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Vaccines and Related Biological Products Advisory Committee (VRBPAC) Meeting

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Evaluation of the Effectiveness of Vaccines Intended to Prevent Group B Streptococcal Disease in Infants

Introduction and Background

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Purpose of the VRBPAC

Today, we will discuss approaches for evaluating the effectiveness of Group B Streptococcus (GBS) vaccines in preventing infant disease in the context of maternal immunization.

Group B Streptococcus (GBS)

- Gram positive, diplococcus bacterium
- Encapsulated (outer polysaccharide)
- Serotyping is based on the capsular polysaccharide
- Ten GBS serotypes have been identified: Ia, Ib, II, III, IV, V, VI, VII, VIII, and IX

Maternal Immunization

- Maternal immunization in this session refers to vaccination during pregnancy.
- It is the passive protection of the infant using antibodies passed from the vaccinated mother to the unborn child.
- There are no vaccines licensed in the US specifically to protect the infant when administered to the pregnant woman.
- A GBS vaccine for maternal immunization has been identified as a priority by the World Health Organization.*
- November 13, 2015, VRBPAC topic:
  - "Considerations for evaluation of the safety and effectiveness of vaccines administered to pregnant women to protect the infant."
- Today's discussion will focus on evaluation of GBS vaccine effectiveness.

*Group B Streptococcus Vaccine Development Technology Roadmap. Priority activities for development, testing, licensure and global availability of Group B streptococcus vaccines. Geneva: World Health Organization, 2017

Current GBS Vaccine Development Approaches

- Product development
  - Polysaccharide vaccines
  - Polysaccharide conjugate vaccines
  - Protein subunit vaccines
  - Multivalent

Today's Speakers

- **Dr. Darcie Everett**, Medical Officer, US Food and Drug Administration
- **Dr. Stephanie Schrag,** Epidemiologist, US Centers for Disease Control and Prevention
- **Dr. Carol Baker,** Professor of Pediatrics, Molecular Virology and Microbiology, Baylor College of Medicine
- **Dr. Shabir Madhi**, Professor of Vaccinology, Director: MRC Respiratory and Meningeal Pathogens Research Unit, University of Witwatersrand, Gauteng, South Africa
- **Pfizer, Inc.,** Group B Streptococcus Maternal Immunization Program
  - Dr. Annaliesa S Anderson, Vice President, Chief Scientific Officer, Pfizer Vaccine Research and Development
  - Dr. Judith Absalon, Senior Medical Director Pfizer Vaccine Research and Development

Questions for the Advisory Committee

1. In addition to laboratory confirmed early or late onset disease, what additional clinical disease endpoints (i.e., unconfirmed and confirmed fetal or infant endpoints, maternal endpoints) could be considered to demonstrate vaccine effectiveness? Please discuss their strengths and limitations.
2. Could immunological endpoints (i.e., functional and ligand binding antibody levels) be used to demonstrate vaccine effectiveness? If so, please discuss their strengths and limitations.
3. Could colonization be used to demonstrate vaccine effectiveness? If so, please discuss its strengths and limitations.