



Introduction to ACIP's Combination Vaccine Work Group

Kelly Moore, MD, MPH

Chair, Combination Vaccines Work Group

Advisory Committee on Immunization Practices

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Work Group Members

ACIP Members

- Kelly Moore (Chair)
- Veronica McNally

***Ex Officio* Members**

- Ann Schwartz (FDA)
- Jillian Doss-Walker (IHS)
- Tom Weiser (IHS)

Liaison Representatives

- Sarah McQueen (AAPA)
- Jennifer Hamilton (AAFP)
- Patsy Stinchfield (NAPNAP)
- Sean O'Leary (AAP)
- Elizabeth Rausch-Phung (AIM)
- Phil Griffin (AIM)

CDC Contributors

- Sara Oliver (CDC Work Group Lead, *Haemophilus influenzae* SME)
- Fiona Havers (Pertussis SME)
- Anna Acosta (Diphtheria/Tetanus SME)
- Janell Routh (Polio SME)
- Sarah Schillie (Hepatitis SME)
- Tamara Pilishvili (*Streptococcus pneumoniae* SME)
- Cindy Weinbaum (Immunization Services Division)
- Pedro Moro (Immunization Safety Office)
- Mike Bruce (AI/AN SME)
- Rosalyn Singleton (AI/AN SME)

Pediatric hexavalent vaccine

- Joint venture with Merck and Sanofi Pasteur
 - Diphtheria, tetanus, pertussis (DTaP5)
 - Polio (IPV)
 - *Haemophilus influenzae* type b (Hib; PRP-OMP)
 - Hepatitis B (Hep B)
- Given in a 3-dose series (2, 4, 6 months)
- Biologics License Application (BLA) was accepted by FDA for review in October 2015, and was approved and licensed by the FDA on December 21, 2018

Policy Topics Under Consideration

- Consider if the new pediatric hexavalent vaccine should be included as an option in the Vaccines for Children (VFC) Program for the infant series at 2, 4, and 6 months of age
- Consider if the new pediatric hexavalent vaccine should be preferentially recommended for the American Indian/Alaskan Native (AI/AN) population

Policy Topics Under Consideration

- Consider if the new pediatric hexavalent vaccine should be included as an option in the Vaccines for Children (VFC) Program for the infant series at 2, 4, and 6 months of age
 - Primarily a VFC question, as all individual components are currently licensed and recommended
- Consider if the new pediatric hexavalent vaccine should be preferentially recommended for the American Indian/Alaskan Native (AI/AN) population
 - Preferential recommendation would require ACIP vote

Work Group Goals

- Review published and unpublished data related to the safety and immunogenicity of the investigational hexavalent pediatric vaccine
- Apply Evidence to Recommendation framework

Previous Combination Vaccine Work Group

- Previously, Combination Vaccine Work Group formed, reviewed data
 - Presentation at October 2015 ACIP meeting in anticipation of FDA approval
- FDA approval delayed with requests for additional information
 - Combination Vaccine Work Group took hiatus pending FDA approval
- Combination Vaccine Work Group re-formed December 2018 upon notification of impending licensure

Current Work Group Activities

- Three calls: December 2018, January and February 2019
 - Reviewed safety and immunogenicity data
 - Reviewed Hib epidemiology and Hib vaccines among AI/AN population
 - Discussed policy options

Upcoming Activities

- Apply Evidence to Recommendation Framework
- VFC Vote (tentatively June 2019)
- Fall 2019: Publication of MMWR

- Manufacturer has stated supply not available until at least 2020

Agenda

- Immunogenicity and Safety of Pediatric Hexavalent Vaccine
 - Andrew Lee, Merck
- Hib Epidemiology and Vaccines in American Indian/Alaskan Native Population
 - Laura Hammitt, Center for American Indian Health, Johns Hopkins
- Summary, Review of Work Group Considerations
 - Sara Oliver, CDC/NCIRD

For more information, contact CDC
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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

