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Meningococcal Disease and Vaccination Overview

Prepared for: Maine Immunization Program

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Medical Science Liaison – Vaccines

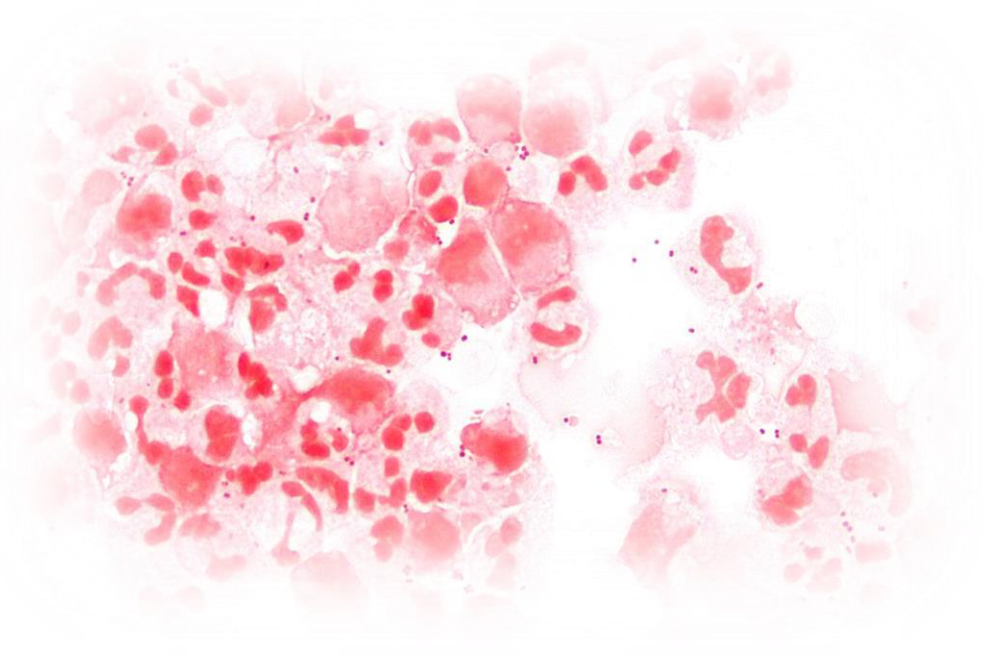
August 17th, 2023

GSK

Meningococcal Disease State Overview

Neisseria meningitidis

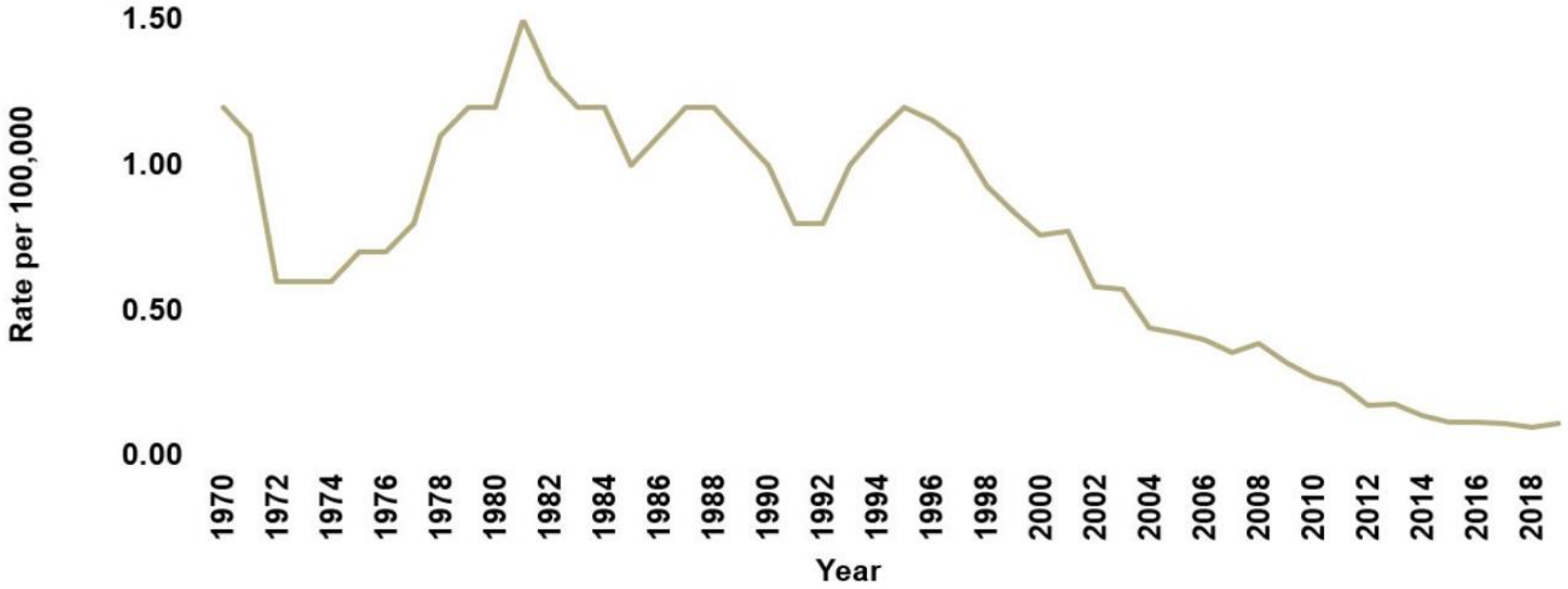
- Gram-negative, encapsulated bacteria[1]
- Virulence depends on the expression of the capsule to help prevent phagocytosis and complement-mediated lysis
- 13 serogroups based on the capsular polysaccharide have been identified



