THE **MATERNAL IMMUNIZATION WORKING GROUP (MIWG)** OF THE NATIONAL VACCINE ADVISORY COMMITTEE

PROPOSED RECOMMENDATIONS

NVAC MEETING - JUNE 2013

MIWG CO-CHAIRS:

DR. RICHARD BEIGI, MD

DR. CATHERINE TORRES, MD

NVAC CHARGE FOR THE MIWG

CHARGE

The Assistant Secretary for Health charges the NVAC to:

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

APPROVAL

- NVAC accepted the charge and formation of the MIWG on June 5, 2012
- MIWG was formed in August 2012 to address the charge

MEMBERSHIP

NVAC	**Catherine Torres** (Co-chair), **Rich Beigi** (Co-chair) **Walt Orenstein, Phil LaRussa, Amy Pisani, Thomas Stenvig, LJ Tan, Vish Viswanath, Clement Lewin, Seth Hetherington**
Federal Ex Officio Members	**Jennifer Liang, Norma Allred, Erin Kennedy, Kris Sheedy, Jenny Mullen** (CDC) **Marion Gruber, Valerie Marshall, Jennifer Read** (FDA) **Barbara Mulach, Mirjana Nesin, Claire Schuster** (NIH) **Anna Jacobs** (OGC/DHHS) **Iris Mabry-Hernandez** (AHRQ) **Richard Martinello** (VA) **Hani Atrash, Juliann DeStefano** (HRSA) **Jennifer Mbuthia** (DoD) **Tina Tah, Amy Groom** (IHS)
Subject Matter Experts	**Isaac Goldberg, Bernard Gonik, Carol Baker, Michael Katz**
Liaison Representatives	**Wayne Rawlins, Natalie Slaughter** (America's Health Insurance Plans) **Gina Burns** (Group B Strep Association) **Rahn K Bailey** (National Medical Association) **Elena V. Rios** (National Hispanic Medical Association) **Catherine Ruhl** (Association of Women's Health, Obstetric and Neonatal Nurses) **Audrey Stevenson** (American Nurses Association) **Phil Heine** (American College of Obstetricians and Gynecologists) **Elizabeth Rosenblum** (American Academy of Family Physicians) **Niteen Wairagkar** (Bill and Melinda Gates Foundation)
NVPO Staff	**Jennifer Gordon, Ankita Nigam**
Special Assistant	**Katy Seib**

UPDATES SINCE THE FEBRUARY NVAC

The WG has:

- Finished calls relevant to the charge
- Identified key focus areas for the recommendations and report
- Drafted recommendations grouped by focus areas through iterative input and feedback from working group members
- Collaborated with similar HHS Efforts (ACCV's MIWG)

HEALTHY PEOPLE 2020 GOALS

<u>Goal 1:</u> Reduce, eliminate, or maintain elimination of cases of vaccine-preventable diseases

- **1.6:** Reduce cases of pertussis among children under 1 year of age

<u>Goal 12:</u> Increase the percentage of children and adults who are vaccinated annually against seasonal influenza

- **12.10:** Increase the percentage of pregnant women who are vaccinated against seasonal influenza

STATE OF MATERNAL IMMUNIZATION TODAY

Influenza	Pertussis
Influenza-related complications increase risk of morbidity and mortality for mother and infant	Infants have the highest rates incidence: 20-100 cases per 100,000 people
Influenza vaccination protects: ▪ the mother ▪ the infant (passive protection)	Vaccinating during pregnancy protects: ▪ the mother ▪ the infant (passive protection)
47.0% - Women vaccinated with influenza during pregnancy	**2.6% -Women vaccinated with Tdap during pregnancy**

FIVE FOCUS AREAS

1	Enhance communication addressing the safety and effectiveness of all currently recommended immunizations during pregnancy as well as future vaccines.
2	Comprehensive efforts to maximize obstetric provider recommendation and administration of all recommended maternal immunizations recommended for this population.
3	Focus efforts to improve financing for immunization services during pregnancy and postpartum.
4	Support efforts to increase use of EHRs by maternal care providers to strengthen Immunization Information Systems (IIS) and vaccine surveillance systems for pregnant women.
5	Recognize and address current vaccine liability law barriers to optimize investigations and uptake of recommended and future vaccines during pregnancy.

DEFINITION OF PROVIDERS:

All providers of maternal health care include: OB/GYNS, family practice physicians, certified nurse midwives, advanced practice nurses, physician's assistants, etc.

