U.S. Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Weekly / Vol. 75 / No. 1
January 8, 2026

Zika Virus Outbreak — Bangladesh, September–December 2024

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Abstract

Zika virus infection is transmitted to humans primarily through the bite of infected *Aedes* species mosquitoes. Although most Zika virus disease cases are mild or asymptomatic, severe neurologic complications can occur. Infection during pregnancy can result in severe congenital anomalies. In Bangladesh, Zika virus was first detected in an archived specimen from 2014; subsequently, five cases of Zika virus disease were identified in 2023. In September 2024, in response to identification of a confirmed Zika virus disease case in Bangladesh's capital, Dhaka, in a woman aged 29 years who was initially thought to have dengue, the Institute of Epidemiology, Disease Control and Research (IEDCR) launched an outbreak investigation. After IEDCR notification to hospitals, five additional Zika virus disease cases were identified in four patients evaluated at three Dhaka hospitals and in a household contact of one of these patients. Another four Zika virus disease cases were identified through Zika virus testing of patients referred to IEDCR during a concurrent chikungunya outbreak. In total, 10 confirmed cases of Zika virus disease were detected in and around Dhaka during September–December 2024 in patients with no history of international travel. None of the patients was pregnant, and all recovered without hospitalization or complications. An entomological investigation detected Zika virus RNA in *Aedes* species mosquitoes in Dhaka. This investigation suggests sporadic Zika virus transmission occurs in Dhaka. Integrated testing and surveillance for arboviral diseases might improve detection of Zika virus disease and support clinical management in areas where transmission of multiple arboviral diseases occurs. Prevention of these infections through vector control and use of personal protective measures should also be emphasized.

Introduction

Zika virus is a single-stranded RNA virus belonging to the Flaviviridae family and was first identified in Uganda in 1947 (*1*). The first documented Zika virus disease outbreak occurred on the Pacific island of Yap in 2007 (*2*). An association between fetal microcephaly and congenital Zika virus infection was observed during a large outbreak in Brazil during 2015–2016 (*3*). Zika virus is primarily transmitted by the bite of infected *Aedes* species mosquitoes. Less common modes of transmission include intrauterine and intrapartum transmission, sexual transmission, transmission through breastfeeding, blood transfusion or laboratory transmission, and transmission through organ and tissue transplantation (*4*). Exposure to Zika virus in early pregnancy can result in congenital Zika syndrome, which is characterized by microcephaly, brain abnormalities, vision problems, low birth weight, and other conditions (*5*).

Zika virus was first detected in Bangladesh when reverse transcription–polymerase chain reaction (RT-PCR) testing of archived dengue-negative serum samples collected between 2013 and 2016 identified a single Zika-positive specimen from 2014 in a patient with no history of international travel (*6*). A study conducted by a nongovernmental research organization

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during July–December 2023 in the capital city of Dhaka identified five Zika virus disease cases among 152 febrile patients tested for dengue, Zika, and chikungunya viruses (*7*). No routine surveillance for Zika virus is conducted in Bangladesh, although it is a notifiable disease (*8*). In September 2024, the Institute of Epidemiology, Disease Control and Research (IEDCR), under the Ministry of Health and Family Welfare in Bangladesh, was notified by a private hospital in Dhaka of a laboratory-confirmed Zika virus disease case in a person with dengue-compatible symptoms and no history of international travel. This report describes the outbreak investigation that was prompted by identification of this case.

Investigation and Results

Identification of Index Case

On September 4, 2024, a woman in Dhaka aged 29 years who was not pregnant (patient A) and had symptoms of dengue (fever, joint pain, and rash) that began on August 31 received a positive Zika virus RT-PCR test result from a multiplex test (Genesig kit | Primer Design | United Kingdom) for dengue, chikungunya, and Zika virus while being evaluated at the outpatient department of hospital 1. The test had been requested because clinicians, after receipt of a negative rapid dengue nonstructural protein-1 (NS1) antigen diagnostic test result, suspected chikungunya. The multiplex test detected Zika virus RNA only. The hospital notified IEDCR and sent a serum sample to the IEDCR virology laboratory for confirmatory testing.* IEDCR also obtained a serum and urine sample from the patient. All samples tested positive for Zika virus RNA by RT-PCR.

Epidemiologic Investigation and Surveillance

On September 4, 2024, IEDCR initiated an investigation to identify the source of the Zika virus infection and determine whether additional cases were occurring. Because in Bangladesh the occurrence of single laboratory-confirmed case with suspected local transmission is treated as an outbreak and prompts an outbreak investigation and response, on September 9, after confirmation of the first case, IECDR declared a Zika virus disease outbreak in Dhaka. A confirmed case was defined as detection of Zika virus RNA by RT-PCR in serum or urine in the IEDCR laboratory. This activity was reviewed by IEDCR and CDC, deemed not research, and was conducted consistent with applicable federal law and CDC policy.†

After obtaining information about patient A's clinical signs and symptoms from the treating physician at hospital 1, investigators visited the woman at home and collected information including demographic data, symptom onset date, clinical manifestations, and possible sources of exposure (e.g.,

* Viral RNA was extracted from 140 μL of serum using the QIAamp Viral RNA Mini Kit and eluted in 30 μL of elution buffer. Multiplex real-time RT-PCR (targeting dengue, Zika, and chikungunya viruses) was performed on an ABI QuantStudio 5. Samples with cycle thresholds <50 and valid internal control were considered positive.

† 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

The *MMWR* series of publications is published by the Office of Science, U.S. Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, Atlanta, GA 30329-4027.

Suggested citation: [Author names; first three, then et al., if more than six.] [Report title]. MMWR Morb Mortal Wkly Rep 2026;75:[inclusive page numbers].

mosquito bite, blood transfusion, organ transplantation, sexual contact, travel history, and travel history of sexual partners). As part of the investigation, all five of patient A's asymptomatic household members (age range = 22–48 years) were interviewed about potential exposures and travel history, and all provided blood specimens. All five household contacts' blood test results were negative for Zika virus. IEDCR reported the case to the International Health Regulations national focal point in Bangladesh, informed Dhaka hospitals and the public through a media briefing, and notified the Obstetrical and Gynecological Society of Bangladesh. IEDCR issued a statement to all government hospitals in Bangladesh instructing them to refer any patient with suspected Zika virus disease, chikungunya, or dengue for testing.

