

Meningococcal Vaccines Work Group Update

Lorry Rubin, M.D.
Chair, Meningococcal Work Group
Advisory Committee on Immunization Practices
June 22, 2016

Work Group Members

ACIP Members

Lorry Rubin (Chair)
Kathleen Harriman
Lee Harrison
Kelly Moore
David Stephens

***Ex Officio* Members**

Lucia Lee (FDA)
Anuja Rastogi (FDA)
Margaret Yacovone (DOD)

CDC Work Group Lead

Jessica MacNeil (CDC/NCIRD)

Liaison and Other Representatives

Carol Baker (IDSA)
Susan Even (ACHA)
Rachel Herlihy (IAC)
Nneka Holder (SAHM)
Martin Luta (CSTE)
Ruth Lynfield (AAP)
Paul McKinney (APTR)
Jeffrey Moore (AAFP)
William Schaffner (NFID)
Bill Atkinson
Mike Brady
Doug Campos-Outcalt
Richard Clover
Mary Healy
Cody Meissner
Paul Offit
Georges Peter

Revised Dosing Schedule for MenB-FHbp (Trumenba®, Pfizer Vaccines)

- **Approved by FDA on April 14, 2016**

- **Section 2: Dosage and Administration**

 - 2.1 Dose and Schedule

 - Three-dose schedule:** Administer a dose (0.5 mL) at 0, 1-2, and 6 months

 - Two-dose schedule:** Administer a dose (0.5 mL) at 0 and 6 months

The choice and dosing schedule may depend on the risk of exposure and the patient's susceptibility to meningococcal serogroup B disease

Today's Session

- **Updates to MenB-FHbp dosing schedule**
 - Discussion on potential policy options for 2-dose and 3-dose schedules
 - No vote planned

- **Use of MenACWY vaccines in HIV-infected persons**
 - Previous discussion at February 2016 meeting
 - Anticipate ACIP and VFC votes during this session

Policy Options

- ❑ **Human Immunodeficiency Virus (HIV)-infected persons aged ≥ 2 months should routinely receive MenACWY vaccine* (Category A)**
OR
- ❑ **Human Immunodeficiency Virus (HIV)-infected persons aged ≥ 11 years should routinely receive MenACWY vaccine** (Category A)**

*Includes MenACWY-D (Menactra®), MenACWY-CRM (Menveo®), and Hib-MenCY-TT (MenHibrix®)

**Includes MenACWY-D (Menactra®) and MenACWY-CRM (Menveo®)

Policy Options

- **Human Immunodeficiency Virus (HIV)-infected persons aged ≥ 2 months should routinely receive MenACWY vaccine* (Category A)**

OR

- **Human Immunodeficiency Virus (HIV)-infected persons aged ≥ 11 years should routinely receive MenACWY vaccine** (Category A)**
 - Majority of Work Group members support vaccinating HIV-infected persons aged ≥ 2 months
 - Cost-effectiveness analysis and GRADE based on vaccinating HIV-infected persons aged ≥ 2 months

*Includes MenACWY-D (Menactra®), MenACWY-CRM (Menveo®), and Hib-MenCY-TT (MenHibrix®)

**Includes MenACWY-D (Menactra®) and MenACWY-CRM (Menveo®)

Agenda

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| 1. Update: Trumenba® Label | Laura York, Pfizer Vaccines |
| 2. Summary of WG Discussion: Trumenba® Label | Jessica MacNeil, CDC |
| 3. Cost-effectiveness of MenACWY in HIV-Infected Persons | Ismael Ortega-Sanchez, CDC |
| 4. GRADE for MenACWY in HIV-Infected Persons | Monica Patton, CDC |
| 5. Considerations for Use of MenACWY in HIV-Infected Persons | Jessica MacNeil, CDC |
| • Proposed Recommendations/Vote | Jessica MacNeil, CDC |
| • VFC Vote | Jeanne Santoli, CDC |
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Proposed Timeline

□ October 2016

- Vote on MenB-FHbp 2-dose and 3-dose schedules
- Informational session:
 - Revised meningococcal disease outbreak guidelines
 - Independent evaluation of hSBA data for MenB-FHbp and MenB-4C against several U.S. outbreak strains
 - Impact of MenB-FHbp on carriage among U.S. college students

□ February or June 2017

- Begin discussion of MenB boosters for persons at increased risk