



## GSK Pentavalent MenABCWY Vaccine: Term of Reference

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

# Pentavalent MenABCWY Vaccines

- Two new MenABCWY vaccines:
  - Pfizer (“Penbraya,” ACIP voted October 2023)
  - GSK (clinical trials)
- Each vaccine is a combination of an existing:
  - MenACWY vaccine *and*
  - MenB vaccine
- Each vaccine assessed separately by Work Group
  - Lack of data directly comparing Pfizer and GSK Pentavalent vaccines

# Pfizer's and GSK's MenABCWY Vaccines

	<b>Pfizer (Penbraya)</b>	<b>GSK*</b>
ACWY component	Nimenrix (not licensed in U.S.)	Menveo
B component	Trumenba	Bexsero
Schedule	2 doses, 6 months apart	2 doses, 6 months apart*
Age	10-25 years	10-25 years*
Clinical trial participants	Studied in MenACWY primed and naive subjects; all MenB naive	Studied in MenACWY primed and naive subjects; MenB naïve in phase 3 trials
Future studies	Longer interval studies underway	Longer interval studies underway
Gonorrhea protection	No	Yes/some

\*Vaccine not yet licensed in U.S. and this slide represents anticipated schedule and age indications

# Policy Questions for GSK's Pentavalent Vaccine

- Should the pentavalent vaccine be included as an option for MenACWY/MenB vaccination in people currently recommended to receive both vaccines at the same visit?
  - For example, 16 year olds\*
- 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

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

# Outcomes Table

Outcome	Importance*	To be 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
Gonorrhea prevention	Important	Yes

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

**PICO policy question #1 (of 3) — Should the GSK pentavalent vaccine be included as an option for MenACWY/MenB vaccination in people currently recommended to receive both vaccines at the same visit?**

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

**PICO policy question #2 (of 3) — Should the GSK pentavalent vaccine be included as an option for people currently recommended to receive MenACWY only?**

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

**PICO policy question #3 (of 3) — Should the GSK pentavalent vaccine be included as an option for people currently recommended to receive MenB only?**

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

# Discussion

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