After investigation of the index case, IEDCR established a suspected Zika virus disease case definition that consisted of onset of fever and maculopapular rash during the previous 2 weeks, with at least one of the following: conjunctivitis, arthralgia, or having a household member with confirmed Zika virus disease. In response to subsequent notifications of suspected Zika virus disease cases, IEDCR collected information from the reporting facilities, confirmed diagnoses by RT-PCR testing at the IEDCR virology laboratory, interviewed patients, and conducted active case finding at patients' residences, including interviewing household members and conducting laboratory testing of those with suspected Zika virus disease.

Identification of Cases by Hospitals

On September 17, IEDCR was notified by a second hospital in Dhaka (hospital 2) of two patients with RT-PCR–confirmed Zika virus disease (patients B and C) (Table). Both were evaluated as outpatients. Physicians had initially suspected dengue and ordered Zika virus testing after receiving negative results for dengue NS1 antigen. An investigation at patient B's home identified a household member who met the suspected case definition and was later confirmed to have Zika virus disease (patient D). On October 5 and October 20, two additional hospitals (hospitals 3 and 4) in Dhaka reported laboratory-confirmed Zika virus disease cases in outpatients (patients E and F). No additional cases were identified among these patients' household members.

Identification of Cases Among Patients with Suspected Chikungunya Referred for Testing

During October, a concurrent chikungunya outbreak was detected in Dhaka (*9*). In response to IEDCR's letter requesting referral of patients with suspected Zika virus disease, chikungunya, or dengue for testing, health facilities began referring patients with presumed chikungunya as part of this outbreak for testing. IEDCR established a sample collection booth and screened patients for testing using a questionnaire that collected demographic and clinical information. During October–December 2024, a total of 394 referred patients, most of whom were suspected to have chikungunya, provided serum samples for testing by RT-PCR multiplex assay. Among these, 34 (8.6%) met the suspected Zika virus disease case definition and provided urine samples for RT-PCR testing as well. Overall, four additional Zika virus disease cases were confirmed: three had Zika virus RNA detected in urine (patients G, H, and J) and one received a positive serum test result (patient I).[§]

Characteristics of Persons with Zika Virus Disease

Among the 10 patients with confirmed Zika virus disease cases identified during the outbreak, the median patient age was 37 years (range = 23–52 years); seven cases occurred in women, none of whom was pregnant (Table). All patients were interviewed using the same questionnaire. Sexual contact, blood transfusion, and organ transplantation were ruled out as possible routes of transmission. No patient had a history of international travel within the 2 weeks preceding symptom onset, and only two cases appeared to be epidemiologically linked. All patients had relatively mild illnesses, all received supportive care, and none were hospitalized. All patients had fever (≥100.4°F [≥38.0°C)]), arthralgias, and myalgias. Nine also had a generalized rash, seven experienced headaches, and six had conjunctivitis. The median duration of illness was 7 days (range = 5–14 days). Zika virus RNA was detected in the serum of two patients, the urine of six patients, and both the serum and urine of two patients. Nine patients lived in various locations in Dhaka, and one lived in the adjacent Gazipur district (Figure). Although there were concurrent dengue and chikungunya outbreaks, no co-infections were detected in patients with confirmed Zika virus disease.

Entomological Investigation

To ascertain whether Zika virus was present in mosquitoes in Dhaka, IEDCR conducted an entomological investigation at seven sites. Each site was within approximately 0.5 miles (1 km) of the home of a patient with confirmed Zika virus disease.[¶] Larvae were collected from one or two ponds or lakes at each site. The larvae were then combined by site, reared to adulthood in the entomology laboratory, and tested for Zika virus RNA by an RT-PCR multiplex test in the virology

[§] Among those tested, positive results for chikungunya, dengue, and Zika virus disease were received by 138, 11, and four persons, respectively.

[¶] Nine confirmed Zika virus disease cases were identified in Dhaka. Seven sites were selected, covering the nine patients' homes within a radius of approximately 0.5 miles (1 km). Two patients lived in the same household, and two patients lived within approximately 0.5 miles (1 km) of each other. No entomological investigation was carried out in Gazipur district.

TABLE. Characteristics of patients with laboratory-confirmed Zika virus disease cases — Bangladesh, September–December 2024

Patient	Age, yrs	Sex*	Date of symptom onset	Clinical features and other characteristics	Specimen positive for Zika virus RNA	Duration of illness, days	Residence
A[†]	29	Female	Aug 31	Fever, arthralgia, myalgia, rash, conjunctivitis, and headache Initially suspected to have chikungunya Positive multiplex test result after negative rapid dengue antigen test result[§]	Serum, urine	8	Dhaka South
B	38	Female	Sep 13	Fever, arthralgia, myalgia, rash, and headache Confirmed by RT-PCR at hospital 2 after negative dengue test result	Urine	14	Dhaka North
C	23	Female	Sep 10	Fever, arthralgia, myalgia, rash, and headache Confirmed by RT-PCR at hospital 2 after negative dengue test result	Serum	10	Dhaka North
D	36	Female	Sep 12	Fever, arthralgia, myalgia, rash, conjunctivitis, and headache Household contact of patient B	Serum, urine	7	Dhaka North
E	42	Male	Sep 29	Fever, arthralgia, myalgia, and rash	Urine	7	Dhaka North
F	33	Female	Oct 18	Fever, arthralgia myalgia, and conjunctivitis	Urine	5	Dhaka North
G	44	Male	Nov 20	Fever, arthralgia, myalgia, rash, and conjunctivitis	Urine	6	Dhaka South
H	50	Male	Nov 23	Fever, arthralgia, myalgia, rash, conjunctivitis, and headache	Urine	6	Dhaka North
I	30	Female	Nov 25	Fever, arthralgia, myalgia, rash, conjunctivitis, and headache	Serum	8	Gazipur
J	52	Female	Dec 29	Fever, arthralgia, myalgia, rash, and headache	Urine	7	Dhaka South

Abbreviation: RT-PCR = reverse transcription–polymerase chain reaction.
* No patients with Zika were pregnant.
† All five of patient A's household members received negative test results.
§ The Zika outbreak was declared after diagnosis confirmation for patient A. Multiplex test: Primer Design Genesig dengue, zika and chikungunya virus multiplex kit.

laboratory. Zika virus RNA was detected in a pooled sample of mosquitoes from one of the seven sites (Figure).

