Licensure of a Meningococcal Conjugate Vaccine (Menveo) and Guidance for Use — Advisory Committee on Immunization Practices (ACIP), 2010

On February 19, 2010, the Food and Drug Administration (FDA) licensed a quadrivalent meningococcal conjugate vaccine, MenACWY-CRM (Menveo, Novartis Vaccines and Diagnostics). MenACWY-CRM is licensed as a single dose for use among persons aged 11–55 years. The Advisory Committee on Immunization Practices (ACIP) reviewed data from prelicensure clinical trials on the safety and immunogenicity of MenACWY-CRM. This report summarizes the approved indications for MenACWY-CRM and provides guidance from ACIP for its use. The following guidance for use of MenACWY-CRM is consistent with licensed indications and ACIP recommendations for meningococcal conjugate vaccines.

MenACWY-CRM consists of two components: 1) 10 μg of lyophilized meningococcal serogroup A capsular polysaccharide conjugated to CRM_{197} (MenA) and 2) 5 μg each of capsular polysaccharide of serogroup C, Y, and W135 conjugated to CRM_{197} in 0.5 mL of phosphate buffered saline, which is used to reconstitute the lyophilized MenA component before injection (*1*). The reconstituted vaccine should be used immediately, but may be held at or below 77°F (25°C) for up to 8 hours. MenACWY-CRM is administered as an intramuscular injection, preferably into the deltoid region (*1*).

The capsular polysaccharide serogroups included in MenACWY-CRM are the same as those contained in Sanofi Pasteur's MCV4 (Menactra). In study participants aged 11–18 years, noninferiority of MenACWY-CRM to MCV4 was demonstrated for all four serogroups using the primary endpoint, hSBA seroresponse (serum bactericidal assay using human complement). The proportions of subjects with hSBA seroresponse were statistically higher for serogroups A, W, and Y in the MenACWY-CRM group, compared with the MCV4 group. The clinical relevance of higher postvaccination immune responses is not known (*1*). Safety and reactogenicity profiles were comparable to those observed with MCV4 (*1*).

Guidance for Use of MenACWY-CRM

MenACWY-CRM is licensed by the FDA as a single dose in persons aged 11–55 years (*1*). ACIP recommends quadrivalent meningococcal conjugate vaccine for all persons aged 11–18 years and for persons aged 2–55 years who are at increased risk for meningococcal disease. Persons at increased risk for meningococcal disease include 1) college freshmen living in dormitories, 2) microbiologists who are exposed routinely to isolates of *Neisseria meningitidis*, 3) military recruits, 4) persons who travel to or reside in countries where meningococcal disease is hyperendemic or epidemic, 5) persons who have persistent complement component deficiencies, and 6) persons with anatomic or functional asplenia (*2*). MenACWY-CRM or MCV4 may be used in persons aged 11–55 years, and are preferred to quadrivalent meningococcal polysaccharide vaccine (MPSV4) (*2*). Persons aged 2–10 years who are recommended to receive a meningococcal vaccine should receive MCV4, and persons aged >55 years should receive MPSV4 (*3*).

Severe allergic reaction (e.g., anaphylaxis) after a previous dose of Menveo, any component of this vaccine, or any other CRM_{197}, diphtheria toxoid, or meningococcal-containing vaccine is a contraindication to administration of Menveo. Details regarding the recommended meningococcal vaccination schedule are available at http://www.cdc.gov/vaccines/recs/schedules/default.htm#child. Adverse events after receipt of any vaccine should be reported to the Vaccine Adverse Event Reporting System at http://vaers.hhs.gov.

References

1. Food and Drug Administration. Product approval information: package insert. Menveo (Meningococcal [Groups A, C, Y and W-135] oligosaccharide diphtheria CRM_{197} conjugate vaccine). Available at http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm201349.pdf. Accessed March 10, 2010.
2. CDC. Prevention and control of meningococcal disease: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2005;54(No. RR-7).
3. CDC. Updated recommendation from the Advisory Committee on Immunization Practices (ACIP) for revaccination of persons at prolonged increased risk for meningococcal disease. MMWR 2009;58:1042–3.

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Invasive Pneumococcal Disease in Young Children Before Licensure of 13-Valent Pneumococcal Conjugate Vaccine — United States, 2007

Invasive pneumococcal disease (IPD), caused by *Streptococcus pneumoniae* (pneumococcus), remains a leading cause of serious illness in children and adults worldwide (*1*). After routine infant immunization with a 7-valent pneumococcal conjugate vaccine (PCV7) began in 2000, IPD among children aged <5 years in the United States decreased by 76%; however, IPD from non-PCV7 serotypes, particularly 19A, has increased (*2*). In February 2010, the Advisory Committee on Immunization Practices (ACIP) issued recommendations for use of a newly licensed 13-valent pneumococcal conjugate vaccine (PCV13) (*3*). PCV13 contains the seven serotypes in PCV7 (4, 6B, 9V, 14, 18C, 19F, and 23F) and six additional serotypes (1, 3, 5, 6A, 7F, and 19A). To characterize the potentially vaccine-preventable IPD burden among children aged <5 years in the United States, CDC and investigators analyzed 2007 data from Active Bacterial Core surveillance (ABCs). This report summarizes the results of that analysis, which found that among 427 IPD cases with known serotype in children aged <5 years, 274 (64%) were caused by serotypes contained in PCV13. In 2007, an estimated 4,600 cases of IPD occurred in children in this age group in the United States, including approximately 2,900 cases caused by serotypes covered in PCV13 (versus 70 cases caused by PCV7 serotypes). PCV13 use has the potential to further reduce IPD in the United States. Post-licensure monitoring will help characterize the effectiveness of PCV13 in different populations and track the potential changes in disease burden caused by non-PCV13 serotypes.

ABCs* of the Emerging Infections Program (EIP) Network is a collaboration between CDC and 10 selected sites. ABCs conducts population- and laboratory-based active surveillance. During 2006 and 2007, IPD surveillance was conducted in Connecticut, Minnesota, and New Mexico, and selected counties in California, Colorado, Georgia, Maryland, New York, Oregon, and Tennessee. In 2007, the total catchment population of children aged <5 years for these 10 sites was 2.1 million. A case of IPD was defined as isolation of *S. pneumoniae* from a normally sterile body site (primarily blood or cerebrospinal fluid) in a resident of an ABCs area. Pneumococcal isolates were serotyped at CDC and reference laboratories. Serotype information was analyzed by vaccine serotype group (Table 1). Age-, race- and vaccine serotype-specific rates of IPD were calculated using observed IPD cases in the 2007 ABCs data as the numerator and U.S. Census Bureau projections of the 2007 population of ABCs sites as the denominator. To estimate the incidence and total number of IPD cases in the United States in 2007, rates were standardized to the entire U.S. population, adjusting for small differences between age and race distributions of ABCs areas and the U.S. population.

Investigators reviewed medical records to identify children aged 24–59 months with underlying medical conditions who are recommended by ACIP to receive the 23-valent pneumococcal polysaccharide vaccine (PPSV23) (*1*). Characteristics of these high-risk children and healthy children were compared by chi-square test; data from 2006 and 2007 were summed

* Available at http://www.cdc.gov/abcs/index.html.

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