1. CDC. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021.

Historical Cases of Meningococcal Disease

United States, 1970–2019

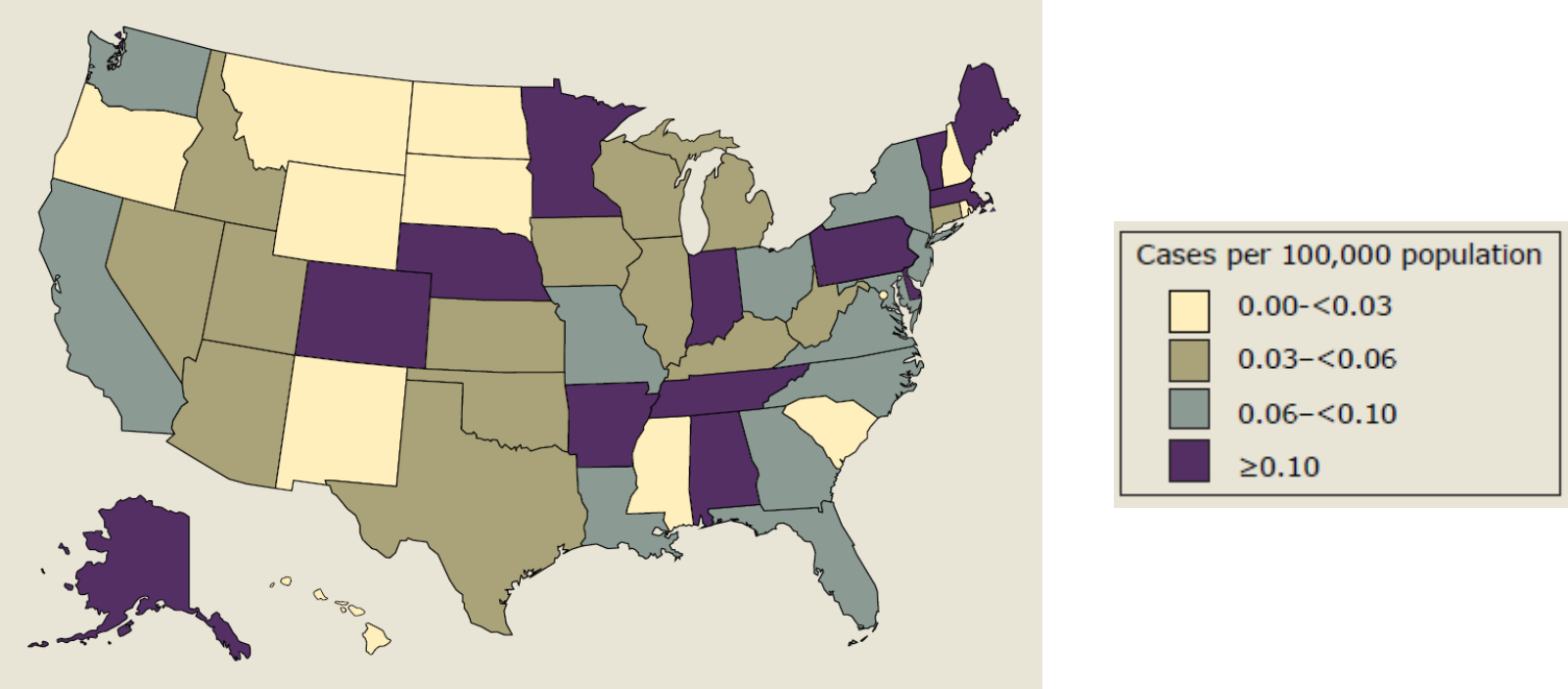


Source: CDC. National Notifiable Diseases Surveillance System

Available at: https://www.cdc.gov/meningococcal/images/meningococcal-disease-incidence.jpg. Accessed May 11, 2022.

Enhanced Case Surveillance Data from CDC (cont.)

Confirmed and Probable Cases Reported to the NNDSS, All Ages 2020



NNDSS = National Notifiable Diseases Surveillance System

CDC. Enhanced Meningococcal Disease Surveillance Report, 2020. Available at: https://www.cdc.gov/meningococcal/downloads/NCIRD-EMS-Report-2020.pdf. Accessed April 28, 2023.

Enhanced Case Surveillance Data from CDC (cont.)

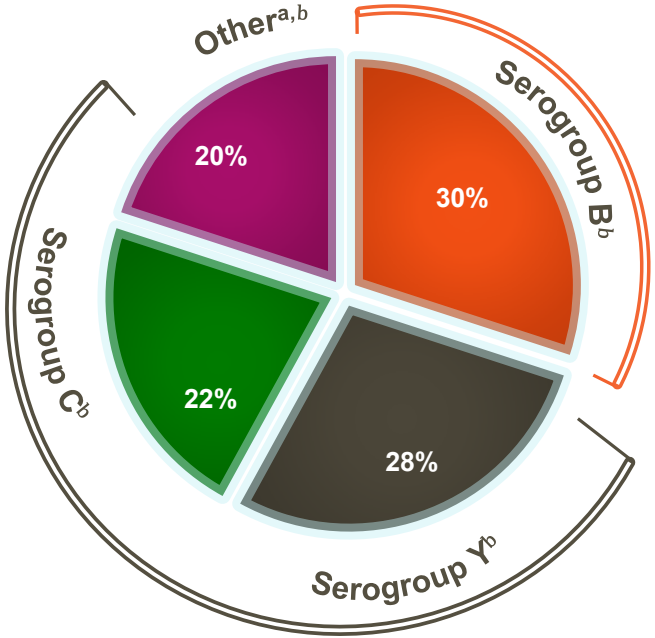
Meningococcal Disease Cases and Incidence by Serogroup and College Attendance*, 2020

	B No. (Incidence†)	C No. (Incidence†)	W No. (Incidence†)	Y No. (Incidence†)	Nongroupable No. (Incidence†)	Total** No. (Incidence†)
Attending college‡	4 (0.03)	0 (0.00)	0 (0.00)	1 (0.01)	1 (0.01)	**10 (0.09)**
Not attending college‡	6 (0.03)	3 (0.02)	1 (0.01)	2 (0.01)	4 (0.02)	**17 (0.09)**

*Among cases in people aged 18-24 years.
**Includes 4 cases with unknown serogroup and 1 serogroup E case.
†Cases per 100,000 population.
‡Assumes 38.3% of 18–24-year-olds attending college

CDC. Enhanced Meningococcal Disease Surveillance Report, 2020. Available at: https://www.cdc.gov/meningococcal/downloads/NCIRD-EMS-Report-2020.pdf. Accessed April 28, 2023.

