

# **Maternal Immunization Working Group Phase II**



**June 7, 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 <sup>1</sup>

**Part 2:**

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

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

# MEMBERSHIP MIWGII

<b>NVAC</b>	<b>Rich Beigi (Co-chair), Saad Omer(Co-chair) Walt Orenstein, Ruth Lynfield, Seth Hetherington</b>
<b>NVPO leads</b>	<b>Jennifer Gordon Karin Bok</b>
<b>Subject Matter Experts</b>	<b>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</b>
<b>Ex Officio Federal Liaisons</b>	<b>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 Jacovone (DoD) Fran Cunningham (VA) Richard Martinello (VA)</b>
<b>Special Assistant</b>	<b>Katy Seib</b>

# MIWG II Meetings

- **Held 12 Subject Matter Expert Meetings to discuss the charge of the MIWG**
- **Held Leadership meetings between February and May 2016 to draft the recommendations**
- **Working Group met in May 2016 to adjudicate the comments and modifications the group had to the initial draft recommendations**
- **Finalized draft recommendations early June 2016, which will be part of the working group report that will be voted during the September 2016 NVAC meeting**

# NVAC-MIWG II

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Barriers To Developing Vaccines for Use During  
Pregnancy  
(Almost Final Draft)

# Maternal Immunizations: Ethical Issues

- **The ASH should work with the Office of Human Research Subjects Protection (OHRP) and other relevant stakeholders and agencies to revise the current exclusionary climate of research in pregnancy. Such areas of focus include but are not limited to:**
  - **Institutional Review Board (IRB) guidance on interpretation on minimal risk**
  - **Code of Federal Regulations language surrounding research in pregnancy**
  - **Collaboration with bioethics experts, regulatory agencies and the scientific community to optimize the design of studies to minimize the risk of interventions for research in pregnancy**
  - **Clarification that pregnant women should be classified as a scientifically complex population rather than a vulnerable population for the purposes of ethical review**
- **The ASH should work with OHRP and the stakeholder community to develop policy and regulatory guidelines that would promote inclusion of pregnant women in clinical trials when scientifically appropriate**

# Maternal Immunizations: Policy Issues

- **The ASH should continue to support maternal immunization as an important public health strategy to encourage manufacturer investment in the development of new and currently licensed vaccines for additional indications for use specifically in pregnant women**
- **The ASH should advocate to the Secretary of Health and Human Services to resolve the uncertainties around coverage under the National Vaccine Injury Compensation Program (VICP) for vaccines administered to pregnant women that are not recommended for use in children by the Center for Disease Control and Prevention (CDC), and for liability protections for live-born infants born to mothers vaccinated during pregnancy**



# Maternal Immunizations: Pre-Clinical and Clinical Research Issues (1)

- **The ASH should prioritize increased support for pre-clinical and early clinical research to develop vaccines for pregnant women:**
  - **The ASH should work with federal and non-federal stakeholders to create or promote mechanisms that support investigators initiated, and other types of research, that foster innovation and expand the field of vaccines for pregnant women**
- **The ASH should emphasize the need for a better understanding of the public health burden of diseases preventable by maternal immunization**
- **The ASH should work with CDC and other relevant federal agencies to support evaluation of the maternal and neonatal outcomes of vaccines administered during pregnancy with respect to the (1) safety of vaccines and (2) effectiveness of vaccines to reduce maternal and infant morbidity and mortality caused by vaccine preventable diseases, and (3) to better understand the potential risks and benefits of maternal immunization**

# Maternal Immunizations: Pre-clinical and Clinical Research Issues (2)

- **The ASH should support continuing evaluation of vaccines in pregnant women and infants born to vaccinated mothers, while advocating for the adoption of standardized approaches to data collection, analysis, and safety evaluation**
- **The ASH should support the adoption and utilization of standardized definitions of possible maternal and neonatal outcomes to evaluate the safety and effectiveness of vaccines administered during pregnancy**
- **The ASH should convene stakeholders and other federal agencies to work on the expansion of pharmacovigilance systems that readily link maternal and fetal electronic health records and safety surveillance systems**

# Maternal Immunizations: Provider Education and Support Issues

- **The ASH should encourage professional societies to continue to advocate for clinical research to be conducted in pregnant women**
- **The ASH should work with relevant stakeholders to increase awareness among obstetric providers and pregnant women about the importance of vaccine research during pregnancy**
- **The ASH should work with professional societies to educate obstetricians and other obstetric providers on vaccination and interpretation of new regulations regarding labelling (i.e., the Pregnancy and Lactation Labeling Rule) so they can make informed decisions and counsel their patients more effectively**

# NVAC DISCUSSION



**THANK YOU**