



Summary of EtR and proposed recommendations for Pfizer's MenABCWY vaccine

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ACIP Recommendations for Meningococcal Vaccines

- **Routine schedule**
 - MenACWY: dose 1 at age 11–12 years, booster dose at age 16 years
 - MenB (shared clinical decision-making): two doses at age 16–23 years (preferred age 16–18 years)
- **Special situations**

Indication		MenACWY (age ≥2 months)	MenB (age ≥10 years)
Medical conditions	Asplenia	X	X
	Complement Deficiency	X	X
	Complement inhibitor use	X	X
	HIV infection	X	
Other	Some microbiologists	X	X
	Exposure during an outbreak	X	X
	Travel to hyperendemic areas	X	
	First-year college students	X	
	Military recruits	X	

Meningococcal vaccines licensed and available in the United States

- MenACWY vaccines are interchangeable

Vaccine	Trade Name	Manufacturer	Minimum age
MenACWY-CRM	Menveo	GSK	2 months
MenACWY-TT	MenQuadfi	Sanofi Pasteur	2 years

- MenB vaccines are **NOT** interchangeable

Vaccine	Trade Name	Manufacturer	Minimum age
MenB-4C	Bexsero	GSK	10 years
MenB-FHbp	Trumenba	Pfizer	10 years

Pfizer's MenABCWY Vaccine

- Licensed as a 2-dose series (6-month interval) for individuals aged 10–25 years
- Comprised of Trumenba (serogroup B) and Nimenrix (serogroups ACWY)
 - Trumenba
 - Consists of two purified recombinant lipidated FHbp antigens, one from each FHbp subfamily (A and B)
 - Currently licensed and available in U.S. (10–25 years)
 - Nimenrix
 - Meningococcal group A, C, W, and Y polysaccharide tetanus toxoid conjugate vaccine
 - Not licensed in U.S. but used extensively in Europe and elsewhere for more than a decade

Policy Questions for 3 PICOs

PICO 1

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

PICO 2

- Should the pentavalent vaccine be included as an option for people currently recommended to receive MenACWY only?

PICO 3

- Should the pentavalent vaccine be included as an option for people currently recommended to receive MenB only?

GRADE Table 1: Combined Policy Question and PICO

Policy Question	Should the pentavalent vaccine be included as an option for people currently recommended to receive <u>MenACWY and MenB, MenACWY only, or MenB only?</u>
Population	All individuals aged 10 years or older currently recommended to receive <u>MenACWY+MenB, MenACWY, or MenB vaccine</u>
Intervention	Vaccination with Pfizer's pentavalent (MenABCWY) vaccine
Comparison	Vaccination with currently licensed <u>MenACWY+MenB, MenACWY, or MenB vaccine</u>
Outcomes	<ul style="list-style-type: none">• Meningococcal disease caused by serogroups A, B, C, W, and Y (<u>as appropriate by PICO</u>)• Short-term immunity• Persistent immunity• Interference with other recommended vaccines administered concurrently• Serious adverse events• Non-serious adverse events

How PICOs Translate into Schedule Options for Healthy Adolescents – assuming MenB #1 at age 16 years

Options	11–12 year old dose	16 year old dose #1	16 year old dose #2
Standard of care (MenACWY only)	Q	Q	–
Standard of care (MenACWY + MenB)	Q	Q+B	B
PICO 1 (MenABCWY as option for MenACWY + MenB)	Q	P	B
PICO 2 (MenABCWY as option for MenACWY)	P	P	±B
PICO 3 (MenABCWY as option for MenB)	Q	P	P
Combination of all 3 PICOs	P	P	P

Legend

Q = MenACWY (quadrivalent)

B = MenB

P = MenABCWY (pentavalent)

Schedule options presented in June

Options	11–12 year old dose	16 year old dose #1	16 year old dose #2	WG Proposal
Standard of care (MenACWY only)	Q	Q	–	N/A
Standard of care (MenACWY + MenB)	Q	Q+B	B	N/A
PICO 1 (MenABCWY as option for MenACWY + MenB)	Q	P	B	✓
PICO 2 (MenABCWY as option for MenACWY)	P	P	B	✗
PICO 3 (MenABCWY as option for MenB)	Q	P	P	?
Combination of all 3 PICOs	P	P	P	✗

Legend

Q = MenACWY (quadrivalent)

B = MenB

P = MenABCWY (pentavalent)

Since June, the WG has refined the EtR and further considered possible implications of each PICO (especially PICO 3) based on

