

Maternal Immunization Working Group Phase II



**February 2, 2016
NVAC**

**Chairs:
Richard Beigi, MD
Saad Omer, PhD**

Maternal Immunizations Facts

- Pregnant women and young infants are at a higher risk for morbidity and mortality from various vaccine-preventable diseases
- A provider recommendation and vaccine offering during pregnancy are key factors that help increase vaccination coverage
- Maternal immunization can help foster positive attitudes towards vaccines in pregnant women that may result in greater awareness, acceptance, and demand for vaccines for both themselves and their children

NVAC CHARGE FOR THE MIWG

CHARGE

The Assistant Secretary for Health charges the NVAC to:

Part 1:

- Review the current state of maternal immunization and existing best practices
- Identify programmatic barriers to the implementation of current recommendations related to maternal immunization and make recommendations to overcome these barriers ¹

Part 2:

- **Identify barriers to and opportunities for developing vaccines for pregnant women and make recommendations to overcome these barriers**

¹ Reducing Patient and Provider Barriers to Maternal Immunizations, Public Health Reports, Jan-Feb 2015

MEMBERSHIP MIWGII

NVAC

**Rich Beigi (Co-chair), Saad Omer(Co-chair)
Walt Orenstein, Ruth Lynfield, Seth Hetherington**

NVPO leads

**Jennifer Gordon
Karin Bok**

Subject Matter Experts

Ajoke Sobanjo-ter Meulen, Steven Black, Mary Healy, Cindy Pellegrini, Flor Muñoz, Jan Bonhoeffer, D. Tomianovic, Geeta Swamy, Kathy Edwards, Leonard Friedland, Debra Hawks, Jeanne Sheffield, N.Bhat, Debbie Higgins, Fernando Polack, Cheryl Broussard, Gina Burns, Sharon Humiston, Amina White, Carol Baker

Ex Officio Federal Liaisons

**Karen Broder (CDC)
Jennifer Liang (CDC)
Stacey Martin (CDC)
Pedro Moro (CDC)
Marion Gruber (FDA)
Jeff Roberts (FDA)
Valerie Marshall (FDA)
Avril Houston (HRSA)
Emily Levine (HHS/OGC)
Barbara Mulach (NIH)
Mirjana Nesin (NIH)
Jennifer Read (NIH)
Margaret Yacovone (DoD)
Fran Cunningham (VA)
Richard Martinello (VA)**

Special Assistant

Katy Seib

MIWG II Meetings

- **January 2015: Updates on Vaccines Administered During Pregnancy (Dr. Nesin)**
- **March 2015: Epidemiology and Vaccine Research of GBS and RSV (Dr. Polack and Dr. Baker)**
- **May 2015: Best Pharmaceuticals for Children Act implementation by NIH (Dr. Zajicek)**
- **June 2015: Pregnancy and Lactation Labeling Rule (Dr. Gruber)**
- **July 2015: Ethical/IRB Considerations of Including Pregnant Women in Clinical Trials, and Ethical Considerations of Surveying/Safety Testing Mother and Child after Vaccination (Dr. White)**
- **August 2015: GlaxoSmithKline's Maternal Immunization Program (Dr. Friedland)**

MIWG II Meetings

- **September 2015: Challenges and Barriers of Monitoring Vaccine Safety for Immunizations Administered During Pregnancy (Drs. Pedro Moro, Allison Naleway, David Martin, and Karen Broder from VAERS, VSD, PRISM and CISA respectively)**
- **October 2015: Novavax Maternal Immunization Program (Dr. August)**
- **November 2015: BioCSL Maternal Immunization Program (Dr. Altman)**
- **January 2016: Sanofi Pasteur Maternal Immunization Program (Dr. Johnson)**
- **January 2016: Pfizer Maternal Immunization Program (Dr. Gruber)**
- **UPCOMING: February 2016: Closing discussion and remarks (Dr. Marion Gruber)**

NVAC-MIWG II

Barriers To Developing
Vaccines for Use During
Pregnancy
(Draft)

Maternal Immunizations: Ethical Issues

- **Consideration of development and articulation of broadly acceptable and applicable ethical framework that can be used at various venues**
- **Clarification on vulnerable populations: Unethical to describe pregnant women as a vulnerable population, they are rather a complex population**
- **Standardized definitions of minimal risk to aid IRB review process**

Maternal Immunizations: Regulatory Issues

- **Clearly define PLLR implementation concerning vaccinations**
- **New OHRP guidelines to include pregnant women in clinical trials**
- **Consideration of advocacy for models (similar to BPCA) that would effectively change from default to exclusion to default to inclusion, unless clear criteria given for why exclusion.**
- **Continued interface and dialogue between manufacturers and FDA on exact requirements for licensure/indication for existing and new vaccine products for use in pregnancy.**
- **Improve interaction and collaborations between manufacturers and government (DHHS) to encourage manufacturer investment in Maternal Immunization**
- **Continue to advocate to avoid liability issues, and to modify the VICP so maternal immunizations are fully covered**

Maternal Immunizations: Safety Monitoring Issues

- **Development of standardized definitions of possible maternal and neonatal outcomes**
- **Work to align current safety systems for optimal output**
- **Create interface with international data systems**
- **Promote education of providers on maternal immunization safety research**
- **Clear guidance/consensus on acceptable newborn surveillance timeframe during trials and post-licensure**
- **Obtain data on the safety profile of individual antigen preparations, not only of a vaccine in general (especially for all the Flu and TDaP formulations)**

Maternal Immunizations: Pre-clinical and Clinical Research

- **Increase support of pre-clinical research to address barriers in developing maternal immunizations at this early stage**
- **Consider increasing research focus/network by creating a Maternal Immunization Research Network**
- **Focus on standardizing post-marketing surveillance for maternal immunization**
- **Encourage continuing studies of post-marketing effectiveness evaluation**

Maternal Immunizations: Provider Education and Support

- **Professional societies should be a valuable partner encouraging and demanding that clinical research be conducted including pregnant women**
- **Obstetrician providers should be aware that currently there is little or no research during pregnancy, and become advocates for testing vaccines during pregnancy**
- **Obstetricians should also advocate for vaccination, and understand the importance of vaccine research during pregnancy**
- **Educate obstetricians on vaccination and interpretation of new labelling so they can make informed decisions**

NVAC DISCUSSION



THANK YOU