ACIP: Vaccine for Meningococcal Disease
Okay for High-Risk Infants

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Children as young as 9 months old who are at high risk for meningococcal disease should be vaccinated with the quadrivalent meningococcal vaccine, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended.

That high-risk group includes those with complement component deficiencies, infants who are in a defined risk group for a community or institutional outbreak, and infants traveling to an area where meningococcal disease is epidemic or highly endemic.

The primary series consists of two doses given at ages 9 and 12 months.

Action Points

- Explain that children as young as 9 months who are at high risk for meningococcal disease should be vaccinated with the quadrivalent meningococcal vaccine, according to the CDC's Advisory Committee on Immunization Practices.

- Note that the high-risk group includes those with complement component deficiencies, infants who are in a defined risk group for a community or institutional outbreak, and infants traveling to an area where meningococcal disease is epidemic or highly endemic.

The new guidance was adopted at one of ACIP's regular meetings at CDC headquarters in Atlanta by a vote of 13 to 1 with one abstention. It was spurred by the FDA's approval in April of Sanofi Pasteur's quadrivalent meningococcal vaccine, Menactra, for use in children as young as 9 months. The vaccine had already been approved for individuals ages 2 to 55.

The other FDA-approved quadrivalent meningococcal vaccine, Novartis' Menveo, has not been approved for use in children younger than 2.

Both vaccines protect against invasive meningococcal disease caused by Neisseria meningitidis serotypes A, C, Y, and W-135.

At the ACIP meeting, David Johnson, MD, MPH, director of scientific and medical affairs at Sanofi Pasteur, presented data from the four clinical trials in children under age 2 that had formed the basis of the FDA's decision to expand the use of Menactra.
In general, the data showed that the vaccine was safe and immunogenic, although there was evidence of some interference from Menactra with protection conferred by the seven-valent pneumococcal conjugate vaccine (PCV7) when the two vaccines were administered together.

Johnson noted, however, that protective levels of PCV7 antibodies were still achieved when given with Menactra.

Amanda Cohn, MD, of CDC’s National Center for Immunization and Respiratory Diseases, said that the clinical impact of the lower PCV7 antibody levels was unclear, although it might be relevant for certain groups of children, such as those with sickle cell disease or anatomic asplenia.

Because of the lack of data on the clinical significance of the finding and because pneumococcal disease represents a greater threat to children with sickle cell disease or anatomic asplenia than meningococcal disease, ACIP decided to leave those groups of children out of the adopted recommendation. The issue will be revisited in future meetings.

The recommendation that was adopted Wednesday called for vaccination with a two-dose series of quadrivalent meningococcal vaccine -- with the doses at least three months apart -- in children ages 9 to 23 months who are at increased risk for meningococcal disease.

Three special considerations were also passed:

- Children requiring protection prior to travel may receive the second dose as early as two months after dose one.
- A two-dose series is required for any child whose first dose was received prior to their second birthday.
- Children who remain at increased risk for meningococcal disease should receive a booster dose three years after the primary series.

Although ACIP’s recommendations do not become official until approved by the CDC director and published in the agency’s Morbidity and Mortality Weekly Report, the CDC has never failed to approve an ACIP recommendation.

Discussion about the role of infant meningococcal vaccination is anticipated to continue into the next ACIP meeting in October, as the FDA is expected to approve two new quadrivalent meningococcal conjugate vaccines within the next year. Those vaccines would be administered in a four-dose series at ages 2, 4, 6, and 12 to 15 months.

ACIP members who conduct clinical vaccine trials or serve on data safety monitoring boards may present to the committee on matters related to vaccines, but they are prohibited from voting on issues related to those vaccines. Regarding other vaccines of the affected company, a member may participate in discussions with the proviso that he or she abstains on all votes related to the vaccines of that company.
ACIP member Janet Englund, MD, reported that her institution receives support from Novartis, Adamas, Chimerix and MedImmune for research support. Member Sara Rosenbaum, JD, reported that her university receives some funding for research support. Member Cody Meissner, MD, reported that payments are made to his university for participation in clinical trials by MedImmune, Pfizer, and Roche.