

### **POLICY STATEMENT**

# Updated Recommendations on the Use of Meningococcal Vaccines

### abstract



Since the last policy statement from the American Academy of Pediatrics (AAP) concerning meningococcal vaccine was published in 2011, 2 meningococcal conjugate vaccines have been licensed for use in infants (HibMenCY-TT and MenACWY-CRM). The Centers for Disease Control and Prevention (CDC) has published new recommendations, "Prevention and Control of Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices," which have been endorsed by the AAP. However, the CDC recommendations were published before licensure of MenACWY-CRM for infant use. This policy statement updates the AAP recommendations for use of meningococcal vaccines in children and adolescents. A more comprehensive review of background and technical information can be found in the CDC publication. *Pediatrics* 2014;134:400–403

Neisseria meningitidis is responsible for a spectrum of infections, such as meningitis, bacteremia, and pneumonia, and may be associated with long-term sequelae and death. Five serogroups of N. meningitidis (A, B, C, W, and Y) are responsible for the vast majority of disease in children and adults. Specific meningococcal serogroups appear to cause a preponderance of disease in certain age groups and geographic areas. For example, in the United States, N. meningitidis serogroup B is predominant in children younger than age 5 years, whereas serogroups C and Y are responsible for the majority of cases in adolescents. N. meningitidis serogroup A is hyperendemic in sub-Saharan Africa (the so-called "meningitis" belt) but it is rarely diagnosed in the United States.

For unknown reasons, the incidence of meningococcal disease has decreased in the United States since the late 1990s. The decrease started before the availability of the meningococcal conjugate vaccine and recommendations for routine meningococcal vaccine use in adolescents. Declines in incidence have occurred in all serogroups, including serogroup B, which is currently not included in any meningococcal vaccine licensed in the United States.

In the United States, 4 licensed meningococcal vaccines are available. One is a quadrivalent (A, C, W-135, Y) polysaccharide vaccine (MPSV4 [Menomune, Sanofi Pasteur, Inc, Swiftwater, PA]). There are 2 quadrivalent conjugate vaccines (A, C, W, Y) (MenACWY-D [Menactra, Sanofi Pasteur, Inc] and MenACWY-CRM [Menveo, Novartis Vaccines and Diagnostics, Inc, Cambridge, MA]), and 1 bivalent (C; Y) conjugate vaccine (HibMenCY-TT [MenHibrix, GlaxoSmithKline Biologicals, Research Triangle Park, NC]), which is also approved as a vaccine for *Haemophilus influenzae* type b (Table 1).

#### COMMITTEE ON INFECTIOUS DISEASES

#### **KEY WORDS**

meningococcus, meningococcal vaccine, adolescent vaccines, immunization schedule

#### **ABBREVIATIONS**

AAP—American Academy of Pediatrics CDC—Centers for Disease Control and Prevention Hib—Haemophilus influenzae type b

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TABLE 1 Licensed Meningococcal Vaccines: United States, 1981–2013

Formulation	Туре	Trade Name	Manufacturer	Licensed (y)	Age Group	Dose(s)	Serogroups
MPSV4 <sup>a</sup>	Polysaccharide	Menomune	Sanofi Pasteur	1981	≥2 y	Single dose	A, C, W, and Y
MenACWY-D <sup>b</sup>	Conjugate	Menactra	Sanofi Pasteur	2005	11 to 55 y	Single dose	A, C, W, and Y
MenACWY-D <sup>b</sup>	Conjugate	Menactra	Sanofi Pasteur	2007	2 to 10 y	Single dose	A, C, W, and Y
MenACWY-D <sup>b</sup>	Conjugate	Menactra	Sanofi Pasteur	2011	9 to 23 mo	2-dose series	A, C, W, and Y
MenACWY-CRM <sup>c</sup>	Conjugate	Menveo	Novartis	2010	11 to 55 y	Single dose	A, C, W, and Y
MenACWY-CRM <sup>c</sup>	Conjugate	Menveo	Novartis	2011	2 to 10 y	Single dose	A, C, W, and Y
MenACWY-CRM <sup>c</sup>	Conjugate	Menveo	Novartis	2013	2 mo to 2 y	4-dose series	A, C, W, and Y
Hib-MenCY-TT <sup>d</sup>	Conjugate	MenHibrix	GlaxoSmithKline	2012	6 wk to 18 mo	4-dose series	C and Y

