Serogroup B Meningococcal Vaccine Booster Doses

Sarah Mbaeyi, MD, MPH
CDC Lead, ACIP Meningococcal Vaccines Work Group
June 27, 2019
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
  - Amputations
  - 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

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<th>Persons aged ≥10 years at increased risk for serogroup B meningococcal disease</th>
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2. Estimated prevalence in all ages of 0.03% (Densen R. Clin Exp Immunol. 1991) though many may be undiagnosed.  
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).  
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<td>120-fold&lt;sup&gt;6&lt;/sup&gt;</td>
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<td>&gt;80,000(^5)</td>
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<td>100,000(^7)</td>
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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

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<td></td>
<td>• Median 83-fold overall</td>
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<td></td>
<td>• 165-fold during college outbreaks (higher in freshmen, on-campus residents, and Greek life students)</td>
<td>35,000 college students annually</td>
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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

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

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
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Work Group interpretation:
- Antibodies wane by 12 months post-vaccination
- Then remain stable for up to 4 years
Clinical trials: Immunogenicity and persistence of MenB-4C primary series in healthy adolescents and adults

Adapted from Read RC, Vaccine 2017; Block SL, Vaccine 2015; Szenborn L, Pediatr Infect Dis J. 2018; Perrett KP, Vaccine 2015; Nolan T, Vaccine 2019; Santolaya ME, Lancet 2012; Watson PS, Expert Review of Vaccines 2019, and results on clinicaltrials.gov; * hSBA titer of 1:5 used in US/Poland study.
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Work Group interpretation:
- Antibodies wane by 2 years following vaccination
- May wane earlier
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.\(^5\)
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

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

Work Group interpretation:
- Antibody persistence for at least 2 years (may be longer)
Immunogenicity and persistence of a MenB-4C/MenAB CWY 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;
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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

<table>
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<tr>
<th>MenB vaccine</th>
<th>Evidence type across outcomes</th>
<th>Certainty of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>MenB-FHbp</td>
<td>4</td>
<td>Very low</td>
</tr>
<tr>
<td>MenB-4C</td>
<td>4</td>
<td>Very low</td>
</tr>
</tbody>
</table>
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.

## Evidence to recommendations framework for MenB booster doses

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

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<td>We favor the intervention</td>
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Persons at increased risk due to a serogroup B meningococcal disease outbreak
## GRADE Summary of evidence

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<td>3 or 4</td>
<td>Low</td>
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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.\(^5-8\)

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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)

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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

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<td>• One-time MenB booster dose is recommended if it has been ≥1 year since completion of a MenB primary series. &lt;br&gt;• 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.</td>
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* 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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* 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.