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Meningococcal Conjugate Vaccines Policy Update: Booster Dose Recommendations

Committee on Infectious Diseases

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POLICY STATEMENT

Meningococcal Conjugate Vaccines Policy Update: Booster Dose Recommendations

COMMITTEE ON INFECTIOUS DISEASES

KEY WORDS

adolescents, meningitis, meningococcal vaccine, immunization, vaccination

ABBREVIATIONS

MCV4—quadrivalent meningococcal conjugate vaccine

CI—confidence interval

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abstract

FREE

The Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention and the American Academy of Pediatrics approved updated recommendations for the use of quadrivalent (serogroups A, C, W-135, and Y) meningococcal conjugate vaccines (Menactra [Sanofi Pasteur, Swiftwater, PA] and Menveo [Novartis, Basel, Switzerland]) in adolescents and in people at persistent high risk of meningococcal disease. The recommendations supplement previous Advisory Committee on Immunization Practices and American Academy of Pediatrics recommendations for meningococcal vaccinations. Data were reviewed pertaining to immunogenicity in high-risk groups, bactericidal antibody persistence after immunization, current epidemiology of meningococcal disease, meningococcal conjugate vaccine effectiveness, and cost-effectiveness of different strategies for vaccination of adolescents. This review prompted the following recommendations: (1) adolescents should be routinely immunized at 11 through 12 years of age and given a booster dose at 16 years of age; (2) adolescents who received their first dose at age 13 through 15 years should receive a booster at age 16 through 18 years or up to 5 years after their first dose; (3) adolescents who receive their first dose of meningococcal conjugate vaccine at or after 16 years of age do not need a booster dose; (4) a 2-dose primary series should be administered 2 months apart for those who are at increased risk of invasive meningococcal disease because of persistent complement component (eg, C5–C9, properdin, factor H, or factor D) deficiency (9 months through 54 years of age) or functional or anatomic asplenia (2–54 years of age) and for adolescents with HIV infection; and (5) a booster dose should be given 3 years after the primary series if the primary 2-dose series was given from 2 through 6 years of age and every 5 years for persons whose 2-dose primary series or booster dose was given at 7 years of age or older who are at risk of invasive meningococcal disease because of persistent component (eg, C5–C9, properdin, factor H, or factor D) deficiency or functional or anatomic asplenia. *Pediatrics* 2011;128:1213–1218

INTRODUCTION

Neisseria meningitidis is an important cause of invasive bacterial disease in infants, children, adolescents, and young adults. The highest rates occur in children younger than 1 year. Unlike infants in whom serogroup B meningococcus causes the majority of invasive disease, the majority of cases in adolescents and young adults in the United States are caused by serogroups that are included in available vac-

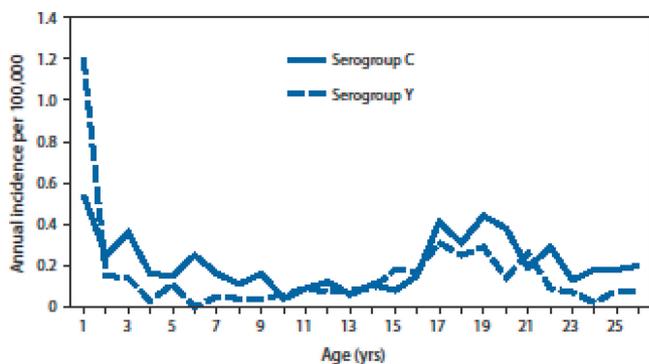


FIGURE 1

Annual incidence of meningococcal disease (serogroup C and serogroup Y), by age—Active Bacterial Core Surveillance (ABCs), United States 1999–2008. (Reproduced with permission from Centers for Disease Control and Prevention. *MMWR Morb Mortal Wkly Rep.* 2011;60[3]:73.)

cines. Adolescents and young adults experience rates of meningococcal disease that exceed those of the general population.¹ Increased risk begins at 14 years of age and persists through the age of 22 years (Fig 1).¹

BACKGROUND AND RATIONALE

In 2005, the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention and the American Academy of Pediatrics developed recommendations for the use of the quadrivalent meningococcal conjugate vaccine (MCV4) with the objective of protecting adolescents as well as young adults aged 16 through 21 years, the time at which meningococcal disease rates peak.^{2–6} Recent information on persistence of antibodies and the occurrence of breakthrough cases indicates that this recommendation for administration of MCV4 at 11 through 12 years of age may not provide protection for more than 5 years or throughout the full period of highest risk.