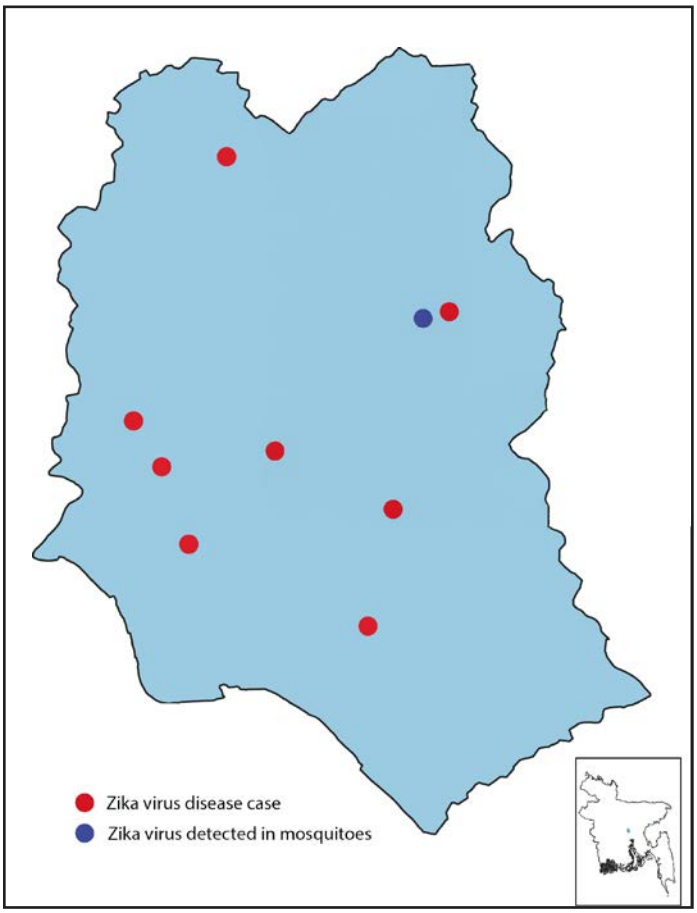
Public Health Response

The Public Health Emergency Operations Center of IEDCR coordinated the response, rapidly deploying teams to investigate each reported Zika virus disease case. IEDCR notified the media about the presence of Zika virus in Dhaka, and the information was distributed online to raise awareness among clinicians and the public. Zika virus screening was incorporated into evaluation of patients referred to IEDCR for RT-PCR testing for chikungunya. Screening for Zika virus, in addition to dengue and chikungunya, has continued during the 2025 dengue and chikungunya season (June–December), and surveillance for acute febrile illness has been initiated in six sites throughout Bangladesh where Zika has been designated a priority disease. In addition, IEDCR initiated an arboviral serosurvey in Dhaka to gain a better understanding of the presence and extent of Zika virus and other arboviruses in the city. Vector control programs for dengue, organized by city authorities are ongoing to reduce mosquito density. Although routine surveillance for Zika virus disease in obstetrics and gynecology departments of health care facilities has not been established, awareness has been raised that obstetric patients with clinical signs and symptoms compatible with Zika virus disease, dengue, or chikungunya should be referred to IEDCR for testing. Provisional data from 2025 indicate fewer than 10 confirmed Zika virus disease cases were identified in Bangladesh during June–November 2025 (IEDCR, unpublished data, November 2025).

Discussion

This investigation found that transmission of Zika virus is occurring in Dhaka, Bangladesh, and surrounding areas. This is the first reported Zika virus disease outbreak of its size in Dhaka, and 2024 is the second consecutive year that Zika virus disease has been detected in Dhaka. Although Zika virus was first identified in an archived sample from 2014, and the first confirmed outbreak occurred in 2023, reoccurrence in 2024 highlights the potential for the virus to become endemic in Bangladesh. The widespread geographic distribution of cases in 2024 suggests established circulation of infected mosquitoes in Dhaka; this distribution is distinctly different from that in 2023, when all five patients with confirmed Zika virus disease lived within a radius of approximately 0.5 miles (1 km) (*7*). The number of Zika virus disease cases detected likely does not reflect the true magnitude and geographic distribution of Zika virus transmission in Bangladesh. Cases are likely underreported because of the absence of systematic surveillance, limited availability of testing, occurrence of mild or asymptomatic infections, and possible misdiagnosis of Zika virus disease cases as chikungunya or dengue.

FIGURE. Distribution of Zika virus disease cases — Dhaka, Bangladesh, September–December 2024*



* Of the 10 persons with confirmed cases, residence locations of nine are displayed. The tenth case occurred in the adjacent Gazipur district (north of Dhaka), which is not included on the map. Two patients lived in the same household.

Summary

What is already known about this topic?

In Bangladesh, Zika virus was first detected in 2014; subsequently, five cases of Zika virus disease were identified in 2023. Zika virus infection is often mild but rarely can result in neurologic complications, and, in early pregnancy, can cause severe congenital anomalies.

What is added by this report?

Ten Zika virus disease cases were detected in and around Dhaka, Bangladesh, during September–December 2024. Most cases were initially suspected to be dengue or chikungunya and were identified incidentally through a multiplex reverse transcription–polymerase chain reaction assay. No patients were pregnant, and none were hospitalized. Zika virus RNA was detected in local mosquitoes.

What are the implications for public health practice?

Integrated testing and surveillance for arboviral diseases might improve detection of Zika virus disease and support clinical management. Prevention through vector control and personal protection should also be emphasized.

Dengue is an important public health concern in Bangladesh, with annual seasonal outbreaks (*10*). The existence of a national dengue surveillance system provides an opportunity to expand surveillance to include Zika virus disease and chikungunya, thereby enabling an integrated approach to monitoring and response to these mosquito-borne infections. The potential for severe neurologic complications of Zika virus disease, along with the risks during pregnancy, including congenital Zika syndrome, underscore the critical importance of detection of Zika virus disease in Bangladesh. These findings highlight the need to reduce transmission and prevent future outbreaks by improving vector control, using personal protection, ensuring timely diagnosis, and integrating Zika virus disease surveillance into the existing dengue surveillance system.

Implications for Public Health Practice

Raising clinician awareness of the presence of Zika virus in Bangladesh might encourage routine Zika virus testing of febrile patients with suspected dengue or chikungunya. This is particularly important for pregnant women with febrile illness or rash to ensure early detection. Efforts to increase community awareness of the importance of preventing mosquito bites should be emphasized, especially for pregnant women.

