Serogroup B Meningococcal Vaccine Booster Doses

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Agenda

- Review rationale for serogroup B meningococcal (MenB) booster doses in persons at increased risk for serogroup B meningococcal disease.

- Summarize Work Group's interpretation of:
  - Persistence of immune response following a MenB primary series
  - Immunogenicity and persistence of MenB booster dose

- Summarize the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) and Evidence to Recommendations (EtR) framework for MenB booster doses.

- Review the Work Group's considerations for policy proposals for MenB booster doses.

Meningococcal disease is a serious infection

Die despite antibiotics

Survivors have long-term sequelae

Hearing loss

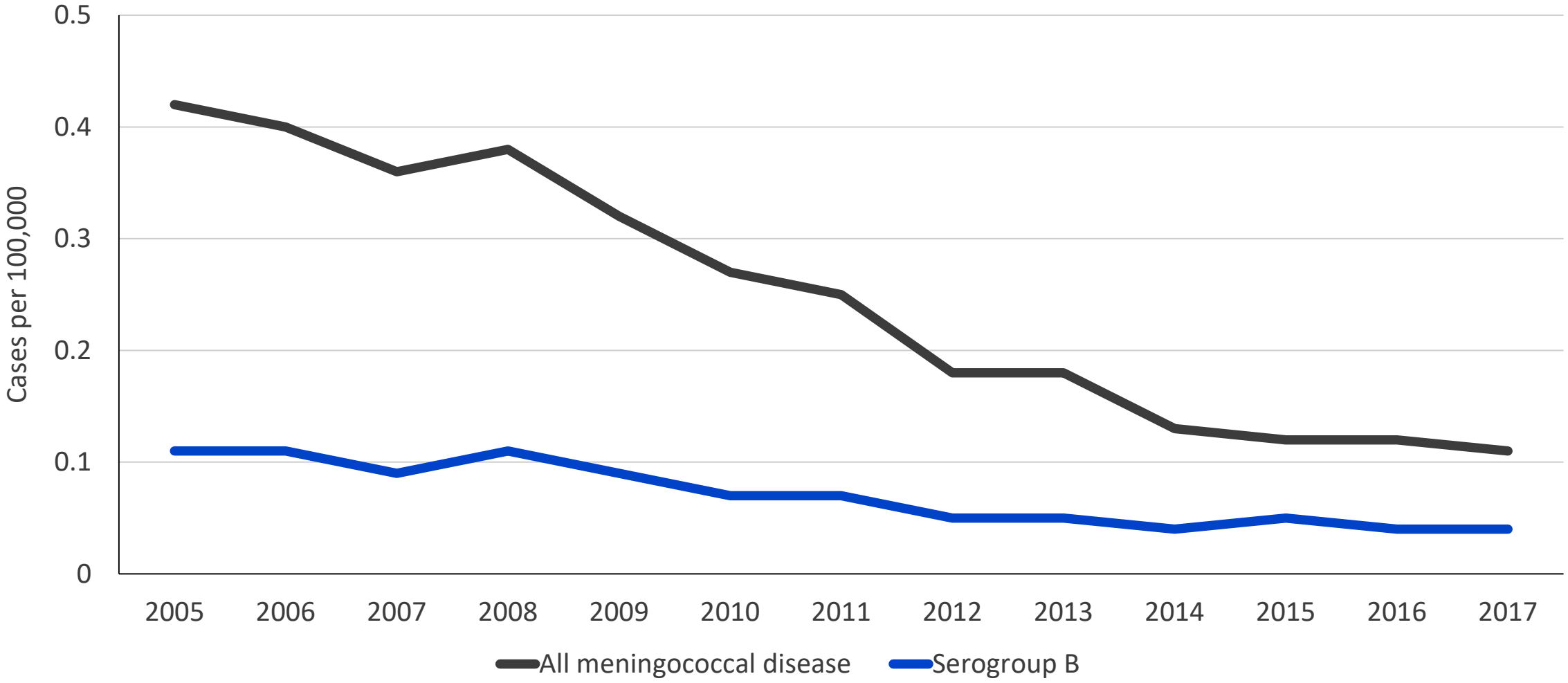
Created by Francesca Arena from Noun Project

Amputations

Created by Jafri Ali from Noun Project

Cognitive deficits

Incidence of meningococcal disease — United States, 2005–2017



Source: National Notifiable Diseases Surveillance System, with additional information on serogroup from state health departments

Groups at increased risk for serogroup B meningococcal disease

Persons aged ≥10 years at increased risk for serogroup B meningococcal disease
Persistent complement component deficiency
Complement inhibitor use (e.g., eculizumab)
Anatomic or functional asplenia (e.g. sickle cell disease)
Microbiologists routinely exposed to *N. meningitidis*

[1] Figueroa JE. Clin Microbiol Rev 1991. [2] Estimated prevalence in all ages of 0.03% (Densen R. Clin Exp Immunol. 1991) though many may be undiagnosed.
[3] Food and Drug Administration. Meeting of the Drug Safety and Risk Management Advisory Committee, Nov 18, 2014. [4] Preliminary estimate projected from 2017 claims data (Marketscan and Medicaid)
[5] Based on estimated 100,000 persons with sickle cell disease (CDC data), minus the ~20,000 children aged <10 years with disease (estimated 1,800-2,000 children identified with sickle cell disease annually through newborn screening, with 95% survival to age 18 years). [6] Sejvar JJ. Journal of Clinical Microbiology. Sept 2005;43(9):4811-14.
[7] Bureau of Labor Statistics, 2016. Adjusted to estimate personnel with occupational exposure to *N. meningiitidis.* https://www.bls.gov/ooh/life-physical-and-social-science/microbiologists.htm#tab-1, https://www.bls.gov/ooh/healthcare/medical-and-clinical-laboratory-technologists-and-technicians.htm ;

Groups at increased risk for serogroup B meningococcal disease

Persons aged ≥10 years at increased risk for serogroup B meningococcal disease	Estimated increased risk
Persistent complement component deficiency	Up to 10,000-fold[1]
Complement inhibitor use (e.g., eculizumab)	2,000-fold[3]
Anatomic or functional asplenia (e.g. sickle cell disease)	Not quantified; Higher case-fatality rate
Microbiologists routinely exposed to *N. meningitidis*	120-fold[6]

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Groups at increased risk for serogroup B meningococcal disease

Persons aged ≥10 years at increased risk for serogroup B meningococcal disease	Estimated increased risk	Estimated population size
Persistent complement component deficiency	Up to 10,000-fold[1]	86,000[2]
Complement inhibitor use (e.g., eculizumab)	2,000-fold[3]	3,000[4]
Anatomic or functional asplenia (e.g. sickle cell disease)	Not quantified; Higher case-fatality rate	>80,000[5]
Microbiologists routinely exposed to *N. meningitidis*	120-fold[6]	100,000[7]

[1] Figueroa JE. Clin Microbiol Rev 1991. [2] Estimated prevalence in all ages of 0.03% (Densen R. Clin Exp Immunol. 1991) though many may be undiagnosed.
[3] Food and Drug Administration. Meeting of the Drug Safety and Risk Management Advisory Committee, Nov 18, 2014. [4] Preliminary estimate projected from 2017 claims data (Marketscan and Medicaid)
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Persons at increased risk due to a serogroup B meningococcal disease outbreak

Persons aged ≥10 years at increased risk for serogroup B meningococcal disease	Estimated increased risk	Estimated population size
Persons exposed during an outbreak	• Median 83-fold overall • 165-fold during college outbreaks (higher in freshmen, on-campus residents, and Greek life students)[1-3]	35,000 college students annually[2]

[1]Soeters et al, Emerging Infectious Diseases 2019; [2]Mbaeyi et al, Pediatrics 2019; [3]Weil et al, presented at the Council of State and Territorial Epidemiologists Conference (2019).

ACIP recommendations for MenB vaccines

- In February 2015, ACIP recommended that persons aged ≥10 years at increased risk for serogroup B meningococcal disease receive a MenB primary series.
  - These groups are also recommended to receive quadrivalent meningococcal conjugate (MenACWY) vaccine, with booster doses every 5 years thereafter for as long as risk remains.

- In June 2015, ACIP recommended that adolescents aged 16–23 years may be vaccinated with a MenB primary series based on individual clinical decision-making (preferred age of 16–18 years).

University-based serogroup B meningococcal disease outbreaks

- College students are at increased risk for serogroup B meningococcal disease and outbreaks.[1]
- 13 serogroup B outbreaks reported during 2013–2019 (to-date). [2]
  - All implemented MenB primary vaccination.
- Over a 3 year period, a New Jersey university experienced two separate outbreaks.
  - 2016: MenB-FHbp recommended for all undergraduates.[3]
  - 2019: MenB recommended, including booster dose for those who completed series ≥1 year ago.
- College students: primary group at risk for outbreaks who may have received MenB series.
  - Current MenB vaccination coverage among adolescents is low (~15% of 17 year olds received ≥1 dose in 2017) but has steadily increased since vaccine licensure.[4,5]

[1]Mbaeyi, et al. Pediatrics. 2019; [2]Soeters, et al. Congress of the European Meningococcal and Haemophilus Society. 2019; [3]Soeters, et al. Emerging Infectious Diseases. 2016; [4]Walker, et al. MMWR. 2018; 5Jones-Jack, presented at the National Immunization Conference (2018).

Serogroup B meningococcal disease in vaccinated patients

- 5 cases reported in persons who received ≥1 MenB dose to-date:
  - MenB-4C: 3 fully vaccinated, 1 partially vaccinated
  - MenB-FHbp: 1 partially vaccinated
- Among patients fully vaccinated with MenB-4C:
  - 2 with underlying conditions, 1 young adult with no known conditions
  - Interval from last MenB dose to disease onset ranged from 5–26 months
- Preliminary analysis on strains:
  - Potential protection dependent on 1 of 4 antigens (NHBA)
  - Human serum bactericidal activity (hSBA) results suggest MenB-4C likely confers limited protection against these strains.
- Information on these patients not sufficient to evaluate or compare effectiveness of MenB vaccines.

MenB booster doses and the rationale for today's vote

- Although incidence of serogroup B meningococcal disease is low in the United States, a small group of individuals is at substantially elevated risk.

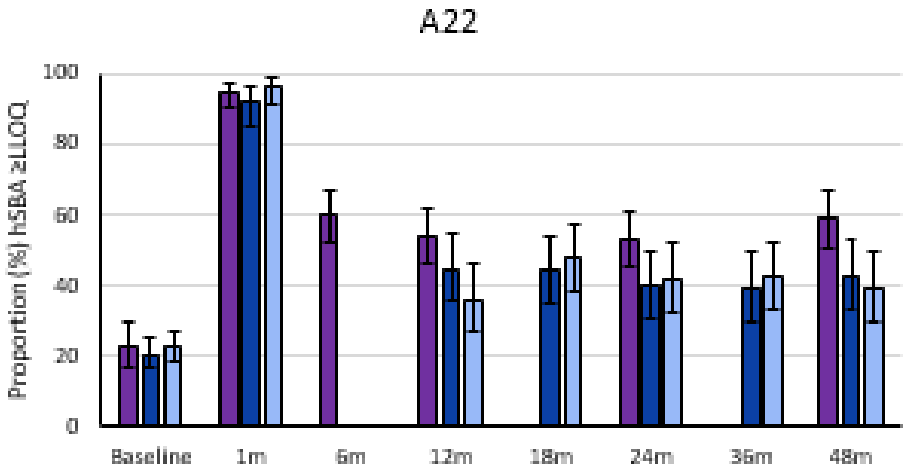
- ACIP recommended a MenB primary series for persons at increased risk 4 years ago.
  - Evidence presented to ACIP in February 2019 suggests waning immunity within 1–2 years.

