



# Introduction and Terms of Reference: Combined Diphtheria and Tetanus Toxoids and Acellular Pertussis, Inactivated Poliovirus, *Haemophilus influenzae* Type B Conjugate, and Hepatitis B vaccine (Vaxelis)

Jamie Loehr

Interim Chair, ACIP Meningococcal/Hib Vaccines Work Group

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# ACIP Meningococcal/Hib Vaccines Work Group

- ACIP Members on the WG
  - Jamie Loehr (Interim Chair)
  - Wilbur Chen
  
- Ex Officio WG Members
  - Margaret Bash (FDA)
  - Matthew Clark (IHS)
  - Mark Connelly (FDA)
  - Francisco Leyva (NIH)
  
- WG Liaisons and Consultants
  - Amra Resic (AAFP)
  - Samir Shah (AAP)
  - Barb Fluty (ACHA)
  - Karyn Lyons (AIM)
  - Paul Cieslak (CSTE)
  - Kathy Hsu (IDSA)
  - Joseline Zafack (NACI)
  - Jeff Goad (NFID)
  - Jessica Cataldi (PIDS)
  - Amy Middleman (SAHM)
  - Kathy Poehling (Wake Forest)
  - Lynn Bahta (Minnesota Department of Health)
  - David Stephens (Emory)
  
- CDC Contributors
  - Jennifer Collins (DBD/NCIRD)
  - Sarah Schillie (DBD/NCIRD)
  - Lucy McNamara (DBD/NCIRD)
  - LeAnne Fox (DBD/NCIRD)
  - Susan Hariri (DBD/NCIRD)
  - Amy Rubis (DBD/NCIRD)
  - Noele Nelson (DBD/NCIRD)
  - Alison Albert (DBD/NCIRD)
  - Angela Jiles (DBD/NCIRD)
  - Marc Fischer (DIDRI/NCEZID)
  - Jonathan Duffy (DHQP/NCEZID)
  - Pedro Moro (DHQP/NCEZID)
  - Tanya Myers (DHQP/NCEZID)
  - Liz Velazquez (ISD/NCIRD)
  - Jessica MacNeil (ACIP Secretariat)
  - Hannah Rosenblum (ACIP Secretariat)
  - Melinda Wharton (ACIP Secretariat)
  
- GRADE/EtR Support
  - Doug Campos-Outcalt (Arizona)
  - Rebecca Morgan (Case Western Reserve)

# Background

- PRP-OMP (PedvaxHIB) is preferentially recommended for American Indian and Alaska Native (AI/AN) infants
  - It provides a protective antibody response after the first dose
  - Historically, Hib meningitis peaked at an earlier age among AI/AN infants
- Vaxelis (DTaP-IPV-Hib-HepB) does not currently have a preferential recommendation for AI/AN infants because
  - It contains PRP-OMP in a lower amount than PedvaxHIB
  - Post-dose 1 immunogenicity data were not previously available

# Policy question

Should Vaxelis (DTaP-IPV-Hib-HepB) be included with PedvaxHIB in the preferential recommendation for American Indian and Alaska Native (AI/AN) infants?

# Work Group activities

- Review the epidemiology of invasive Hib disease in AI/AN populations and evidence supporting the existing preferential recommendation for PedvaxHIB
- Review clinical trial data on post-dose 1 immunogenicity of Vaxelis vs. PedvaxHIB
- Develop draft policy recommendation based on grading of recommendations, assessment, development, and evaluation (GRADE) and the evidence to recommendations (EtR) framework

# Today's agenda

Topic	Presenter
Background on Hib disease and vaccination among American Indian and Alaska Native populations	Dr. Jennifer Collins (CDC/NCIRD)
Immunogenicity of <i>H. influenzae</i> type b PRP-OMP vaccines in American Indian and Alaska Native infants	Dr. Laura Hammitt (Johns Hopkins Bloomberg School of Public Health – Center for Indigenous Health)
Work Group Considerations	Dr. Jennifer Collins (CDC/NCIRD)

**All topics will be presented for information and discussion**

# Next steps

- Present evidence to recommendations (EtR) framework and draft policy recommendations for a vote in June