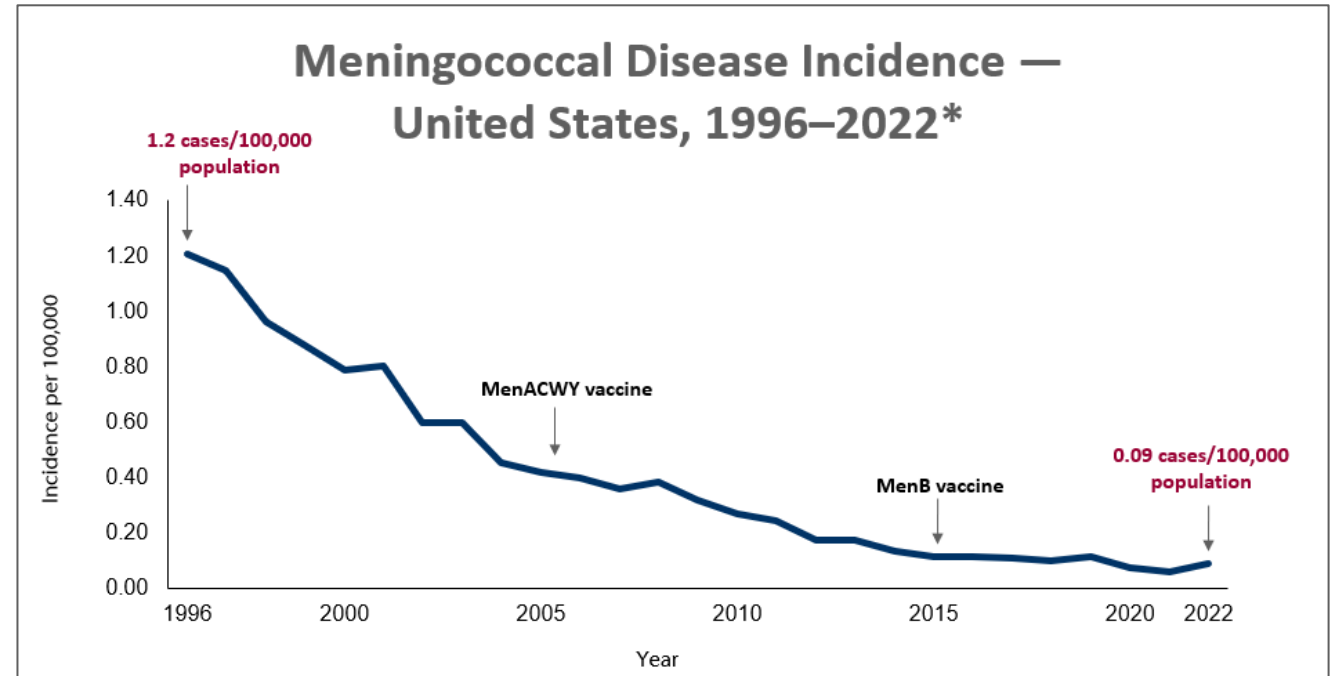
- ACIP members' concerns raised during the June meeting
 - Cost effectiveness
 - Concerns about increasing exposure to B component related to reactogenicity, low burden of disease, and limitations to protection
 - Optimal timing of B component is often not age 16 years
 - Fidelity to clinical trial data and licensure
 - Stocking and administration considerations
- Cost effectiveness analysis
 - Updates to quoted price of the pentavalent vaccine
 - Refinements to the CDC model

Summary of updated EtR

PUBLIC HEALTH PROBLEM

Is meningococcal disease a problem of public health importance?

- Incidence of meningococcal disease is low and decreasing
- Causes very severe disease
- Poor outcomes even with treatment
 - Case fatality 10–15%
 - 10–20% of survivors have permanent sequelae



WG interpretation	PICO 1 MenABCWY vs. MenACWY + MenB	PICO 2 MenABCWY vs. MenACWY	PICO 3 MenABCWY vs. Men B
	Yes	Yes	Yes

BENEFITS & HARMS

- Three randomized control trials studied
 - MenABCWY 2 doses (0, 6 months and 0, 12 months) vs. MenACWY-CRM 1 dose + MenB-FHbp 2 doses (0, 6 months)
 - Among ACWY-naïve and ACWY-primed participants
 - Available data facilitated assessment of select outcomes through GRADE
 - Short-term immunity
 - Persistent immunity
 - Serious adverse events
 - Non-serious adverse events
- Other important benefits and harms were not assessed through GRADE but factored into WG interpretations
 - Increased reactogenicity of MenB relative to MenACWY
 - Limitations to B protection
 - Low VE expected following a single dose
 - Rapidly waning protection following 2-dose series
 - Multiple studies demonstrating MenB vaccination has no effect on meningococcal carriage

BENEFITS AND HARMS: Summary of GRADE

Type	Outcome	Importance	Design (# studies)	Findings	Evidence type*	
					Healthy	Increased risk
Benefits	Meningococcal disease caused by serogroups, A, B, C, W, and Y	Critical	n/a	No data available	ND	ND
	Short-term immunity	Critical	RCT (1)	Serogroup-specific seroresponses one month after the first trial dose of ACWY- or B-containing vaccine occurred as often or more often in the pentavalent group compared with the control group	Moderate	Low
	Persistent immunity	Important	RCT (2)	Seroresponse rates by serogroup were similar: - 48 months after 2 doses pentavalent vs. 54 months after 1 dose MenACWY-CRM - 48 months after 2 doses pentavalent vs. 2 doses MenB-FHbp	Low–moderate	Low
Harms	Serious adverse events	Critical	RCT (3)	Significantly more SAEs occurred in the pentavalent group vs. comparison group; none were attributed to the vaccine	Low	Very low
	Non-serious adverse events	Important	RCT (3)	Significantly more non-serious adverse events occurred in the pentavalent group vs. comparison group	Low	Very low
	Interference with other recommended vaccines administered concurrently	Important	n/a	No data available	ND	ND

*Downgrades primarily related to indirectness of intervention and comparison groups relative to PICOs, people at increased risk not being included, and wide confidence intervals for adverse events

BENEFITS & HARMS – Work Group interpretations

Question	PICO 1 MenABCWY vs. MenACWY + MenB	PICO 2 MenABCWY vs. MenACWY	PICO 3 MenABCWY vs. Men B
How substantial are the desirable anticipated effects?	Small	Minimal, small, or moderate	Minimal
How substantial are the undesirable anticipated effects	Small	Minimal or small	Minimal or small
Do the desirable effects outweigh the undesirable effects?	Favors intervention	Favors intervention, comparison, or both	Favors intervention or comparison
What is the overall certainty?	Varies by group	Varies by group	Varies by group

VALUES

- Limited data were available
 - Among adolescents during 2021, vaccination coverage of at least 1 dose
 - 89% for MenACWY
 - 31% for MenB
 - Limited data are available on vaccine uptake in other individuals recommended to receive MenACWY or MenB vaccine
- Use of combination vaccines can reduce number of injections and is generally preferred over separate injections of the equivalent component vaccines^{1,2}