Certain immunocompromising conditions predispose to invasive meningococcal infection, including persistent complement component (such as C5–C9, properdin, factor H, or factor D) deficiency, functional or anatomic asplenia, and HIV infection. These immunocompromising conditions may reduce immune response to the me-

ningococcal conjugate vaccine or may require higher titers of antibody to provide protection. Thus, people with these conditions are likely to benefit from a 2-dose primary series.

RATIONALE FOR ADDING A BOOSTER DOSE TO THE ADOLESCENT MENINGOCOCCAL IMMUNIZATION SCHEDULE

In 2005, when the recommendation was made for routine administration of meningococcal vaccine to 11- through 12-year-olds,^{2,4} with catch-up immunization through 18 years of age, protective anti-

body concentrations were expected to persist for 10 years, through the period of increased vulnerability. Recent studies that evaluated antibody persistence after administration of MCV4 demonstrated that approximately 50% of persons vaccinated 5 years earlier will not have protective bactericidal antibody concentrations for serogroups C and Y (Table 1).^{7–12} These serologic data demonstrated waning immunity 5 years after MCV4 administration, and serum antibody concentrations returned to levels similar to those detected in vaccine-naïve individuals (Sanofi Pasteur [5-year follow-up of 11- to 18-year-olds at first dose], personal communication, sanofi provided slides with the data to the ACIP Meningococcal Working Group. Written communication/unpublished data.).

Additional data suggest that waning antibody concentrations result in increased susceptibility to meningococcal disease in older adolescents and young adults.¹³ Comparisons of the numbers of estimated annual cases of serogroup C and Y disease in the period before the vaccine recommendation (2000–2004) with those from post-vaccine-recommendation years

TABLE 1 Summary of Serogroup C Bactericidal Antibody Persistence as Determined by Serum Bactericidal Activity (SBA) 2–5 Years After Vaccination With Menveo and/or Menactra

Age Group (yrs) at Vaccination	Years Postvaccination	Serogroup C SBA	Vaccine	No. of Vaccine Recipients in Study	% of Recipients With Protective Antibody Levels
11 through 18*	2	% hSBA "" 1:8	Menveo	273	62
			Menactra	185	58
11 through 18†	3	% hSBA "" 1:4	Menactra	52	35
			MPSV4	48	35
11 through 18§	3	% brSBA "" 1:128	Menactra	71	75
			MPSV4	72	60
2 through 10§	5	% brSBA "" 1:128	Menactra	108	55
11 through 18§	5	% brSBA "" 1:128	MPSV4	207	42
			Menactra	16	56
			MPSV4	10	60

Abbreviations: hSBA-SBA using human complement; brSBA-SBA using baby rabbit complement; MPSV4-quadrivalent meningococcal polysaccharide vaccine.

* Source: Gill C, Baxter R, Anemona A, Cavarro G, Dull P. Persistence of immune responses after a single dose of Novartis meningococcal serogroup A, C, W-135 and Y CRM-197 conjugate vaccine (Menveo) or Menactra among healthy adolescents. *Human Vaccines*; 2010, 6:881–7.

† Source: Vu DM, Welsch JA, Zuno-Mitchell P, Dela Cruz N, Granoff DM. Antibody persistence 3 years after immunization of adolescents with quadrivalent meningococcal conjugate vaccine. *J Infect Dis* 2006;193:821–8.

§ Source: Proceedings of the Advisory Committee on Immunization Practices (ACIP) meeting, June 2009.

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(2005–2009) revealed a greater reduction in the number of cases among adolescents aged 11 through 14 years (74% reduction) when compared with older adolescents of aged 15 through 18 years (27% reduction).