FOCUS AREA 1:

Enhance communication addressing the safety and effectiveness of all currently recommended immunizations during pregnancy as well as future vaccines

FOCUS AREA 1: RATIONALE

- Patient barriers to acceptance of immunizations during pregnancy include:
  - Vaccine safety concerns (mother and infant)
  - Lack of understanding of:
    - The effect of infectious diseases on pregnant women
    - The benefits of vaccinations in disease prevention during pregnancy
- Individuals with varying levels of health literacy require tailored and diverse communication strategies.
- OB providers remain suboptimal vaccinators because of a general lack of vaccine-related knowledge.
  - Professional organizations, advocacy groups, and other stakeholders can play an important role to reach and educate providers

FOCUS AREA 1: RECOMMENDATIONS

1.1	The ASH should work with federal partners and professional organizations to develop and distribute communication strategies and educational materials to healthcare providers delivering maternity care. These educational materials should clearly state the benefits of maternal immunization such as reducing the morbidity and mortality for mothers and newborns. In addition, they should enable providers to educate women who are pregnant or may become pregnant on the safety and effectiveness of all ACIP recommended maternal immunizations for themselves and their unborn child.
1.2	The ASH should recommend the use of current and newly emerging communication technologies to maximize the effectiveness and reach of communication efforts addressing the safety and effectiveness of maternal immunization.
1.3	The ASH should provide regular updates to relevant stakeholders regarding vaccines that are recommended by ACIP for use in pregnant women. Doing so will maximize the potential for disease prevention through vaccine use thereby benefiting the mother and her fetus/infant.
1.4	The ASH should work with CDC and FDA to assure that the safety and impact of currently recommended vaccines for pregnant women are monitored.

FOCUS AREA 2: RATIONALE

- Provider recommendations are one of the most important factors influencing a woman's decision to be immunized during pregnancy. They result in:
  - Higher vaccination rates
  - More positive patient attitudes regarding vaccine effectiveness and safety

- Providers concerns regarding vaccinations include:
  - Lack of pregnancy-specific vaccine data regarding efficacy and safety
  - Lack of general knowledge about vaccinations/vaccine preventable diseases
  - Challenges in establishing maternal immunization as routine practice, for e.g., lack of quality indicators to measure performance

FOCUS AREA 2:

Comprehensive efforts to maximize obstetric provider recommendation and administration of all recommended maternal immunizations recommended for this population

FOCUS AREA 2: RECOMMENDATIONS

2.1	The ASH should work with all relevant federal and non-federal partners to assure that focused efforts are undertaken to routinize obstetrical provider vaccine recommendations and administration of all recommended vaccines during pregnancy.
2.2	The ASH should work to broaden programs such as the Assessment, Feedback, Incentives, and Exchange (AFIX) programs that support and evaluate obstetric and gynecological providers and integrate women's healthcare into this program's purview.
2.3	The ASH should recommend that obstetric providers follow the published guidelines of professional organizations to improve adult vaccination rates in their medical practices.

FOCUS AREA 2: RECOMMENDATIONS (cont.)

2.4	The ASH should collaborate with federal partners, professional organizations, and other relevant maternal immunization stakeholders to develop formal educational and continuing medical education curricula regarding the demonstrated benefits on maternal and neonatal morbidity and mortality as well as benefits and risks of immunizations during pregnancy and postpartum for trainees and providers of obstetric care. Curricula should include information about the scientific basis and practical use of immunizations to facilitate the incorporation of immunizations into the obstetric/gynecological care settings.
2.5	The ASH should work with the NCQA and other key groups to have immunization of pregnant women with recommended vaccines incorporated into measures or health care quality performance of healthcare providers and institutions that serve pregnant women. This should include advocacy to assure information systems are developed and/or enhanced, if required to allow measurement of coverage in this population. OR The ASH should work with the NCQA and other key groups to develop maternal immunization as a measurement for health care quality performance of healthcare providers and institutions. This includes developing mechanisms to reliably and reproducibly measure rates of maternal immunizations given by maternity care providers

FOCUS AREA 3: RATIONALE

- Financial challenges for delivery of vaccinations at the provider level include (but are not limited to):
  - Variations in vaccine costs by practice and vaccine order (quantity)
  - Reimbursement adequacy of providers by health plans, public & private payers
  - Provider administrative costs for vaccines (labor, storage, insurance against loss, inventory, counseling)
  - Lack of understanding of:
    - Efficient business practices
    - Payer contracting of immunization services
    - Appropriate billing practices
    - Participation in vaccine purchase pools

FOCUS AREA 3:

Focus efforts to improve financing for immunization services during pregnancy and postpartum.