Serogroup Distribution of IMD Cases in the US (2009-2019)

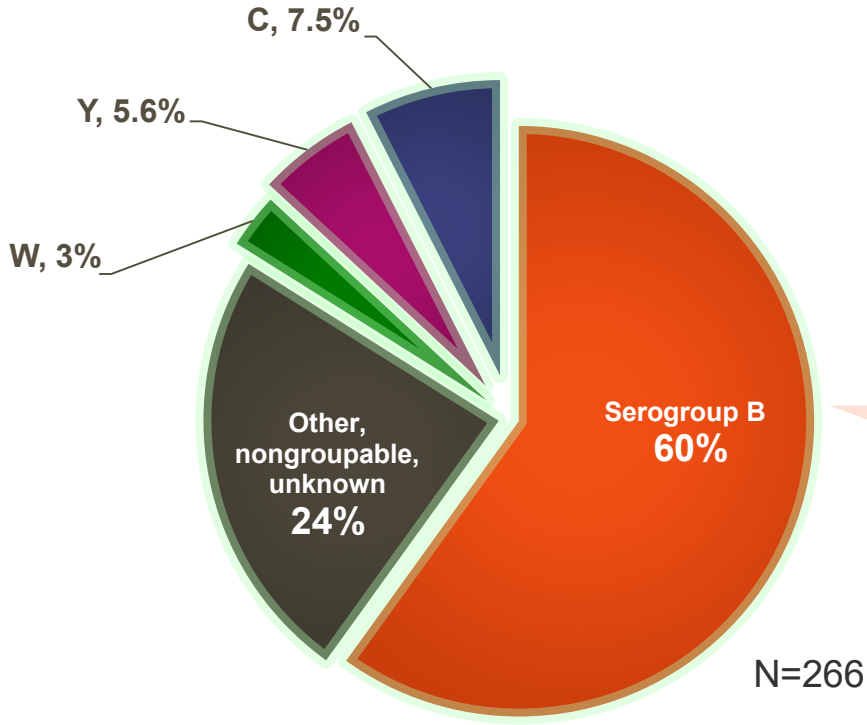


[a]Includes serogroup W, ungroupable, and unknown

[b]In individuals aged <1 to ≥65 years, from 2009-2019, N = 613.

Active Bacterial Core surveillance (ABCs): Neisseria meningitidis. Centers for Disease Control and Prevention. Reviewed July 21, 2021. Accessed July 5, 2022. https://www.cdc.gov/abcs/reports-findings/surv-reports.html.

Serogroup Distribution* of IMD Cases in the US (2 of 2) (2015-2019)

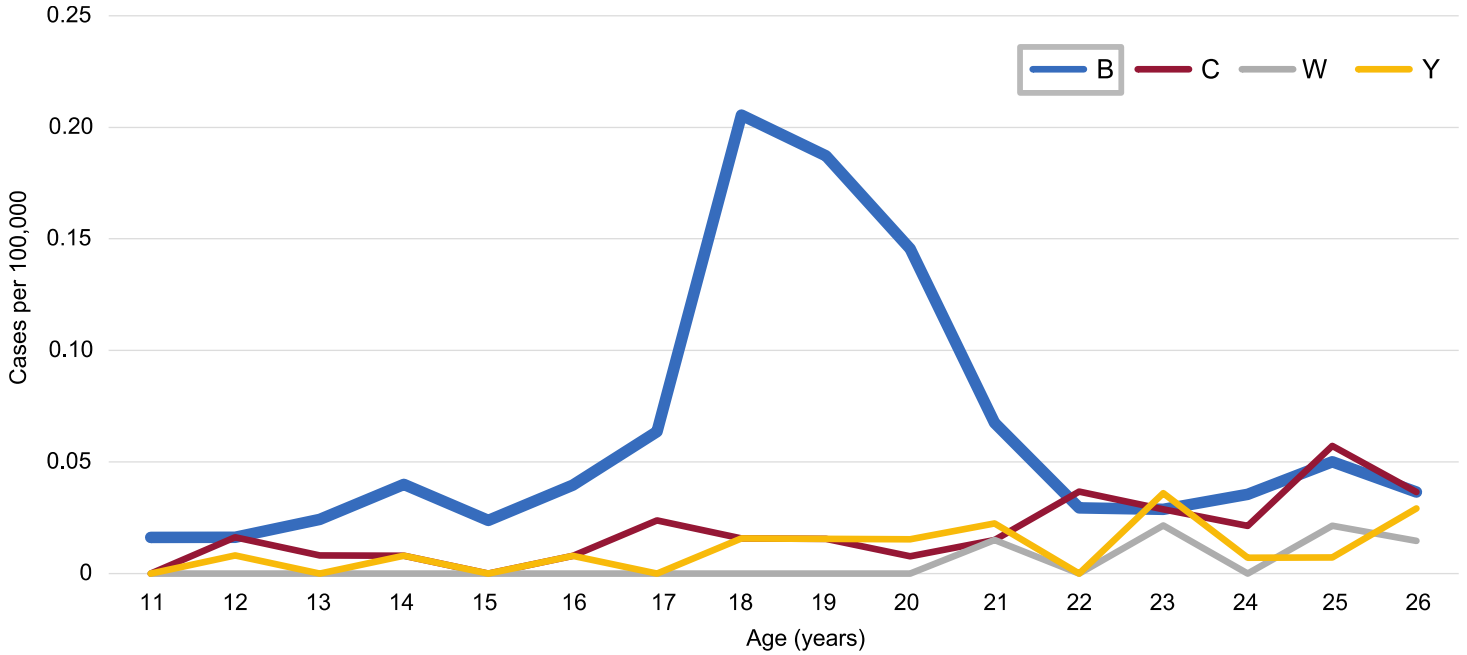


Among adolescents and young adults aged 16-23 years, **serogroup B caused 60%** of all meningococcal disease cases from 2015 to 2019 (N=266)

*Values are rounded from decimal figures that total 100%.

