

**NATIONAL VACCINE PROGRAM OFFICE**

**TASK FORCE ON RESEARCH SPECIFIC  
TO PREGNANT WOMEN AND LACTATING  
WOMEN (PRGLAC)**

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**AUGUST 21, 2017**



THE NATIONAL VACCINE PROGRAM OFFICE



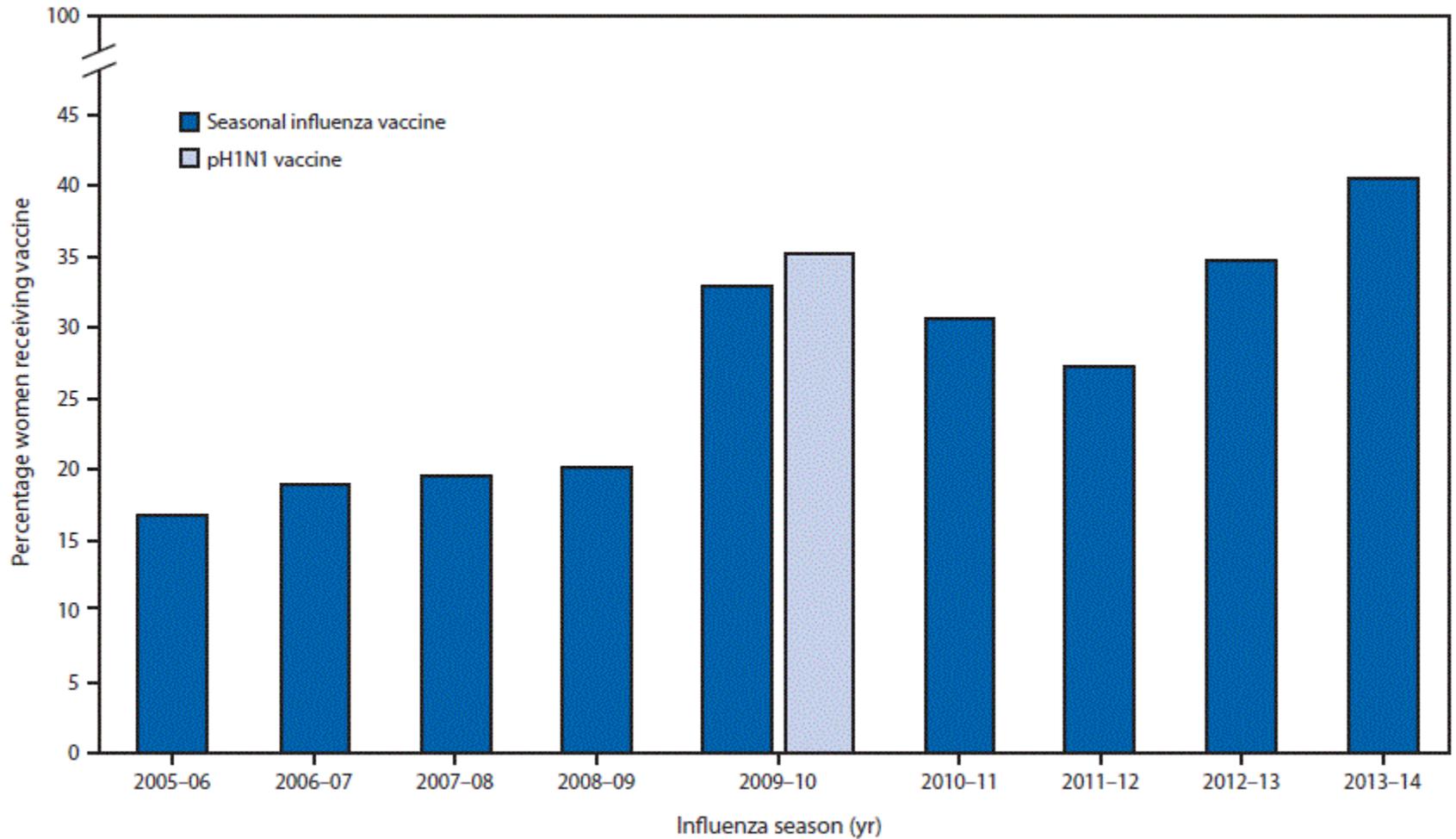
U.S. DEPARTMENT  
OF HEALTH AND  
HUMAN SERVICES

# MATERNAL IMMUNIZATIONS RECOMMENDED BY THE CDC, BUT WITHOUT A SPECIFIC INDICATION BY FDA

- ✓ **Influenza:** Any trimester (updated in 2004)
- ✓ **Tdap:** every pregnancy between 27 and 36 weeks of gestation (2012)

