

Routine Vaccination With Quadrivalent Meningococcal Conjugate Vaccine Not Recommended for Certain Children

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May 5, 2008 — The Advisory Committee on Immunization Practices (ACIP) has decided not to recommend routine vaccination of children aged 2 to 10 years with quadrivalent meningococcal conjugate vaccine (MCV4), according to a report in the May 2 issue of the *Morbidity and Mortality Weekly Report*.

"At its February 2008 meeting, the Advisory Committee on Immunization Practices (ACIP) decided not to recommend routine vaccination of children aged 2 – 10 years against meningococcal disease unless the child is at increased risk for the disease," the report states. "This report summarizes the deliberations of ACIP and the rationale for its decision and restates existing recommendations for meningococcal vaccination among children aged 2 – 10 years at increased risk for meningococcal disease. ACIP continues to recommend routine vaccination against meningococcal disease for all persons aged 11 – 18 years and those persons aged 2 – 55 years who are at increased risk for meningococcal disease."

The ACIP decision not to recommend routine vaccination against meningococcal disease for all children aged 2 to 10 years was based on reviews of safety and immunogenicity data, the epidemiology of meningococcal disease, cost-effectiveness analysis, and programmatic considerations.

However, ACIP continues to recommend vaccination for children aged 2 to 10 years who are at increased risk for meningococcal disease because they are traveling to or are residents of countries where meningococcal disease is hyperendemic or epidemic, or because they have terminal complement deficiencies or anatomic or functional asplenia. On an individual basis according to clinical judgment, clinicians may also decide to vaccinate children aged 2 to 10 years who are infected with HIV.

For children aged 2 to 10 years at increased risk and also for control of outbreaks of meningococcal disease, MCV4 is preferred to quadrivalent meningococcal polysaccharide vaccine (MPSV4; *Menomune*; Sanofi Pasteur). When healthcare clinicians or parents decide on meningococcal vaccination for other children aged 2 to 10 years, MCV4 is also preferred to MPSV4.

Recommendations for use of MCV4 in persons aged 11 to 55 years remain unchanged from earlier published guidelines. These include a recommendation that persons aged 11 to 18 years be routinely vaccinated with MCV4.

For children aged 2 to 10 years who have received MPSV4 and who are still at increased risk for meningococcal disease, ACIP recommends that they be vaccinated with MCV4 3 years after receiving MPSV4. Children who last received MPSV4 more than 3 years before and who are still at increased risk for meningococcal disease should be given MCV4 vaccination as soon as possible.

Children at increased risk for meningococcal disease throughout their lifetime will most likely need subsequent doses of MCV4. To determine whether revaccination with MCV4 is indicated, and in what manner and timetable, ACIP will monitor available data on duration of protection.

A history of Guillain-Barré syndrome (GBS) is a precaution to administration of MCV4 because these individuals might be at increased risk for GBS after MCV4 vaccination.

"Effective meningococcal conjugate vaccines for infants might be available in the near future," the report states. "Phase III clinical trials for meningococcal conjugate vaccine in infants are ongoing, and published data suggest these vaccines are safe and immunogenic. Vaccines that provide protection against meningococcal disease early in life have the potential to greatly reduce the burden of meningococcal disease, especially if they provide protection against serogroup B meningococcal disease."

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Clinical Context

The MCV4 (*Menactra*; Sanofi-Pasteur) was approved by the US Food and Drug Administration on October 17, 2007, for use in children aged 2 to 10 years, adding to the existing approval for use in persons aged 11 to 55 years. MCV4 licensure was based on clinical trials in which the safety and immunogenicity of MCV4 was compared with the MPSV4 and was found to be safe and noninferior to the MPSV4 for all serogroups.

From June 2007 to February 2008, the ACIP Meningococcal Vaccine Workgroup considered use of MCV4 in children aged 2 to 10 years. They reviewed data on MCV4 immunogenicity and safety in this age group, the epidemiology and burden of meningococcal disease, the cost-effectiveness of different vaccination strategies, and the programmatic implications. Based on this review, the expert opinion of workgroup members, and feedback from partner organizations, the ACIP decided at its February 2008 meeting not to routinely vaccinate children aged 2 to 10 years.

Study Highlights

- ACIP evaluated data and concluded that evidence was insufficient to determine that 1 dose of MCV4 administered at age 2 years would protect against meningococcal disease through late adolescence and college entry.
- Serum bactericidal activity among children aged 2 to 3 years who received MCV4 was lower vs children aged 4 to 10 years.
- ACIP also reviewed the burden of meningococcal disease among children aged 2 to 10 years.
- Between 1998 and 2007 in the United States, overall rates of meningococcal disease were lower in children aged 2 to 10 years vs infants younger than 2 years and adolescents aged 11 to 19 years.
- Of cases in children aged 2 to 10 years, 41% occurred among children aged 2 to 3 years.
- Among cases that occurred in children 2 to 10 years old, 59% were caused by serogroups contained in MCV4 (A, C, Y, and W-135) vs 77% of cases among those 11 to 19 years old.
- A cost-effectiveness analysis determined that vaccinating children aged 2 years was less cost effective than vaccinating children aged 11 years.
- As of February 2008, the ACIP does not recommend routine vaccination of children aged 2 to 10 years against meningococcal disease unless the child is at increased risk.
- ACIP continues to recommend vaccination for children aged 2 to 10 years who are at increased risk for meningococcal disease.
- Risk factors for meningococcal disease include travel to or residence in countries where meningococcal disease is hyperendemic or epidemic, terminal complement deficiencies, and anatomic or functional asplenia.
- Using clinical judgment on a case-by-case basis, clinicians may also decide to vaccinate children aged 2 to 10 years who are infected with HIV.
- MCV4 is preferred to MPSV4 for children aged 2 to 10 years at increased risk, for control of meningococcal disease outbreaks, and when clinicians or parents decide on meningococcal vaccination for other children aged 2 to 10 years.
- Children aged 2 to 10 years who have received MPSV4 and who are still at increased risk for meningococcal disease should be vaccinated with MCV4 3 years after receiving MPSV4.
- Children who last received MPSV4 less than 3 years before and who are still at increased risk for meningococcal disease should receive MCV4 vaccination as soon as possible.
- Recommendations for use of MCV4 in persons aged 11 to 55 years remain unchanged from earlier published guidelines.
- ACIP continues to recommend routine vaccination against meningococcal disease for all persons aged 11 to 18 years.
- ACIP recommends vaccination against meningococcal disease for persons aged 2 to 55 years who are at increased risk for meningococcal disease.
- Children at increased risk for meningococcal disease throughout their lifetime will most likely need subsequent doses of MCV4, with specific recommendations anticipated based on ongoing ACIP monitoring on duration of protection.
- A history of GBS is a precaution to MCV4 vaccination because these individuals might be at increased risk for GBS after MCV4 vaccination.

Pearls for Practice

- As of February 2008, the ACIP does not recommend routine vaccination of children aged 2 to 10 years against meningococcal disease unless the child is at increased risk because of travel to or residence in countries where meningococcal disease is hyperendemic or epidemic, terminal complement deficiencies, or anatomic or functional asplenia.

Recommendations for use of MCV4 in persons aged 11 to 55 years remain unchanged from earlier published guidelines. ACIP continues to recommend routine vaccination against meningococcal disease for all persons aged 11 to 18 years. ACIP recommends vaccination against meningococcal disease for persons aged 2 to 55 years who are at increased risk for meningococcal disease.