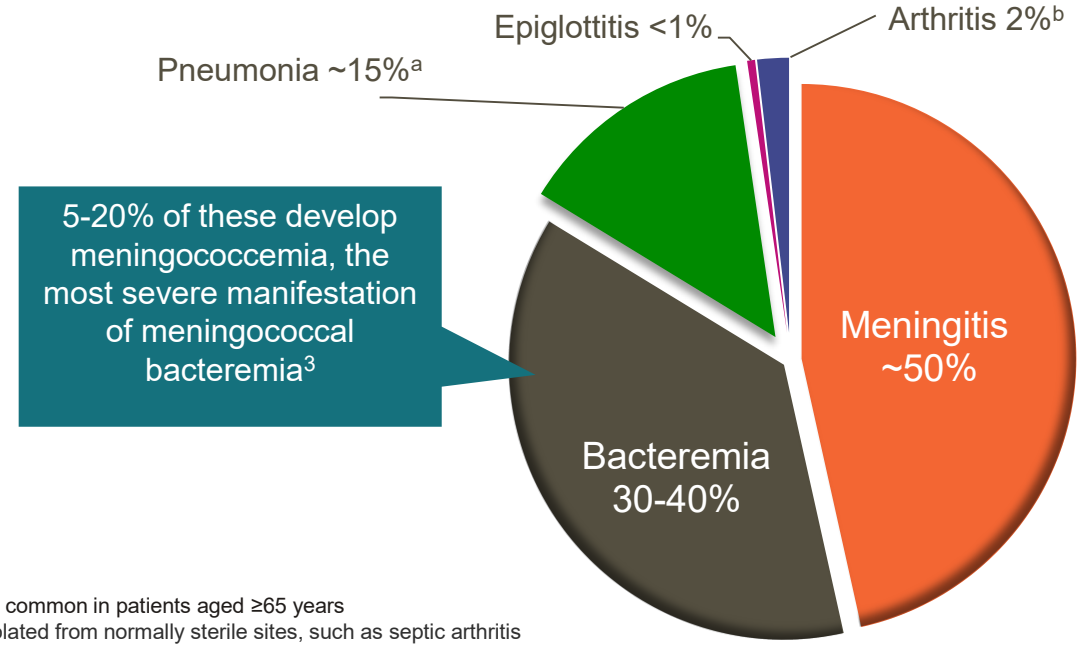
Centers for Disease Control and Prevention website. Enhanced Meningococcal Disease Surveillance Reports, 2015-2019. www.cdc.gov/meningococcal/surveillance/index.html#enhanced-reports. Accessed June 16, 2022.

Incidence of Meningococcal Disease by Serogroup among US Adolescents and Young Adults, 2014-2016 (2 of 2)



Source: National Notifiable Diseases Surveillance System (NNDSS) data with additional serogroup data from Active Bacterial Core surveillance (ABCs) and state health departments.
Meyer S. Epidemiology of meningococcal disease among college students—United States, 2014-2016. https://stacks.cdc.gov/view/cdc/59918. Presented at the Advisory Committee on Immunization Practices; February 22, 2018.

Clinical Manifestations of Invasive Meningococcal Disease[1-3]

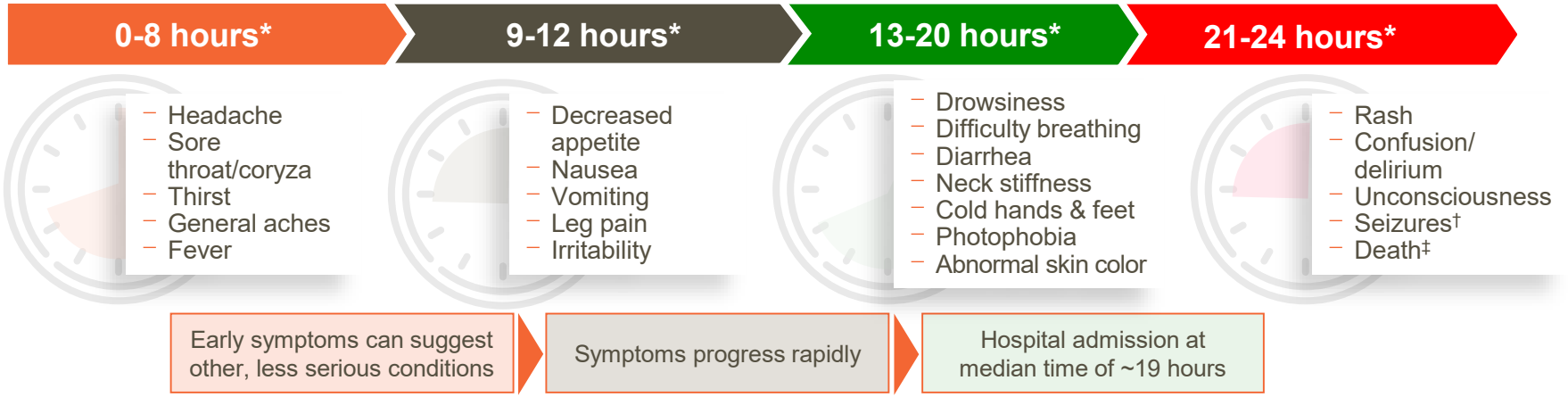


[a]Pneumonia most common in patients aged ≥65 years
[b]Meningococci isolated from normally sterile sites, such as septic arthritis

1. Adapted from CDC. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021. https://www.cdc.gov/vaccines/pubs/pinkbook/mening.html.
2. McNamara LA, Blain A. Meningococcal Disease in: Roush SW, Baldy LM, Hall MAK, eds. Manual for the Surveillance of Vaccine-Preventable Diseases (italics). National Center for Immunization and Respiratory Diseases. Reviewed December 27, 2019. Accessed March 12, 2020. https://www.cdc.gov/vaccines/pubs/surv-manual/chpt08-mening.html.
3. Pelton SI. Meningococcal Disease Awareness: Clinical and Epidemiological Factors Affecting Prevention and Management in Adolescents. *J Adolesc Health*. 2010;46:S9–S15. https://doi.org/10.1016/j.jadohealth.2009.11.220.

Early Symptoms of IMD Are Nonspecific and Progression Is Rapid

Hypothetical IMD Case[1]



Because IMD progresses so rapidly, innate immunity may be inadequate and circulating, vaccine-induced antibodies are necessary to help protect against the serious consequences of IMD[2]

NOTE: This list of clinical features and their median time to onset is representative of what may be experienced by adolescents 15 to 16 years of age; clinical symptoms may vary by age group.

*Hours expressed as medians for patients 15 to 16 years of age.
†Seizures occurred at a median of 26 hours.
‡Even with appropriate treatment, case-fatality rate is 10% to 15%.[3]

Data obtained from parents of patients via questionnaire (n = 313) or interview with study investigator (n = 135). Additional data obtained from medical records (345 nonfatal cases, 103 fatal). Diagnoses were confirmed in 83% of cases (n = 373); the remainder (n = 75) were probable cases.

