

Maternal Immunization Working Group: Presentation of Draft Report and Draft Recommendations

11 June 2014
June NVAC

Chairs:
Richard Beigi, MD
Catherine Torres, MD

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

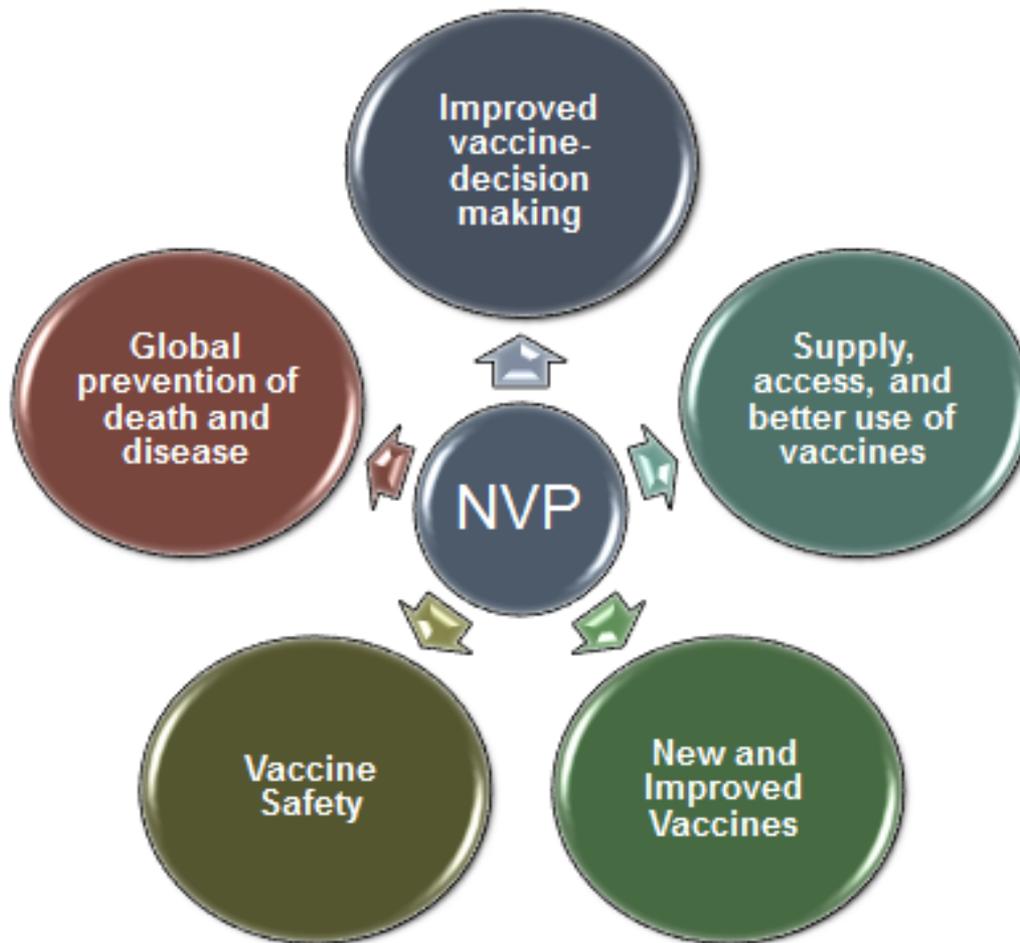
Part 2:

- Identify barriers to and opportunities for developing vaccines for pregnant women and make recommendations to overcome these barriers (*will be addressed separately in future discussions*)