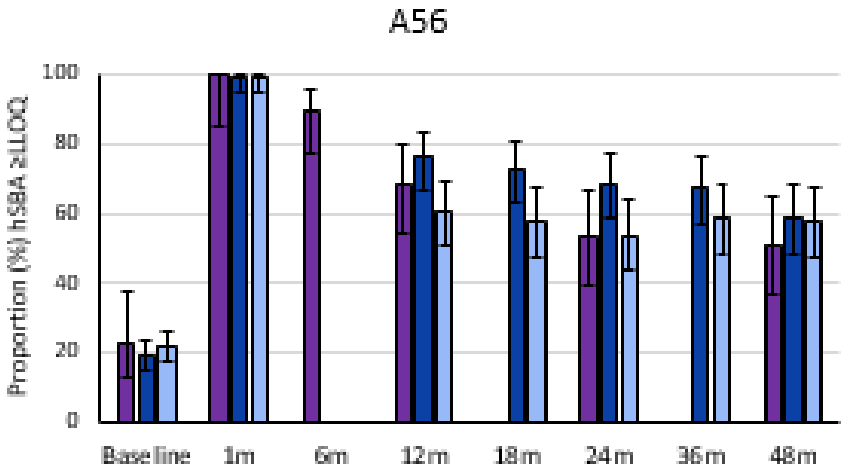
- Serogroup B outbreaks among college students continue to occur.
  - 1 university implemented off-label/ACIP booster dose recommendations to-date.

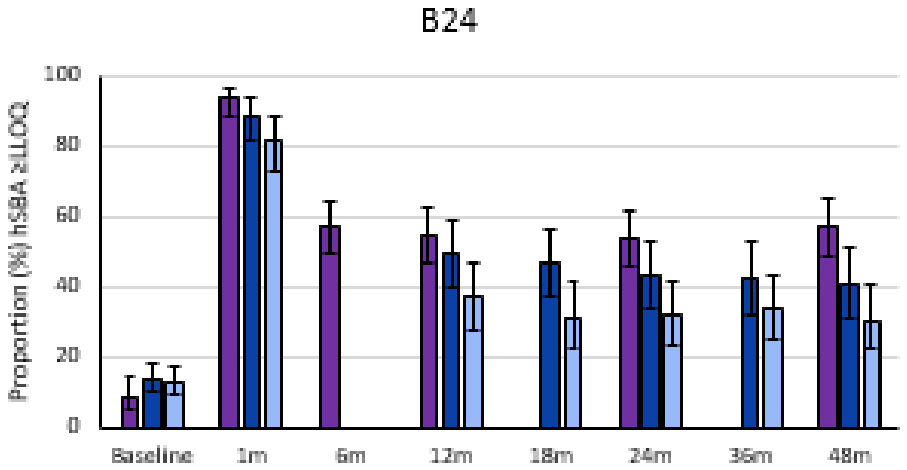
- No further data expected from manufacturers.
  - Additional data on MenB effectiveness and duration of protection in adolescents/adults or U.S. populations may take years to generate.

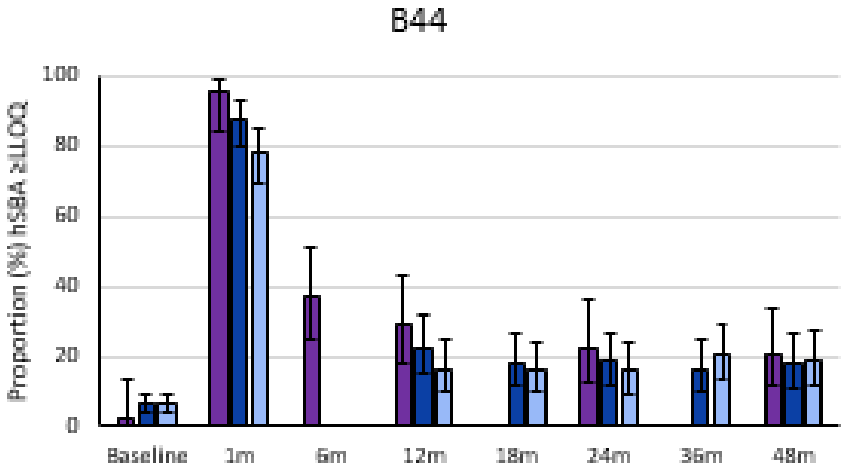
Persistence of the immune response following a MenB primary series

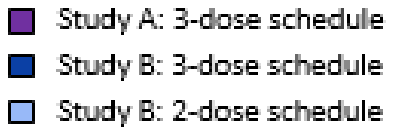
Clinical trials: Immunogenicity and persistence of a MenB-FHbp primary series in healthy adolescents











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3-dose schedule: 0, 2, 6 months; 2-dose schedule: 0, 6 months; LLOQ=lower limit of quantification of the assay (1:8 for A56, B24, B44; 1:16 for A22)

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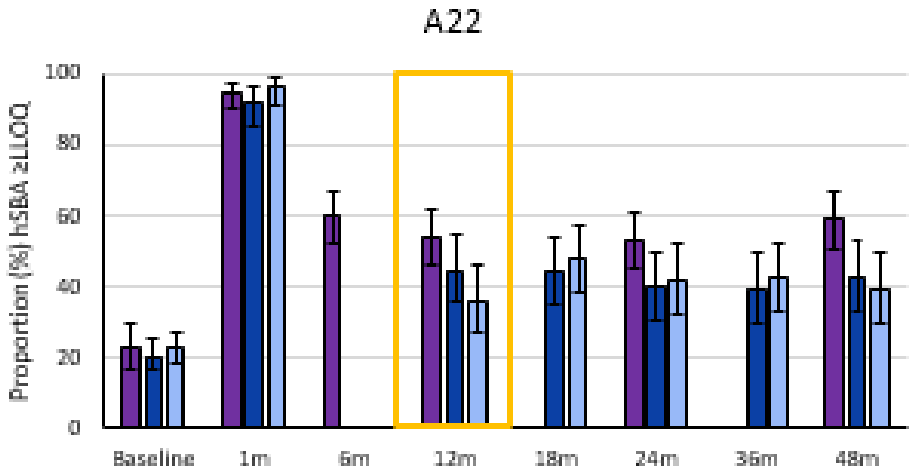

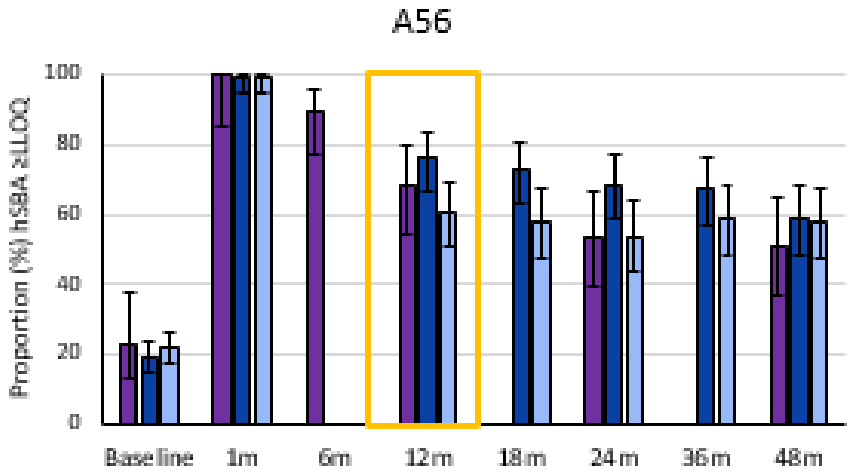

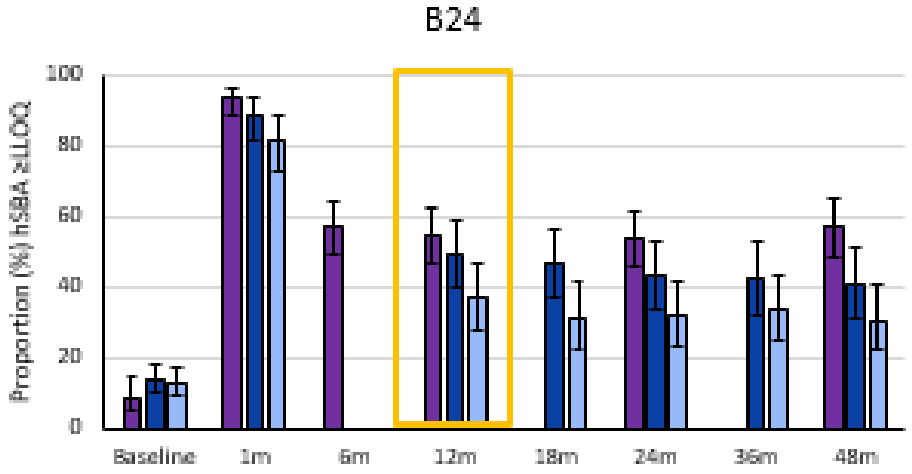

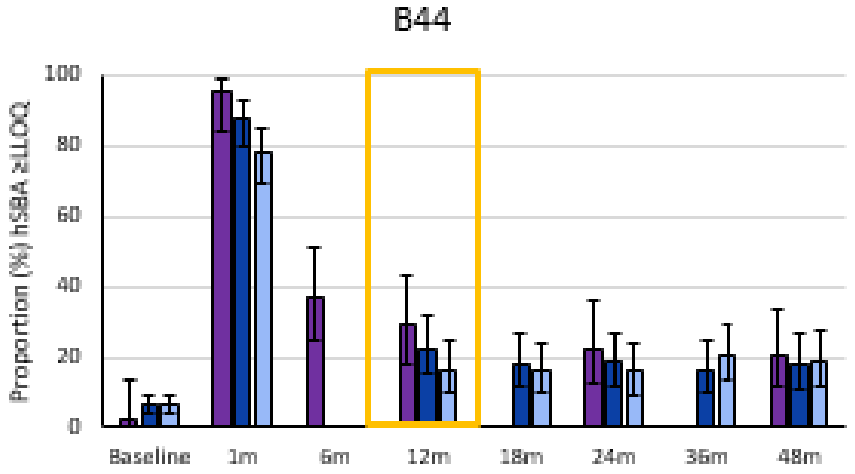

Work Group interpretation:

