



## Work Group Considerations

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# Policy question

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

# Work Group Considerations

- 574 federally recognized tribes in the United States
  - Listening to tribal communities is very important
  - CDC's Office of Tribal Affairs and Strategic Alliances (OTASA) is helping facilitate
- ACIP preferential recommendations must be evidence-based

# CDC/NCIRD held a listening session with tribal communities in January 2024

- 80 attendees, including
  - 9 from tribes or tribal serving organizations
  - 46 from Indian Health Service (IHS)
- Key questions and concerns raised by participants
  - Will Vaxelis offer the same protection as PedvaxHIB?
  - Need to monitor for possible breakthrough cases
  - Safety and side effects

**Key considerations regarding post-dose 1  
immunogenicity of Vaxelis among American  
Indian and Alaska Native populations**

# Study enrollment included Navajo Nation and Alaska Native infants

## Study Enrollment

- Enrollment began in Jan 2022 in Anchorage, AK and four sites in the Navajo Nation (Southwest US)
- All study visits completed by Oct 2023

<b>Total enrollment</b>	<b>333</b>
Anchorage, AK	26
<u>Chinle, AZ</u>	61
Fort Defiance, AZ	115
Gallup, NM	81
Shiprock, NM	50



# Anti-Hib GMC 30 days post-dose 1 was non-inferior after Vaxelis vs. PedvaxHIB

## Primary Outcome: Anti-Hib IgG Geometric Mean Concentration (GMC) 30 Days Post-Dose 1

		PedvaxHIB®	Vaxelis®
Anti-Hib Antibody GMC µg/mL (95% CI)	Observed Data	0.39 (0.31 - 0.50)	0.41 (0.33 - 0.52)
	Modeled by cLDA	0.40 (0.31 - 0.50)	0.41 (0.33 - 0.51)

CI: confidence interval; cLDA: constrained longitudinal data analysis

### Ratio of GMCs (Vaxelis : PedvaxHib)

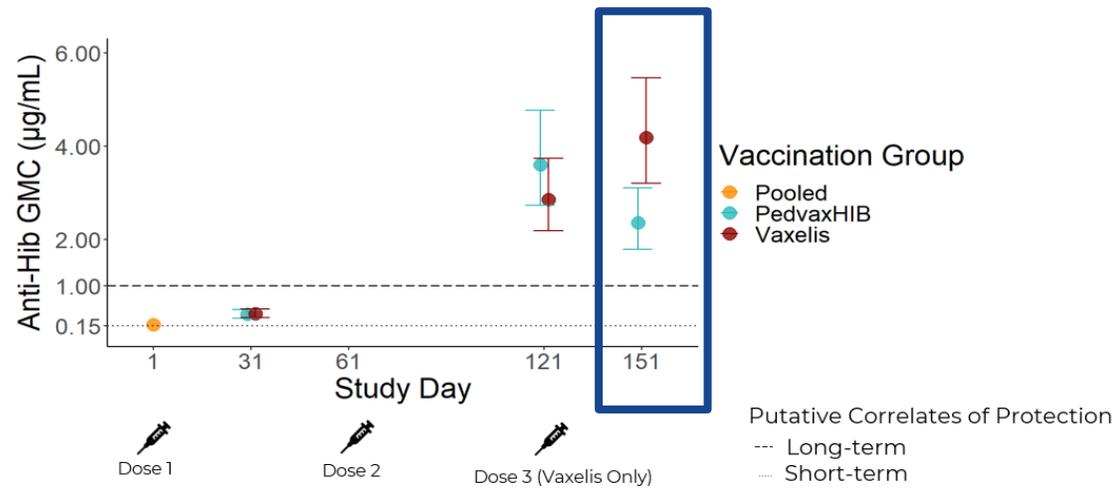
1.03 (0.75 - 1.41)

The pre-specified non-inferiority criterion was met based on the lower bound of the 95% confidence interval (CI) around the antibody concentration ratio [Vaxelis / PedvaxHIB] being > 0.67

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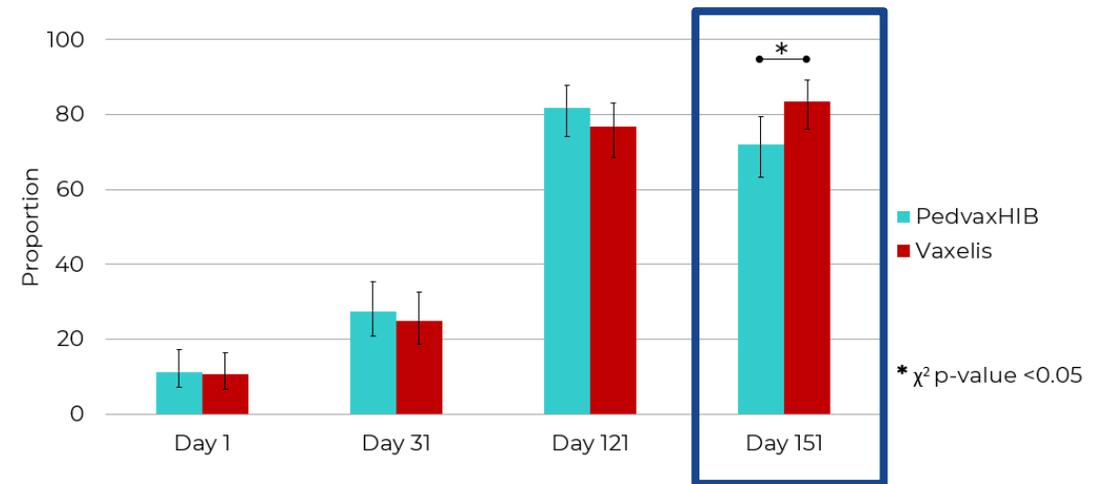
# GMC differences on day 151 post-dose 1 likely reflect the 3<sup>rd</sup> primary series dose of Vaxelis

