

# Meningococcal Vaccination

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THE UNIVERSITY OF ARIZONA  
COLLEGE OF MEDICINE TUCSON  
**Pediatrics**



# Financial Disclosures

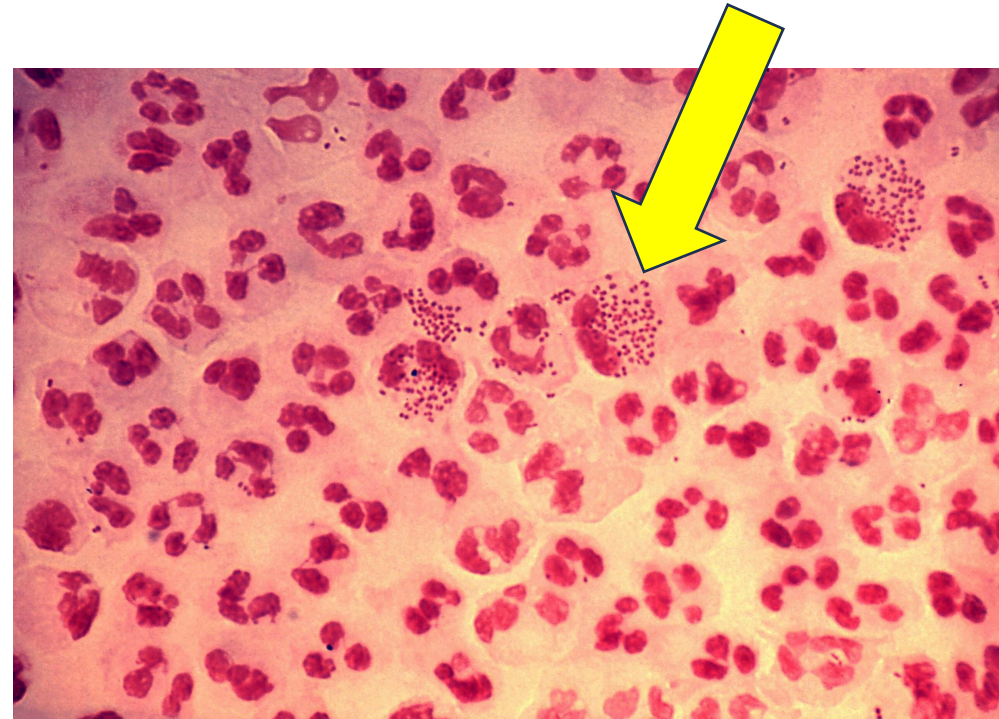
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- The Arizona Alliance for Community Health Centers is accredited by the Arizona Medical Association to provide medical education for physicians.
- The Arizona Alliance for Community Health Centers designated the 2025 Arizona Immunization Conference educational activity for a maximum of 11 hours AMA PRA Category 1 Credits Physicians should only claim credit commensurate with the extent of their participation in the activity.
- The Arizona Pharmacy Association is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education.

# Objectives

- Examine the epidemiology of meningococcal disease
- Review meningococcal disease clinical presentation
- Review vaccine products and recommendations, including considerations in high-risk patients

# *Neisseria meningitidis*

- Aerobic gram-negative diplococcus
  - Humans only natural reservoir
  - Closely related to *N. gonorrhoeae*
- 12 serogroups based on polysaccharide capsule
  - A, B, C, W, X, and Y cause > 90% of human disease

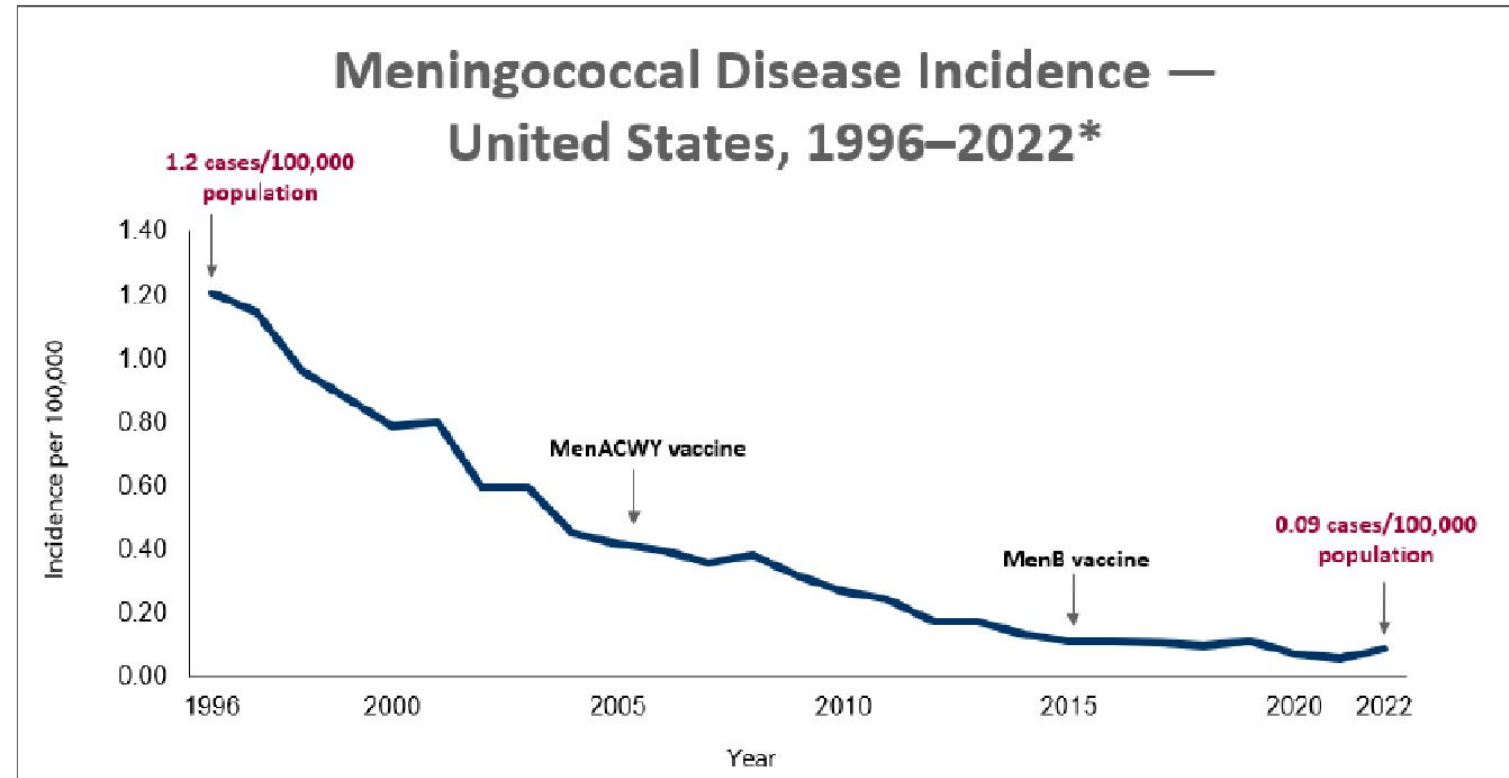


# Microbiology

- Transmitted person-to-person by large respiratory droplets
  - Can be transmitted by asymptomatic carriers or those with disease
- Colonizes naso- and oro-pharyngeal mucosa
  - Rates of highest in adolescents and young adults
  - 4-5% in infants, 20-25% in adolescents, then down to 7-8% in adults
  - Many of carriage strains are non-groupable
- Invasive disease is a rare outcome of colonization (<1%)

# Epidemiology

- In the United States:
  - Rates decreased from 1.2 cases per 100k in 1996
  - Incidence highest in late winter and early spring
  - Outbreaks account for 5% of cases

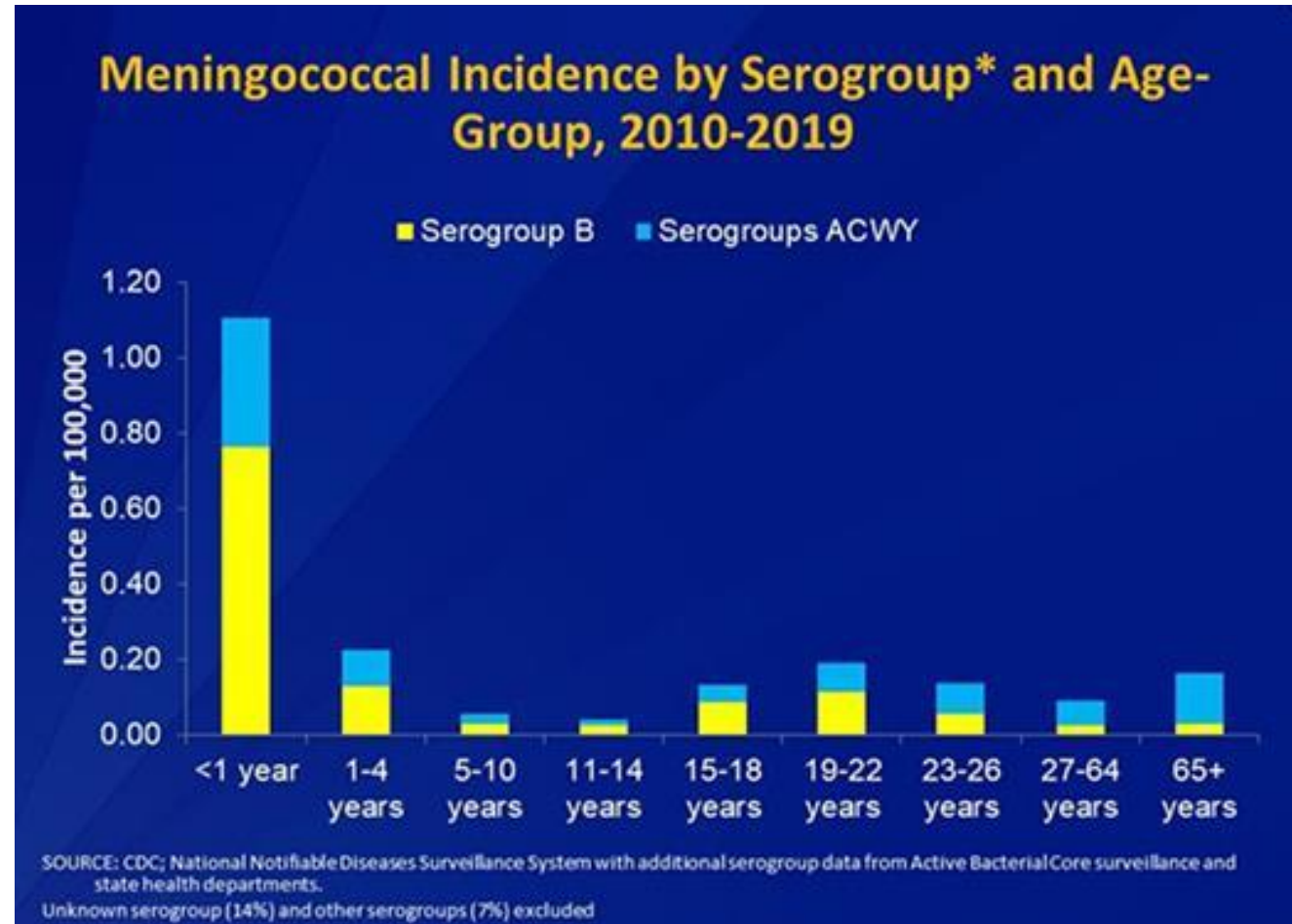


ACIP presentation:

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-10-25-26/04-Meningococcal-Collins-508.pdf>

# Epidemiology

- In the United States:
  - Highest incidence in infants < 1 year, followed by children aged 1 year and adolescents/young adults 16-22 years old
  - 66% in infants due to MenB
  - >85% in adolescents due to Men B, C, Y, and W



# What about infants?

- If highest incidence of disease, why not vaccinate?
- Since 1990s, rates have been decreasing despite not vaccinating
  - Incidence of IMD in infants declined by 85%
- Around 2/3 of infections in infants are serogroup B
  - Vaccination with MenACWY recommended only for high-risk infants
  - Has been used in parts of world with higher incidence of disease (UK, Europe)

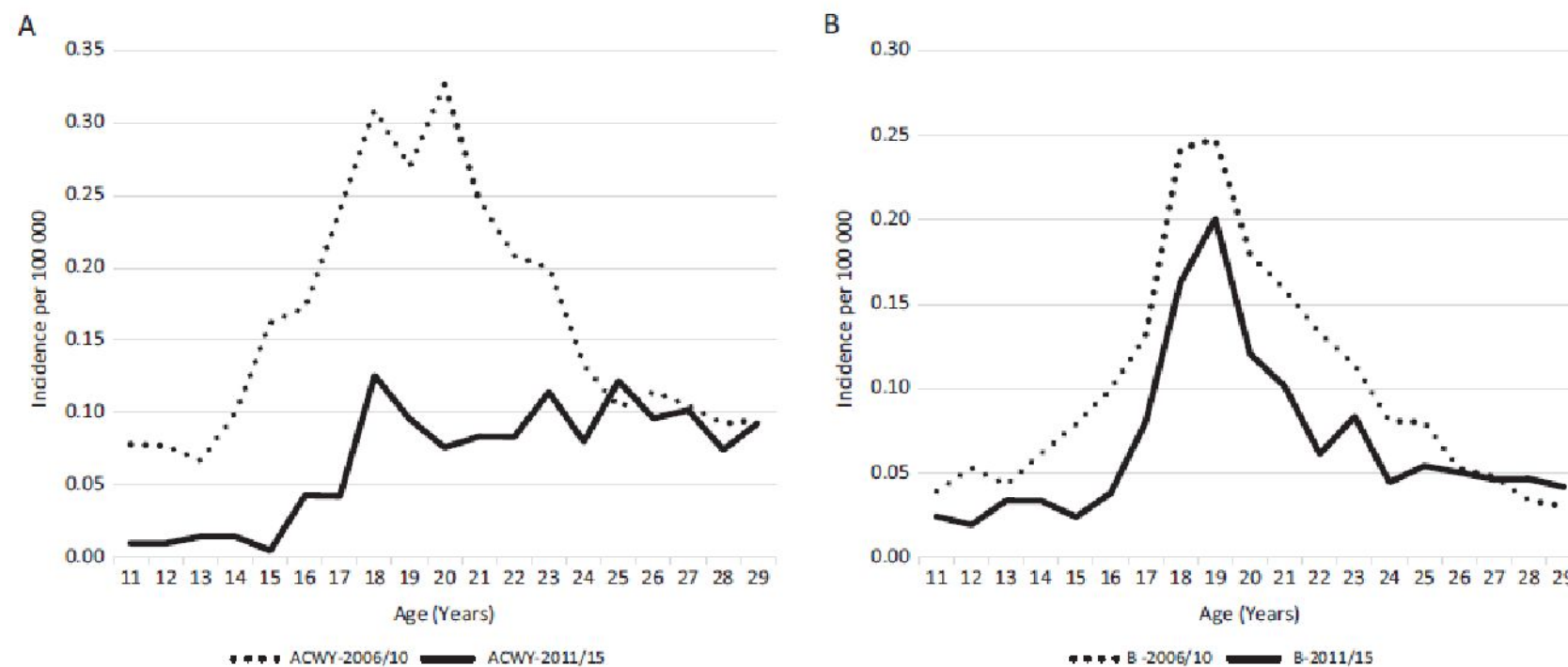


# Current Epidemiology and Trends in Meningococcal Disease—United States, 1996–2015

Jessica R. MacNeil, Amy E. Blain, Xin Wang, and Amanda C. Cohn

National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia

Distribution shifted in last 2 decades, with serogroup B now accounting for most cases, followed by C, W, and Y

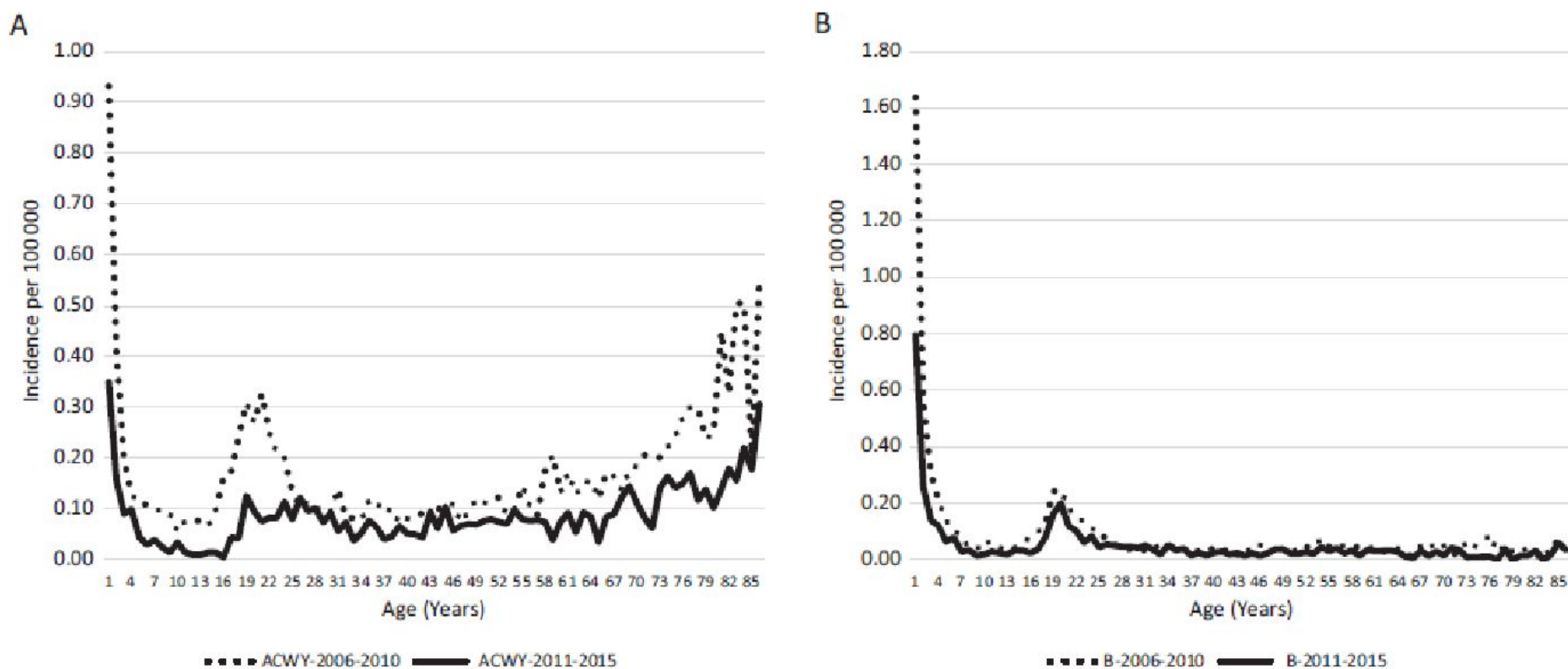


**Figure 1.** Changes in the incidence of serogroups A, C, W, Y combined (A) and serogroup B (B) among adolescents from 2006–2010 to 2011–2015, National Notifiable Diseases Surveillance System, United States, 2006–2015.

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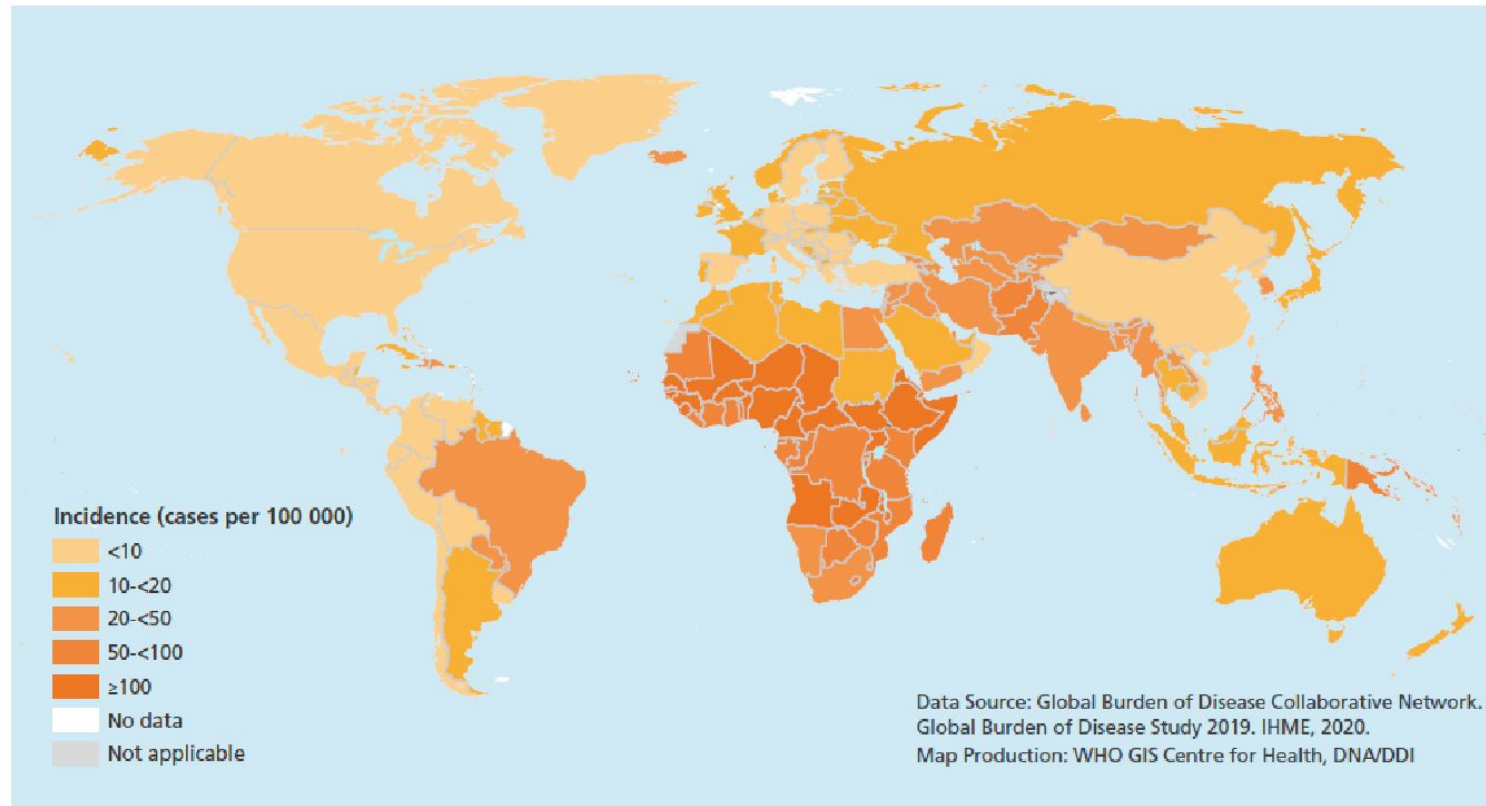
**Figure 2.** Changes in the incidence of serogroups A, C, W, Y combined (A) and serogroup B (B) among all age groups from 2006–2010 to 2011–2015, National Notifiable Diseases Surveillance System, United States, 2006–2015.