Integration of Zika virus testing and surveillance with that for other arboviral diseases in patients with compatible signs and symptoms might improve the detection of Zika virus disease and support appropriate clinical management, including antenatal monitoring of pregnant patients with Zika virus disease. This outbreak suggests that Zika virus is established in mosquitoes in Bangladesh. Establishing Zika virus surveillance, strengthening vector control measures, and educating providers and the public are important to prevent further transmission, improve case detection, and guide clinical management.

Acknowledgments

Susan C. Kaydos-Daniels, W. Randolph Daley, Tai-Ho Chen, CDC; hospitals that reported cases; patients who participated in the investigation; members of the Virology Department, Entomology Department and Public Health Emergency Operations Center of the Institute of Epidemiology, Disease Control and Research, Bangladesh.

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All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

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Use of the GSK MenACWY-CRM/MenB-4C Pentavalent Meningococcal Vaccine Among Persons Aged ≥10 Years: Recommendations of the Advisory Committee on Immunization Practices — United States, 2025

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Abstract

Meningococcal disease is a serious bacterial infection caused by *Neisseria meningitidis*. Serogroups B, C, W, and Y cause the majority of cases of this disease in the United States. These serogroups are targeted by different meningococcal vaccines available in the United States. Two quadrivalent (serogroups A, C, W, and Y) meningococcal conjugate vaccines (MenACWY) (MenACWY-CRM [Menveo, GSK] and MenACWY-TT [MenQuadfi, Sanofi Pasteur]) and two serogroup B meningococcal vaccines (MenB) (MenB-4C [Bexsero, GSK] and MenB-FHbp [Trumenba, Pfizer]) are licensed for use in the United States and recommended by CDC's Advisory Committee on Immunization Practices (ACIP). Indications for MenACWY and MenB vaccination have not changed since indications for their use were published in 2020. A pentavalent (serogroups A, B, C, W, and Y) meningococcal vaccine (MenABCWY) (MenACWY-TT/MenB-FHbp [Penbraya, Pfizer]) has been licensed and recommended for use since October 2023. On February 14, 2025, the Food and Drug Administration licensed a second pentavalent MenABCWY vaccine (MenACWY-CRM/MenB-4C [Penmenvy, GSK]) for prevention of invasive disease caused by *N. meningitidis* serogroups A, B, C, W, and Y in persons aged 10–25 years, the same indication for which MenACWY-TT/MenB-FHbp is licensed. On April 16, 2025, ACIP recommended that MenACWY-CRM/MenB-4C may be used when both MenACWY and MenB are indicated at the same visit for 1) healthy persons aged 16–23 years (routine schedule) when shared clinical decision-making favors administration of MenB vaccine and 2) persons aged ≥10 years who are at increased risk for meningococcal disease (e.g., because of persistent complement deficiencies, complement inhibitor use, or functional or anatomic asplenia). Different manufacturers' serogroup B–targeting vaccines are not interchangeable; therefore, when MenACWY-CRM/MenB-4C is used, MenB-4C should be used for the other MenB doses. This report summarizes evidence considered for these recommendations and provides clinical guidance for the use of MenACWY-CRM/MenB-4C.

Introduction

Meningococcal disease, caused by *Neisseria meningitidis*, is a serious bacterial infection that can cause invasive or noninvasive disease. Serogroups B, C, W, and Y cause the majority of cases of meningococcal disease in the United States (*1*). Risk factors for meningococcal disease include anatomic or functional asplenia, persistent complement component deficiencies, use of complement inhibitors (e.g., eculizumab or ravulizumab), HIV infection, active or passive exposure to tobacco smoke, and recent upper respiratory tract infection (*1*). Persons living in crowded settings, such as college residence halls, and those who are close contacts of persons with meningococcal disease are also at increased risk for acquiring meningococcal disease (*1*).

CDC's Advisory Committee on Immunization Practices (ACIP) recommends administration of a single dose of quadrivalent (serogroups A, C, W, and Y) meningococcal vaccine (MenACWY) to persons aged 11–12 years, with a booster dose at age 16 years, as part of the routine childhood immunization schedule. For persons aged ≥2 months who are at increased risk for meningococcal disease because of certain medical conditions or other exposures, ACIP recommends a multiple-dose MenACWY series, with regular booster doses if the recipient remains at increased risk (Box) (*2*). Two MenACWY vaccines (MenACWY-CRM [Menveo, GSK] and MenACWY-TT [MenQuadfi, Sanofi Pasteur]) are licensed and recommended for use in the United States. In addition, ACIP recommends serogroup B meningococcal vaccine (MenB) as a 2-dose series for healthy persons aged 16–23 years based on shared clinical decision-making (e.g., given the estimated relatively short [1–2 years] duration of MenB protection and the high cost per quality-adjusted life year [QALY] gained), and for risk-based administration to persons aged ≥10 years (*2*). Two MenB vaccines (MenB-4C [Bexsero, GSK] and MenB-FHbp [Trumenba, Pfizer]) are licensed and recommended for use in the United States.

Since October 25, 2023, ACIP has recommended that a pentavalent (serogroups A, B, C, W, and Y) meningococcal vaccine (MenABCWY) (MenACWY-TT/MenB-FHbp [Penbraya, Pfizer]) may be used when both MenACWY and MenB are indicated at the same visit for 1) healthy persons aged 16–23 years when shared clinical decision-making favors MenB administration and 2) persons aged ≥10 years who are at increased risk for meningococcal disease (*3*). Different manufacturers' serogroup B–targeting vaccines are not interchangeable; therefore, persons who receive pentavalent

BOX. Meningococcal vaccination recommendations — Advisory Committee on Immunization Practices, United States, 2025

The Advisory Committee on Immunization Practices (ACIP) recommends quadrivalent (serogroups A, C, W, Y) meningococcal conjugate (MenACWY) vaccination* for the following groups:

- **Healthy persons aged 11–12 years:** Routine vaccination with a single dose for all persons aged 11–12 years, with a booster dose at age 16 years
- **Persons aged ≥2 months who are at increased risk for meningococcal disease:** Routine and booster vaccination. (Dosing schedule varies by age and indication; interval for booster doses varies by age.)†
  - Persons with certain medical conditions, including anatomic or functional asplenia, HIV infection, and persistent complement component deficiency, and those who use complement inhibitors (e.g., eculizumab or ravulizumab)
  - Persons traveling to countries with hyperendemic or epidemic meningococcal disease, including countries in the African meningitis belt or during Hajj
  - First-year college students who live in residential housing, if not previously vaccinated
  - Military recruits
  - Microbiologists routinely exposed to *Neisseria meningitidis* isolates
  - Persons at increased risk during an outbreak of meningococcal disease caused by serogroup A, C, W, or Y

