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ACIP update: 2 new recommendations for meningococcal vaccine

You now need to give previously vaccinated teens a booster dose at age 16 and protect high-risk patients with a 2-dose primary series.

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A t its October 2010 meeting, the Advisory Committee on Immunization Practices (ACIP) made 2 additions to its recommendations for quadrivalent meningococcal conjugate vaccine (MCV4), based on evolving knowledge of the vaccine and its duration of protection.

- A booster dose at age 16 has been added to the routine schedule for those vaccinated at ages 11 to 12 years. A booster dose has also been added for those vaccinated at ages 13 to 15 years, although the recommended timing of this booster had not been finalized at press time.
- A 2-dose primary series, 2 months apart, is now recommended for patients at higher risk of meningococcal disease. The high-risk category includes those with persistent complement component deficiency, asplenia, or human immunodeficiency virus (HIV). High-risk patients who were previously vaccinated should receive a booster dose at the earliest opportunity and continue to receive boosters at the appropriate interval (3-5 years).

Meningitis is rare but serious

Meningococcal meningitis is a potentially devastating disease in adolescents and young adults. It has a case fatality rate of about 20%, and the sequelae for survivors can be severe: 3.1% require limb amputations and another

10.9% suffer neurological deficits.¹ Thankfully, meningococcal disease is rare, occurring at rates below 1 in 200,000 in the 11- to 15-year-old age group and less than 1 in 100,000 in the 16- to 21-year-old age group.²

Routine immunization with MCV4 is recommended for adolescents

In 2007, ACIP recommended routine use of MCV4 for adolescents between the ages of 11 and 18 years. The recommendation gave preference to immunization at ages 11 to 12 years, along with the other adolescent vaccines given at that time.3 Updated recommendations in effect in 2010 state that those at highest risk for meningococcal infection (those with functional or anatomic asplenia, C3 complement deficiency, or HIV infection) should be vaccinated with MCV4 starting at age 2 and revaccinated every 3 years if last vaccinated at 2 to 6 years, and every 5 years if last vaccinated at or after age 7.4,5 TABLE 1 lists the recommendations for MCV4 in place prior to the October 2010 ACIP meeting.

Two MCV4 products are licensed for use in the United States: Menactra (Sanofi Pasteur) and Menveo (Novartis). Both contain antigens against 4 serotypes, A, C, Y, and W-135. Neither protects against type B, which causes a majority of the disease in infants.⁶ In recent years, serotype A disease has become extremely rare in the United States.⁶ MCV4 coverage for adolescents ages 13 to 17 years is

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increasing, going from 41.8% in 2008 to 53.6% in 2009.7 $\,$

The new recommendations: One is more controversial than the other

The recommendation for a 2-dose primary series in high-risk groups was not controversial. The same conditions that place individuals at highest risk for meningococcal infection also result in a less robust response to a single dose of the vaccine, and a 2-dose series is needed to achieve protective antibody levels in a high proportion of those vaccine recipients.⁸ This recommendation will affect relatively few patients.

The recommendation for booster doses in the general adolescent population generated a lot more debate. Studies performed since the licensure of MCV4 have shown that levels of protective antibodies decline over time. Five years after vaccination, 50% of vaccine recipients have levels below that considered fully protective.² One small case-control study of 107 cases suggested that the number of years from receipt of the vaccine was a risk factor for meningococcal disease.²

However, rates of meningococcal meningitis in adolescents have been declining over the past few years (TABLE 2), and there are no surveillance data to support the conclusion that teens vaccinated at ages 11 to 12 years are at increased risk as they age. In addition, the number of cases is very low (TABLE 3) and the cost benefit analysis of a booster dose of MCV4 is very unfavorable.^{1,2}

ACIP weighed the options for a booster dose

Three options were presented at the October 2010 ACIP meeting:

- **Option 1:** No change to the current recommendation for vaccination of 11- to 12year-olds. Wait and see what happens to disease incidence over several more years.
- **Option 2:** Move the age of vaccination to 15 years with no booster. This would allow protection to persist through the years of highest risk (16-21 years).
- **Option 3:** Keep the recommendation for vaccination at ages 11 to 12 years, and add a booster dose at age 16.

The first option was the least cost effective: \$281,000/quality-adjusted life year (QALY). The second option was the most cost effective at \$121,000/QALY. The last option came out in the middle: \$157,000/QALY, but it would save the most lives—9 more per year compared with Option 2.¹ There is, however, a caveat with regard to the cost-effectiveness estimates. The numbers were obtained using incidence data from the year 2000; incidence has declined since then, and cost-effectiveness estimates would be much less favorable using today's rates.

These issues were discussed at length, and the decision to add a booster dose at age 16 was made on a close vote. This decision illustrates how difficult vaccine policymaking has become in recent years, when choices must be made about recommending safe, effective, and expensive vaccines to prevent illnesses that are both rare and serious.

TABLE 1

Recommendations for MCV4 prior to October 2010³⁻⁵

- Immunize all adolescents between the ages of 11 and 18. Immunization at the 11- to 12-year visit is preferred.
- Immunize all individuals between the ages of 2 and 55 who are at increased risk for meningococcal disease: college freshmen living in dormitories, microbiologists routinely exposed to isolates of *Neisseria meningitidis*, military recruits, travelers to (or residents of) countries in which *N meningitidis* meningitis is hyperendemic or epidemic, individuals with terminal complement component deficiencies, and individuals with anatomic or functional asplenia.
- Administer a booster dose for those at continued high risk 3 years after a first dose given between ages 2 and 6, and 5 years after a first dose given at age 7 or older. Revaccinate those in increased risk groups at 5-year intervals indefinitely. The recommendation for a second dose does not apply to college freshmen living in dorms.

MCV4, meningococcal conjugate vaccine

The decision to add a booster dose at age 16 was made on a close vote.

In 2011, advise

patients between the ages of 16 and 20 that it is recommended

that they

receive a booster dose

of MCV4.

TABLE 2

Rates* of serogroup C, Y, and W-135 meningococcal disease⁺

| | Age group (y) | | |
|-----------|---------------|------|--|
| Year | 11-19 | ≥20 | |
| 2004-2005 | 0.23 | 0.16 | |
| 2006-2007 | 0.27 | 0.22 | |
| 2008-2009 | 0.14 | 0.21 | |

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*Annual rate per 100,000.

⁺Serogroup A disease is too rare for inclusion here.

Source: Cohn A. Advisory Committee on Immunization Practices Meeting; October 27, 2010.²

TABLE 3

Average annual number of cases of C, Y, and W-135 meningococcal disease

| Age group (y) | 2000-2004 | 2005-2009 | Change |
|---------------|-----------|-----------|--------|
| 11-14 | 46 | 12 | -74% |
| 15-18 | 106 | 77 | -27% |
| 19-22 | 62 | 52 | -16% |
| Total (11-22) | 214 | 141 | -34% |

Source: Cohn A. Advisory Committee on Immunization Practices Meeting; October 27, 2010.²

The new MCV4 recommendations will be added to the child immunization schedule for 2011.

The take-home message for family physicians is to strive to increase the propor-

tion of 11- to 12-year-olds who are fully vaccinated and in 2011 to begin to advise those who are between the ages of 16 and 20 years of the recommendation for a booster dose of MCV4.

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