<sup>&</sup>lt;sup>a</sup> Package insert available at: http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/Approvedproducts/UCM308370.pdf

### **BACKGROUND AND RATIONALE**

Meningococcal vaccines are recommended routinely for adolescents and for selected groups of children at increased or persistent risk for invasive meningococcal disease (Table 2). There are 2 types of meningococcal vaccines: (1) polysaccharide and (2) conjugated polysaccharide vaccines. Conjugated polysaccharide vaccines use a T-cell-dependent mechanism that results in a more robust primary immune response and immunologic memory and boosting potential, as compared with polysaccharide-only vaccines that use a T-cell independent mechanism. The new indications and newly licensed vaccines address immunization of younger children at increased risk for meningococcal disease.

This document provides a complete update of policy recommendations of the American Academy of Pediatrics for children and adolescents.

### **RECOMMENDATIONS**

The following are meningococcal vaccination recommendations (Table 3):

- For the pediatric population, an ageappropriate meningococcal conjugate vaccine is preferred to the meningococcal polysaccharide vaccine, unless there is a contraindication for the meningococcal conjugate vaccine.
- 2. Adolescents should be routinely immunized at 11 to 12 years of age and given a booster dose at

16 years of age with a quadrivalent conjugated meningococcal vaccine.

- 3. Adolescents who received their first dose at age 13 to 15 years should receive a booster at age 16 to 18 years at least 8 weeks or up to 5 years after their first dose.
- Adolescents who receive their first dose of meningococcal conjugate vaccine at or after 16 years of age do not need a booster dose.
- 5. Unvaccinated or previously vaccinated first-year college students through age 21 years living in residence halls who received their last dose before their 16th birthday (ie, incompletely vaccinated) should receive a single dose of quadrivalent meningococcal conjugate vaccine.
- 6. For individuals who are at increased risk for invasive meningococcal disease because of persistent complement (eg, C3, C5–C9, properdin, factor H, or factor D) deficiency or functional or anatomic asplenia, a 2dose primary series (MenACWY-D or MenACWY-CRM) is administered to individuals 2 to 55 years of age, and a 4-dose primary series (MenACWY-CRM or Hib-MenCY-TT) is administered to children 2 to 18 months of age. MenACWY-D can be administered as a 2-dose series to infants 9 to 23 months of age with persistent complement component deficiency, and in infants up to 23 months of age after the fourth dose of the primary pneu-

- mococcal conjugate vaccine has been given in children who have functional or anatomic asplenia.
- 7. HIV infection is not an indication for routine MenACWY immunization before 11 years of age. However, HIV-infected children 11 years of age or older should be given a 2-dose primary series 8 to 12 weeks apart (MenACWY-D or MenACWY-CRM) with a single booster dose, consistent with recommendations for healthy adolescents.
- 8. For children older than age 2 years who have persistent risk for meningo-coccal disease because of complement component deficiency or asplenia, their primary series should include 2 doses of quadrivalent meningococcal conjugate vaccine 8 to 12 weeks apart (MenACWY-D or MenACWY-CRM).
- 9. For children 2 months to 6 years of age at persistent risk for meningococcal disease (Table 2), a booster dose should be given 3 years after the primary series and every 5 years thereafter. For children and adolescents 7 years or older at persistent risk for meningococcal disease (Table 2)

**TABLE 2** Children at Increased Risk for Meningococcal Disease

Persistent complement component deficiencies (C3, C5–C9, properdin, factor D, and factor H) Functional or anatomic asplenia

Travel to or reside in an area with hyperendemic or epidemic meningococcal disease

