



NVPO update on Vaccine Safety

Dr. Karin Bok
June 9, 2015



Overview: National Vaccine Safety System

Assistant Secretary
for Health



National Vaccine Program Office

NVAC

ISTF

Discovery and
Development

Licensure

Post-Marketing
Surveillance

NIH

National Institutes of Health

FDA

Food and Drug Administration



Centers for Disease
Control and Prevention



Department of Defense



Dept. of Veteran Affairs



Indian Health Service

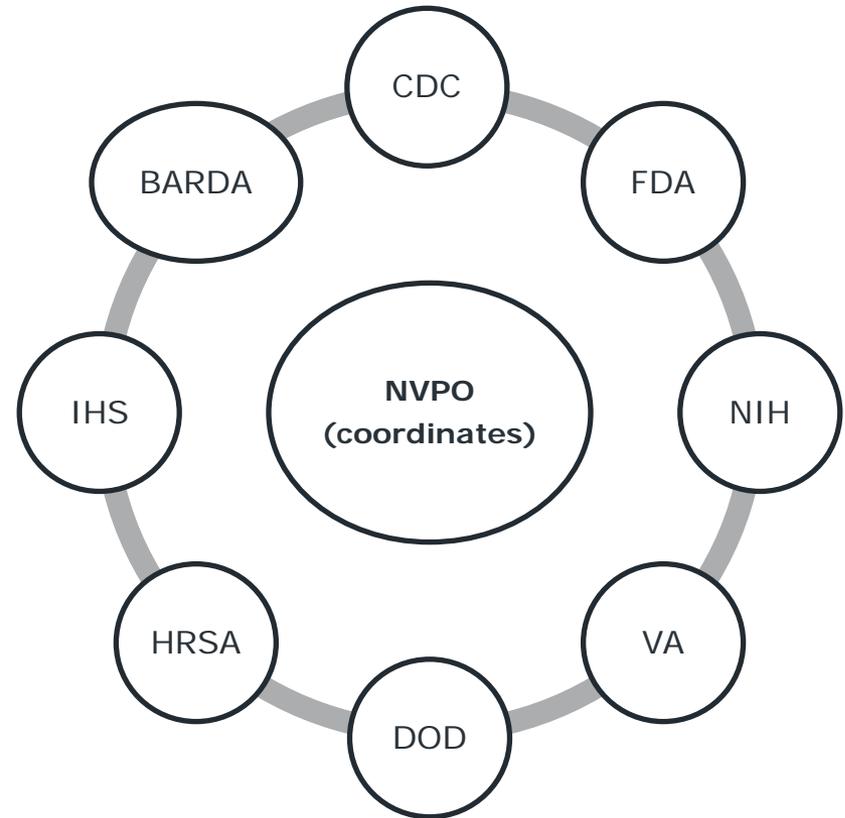


Immunization Safety Task Force Activities



Enhance Collaboration of Vaccine Safety Activities: The Immunization Safety Task Force

NVPO coordinates and leads the ISTF: Ensures that all federal efforts relevant to immunization safety are coordinated and integrated and that opportunities to enhance synergies across the federal government in immunization safety are identified



ISTF Members

CDC

Rita Helfand
Cindy Weinbaum
Frank DeStefano
Tom Shimabukuro

HRSA

Melissa Houston
Tamara Overby

BARDA

Jo Schweinle

FDA

Steven Anderson
Marion Gruber
Karen Midthun
Peter Marks
David Martin
Phil Krause

NIH

Barbara Mulach
Charles Hackett
Claire Schuster
Andrew Ford

DOD

Limone Collins
Jorge Carrillo
Catherine Witkop
Ava Conlin
Amy Costello

VA

Fran Cunningham

IHS

Amy Groom



Vaccine Safety Scientific Agenda

Text Size: **A A A**      Share

[NVPO Home](#)

[About NVPO](#)

[National Vaccine Advisory Committee](#)

[National Vaccine Plan](#)

[Resources](#)

Vaccine Safety Scientific Agenda

There is no question that vaccines provide substantial benefits to support and protect public health. To ensure their continued success, it is critical to continually assess vaccine safety. The [2010 National Vaccine Plan](#) called for the development of a vaccine safety scientific agenda summarizing the contributions of the federal partners to the overall safety of vaccines in the U.S.



[Read the Vaccine Safety Scientific Agenda](#)

The [agenda](#) outlines the efforts of federal agencies on vaccine safety and the ongoing and planned associated scientific activities and interagency coordination that contribute to the safety system.

