

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

**07 JUNE 2013
ACCV MEETING
DR. CATHERINE TORRES, MD**



Maternal Immunizations

Maternal and Neonatal Tetanus:

- Tetanus-related mortality rates are extremely high in developing countries, especially when appropriate medical care is lacking
- Hygienic delivery and cord care practices, and immunizing mothers with tetanus vaccine has led to a 93% decrease in neonatal tetanus since the 1980s

Influenza:

- High morbidity/mortality rates have been associated among pregnant women with influenza during the pandemics of 1918, 1957, 2009
- Pregnancy is a significant risk factor for increased illness and death for seasonal and pandemic influenza
- Maternal influenza vaccination has documented benefits to both the mother and newborn

Pertussis:

- Infants less than 3 months of age (too young to be immunized) are particularly vulnerable to severe disease and death
- Focus on maternal immunization as a primary strategy to protect infants until they are old enough to be vaccinated

Maternal Immunization is an important disease control strategy to protect the most vulnerable patient, the newborn



Improving Maternal Immunization in the U.S.



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

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

Tdap: Feb 2013: ACIP recommended that pregnant women receive a Tdap booster in the 3rd trimester of *each* pregnancy

Influenza: April 1995: ACIP recommended that all pregnant women receive an inactivated influenza vaccine (dose can be given at any stage of pregnancy)

Where are we today?

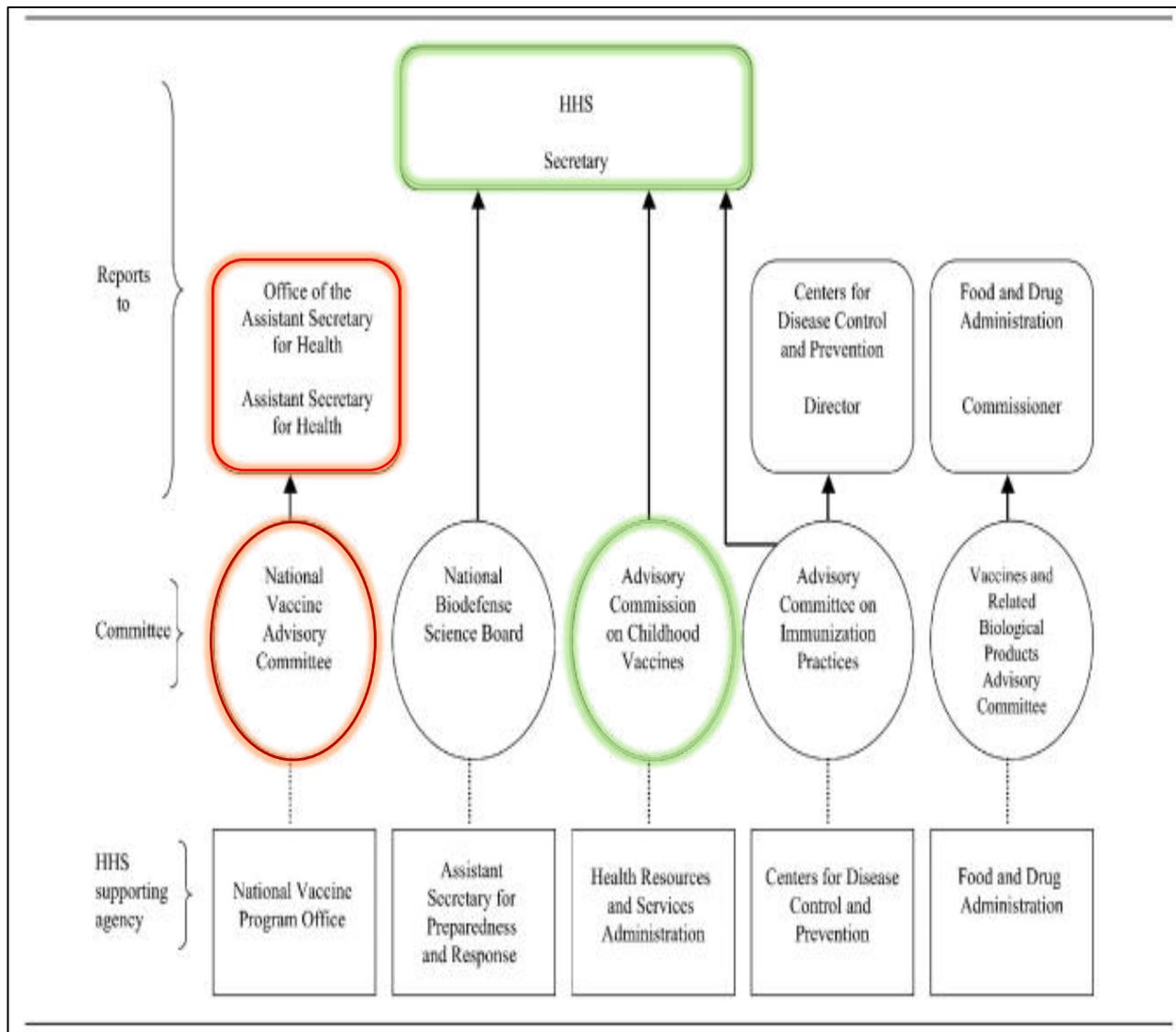
Pertussis	Influenza
2.6% - Women vaccinated with Tdap during pregnancy	53% - Women vaccinated with influenza during pregnancy