Residence in a community with a meningococcal outbreak

 $<sup>^</sup>b \ Package \ insert \ available \ at: \ http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/Approvedproducts/UCM131170.pdf$ 

c Package insert available at: http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/Approvedproducts/UCM201349.pdf

<sup>&</sup>lt;sup>d</sup> Package insert available at: http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/Approvedproducts/UCM308577.pdf

TABLE 3 Recommended Meningococcal Vaccines by Age Group

Age Group	Vaccine	Routine Recommendation	Dosing Schedule
2 mo to 10 y	MCV4-D (Menactra, Sanofi) <sup>a</sup>	High-risk only <sup>a</sup>	Primary
		High-risk only <sup>b</sup>	<ul> <li>Age 9 to 23 mo: 2-dose series with 12 weeks between doses</li> </ul>
		High-risk only <sup>c</sup>	• Age 2 to 10 y: 1 dose
			Booster (for persons who remain at risk)
			• First booster 3 y after primary series for children who received primary
			series before age $<$ 7 y, then every 5 y
			<ul> <li>Every 5 y for children who received primary series after 7th birthday</li> </ul>
	MCV4-CRM (Menveo, Novartis)		Primary
			<ul> <li>Age 2 to 6 mo: 4 doses at 2, 4, 6, and 12 mo</li> </ul>
			<ul> <li>Age 7 to 23 mo: 2 doses should be given, with the 2nd dose given in the 2nd year of life</li> </ul>
			• Age 2 to 10 y: 1 dose
			Booster (for persons who remain at risk)
			<ul> <li>First booster 3 y after primary series for children who received primary</li> </ul>
			series before age $<$ 7 y, then every 5 y
			<ul> <li>Every 5 y for children who received primary series after 7th birthday</li> </ul>
	HibMenCY-TT (MenHibrix, GSK)		Primary
			• Age 2 to 18 mo: 4-dose series with doses at 2, 4, 6, and 12 to 15 mo
			Booster (for persons who remain at risk)
	1407/4 407/07 (14		• Use MCV4-D or MCV4-CRM (see above)
11 to 21 y	MCV4-ACWY-D (Menactra, Sanofi)	Healthy and high-risk	Primary: healthy
			<ul> <li>Age 11 to 15 y: 1-dose primary series with booster at 16 to 21 y</li> </ul>
			<ul> <li>Age 16 to 21 y: 1 dose, no booster necessary</li> </ul>
			Booster: healthy
			• Age 16 to 21 y: 1 dose
			Primary: high risk
			2-dose primary series for those who have asplenia, HIV infection,
			or persistent compliment component deficiency
			Booster (for persons who remain at risk)
			• First booster 3 y after primary series for children who received primary
			series before age <7 y, then every 5 y  • Every 5 y for children who received primary series after 7th birthday
	MCV4-ACWY-CRM (Menveo,	Healthy and high risk	Primary: healthy
	Novartis)	fleating and flight risk	
			• Age 11 to 15 y: 1-dose primary series with booster at 16 to 21 y
			• Age 16 to 21 y: 1 dose, no booster necessary
			Booster: healthy
			• Age 16 to 21 y: 1 dose
			Primary: high risk
			<ul> <li>2-dose primary series for those who have asplenia, HIV infection, or persistent compliment component deficiency</li> </ul>
			Booster (for persons who remain at risk)
			• First booster 3 y after primary series for children who received
			primary series before age <7 y, then every 5 y
	HibMonCVTT (Manufibration	Not approved for this	• Every 5 y for children who received primary series after 7th birthday
	HibMenCY-TT (MenHibrix, GlaxoSmithKline)	Not approved for this age group	

<sup>&</sup>lt;sup>a</sup> For children who have complement component deficiency or functional or anatomic asplenia or who are part of a community or organizational outbreak or who are traveling internationally to a region with hyperendemic or endemic meningococcal disease. For infants receiving the vaccine before travel, the 2 doses may be administered as early as 8 weeks apart. Infants who have functional or anatomic asplenia should wait until 2 years of age to prevent immune interference with PCV13.

whose initial meningococcal vaccination was administered at 7 years or older, boosters of quadrivalent meningococcal conjugate should be repeated every 5 years (Table 4).