ACIP recommends serogroup B meningococcal (MenB) vaccination§ for the following groups:

- **Healthy persons aged 16–23 years:** Vaccination with a 2-dose MenB series on the basis of shared clinical decision-making, with 16–18 years the preferred age for MenB vaccination
- **Persons aged ≥10 years who are at increased risk for meningococcal disease:** Routine and booster vaccination. (Dosing schedule varies by indication; the first booster dose should be given 1 year after the primary series, with additional boosters every 2–3 years if the risk remains.)
  - Persons with certain medical conditions, including anatomic or functional asplenia and persistent complement component deficiency, and those who use complement inhibitors (e.g., eculizumab or ravulizumab)
  - Microbiologists routinely exposed to *N. meningitidis* isolates
  - Persons at increased risk during an outbreak of meningococcal disease caused by serogroup B

ACIP recommends pentavalent (serogroups A, B, C, W, and Y) meningococcal (MenABCWY) vaccination¶ for the following groups:

- **Persons aged ≥10 years for whom MenACWY and MenB are both indicated:** Primary series vaccination if MenACWY and MenB would be administered as separate vaccines at the same health care visit
- **Persons aged ≥10 years who are at increased risk for meningococcal disease who previously received MenABCWY or MenB ≥6 months earlier:** Booster vaccination if MenACWY and MenB would be administered as separate vaccines at the same health care visit; if the previous doses included a MenB-FHbp component, MenACWY-TT/MenB-FHbp would be used, whereas MenACWY-CRM/MenB-4C would be used if the previous doses included a MenB-4C component

* Quadrivalent MenACWY vaccines from different manufacturers are interchangeable, although the same vaccine product is recommended for all doses.
† Meningococcal Vaccination | Recommendations of the Advisory Committee on Immunization Practices, United States, 2020
§ MenB vaccines from different manufacturers are not interchangeable. All doses used for the primary series (and booster doses, if applicable) should be from the same manufacturer.
¶ Pentavalent MenABCWY vaccines from different manufacturers are not interchangeable because the MenB components are not interchangeable. If a serogroup B–targeting vaccine has already been administered, subsequent doses should be from the same manufacturer.

MenACWY-TT/MenB-FHbp should have already received or should next receive MenB-FHbp for other MenB doses.

On February 14, 2025, a second pentavalent meningococcal vaccine (MenACWY-CRM/MenB-4C [Penmenvy, GSK]) was licensed for use in persons aged 10–25 years (*4*). Both pentavalent vaccines are licensed for the same indications. MenACWY-CRM/MenB-4C contains the same components as those in two existing meningococcal vaccines licensed for use in the United States: 1) *N. meningitidis* serogroup A, C, W, and Y capsular polysaccharides conjugated to CRM197 (MenACWY-CRM [Menveo, GSK]) and 2) *N. meningitidis* serogroup B outer-membrane recombinant proteins (factor H binding protein [fHbp], *Neisseria* adhesin A [NadA], and neisserial heparin binding antigen [NHBA]) and an outer-membrane vesicle component containing porin A (PorA) (MenB-4C [Bexsero, GSK]). This report summarizes the

evidence considered for MenACWY-CRM/MenB-4C vaccine recommendations and provides clinical guidance for use.

Methods

Meningococcal Vaccines Work Group Activities

During January 2024–March 2025, the ACIP Meningococcal Vaccines Work Group held monthly or bimonthly conference calls to review meningococcal disease epidemiology and evidence regarding the use of MenACWY-CRM/MenB-4C in persons who are currently recommended to receive both MenACWY and MenB (policy question 1), MenACWY only (policy question 2), or MenB only (policy question 3). These policy questions were chosen for parity with a previous evaluation of MenACWY-TT/MenB-FHbp (*3*).

Review of Meningococcal Disease Epidemiology and Evidence Regarding Vaccine Use

To guide deliberations, ACIP used the Evidence to Recommendations framework and considered the importance of invasive meningococcal disease as a public health problem, benefits and harms of MenACWY-CRM/MenB-4C, values of the target population, acceptability, resource use, health equity, and feasibility (ACIP Evidence to Recommendations for Use of GSK's Pentavalent Meningococcal Vaccine | MenACWY-CRM/MenB-4C). ACIP evaluated the available evidence on prespecified benefits and harms, each with a ranked importance, using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach (GSK's Pentavalent Meningococcal Vaccine | MenACWY-CRM/MenB-4C | GRADE). Critical outcomes included disease caused by serogroups A, B, C, W, and Y; short-term immunity; and serious adverse events. Important outcomes included persistence of immunity, interference with other recommended vaccines administered concurrently, and nonserious adverse events. Evidence for these outcomes was identified through a systematic review (*5*). During the evidence review, the recommended interval between MenB-4C doses for healthy persons aged 16–23 years was increased from ≥1 month to ≥6 months based on new data suggesting better immunogenicity with a longer dosing interval (*6*). This change raised the immunogenicity standard used for policy questions 1 and 3, as information from study arms that received MenB-4C on the new dosing interval was considered.

Summary of Evidence for Use of MenACWY-CRM/MenB-4C in Persons Aged ≥10 Years

Studies Included in Safety and Immunogenicity Assessment

The evidence comprised data from seven multisite randomized controlled trials assessing immunogenicity and safety among healthy participants aged 10–25 years. Evidence for two outcomes (disease caused by serogroups A, B, C, W, and Y and interference with other recommended vaccines administered concurrently) was lacking.

Trials were conducted in Argentina, Australia, Canada, Chile, Colombia, Czechia, Estonia, Finland, Panama, Poland, Turkey, and the United States (*7*–*13*). Depending on the trial, participants who had or had not previously received MenACWY vaccine were included. All study participants had never received MenB vaccine. Across the different trials, participants were randomized to either a pentavalent vaccine group (≥2 doses of MenACWY-CRM/MenB-4C, with or without a booster dose in longer-term extension studies among participants in original studies) or to an active control group reflecting real-world meningococcal vaccination schedules. The control group or groups in each trial varied (Figure). For the safety and immunogenicity assessment, control group participants were classified into one of three groups: 1) 1 dose of only MenACWY-CRM (*7*–*9*,*11*–*13*); 2) ≥2 doses of only MenB-4C, with or without a booster dose in extension studies (*8*,*10*,*11*,*13*); or 3) 2 doses of concomitantly administered MenACWY-CRM + MenB-4C (*5*,*11*).