# Individuals at increased risk

- Complement deficiencies: (C5-C9, properdin, factor H or D), *up to 10,000-fold increased risk*
- Complement inhibitors: eculizumab (Solaris) and ravulizumab (Ultomiris), *1,000-2,000 fold increased risk*
- Functional or anatomic asplenia: higher mortality rate (40-70%)
- Human immunodeficiency (HIV) infection
- Microbiologists routinely exposed to *Neisseria meningitidis*
- Outbreak setting: attack rate up to 1,400-fold higher than baseline
- Travel to hyperendemic or epidemic regions
- College students and Military recruits
- Men who have sex with men: reported outbreaks of MenC
- Close contact with index case (importance of chemoprophylaxis)

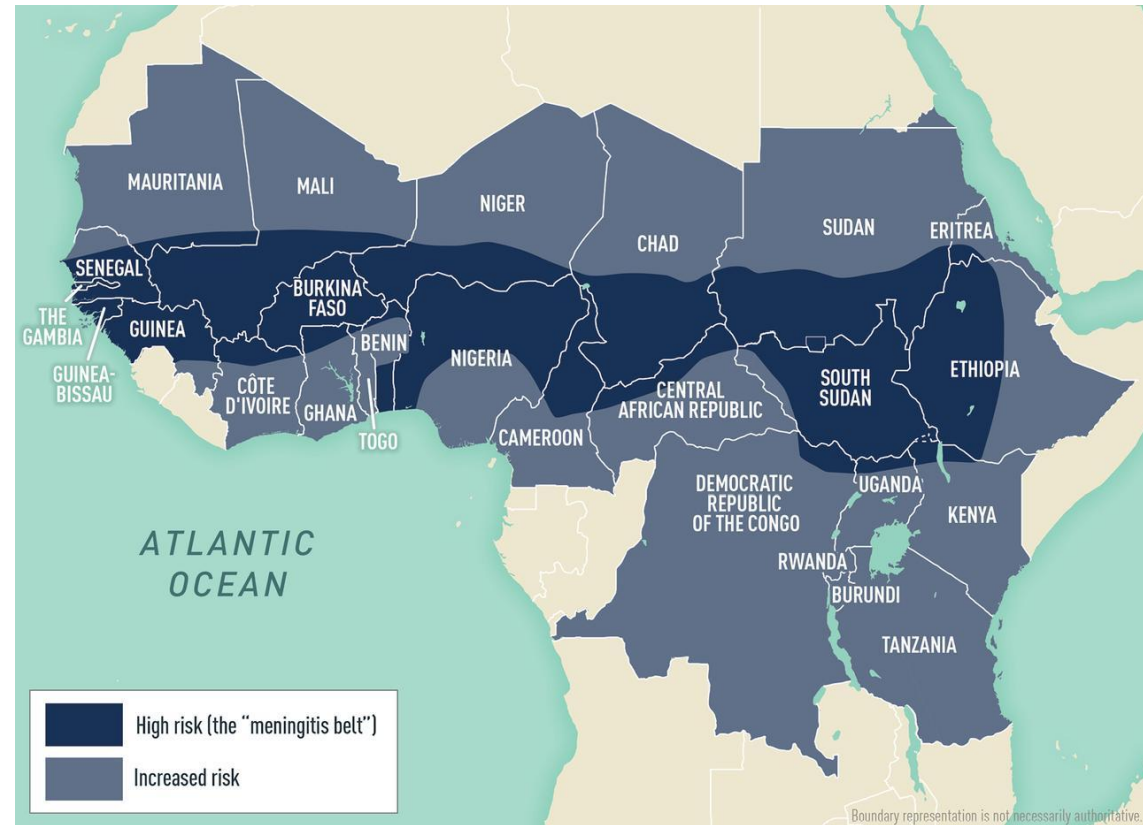
# International considerations

- Any destination where outbreaks of IMD are occurring
- Considerations: Mass gatherings, disaster relief, military missions, crowded colleges



# International considerations

- Meningitis belt in Africa
  - Mainly occurs during dry months
  - Serogroup A
  - Increasing rates of C, W, and X
- Hajj in Saudi Arabia
  - Outbreaks of A and W
  - Imported cases after travel
  - Decreased after KSA required ACWY for travel





# Concerns for disease in patients with HIV

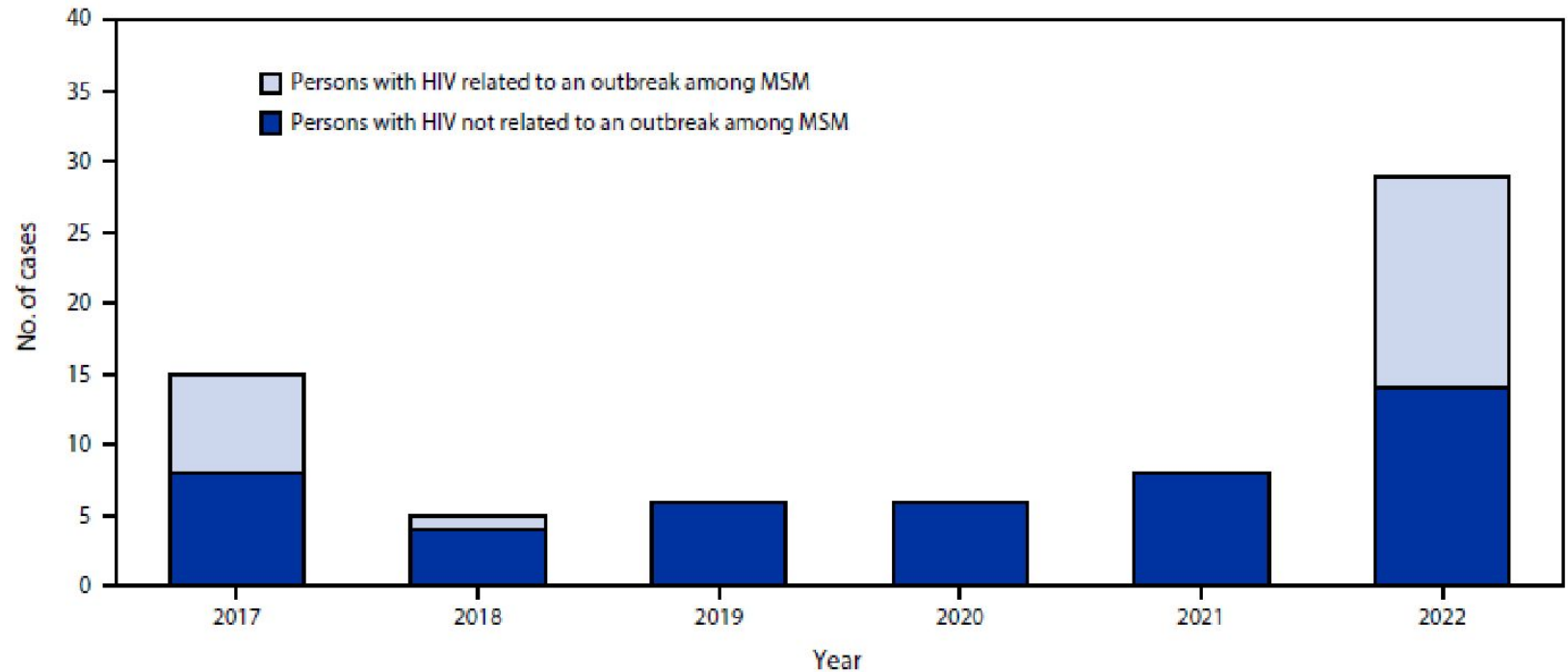
## *Notes from the Field*

### Increase in Meningococcal Disease Among Persons with HIV — United States, 2022

Amy B. Rubis, MPH<sup>1</sup>; Rebecca L. Howie, PhD<sup>1</sup>; Daya Marasini, PhD<sup>1</sup>; Shalabh Sharma, MS<sup>1</sup>; Henju Marjuki, PhD<sup>1</sup>; Lucy A. McNamara, PhD<sup>1</sup>

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FIGURE. Meningococcal disease cases among persons with HIV, by year — United States, 2017–2022\*



# Why are we so concerned if rates are so low?



Fever



Stiff neck



Headache



If you or your child has any of these symptoms, call the doctor right away.