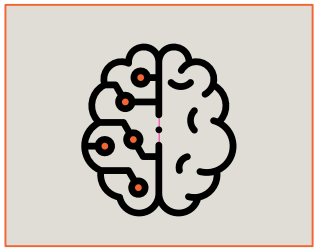
1. Thompson MJ, et al. *Lancet.* 2006;367:397-403. 2. Pichichero ME. *Pediatrics*. 2009;124(6):1633-1641. 3. CDC. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021.

Morbidity (1 of 4)

Up to 20% of survivors may have permanent sequelae including[1,2]:

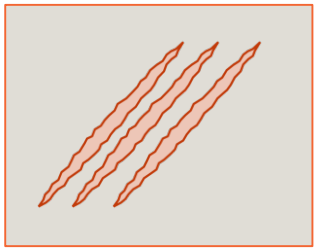
Hearing loss

Neurologic damage



Loss of limb

Extensive skin scarring



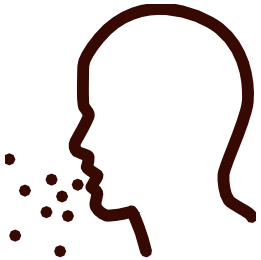
Others

1.CDC. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021.
2.McNamara LA, Blain A. Meningococcal Disease in: Roush SW, Baldy LM, Hall MAK, eds. Manual for the Surveillance of Vaccine-Preventable Diseases (italics). National Center for Immunization and Respiratory Diseases. Reviewed December 27, 2019. Accessed March 12, 2020. https://www.cdc.gov/vaccines/pubs/surv-manual/chpt08-mening.html.

Transmission

- Humans are the only natural reservoir of *N. meningitidis*[1]
- As many as 1 in 10 adolescents and adults are healthy carriers[1]
  - Mostly nonpathogenic strains
- Transmission[2,3]:

Direct contact with respiratory secretions from a nasopharyngeal carrier or an infected person (eg, kissing)



Less efficiently, through aerosolized respiratory droplets (eg, coughing, sneezing)

1. CDC. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021.
2.Yazdankhah SP, et al. *J Med Microbiol*. 2004;53(Pt 9):821-832.
3.National Foundation for Infectious Diseases. The changing epidemiology of meningococcal disease among U.S. children, adolescents and young adults.Schaffner W, Harrison LH, Kaplan SL, et al, eds. Bethesda, MD, 2004.

Recommendations from the Advisory Committee on Immunization Practices (ACIP) and Immunize.org for Meningococcal Groups ACWY Vaccines in Adolescents and Adults

To date, CDC has not made recommendations specific to the one-vial presentation of *Menveo*. In their December 2022 meeting, the ACIP working group stated they'll consider incorporation of *Menveo* one-vial into the current *Menveo* recommendations "over the next year".[1] The 2023 CDC Recommended Child and Adolescent Immunization Schedule states, "Menveo has two formulations: lyophilized [two-vial presentation] and liquid [one-vial presentation]. The liquid formulation should not be used before age 10 years."[2]

The one-vial presentation of *Menveo* is not approved for use in individuals <10 years of age.

Safety and effectiveness of the one-vial presentation of *Menveo* in children aged younger than 10 years have not been established.

1. Centers for Disease Control and Prevention Immunization Safety Office (ISO) Update. Advisory Commission on Childhood Vaccines (ACCV) meeting December 1, 2022. Available at: https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/cdc-update-dec-2022.pdf. Accessed December 9, 2022.
2. Centers for Disease Control and Prevention. Recommended child and adolescent immunization schedule for ages 18 years or younger, United States. Available at: http://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf.

Published Recommendations of the Advisory Committee on Immunization Practices (ACIP) to the Centers For Disease Control and Prevention (CDC)

- "Minimum age [for administration] is 2 months [for] MenACWY-CRM [*Menveo*]...[1]
- **Routine vaccination**
  - 2-dose series at 11–12 years, 16 years[1]
- **Catch-up vaccination**
  - Age 13–15 years: 1 dose now and booster at age 16–18 years (minimum interval: 8 weeks)[1]
  - Age 16–18 years: 1 dose
  - Persons aged 19–21 years who have not received a dose after their 16th birthday can receive a single MenACWY dose as part of catch-up vaccination.[2]

Please visit https://www.cdc.gov/vaccines/schedules for complete information regarding child, adolescent and adult immunization schedules.

1. Centers for Disease Control and Prevention. Recommended child and adolescent immunization schedule for ages 18 years or younger, United States. Available at: http://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf
2. Centers for Disease Control and Prevention. Meningococcal Vaccination: Recommendations of the Advisory Committee on Immunization Practices, United States, 2020. *MMWR*. 2020;69(9):1-42. Available at: https://www.cdc.gov/mmwr/volumes/69/rr/pdfs/rr6909a1-H.pdf.

Two meningococcal vaccines targeting serogroups ACWY are approved in the US: MENVEO[a] and MenQUADFI

	MENVEO[1]	MenQUADFI[2]
Number of Doses	Primary Series: 4 doses or 2 doses or 1 dose; Booster dose[b]	Primary Series: 1 dose; Booster dose[b]
Dosing Schedules	Age-based (see MENVEO Prescribing Information for complete dosing info)	Age-based (see MenQuafi Prescribing Information for complete dosing info)
Administration	Intramuscular	Intramuscular
Approved Ages	2 months through 55 years of age (2-vial)[a] 10 through 55 years of age (1-vial)[a]	2 years and older
Description	Serogroups A (10 mcg), C, Y, W-135 (5 mcg ea.) oligosaccharides conjugated individually to *Corynebacterium diphtheriae* CRM_{197} protein	Serogroups A, C, Y, W-135 (10 mcg ea.) capsular polysaccharides individually conjugated to tetanus toxoid protein

[a]MENVEO is available in 2 presentations- 1-vial (approved for use in individuals 10 through 55 years of age) and 2-vial (approved for use in 2 months through 55 years of age). Safety and effectiveness of the 1-vial presentation of MENVEO in children aged younger than 10 years have not been established.
[b]A single booster dose may be administered to individuals aged 15 through 55 years (Menveo) and ≥15 years (MenQuadfi) who are at continued risk for meningococcal disease if at least 4 years have elapsed since a prior dose of a meningococcal (serogroups A, C, Y, W-135) conjugate vaccine.