- Antibodies wane by 12 months post-vaccination

Study A: 3-dose schedule
Study B: 3-dose schedule
Study B: 2-dose schedule

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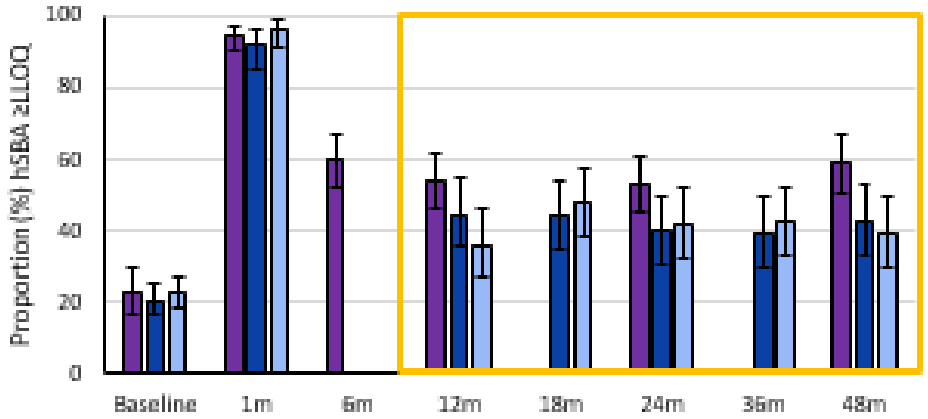
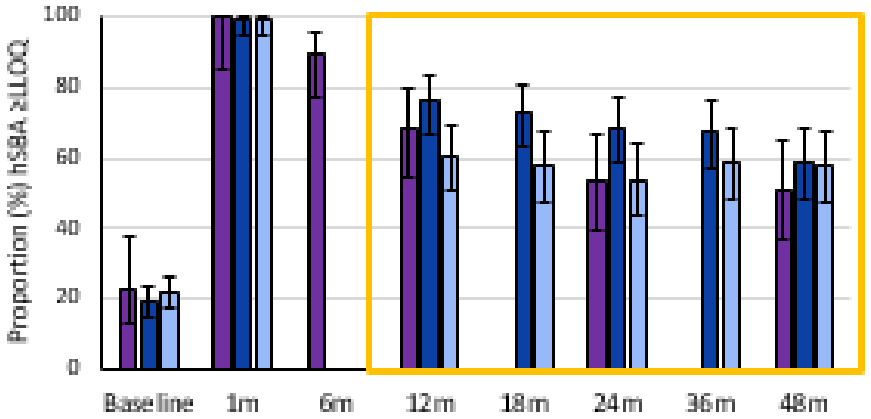
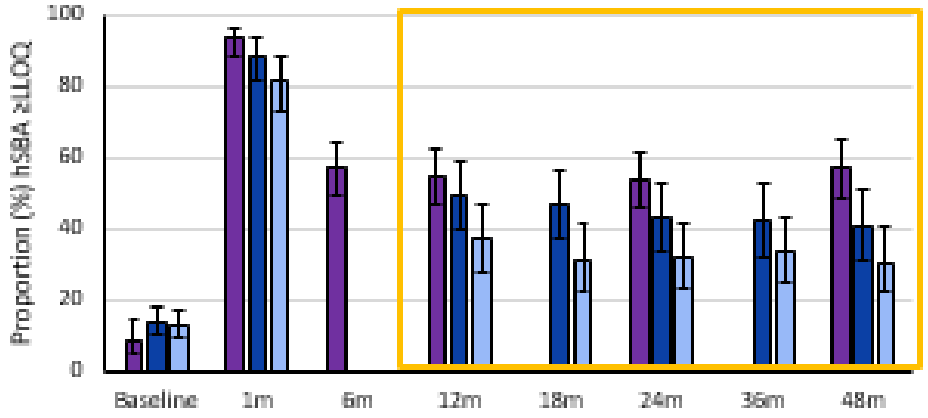




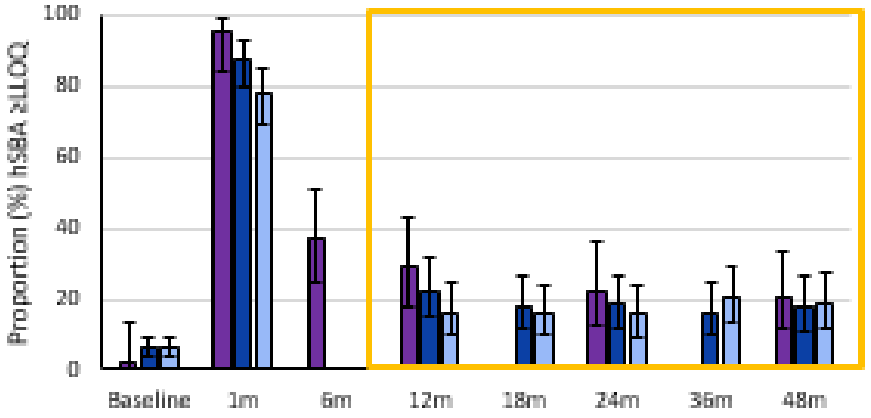
Work Group interpretation:

- Antibodies wane by 12 months post-vaccination
- Then remain stable for up to 4 years

B24



B44



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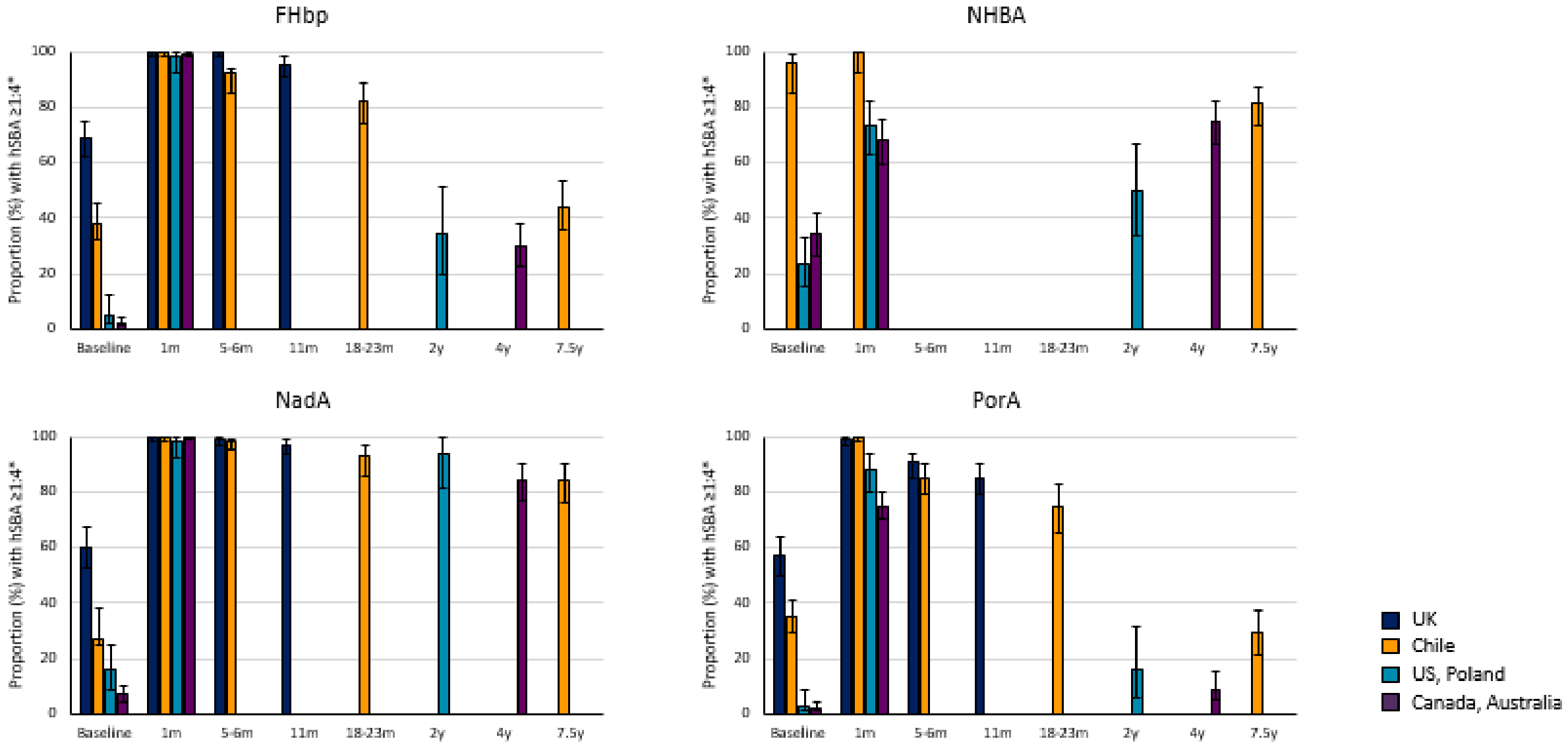
Clinical trials: Immunogenicity and persistence of MenB-4C primary series in healthy adolescents and adults



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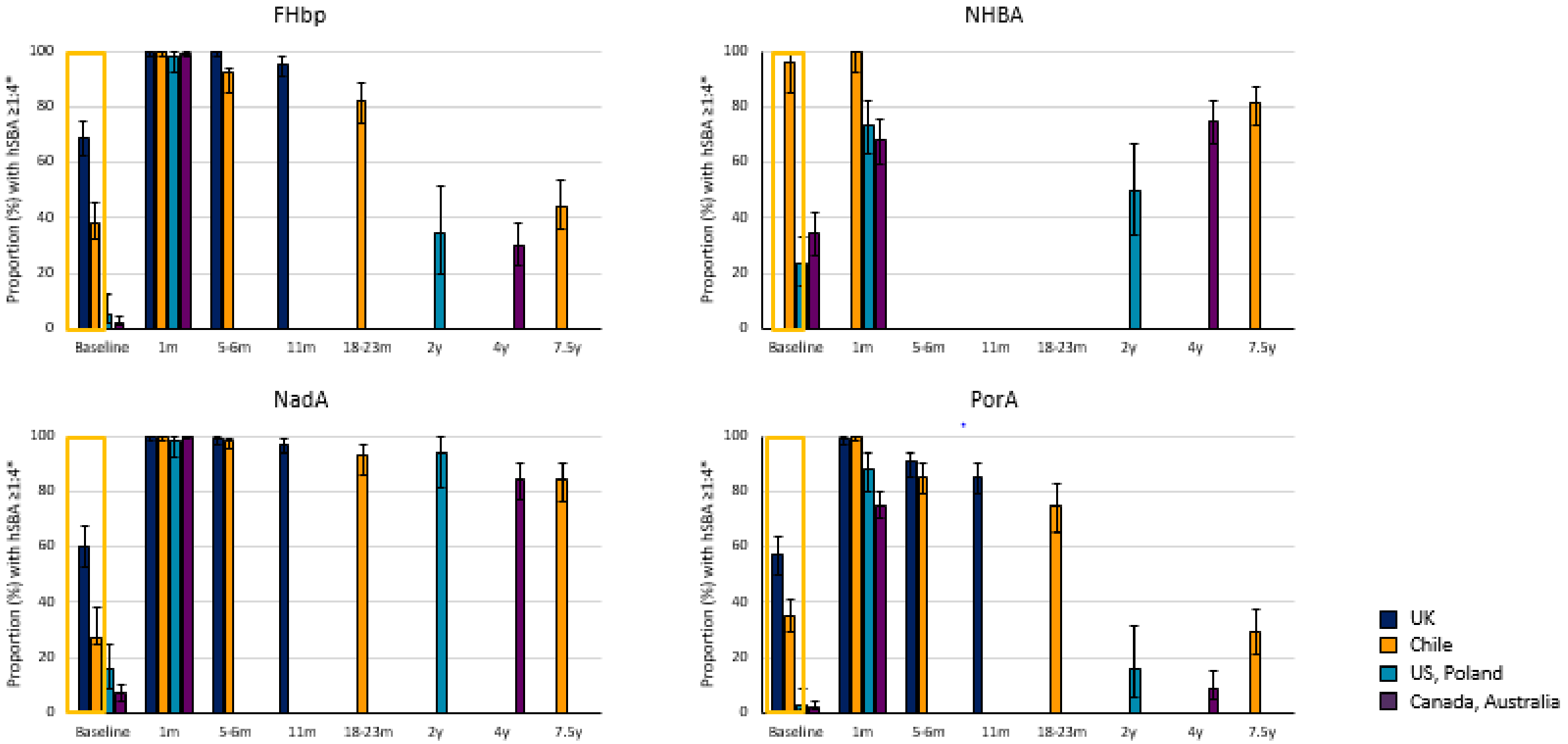