Confusion



Increased  
sensitivity  
to light

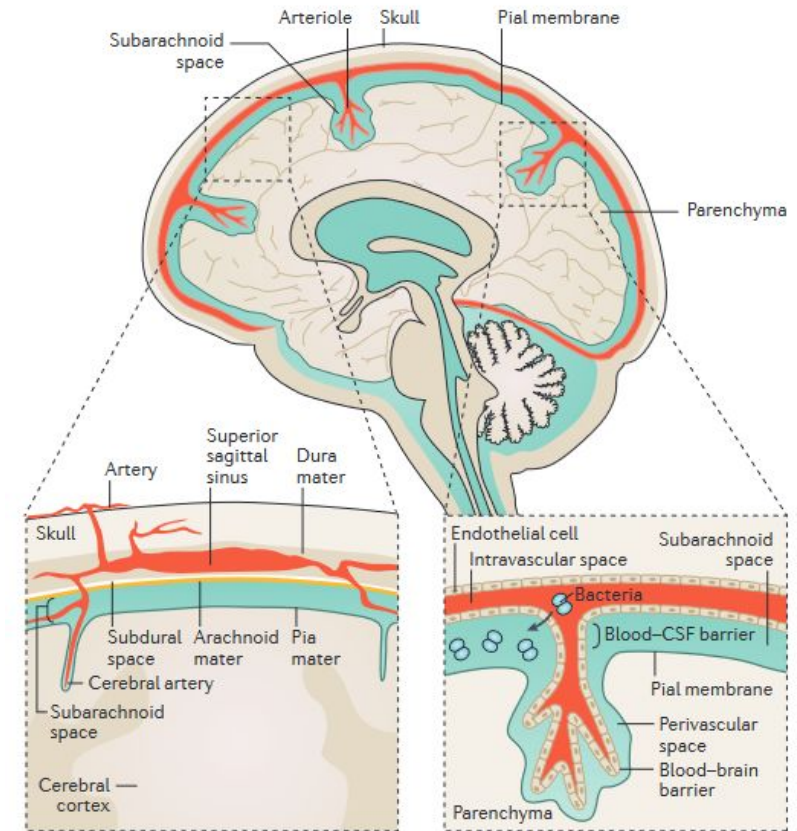


Nausea  
and  
vomiting

<https://www.cdc.gov/meningococcal/about/symptoms.html>

# Invasive Meningococcal Disease (IMD)

- Occurs with invasion of blood stream from mucosal colonization
- Incubation period of 3-4 days (up to 10)
- Bacterial meningitis
  - 50% of invasive disease in US
  - Fevers, severe headaches, stiff neck, nausea/vomiting, photophobia, altered mental status, seizures
  - Can isolate from blood in 75% of cases

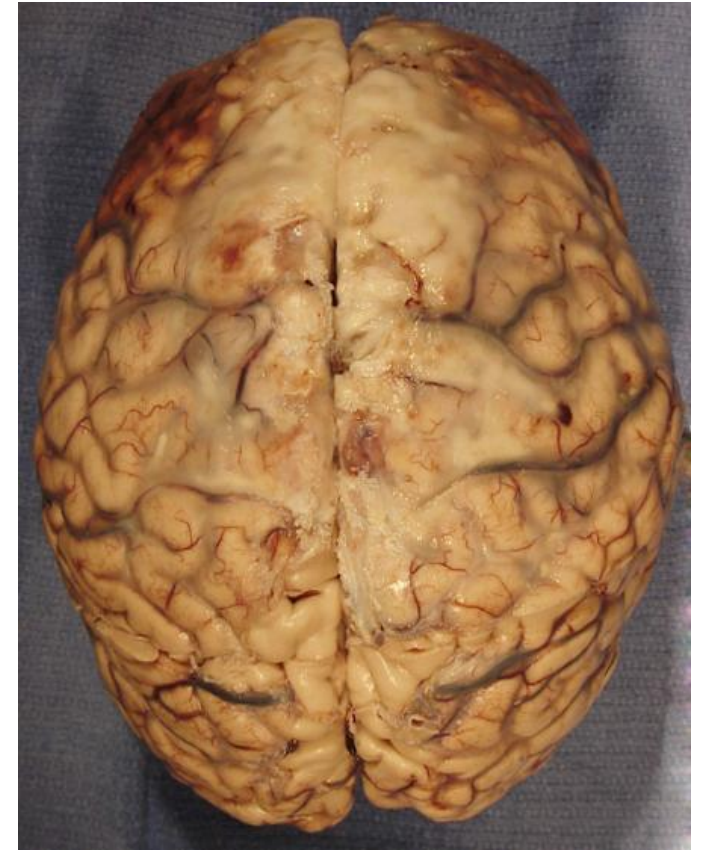


Van de Beek et al, Nature rev 2016



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AAP Red Book 2024



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- Meningococccemia/septicemia
  - 35-40% of cases
  - Onset usually abrupt, with fevers, chills, malaise, myalgia, limb pain, prostration, purpura fulminans
  - Often also involves meningitis
  - Within hours can progress to limb ischemia, coagulopathy, pulmonary edema, shock, coma, and death despite appropriate management

- Bacteremic pneumonia; 15% of cases
  - Most common presentation in adults over 65 years
- Less frequent: arthritis, pericarditis, conjunctivitis, endophthalmitis, urethritis
- Even with appropriate treatment, case fatality of 15% in US
  - Predictors of mortality: coma, hypotension, leukopenia, and thrombocytopenia
  - 10-20% of survivors with long-term sequelae such as neurologic deficits, hearing loss, limb or digit loss, adrenal hemorrhage, skin scarring
  - Neurodevelopmental impacts: Impaired school performance, behavioral problems, ADHD



*M.P. Romero-Gomez et al. / Respiratory Medicine Case Reports 5 (2012) 23–24*

# How can we prevent Meningococcal disease?

- Chemoprophylaxis:
  - Recommended for close contacts of patient with invasive disease
  - Household contacts, childcare/preschool, direct exposure to secretions, resuscitation or intubation without mask
  - Can be considered in some outbreak settings (guidance from local dept of health)
  - Can use Rifampin, Ciprofloxacin, or Ceftriaxone



# How else ... ?



# Meningococcal Vaccine Products

## Quadavalent Conjugate Vaccines

- Menveo, GSK      MenACWY-CRM<sub>197</sub>
- MenQuadfi, Sanofi      MenACWY-TT

## Serogroup B Vaccines

- Trumenba, Pfizer      MenB-FHbp
- Bexsero, GSK      MenB-4C

## Pentavalent Vaccines

- Penbraya, Pfizer 2023      MenABCWY (Trumenba + Nimenrix/MenACWY-TT)
- Penmenvy, GSK 2025      MenABCWY (Bexsero + Menveo)

# Quadraivalent vaccines

Vaccine		Licensed for ages	CDC Recommended Schedule
Menveo	MenACWY-CRM	2 mos – 55 years	11-12y and 16 years
MenQuadfi	MenACWY-TT	≥ 2 years	--If first dose 13-15y, booster at 16-18y --If first dose ≥ 16y, no booster indicated

## Both Quadraivalent vaccines:

- No adjuvants
- No antibiotics
- No preservatives
- Can use interchangeably if needed

# Quadavalent vaccines in High-risk patients

- If patient is at risk for infection
  - Vaccinate starting at 2 months old
  - Use Menveo
  - 2 dose primary series, 8 weeks apart
  - Boosters every 5 years if still high risk
    - If < 7 y/o at primary series then booster 3 years after primary series



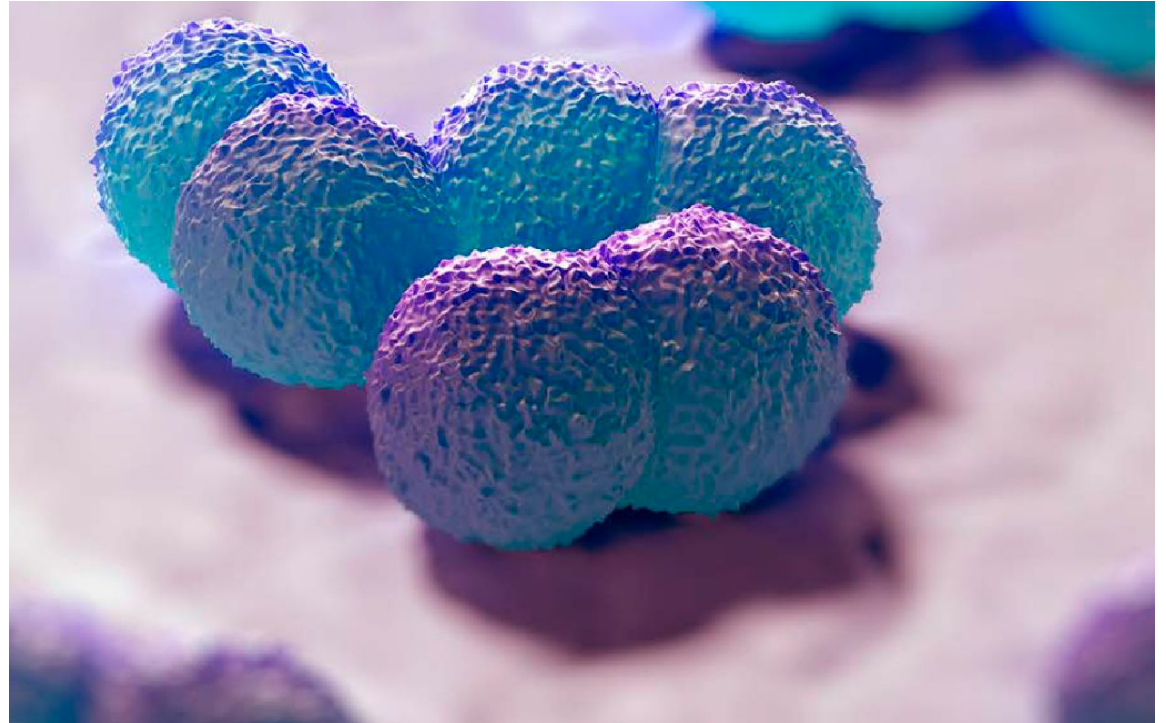
# How is vaccine efficacy determined?

- Because of low incidence of IMD, licensure based on demonstration of specific immune responses instead of direct evidence of clinical effectiveness
  - Serum bactericidal activity (hSBA) as a correlate of protection
  - Immunogenicity assessed based on proportion of participants with four-fold or greater rise in SBA titers to each serogroup or titers  $\geq 1:8$

# Vaccine Effectiveness

- Quadravalent MenACWY \*
  - Overall effectiveness 69% (51 to 80%) following vaccination
  - At one year effectiveness 79% (49-91%)
  - Effectiveness waned to 61% (25 to 79%) at 3-8 years
  - Informed decision to recommend booster at age 16 years

\*based on study of MenACWY-D/Menactra

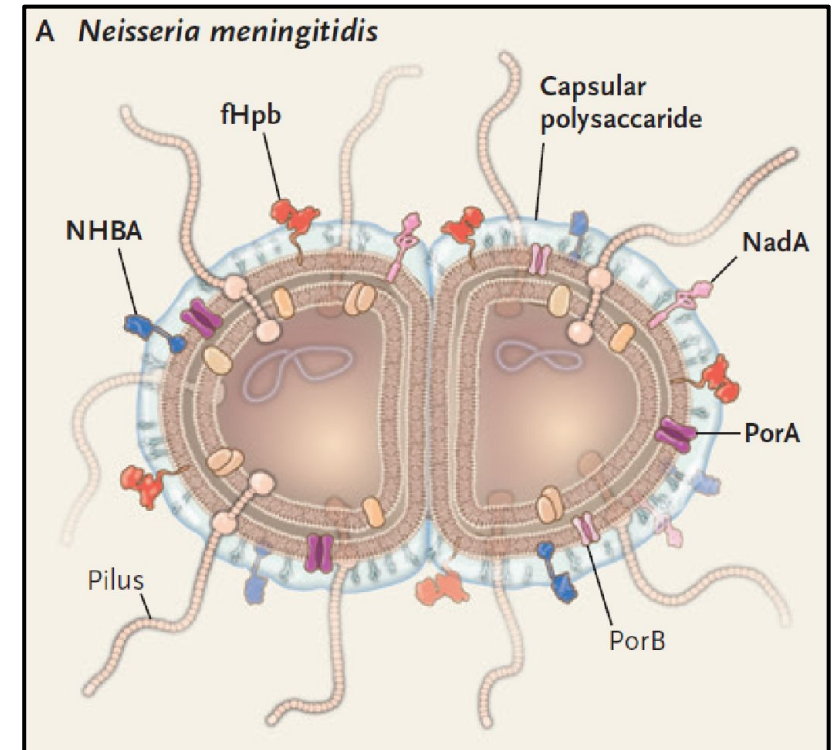


# MenACWY Vaccine Safety

- Severe allergic reaction (anaphylaxis) to a vaccine component or to a prior dose is a contraindication
- A moderate or severe acute illness is a precaution; vaccination should be deferred until the person's condition has improved
- Because inactivated vaccine, it **can be administered to people who are immunosuppressed**; response to the vaccine might be less than optimal
- **Can be administered during pregnancy.** No safety concerns associated with vaccination have been identified in mothers vaccinated during pregnancy or their infants
- A history of GBS had previously been a precaution for Menactra (MenACWY-D). Findings from two studies that examined more than 2 million doses of Menactra given since 2005 showed **no evidence of an increased risk of GBS**
  - Removed as a precaution in 2010