A case-control study that evaluated vaccine effectiveness of the first licensed MCV4 (Menactra [Sanofi Pasteur, Swiftwater, PA]) noted a decrease in vaccine effectiveness with time since immunization.¹⁴ The overall vaccine effectiveness for adolescents immunized 0 to 5 years previously was 78.0% (95% confidence interval [CI]: 29%–93%). The effectiveness of the vaccine for persons vaccinated less than 1 year earlier, 1 year earlier, and 2 through 5 years earlier was 95% (95% CI: 10%–100%), 91% (95% CI: 10%–101%), and 58% (95% CI: 72%–89%), respectively. Although the 95% CIs around the point estimate were wide, the trend supports waning immunity. Data for vaccine effectiveness beyond 5 years since immunization are not available.

Between July 1, 2006, and October 31, 2010, the Centers for Disease Control and Prevention received 30 reports of serogroup C or Y invasive meningococcal disease in persons aged 15 through 22 years who had previously received a meningococcal conjugate vaccine; 12 of the 30 cases of meningococcal disease occurred in 2010. The mean age of people in these cases from 2010 was 18.2 years (range: 16–22 years). The mean time since they had received their meningococcal conjugate vaccine and the development of meningococcal disease was 3.25 years (range: 1.5–4.6 years). Five of these 12 people with breakthrough meningococcal disease had an underlying condition that might have affected their risk of meningococcal disease (Centers for Disease Control and Prevention, personal communication from Amanda Cohn MD, 2010).¹

Cases of breakthrough meningococcal disease in MCV4 recipients seem to

have clinical manifestations similar to disease occurring in vaccine-naïve persons.^{14,15} The lack of modification of illness suggests that an anamnestic immune response was not sufficient to modify disease severity. Recent data suggest that the memory response after meningococcal C conjugate vaccine is not rapid enough to protect against disease.¹⁵ The incubation period for invasive meningococcal disease is usually less than 3 days. After initial priming with monovalent meningococcal C (MenC) conjugate vaccine, a memory response after a booster dose is not measurable until 5 to 7 days after the booster.⁹

Herd immunity seems to be important for long-term protection after widespread use of monovalent meningococcal C conjugate vaccine in the United Kingdom. Immunization coverage with MCV4 has been slow in the United States. In the 2009 National Immunization Survey-Teen, 53.6% of adolescents aged 13 through 17 years had received a dose of meningococcal vaccine.¹⁶ To date, there is no evidence that this level of uptake of a single dose of MCV4 provides herd immunity in the United States.

Two studies have assessed the serologic response after a booster dose of MCV4 (Menactra).^{7,14} When a booster dose was administered either 3 or 5 years after the first dose, the geometric mean titer elicited after the booster dose was substantially higher than that after the primary dose. This finding is consistent with expectations that the first dose of MCV4 primes the immune system and results in a strong response to the booster dose. Local and systemic reactions to the booster dose were comparable to reactions noted in persons who received a first dose. The duration of protective concentrations of antibody after a booster dose is not known. A booster dose administered at 16 through 18 years of

age is expected to result in protective antibody concentrations through the age of 21 years.

The cost of a second dose of MCV4 in adolescents was considered in deliberations that led to the new recommendation. When using the cost-effectiveness measure of quality-adjusted life-years (QALYs), the 2-dose schedule had a lower cost per QALY than did the recommendation for a single dose given at 11 through 12 years of age, because the 2-dose series results in a greater reduction in the number of cases, morbidities, and mortalities attributable to invasive meningococcal disease.¹⁷ Another option was a single dose of MCV4 at 15 years of age. This had the lowest cost per QALY of the 3 options considered (no change in recommendation; single dose at 15 years of age; and 2 doses: at 11–12 years of age and a booster at 16 years of age).¹⁷ However, the cost per QALY for the single dose at 15 years of age and the 2-dose series at 11 and 16 years of age was not significantly different, and the 2-dose series resulted in fewer cases of invasive meningococcal disease and fewer deaths.¹⁷

RATIONALE FOR A 2-DOSE PRIMARY SERIES FOR PERSONS WITH PERSISTENT COMPLEMENT COMPONENT DEFICIENCY, FUNCTIONAL OR ANATOMIC ASPLENIA, OR HIV

People with persistent complement component deficiency or properdin deficiency respond similarly to healthy children when immunized with the quadrivalent meningococcal polysaccharide vaccine (MPSV4). However, their antibodies wane more quickly than do those of healthy children. Antibody data from this population after administration of MCV4 are lacking. Maintaining high antibody concentrations is important for people with complement component deficiency, because higher antibody con-

centrations are needed for other clearance mechanisms, such as opsonophagocytosis, to kill meningococci.^{18,19}