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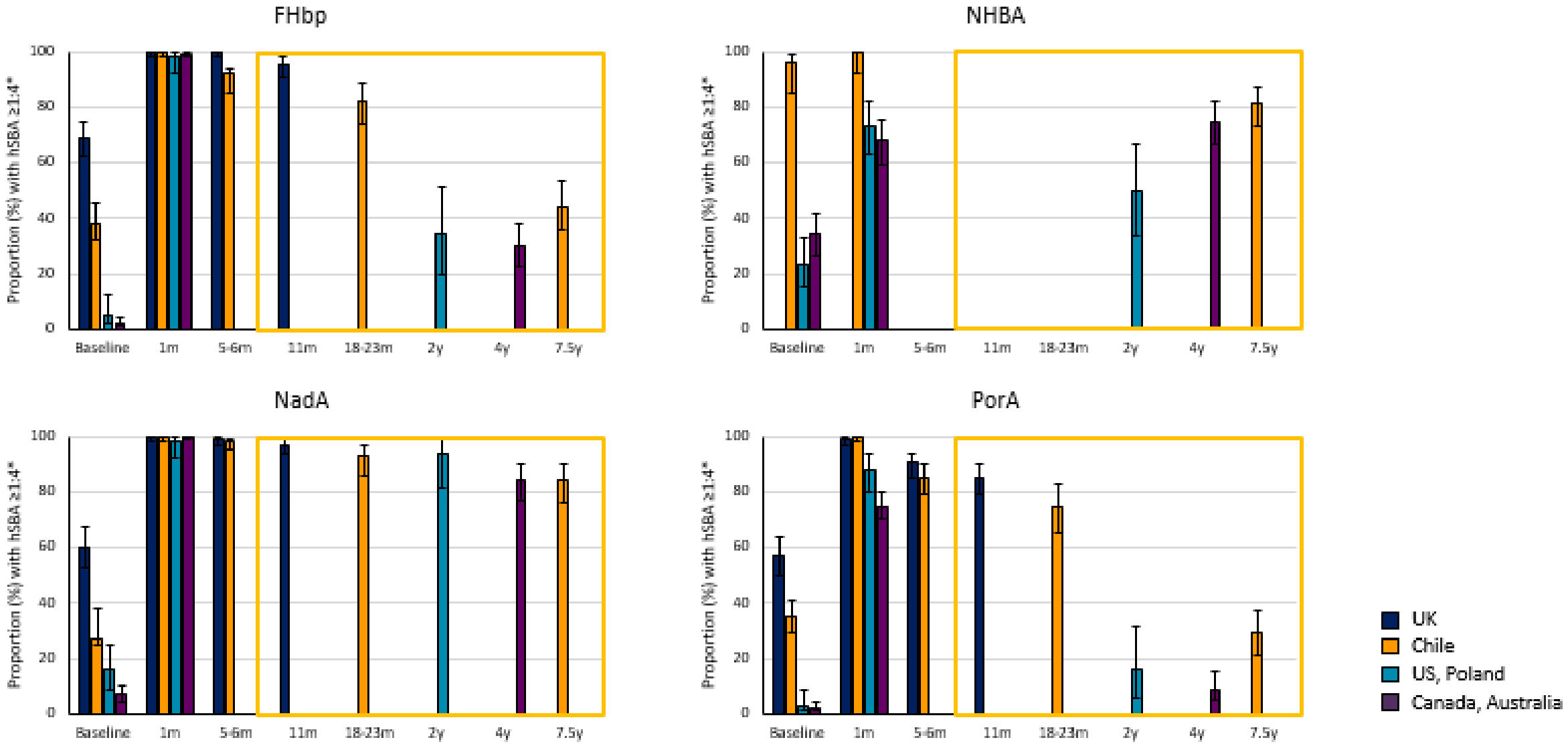

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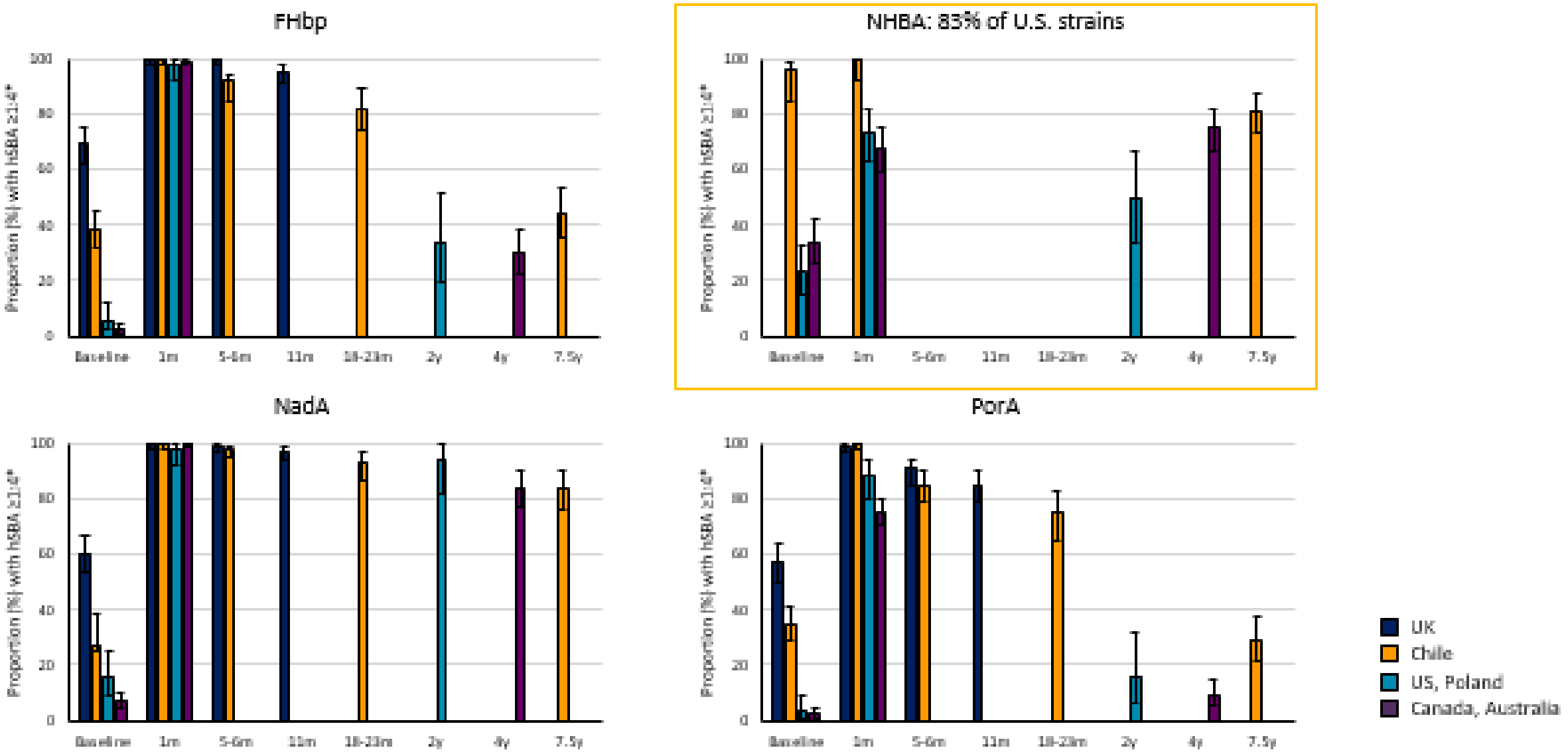

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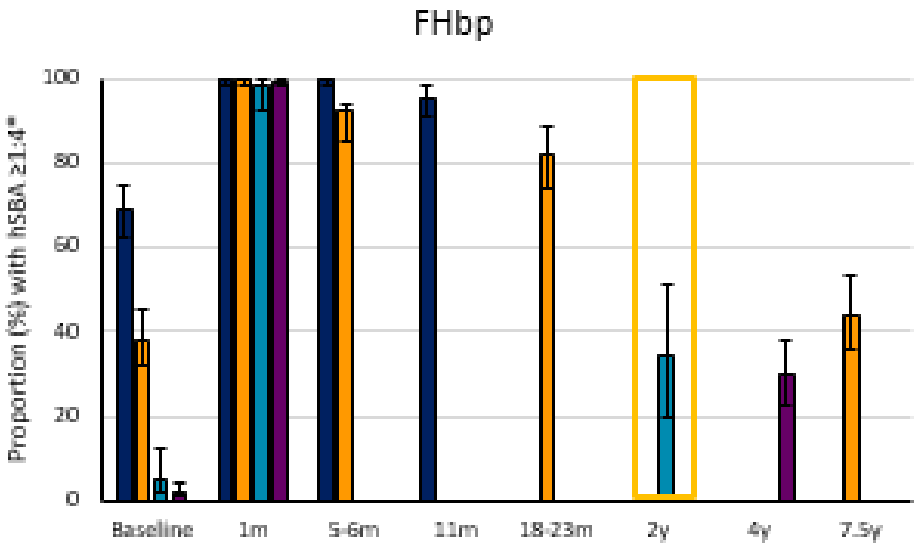
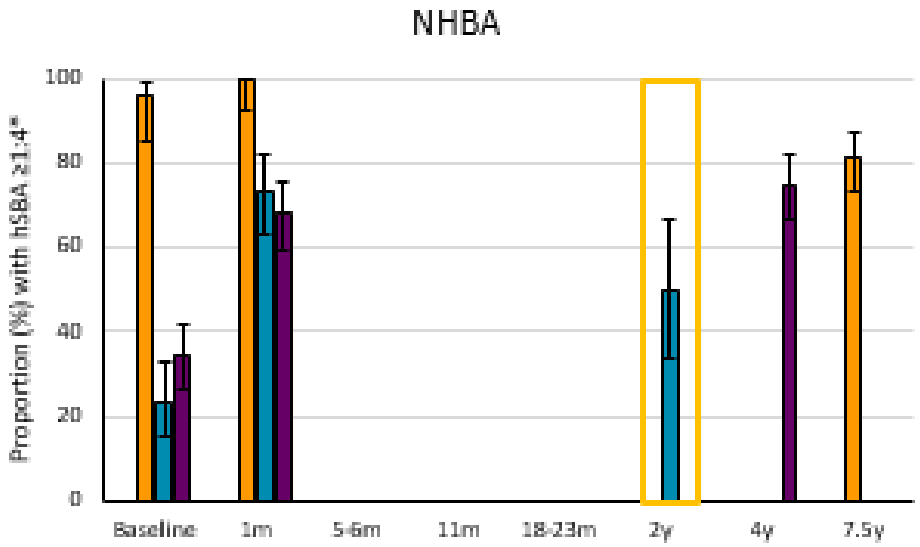
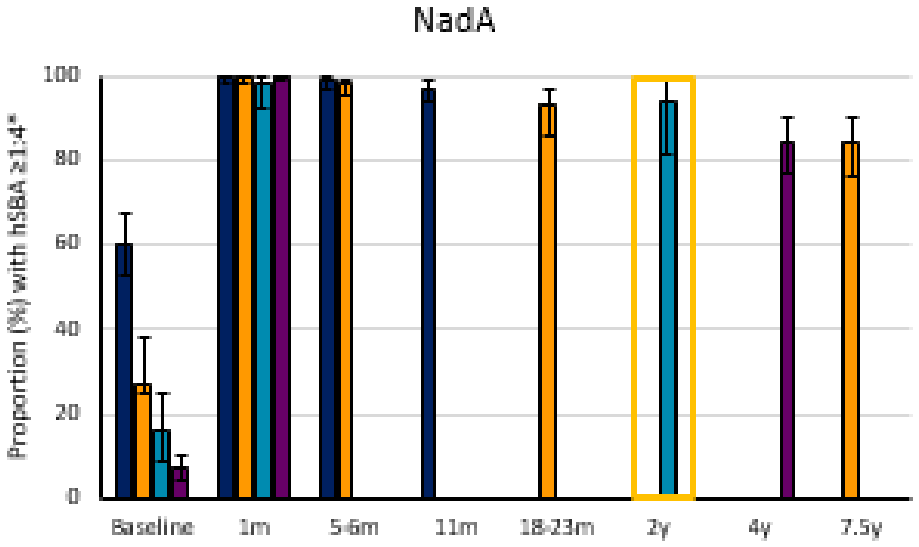
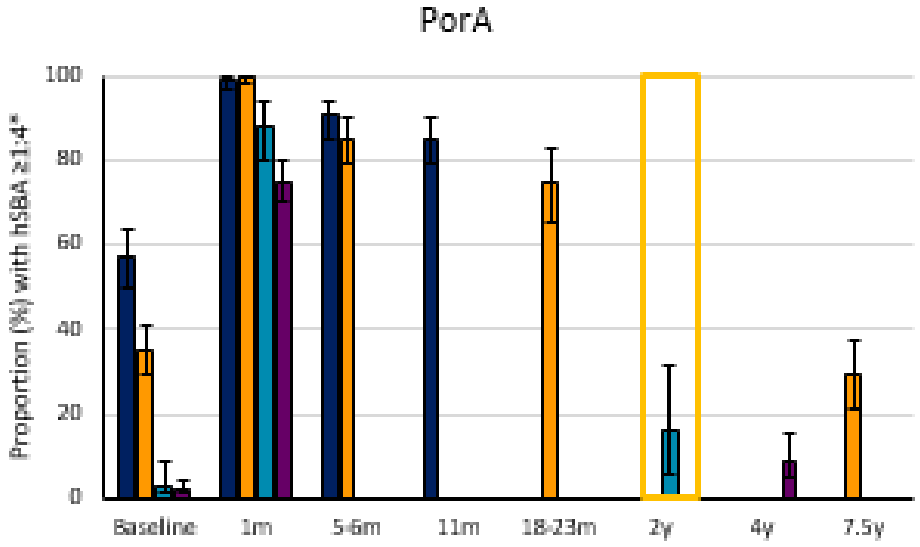