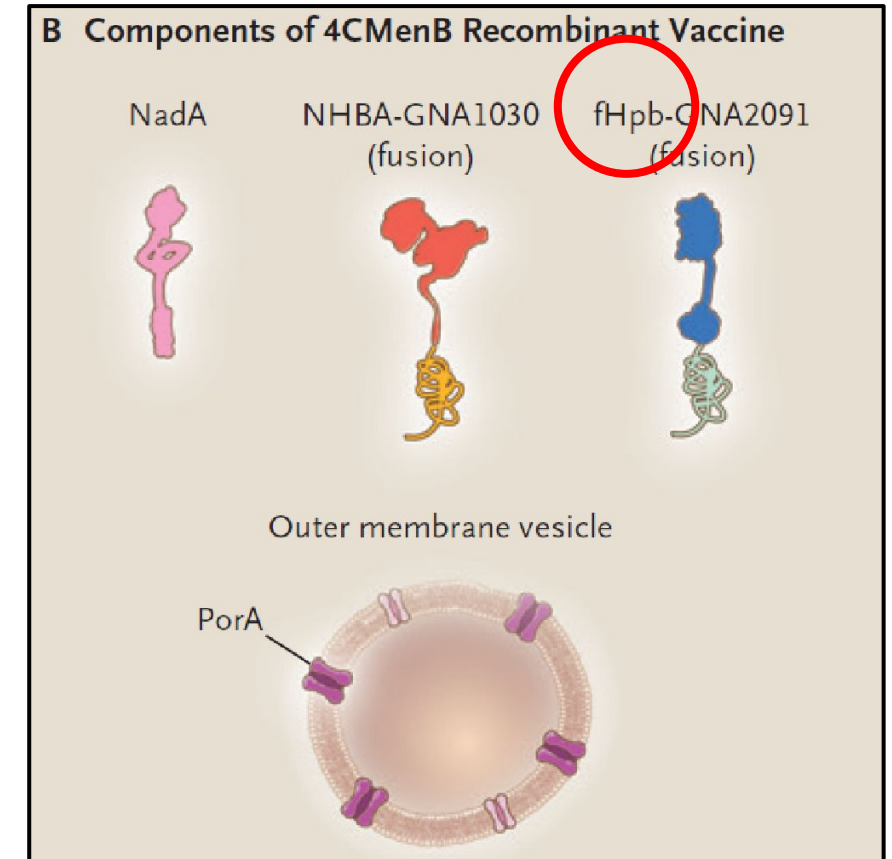
# Meningococcal B vaccines

- Unique challenges in the development of a MenB vaccine:
  - Inability to use the Men B capsule because its structure resembles a self-antigen, concerns for triggering autoimmunity
  - High variability of the antigenic membrane protein mix
  - Low incidence of overall disease in adolescent patients



# Meningococcal B vaccines

- Utilize surface antigens other than polysaccharide capsule
  - Trumenba, Pfizer
    - fHbp protein (subtype A and B)
  - Bexsero, GSK
    - fHbp protein
    - NadA protein
    - NHBA protein
    - OMV



# Meningococcal B vaccines

Vaccine		Licensed for ages	CDC Recommended Schedule
Trumenba	MenB-FHbp	10 – 25 years	16-18 years; 2 doses at 0 and 6+ mos
Bexsero	MenB-4C		16-18 years; 2 doses at 0 and 6+ mos

## **Both Meningococcal B vaccines:**

- No preservatives
- Contain Aluminum as adjuvant
- *Not interchangeable*

## **Bexsero:**

- Kanamycin antibiotic
- Tips of prefilled syringe may contain latex

# What is “Shared Decision Making?”

- Specific to meningococcal B vaccinations
- Disease is rare enough that number needed to vaccinate is high
  - Estimate in 2016 that “vaccination of all adolescents would prevent 15-29 cases and 5-9 deaths annually in the US”
  - Short lived immunity following vaccination
  - ACIP/CDC do not suggest as routine vaccination
- ACA requires coverage of vaccine, even if shared decision making
  - Covered by VFC

What do you say to patients and families during the “shared decision making”?





# Meningococcal B Vaccination

All adolescents and young adults who are at increased risk for serogroup B meningococcal disease should receive Meningococcal B (MenB) vaccine. This includes patients with anatomic or functional asplenia (including sickle cell disease), persistent complement component deficiency, or complement inhibitor use.

Shared clinical decision-making (SCDM) is recommended regarding MenB vaccination for healthy people 16–23 years of age. SCDM recommendations are meant to be flexible and informed by the characteristics, values, and preferences of the individual patient and the clinical discretion of the health care provider.

## When you decide to discuss MenB vaccination with people 16–23 years of age:

### Remember:



- MenB vaccine is not routinely recommended for all people in this age group.
- The vaccine series provides short-term protection against most strains of serogroup B meningococcal bacteria circulating in the United States.

### Consider:



- Serogroup B meningococcal disease is an uncommon but deadly disease. In recent years, between 20 and 50 cases occurred each year in 16- through 23-year-old people in the United States.
- A low risk of exposure or infection does not mean a person cannot get a MenB vaccine. It is just one potentially important consideration in SCDM.
- Serogroup B meningococcal disease cases most commonly affect young adults who attend a four-year university, are freshmen, live in on-campus housing, or participate in sororities or fraternities.
- MenB vaccines are safe and effective, but they only offer short-term protection (1 to 2 years) to those who get vaccinated.

### How to vaccinate:



- If you and your patient decide MenB vaccination is appropriate, administer a 2-dose series of a MenB vaccine, one each at month 0 (the first vaccine appointment) and 6 months later.
  - To optimize rapid protection (e.g., for students starting college in less than 6 months), a 3-dose series (0, 1–2, 6 months) may be administered.
- MenB-4C and MenB-FHbp are not interchangeable.
- MenB vaccines should not be administered to a person who has had a severe allergic reaction (e.g., anaphylaxis) to a:
  - Previous dose of MenB vaccine
  - Component of the vaccine
- In pregnant women, delay vaccination until after pregnancy unless the patient is at increased risk and the benefits of vaccination outweigh the potential risks.



#### Additional information:

CDC Child and Adolescent Immunization Schedule by Age:  
[www.cdc.gov/vaccines/hcp/immunization-schedules/child-adolescent-age.html](http://www.cdc.gov/vaccines/hcp/immunization-schedules/child-adolescent-age.html)

CDC Adult Immunization Schedule by Age:  
[www.cdc.gov/vaccines/hcp/immunization-schedules/adult-age.html](http://www.cdc.gov/vaccines/hcp/immunization-schedules/adult-age.html)

CDC Meningococcal Vaccine Recommendations:  
[www.cdc.gov/meningococcal/hcp/vaccine-recommendations/index.html](http://www.cdc.gov/meningococcal/hcp/vaccine-recommendations/index.html)

# What should we be sharing?

- Serious nature of invasive meningococcal serogroup B infection, with a high risk of death and permanent complications
- Low level of MenB disease in US
- Increased risk among college students
- Protection of MenB vaccine against most strains of meningococcal serogroup B bacteria
- Estimated relatively short duration of MenB vaccine protection

# Meningococcal B vaccine in High-risk patients

- Start series at 10 years if high risk patient
- Trumenba (MenB-FHbp) requires third dose if high risk (0, 1-2, 6 mos)
- If patient remains high risk, then booster at 1 year followed by every 2-3 years
- High Risk:
  - functional or anatomic asplenia
  - complement deficiency or complement inhibitor
  - exposed during an outbreak caused by serogroup B
  - microbiologists who work with meningococcal isolates in a laboratory

# Immunogenicity and Vaccine Effectiveness (VE)

- MenB vaccines
  - Serum bactericidal activity using human complement titer (hSBA) for each serogroup B strain tested
  - hSBA of  $\geq 1:4$  and/or four-fold rise infers vaccine-mediated immunologic protection
  - Trumenba composite response in 84%
  - Bexsero composite response in 88% (waned to 66% at 11 months)
  - Evidence of waning immunity within 1-2 years, so booster recommended

# College outbreaks

- Estimated 14.5% coverage with  $\geq 1$  dose of MenB vaccine among US adolescents and only 2% of universities require vaccine
  - Therefore, mass vaccine a necessary response in outbreaks
  - Chemoprophylaxis of close contacts also necessary
- For the purpose of public health decision making, risk assumed to return to baseline 1 year following last identified case

# MenB vaccination during college outbreaks

- 2014 outbreak on US college campus offered unique insights on efficacy

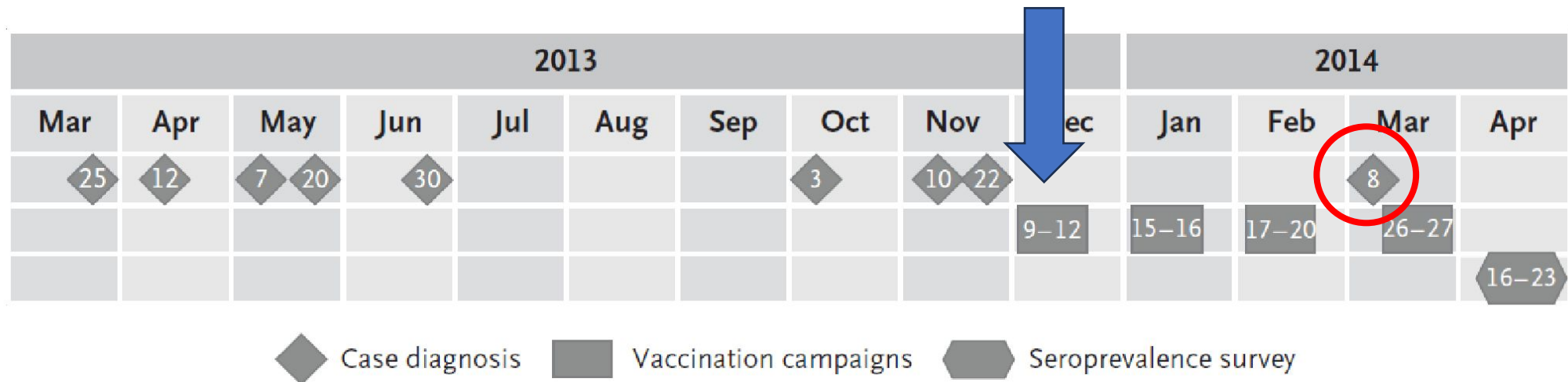
ORIGINAL ARTICLE

## Immunogenicity of a Meningococcal B Vaccine during a University Outbreak

Nicole E. Basta, Ph.D., Adel A.F. Mahmoud, M.D., Ph.D., Julian Wolfson, Ph.D., Alexander Ploss, Ph.D., Brigitte L. Heller, B.S., Sarah Hanna, A.B., Peter Johnsen, M.D., Robin Izzo, M.S., Bryan T. Grenfell, D.Phil., Jamie Findlow, Ph.D., Xilian Bai, Ph.D., and Ray Borrow, Ph.D.