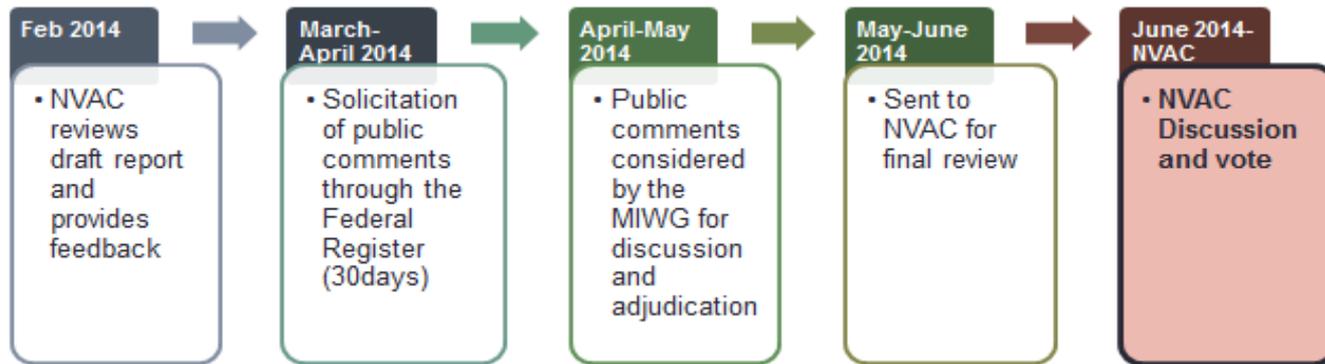
MIWG Report

- **Background**
- **Barriers to maternal immunization**
 - Patient Barriers
 - Provider Barriers
- **NVAC Conclusions and Recommendations**
 - 1) Enhance communication addressing the safety and effectiveness of all currently recommended immunizations during pregnancy
 - 2) Maximize obstetric provider recommendation and administration of recommended maternal immunizations
 - 3) Focus efforts to improve financing for immunization services during pregnancy and postpartum
 - 4) Support efforts to increase the use of electronic health records (EHRs) by obstetrical care providers
 - 5) Recognize and address current vaccine liability law barriers to optimize investigations and uptake of recommended and future vaccines during pregnancy

MIWG Recommendations and the National Vaccine Plan



Finalizing Report: Timeline



Feb 2014

- NVAC reviews draft report and provides feedback

March-April 2014

- Solicitation of public comments through the Federal Register (30 days)

April-May 2014

- Public comments considered by the MIWG for discussion and adjudication

May-June 2014

- Sent to NVAC for final review

June 2014-NVAC

- NVAC Discussion and vote

Highlights of Public Comments Received as of April 25, 2014

- 14 public comments received representing individuals, organizations, professional associations, and industry

Group B Strep Association
Group B Strep International
Group B Strep Support
American Academy of Family Physicians
American Academy of Pediatrics

America's health Insurance Plans
Association of State and Territorial Health Officials
Biotechnology Industry Organization
March of Dimes
National Vaccine Information Center
Novavax

- Vast majority of comments indicated public support of the recommendations
- 5/14 comments specifically addressed strong support for recommendation 5.1 addressing inclusion of *in utero* injuries allegedly incurred following maternal immunization within the Vaccine Injury Compensation Program (VICP).

A summary of these comments have been shared with ACCV

- The working group considered all comments received and revised the text of the report to reflect their consensus following these discussions



Revisions to recommendations based on feedback received from Public Comment

Previous Recommendation

1.5: The ASH should encourage appropriate professional and healthcare organizations to educate obstetrical care providers on the available vaccine safety surveillance systems to improve provider knowledge and reporting of potential vaccine adverse events. Educational materials and trainings should include the importance of reporting these events as well as how post-marketing surveillance systems are used to track safety data, and the strengths and limitations of these systems.

Revised Recommendation

1.5: The ASH should encourage appropriate professional and healthcare organizations to educate obstetrical care providers on the available post-marketing surveillance systems used to track vaccine safety data in order to improve provider knowledge and reporting of potential vaccine adverse events. **Educational materials and trainings should include how to report possible events to the relevant post-marketing surveillance systems, the strengths and limitations of these systems, the importance of reporting possible serious vaccine adverse events, and information regarding federal reporting requirements.**

Revisions to recommendations based on feedback received from Public Comment

Previous Recommendation

2.5: The ASH should work with the NCQA, the NQF, and other stakeholders to establish immunization metrics for vaccines recommended to pregnant women in order to reliably measure rates of immunizations given by obstetrical care providers. Doing so will help to develop health care quality performance measures for immunization of pregnant women for healthcare providers and institutions.

Revised Recommendation

2.5: The ASH should work with the stakeholder community **to evaluate the applicability of existing measures and/ or the development of new measures for vaccines recommended to pregnant women.** Standardized metrics will help to reliably measure rates of immunizations given by obstetrical care providers to improve vaccine delivery in this population and to better measure progress towards institutional and national goals.

Revisions to recommendations based on feedback received from Public Comment

Previous Recommendation

3.1: The ASH should work with CMS and CDC to determine the costs to deliver immunizations in various types of obstetrical practices to help evaluate cost as a factor in the provision of adult immunizations. Doing so may allow for more effective reimbursement processes in the future

Revised Recommendation

3.1: The ASH should work with CMS and CDC to determine the costs **to provide immunizations** in various types of obstetrical practices to help evaluate **the various factors influencing** the provision of adult maternal immunizations.

Revisions to recommendations based on feedback received from Public Comment

Previous Recommendation

3.2. The ASH should work with CMS, HRSA and private payers to determine appropriate financial reimbursement processes for the provision of maternal and other adult immunizations by obstetrical health care providers, such as adult vaccine counseling and vaccine administration.

Revised Recommendation

3.2 ASH work with CMS, HRSA and private payers **to identify and improve upon current process issues related to billing, coding and subsequent payment** for the provision of maternal and other adult immunizations by obstetrical health care providers, such as adult vaccine counseling and vaccine administration.

Other Revisions?

