

NATIONAL VACCINE ADVISORY COMMITTEE

NVAC | NATIONAL
VACCINE
ADVISORY
COMMITTEE

**MATERNAL IMMUNIZATION WORKING
GROUP PHASE II-FINAL REPORT**

SEPTEMBER 20, 2016



U.S. DEPARTMENT
OF HEALTH AND
HUMAN SERVICES



MATERNAL IMMUNIZATION WORKING GROUP PHASE II

Maternal Immunization Working Group Chairs

Richard H. Beigi, MD, MSc, Magee-Womens Hospital, Pittsburgh, PA
Saad Omer, MBBS, MPH, PhD, Emory University, Atlanta, GA

NVAC Members

Ruth Lynfield, MD, Minnesota Department of Health, St. Paul, MN
Seth Hetherington (former NVAC member), MD, Genocea Biosciences, Cambridge, MA

NVAC Liaison Representatives

Ajoke Sobanjo-ter Meulen, MD, MSc, Bill & Melinda Gates Foundation, Seattle, WA

Cynthia Pellegrini, March of Dimes, Washington, DC

Jan Bonhoeffer, MD, Brighton Collaboration, Switzerland

Danitza Tomianovic, PhD, Brighton Collaboration, Switzerland

Leonard Friedland, MD, Biotechnology Innovation Organization, Washington, DC

Debra Hawks, MPH, American Congress of Obstetricians and Gynecologists, Washington, DC

Jeanne Sheffield, MD, Society for Maternal-Fetal Medicine, Washington, DC

Niranjan Bhat, MD, MHS, PATH, Seattle, WA

Deborah Higgins, PATH, Seattle, WA

Gina Burns, BSN, The Group B Strep Association, Chapel Hill, NC

Sharon Humiston, MD, MPH, American Academy of Pediatrics, Vancouver, WA

Carol J. Baker, MD, Infectious Disease Society of America, Arlington, VA

NVAC Subject Matter Experts

Steven Black, MD, Cincinnati Children's Hospital Medical Center, Cincinnati, OH

Catherine Mary Healy, MBBCh, Baylor College of Medicine, Houston, TX

Flor M. Muñoz, MD, MSc, Baylor College of Medicine, Houston, TX

Geeta K. Swamy, MD, Duke University, Durham, NC

Kathryn M. Edwards, MD, Vanderbilt University, Nashville, TN

Fernando Polack, MD, Fundacion INFANT, Argentina

NVAC Ex-Officio Members

Karen R. Broder, MD, Centers for Disease Control and Prevention, Atlanta, GA

Jennifer Liang, DVM, MPVM, Centers for Disease Control and Prevention, Atlanta, GA

Stacey Martin, MSc, Centers for Disease Control and Prevention, Atlanta, GA

Pedro L. Moro, MD, MPH, Centers for Disease Control and Prevention, Atlanta, GA

Cheryl Broussard, PhD, Centers for Disease Control and Prevention, Atlanta, GA

Marion F. Gruber, PhD, Food and Drug Administration, Silver Spring, MD

Jeffrey Roberts, MD, Food and Drug Administration, Silver Spring, MD

Valerie Marshall, MPH, Food and Drug Administration, Silver Spring, MD

Avril Houston, MD, MPH, Health Resources and Services Administration, Rockville, MD

Narayan Nair, MD, Health Resources and Services Administration, Rockville, MD

Emily Levine, JD, Office of the General Counsel, U.S. Department of Health and Human Services, Washington, DC

Barbara Mulach, PhD, National Institutes of Health, Bethesda, MD

Mirjana Nesin, MD, National Institutes of Health, Bethesda, MD

Jennifer S. Read, MD, MS, MPH, National Institutes of Health, Bethesda, MD

Amina White, MD, National Institutes of Health, Bethesda, MD

Margaret Jacobovone, MD, Department of Defense, Washington, DC

Fran Cunningham, PharmD, U.S. Department of Veterans Affairs, Washington, DC

Richard Martinello, MD, U.S. Department of Veterans Affairs, Washington, DC

U.S. Department of Health and Human Services, National Vaccine Program Office Staff and Technical Advisors

Karin Bok, MS, PhD, National Vaccine Program Office, U.S. Department of Health and Human Services, Washington, DC

Jennifer Gordon, PhD, National Vaccine Program Office, U.S. Department of Health and Human Services, Washington, DC

Bruce G. Gellin, MD, MPH National Vaccine Program Office, U.S. Department of Health and Human Services, Washington, DC

Cristina H. Messina, MS, PhD, National Vaccine Program Office, U.S. Department of Health and Human Services, Washington, DC

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

RECOMMENDATIONS

- **Focus Area 1:** Ethical Issues
- **Focus Area 2:** Policy Issues
- **Focus Area 3:** Pre-Clinical and Clinical Research Issues
- **Focus Area 4:** Provider Education and Support Issues

