

Meningococcal Vaccines Work Group Update

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Serogroup B Meningococcal (MenB) Vaccines

- ❑ Two MenB vaccines are licensed in the United States and approved for use in persons 10–25 years of age
 - MenB-FHbp (Trumenba[®], Pfizer) licensed on October 29, 2014
 - MenB-4C (Bexsero[®], Novartis) licensed on January 23, 2015
- ❑ Both vaccines were licensed under an accelerated pathway
- ❑ MenB vaccines are distinct from MenACWY conjugate vaccines because protection is based on developing immunity to bacterial proteins rather than capsular polysaccharides

Recent Presentations to ACIP

□ February and June 2014

- Epidemiology of meningococcal disease outbreaks and outbreaks of serogroup B meningococcal disease on university campuses
- Interim guidance for the use of a MenB vaccine under a CDC-sponsored expanded access IND

□ October 2014

- Safety and immunogenicity for MenB-FHbp and MenB-4C
- Epidemiology of serogroup B meningococcal disease in the US
- Considerations for use of MenB vaccines in the US

□ February 2015

- Considerations for use of MenB vaccines in persons at increased risk: discussion and vote

ACIP Recommendations for Use of MenB Vaccine in Persons at Increased Risk

- A serogroup B meningococcal (MenB) vaccine series should be administered to persons aged ≥ 10 years at increased risk for meningococcal disease. (Category A) This includes:

- Persons with persistent complement component deficiencies¹
- Persons with anatomic or functional asplenia²
- Microbiologists routinely exposed to isolates of *Neisseria meningitidis*
- Persons identified to be at increased risk because of a serogroup B meningococcal disease outbreak

¹Including inherited or chronic deficiencies in C3, C5-9, properdin, factor D, factor H, or taking eculizumab (Soliris®)

²Including sickle cell disease

ACIP Meningococcal Vaccine Work Group Activities

- **Policy Note: Use of MenB Vaccines in Persons Aged ≥ 10 Years at Increased Risk for Serogroup B Meningococcal Disease**
 - Published June 12, 2015
- **Review of available safety, immunogenicity and epidemiologic data and discussion about policy options for broader use of MenB vaccines in adolescents and college students**

Policy Options for Broader Use of MenB Vaccines

□ Administration of a MenB series at:

- 11–12 years, booster (anticipated) @ 16 years
- 16 years
- 18 years
- College students only

□ Recommendation type:

- Category A (for all persons in an age- or risk-factor-based group)
- Category B (for individual clinical decision making)
- No recommendation

Today's Session

- ❑ **GRADE: Evidence for use of MenB vaccines in adolescents and college students (Temi Folaranmi, CDC)**
- ❑ **Considerations for routine use of MenB vaccines in adolescents (Jessica MacNeil, CDC)**
- ❑ **Public comment**
- ❑ **Proposed policy option language and vote**
- ❑ **VFC vote**

MenB Vaccines: Challenges for ACIP

- ❑ Goal is to prevent the largest proportion of cases of meningococcal disease possible
- ❑ The recently licensed MenB vaccines are an important step forward
- ❑ However, complete data for making policy decisions for vaccine use are not currently available
 - Effectiveness, strain coverage in U.S., duration of protection, carriage & herd immunity, safety
- ❑ Burden of serogroup B meningococcal disease in adolescents & young adults is currently low

Thank You

National Center for Immunization and Respiratory Diseases
Division of Bacterial Diseases