Short-Term (≤1 Year Postvaccination) Immunity

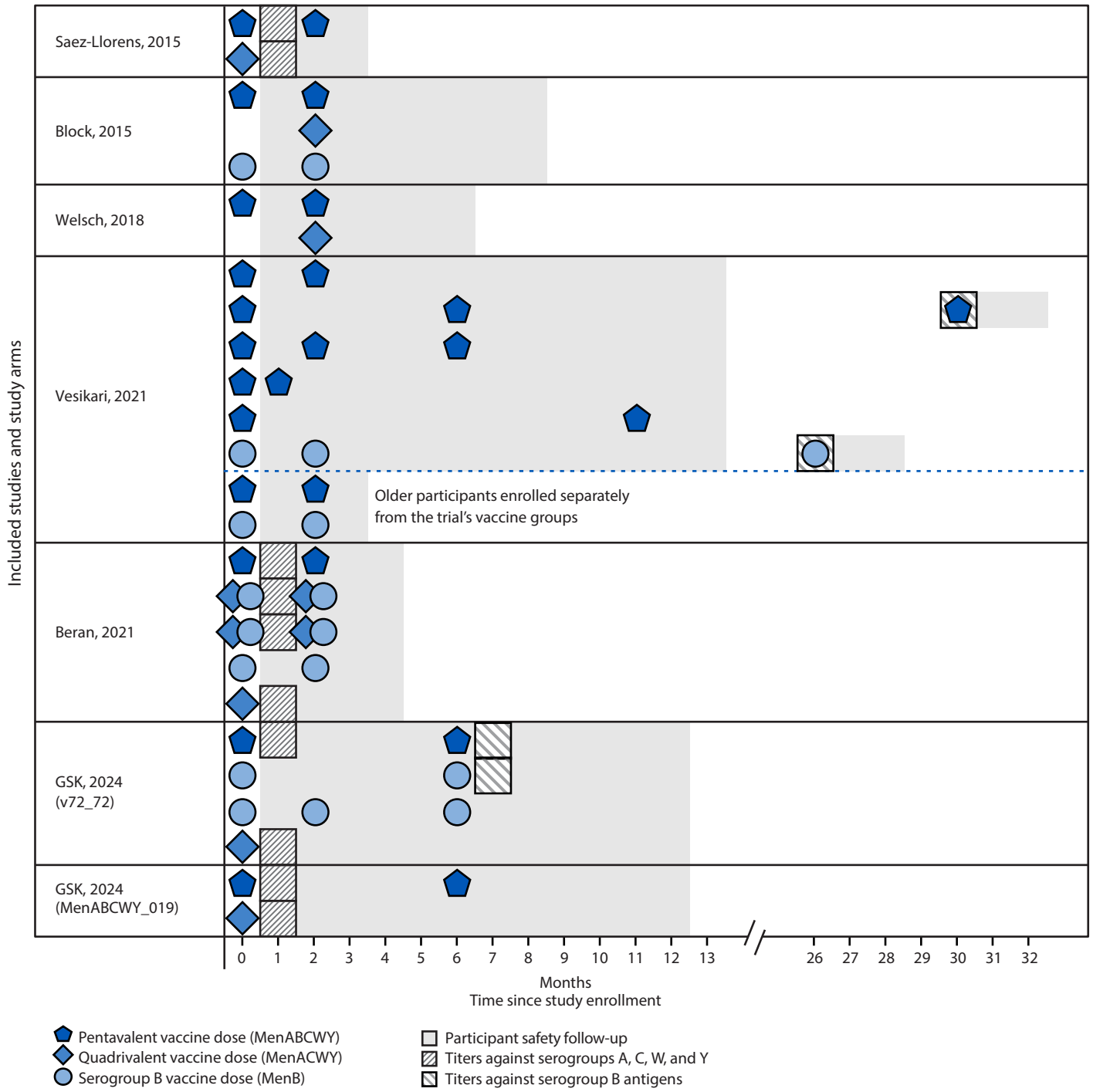
Four studies contributed evidence for short-term immunogenicity against serogroups A, C, W, and Y. In one, participants in the MenACWY-CRM control group received doses of MenACWY-CRM and MenB-4C at the same study visit, while control group participants in the other three studies had only received MenACWY-CRM before titers were assessed. Two studies required individuals to have no prior history of MenACWY receipt, one study required individuals to have previously received MenACWY, and one did not have a requirement regarding MenACWY history. One month after receipt of 1 dose of ACWY–targeting vaccine, participants in the pentavalent group (MenACWY-CRM/MenB-4C) and control group (MenACWY-CRM) were similarly likely* to have seroprotective titers against serogroups A, C, W, and Y.

One month after receipt of 2 doses of serogroup B–targeting vaccine administered 6 months apart, participants in the pentavalent group (MenACWY-CRM/MenB-4C) and control group (only MenB-4C, with no concomitant administration of MenACWY-CRM) were similarly likely† to have seroprotective

* This judgment is based on the 95% CIs for the relative effect on seroprotective titers when comparing MenABCWY with MenACWY: 0.86–1.01 for serogroup A, 0.97–1.10 for serogroup C, 1.00–1.04 for serogroup W, and 0.93–1.03 for serogroup Y. GSK's Pentavalent Meningococcal Vaccine | MenACWY-CRM/MenB-4C | GRADE

† This judgment is based on the 95% CIs for the relative effect on seroprotective titers when comparing MenABCWY with MenB: 0.99–1.04 for fHbp, 0.96–1.00 for both NadA and NHBA, and 0.86–0.96 for PorA. GSK's Pentavalent Meningococcal Vaccine | MenACWY-CRM/MenB-4C | GRADE

FIGURE. Summary of vaccine studies,* vaccine groups,† immunogenicity timepoints,§ and safety follow-up¶ included in the assessment of evidence for use of pentavalent (MenABCWY) vaccine — United States, 2025



* Saez-Llorens, 2015: https://doi.org/10.1080/21645515.2015.1029686; Block, 2015: https://doi.org/10.1016/j.vaccine.2015.03.001; Welsch, 2018: https://doi.org/10.1016/j.vaccine.2018.07.016; Vesikari, 2021: https://doi.org/10.1080/21645515.2021.1968214; Beran, 2021: https://doi.org/10.1128/mSphere.00553-21; GSK, 2024 (v72_72): https://clinicaltrials.gov/study/NCT04502693; GSK, 2024 (MenABCWY_019): https://clinicaltrials.gov/study/NCT04707391. For the Beran (2021) study, the two vaccine groups with concomitant administration of MenACWY and MenB doses differed slightly; participants of one group received both doses in the same arm, whereas the other received each dose in a different arm.