Question	PICO 1 MenABCWY vs. MenACWY + MenB	PICO 2 MenABCWY vs. MenACWY	PICO 3 MenABCWY vs. Men B
Does the target population feel that desirable effects are large relative to undesirable effects?	Probably yes	Probably yes	Probably yes or don't know
Important uncertainty or variability in how much people value the main outcomes?	Probably no	Probably yes	Probably yes

¹ General Best Practice Guidelines for Immunization. Best Practice Guidance of the ACIP. <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf>

² American Academy of Pediatrics. Red Book 2018. Report of the Committee on Infectious Diseases. 31st Ed. <https://seciss.facmed.unam.mx/wp-content/uploads/2021/02/Red-Book-31th-Edition.pdf>

ACCEPTABILITY

Is the intervention acceptable to key stakeholders?

- Limited data were available
- Acceptability likely depends on PICO and balance of stakeholder values
 - Health care providers likely supportive of options that allow stocking fewer vaccines^{1,2}
 - Potential to increase vaccination rates against serogroup B disease
 - Reduces number of injections from 4 to 3 for some patients
 - Potential to incentivize MenB administration at age 16 years with waning immunity by peak risk for some patients
 - Many vaccine providers prefer waiting until closer to exposure to congregate settings (college/military)
 - Concerns about increasing exposure to MenB (which is more reactogenic than MenACWY) when burden of MenB disease is already low despite low vaccine coverage
 - 31% single dose
 - <12% second dose

WG interpretation	PICO 1 MenABCWY vs. MenACWY + MenB	PICO 2 MenABCWY vs. MenACWY	PICO 3 MenABCWY vs. Men B
	Probably yes or yes	Probably yes or yes	Don't know

¹ CDC. Timing and Spacing of Immunobiologics: General Best Practice Guidelines for Immunization. [ACIP Timing and Spacing Guidelines for Immunization | CDC](#).

² Hall E, Odafe S, Madden J, Schillie S. Qualitative Conceptual Content Analysis of COVID-19 Vaccine Administration Error Inquiries. *Vaccines*. 2023; 11(2):254.

RESOURCE USE

Is the intervention a reasonable and efficient allocation of resources?

- All proposed meningococcal vaccine strategies are expensive, including currently recommended options for adolescents (QQ and QQBB)
- With new price estimates, QPP is the most cost-effective option when MenB protection is desired

	Strategy	Cost/person
Public sector	QQ	241.2
	QQBB	554.88
	QPB	479.94
	QPP	465.6
	QQPP	586.2
Private sector	QQ	372.0
	QQBB	854.64
	QPB	707.32
	QPP	666.0
	QQPP	852.0

WG interpretation	PICO 1 MenABCWY vs. MenACWY + MenB	PICO 2 MenABCWY vs. MenACWY	PICO 3 MenABCWY vs. Men B
	Probably yes or yes	Probably no or no	Probably yes or yes

EQUITY

What would be the impact on health equity?

- Limited data were available
- The pentavalent vaccine is not expected to negatively impact equity
- It could potentially reduce disparities among those who might be interested in being vaccinated against serogroup B but who might not receive clinical care that includes discussion of the MenB vaccine
- Possible risk of clinics not stocking monovalent B vaccines with some policy options, which could affect availability for
 - Outbreaks
 - People at increased risk recommended to receive 3 doses of MenB-FHbp

WG interpretation	PICO 1 MenABCWY vs. MenACWY + MenB	PICO 2 MenABCWY vs. MenACWY	PICO 3 MenABCWY vs. Men B
	Probably no impact or varies	Probably increased, varies, or don't know	Don't know

FEASIBILITY

Is the intervention feasible to implement?

- Challenges with insurance coverage specific to the pentavalent vaccine not expected
- Substantial financial burdens for providers or health systems not expected
- Pentavalent vaccine would provide additional option in current schedule and may reduce number of doses for some people
- Administration requires reconstitution, which may lead to administration errors¹
- Stocking three different meningococcal vaccine types may be prohibitive for some providers
- Lack of B vaccines interchangeability complicates stocking considerations

WG interpretation	PICO 1 MenABCWY vs. MenACWY + MenB	PICO 2 MenABCWY vs. MenACWY	PICO 3 MenABCWY vs. Men B
	Probably yes or yes	Probably yes or yes	Probably yes or yes

¹<https://www.cdc.gov/mmwr/volumes/65/wr/mm6506a4.htm>

EtR summary – all 3 PICOs

Domain		PICO 1 MenABCWY vs. MenACWY + MenB	PICO 2 MenABCWY vs. MenACWY	PICO 3 MenABCWY vs. Men B
Public health problem		Yes	Yes	Yes
Benefits & harms	Desirable anticipated effects	Small	Minimal, small, or moderate	Minimal
	Undesirable anticipated effects	Small	Minimal or small	Minimal or small
	Desirable effects > undesirable effects?	Favors intervention	Favors intervention, comparison, or both	Favors intervention or comparison
	Overall certainty	Varies by group	Varies by group	Varies by group
Values	Are desirable effects large relative to undesirable effects?	Probably yes	Probably yes	Probably yes or don't know
	Important uncertainty or variability?	Probably no	Probably yes	Probably yes
Acceptability		Probably yes or yes	Probably yes or yes	Don't know
Resource use		Probably yes or yes	Probably no or no	Probably yes or yes
Equity		Probably no impact or varies	Probably increased, varies, or don't know	Don't know
Feasibility		Probably yes or yes	Probably yes or yes	Probably yes or yes