Asplenic people achieve significantly lower geometric mean serum bactericidal activity than do healthy people immunized with monovalent meningococcal C conjugate vaccine. In 1 study, a protective antibody concentration was not achieved in 20% of asplenic people after vaccination.²⁰ However, the percentage of those in whom protective antibody concentrations did not develop decreased to 7% when a booster dose was given 2 months later, which suggests that a booster dose can increase the proportion of asplenic people who have protective antibody concentrations and might be able to achieve higher circulating antibody concentrations and improve immunologic memory.

Although HIV-infected children may have an increased risk of meningococcal disease, the magnitude of the increased risk has not been established. MCV4 is not routinely recommended for HIV-infected children younger than 11 years. Response rates to MCV4

among HIV-infected adolescents are lower than those in healthy adolescents. In 1 study, seroconversion rates were significantly lower in adolescents with CD4⁺ T-lymphocyte percentages less than 15% or viral loads greater than 10 000 copies per mL.²¹

A 2-dose primary series has not been studied in older children or adolescents. However, immunogenicity and safety of a 2-dose primary series of MCV4 with either Menactra or Menveo (Novartis, Basel, Switzerland) have been evaluated in infants and young children. Infants who received a 2-dose primary series of Menactra at 9 months and 12 through 15 months of age developed high antibody titers after the second dose. Data provided by Sanofi Pasteur has noted decreases in antibody concentrations for some pneumococcal serotypes when Menactra is administered at the same time as Prevnar 7 (Wyeth Pharmaceuticals, Philadelphia, PA) at 9 months and 12 to 15 months of age. The clinical significance of these decreased antibody concentrations is not clear. Because pneumococcal infections are a more common

problem in children with asplenia (functional or anatomic), it would be prudent to provide age-appropriate pneumococcal conjugate vaccines to asplenic children and provide MCV4 after completion of the pneumococcal conjugate vaccine series. Adverse events after 2 doses of Menveo given 2 months apart to children 2 through 5 years of age had similar rates as after a single dose.²²

UPDATED MENINGOCOCCAL CONJUGATE VACCINE RECOMMENDATIONS

Routine Vaccination of Adolescents 11 Through 18 Years of Age

Routine immunization of adolescents with MCV4 is recommended at age 11 through 12 years along with a 1-time booster dose at 16 years of age (Table 2). For adolescents who receive their first dose of MCV4 at age 13 through 15 years, a 1-time booster should be administered, preferably at age 16 through 18 years, to provide additional protection during the period of increased risk. Adolescents who receive their first dose of MCV4 at or after 16 years of age do not need a booster

TABLE 2 Recommended Vaccination Schedule and Intervals

	Subgroup	Primary Vaccination	Booster Dose
9–23 mo, with high-risk conditions	Children with complement deficiencies	2 doses of MCV4, 3 mo apart	If the first dose is received at 9 mo to 6 y of age and child remains at increased risk for meningococcal disease , child should receive an additional dose of MCV4 3 y after primary vaccination; boosters should be repeated every 5 y thereafter
	Children with HIV, if another indication for vaccination exists	2 doses of MCV4, 3 mo apart	
	All others in this age group recommended for vaccination (travelers to the “meningitis belt,” etc)	2 doses of MCV4, 3 mo apart (infants receiving the vaccine before travel can receive the doses as early as 2 mo apart)	
2–18 y, with high risk conditions ^a	Children with complement deficiencies or functional or anatomic asplenia	2 doses of MCV4, 2 mo apart	If the first dose is received at 7 y of age or older and child remains at increased risk for meningococcal disease , child should receive an additional dose of MCV4 5 y after primary vaccination; boosters should be repeated every 5 y thereafter
	Children with HIV, if another indication for vaccination exists	2 doses of MCV4, 2 mo apart	
	All others in this age group recommended for vaccination (travelers to the Meningitis Belt, etc)	1 dose of MCV4	
All other children aged 11–18 y	—	Routine vaccination with MCV4 at ages 11–12 y	If vaccinated at age 11–12 y , should receive a 1-time booster dose at the age of 16 y If vaccinated at age 13–15 y , should receive a 1-time booster dose at the age of 16–18 y

Currently, there are currently 2 licensed MCV4 products. One product, Menactra, is manufactured by Sanofi Pasteur and is licensed for use in persons aged 9 months through 55 years of age. The second product, Menveo, is manufactured by Novartis Vaccines and Diagnostics, Inc and is licensed for use in persons aged 2 through 55 years of age. A meningococcal polysaccharide vaccine is also available. This product is licensed for use in persons 2 years of age and older and may be used when meningococcal conjugate vaccine is unavailable or contraindicated.

