



# NATIONAL VACCINE PROGRAM OFFICE UPDATE



**National  
Vaccine  
Program  
Office**

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THE NATIONAL VACCINE PROGRAM OFFICE



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# National Adult Immunization Plan Rollout



## NAIP OVERVIEW

- Outlines actions needed to be carried out by federal and nonfederal stakeholders to protect public health and achieve optimal prevention of infectious disease through immunization of adults
- Provides guidance through goals, objective and strategies aimed at strengthening infrastructure, improving access, increasing demand and fostering innovation for adult immunization



## GOAL 1: STRENGTHEN THE ADULT IMMUNIZATION INFRASTRUCTURE

### GOAL 1 INCLUDES SIX OBJECTIVES TO STRENGTHEN THE ADULT IMMUNIZATION INFRASTRUCTURE

GOAL 1 OBJECTIVE 1.1	GOAL 1 OBJECTIVE 1.2	GOAL 1 OBJECTIVE 1.3	GOAL 1 OBJECTIVE 1.4	GOAL 1 OBJECTIVE 1.5	GOAL 1 OBJECTIVE 1.6
Monitor and report trends in adult vaccine-preventable disease levels and vaccination coverage data for all ACIP/CDC-recommended vaccines. In cases where there are associated Healthy People 2020 goals, measure progress toward established targets.	Enhance current vaccine safety monitoring systems and develop new methods to accurately and more rapidly assess vaccine safety and effectiveness in adult subpopulations (e.g., pregnant women).	Continue to analyze claims filed as part of the National Vaccine Injury Compensation Program (VICP) to assess whether there was an association between vaccines that a claimant received and adverse events experienced.	Increase the use of electronic health records (EHRs) and immunization information systems (IIS) to collect and track adult immunization data.	Evaluate and advance targeted quality improvement initiatives.	Generate and disseminate evidence about the health and economic impact of adult immunization, including potential diseases averted and cost-effectiveness with the use of current vaccines.

# NVAC MATERNAL IMMUNIZATION WORKING GROUP

## 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**

# MATERNAL IMMUNIZATIONS: ETHICAL ISSUES

- **Consideration of development and articulation of broadly acceptable and applicable ethical framework that can be used at various venues**
- **Clarification on vulnerable populations: Unethical to describe pregnant women as a vulnerable population, they are rather a complex population**
- **Standardized definitions of minimal risk to aid IRB review process**

# MATERNAL IMMUNIZATIONS: REGULATORY ISSUES

- **Clearly define PLLR implementation concerning vaccinations**
- **New OHRP guidelines to include pregnant women in clinical trials**
- **Consideration of advocacy for models (similar to BPCA) that would effectively change from default to exclusion to default to inclusion, unless clear criteria given for why exclusion.**
- **Continued interface and dialogue between manufacturers and FDA on exact requirements for licensure/indication for existing and new vaccine products for use in pregnancy.**
- **Improve interaction and collaborations between manufacturers and government (DHHS) to encourage manufacturer investment in Maternal Immunization**
- **Continue to advocate to avoid liability issues, and to modify the VICP so maternal immunizations are fully covered**

# MATERNAL IMMUNIZATIONS: SAFETY MONITORING ISSUES

- **Development of standardized definitions of possible maternal and neonatal outcomes**
- **Work to align current safety systems for optimal output**
- **Create interface with international data systems**
- **Promote education of providers on maternal immunization safety research**
- **Clear guidance/consensus on acceptable newborn surveillance timeframe during trials and post-licensure**
- **Obtain data on the safety profile of individual antigen preparations, not only of a vaccine in general (especially for all the Flu and TDaP formulations)**

# MATERNAL IMMUNIZATIONS: PRE-CLINICAL AND CLINICAL RESEARCH

- Increase support of pre-clinical research to address barriers in developing maternal immunizations at this early stage
- Consider increasing research focus/network by creating a Maternal Immunization Research Network
- Focus on standardizing post-marketing surveillance for maternal immunization
- Encourage continuing studies of post-marketing effectiveness evaluation

# MATERNAL IMMUNIZATIONS: PROVIDER EDUCATION AND SUPPORT

- Professional societies should be a valuable partner encouraging and demanding that clinical research be conducted including pregnant women
- Obstetrician providers should be aware that currently there is little or no research during pregnancy, and become advocates for testing vaccines during pregnancy
- Obstetricians should also advocate for vaccination, and understand the importance of vaccine research during pregnancy
- Educate obstetricians on vaccination and interpretation of new labelling so they can make informed decisions



# NATIONAL VACCINE PROGRAM OFFICE VACCINE CONFIDENCE COOPERATIVE AGREEMENT

- Request for Cooperative Agreement related to vaccine confidence: this announcement is accepting applications, with the funding (\$250,000 for up to 18 months) supporting a project that is in line with the NVPO vaccine confidence strategy document and June 2015 NVAC Report on Vaccine Confidence.

THANK YOU