■ Favorable

■ Somewhat favorable

■ Uncertain

■ Unfavorable

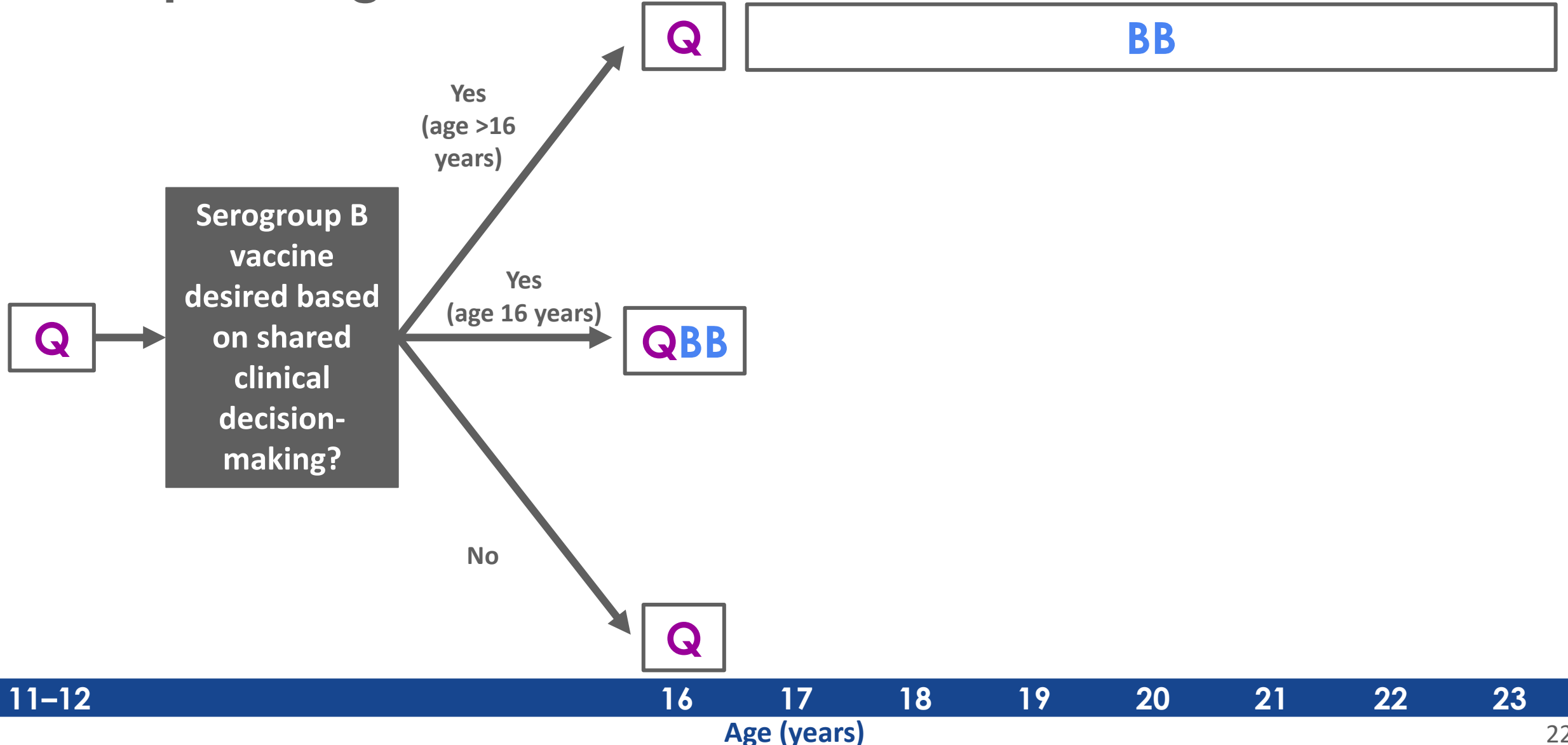
Summary of work group consensus and debate

- **Strong consensus in favor of PICO 1:** MenABCWY as an option for MenACWY + MenB (QPB)
- **Strong consensus against PICO 2:** MenABCWY as an option for MenACWY only (PPB)
- **Limited consensus regarding PICO 3:** MenABCWY as an option for MenB only