FOCUS AREA 1: ETHICAL ISSUES

- **1.1 The ASH should work with the Office for Human Research Protections (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:**
 - **1.1.1 Institutional Review Board (IRB) guidance on interpretation of minimal risk**
 - **1.1.2 Code of Federal Regulations language surrounding research in pregnancy**
 - **1.1.3 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**
 - **1.1.4 Relevant regulations, statutes, and policies that should be modified to indicate that pregnant women are not a vulnerable population for the purposes of ethical review**
- **1.2 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**

FOCUS AREA 2: POLICY ISSUES

- **2.1 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**
- **2.2 The ASH should advocate to the Secretary of Health and Human Services to resolve the uncertainties around coverage under the Vaccine Injury Compensation Program (VICP) for vaccines administered to pregnant women that are not recommended for use in children by the CDC, and for liability protections for live-born infants born to mothers vaccinated during pregnancy**

FOCUS AREA 3: PRE-CLINICAL AND CLINICAL RESEARCH ISSUES

- **3.1 The ASH should prioritize increased support for pre-clinical and early clinical research to understand the immune response during pregnancy and to develop vaccines for pregnant women:**
 - **3.1.1 The ASH should work with federal and non-federal stakeholders to create or promote mechanisms that support investigator-initiated and other types of research that fosters innovation and expands the field of vaccines for pregnant women**
- **3.2 The ASH should emphasize the need for a better understanding of the public health burden of diseases preventable by maternal immunization**
- **3.3 The ASH should work with CDC, NIH, 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**

FOCUS AREA 3 (CONT.): PRE-CLINICAL AND CLINICAL RESEARCH ISSUES

- **3.4 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**
- **3.5 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**
- **3.6 The ASH should convene stakeholders and other federal agencies to work on the expansion of pharmacovigilance systems that readily link maternal and infant electronic health records and safety surveillance systems**

FOCUS AREA 4: PROVIDER EDUCATION AND SUPPORT ISSUES

- **4.1 The ASH should encourage professional societies to continue to support the inclusion of pregnant women in clinical research**
- **4.2 The ASH should work with relevant stakeholders to increase awareness among obstetric providers and pregnant women about the importance of vaccine research during pregnancy**
- **4.3 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**

SUMMARY OF PUBLIC COMMENTS RECEIVED AS OF SEPTEMBER 9TH, 2016

- Total of 20 public comments received representing individuals, organizations, and industry
 - BIO Group B Strep Association
 - NOVAVAX Group B Strep Support (UK)
 - National Vaccine Information Center
- Majority of the comments indicated public support of the recommendations
- All comments addressed strong support for recommendations in *Focus Area #2- Policy Issues*, addressing the need to resolve uncertainties around VICP coverage for vaccines administered to pregnant women

The maternal immunization working group discussed all comments and decided to leave the recommendations and justifications unchanged

Type of Comment	Summary of Comment(s)	Working Group Adjudication
Individual Comments -14 total	-General comment in support of maternal immunizations, modifying VICP to include pregnant women and their babies. -Agree with the need for a GBS vaccine to protect pregnant mothers and their babies.	-Thank you for your comments. Recommendations already addressed your comments.
Stakeholder - Group B Strep Association	-General comment in support of maternal immunizations, modifying VICP to include pregnant women and their babies.	-Thank you for your comments. Recommendations already addressed your comments.
Stakeholder -Group B Strep Support (national charity based in the United Kingdom)	-General comments in support of maternal immunizations. -Agreed on the need for a GBS maternal vaccine as a prevention measure.	-Thank you for your comments. Recommendations already addressed your comments.

Type of Comment	Summary of Comment(s)	Working Group Adjudication
Stakeholder -Novavax	-Agreed with recommendations but urge caution for NVAC moving forward with the recommendations in regards to asking clinical trials to justify the exclusion of pregnant women in their studies.	-Thank you for your comments. The maternal immunization working group discussed your suggestions and decided to leave the recommendation and justification unchanged.
Stakeholder -BIO	-Agreed with recommendations. -Suggested to mention specific stakeholders in the recommendations.	-Thank you for your comments. These recommendations were intended to include the broader group of federal stakeholders that deal with immunizations.
Stakeholder -NACCHO	-Agree with recommendations, specifically the strengthening of surveillance systems and the need for understanding disease burden.	-Thank you for your comments.

Type of Comment	Summary of Comment(s)	Working Group Adjudication
<p>Stakeholder - NVIC (National Vaccine Information Center)</p>	<p>-Opposes the recommendations. -NVIC states that health care providers should not conform to ACIP recommendation and maternal immunization should not be standard of practice. -NVIC disagrees with recommendation to clarify uncertainties around VICP. They state that vaccine manufacturers, vaccine providers, vaccine regulators, and policymakers should be held accountable.</p>	<p>-Thank you for your comments. The maternal immunization working group respectfully disagrees.</p>

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



DISCUSSION

&

VOTE

THE NATIONAL VACCINE PROGRAM OFFICE