Work Group interpretation:

- Antibodies wane by 2 years following vaccination
- May wane earlier





UK
Chile
US, Poland
Canada, Australia

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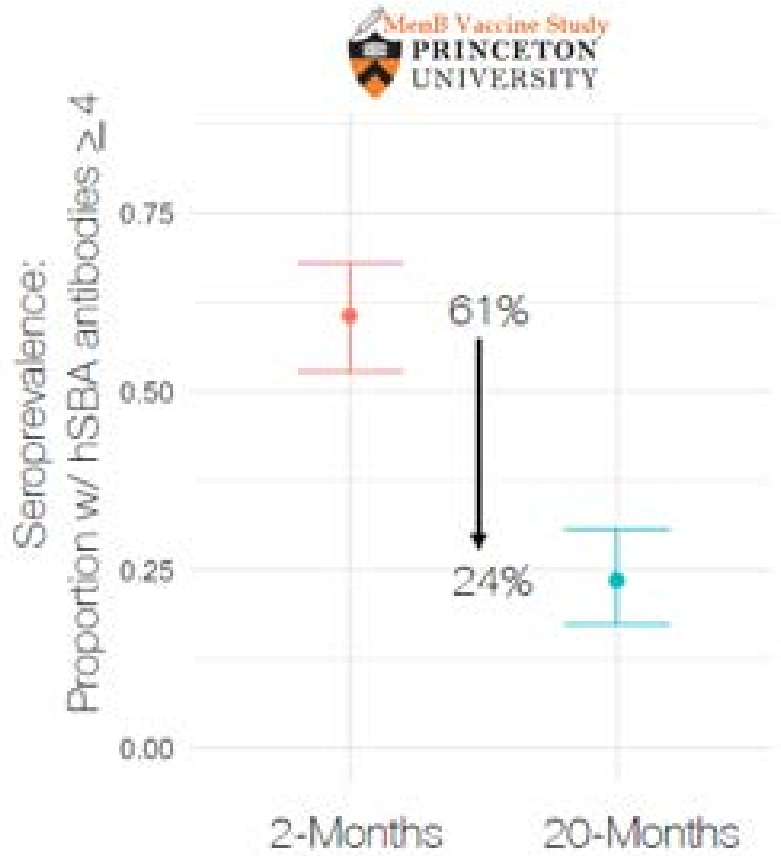
Persistence of MenB primary series against diverse serogroup B strains

- Short-term persistence of MenB primary vaccination against diverse serogroup B strains has been assessed in several observational studies.
  - Variable patterns of short-term persistence when measured up to 12 months post-vaccination.[1-4]

- Seroprevalence study at Princeton University: substantial antibody waning to outbreak strain by 20 months post-vaccination with MenB-4C.[5]



[1]Lujan, et al. Clin Vaccine Immunol. 2017; [2]Lujan, et al. Clin Infect Dis. 2017; [3]Giuntini et al, Clin Vaccine Immunol. 2017.
[4]Basta, et al International Pathogenic *Neisseria* Conference (2018); [5] Basta, et al. Congress of the European Meningococcal and Haemophilus Disease Society (2019).

Summary of Work Group interpretation for persistence of immune response following a MenB primary series

- Variable rate of waning observed between vaccine type and studies.

- Results from clinical trials cannot be directly compared between vaccine types.

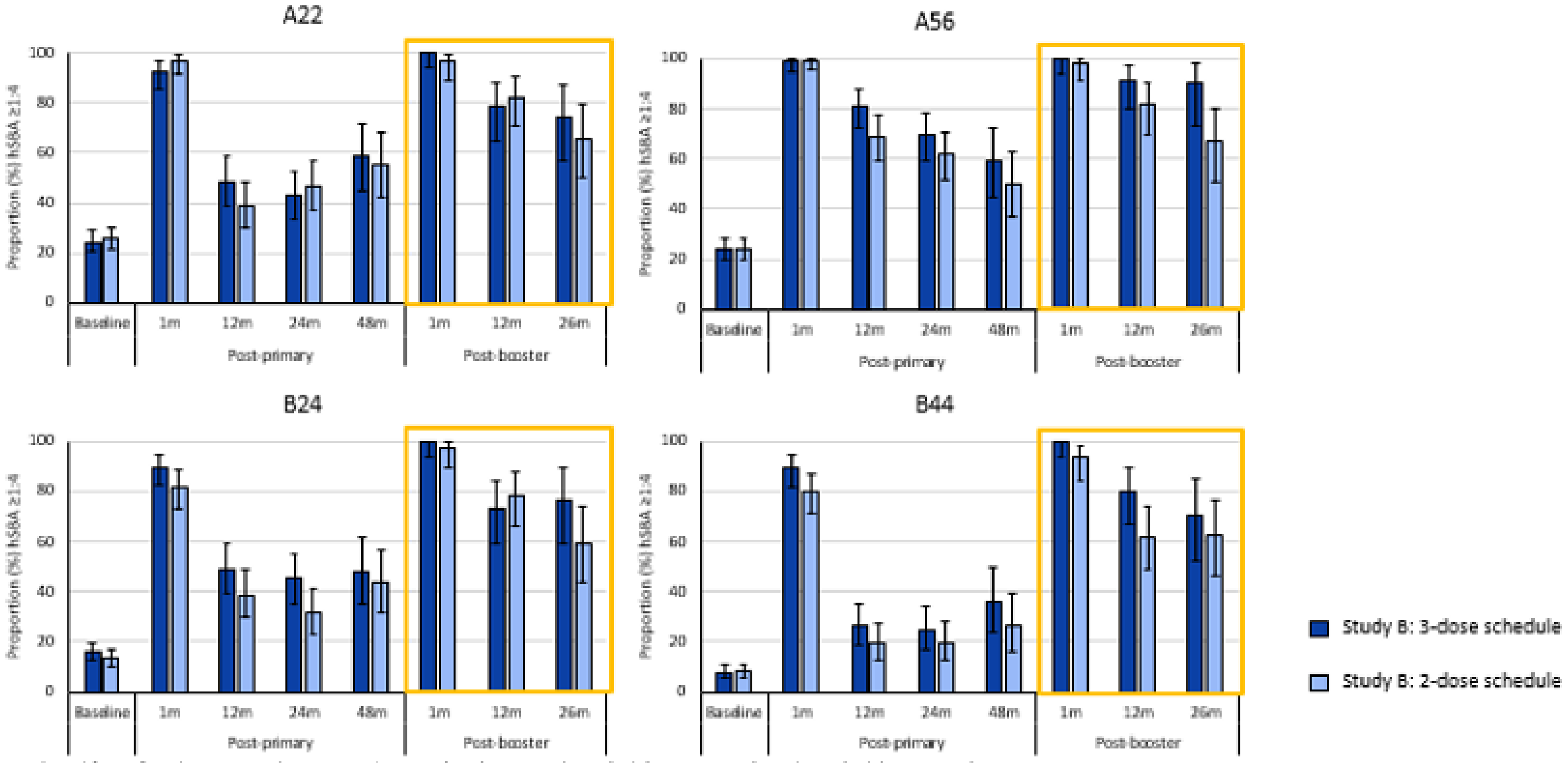
Summary of Work Group interpretation for persistence of immune response following a MenB primary series

- Variable rate of waning observed between vaccine type and studies.
- Results from clinical trials cannot be directly compared between vaccine types.

Work group interpretation: By 1–2 years following primary MenB vaccination, booster vaccination is indicated in persons who remain at increased risk.

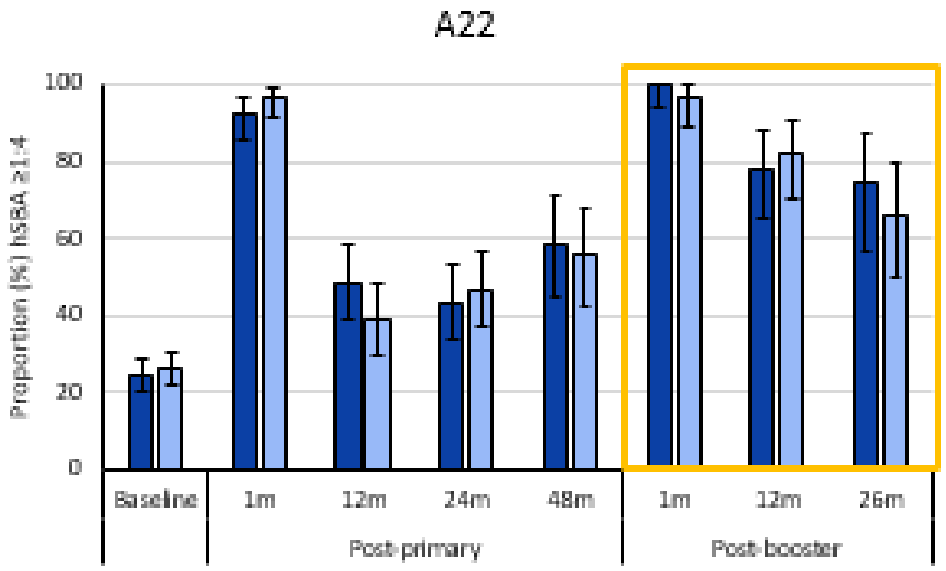
Immunogenicity and persistence of a MenB booster dose

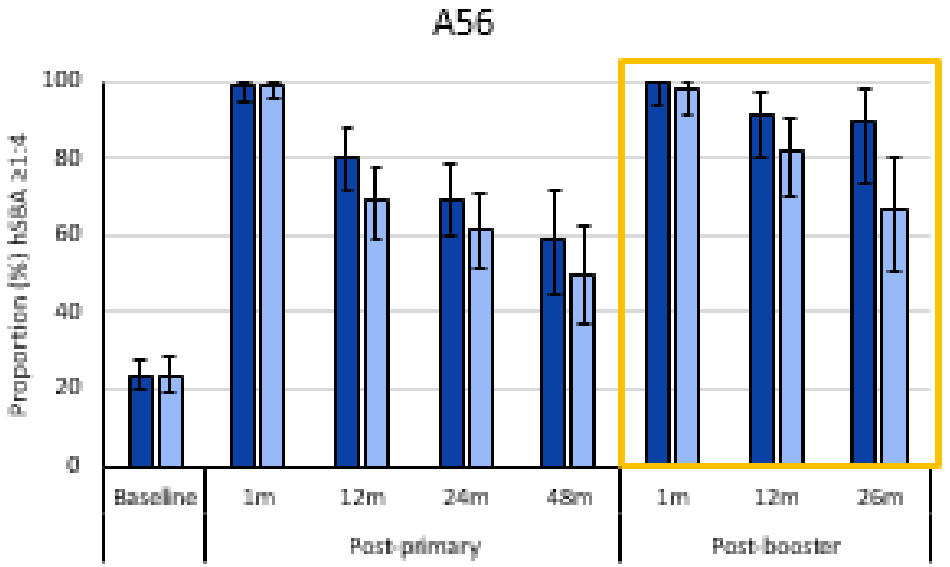
Immunogenicity and persistence of a MenB-FHbp booster dose in healthy adolescents

