NVPO update on Vaccine Safety

Dr. Karin Bok
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Overview: National Vaccine Safety System

Assistant Secretary for Health

National Vaccine Program Office

Discovery and Development

Licensure

Post-Marketing Surveillance

National Institutes of Health

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
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

**DOD**
- Limone Collins
- Jorge Carrillo
- Catherine Witkop
- Ava Conlin
- Amy Costello

**NIH**
- Barbara Mulach
- Charles Hackett
- Claire Schuster
- Andrew Ford

**VA**
- Fran Cunningham

**IHS**
- Amy Groom
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.

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

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-adjuvanted 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?