† Only vaccine groups considered in the evidence assessment are depicted. When multiple doses were administered, the per-protocol interval between doses is depicted.

§ Immunogenicity timepoints are the timepoints considered in the evidence assessment, not all protocol-specified timepoints at which immunogenicity was evaluated.

¶ Safety follow-up refers to the follow-up period for protocol-specified reporting of serious adverse events.

antibody titers against three of four serogroup B antigens (fHbp, NadA, and NHBA). Participants in the pentavalent group were less likely than control group participants were to have seroprotective antibody titers against the fourth antigen, PorA. PorA is thought to be responsible for broad cross-protection against various serogroup B strains; however, the clinical implications of the reduced PorA response are unknown, as differences in titer assay choices and circulating strains make comparing data across studies complex (*14*,*15*). In addition, whether the reduced response might result from immune interference could not be assessed because of limited data comparing titers after 2 doses given 2 months apart, rather than 6 months apart. The overall level of certainty for the evidence regarding short-term immunity was moderate for healthy persons and low for persons at increased risk for meningococcal disease (*5*).

Persistent (>1 Year Postvaccination) Immunity

No identified studies evaluated persistence of immunity against serogroups A, C, W, and Y. Two years after receipt of 2 doses of serogroup B–targeting vaccine, participants in the pentavalent group (MenACWY-CRM/MenB-4C doses administered 6 months apart) and the control group (MenB-4C doses administered 2 months apart) were similarly likely to have seroprotective antibody titers against all four serogroup B antigens. The overall level of certainty for the evidence regarding persistent immunity was low for healthy persons and very low for persons at increased risk for meningococcal disease (*5*).

Adverse Events

A serious adverse event (SAE) is an untoward medical occurrence that results in death, disability, or incapacity; is life threatening; or requires hospitalization or prolongation of existing hospitalization. The possible relationship between an event and the study vaccine was judged by the study investigator, not the study sponsor. Certain studies also included an untoward medical occurrence that resulted in a congenital anomaly or birth defect in the offspring of a participant in SAE assessments. Solicited adverse events (e.g., injection site redness or pain, fever, or fatigue) were used as a surrogate for nonserious adverse events.

SAEs possibly related to vaccination after any vaccine dose were rare overall and were similarly frequent among participants in the pentavalent (MenACWY-CRM/MenB-4C) and control (MenACWY-CRM, MenB-4C, or both) groups. Six SAEs possibly related to vaccination occurred among 7,847 participants enrolled in relevant vaccine groups considered in the evidence assessment across all seven studies, including three in the pentavalent group (seizure, connective tissue disorder, and neuromyelitis optica among 3,925 participants) and three in the control groups (syncope [MenB-4C group], pyrexia [MenACWY-CRM group], and ulcerative colitis [MenB-4C group] among 3,922 participants). The events of neuromyelitis optica, pyrexia, and ulcerative colitis were assessed as related to study vaccination by the study investigators; however, after evaluations by GSK and an independent evaluator, this condition was not considered an adverse drug reaction. The overall level of certainty for the evidence regarding frequency of SAEs possibly related to vaccination was moderate for healthy persons and low for persons at increased risk for meningococcal disease (*5*).

Persons in the pentavalent group (MenACWY-CRM/MenB-4C) and serogroup B–targeting control groups (MenB-4C or MenACWY-CRM + MenB-4C) were similarly likely[§] to experience or report one or more nonserious adverse events after 1 or ≥2 doses. The overall level of certainty for the evidence regarding frequency of nonserious adverse events after 1 dose of pentavalent versus MenB alone or ≥2 doses of pentavalent versus MenB alone was high for healthy persons and moderate for persons at increased risk for meningococcal disease (*5*). The overall level of certainty for the evidence regarding frequency of nonserious adverse events after 1 dose of pentavalent versus 1 dose of MenB concomitantly with 1 dose of MenACWY was moderate for healthy persons and low for persons at increased risk for meningococcal disease (*5*).

Compared with persons who received a single MenACWY-CRM dose, those in the pentavalent group were significantly more likely[¶] to experience or report nonserious adverse events after either 1 dose or 2 doses administered 6 months apart. The overall level of certainty for the evidence regarding frequency of nonserious adverse events after 1 dose of pentavalent versus 1 dose of MenACWY and ≥2 doses of pentavalent versus 1 dose of MenACWY was moderate for healthy persons and low for persons at increased risk for meningococcal disease (*5*).

Resource Use

To assess the cost-effectiveness of MenACWY-CRM/MenB-4C for each policy question, ACIP considered findings from a CDC model (*16*,*17*) and a GSK model (*18*). The CDC model estimated that pentavalent vaccines would be cost-saving under policy question 1 (replacing MenACWY and MenB when both are indicated). Under policy question 2 (replacing

[§] This judgment is based on the 95% CIs for the relative risk of experiencing one or more nonserious adverse event when comparing MenABCWY with serogroup B–targeting control groups: 0.96–1.02 for 1 dose of MenABCWY versus 1 dose of MenB only, 0.90–1.01 for 1 dose of MenABCWY versus 1 dose of MenACWY + MenB, and 0.98–1.02 for ≥2 doses of MenABCWY versus ≥2 doses of MenB.

[¶] This judgment is based on the 95% CIs for the relative risk of experiencing one or more nonserious adverse event when comparing MenABCWY with MenACWY: 1.46–2.22 for 1 dose of MenABCWY versus 1 dose of MenACWY and 1.83–2.21 for ≥2 doses of MenABCWY versus 1 dose of MenACWY.

MenACWY), pentavalent vaccine would cost $11.3 million per QALY gained. For policy question 3 (replacing MenB), the cost-effectiveness of pentavalent vaccine would range from being cost-saving (though less cost-saving than policy question 1) to costing $4.5 million per QALY (*16*,*17*). Using pentavalent vaccine as an alternative to concomitant administration of MenACWY and MenB (policy question 1) was the most cost-saving of the policy questions under consideration. The GSK model included several differences in assumptions and inputs but yielded similar conclusions overall (*18*).