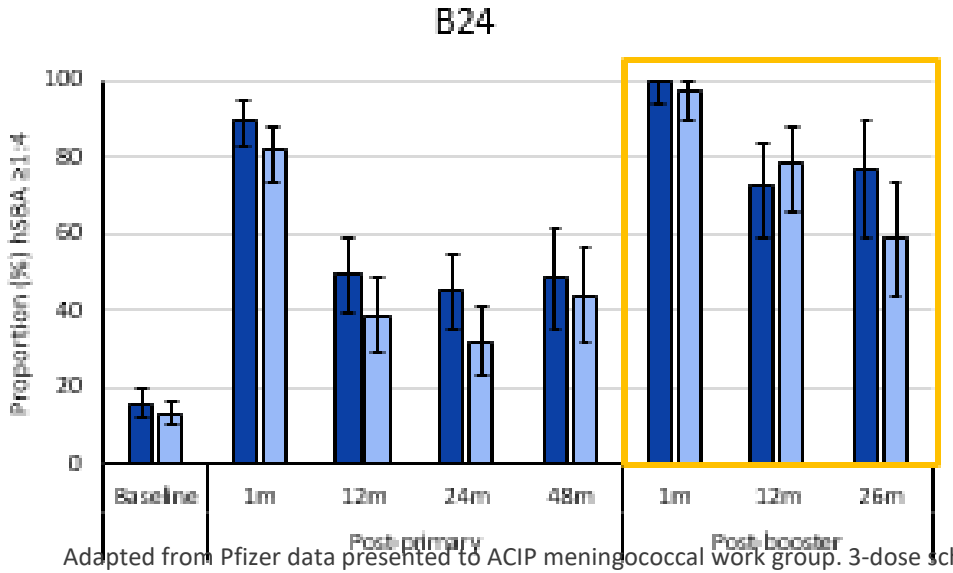


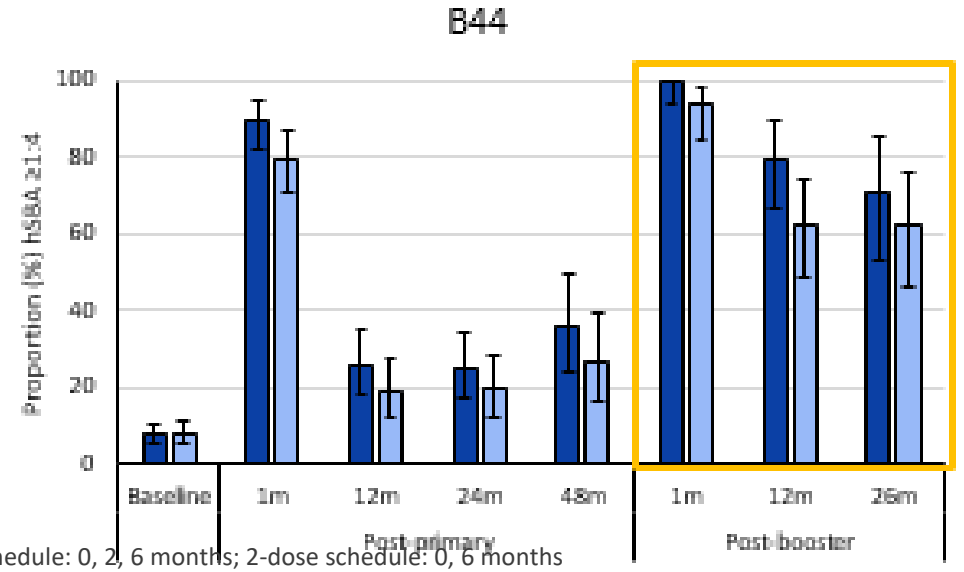
Adapted from Pfizer data presented to ACIP meningococcal work group. 3-dose schedule: 0, 2, 6 months; 2-dose schedule: 0, 6 months

Immunogenicity and persistence of a MenB-FHbp booster dose in healthy adolescents









Work Group interpretation:

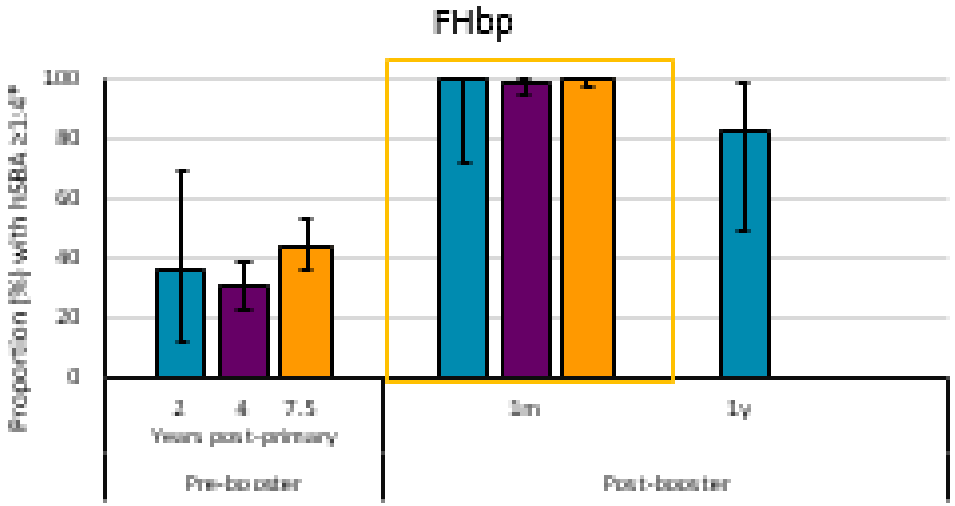
- Antibody persistence for at least 2 years (may be longer)

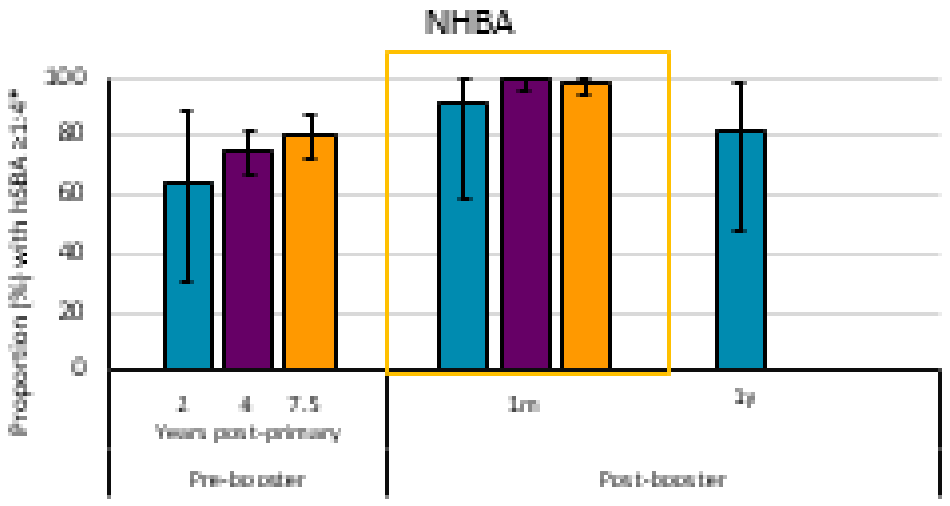
Study B: 3-dose schedule

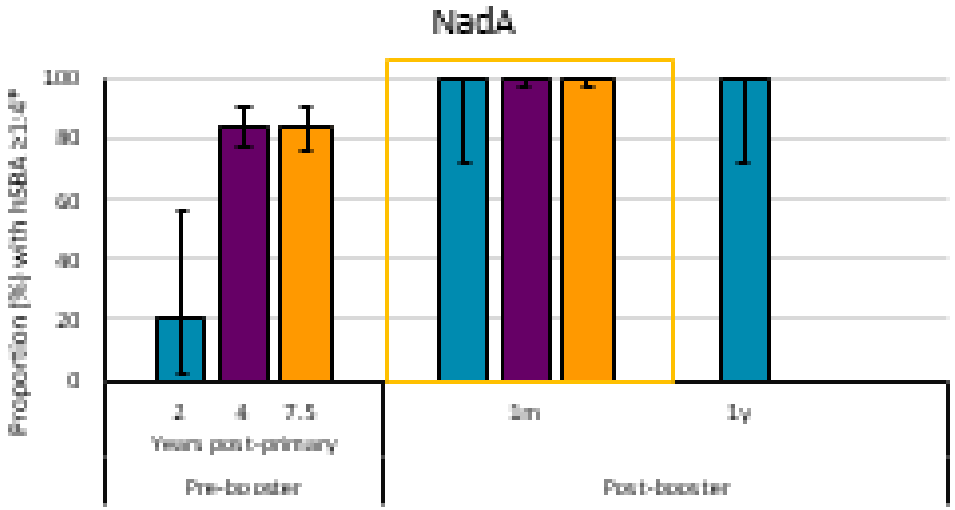
Study B: 2-dose schedule

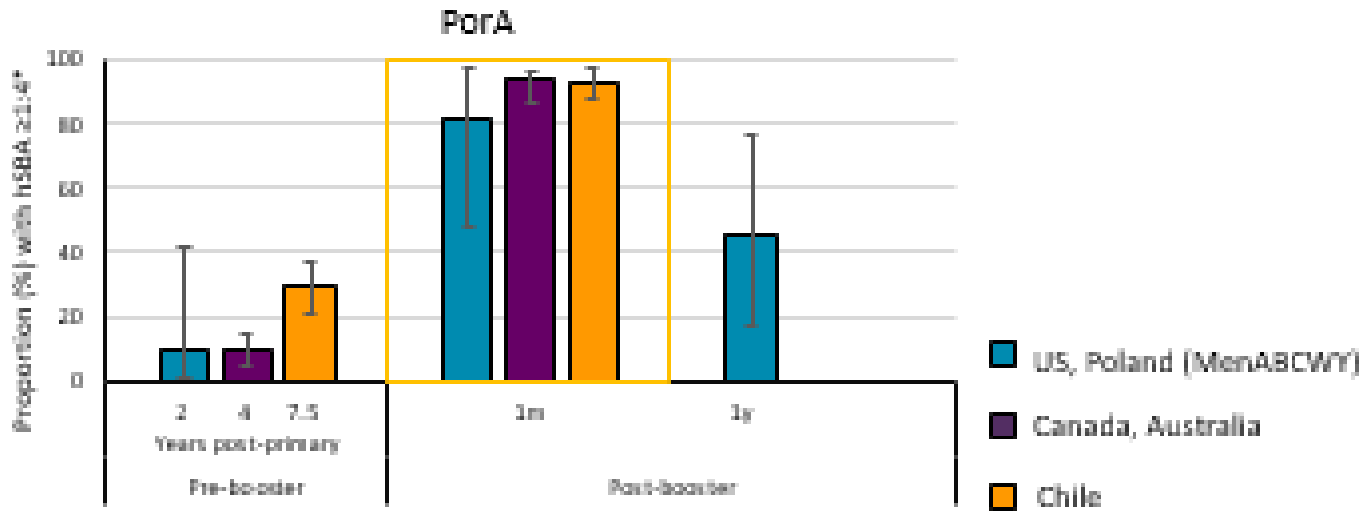
Adapted from Pfizer data presented to ACIP meningococcal work group. 3-dose schedule: 0, 2, 6 months; 2-dose schedule: 0, 6 months

Immunogenicity and persistence of a MenB-4C/MenABCWY booster dose in healthy adolescents and adults



