vaccinated to prevent one death.[1] These numbers are subject to yearly variation and would be more favorable should the incidence of the disease increase. (For a look at the historical incidence of meningococcal meningitis from all serotypes, see the **FIGURE**.[1]) The question facing ACIP was whether the current very low levels of meningococcal B disease merit widespread, routinely-recommended use of the vaccine.

## A look at the 2 meningococcal B vaccines

Two meningococcal B vaccines are now licensed for use in the United States. MenB-FHbp (Trumenba, Pfizer) was licensed in October 2014 as a 3-dose series given at 0, 2, and 6 months.[2] MenB-4C (Bexsero, Novartis/GSK) was licensed in January 2015 and requires 2 doses at 0 and ≥1 month.[3] Both vaccines induce a level of antibody production that is considered immunogenic in a high proportion of those vaccinated, but the level of immunity wanes after 6 to 24 months. The clinical significance of this drop in immunity is unknown and cannot be tested currently because of the rarity of the disease. Unfortunately, the rate of asymptomatic carriage of meningococcal B does not appear to be affected by vaccination.[1]

Both vaccines produce local and systemic reactions at rates higher than other recommended vaccines for this age group: pain at the injection site (83%-85%), headache (33%-35%), myalgia (30%-48%), fatigue (35%-40%), indu-

**TABLE 1**

## Average annual figures for meningococcal B cases, deaths, and incidence rates, 2009-2013 (estimated)[1]

| Population | Cases | Deaths | Incidence per 100,000 |
|---|---|---|---|
| All individuals, ages 18-23 | 36 | 5 | 0.14 |
| College students | 14 | 2 | 0.09 |
| Non-students | 22 | 3 | 0.21 |

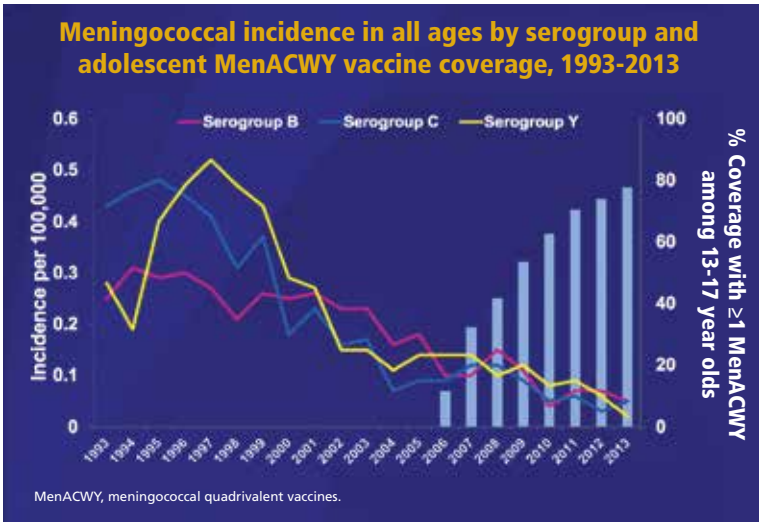
ration (28%), nausea (18%), chills (15%), and arthralgia (13%).[2,3] There is some theoretical concern about the potential for autoimmune disease from the use of meningococcal B vaccines that will be studied as the vaccines are used more widely.[1] In addition, the CDC estimates that serious anaphylactic reactions can occur after administration of any vaccine, estimated at about one per every million doses.[1]

**FIGURE**

## The decline of meningococcal meningitis[1]

The currently recommended meningococcal quadrivalent vaccines (MenACWY) contain antigens from serotypes A, C, W, and Y that do not protect against serotype B. In examining the historical incidence of meningococcal meningitis from all serotypes from 1993 through 2013, 2 facts are apparent: 1) The incidence of meningococcal meningitis from all serotypes has been declining, and 2) This decline began before the widespread use of MenACWY in 2006 (indicated with vertical blue lines, below).

Most infectious diseases have a natural history of increasing and declining incidences (peaks and valleys), and introducing an effective vaccine levels off annual incidences to much lower rates than occur naturally. (ACIP's recommendations for MenACWY use can be found at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm.)




MenACWY, meningococcal quadrivalent vaccines.