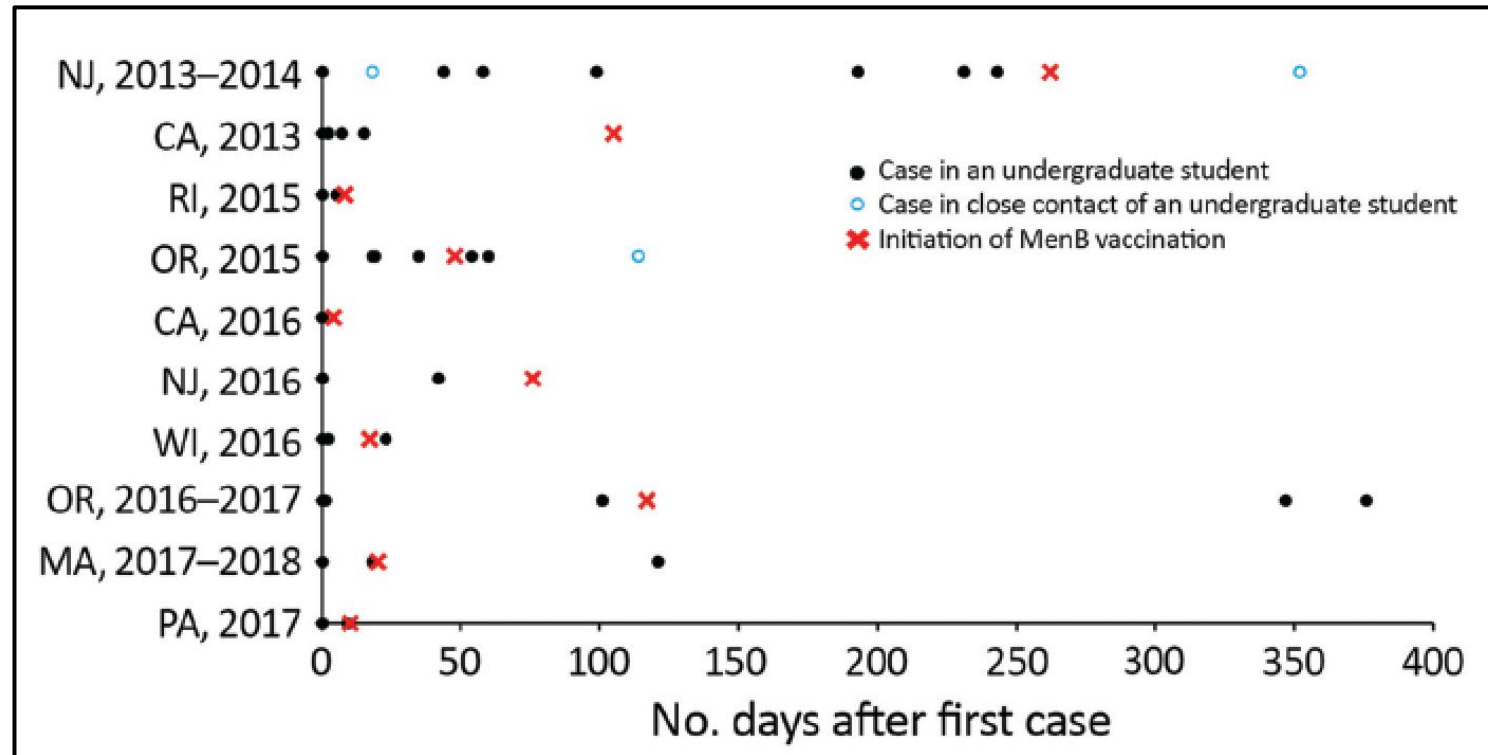


**Table 2. Seropositivity and Geometric Mean Titers for the Meningococcal B Outbreak Strain According to Vaccination Status.\***

Characteristic	Two Doses (N=499)	One Dose (N=17)	No Vaccination (N=19)
hSBA ≥4			
No. of participants	330	10	4
% (95% CI)	66.1 (61.8–70.3)	58.8 (32.9–81.6)	21.1 (6.1–45.6)
GMT (95% CI)	7.6 (6.7–8.5)	5.4 (2.5–11.7)	2.8 (2.3–3.5)

# University-Based Outbreaks of Meningococcal Disease Caused by Serogroup B, United States, 2013–2018

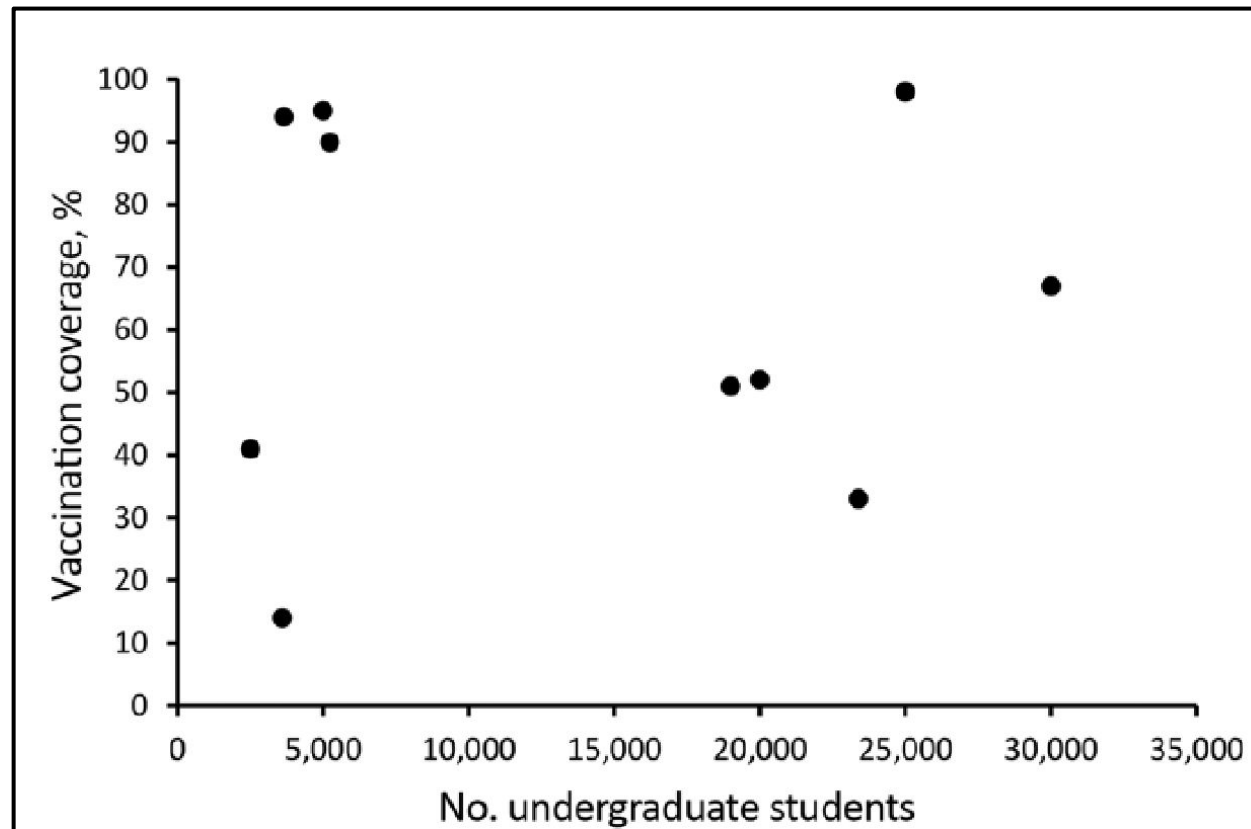
Heidi M. Soeters, Lucy A. McNamara, Amy E. Blain, Melissa Whaley, Jessica R. MacNeil, Susan Hariri, Sarah A. Mbaeyi, for the Serogroup B Meningococcal Disease University Outbreak Group<sup>1</sup>





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# MenB Vaccine Safety

- Most common local adverse events within 7 days of receiving MenB were injection site pain, swelling or redness and the most common systemic symptoms were headache, fatigue and body aches
  - In general, these types of self-limited reactions are reported more frequently than with MenACWY vaccination.
- Severe allergic reaction (anaphylaxis) to a vaccine component or to a prior dose is a contraindication to further doses of that vaccine
- The tip caps of the Bexsero pre-filled syringes contain **natural rubber latex** which may cause allergic reactions in latex sensitive individuals
- A moderate or severe acute illness is a precaution
- Because MenB is an inactivated vaccine it **can be administered to persons who are immunosuppressed**; however, response to the vaccine might be less than optimal
- Data on MenB vaccination during **pregnancy is limited**. In general, vaccination against MenB should be deferred during pregnancy; however, MenB may be administered if, in the judgment of the clinician, the benefits outweigh any potential risk

# Penbraya

- Approved by US FDA 2023, Pfizer
- Pentavalent Meningococcal vaccination
  - Serogroups A, B, C, W, and Y
  - Trumenba + Nimenrix/MenACWY-TT (used for decades in Europe)
- CDC recommends as an option when both MenACWY and MenB are indicated at the same visit
  - Healthy individuals 16-23 years who choose to receive MenB vaccine based on shared decision making
  - High-risk individuals 10 years and older
- ACIP reevaluating recommended meningococcal schedule in 2025 (...??)
  - Old schedule recommendations still in place

# Other Pentavalent vaccines

- Menveo plus Bexsero, GSK – Penmenvy approved by FDA Feb 2025
  - Awaiting review by ACIP ...
- MenFive/Men5CV; Conjugate vaccine against NmX
  - Serogroups A, C, W, Y, and X
  - PATH and Serum Institute of India, approved by WHO 2023
  - Recommended in Meningitis belt where higher circulation of NmX has been reported since decreases in MenA