Below in three charts are the vaccine safety activities of our federal partners, including:

- [Pre-licensure Vaccine Safety Activities](#)
- [Routine Vaccine Safety Monitoring and Research Systems](#)
- [Post-licensure Vaccine Safety Activities](#)

Related Resources

- [Vaccine Safety Introduction](#)
- [Overview of the Vaccine Safety Surveillance Systems & Ongoing Scientific Activities to Monitor Maternal Vaccine Safety](#)
- **Funding Opportunity:** [Vaccine Safety Research](#)

http://www.hhs.gov/nvpo/vacc_plan/vaccine-safety-scientific-agenda.html



Vaccine Safety Cooperative Agreement

[NVPO Home](#)

[About NVPO](#)

[National Vaccine Advisory Committee](#)

[National Vaccine Plan](#)

[Resources](#)

Text Size: **A A A**      Share

Funding Opportunity for Vaccine Safety Research

NVPO announces a unique opportunity to partner with us on research that will strengthen the current U.S. vaccine safety enterprise. With the potential for two awardees to receive up to \$250,000 in funds, we encourage your participation—and look forward to reviewing applications following the April 15, 2015 closing date.

Types of Vaccine Safety-Related Research

Our objective is to conduct research in vaccine safety that

- determines the safety profile of new vaccines during the early development stage,
- develops or modifies existing vaccines to improve their safety,
- directly impacts the current vaccine safety monitoring system, and/or
- produces consensus definitions of vaccine safety outcomes that could be utilized to collect consensus data in clinical research conducted globally.

Projects Related to Pregnant Women and Newborns

Of particular interest are projects related to researching, establishing or testing the vaccine safety profile of vaccines that are either currently recommended for, or are expected to be, routinely administered to pregnant women and/or newborns. Topics of research may cover establishing the safety of a vaccine in either the pregnant woman, her newborn, or both, at any stage of the vaccine development, testing and/or pre-clinical or clinical research and monitoring of vaccine safety.

Application Close Date: April 15, 2015

Award Ceiling: \$250,000 per grant; a maximum of two grants to be awarded

Questions? Contact Dr. Karin Bok via [email](#) or at 202.690.1191

Apply now at [Grants.gov](#)



OASH Funded Vaccine Safety Evaluation

FY 2015 OASH Evaluation Set-Aside Evaluation Description and Justification

1. Initiative Title

Evaluation of Federal Vaccine Safety Systems Ability to Test and Survey the Safety of Vaccines Administered During Pregnancy

2. Total Annual Budget

\$400,000

3. Proposal Information

Indicate submitting office and any offices with which you are collaborating if appropriate:

Submitting office: National Vaccine Program Office (HHS/OASH)

Collaborating offices: Immunization Safety Office (HHS/CDC)

The Immunization Safety Task Force (ISTF; NIH, CDC, DoD, VA, HHS, FDA, IHS, BARDA)

Point of Contact: Dr. Karin Bok





NVPO Collaborations on Vaccine Safety Research



Enhanced Evaluation of Risk of Narcolepsy Associated with Pandemrix and Arepanrix and MF59-adjvanted H1N1 vaccines

Relevance

- SOMNIA is a landmark study for estimating the risk of narcolepsy following H1N1pdm09 vaccines. Due to its unprecedented sample size from other than signaling countries and
- the availability of data on ASO3 and MF59 adjuvanted vaccines, it will yield important
- information for future pandemic influenza preparedness plans and policy.

Study Progress

- 13 sites are enrolled in 9 countries in 4 continents
- 9 sites contribute to incidence rate study
- First report submitted in February with population based data from 5 sites
- Second report is scheduled for September 2015
- 8 sites contribute to case control study
- Data submission time line postponed to July 31, 2015



Clinical Study of Tdap Safety in Pregnant Women

- Collaboration with CDC/CISA
 - Compare the rates of local and systemic reactions following Tdap in pregnant women with non-pregnant women
 - Assess rates of preterm and small for gestational age (SGA) births in women who received Tdap during pregnancy
 - Explore differences in local and systemic reactions in pregnant women who are receiving their 1st Tdap versus those who have received Tdap in the past
- **Evaluate health outcomes and growth parameters in infants born to women who received Tdap (first 6 months of life)**
- Registered in www.clinicaltrials.gov (NCT02209623)



THANK YOU!

QUESTIONS/COMMENTS?