Meningococcal serotype B bacteria consist of different strains. The 2 approved vaccines cover today's most frequently found strains in the United States, but it's uncertain if this will hold true in the future.

## Recommendation considerations that came into play

A number of factors affected ACIP's recommendation decision: the low incidence of the meningococcal B disease; the large number-needed-to-vaccinate to prevent a case and a death; uncertainties regarding the duration of protection; cost, lack of effect on carriage rates, and limited safety data with the potential for serious reactions to exceed the number of cases prevented; and the severity of the disease and the concern it elicits.

ACIP has multiple options when considering a vaccine: recommend it routinely for everyone or everyone in a defined group (A recommendation), recommend for individual decision making (B recommendation), recommend against use, and make no recommendation at all. Given that 2 meningococcal B vaccines are licensed in the United States and can be used by those who want them—and the Committee's opinion that these vaccines should not (at this time) be included in the schedule of routinely-recommended vaccines—ACIP chose to make a B recommendation on their use (**TABLE 2**).[1] Vaccines recommended by ACIP (both A and B recommendations) are mandated in the Affordable Care Act to be provided by commercial health insurance at no out-of-pocket expense to the patient.

### A word about high-risk populations

At its February 2015 meeting, ACIP voted to recommend meningococcal B vaccine for use

## LATE BREAKING NEWS

### USPSTF: Screen obese/-overweight adults for type 2 diabetes

The United States Preventive Services Task Force (USPSTF) recently updated its recommendation for screening for type 2 diabetes in adults. USPSTF recommends screening adults, ages 40 to 70 years, who are obese or overweight and referring those who have abnormal blood glucose to intensive behavioral counseling to promote a healthful diet and physical activity.

The Task Force gave this recommendation a grade of B, meaning that it is likely to result in a moderate level of benefit from a reduction in progression to diabetes. The Task Force also emphasized that lifestyle modifications have a greater risk-reducing effect than metformin and other medications.

The recommendation rationale points out that screening might also benefit those at high risk of diabetes based on family history or race/ethnicity and does not apply to those with signs and symptoms of diabetes; testing in this latter group is considered diagnostic testing, not screening.

Screening can be done by measuring glycated hemoglobin A1c or fasting glucose or with a glucose tolerance test. The recommendation includes tables that list the cutoffs for abnormal glucose levels for impaired fasting glucose, impaired glucose tolerance, and increased average glucose level. Obesity is defined as a body mass index ≥30 kg/m$^2$ and overweight as >25 kg/m$^2$.

This new recommendation expands the list of those at risk and those who should be screened compared to the previous recommendation, but the Task Force found no evidence to support universal screening in adults as advocated by other organizations.

**Source:** USPSTF. Final recommendation statement. Abnormal blood glucose and type 2 diabetes mellitus: screening. Available at: http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/screening-for-abnormal-blood-glucose-and-type-2-diabetes . Accessed November 13, 2015.

**TABLE 2**

### ACIP's recommendations on the use of meningococcal B vaccine in young adults[1]

A serogroup B meningococcal (MenB) vaccine series may be administered to adolescents and young adults ages 16 to 23 years to provide short-term protection against most strains of serogroup B meningococcal disease. The preferred age for MenB vaccination is 16 to 18 years.

- Administer MenB as either a 2-dose series of MenB-4C or a 3-dose series of MenB-FHbp. Neither product is preferred.
- Use the same vaccine product for all doses.
- Keep in mind that MenB-4C and MenB-FHbp may be administered concomitantly with other vaccines indicated for this age range, but at a different anatomic site (if feasible), according to available data and expert opinion.

**TABLE 3**

### Using meningococcal B vaccines in those at high risk and during outbreaks[4]

Recommend MenB vaccine for individuals ≥10 years of age who have any of the following risk factors:

- persistent complement component deficiencies
- anatomic or functional asplenia
- routine exposure to isolates of Neisseria meningitidis (ie, microbiologists)
- exposure to a community experiencing a serogroup B meningococcal disease outbreak.

in high-risk populations and during outbreaks (**TABLE 3**).[4] This recommendation—plus the most recent B recommendation for general use—comprise the totality of current recommendations for the prevention of meningococcal B disease in the United States. JFP


References

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