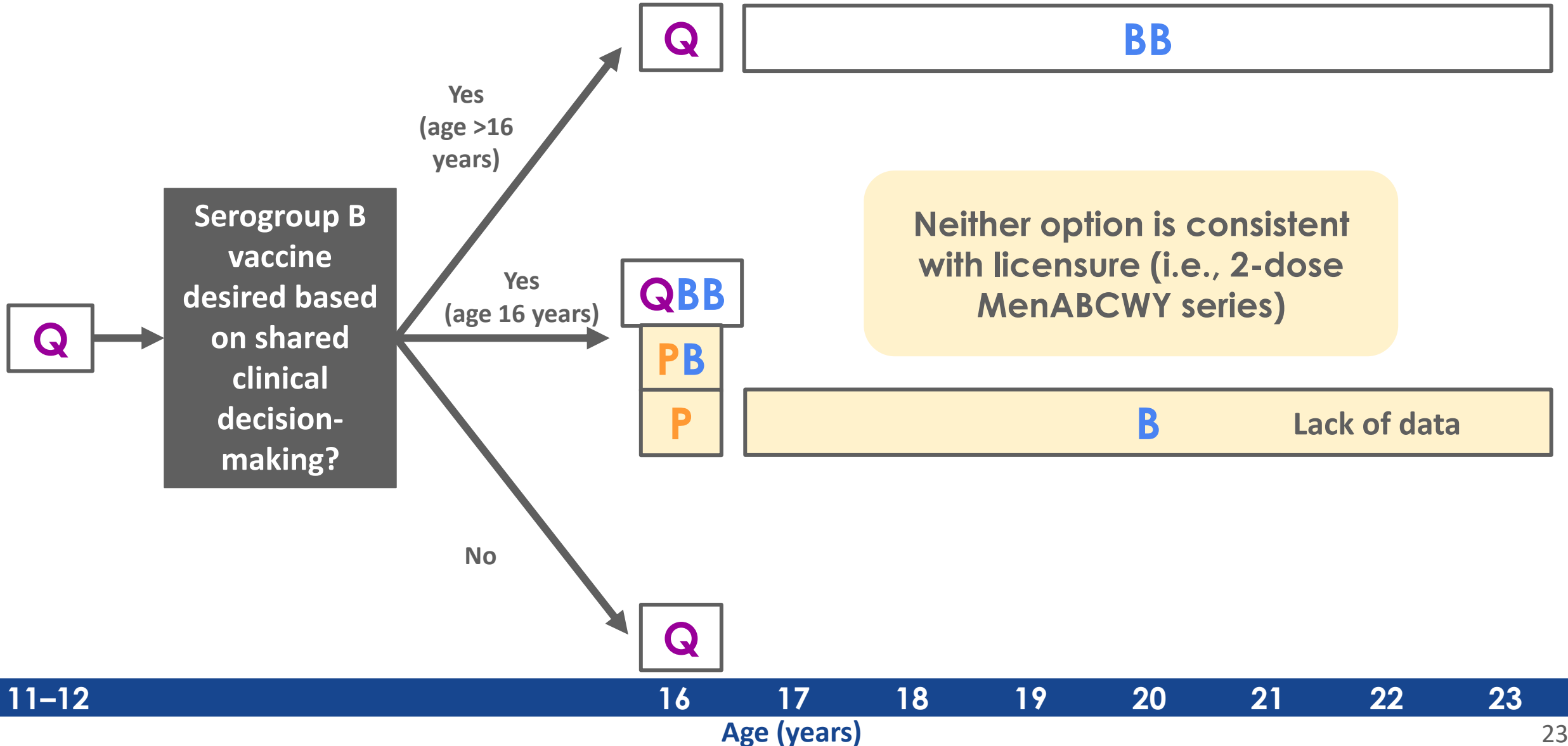
- **Options debated for PICO 3**

Option	Preference
A	Reject outright
B	Accept with limitations (i.e., QPP only)
C	Accept fully (i.e., QPP, QQPP, QQP B)

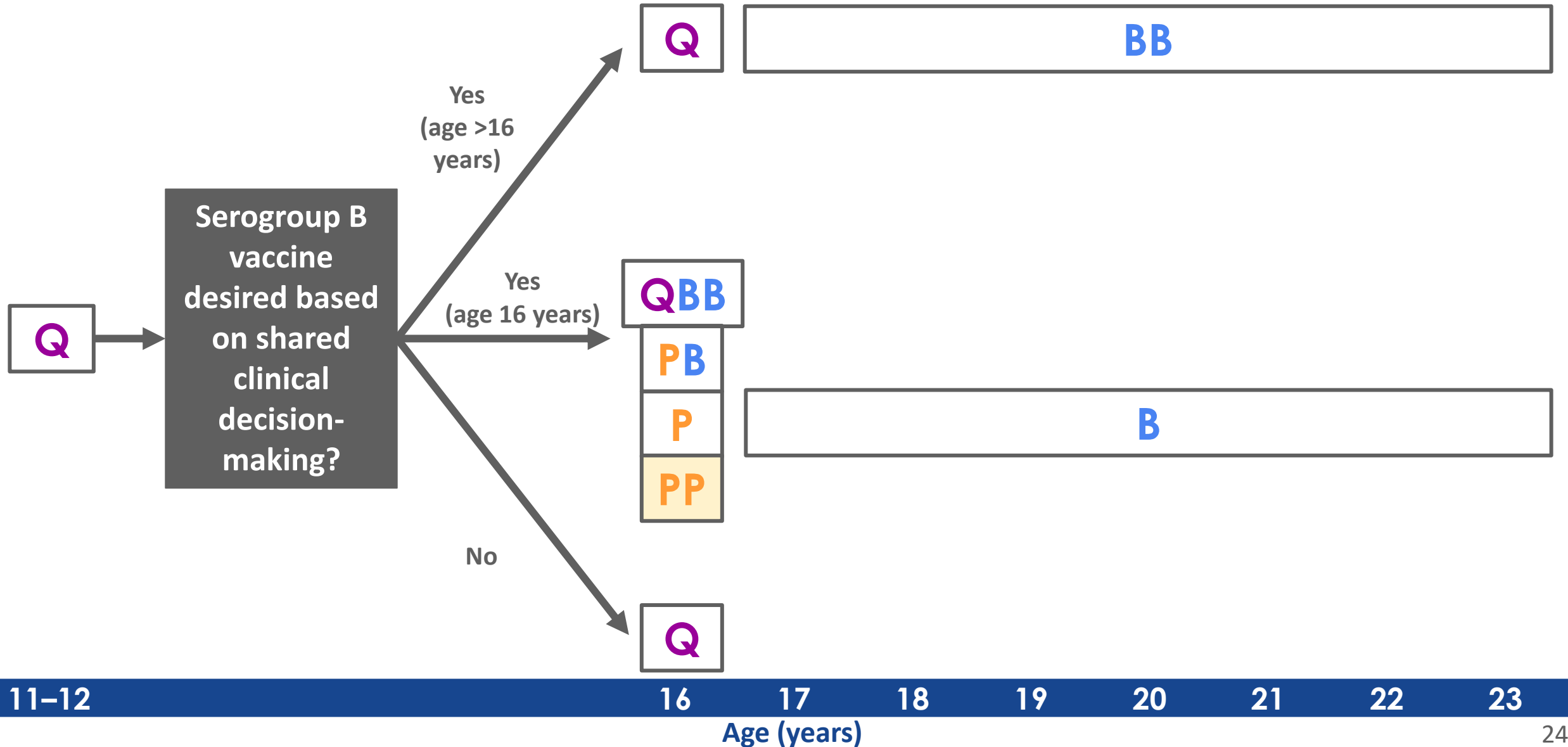
Existing recommendations for routine schedule incorporating SCDM