Recommendations for Use of MenACWY-CRM/MenB-4C

ACIP recommended that MenACWY-CRM/MenB-4C may be used when both MenACWY and MenB are indicated at the same visit for 1) healthy persons aged 16–23 years (routine schedule) when shared clinical decision-making favors administration of MenB vaccine and 2) persons aged ≥10 years who are at increased risk for meningococcal disease (e.g., because of persistent complement deficiencies, complement inhibitor use, or functional or anatomic asplenia). Indications for MenACWY and MenB vaccination have not changed since they were published in 2020 (*2*).

Clinical Guidance

Shared clinical decision-making for MenB. For healthy persons, MenACWY-CRM/MenB-4C may be administered on the basis of shared clinical decision-making. Providers can refer to previously published considerations for shared clinical decision-making regarding MenB administration (*3*).

Interchangeability of vaccine products. MenACWY products are interchangeable, although the same vaccine product is preferred for all doses (*2*). However, because MenB products from different manufacturers contain different antigens, they are not interchangeable; existing recommendations for administering MenB products are based on evidence for which only the same manufacturer's product was administered. All doses of a serogroup B–targeting vaccine administered to an individual person, including booster doses, should be from the same manufacturer. If doses from multiple manufacturers have been administered to the same person, the person should receive a complete series of either manufacturer's product without counting doses from the other manufacturer as valid (*6*). Providers should always check the packaging label to be certain they are administering the intended vaccine product to the recipient (*19*).

If MenB doses have been previously received by an individual but the vaccine manufacturer is unknown, an attempt should be made to obtain past immunization records (e.g., from the health care provider or immunization information system [immunization registry]) to ascertain the vaccine brand used for previous MenB doses. If the brand cannot be determined, the series should be restarted with any licensed MenB–targeting vaccine to ensure receipt of a complete MenB series with products from a single manufacturer.

Indavertent administration of MenACWY-CRM/MenB-4C. If MenACWY-CRM/MenB-4C is inadvertently administered when either MenACWY only or MenB only is indicated, the dose can be considered valid if it otherwise would have been a valid administration of MenACWY or MenB.

Dosing intervals. Healthy adolescents and young adults aged 16–23 years who receive a dose of MenACWY-CRM/MenB-4C on the basis of shared clinical decision-making should complete the MenB series with a dose of MenB-4C administered 6 months after the MenACWY-CRM/MenB-4C dose (*3*). Persons at increased risk for meningococcal disease who receive a dose of MenACWY-CRM/MenB-4C and who are recommended to receive additional doses of MenACWY and MenB <6 months after a dose of pentavalent meningococcal vaccine should receive separate MenACWY and MenB-4C vaccines, rather than MenACWY-CRM/MenB-4C, following recommended intervals (*3*). Additional details regarding when doses might need to be administered <6 months apart are available in the Child Immunization Schedule Notes (Meningococcal Serogroup A, C, W, Y Vaccination and Meningococcal Serogroup B Vaccination) and the Adult Immunization Schedule Notes (Meningococcal Vaccination).

MenACWY-CRM/MenB-4C may be used for booster doses among persons at increased risk for meningococcal disease if a booster dose of both MenACWY and MenB are indicated at the same visit. MenACWY-CRM/MenB-4C doses deviating from the licensed 6-month interval can be considered valid for MenACWY or MenB if the timing would otherwise have been valid for that component.

Contraindications and Precautions

Severe allergy. MenACWY-CRM/MenB-4C is contraindicated for persons who have a history of a severe allergic reaction, such as anaphylaxis, to any component of the vaccine or to a diphtheria toxoid–containing vaccine (Penmenvy [Meningococcal Groups A, B, C, W, and Y vaccine] | Highlights of Prescribing Information).

Pregnancy and breastfeeding. No high-quality data have been published on use of MenACWY-CRM/MenB-4C during pregnancy or while breastfeeding. Because data regarding MenB vaccination during pregnancy are limited, vaccination with MenB during pregnancy should be deferred until after pregnancy unless an increased risk for acquiring meningococcal disease exists and, after consulting a health care provider, the benefits of vaccination are considered to outweigh the

Summary

What is already known about this topic?

Meningococcal disease is a serious bacterial infection caused by *Neisseria meningitidis*. A new pentavalent meningococcal vaccine (MenACWY-CRM/MenB-4C [Penmenvy, GSK]) protects against *N. meningitidis* serogroups A, B, C, W, and Y and is licensed for use in persons aged 10–25 years. MenACWY-CRM/MenB-4C is the second pentavalent meningococcal vaccine approved in the United States.

What is added by this report?

On April 16, 2025, the Advisory Committee on Immunization Practices recommended that, when both quadrivalent (serogroups A, C, W, and Y) and serogroup B meningococcal (MenB) vaccine are indicated concurrently for persons aged ≥10 years, MenACWY-CRM/MenB-4C may be administered instead.

What are the implications for public health practice?

Because different manufacturers' serogroup B–targeting vaccines are not interchangeable, this recommendation provides a pentavalent vaccine option for persons receiving the GSK MenB vaccine (MenB-4C) for other doses.

potential risks. When MenACWY is indicated while pregnant or breastfeeding, MenACWY-CRM or MenACWY-TT may be administered.

Moderate or severe acute illness. As with other vaccines, vaccination should generally be deferred for persons with a moderate or severe acute illness.

Reporting of Vaccine Adverse Events

Adverse events that occur in a patient after meningococcal vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS), even if it is uncertain whether the vaccine caused the event. Instructions for reporting to VAERS are available online at VAERS | Report an Adverse Event or by telephone (800-822-7967).

ACIP Meningococcal Vaccines Work Group

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Acknowledgments

Alison Albert, Isha Berry, Gabrielle Cooper, LeAnne Fox, Susan Hariri, Katherine Lean, Shelby Miller, John Neatherlin, Noele Nelson, Amy Rubis, Dennis Wang, Division of Bacterial Diseases, National Center for Immunization and Respiratory Diseases, CDC; Sam Graitcer, Liz Velazquez, Fangjun Zhou, Immunization Services Division, National Center for Immunization and Respiratory Diseases, CDC; Jessica MacNeil, Melinda Wharton, Office of the Director, National Center for Immunization and Respiratory Diseases, CDC.

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All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

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ISSN: 0149-2195 (Print)