Maternal immunizations that might become available: **RSV, GBS, CMV**

# INFLUENZA VACCINATION COVERAGE DURING PREGNANCY



## IMMUNIZATION DURING PREGNANCY APPROACH

- Increasing support of maternal immunization research
- Communicating and educating about maternal immunizations
- Overcoming barriers and identifying opportunities for developing additional maternal immunizations

# SUPPORTING MATERNAL VACCINATION RESEARCH WITH FEDERAL PARTNERS

| Leading Agency/System | Scientific Activities   |
|-----------------------|---|
| <b>CDC/CISA</b>       | Clinical Study of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine (Tdap) Safety in Pregnant Women  |
| <b>CDC/CISA</b>       | Clinical Study of the Safety of Simultaneous Administration of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine (Tdap) and Inactivated Influenza Vaccine (IIV) in Pregnant Women – Pilot |
| <b>FDA/BARDA/NVPO</b> | Analysis of the association between infections, vaccinations, and medications during pregnancy and possible birth defects outcomes, and Creation of an archived database  |
| <b>CDC-VSD/OASH</b>   | Development and evaluation of novel methods to identify possible increased risks of fetal loss (spontaneous abortion and stillbirth) following vaccination in pregnancy in the Vaccine Safety Datalink            |

# SUPPORTING MATERNAL VACCINATION SAFETY RESEARCH WITH NON FEDERAL COLLABORATORS

**Awardee:** Kaiser Foundation Hospitals—Kaiser Foundation Research Institute

**Principal Investigator:** Roger Baxter, MD and Co-Principal Investigator Nicola Klein, MD, PhD

**Description:** NVPO funded the creation of a maternal-neonatal vaccine safety database and analysis of outcomes using the database. The first analysis compares the likelihood of fever in babies born to vaccinated versus unvaccinated mothers after receiving their first pertussis vaccination. The second analysis compares alternative benefits of influenza vaccination during pregnancy.

Published Research:

-- [Kaiser Permanente Northern California Pregnancy Database: Description and proof of concept study](#)

-- [No association between influenza vaccination during pregnancy and adverse birth outcomes](#)

# SUPPORTING MATERNAL VACCINATION SAFETY RESEARCH WITH INTERNATIONAL COLLABORATORS

- **Awardee:** Cincinnati Children's Hospital Medical Center  
**Principal Investigator:** Steven Black, MD
- **Description:** This project aims to validate the Global Alignment of Immunization Safety Assessment in pregnancy (GAIA) maternal and neonatal outcome definitions to standardize the evaluation of the safety of vaccines. (US, Australia and UK)

# EDUCATION: VACCINES.GOV

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Basics Diseases **Who & When** Getting Vaccinated Travel More Info

[Home](#) > [Who & When](#) > Pregnant

**Infants, Children, & Teens**  
*birth-18*

**Child Catch-up**  
*age 4 mos-18*

**College & Young Adults**  
*age 19-24*

**Adults**  
*age 19 and older*

**Seniors**  
*age 65 and older*

**Pregnant**

**Health Conditions**

Text Size: [A](#) [A](#) [A](#)

## Vaccinations during Pregnancy

Vaccines can help protect both you and your baby from vaccine-preventable diseases. During pregnancy, vaccinated mothers pass on protective antibodies—infection-fighting molecules—to their babies before they are born. This provides some immunity against certain vaccine-preventable diseases during their first few months of life, when your baby is still too young to be vaccinated. It also helps provide important protection for you throughout your pregnancy.