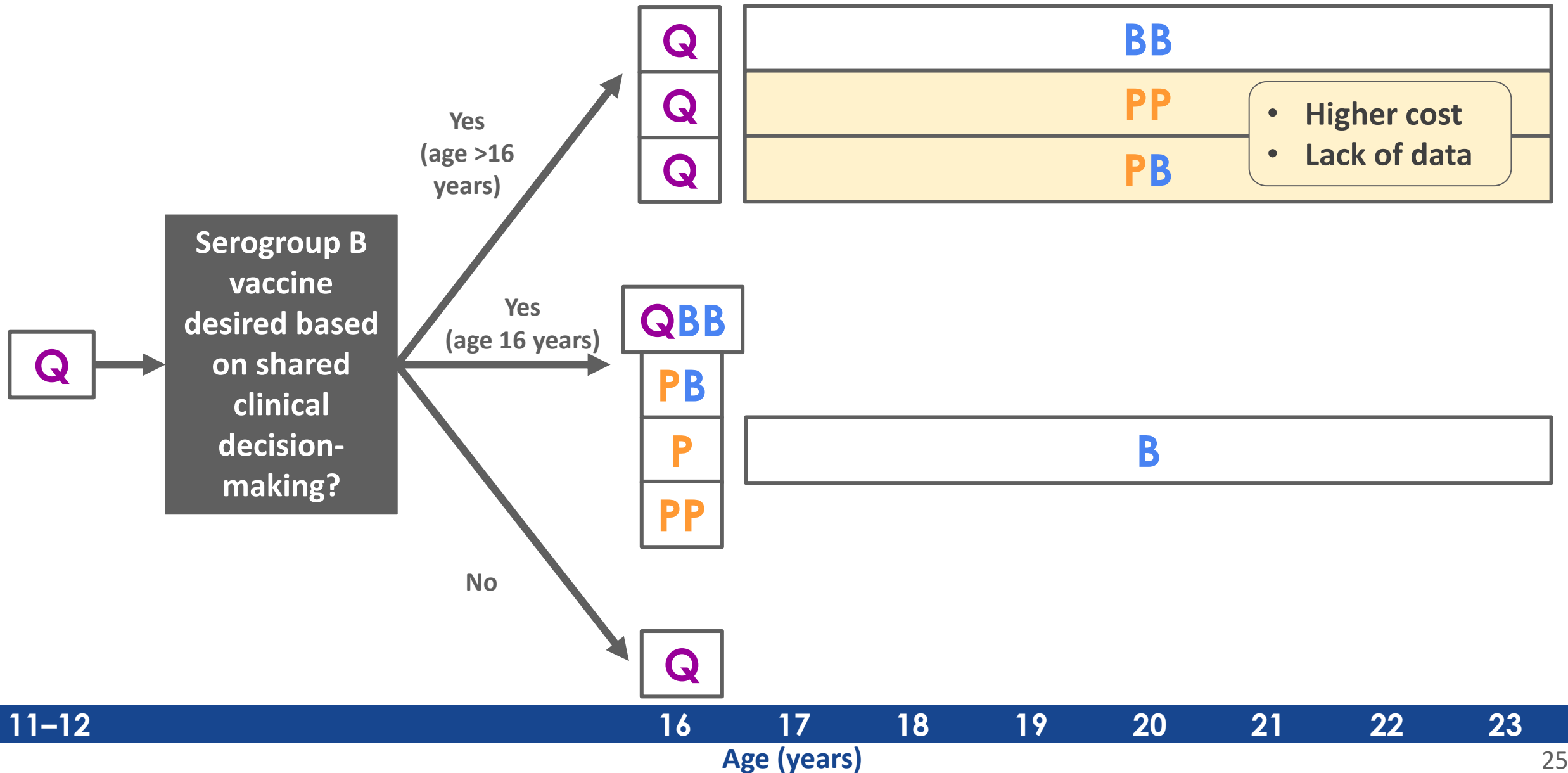
Option A adds QPB to the existing options



Option B adds QPP to Option A



Option C adds QQPP and QQPB to option B



Summary of routine schedule interpretation for 3 options

All options would permit current standard of care (i.e., QQ vs. QQBB under SCDM)

Option*	Preference for PICO 3	Schedule options incorporating SCDM for MenB
A	Reject outright	QPB
B	Accept with limitations	QPB + QPP
C	Accept fully	QPB + QPP + QQPP + QQPB

*All options include a recommendation in favor of PICO 1 and against PICO 2

WG deliberations regarding 3 most favored options

CONSIDERATION	Option A PICO 1 (QPB)	Option B PICO 1 + PICO 3 (QPP only)	Option C PICO 1 + PICO 3 (QPP, QQPP, QQPb)
CLINICAL			
Alignment with clinical trial data	Not directly assessed; however, second pentavalent dose is primarily for additional B protection	Directly assessed in clinical trial (6- or 12- month interval between pentavalent doses)	Options with additional antigenic exposures for which safety and immunogenicity have not been assessed (QQPP, QQPb)
Alignment with licensure	Off-label	Yes	Yes
Excess doses for ≥1 serogroup	No	Yes (1 dose)	Yes (multiple doses)
STOCKING AND ADMINISTRATION			
Flexibility (especially for under-resourced clinics)	Least	Intermediate	Most
Minimum # vaccines to stock if using MenABCWY for routine indications*	3	2	2
ECONOMIC			
Projected cost effectiveness	Unclear cost effectiveness	Most cost-effective option based on recent price update from Pfizer	Includes more expensive options not assessed in CE model (e.g., QQPP)
Potential for insurance reimbursement issues	Yes	No	No

*All options would require stocking 3 vaccines for special situations if using MenABCWY. Minimum number of vaccines to stock will remain 2 (MenACWY, MenB) if not using MenABCWY.

