

Maternal Immunization Working Group Phase II



**June 9, 2015
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 Negin (NIH)
Jennifer Read (NIH)
Margaret Jacovone (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)

Upcoming 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)
- **December 2015:** Sanofi Pasteur Maternal Immunization Program (Dr. Johnson)
- **January 2016:** Pfizer Maternal Immunization Program (Dr. Gruber)

Initial Impressions I

- Potential opportunities to clarify federal regulations, suggest OHRP guidance,
 - Develop special training for IRBs
 - Define “minimal risk” in the context of maternal immunization
 - A “working group” to define what is minimal risk?
 - Data needed on IRBs interpreting regulations

Initial Impressions II

- Efforts needed to increase availability of pregnant women to be enrolled in clinical trials
- Challenges to link datasets of mother and child
- Length of follow-up for AEs in mother and her child, including developmental assessment in the child
- Flashback (2014 NVAC Maternal Immunization Working Group recommendation): “The ASH should support efforts by HRSA to address the issue of including in utero injuries allegedly incurred following maternal immunization within the Vaccine Injury Compensation Program.

Initial Impressions III

- A potential independent ethics panel
 - could support the maternal IZ community on maternal IZ-specific ethical challenges and develop clear guidelines together with FDA
 - E.g. maternal risk for infant benefit

THANK YOU

