Summary, Review of Work Group Considerations

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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

Information Reviewed by Work Group

- Immunogenicity Data
- Safety Data
- Hib Epidemiology and Hib Vaccines in AI/AN Population
- Pediatric Hexavalent Vaccine and AI/AN Population

Immunogenicity of Pediatric Hexavalent Vaccine

- Non-inferiority criteria met
  - Exceptions:
    - GMC for one Pertussis antigen (FHA) post-dose 3
      - However, achieved with % vaccine response
    - GMC for one Pneumococcal antigen (PN6B) post-dose 3
      - Met non-inferiority endpoints set in PCV13 studies (0.5)

Safety of Pediatric Hexavalent Vaccine

- Safety profile consistent with component vaccines
- Higher rate of fever, particularly compared to pentavalent regimens
  - No increase in fever-related medical events

Current Work Group Thoughts

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Work Group is supportive of including this vaccine in the VFC program as a recommended option

Hib Epidemiology and Hib Vaccines in AI/AN Population

- In the pre-vaccine era, Hib disease occurred at younger age among AI/AN population

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PRP-OMP vaccines have preferential recommendation for AI/AN population

Pediatric Hexavalent Vaccine and AI/AN population

- Vaxelis™ same antigen and manufacturer as PedvaxHIB®
  - PedvaxHIB®: 7.5µg PRP-OMP
  - Vaxelis™: 3µg PRP-OMP

- Previous preferential recommendation based on immunogenicity data after 1st dose
  - Available data for Vaxelis™ shows robust response
    - Post-dose 2, post-dose 3, post-toddler dose
    - No data post-dose 1

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The Work Group feels that immunogenicity data post-dose 1 is needed before ACIP considers a preferential recommendation for the AI/AN population

Next Steps

- Apply the Evidence to Recommendations Framework

For more information, contact CDC
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