WG deliberations regarding 3 most favored options

CONSIDERATION	Option A PICO 1 (QPB)	Option B PICO 1 + PICO 3 (QPP only)	Option C PICO 1 + PICO 3 (QPP, QQPP, QQPb)
CLINICAL			
Alignment with clinical trial data	Not directly assessed; however, second pentavalent dose is primarily for additional B protection	Directly assessed in clinical trial (6- or 12- month interval between pentavalent doses)	Options with additional antigenic exposures for which safety and immunogenicity have not been assessed (QQPP, QQPb)
Alignment with licensure	Off-label	Yes	Yes
Excess doses for ≥1 serogroup	No	Yes (1 dose)	Yes (multiple doses)
STOCKING AND ADMINISTRATION			
Flexibility (especially for under-resourced clinics)	Least	Intermediate	Most
Minimum # vaccines to stock if using MenABCWY for routine indications*	3	2	2
ECONOMIC			
Projected cost effectiveness	Unclear cost effectiveness	Most cost-effective option based on recent price update from Pfizer	Includes more expensive options not assessed in CE model (e.g., QQPP)
Potential for insurance reimbursement issues	Yes	No	No

*All options would require stocking 3 vaccines for special situations if using MenABCWY. Minimum number of vaccines to stock will remain 2 (MenACWY, MenB) if not using MenABCWY.

WG deliberations regarding 3 most favored options

CONSIDERATION	Option A PICO 1 (QPB)	Option B PICO 1 + PICO 3 (QPP only)	Option C PICO 1 + PICO 3 (QPP, QQPP, QQPb)
CLINICAL			
Alignment with clinical trial data	Not directly assessed; however, second pentavalent dose is primarily for additional B protection	Directly assessed in clinical trial (6- or 12- month interval between pentavalent doses)	Options with additional antigenic exposures for which safety and immunogenicity have not been assessed (QQPP, QQPb)
Alignment with licensure	Off-label	Yes	Yes
Excess doses for ≥1 serogroup	No	Yes (1 dose)	Yes (multiple doses)
STOCKING AND ADMINISTRATION			
Flexibility (especially for under-resourced clinics)	Least	Intermediate	Most
Minimum # vaccines to stock if using MenABCWY for routine indications*	3	2	2
ECONOMIC			
Projected cost effectiveness	Unclear cost effectiveness	Most cost-effective option based on recent price update from Pfizer	Includes more expensive options not assessed in CE model (e.g., QQPP)
Potential for insurance reimbursement issues	Yes	No	No

*All options would require stocking 3 vaccines for special situations if using MenABCWY. Minimum number of vaccines to stock will remain 2 (MenACWY, MenB) if not using MenABCWY.

WG deliberations regarding 3 most favored options

CONSIDERATION	Option A PICO 1 (QPB)	Option B PICO 1 + PICO 3 (QPP only)	Option C PICO 1 + PICO 3 (QPP, QQPP, QQPb)
CLINICAL			
Alignment with clinical trial data	Not directly assessed; however, second pentavalent dose is primarily for additional B protection	Directly assessed in clinical trial (6- or 12- month interval between pentavalent doses)	Options with additional antigenic exposures for which safety and immunogenicity have not been assessed (QQPP, QQPb)
Alignment with licensure	Off-label	Yes	Yes
Excess doses for ≥1 serogroup	No	Yes (1 dose)	Yes (multiple doses)
STOCKING AND ADMINISTRATION			
Flexibility (especially for under-resourced clinics)	Least	Intermediate	Most
Minimum # vaccines to stock if using MenABCWY for routine indications*	3	2	2
ECONOMIC			
Projected cost effectiveness	Unclear cost effectiveness	Most cost-effective option based on recent price update from Pfizer	Includes more expensive options not assessed in CE model (e.g., QQPP)
Potential for insurance reimbursement issues	Yes	No	No


*All options would require stocking 3 vaccines for special situations if using MenABCWY. Minimum number of vaccines to stock will remain 2 (MenACWY, MenB) if not using MenABCWY.

Balance of Consequences — PICO 1

MenABCWY as an option for MenACWY+MenB

<p>Undesirable consequences <i>clearly outweigh</i> desirable consequences in most settings</p>	<p>Undesirable consequences <i>probably outweigh</i> desirable consequences in most settings</p>	<p>The balance between desirable and undesirable consequences is closely balanced or uncertain</p>	<p>Desirable consequences <i>probably outweigh</i> undesirable consequences in most settings</p>	<p>Desirable consequences <i>clearly outweigh</i> undesirable consequences in most settings</p>	<p>There is insufficient evidence to determine the balance of consequences</p>
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Majority of WG members think desirable consequences *probably* or *clearly outweigh* undesirable consequences in most settings

 Most common

 2nd most common

 3rd most common

Work Group Interpretation — PICO 1

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

We do not recommend the intervention, but it may be used within FDA licensed indications

We recommend the intervention for individuals based on shared clinical decision-making