# So what should we give and when?

- Routine **MenACWY** vaccination for:
  - All preteens and teens at 11 to 12 years old, booster dose at 16 years old
  - Children and adults at increased risk for meningococcal disease
- Routine **MenB** vaccination for:
  - People 10 years or older at increased risk for meningococcal disease
- Consider **MenB** vaccination for:
  - 16-18 years based on shared-decision making
- **MenABCWY** vaccination as an option for:
  - People 10 years or older who are getting MenACWY and MenB vaccines at the same visit

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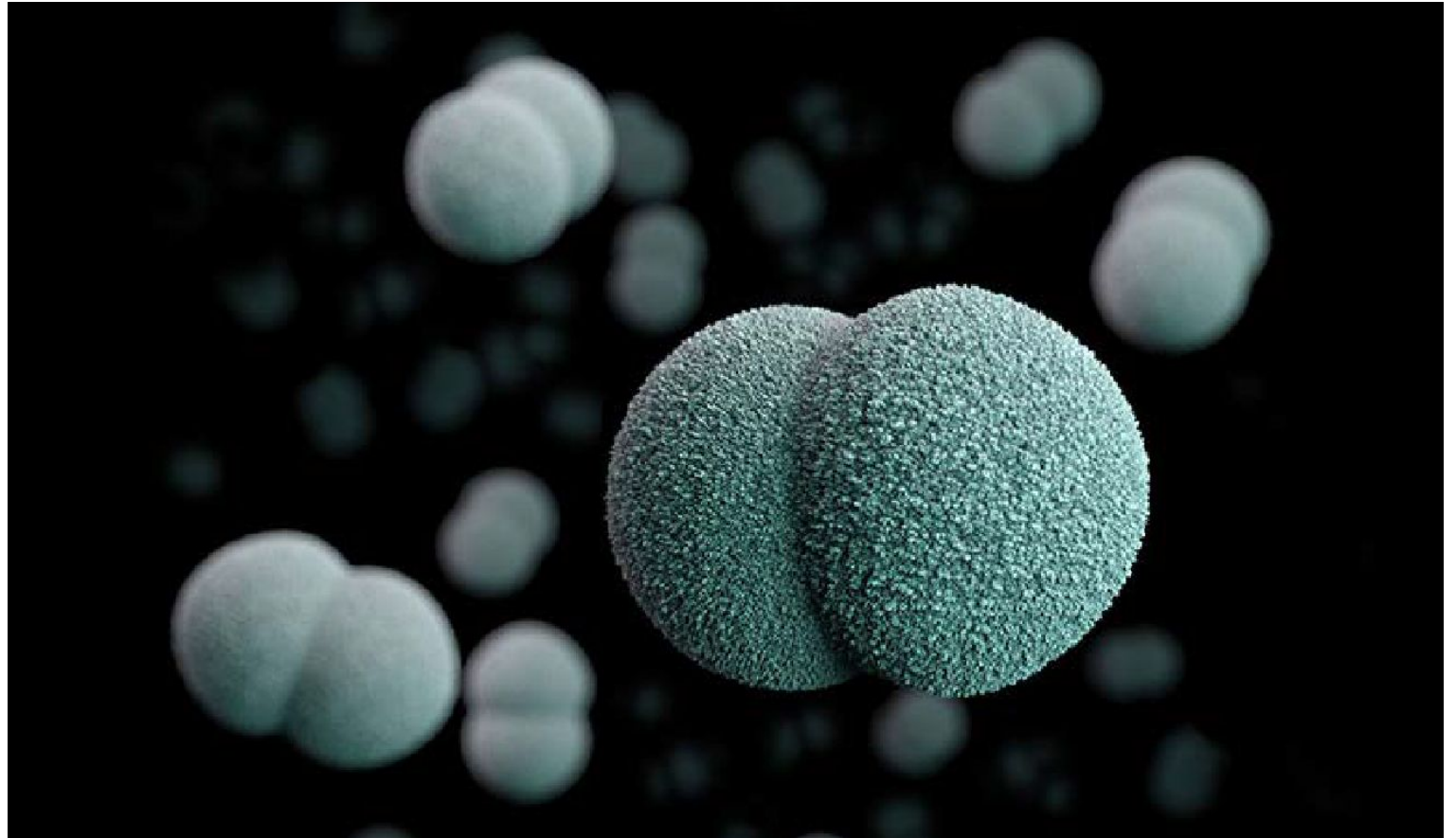
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# Thank you for your attention

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Any questions?



# Meningococcal Vaccine Products

## Quadraivalent Conjugate Vaccines

- Menveo, GSK      MenACWY-CRM<sub>197</sub>
- MenQuadfi, Sanofi      MenACWY-TT

## Serogroup B Vaccines

- Trumenba, Pfizer      MenB-FHbp
- Bexsero, GSK      MenB-4C

## Pentavalent Vaccine

- Penbraya, Pfizer 2023      MenABCWY (Trumenba + Nimenrix/MenACWY-TT)
- Penmenvy, GSK 2025      MenABCWY (Bexsero + Menveo)

# Meningococcal immunizations

## Quadavalent Conjugate Vaccines

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## Serogroup B Vaccines

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## Pentavalent Vaccine

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# Meningococcal immunizations

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- Bexsero, GSK      MenB-4C

## Pentavalent Vaccine

- Penbraya, Pfizer 2023      MenABCWY (Trumenba + Nimenrix/MenACWY-TT)
- Penmenvy, GSK 2025      MenABCWY (Bexsero + Menveo)

“Wait a minute ... what about Menactra?”

## VFC Program Update

### Meningococcal Conjugate Vaccine Transition

Earlier this year, [Sanofi Pasteur sent a letter](#) to customers about their transition from Menactra<sup>®</sup> to MenQuadfi<sup>™</sup>. CDC anticipates the completion of the transition between Menactra<sup>®</sup> and MenQuadfi<sup>™</sup> will be by the end of July. While the transition timing from Menactra<sup>®</sup> to MenQuadfi<sup>™</sup> is anticipated to be similar in the public and private sectors, Menactra<sup>®</sup> may still be available for purchase through the private sector. However, since this vaccine is being discontinued on CDC contracts, it will no longer be available through the VFC Program once our inventory at McKesson is depleted. Submission of the form to update vaccine brand products administered in your practice will not be required for this transition.

Since MenQuadfi<sup>™</sup> is indicated for use in children 2 years of age and older, beginning August 1 providers who need MCV4 vaccine for children less than 2 years of age should order Menveo<sup>®</sup>. Please plan accordingly for this transition and refer to the [MenACWY Vaccine Fact Sheet](#) for a comparison of the different Meningococcal vaccine products.

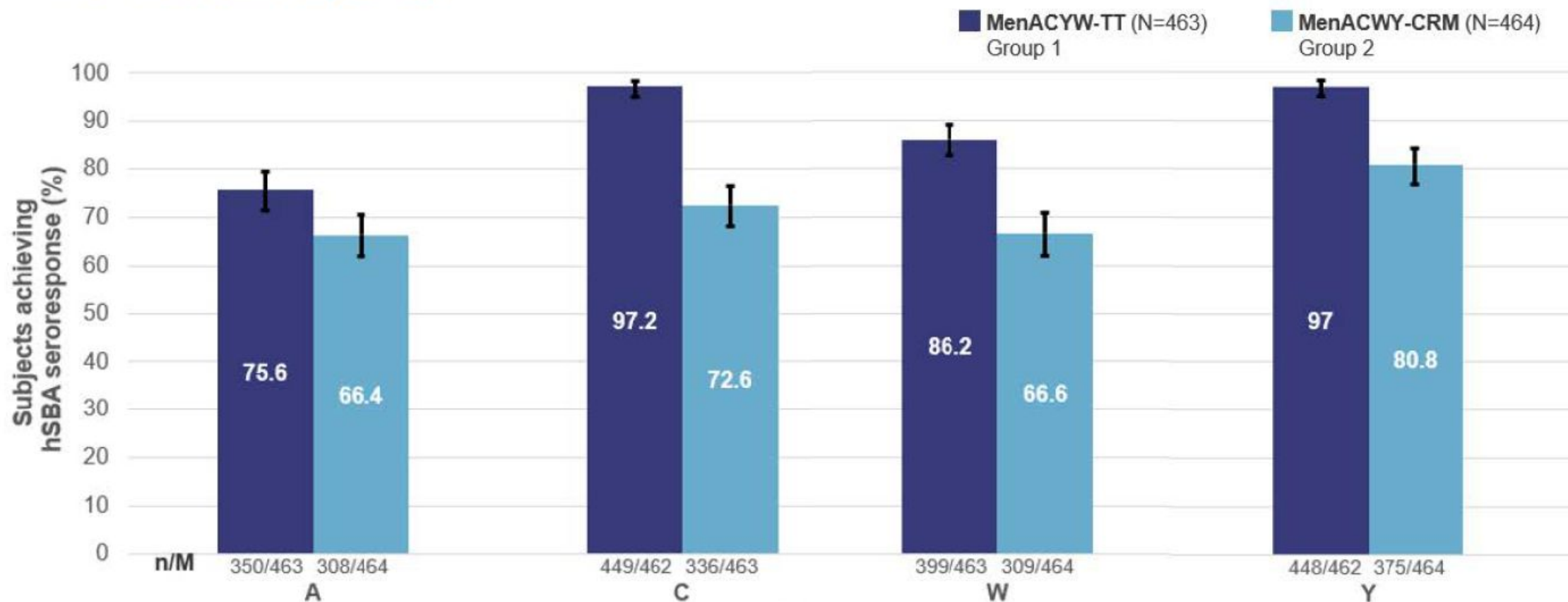
# What about patients who undergo splenectomy?