Please see Prescribing Information for complete product information.
1. Prescribing Information for MENVEO. 2. Prescribing Information for MenQUADFI.

Highlights from the Prescribing Information for MENVEO

DOSAGE AND ADMINISTRATION (cont.)

Dosing Schedule

Primary Vaccination

MENVEO Two-Vial Presentation	
Infants Aged 2 Months	4-dose series at 2, 4, 6, and 12 months of age
Children Aged 7 through 23 Months	2-dose series with the second dose administered in the second year of life and at least 3 months after the first dose
Children Aged 2 through 10 Years	A single dose For children aged 2 through 5 years at continued high risk of meningococcal disease, a second dose may be administered 2 months after the first dose.
Adolescents and Adults Aged 11 through 55 Years	A single dose
MENVEO One-Vial Presentation	
Adolescents and Adults Aged 10 through 55 Years	A single dose

Booster Vaccination

Adolescents and Adults Aged 15 through 55 Years: A single booster dose of MENVEO using either the two-vial presentation or the one-vial presentation may be administered to individuals who are at continued risk for meningococcal disease if at least 4 years have elapsed since a prior dose of a meningococcal (serogroups A, C, Y, W-135) conjugate vaccine.

MENVEO 2-vial vs. 1-vial Presentations

MENVEO lyophilized[1]

MenCWY (liquid) MenA (lyophilized)

Reconstitution required

MENVEO 1-vial presentation[2]

All components in a liquid presentation

The same excipients and antigen content; the only change is adaptation of the manufacturing process used for the MenCWY liquid component to include MenA[1,2]

Reconstitution NOT required

MenACWY, meningococcal serogroups A, C, W, Y

1. Prescribing Information for MENVEO
2. ClinicalTrials.gov, 2021.NCT03652610. https://clinicaltrials.gov/ct2/show/NCT03652610. URLs accessed July 2021

MENVEO 2-vial vs. 1-vial Presentations

Different Carton Colors

Different Vial Cap Colors

2-vial presentation

MenCYW-135 Liquid Conjugate Component (Vial 1; gray cap)

MenA Lyophilized Conjugate Component (Vial 2; orange cap)

The contents of both vials must be combined to form MENVEO

1-vial presentation

MENVEO (pink cap)

Vial label calls out **DO NOT RECONSTITUTE** in large, red text

Dimensions of both boxes: 1.65 in. x 1.73 in. x 3.46 in.

Interchangeability of MenACWY Conjugate Vaccines

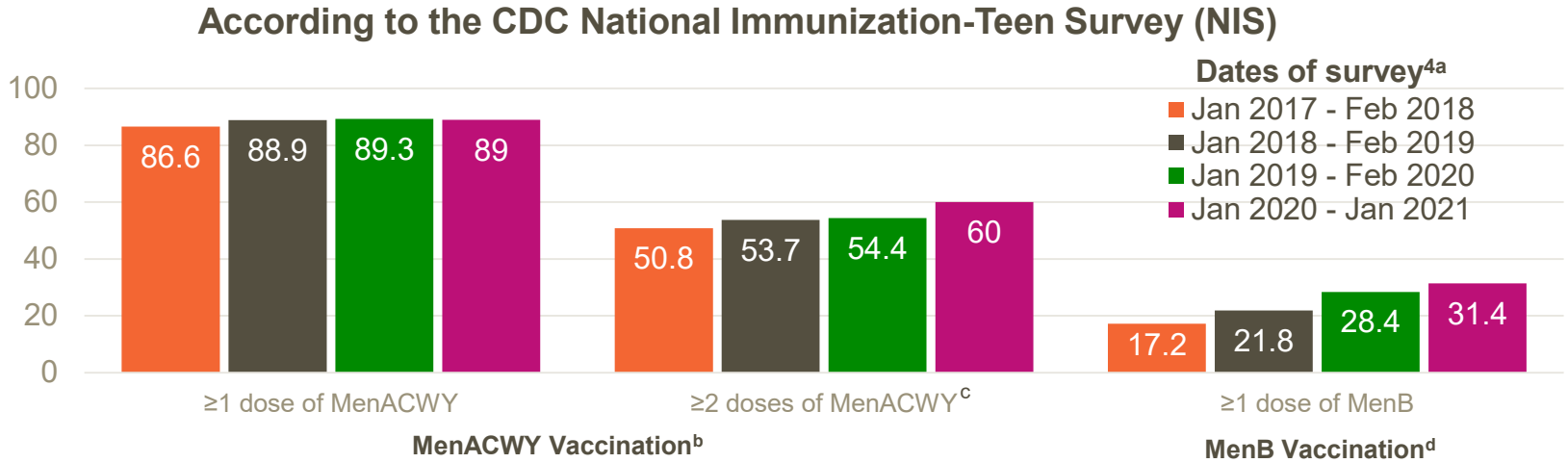
- **From the Centers for Disease Control and Prevention[1]**
  - MenACWY vaccines are interchangeable; the same vaccine product is recommended, but not required, for all doses.

Please visit https://www.cdc.gov/vaccines/schedules for complete information regarding child, adolescent and adult immunization schedules.

1. Centers for Disease Control and Prevention. Meningococcal Vaccination: Recommendations of the Advisory Committee on Immunization Practices, United States, 2020. *MMWR*. 2020;69(9):1-42. Available at: https://www.cdc.gov/mmwr/volumes/69/rr/pdfs/rr6909a1-H.pdf.

Meningococcal Vaccination Rates in the US (1 of 5)

Individuals 13-17 years old, 2018-2021



According to the 2021 NIS-Teen Survey report, coverage with ≥1 MenACWY dose remained high and stable. Coverage with MenACWY was lower among adolescents living in non-metropolitan statistical areas (MSAs) than among adolescents living in MSA principal cities.

