



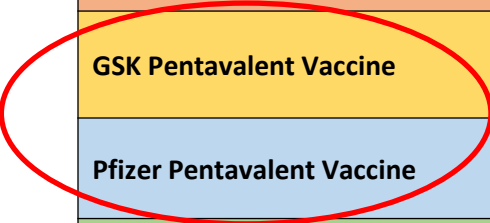
Meningococcal Vaccines Work Group Plan for Assessing the MenABCWY Vaccines

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Project Timeline

Task	2022												2023												2024					
	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6					
Menveo One-Vial	Active			Active		Completed																								
GSK Pentavalent Vaccine	Completed	Active							Active							Active							Completed							
Pfizer Pentavalent Vaccine	Completed	Active											Active											Completed						
People Experiencing Homelessness	Completed											Active			Active					Active										



Background

- Two new MenABCWY vaccines currently in clinical trials
 - GSK
 - Pfizer
- Each vaccine is a combination of an existing MenACWY vaccine and an existing MenB vaccine
- Work group will assess each pentavalent vaccine separately
- Tentative goal to have votes on use of these vaccines at the October 2023 ACIP meeting


GSK MenABCWY Vaccine

- Comprised of Menveo 1 Vial (serogroups ACWY) and Bexsero (serogroup B)
 - Both currently licensed in US
- Anticipated clinical trial data
 - Assessing a two-dose schedule (0,6 months)
 - Studying 10 through 25 years of age
 - Both MenACWY primed and naive subjects
 - Longer interval studies underway (not available in time for initial product licensure)

Pfizer MenABCWY Vaccine

- Comprised of Nimenrix (serogroups ACWY) and Trumenba (serogroup B)
 - Trumenba currently licensed and available in US
 - Nimenrix not licensed in US but used extensively in Europe and elsewhere
- Anticipated clinical trial data
 - Assessing
 - Two doses (0,6 m and 0,12 m apart)
 - Two doses at 11–12 years and a booster at 16 years
 - A single dose of pentavalent as an alternative to MenACWY vaccine
 - Studying 10 through 25 years of age
 - Both MenACWY primed and naive subjects
 - Longer interval studies underway (not available in time for initial product licensure)

Evidence to be Reviewed by the Work Group

- Epidemiology of meningococcal disease
 - Immunogenicity and safety for each vaccine
 - Expected public health impact of each vaccine
 - GRADE and EtR
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Policy Questions for Each Pentavalent Vaccine

- Should the pentavalent vaccine be included as an option for MenACWY/MenB vaccination in people currently recommended to receive both vaccines?
 - For example, 16 year olds¹
- Should the pentavalent vaccine be included as an option for people currently recommended to receive MenACWY only?
 - For example, 11–12 year olds
- Should the pentavalent vaccine be included as an option for people currently recommended to receive MenB only?
 - For example, during a serogroup B outbreak

¹ 16 year olds who decide to receive the MenB vaccine based on shared clinical decision making

PICO policy question — Should the pentavalent vaccine be included as an option for MenACWY/MenB vaccination in people currently recommended to receive both vaccines?

Population	All individuals aged 10 years or older currently recommended to receive <u>MenACWY and MenB vaccines</u>
Intervention	Vaccination with the pentavalent vaccine
Comparison	Vaccination with a currently licensed <u>MenACWY vaccine and a MenB vaccine</u>
Outcomes	<ul style="list-style-type: none">• Meningococcal disease caused by <u>serogroups A, B, C, W, and Y</u>• Short-term immunity• Persistent immunity• Interference with other recommended vaccines administered concurrently• Serious adverse events• Non-serious adverse events

PICO policy question — Should the pentavalent vaccine be included as an option for people currently recommended to receive MenACWY only?

Population	All individuals aged 10 years or older currently recommended to receive <u>MenACWY vaccine only</u>
Intervention	Vaccination with the pentavalent vaccine
Comparison	Vaccination with a currently licensed <u>MenACWY vaccine</u>
Outcomes	<ul style="list-style-type: none">• Meningococcal disease caused by <u>serogroups A, C, W, and Y</u>• Short-term immunity• Persistent immunity• Interference with other recommended vaccines administered concurrently• Serious adverse events• Non-serious adverse events

PICO policy question — Should the pentavalent vaccine be included as an option for people currently recommended to receive MenB only?

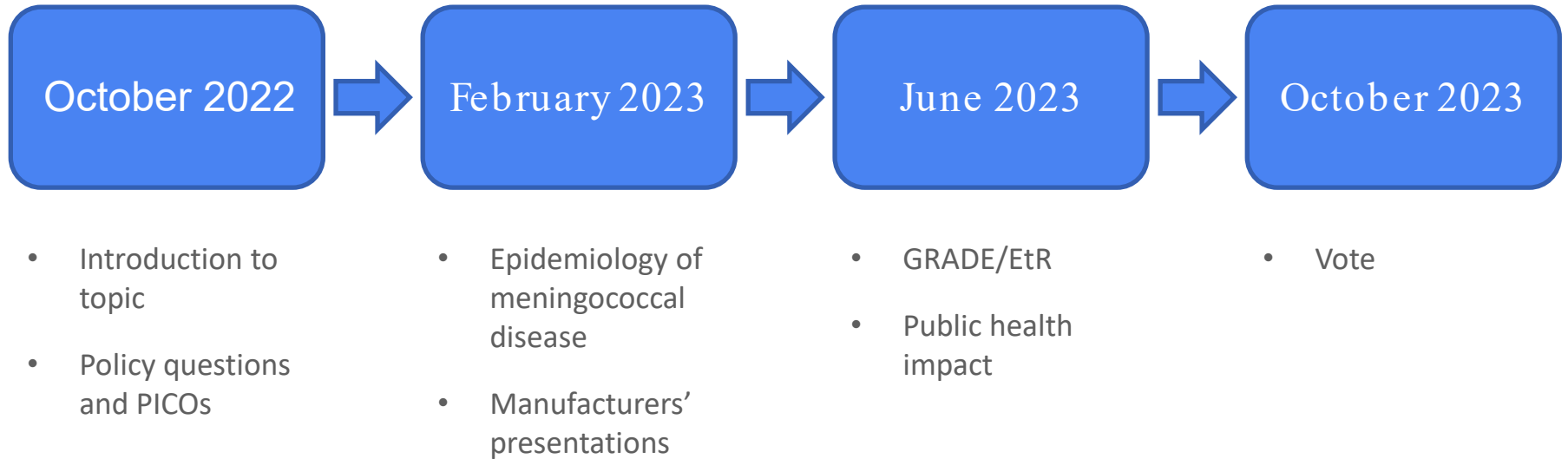
Population	All individuals aged 10 years or older currently recommended to receive <u>MenB vaccine only</u>
Intervention	Vaccination with the pentavalent vaccine
Comparison	Vaccination with a currently licensed <u>MenB vaccine</u>
Outcomes	<ul style="list-style-type: none">• Meningococcal disease caused by <u>serogroup B</u>• Short-term immunity• Persistent immunity• Interference with other recommended vaccines administered concurrently• Serious adverse events• Non-serious adverse events

Outcomes Table

Outcome	Importance¹	Included in Evidence Profile
Meningococcal disease caused by serogroups A, B, C, W, and Y	Critical	Yes
Persistent immunity	Important	Yes
Short-term immunity	Critical	Yes
Interference with other recommended vaccines administered concurrently	Important	Yes
Serious adverse events	Critical	Yes
Non-serious adverse events	Important	Yes

¹ Three options: critical, important but not critical, of limited importance for decision making.

Proposed Timeline of ACIP Presentations



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