- PCV, Hib, MenACWY, and MenB vaccine should be given at least 14 days before a scheduled splenectomy, if possible
- Protection from encapsulated bacterial infection before the spleen is removed
  - Doses given during the 14 days before surgery also can be counted as valid
- If the doses cannot be given prior to the splenectomy, they should be given as soon as the patient's condition has stabilized after surgery



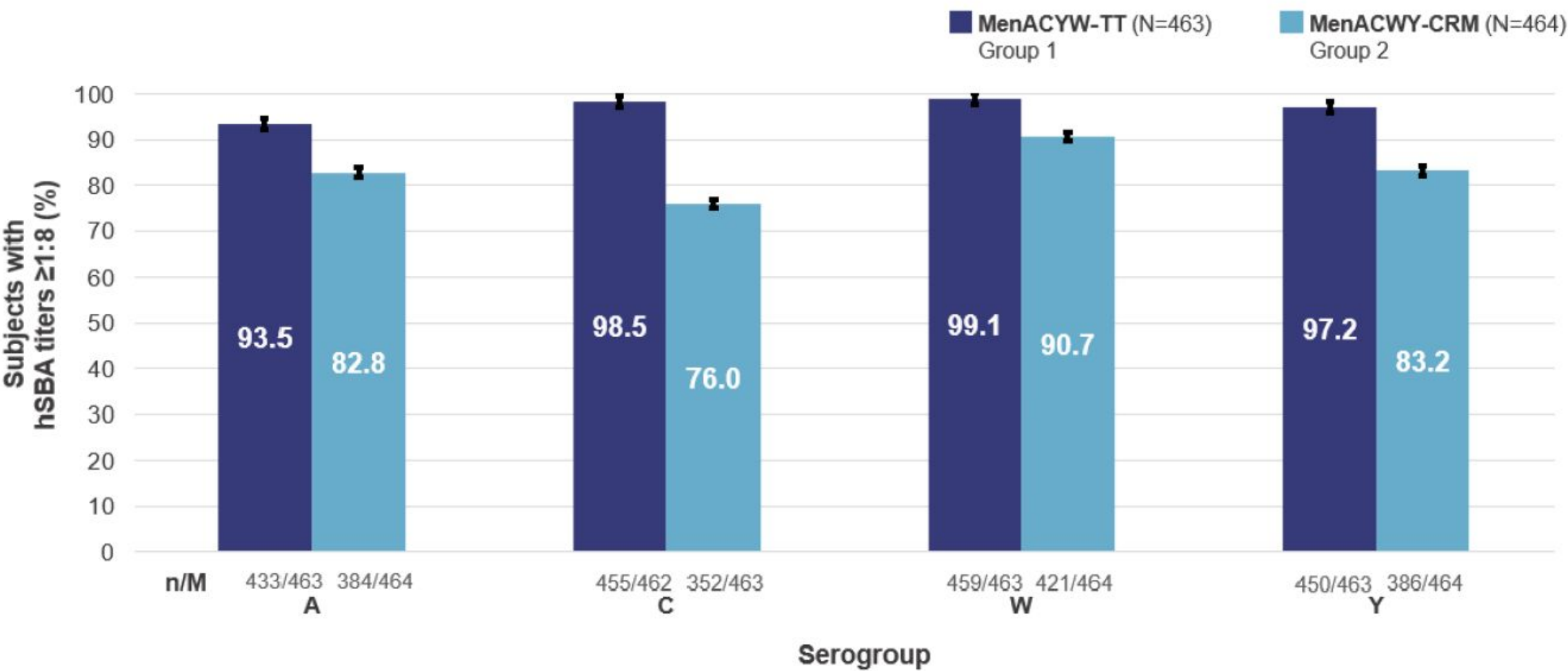
# MET50: Non-inferiority demonstrated, as assessed by SERORESPONSE rates at D30 in adolescents 10–17 years of age

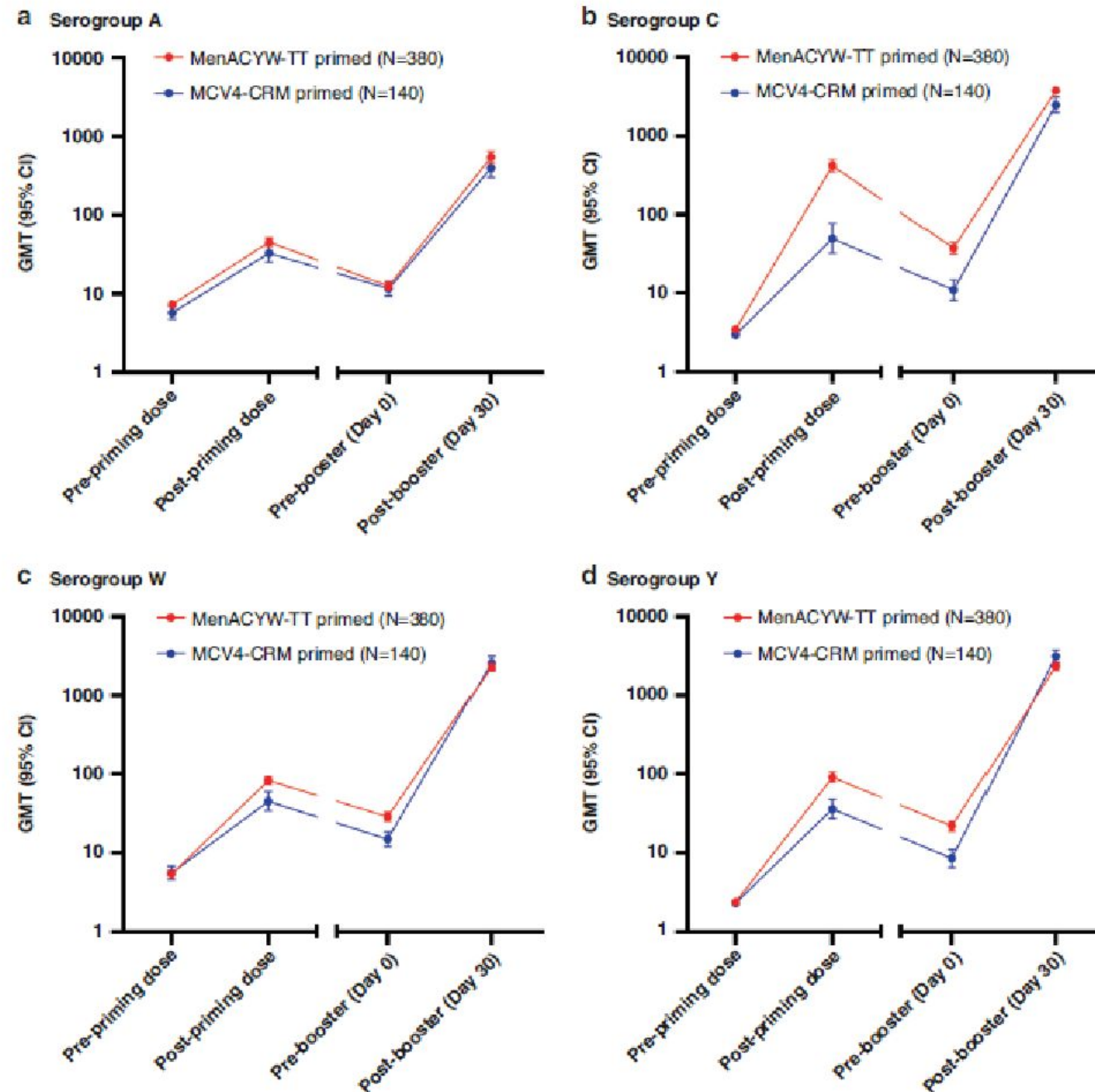
Per-Protocol Analysis Set



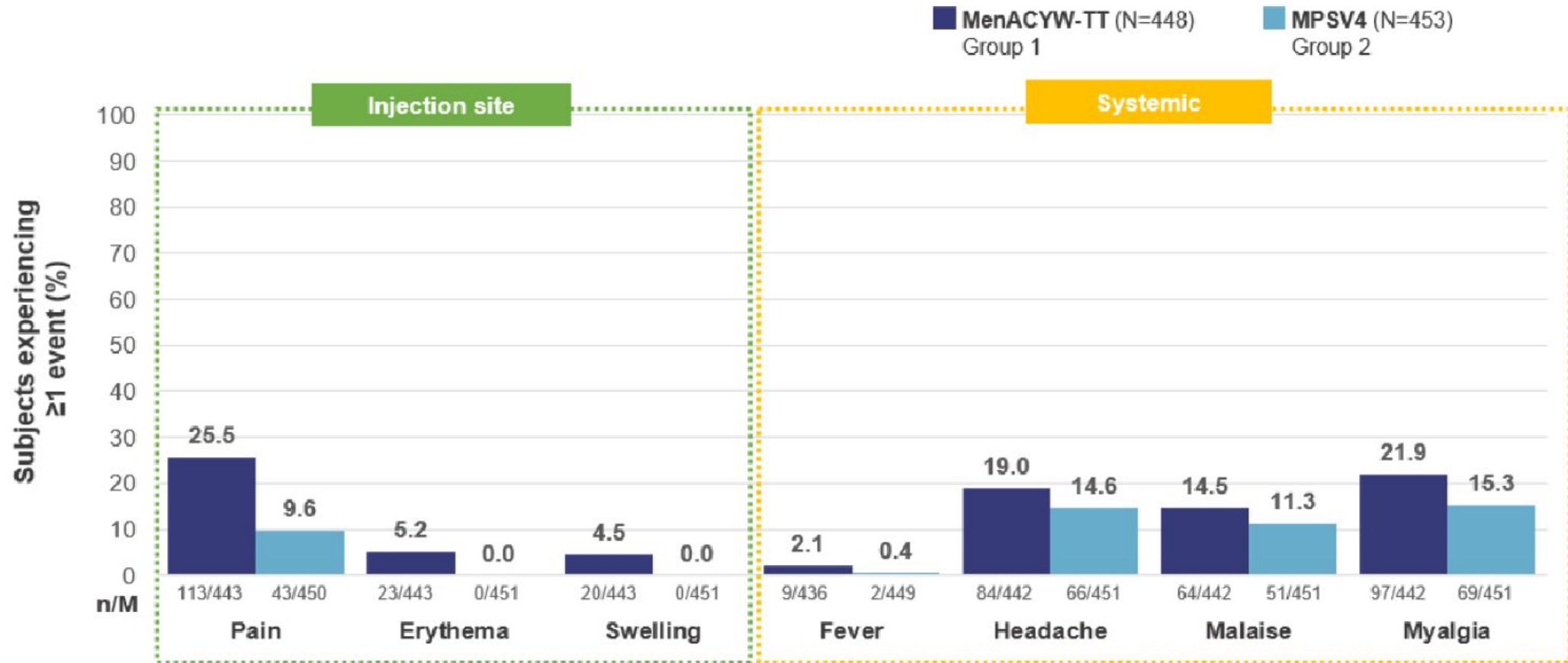
# MET50: Percentage of subjects 10–17 years of age with hSBA TITERS ≥1:8 at D30

Per-Protocol Analysis Set





# Common adverse events







# DEFEATING MENINGITIS BY 2030 A GLOBAL ROAD MAP

## Vision

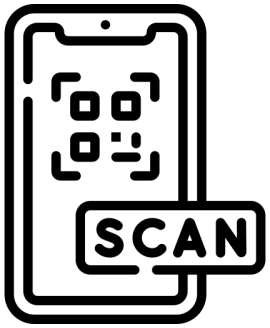
### → Towards a world free of meningitis

Our collective vision is “Towards a world free of meningitis”. Because meningitis has so many causes, it cannot be eliminated or eradicated. There will be no “world free” moment for meningitis, but we are committed to get as close as possible. This plan, therefore, aims to defeat meningitis as a public health threat, reducing the number of cases substantially and keeping them down.

## Visionary goals by 2030

- ✓ Eliminate bacterial meningitis epidemics<sup>5</sup>
- ✓ Reduce cases of vaccine-preventable bacterial meningitis by 50% and deaths by 70%<sup>6</sup>
- ✓ Reduce disability and improve quality of life after meningitis due to any cause

All United Nations Member States are committed to achieving universal health coverage by 2030 (20). The visionary goals of eliminating epidemics, reducing the number of cases and deaths, and giving priority to caring for those with disability are fully aligned with universal health coverage and have equity as a guiding principle.



# Claim your Continuing Education Credit

Event Evaluation - April 15, 2025 -  
Session 2 Breakouts -  
Meningococcal Disease



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