### **SPECIAL CIRCUMSTANCES**

Routine vaccination against meningococcal disease is not recommended for healthy children 2 months to 10 years of age unless they are at increased or persistent

risk for meningococcal disease (Table 2). Hib-MenCY-TT (MenHibrix) may be administered to any infant for routine vaccination against *Haemophilus influenza*e type b (Hib). If Hib-MenCY-TT is used for

<sup>&</sup>lt;sup>b</sup> For children who have complement component deficiency or functional or anatomic asplenia, or who are part of a community or organizational outbreak or who are traveling internationally to a region with hyperendemic or endemic meningococcal disease.

<sup>&</sup>lt;sup>c</sup> For children who have complement component deficiency or functional or anatomic asplenia, or who are part of a community or organizational outbreak. Hib-MenCY-TT is not recommended for use in children who are traveling internationally to a region with hyperendemic or endemic meningococcal disease. MCV4 should be used as booster doses for children who are given a primary series with Hib-MenCY-TT.

TABLE 4 Schedule for Booster Doses in Individuals Who Have Persistent Increased Risk for Invasive Meningococcal Disease

Age at Last	Duration Until Next
MCV4 Dose	Booster Dose
2 mo to 6 y	3 y <sup>a</sup>
>6 y	5 y

<sup>&</sup>lt;sup>a</sup> If last dose was HibMenCY-TT, the booster dose should be MenACWY-D or MenACWY-CRM

protection against meningococcal disease, it should be used for all 4 doses of Hib vaccine, and other Hib-containing vaccines should not be used.

Limited data suggest that different conjugate vaccine products can be used interchangeably. If the same vaccine product used for the first dose is not available or if it is not known which vaccine product was used previously, administration of the vaccine should not be deferred if indicated, and any licensed age-appropriate conjugate vaccine can be administered.

The meningococcal vaccine is not routinely recommended for HIV-infected children until they reach 11 years of age, similar to other non-HIV-infected adolescents. HIV-infected children should receive 2 doses as their primary series.

A primary series consisting of 2 or more doses (depending on the age of the child) is indicated for children who have asplenia (reduced antibody response after a single primary dose) and complement component deficiency (higher antibody levels are needed for bacterial clearance mechanisms, such as opsonization, and more rapid antibody waning).<sup>1</sup>

For travelers to areas with high meningococcal endemicity (parts of sub-Saharan Africa [the so-called "meningitis belt"] or the Hajj in Saudi Arabia), an age-appropriate meningococcal vaccine that includes serogroups A and W is indicated. Periodically, there may be other areas in the world with meningococcal outbreaks (eg. serogroup W in Chile). Travelers need to monitor this possibility. Completion of the entire series is preferred before travel as follows: (1) for children <9 months of age: 2, 4, and 6 months of age (with booster at 12 to 18 months of age) with MenACWY-CRM; (2) for children  $\geq 9$  months to 23 months of age: 2 doses separated by at least 8 weeks (MenACWY-D) or 2 doses separated by at least 3 months (Menveo); and (3) for people >24 months of age: a single dose (MenACWY-D or MenACWY-CRM).

Pregnancy and breastfeeding do not preclude vaccination with MenACWY (Menactra or Menveo) or MPSV4 (Menomune) if indicated.

### PRECAUTIONS AND CONTRAINDICATIONS

Vaccination with any meningococcal vaccine is contraindicated in people known to have a severe allergic reaction to any component of the vaccine. Conjugate vaccines that contain diphtheria or tetanus toxoid are contraindicated in people who have severe allergic reactions to these toxoids. A history of Guillain-Barré syndrome is not a contraindication or precaution for meningococcal vaccination. A previous temporal relationship between MenACWY-D and Guillain-Barré syndrome was not determined to be causally related. All currently licensed meningococcal vaccines are inactivated. They can be administered to people who are immunosuppressed as a result of disease or medication. However, the response to meningococcal vaccine in immunosuppressed children may be less than optimal.

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