### Vaccines for Pregnant Women

There are two vaccines routinely recommended by CDC to be administered during pregnancy:

- **Flu Vaccine:** During **each** pregnancy you should get the inactivated influenza (flu) vaccine (IIV) (flu shot) to protect yourself and your baby from the flu. It can be given during any trimester of pregnancy. A pregnant woman who gets the flu is at increased risk for serious complications and



# COMMUNICATION: @HHSVACCINES



**Natl Vaccine Program** @HHSVaccines · 22 Sep 2016

Do you know which vaccines pregnant women need? [bit.ly/1E4Glgk](https://bit.ly/1E4Glgk)



STAYING UP-TO-DATE  
ON VACCINES  
BEFORE, DURING,  
& AFTER PREGNANCY  
KEEPS BOTH  
MOM AND BABY  
HEALTHY



**Natl Vaccine Program** @HHSVaccines · Aug 11

Take @CDCgov's quiz to find information about vaccines for women before, during & after pregnancy: [bit.ly/2kp7zTE](https://bit.ly/2kp7zTE) #NIAM17



**Vaccines and Pregnancy: Take the Quiz to Learn More**

Getting vaccinated is an important part of a healthy pregnancy.

[cdc.gov](https://www.cdc.gov)



**Natl Vaccine Program** @HHSVaccines · 8 Aug 2016

2 vaccines are routinely recommended for pregnant women: TDaP & #flu. Learn more: [bit.ly/1E4Glgk](https://bit.ly/1E4Glgk) #NIAM2016



## PROVIDER ENGAGEMENT



# Upshot Webinar Series

The Path to a World Free of Polio,  
Measles, and Rubella, and Remaining  
Risks for the United States

**Tuesday, April 25 from 12 pm – 1:30 pm ET**

Register now at [hhs.gov/nvpo/webinars](https://hhs.gov/nvpo/webinars)

## UpShot Awards Program

# 2017 WINNER

For work optimizing the vaccine  
and immunization system



[hhs.gov/nvpo/awards](https://hhs.gov/nvpo/awards)

# THANKS



30 Years Optimizing Immunization

# NVAC AND MATERNAL IMMUNIZATION CHALLENGES IN THE U.S.

1. Enrolling susceptible populations in clinical trials
2. Case-control studies on vaccines currently recommended for pregnant women (Flu and Tdap)
3. Large cohorts that will enable studying rare adverse events (birth defects)
4. Defining the endpoint of a vaccine safety clinical trial: creating consensus across trials nationally and globally
5. Liability concerns when administering vaccines recommended for pregnant women only and/or intended to protect the baby
6. Linking health records of pregnant women and infants to enable long-term follow-up of infant
7. Safety and regulatory requirements to obtain an indication specific for pregnancy

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

# NVAC REPORT ON MATERNAL IMMUNIZATIONS

*Reports and Recommendations*

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PUBLIC  
HEALTH  
*Reports*

## **Overcoming Barriers and Identifying Opportunities for Developing Maternal Immunizations: Recommendations From the National Vaccine Advisory Committee**

Public Health Reports

Vol. 132(3) 1-14

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**Approved by the National Vaccine Advisory Committee on September 20, 2016**

## 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 (via update to Common Rule Subpart A)**
- **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 (PGRLAC addressed in the 21<sup>st</sup> Century Cures Act)**

## **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 (via 21<sup>st</sup> Century Cures Report on Vaccine Innovation)**
- **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**

## 21<sup>ST</sup> CENTURY CURES ACT

- **The Vaccine Injury Compensation Program:**
  - The Secretary shall revise the Vaccine Injury Table included in subsection (a), through the process described in subsection (c), **to include vaccines recommended by the Centers for Disease Control and Prevention for routine administration in pregnant women** and the information described in paragraphs (B) and (C) with respect to such vaccines.
  - (1) IN GENERAL.—Notwithstanding any other provision of law, for purposes of this subtitle, **both a woman who received a covered vaccine while pregnant and any child who was in utero at the time such woman received the vaccine shall be considered persons to whom the covered vaccine was administered** and persons who received the covered vaccine. Section 2111(b)(2) of the Public Health Service Act (42 U.S.C. 300aa– 10 11(b)(2)) is amended by adding “A covered vaccine administered to a pregnant woman shall constitute more than one administration, one to the mother and one to each child (as such term is defined in subsection (f)(2)) who was in utero at the time such woman was administered the vaccine.” at the end.

# 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**