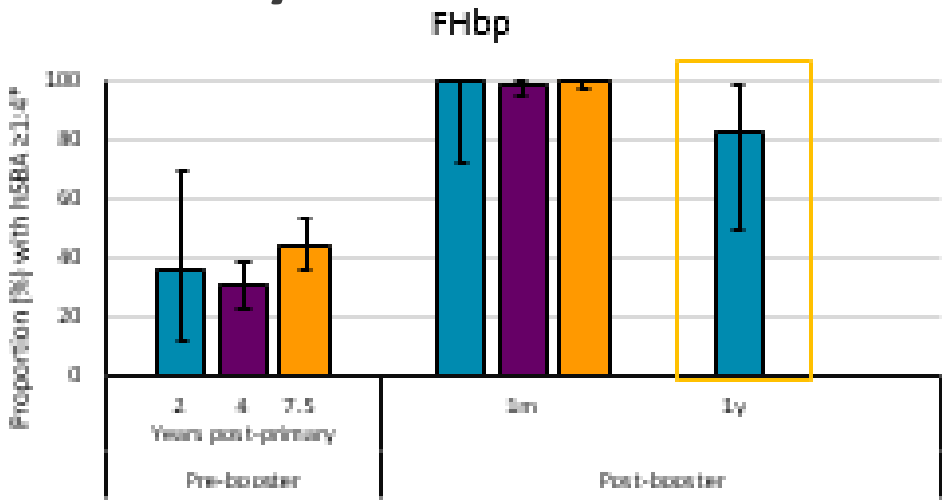


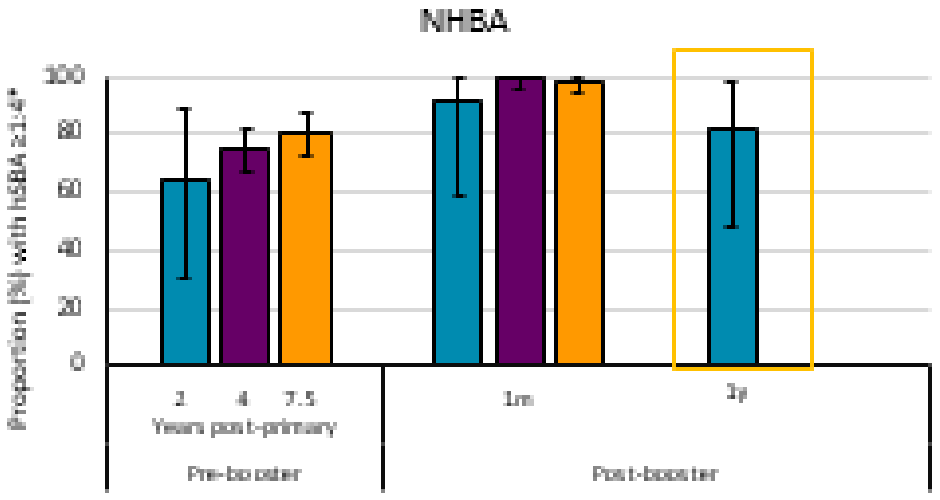


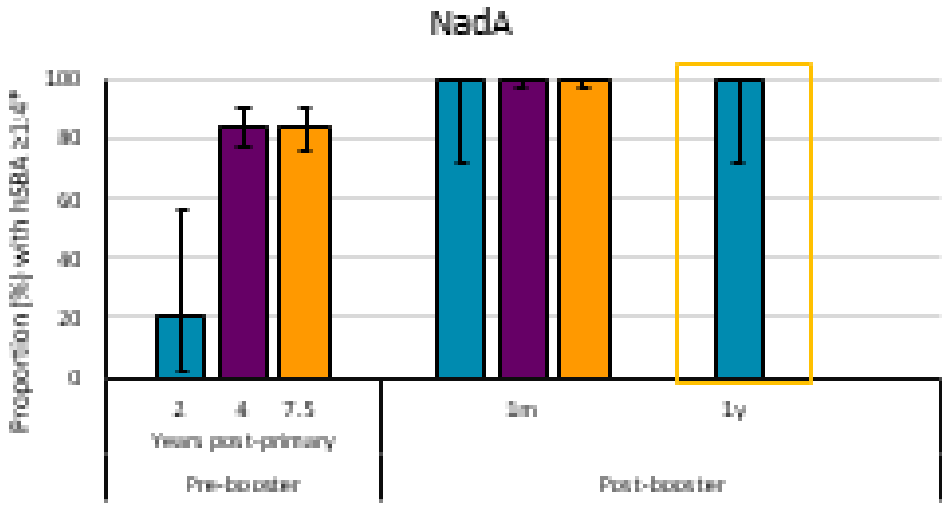


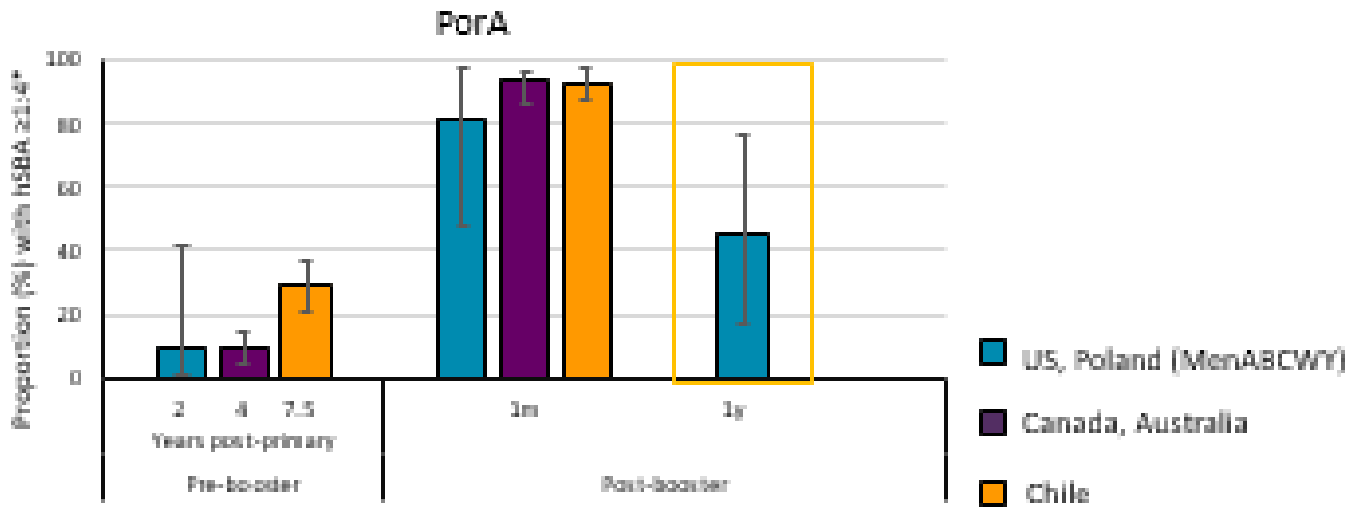
Adapted from Szenborn L, Pediatr Infect Dis J. 2018; Nolan T, Vaccine 2019; Watson PS, Expert Review of Vaccines 2019;
* hSBA titer of 1:5 used in US/Poland study.

Immunogenicity and persistence of a MenB-4C/MenABCWY booster dose in healthy adolescents and adults









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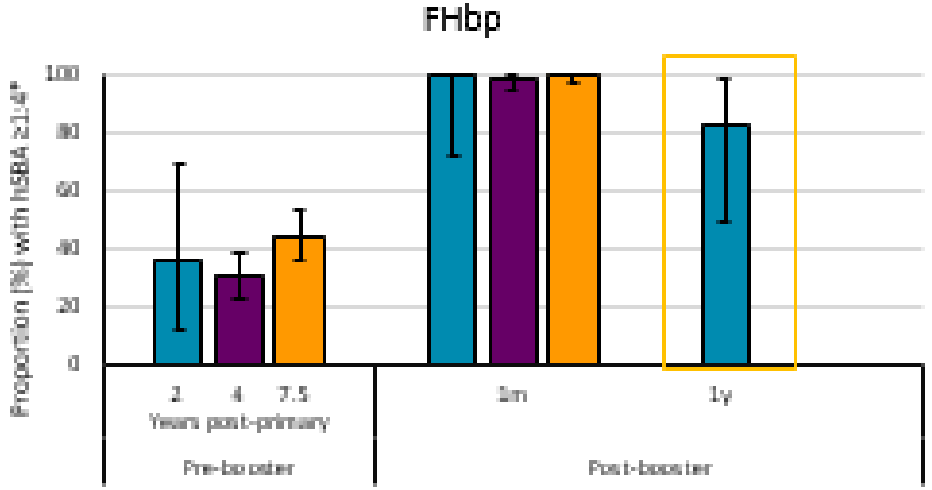
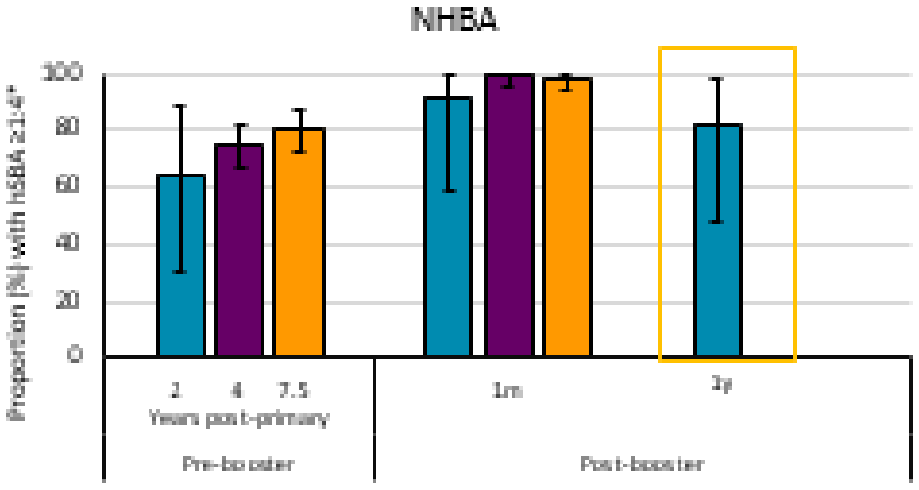
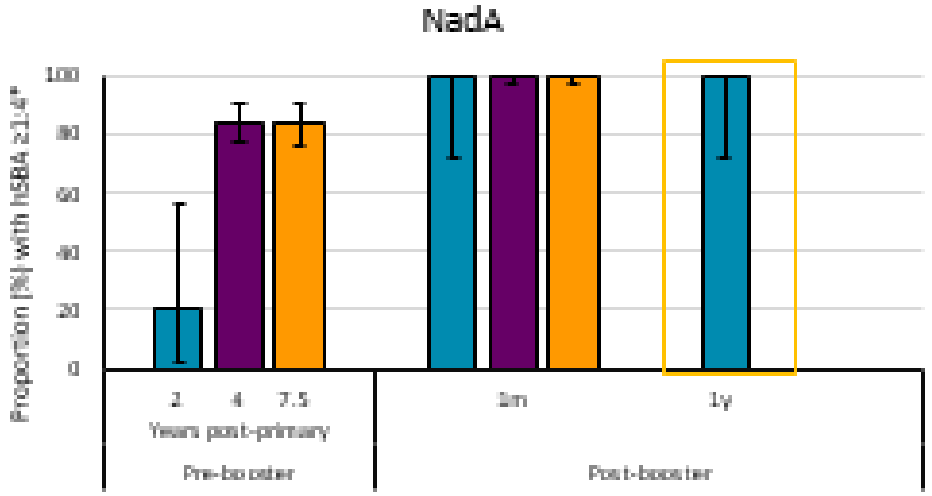
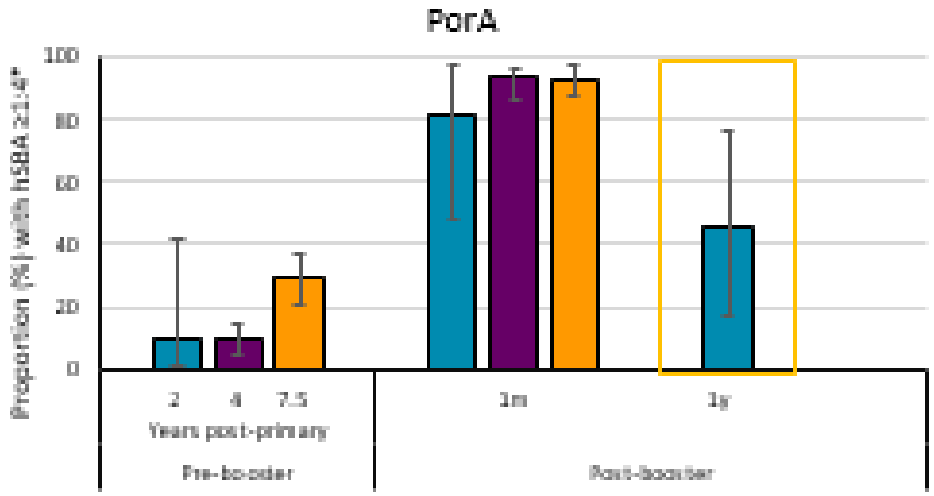




Work Group interpretation:

- MenABCWY persistence for ≥1 year
- Modelled data suggests MenB-4C persistence for several years





US, Poland (MenABCWY)

Canada, Australia

Chile

Adapted from Szenborn L, Pediatr Infect Dis J. 2018; Nolan T, Vaccine 2019; Watson PS, Expert Review of Vaccines 2019;
* hSBA titer of 1:5 used in US/Poland study.