The National Vaccine Advisory Committee (NVAC)

- Formed in 1987 under Title XXI of the Public Health Service Act, NVAC is a federal advisory committee that advises and makes vaccine/immunization policy recommendations to the Assistant Secretary of Health in his capacity as the Director of the National Vaccine Program (NVP) on matters related to program responsibilities
- Specifically, NVAC does the following:
 - Study and recommend ways to encourage the availability of an adequate supply of safe and effective vaccination products in the US
 - Recommend research priorities and other measures the Director should take to enhance the safety and efficacy of vaccines
 - Advise the Director in the implementation of the National Vaccine Program's responsibilities and the National Vaccine Plan
 - Identify annually for the Director the most important areas of government and non-government cooperation related to the National Vaccine Program responsibilities and implementation of the National Vaccine Plan
- NVAC convenes working groups (WGs) that represent diverse stakeholders such as: academics; manufacturers; health insurance industry; health-care providers; consumers; NGOs; federal, state and local departments of health



Reporting Structure of vaccine/immunization-related HHS Federal Agencies



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)

APPROVAL

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

Potential Synergies between ACCV and NVAC for advancing maternal immunizations

- The NVAC Maternal Immunizations Working Group has been in close communication with the ACCV in developing discussions and recommendations

Why NVAC?

- Uncertainties surrounding maternal immunizations and vaccine liability may create barriers that limit obstetrical providers' willingness to administer important immunizations during pregnancy
- Uncertainties surrounding maternal immunizations and vaccine liabilities create barriers to the development of future vaccines that have the potential to greatly impact newborn health
- Consensus among multiple advisory groups that this is an important issue sends a powerful message to HHS and others and helps build solidarity around the proposed recommendations



MEMBERSHIP

NVAC	Catherine Torres (Co-chair), Rich Beigi (Co-chair) Walt Orenstein, Phil LaRussa, Amy Pisani, LJ Tan, Vish Viswanath, 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

NVAC Maternal Immunization Working Group Process

- Inaugural meeting August 2012
- Working group meets 1-2x per month by phone
 - Presentation by a subject matter expert followed by group discussion
- 13 presentations on Maternal Immunization topics such as :
 - **Epidemiology** of pertussis and influenza in pregnant women and infants and rationale for maternal vaccination
 - **Patient barriers** to currently recommended vaccines and opportunities to overcome these barriers
 - **Provider barriers** to currently recommended vaccines and opportunities to overcome these barriers
 - **Vaccine financing & vaccine liability**
 - **Public financing** – Medicare and CHIP coverage of immunization in pregnant women
 - **Development of vaccines for use in pregnant women:** barriers to the development of these vaccines and opportunities to overcome these barriers
 - **Regulatory considerations** for developing vaccines specifically for use in pregnant women
 - **Communication issues** surrounding maternal immunizations
- Develop recommendations for presentation to the NVAC through iterative WG discussions
- Develop a white paper that provides background and rationale for the recommendations
Coming soon!



NVAC MIWG

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.

Recommendations fall within 5 focus areas

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| 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. |

The MIWG recommendations align with goals 2, 3, and 4 of the National Vaccine Plan

Goal 1 Develop new and improved vaccines

Goal 2 *Enhance Vaccine Safety*

Goal 3 *Support Communications to enhance informed vaccine decision-making*

Goal 4 *Ensure a stable supply of, access to, and better use of recommended vaccine in the U.S.*

Goal 5 Increase global prevention of death and disease through safe and effective vaccination



**National
Vaccine
Program
Office**

For more information about the National Vaccine Plan
Visit: http://www.hhs.gov/nvpo/vacc_plan/

Next Steps

- JUNE 2013: Present draft recommendations to full NVAC committee for discussion. Recommendations revised based on NVAC feedback
- SEPTEMBER 2013: Draft recommendations and draft report are presented to the full NVAC for deliberation and vote
- FALL/WINTER 2013: Proceed with the third component of the charge to begin analyzing barriers and opportunities for developing vaccines specifically for use in pregnant women (e.g., GBS vaccine, RSV vaccine, etc.) – Recommendations on this aspect of the charge to follow.

Thank you!



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