[a]Results reflect vaccinations of 17-year-olds (1 dose of MenB or 2nd dose of MenACWY) performed during the 2 years prior to the end of the survey period; [b]Includes percentages receiving MenACWY and meningococcal-unknown type vaccine; [c]≥2 doses of MenACWY or meningococcal-unknown type vaccine. Calculated only among adolescents aged 17 years at interview. Does not include adolescents who received 1 dose of MenACWY at age ≥16 years;[d]≥1 dose of MenB. Calculated only among adolescents who were aged 17 years at interview. Administered, based on shared clinical decision making.

1. Elam-Evans LD, et al. *MMWR Morb Mortal Wkly Rep.* 2020;69(33):1109-1116. https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6933-H.pdf.
2. Pingali C, et al. *MMWR Morb Mortal Wkly Rep.* 2021;70(35):1183-1190. https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7035a1-H.pdf.
3. Pingali C, et al. *MMWR Morb Mortal Wkly Rep.* 2022;71(35):1101-1109. https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7135a1-H.pdf.
4. CDC. Technical Notes for NIS-Teen Vaccination Coverage Tables: https://www.cdc.gov/vaccines/imz-managers/coverage/nis/teen/tech-notes.html.

Recommendations from the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Pediatrics (AAP) for Meningococcal Group B Vaccines

Number of Doses, Dosing Schedule, Administration, Approved Age, Antigens*

	BEXSERO[1]	TRUMENBA[2]
Number of Doses	2 doses	2 or 3 doses
Dosing Schedule	≥1 month apart	At months 0 and 6 or 0, 1-2, 6
Administration	Intramuscular	Intramuscular
Approved Age	10 to 25 years of age	10 to 25 years of age
Antigens	NadA, fHbp (subfamily B), NHBA, PorA P1.4 (found in OMV)	fHbp (subfamilies A and B)

fHbp = Factor H binding protein, NadA = Neisserial adhesin A, NHBA = Neisserial Heparin Binding Antigen, PorA P1.4 = Porin A subtype P1.4), OMV= Outer Membrane Vesicle

*Please see Prescribing Information for complete product information

1. Prescribing Information for *Bexsero*. 2. Prescribing Information for *Trumenba*

ACIP Recommendations for Serogroup B Meningococcal Vaccines in Adolescents and Young Adults who are Not at Increased Risk

- A MenB vaccine series may be administered to adolescents and young adults aged 16-23 years to provide short-term protection against most strains of serogroup B meningococcal disease. The preferred age for MenB vaccination is 16-18 years of age.[1a]
- On the basis of available data and expert opinion, MenB-FHbp or MenB-4C may be administered concomitantly with other vaccines indicated for this age, but at a different anatomic site, if feasible[1]
- Children aged 16-18 who are eligible for the Vaccines for Children (VFC) Program may be vaccinated against meningococcal serogroup B through the program[2]

[a]ACIP recommends a MenB primary series for individuals aged 16-23 years based on shared clinical decision-making.[2]
ACIP = Advisory Committee on Immunization Practices; MenB-4C = MenB-4C, GSK; MenB-FHbp = Trumenba, Pfizer, Inc.

1. CDC. Use of serogroup b meningococcal vaccines in adolescents and young adults: recommendations of the Advisory Committee on Immunization Practices, 2015. *MMWR. 2015;64(41):1171-1176.*; 2. CDC. Advisory Committee on Immunization Practices. Vaccines for Children (VFC) program. Vaccines to prevent meningococcal disease. VFC Resolution No. 6/15-1. Jun 24, 2015. http://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html. Accessed March 30, 2017.

2. Advisory Committee on Immunization Practices (ACIP) Presentation Slides: June 2019 Meeting. Meningococcal Vaccines. Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2019-06/Meningococcal-3-Mbaeyi-508.pdf.

‘Shared Clinical Decision Making’ Recommendations for the Use of Meningococcal Group B Vaccines[1] (slide 1 of 3)

“Shared clinical decision-making refers to an individually based vaccine recommendation informed by a decision-making process between the health care provider and the patient or parent/guardian. Considerations for shared clinical decision-making for vaccine administration and timing of administration might include:

- the serious nature of meningococcal infections, with high rates of death and permanent sequelae in those who develop invasive disease;
- the low number of serogroup B meningococcal disease cases (average of 34 serogroup B cases annually among persons aged 16–23 years in the United States during 2015–2018);
- the increased risk among college students, especially those who are freshmen, attend a 4-year university, live in on-campus housing, or participate in sororities and fraternities;
- the protection provided by MenB vaccines against most strains of serogroup B *N. meningitidis;*
- the estimated relatively short duration of MenB protection (antibody waning within 1–2 years postcompletion of the primary series); and
- the evidence to date suggesting that MenB vaccination has no effect on meningococcal carriage (i.e., MenB vaccines might provide individual protection against serogroup B disease but herd protection is unlikely).”

1. Centers for Disease Control and Prevention. Meningococcal Vaccination: Recommendations of the Advisory Committee on Immunization Practices, United States, 2020. *MMWR*. 2020;69(9):1-42. Available at: https://www.cdc.gov/mmwr/volumes/69/rr/pdfs/rr6909a1-H.pdf.

‘Shared Clinical Decision Making’ Recommendations for the Use of Meningococcal Group B Vaccines (slide 2 of 3)

- ACIP recommendations are a call for shared decision-making, where HCPs[1,2]:
  - Have a conversation with patients[3,4]
  - Determine, with the patient, if clinical action is the best course[2]

> **"In the absence of such a discussion, disparities could arise between the “information haves” (families who know about the disease and seek vaccination) and the “information have-nots” (those who do not know about the disease or the vaccine)."**[3]
> — Marshall and Tan

- If the physician and the family discuss MenB vaccination but no vaccination is administered, the American Academy of Pediatrics (AAP) recommends the decision should be documented in the patient's health record[4]
- The Affordable Care Act (ACA) requires all federal and commercial insurance plans to pay for vaccines routinely recommended by ACIP when administered by in-network providers[5]
- The Vaccines for Children Program (VFC) will cover the cost of MenB vaccination for those either 16 through 18 years of age, 10 through 18 years of age identified as being at increased risk due to a medical condition, or 10 through 18 years of age identified as being at increased risk due to a serogroup B meningococcal disease outbreak.[6]