^a Includes children who have complement (eg, C5–C9, properdin, factor H, or factor) deficiencies or anatomic or functional asplenia and children with HIV infection; travelers to or residents of countries in which meningococcal disease is hyperendemic or epidemic; and children who are part of a community outbreak of a vaccine-preventable serogroup.

dose. Immunization with the MCV4 vaccine is not recommended after 21 years of age in healthy people because of diminished risk of meningococcal disease after that age.

People at Persistent Increased Risk of Meningococcal Disease

People with persistent complement deficiencies, functional or anatomic asplenia, or HIV infection should receive a 2-dose primary series given 2 months apart. Children aged 9 months or older with persistent complement deficiencies or functional or anatomic asplenia should receive the 2-dose primary series of MCV4. Children aged 2 years or older with functional or anatomic asplenia should receive the 2-dose primary series of MCV4. HIV-infected adolescents (>11 years) should receive a 2-dose primary series of MCV4 if they have not received any doses of MCV4 previously. HIV-infected children aged 2 through 10 years are likely to be at increased risk of meningococcal disease, but the risk is not as great as for invasive *Streptococcus pneumoniae*. MCV4 is not routinely recommended for HIV-infected children younger than 11 years. Providers may elect to give HIV-infected children aged 2 through 10 years a 2-dose primary series of MCV4. People with a history of complement component deficiency, asplenia, or HIV infection who have previously received a single dose of meningococcal conjugate vaccine as their primary dose should receive a second dose at least 2 months later. Booster doses should be given 3 years after the primary series if the primary 2-dose series was given from 2 through 6 years of age and 5 years after the primary series if the primary 2-dose series was given at 7 years of age or older. Boosters should then be given every 5 years. People who are at increased risk of meningococcal disease other than those with immunocompromising conditions (microbiologists who work routinely with *N meningi-*

tidis or travelers to or residents of countries in which meningococcal disease is hyperendemic) should receive a single-dose primary series. If they remain at increased risk, a booster dose should be given 3 years later if the primary dose was given from 2 through 6 years of age and 5 years after the last dose if the previous dose was given at 7 years of age or older. If they continue to remain at risk, additional boosters should be given every 5 years.

IMPLEMENTATION ISSUES

Whenever feasible, the same brand of vaccine should be used for all doses of the vaccination series. Data are limited on the interchangeability of meningococcal vaccine products from different manufacturers. A small study revealed similar antibody responses when either Menactra or Menveo was given after a first dose of Menactra. If vaccination providers do not know or do not have available the brand of vaccine product previously administered, any product should be used to continue or complete the series. People who received quadrivalent meningococcal polysaccharide vaccine 5 or more years previously and remain at risk of meningococcal disease should be revaccinated with MCV4. There are no data to provide guidance as to how to address future needs for MCV4 vaccine in children who may have received vaccine products overseas that differ from products available in the United States. If these children remain at risk of meningococcal disease (healthy adolescent aged 11 years or older, complement deficiency, asplenia, etc), it would be prudent to provide MCV4 according to the recommendations for their risk group.

MCV4 is safe and immunogenic among nonpregnant women aged 11 through 55 years. No data are available on the safety of MCV4 during pregnancy. MCV4 should only be given to a pregnant woman if the benefit of providing vaccine during pregnancy outweighs the potential for risk.

There is no contraindication to administering any dose of MCV4 to a woman who is breastfeeding.

Some states, secondary schools, colleges, or universities have policies that require immunization against meningococcal disease as a condition of enrollment. A single dose of MCV4 5 or fewer years before matriculation should be considered acceptable. A booster dose should be administered before matriculation if the adolescent was immunized more than 5 years previously.

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