Current Recommendation

1.4: The ASH should work with the appropriate federal agencies to assess data collected through post-marketing surveillance systems on the safety, efficacy, and effectiveness of currently recommended vaccines for pregnant women and their infants. **The ASH also should work with Federal agencies to determine the data needs for vaccine safety in pregnant women, the ability of these systems to capture these data, and modify/develop new systems if data needs are not being met.**

Public Comments for broader NVAC consideration

- Several public comments highlighted a need to identify and address EHRs barriers
 - Interoperability
 - Linking mother/infant records
 - Linking EHRs to vaccine safety monitoring
- A number of comments indicated strong support for future NVAC discussions to support vaccine research and development of vaccines for use in pregnant women (e.g., Group B Strep vaccines, RSV vaccines)



NVAC DISCUSSION

EXTRA SLIDES

MEMBERSHIP

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

Recommendations fall within 5 focus areas

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

1. Enhance communication addressing the safety and effectiveness of all currently recommended immunizations during pregnancy

1.1 The ASH should provide regular updates to relevant stakeholders regarding vaccines that are recommended by ACIP/CDC for use in pregnant women. Doing so will maximize the potential for disease prevention through vaccine use, thereby benefiting the mother and her infant.

1.2 The ASH should work with federal partners and professional organizations to develop and distribute communication strategies and educational materials to healthcare providers, especially those delivering maternity care. These educational materials should clearly state the benefits of maternal immunization such as reducing the morbidity and mortality for mothers and young infants. In addition, they should enable providers to educate women who are pregnant or may become pregnant on the available clinical data regarding the safety and effectiveness of all ACIP/CDC-recommended maternal immunizations for themselves and their infants.

1.3 The ASH should encourage the use of current and newly emerging communication technologies to maximize the effectiveness and reach of communication efforts addressing the clinical benefits of maternal immunization.

1.4 The ASH should work with the appropriate federal agencies to assess data collected through post-marketing surveillance systems on the safety, efficacy, and effectiveness of currently recommended vaccines for pregnant women and their infants.

1.5 The ASH should encourage appropriate professional and healthcare organizations to educate obstetrical care providers on the available post-marketing surveillance systems used to track vaccine safety data in order to improve provider knowledge and reporting of potential vaccine adverse events. Educational materials and trainings should include how to report possible events to the relevant post-marketing surveillance systems, the strengths and limitations of these systems, the importance of reporting possible serious vaccine adverse events, and information regarding federal reporting requirements.

2. Maximize obstetric provider recommendation and administration of recommended maternal immunizations

2.1 The ASH should recommend that obstetric providers follow the published guidelines of professional organizations and government agencies to improve vaccination rates in their practices.

2.2 The ASH should collaborate with federal partners, professional educational organizations, and other relevant maternal immunization stakeholders to develop curricula for trainees and healthcare providers that should include information about the recognized benefits and risks of immunizations during pregnancy and postpartum. Curricula should also include information about both the scientific basis for immunizations, as well as the basics of establishing and administering immunization services in outpatient obstetrical care settings

2.3 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.

2.4 The ASH should work with obstetrical care stakeholders to incorporate the widespread use of programs such as the Assessment, Feedback, Incentives, and eXchange (AFIX) to support and evaluate the incorporation of immunization services into obstetrical care practices.

2.5 The ASH should work with the stakeholder community to evaluate the applicability of existing measures and/ or the development of new measures for vaccines recommended to pregnant women. Standardized metrics will help to reliably measure rates of immunizations given by obstetrical care providers to improve vaccine delivery in this population and to better measure progress towards institutional and national goals.

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

3.1 The ASH should work with CMS and CDC to determine the costs to provide immunizations in various types of obstetrical practices to help evaluate the various factors influencing the provision of adult maternal immunizations.

3.2 The ASH work with CMS, HRSA and private payers to identify and improve upon current process issues related to billing, coding and subsequent payment for the provision of maternal and other adult immunizations by obstetrical health care providers, such as adult vaccine counseling and vaccine administration.

3.3 The ASH should continue to monitor the effectiveness of the 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.

3.4 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 and practice 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 participation in vaccine purchasing groups.

4. EHRs, meaningful use, and promoting information exchange with Immunization Information Systems (IISs)

4.1 The ASH should continue to support efforts to promote increased adoption by all obstetrical care providers of EHRs that can exchange data with Immunization Information Systems (IIS) of the appropriate public health jurisdictions. This should include bidirectional data exchange standards where supported, according to current and future national standards and regulations set by CDC and ONC (Office of the National Coordinator for Health Information Technology).

4.2 The ASH should promote collaborations among ONC, CDC, and FDA to establish automated, electronic interactions between EHRs and vaccine safety surveillance systems in order to strengthen vaccine safety monitoring systems in pregnant women.

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

5.1 The ASH should support efforts by the Health Resources and Services Administration (HRSA) to address the issue of inclusion of *in utero* injuries allegedly incurred following maternal immunization within the Vaccine Injury Compensation Program (VICP). The ASH should support resolution of the issue regarding infants born with alleged *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.