**Anti-Hib IgG Geometric Mean Concentration Days 1, 31, 121, and 151**



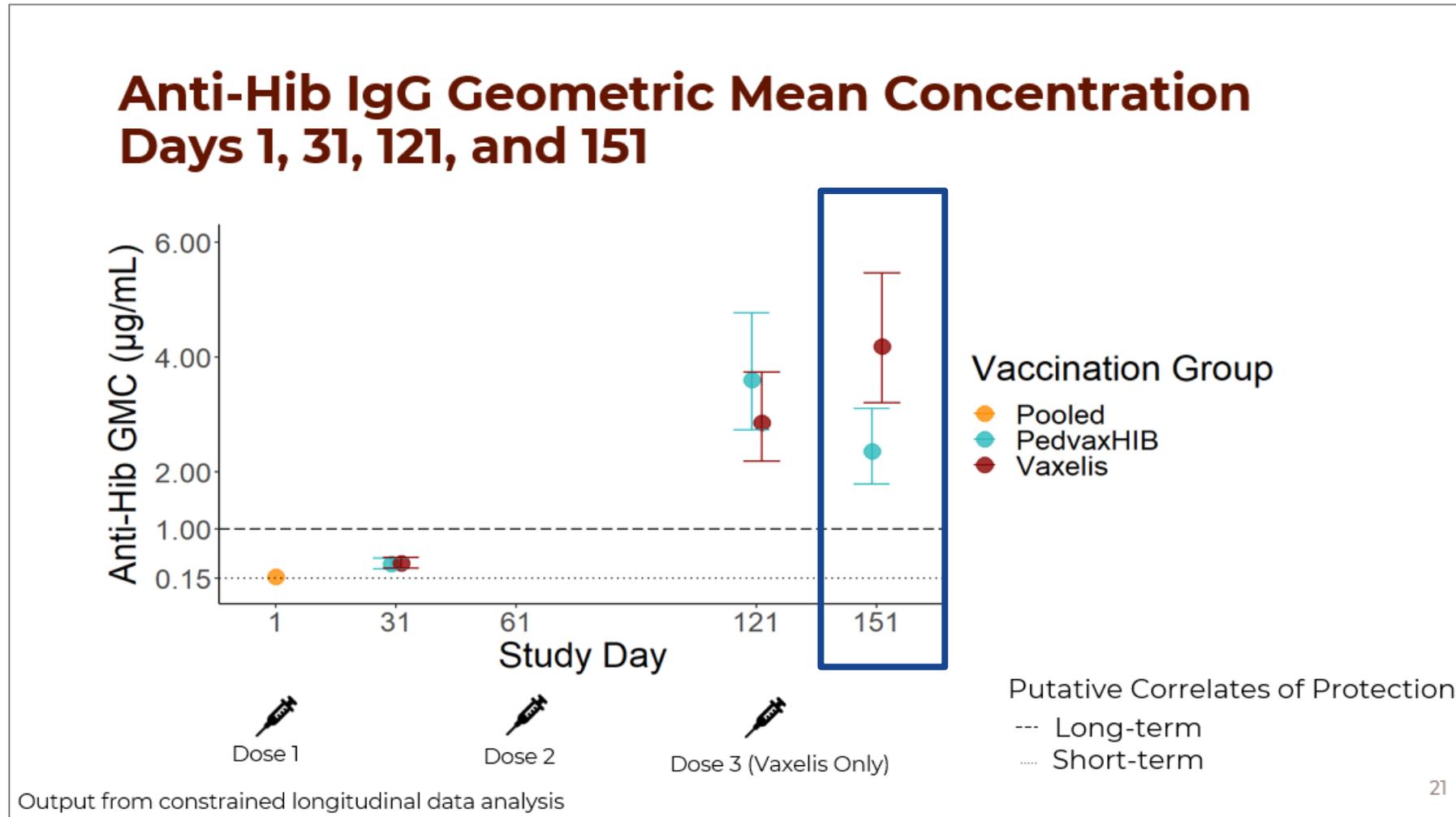
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**Proportion with Anti-Hib Concentration  $\geq 1.0$  µg/mL**



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# GMC titers not available beyond day 151 to assess longer-term protection in this population



# Additional Work Group Considerations

- Having a second preferred Hib vaccine option that is a combination vaccine may improve equity and reliability of vaccine supply
- Immunologic data are reassuring, however
  - Some concern about generalizing to broader AI/AN populations, though precedent for this with preferential recommendation for PedvaxHIB
  - Lack of direct vaccine effectiveness data
  - Study did not collect titers beyond infancy re: whether Vaxelis might better prevent residual cases occurring pre-booster
  - Some uncertainty as to why AI/AN populations are particularly affected by changes in vaccination type; potentially more than just antibody response?

# Final reflections and next steps

- Including Vaxelis as a second preferred option for AI/AN populations may improve equity and reliability of vaccine supply
- Post-dose 1 GMCs of Vaxelis appear non-inferior to that of PedvaxHIB among Navajo Nation and Alaska Native populations
- Data gaps
  - Studies in broader AI/AN populations
  - Short-term efficacy
  - Longer-term immunogenicity and efficacy
- Next steps
  - GRADE/EtR framework to be presented in June
  - Plan for vote in June

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- WG Liaisons and Consultants
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**Thank you!**  
**Questions?**