FOCUS AREA 3: RECOMMENDATIONS

3.1	The ASH should work with Centers for Medicare and Medicaid Services (CMS), HRSA and private payers to determine appropriate financial reimbursement processes for the provision of maternal and other adult immunizations by maternal health care providers, such as adult vaccine counseling and vaccine administration.
3.2	The ASH and HHS should work with professional organizations and other relevant maternal immunization stakeholders to develop a comprehensive toolkit that provides guidance on office logistics (such as storage, inventory, etc.) to optimize the ability for providers to efficiently and effectively implement vaccination services within their practices. Such a toolkit should also provide technical assistance regarding efficient business practices including payer contracting for immunization services, appropriate vaccine billing practices, and support participation in vaccine purchasing groups.
3.3	The ASH should continue to monitor the effectiveness of the newly evolving payment and delivery models, outside of fee-for-service, within the new framework of federal and state exchanges, patient centered medical homes, and accountable care organizations. These new models should be encouraged to utilize cost studies of efficient practices and evidence-based economic principles as they pertain to maternal immunization programs.

FOCUS AREA 4: RATIONALE

- Challenges exist with tracking data collection in regards to vaccine use, including duplicate interventions, missed opportunities, etc.
- Limited data exists on safety and effectiveness of vaccines used in pregnancy
- Several post-marketing surveillance systems can be used as additional sources of safety data on vaccine use in pregnancy
- Well-designed post-licensure safety studies conducted in pregnant women may be included in product labeling (provided that the FDA has access to primary data and conducts its own review and analysis of the data). This would augment provider confidence in maternal immunization and enable more informed use of vaccines.

FOCUS AREA 4:

Support efforts to increase use of EHRs by maternal care providers to strengthen Immunization Information Systems (IIS) and vaccine surveillance systems for pregnant women

FOCUS AREA 4: RECOMMENDATIONS

4.1	The ASH should continue to support efforts to promote increased adoption of EHRs by all maternal health providers and pharmacists that can exchange data with Immunization Information Systems (IIS) of the appropriate public health jurisdictions according to current and future national standards and regulations set by CDC and ONC (Office of the National Coordinator for Health Information Technology). This should include bidirectional data exchange standards where supported. Bidirectional exchange of health data will improve tracking of a pregnant woman's immunization history, enable forecasting of needed vaccines during health visits, and ensure timely and appropriate administration of vaccines.
4.2	The ASH should promote collaborations between ONC, CDC, and FDA to conduct pilot projects that increase automated, electronic interactions between EHRs and surveillance systems in order to develop national standards to strengthen vaccine safety monitoring systems in pregnant women. Use of these systems can provide ongoing data regarding the safety of vaccines recommended by ACIP for use in pregnancy.

FOCUS AREA 5: RATIONALE

- The VICP maintains stability of vaccine markets by:
  - Diverting lawsuits away from vaccine manufacturers and administrators
  - Providing compensation to those who have been injured by vaccines
- Currently, manufacturers and administrators are afforded liability protections for injuries sustained by pregnant women as a result of direct vaccinations
- Courts have not definitively resolved whether such protections extend to injuries sustained by a child while *in utero* as a result of vaccination of the mother
- Lack of protection from liability has been raised as a potential obstacle to developing vaccines specifically targeting pregnant women in the United States

FOCUS AREA 5:

Recognize and address current vaccine liability law barriers to optimize investigations and uptake of recommended and future vaccines during pregnancy.

FOCUS AREA 5: RECOMMENDATIONS

5.1	The ASH should support efforts by Health Resources and Services Administration (HRSA) to address the issue of in utero injuries putatively incurred following maternal immunization within the Vaccine Injury Compensation Program (VICP). The ASH should support resolution of the issue of in utero injuries in favor of allowing such claims to be pursued under the VICP and in favor of providing settled liability protections to vaccine manufacturers and administrators. Doing so would remove a large obstacle to robust investigation of alleged vaccine adverse events following maternal immunization and remove real world barriers to widespread implementation of maternal immunization services by many providers.

NEXT STEPS

- SEPTEMBER 2013: Recommendations and draft report are presented to the full NVAC
- FALL/WINTER 2013: Proceed with the third component of the charge