We recommend the intervention

Majority of WG members favored recommending the intervention



Most common




2nd most common

Balance of Consequences — PICO 2

MenABCWY as an option for MenACWY

<p>Undesirable consequences <i>clearly outweigh</i> desirable consequences in most settings</p>	<p>Undesirable consequences <i>probably outweigh</i> desirable consequences in most settings</p>	<p>The balance between desirable and undesirable consequences is closely balanced or uncertain</p>	<p>Desirable consequences <i>probably outweigh</i> undesirable consequences in most settings</p>	<p>Desirable consequences <i>clearly outweigh</i> undesirable consequences in most settings</p>	<p>There is insufficient evidence to determine the balance of consequences</p>
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Majority of WG members think undesirable consequences *probably* or *clearly outweigh* desirable consequences in most settings

 Most common

 2nd most common

 3rd most common

Work Group Interpretation — PICO 2

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

We do not recommend the intervention, but it may be used within FDA licensed indications

We recommend the intervention for individuals based on shared clinical decision-making

We recommend the intervention

Majority of WG members favored not recommending the intervention



Most common



2nd most common

Balance of Consequences — PICO 3

MenABCWY as an option for MenB

Undesirable consequences <i>clearly outweigh</i> desirable consequences in most settings	Undesirable consequences <i>probably outweigh</i> desirable consequences in most settings	The balance between desirable and undesirable consequences is closely balanced or uncertain	Desirable consequences <i>probably outweigh</i> undesirable consequences in most settings	Desirable consequences <i>clearly outweigh</i> undesirable consequences in most settings	There is insufficient evidence to determine the balance of consequences
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The WG did not reach a majority consensus on the balance of consequences



Most common



2nd most common

Work Group Interpretation — PICO 3

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

We do not recommend the intervention, but it may be used within FDA licensed indications
We recommend the intervention for individuals based on shared clinical decision-making
We recommend the intervention but only in certain circumstances (i.e., QPP)
We recommend the intervention in all circumstances

Added an additional option because some WG members favored QPP only

Work Group Interpretation — PICO 3

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

We do not recommend the intervention, but it may be used within FDA licensed indications

We recommend the intervention for individuals based on shared clinical decision-making

We recommend the intervention but only in certain circumstances (i.e., QPP)

We recommend the intervention in all circumstances

- WG was divided regarding PICO 3
- **Majority favored PICO 3 in some form**
- Substantial minority of work group members favored not recommending the intervention



Most common



2nd most common



3rd most common



4th most common

Combined draft proposal for option B

PICO 1 (QPB)	✓
PICO 2 (PPB)	✗
PICO 3 (QPP only)	✓

Pfizer's MenABCWY vaccine may be used when both MenACWY and MenB are indicated at the same visit.* If MenABCWY is administered in this way, a second dose of MenABCWY may be administered 6 months later to complete the series.

*1) Healthy individuals aged 16–23 years (routine schedule) when shared clinical decision-making favors administration of MenB vaccination, 2) individuals aged 10 years and older at increased risk of meningococcal disease (e.g., due to persistent complement deficiencies, complement inhibitor use, or functional or anatomic asplenia) due for both vaccines.

■ Remarks:

- for Pfizer's MenABCWY vaccine, data are not available regarding safety or immunogenicity of dosing intervals exceeding 12 months
- the licensed B component vaccines are not interchangeable by manufacturer. Administration of a B component vaccine (MenB or MenABCWY) requires that subsequent B component vaccine doses be from the same manufacturer
- the minimum interval for Pfizer's MenABCWY vaccine is 6 months. Individuals at increased risk of meningococcal disease who are recommended to receive additional doses of MenACWY and MenB less than 6 months after a dose of pentavalent meningococcal vaccine should instead receive separate MenACWY and MenB-FHbp vaccines

Rationale in favor of combined draft proposal

- Aligns with clinical trial data and licensure
- Allows for fewer injections than QQBB
- Provides flexibility with vaccine inventory, including for clinics that prefer to stock 2 vaccines for routine indications
- Stocking fewer vaccines may increase equity (e.g., if under-resourced clinics are less likely to stock 3 vaccines)
- Most cost-effective option based on recent price update from Pfizer

Rationale against combined draft proposal

- Unnecessary ACWY antigen exposure for second pentavalent dose in routine schedule (i.e., when only MenB is indicated)
- Not as much flexibility for providers as Option 3

General considerations (all options):

- Potential to incentivize MenB at age 16 years with waning immunity by peak risk (i.e., college/military) for some patients
- Uncertainty regarding cost estimates
- If using MenABCWY, it will be necessary to stock 3 vaccines to cover all indications (routine schedule + special situations), which may be challenging for some vaccine providers

Acknowledgments

- ACIP Members on the WG
 - Kathy Poehling (Chair)
 - Lynn Bahta
 - Jamie Loehr
- Ex Officio WG Members
 - Margaret Bash (FDA)
 - Mark Connelly (FDA)
 - Francisco Leyva (NIH)
- WG Liaisons and Consultants
 - Amra Resic (AAFP)
 - Samir Shah (AAP)
 - Sharon McMullen (ACHA)
 - Cacky Tate / Karyn Lyons (AIM)
 - Paul Cieslak (CSTE)
 - Kathy Hsu (IDSA)
 - Joseline Zafack (NACI)
 - Jeff Goad (NFID)
 - Jessica Cataldi (PIDS)
 - Amy Middleman (SAHM)
 - David Stephens (Emory)
- CDC Contributors
 - Sam Crowe (DBD/NCIRD)
 - Lucy McNamara (DBD/NCIRD)
 - Ismael Ortega-Sanchez (DVD/NCIRD)
 - Andrew Leidner (ISD/NCIRD)
 - LeAnne Fox (DBD/NCIRD)
 - Susan Hariri (DBD/NCIRD)
 - Amy Rubis (DBD/NCIRD)
 - Noele Nelson (DBD/NCIRD)
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- GRADE/EtR Support
 - Doug Campos-Outcalt (Arizona)
 - Rebecca Morgan (Case Western Reserve)

Thank you!
Questions?