Summary of Work Group interpretation for persistence of immune response following a MenB booster dose

- MenB booster elicits robust immune response; persistence appears to exceed that of a MenB primary series.

Summary of Work Group interpretation for persistence of immune response following a MenB booster dose

- MenB booster elicits robust immune response; persistence appears to exceed that of a MenB primary series.

Work group interpretation: Antibody persistence of a MenB booster dose is likely at least 2–3 years in healthy adolescents and adults.

Summary of GRADE and EtR for MenB booster doses in persons at increased risk for serogroup B meningococcal disease

	Policy question: Should persons vaccinated with a MenB primary series who remain at increased risk for serogroup B meningococcal disease receive a MenB booster dose?
Population	Persons aged ≥10 years who have previously completed a MenB-FHbp or MenB-4C primary series at increased risk for serogroup B meningococcal disease due to: • Persistent complement component deficiencies, complement inhibitor use, functional or anatomic asplenia, and microbiologists, *or* • An outbreak of serogroup B meningococcal disease
Intervention	MenB-FHbp or MenB-4C booster dose
Comparison	No MenB-FHbp or MenB-4C booster dose
Outcome	• **MenB booster vaccine effectiveness against serogroup B meningococcal disease** • **Short-term immunogenicity of booster dose** • Persistence of immune response to booster dose • Immune interference due to co-administration of booster dose with other vaccines • **Serious adverse events from booster dose**

Bold font indicates outcomes considered by the WG "Critical" for GRADE analysis

Persons at increased risk due to underlying conditions or microbiologists

GRADE Summary of evidence

MenB vaccine	Evidence type across outcomes	Certainty of evidence
MenB-FHbp	4	Very low
MenB-4C	4	Very low

Evidence to recommendations framework: Key considerations

- Small group (<0.1% of U.S. population) at substantially increased risk.
- Persons with complement deficiency or complement inhibitor use have reduced MenB immunogenicity and may be at risk despite vaccination.[1-3]
- MenB primary series safety demonstrated in several large evaluations in healthy persons. [4-7]
  - Booster doses (included repeated doses) not assessed in persons with underlying conditions.
- Survey: majority of pediatricians and family physicians would recommend MenB primary series for children aged ≥10 years at increased risk, though disparity by provider type.[8]
- No data on cost-effectiveness.

[1]Martinon-Torres et al., Pediatrics, 2018; [2]FDA. Trumenba package insert; [3]FDA. Bexsero package insert. [4]Nolan et al, Vaccine, 2015; [5]Perez et al., Expert Review of Vaccines, 2018; [6]Fiorito et al., Pediatric Infectious Disease Journal, 2018; [7]Institut National de Sante Publique du Quebec: https://www.inspq.qc.ca/pdf/publications/1902_SerogroupB_Meningococcal_Vaccine.pdf; [8]Kempe, et al. Pediatrics. 2018;

Evidence to recommendations framework for MenB booster doses

Criteria	Question	Work Group Interpretation
Problem	• Is the problem of public health importance?	Yes
Benefits and Harms	• How substantial are the desirable anticipated effects? • How substantial are the undesirable anticipated effects? • Do the desirable effects outweigh the undesirable effects? • What is the overall certainty of the evidence for the critical outcomes?	Varies Minimal Favors intervention Very low
Values and preferences	• Does the target population feel that the desirable effects are large relative to undesirable effects? • Is there important uncertainty about or variability in how much people value the main outcomes?	Uncertain Yes
Acceptability	• Is the intervention acceptable to key stakeholders?	Probably yes
Resource Use	• Is the intervention a reasonable and efficient allocation of resources?	Uncertain
Feasibility	• Is the intervention feasible to implement?	Uncertain

Proposed recommendation

Group	Work Group's proposed recommendation
Persons with persistent complement component deficiencies, complement inhibitor use, functional or anatomic asplenia, and microbiologists	We favor the intervention

Persons at increased risk due to a serogroup B meningococcal disease outbreak

GRADE Summary of evidence

MenB vaccine	Evidence type across outcomes	Certainty of evidence
MenB-FHbp	4	Very low
MenB-4C	3 or 4	Low

Evidence to recommendations framework: key considerations

- 7% of serogroup B cases in the United States are outbreak-related.[1]
  - College students disproportionately affected.
- Limited data are available on MenB vaccine effectiveness and duration of protection.
  - Quebec: MenB-4C 79% (95% CI: -231 to 99%) effective in persons age <20 years up to 4 years.[2]
- Evidence suggests no impact of MenB on meningococcal carriage; herd immunity unlikely.[3,4]
- Evaluations following mass vaccination campaigns during outbreaks have demonstrated the safety of MenB primary series.[5-8]

[1]Mbaeyi, et al. Clin Infect Dis 2018; [2]Institut National de Sante Publique du Quebec https://www.inspq.qc.ca/sites/default/files/publications/2491_impact_vaccination_meningocoque_serogroupe_b.pdf;
[3]Soeters et al., CID, 2017; [4] McNamara et al., JID, 2017; [5]Duffy, et al. J Am Coll Health. 2017; [6]Fiorito, et al. Pediatr Infect Dis J. 2018; [7]Langley, et al. Vaccine, 2016. [8]De Serres, et al. Vaccine. 2018;

Evidence to recommendations framework: Key considerations for college outbreaks

- All 13 universities that experienced outbreaks during 2013–2019 implemented a MenB primary series, though coverage with ≥1 dose varied widely.[1]
  - 1 university to-date has implemented a booster dose
- MenB mass vaccination during college outbreaks is resource intensive, though estimated to be more cost-effective than universal vaccination of students at college entry.[2-3]
- Outbreaks require intensive coordination, significant human resources, and action among multiple stakeholders to efficiently respond within a short time.[4-7]
- Booster dose implementation at a New Jersey university:
  - Additional communication/logistical challenges related in part to lack of ACIP recommendation
  - Challenges in determining booster eligibility (e.g., if primary series completed and which product)

[1]Soeters, et al. Congress of the European Meningococcal and Haemophilus Society. 2019; [2]Fisher, et al. J Adol Health, 2018; [3]Leeds et al., Am J Prev Med, 2018; [4]Capitano et al., Hum Vacc and Imm, 2018; [5]Ritscher et al., J Am Coll Health, 2018; [6]Fiorito et al., J Am Coll Health, 2017; [7]Fisher et al., J Adol Health, 2018;

Evidence to recommendations framework for MenB booster doses

Criteria	Question	Work Group Interpretation
Problem	• Is the problem of public health importance?	Yes
Benefits and Harms	• How substantial are the desirable anticipated effects? • How substantial are the undesirable anticipated effects? • Do the desirable effects outweigh the undesirable effects? • What is the overall certainty of the evidence for the critical outcomes?	Large Minimal Favors intervention Very low
Values and preferences	• Does the target population feel that the desirable effects are large relative to undesirable effects? • Is there important uncertainty about or variability in how much people value the main outcomes?	Yes Probably yes
Acceptability	• Is the intervention acceptable to key stakeholders?	Yes
Resource Use	• Is the intervention a reasonable and efficient allocation of resources?	Yes
Feasibility	• Is the intervention feasible to implement?	Yes

Proposed recommendation

Group	Work Group's proposed recommendation
Persons at risk during a serogroup B outbreak	We favor the intervention

Summary of Work Group deliberations for MenB booster policy options in persons at increased risk for serogroup B meningococcal disease

Summary of Work Group deliberations for MenB booster doses

- The Work Group reviewed data on:
  - Persistence of the immune response following a MenB primary series
  - Immunogenicity, persistence, and safety of a MenB booster dose
  - Results of GRADE and EtR evaluations

- The majority of Work Group members agreed upon the need for and timing of MenB booster doses.
  - A small minority felt there was insufficient evidence on safety and efficacy of MenB booster doses to inform policy options.

- The following slides represent the views of the majority of work group members.

Work Group interpretation: Need for and timing of MenB booster doses

- MenB booster vaccination is necessary to sustain protection against serogroup B meningococcal disease in persons who remain at increased risk.

- MenB booster dose is indicated at 1 year following completion of the primary series.
  - Greater persistence is expected after the booster dose, and thus, a longer interval for repeat booster doses may be considered.

- Given the serious nature of meningococcal disease, potential benefits of MenB booster vaccination outweigh risks in persons at increased risk.

- Although implementation challenges are anticipated, potential benefits of booster vaccination justify the additional implementation efforts that will be needed.

Policy proposal for MenB booster doses in persons at increased risk

- Proposal: ACIP recommends MenB booster vaccination in persons aged ≥10 years at increased risk for serogroup B meningococcal disease who previously completed a MenB primary series.

- This recommendation does not apply to persons who previously completed a MenB primary series as an adolescent based on individual clinical decision-making and who are not at increased risk for serogroup B meningococcal disease.

Policy proposal for MenB booster doses in persons at increased risk

Group	Policy proposal
Persons with complement deficiency, complement inhibitor use, asplenia, or microbiologists	• MenB booster dose 1 year following completion of a MenB primary series, followed by MenB booster doses every 2-3 years thereafter, for as long as increased risk remains.
Persons determined by public health officials to be at increased risk during an outbreak	• One-time MenB booster dose is recommended if it has been ≥1 year since completion of a MenB primary series. • A booster dose interval of ≥6 months may be considered by public health officials depending on the specific outbreak, vaccination strategy, and projected duration of elevated risk.

* MenB vaccines are not interchangeable. The same vaccine product must be used for all doses, including booster doses

Today’s vote

- ACIP will vote on the policy proposal for MenB booster doses in persons at increased risk for serogroup B meningococcal disease.

- Does ACIP have feedback on the Work Group’s policy proposal for MenB booster doses?

Policy proposal for MenB booster doses in persons at increased risk

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Persons with complement deficiency, complement inhibitor use, asplenia, or microbiologists	• MenB booster dose 1 year following completion of a MenB primary series, followed by MenB booster doses every 2-3 years thereafter, for as long as increased risk remains.
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* MenB vaccines are not interchangeable. The same vaccine product must be used for all doses, including booster doses.

Vote #1

- ACIP recommends MenB booster vaccination in persons aged ≥10 years at increased risk for serogroup B meningococcal disease who previously completed a MenB primary series.