1. Advisory Committee on Immunization Practices (ACIP) Presentation Slides: June 2019 Meeting. Meningococcal Vaccines. Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2019-06/Meningococcal-3-Mbaeyi-508.pdf. **2.** Centers for Disease Control and Prevention. Meningococcal Vaccination: Recommendations of the Advisory Committee on Immunization Practices, United States, 2020. *MMWR*. 2020;69(9):1-42. Available at: https://www.cdc.gov/mmwr/volumes/69/rr/pdfs/rr6909a1-H.pdf. **3.** Marshall GS, et al. Understanding the Category B recommendation for serogroup B meningococcal vaccine. *Pediatrics*. 2017;139(5):e20163484. **4**. Byington CL, Maldonado YA, Barnett ED, et al. American Academy of Pediatrics Committee on Infectious Diseases. Recommendations for serogroup B meningococcal vaccine for persons 10 years and older. *Pediatrics*. 2016;138(3):1-9. www.dx.doi.org/10.1542/peds.2016-1890. **5.** Kempe A, Allison MA, et al. Knowledge and attitudes regarding category B ACIP recommendations among primary care providers for children. *Acad Pediatr*. 2018;18(7):763-768. http://dx.doi.org/10.1016/j.acap.2018.04.005.
6. CDC website. https://www.cdc.gov/vaccines/vpd/mening/hcp/adolescent-vaccine.html. Reviewed July 26, 2019. Accessed April 6, 2020.

Vaccination Completion Rates for *Bexsero* across the United States — 2018-2020

GSK

Summary and Key Points

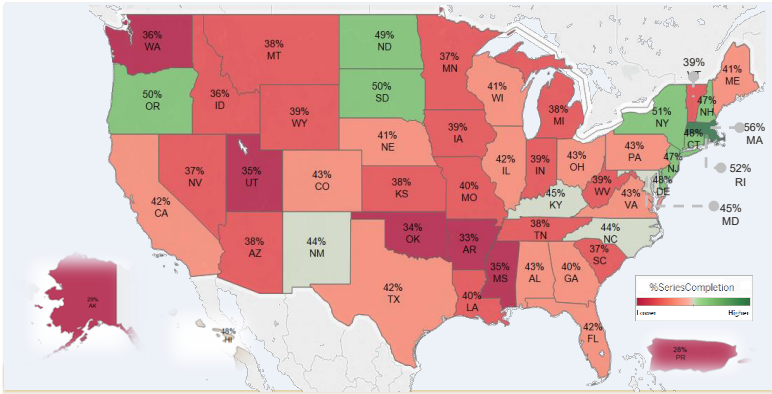
Prescribing Info

- The average national vaccination series completion rate for *Bexsero* (Meningococcal Group B Vaccine) in the US was 43% from 2018-2020.[1]
- Pre-pandemic completion rate was at 50% through 2018-2019.
- Data suggest that ~65% and 70% patients completed series in 2 and 3 months, respectively.[2]

Indication and Dosing[3]

- *Bexsero* is a vaccine indicated for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B. *Bexsero* is approved for use in individuals aged 10 through 25 years. Approval of *Bexsero* is based on demonstration of immune response, as measured by serum bactericidal activity against three serogroup B strains representative of prevalent strains in the United States. The effectiveness of *Bexsero* against diverse serogroup B strains has not been confirmed.
- *Bexsero* is administered as a 2-dose series (0.5-mL each) at least 1 month apart.

Series Completion for Bexsero by State from January 2018 to December 2020[1]



Data Source: Claims Data January 2018 – December 2020; **Analysis cohort:** ~1.1 million patients aged 10-25 years vaccinating in-office; **Data Caveats:** Claims data is nationally representative of U.S. claims, covering ~90% of retail pharmacy claims and at least 60% of mail order claims. Claims during analysis period indicated above, determined patients in ages 10 to 25, with at least one claim for *Bexsero*, and consisted of 95% patients Commercially insured, 3% Medicaid, and 2% of patients covered by cash or another type of payor; **Initiation window:** All patients initiating series in Jan 2018 – Sep 2020 to allow enough time for series completion; **Methodology:** 1. # of patients aged 10-25 years that completed the series between Jan 2018-Dec 2020 by state; 2. # of patients aged 10-25 years that initiated the series between Jan 2018 – Sep 2020 by state; 3. Divide (1) by (2) for statewise % series completion 2018-2020; 4. Divide SUM of (1) by SUM of (2) for average national % series completion. (Pre-pandemic completion rate calculated using same methodology).

Some information contained in this response may be outside the approved Prescribing Information. This response is not intended to offer recommendations for administering this product in a manner inconsistent with its approved labeling. In order for GSK to monitor the safety of our products, we encourage healthcare professionals to report adverse events or suspected overdoses to the company at 888-825-5249. Please consult the Prescribing Information. This response was developed according to the principles of evidence-based medicine and, therefore, references may not be all-inclusive.

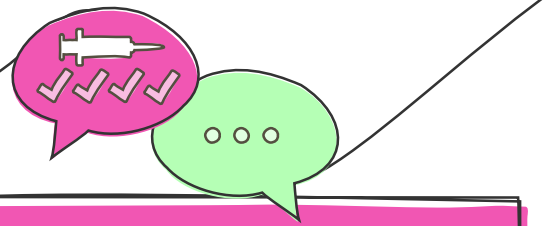
References: 1. GSK Data on File 2021N477945. **2.** GSK Data on File 2021N477946. **3.** Prescribing Information for *Bexsero*.

For more information

CLICK FOR GSK US Medical Affairs Website

The Prescribing Information can also be accessed at GSK Products.

CDC: STANDARD FOR ADULT IMMUNIZATION PRACTICE - RECOMMEND



Recommending vaccines prompts most patients to get immunized

S Share tailored reasons why the recommended vaccine is right for the patient, given his or her age, health status, lifestyle, occupation, or other risk factors

H Highlight positive experiences with vaccines, as appropriate, to reinforce the benefits and strengthen confidence in vaccination

A Address patient questions and any concerns about the vaccine in plain and understandable language

R Remind patients that vaccines protect them and their loved ones from many common and serious diseases

E Explain the potential costs of getting the disease, including serious health effects, time lost, and financial costs

Centers for Disease Control and Prevention. Vaccine recommendation. https://www.cdc.gov/vaccines/hcp/adults/downloads/standards-immz-practice-recommendation.pdf. Accessed October 24, 2021.