



# Vaccine Safety Introduction

Dr. Karin Bok

September 9, 2014



# Overview: National Vaccine Safety System

Assistant Secretary  
for Health



National Vaccine Program Office

NVAC

ISTF

Discovery and  
Development

Licensure

Post-Marketing  
Surveillance

NIH

Nat'l Institutes of Health

FDA

Food and Drug Administration



Centers for Disease  
Control and Prevention



Department of Defense



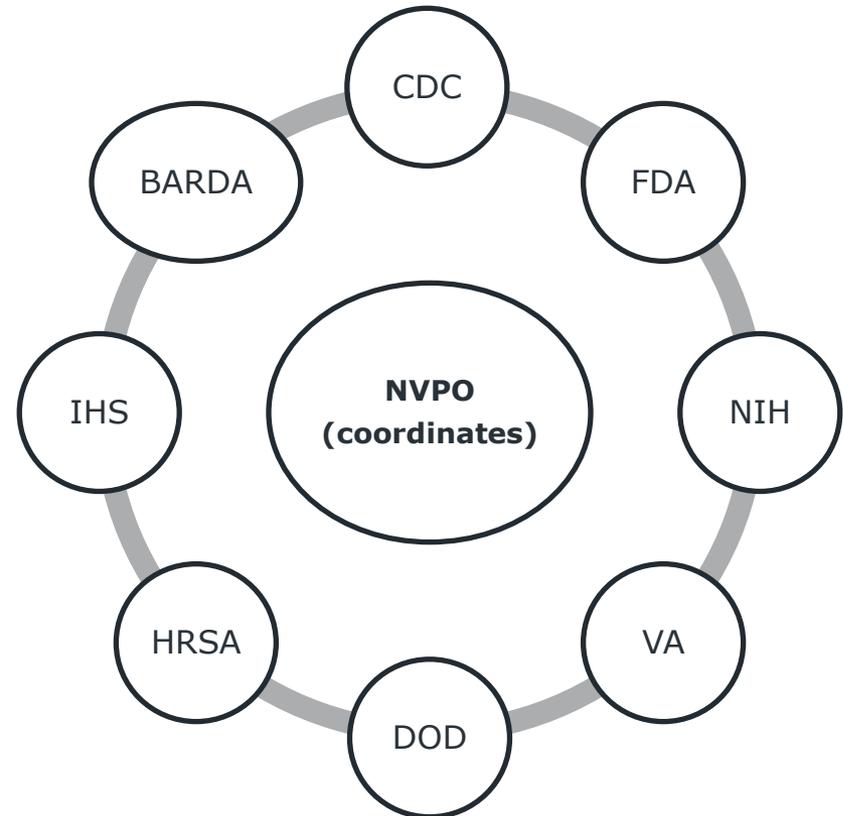
Dept. of Veteran Affairs



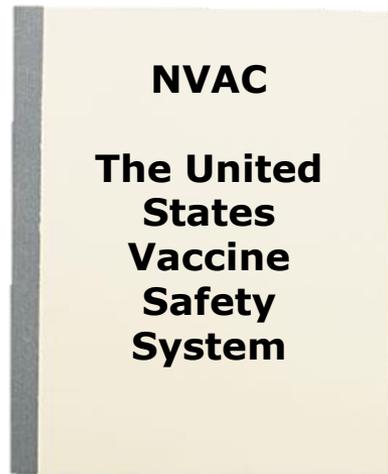
Indian Health Service

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

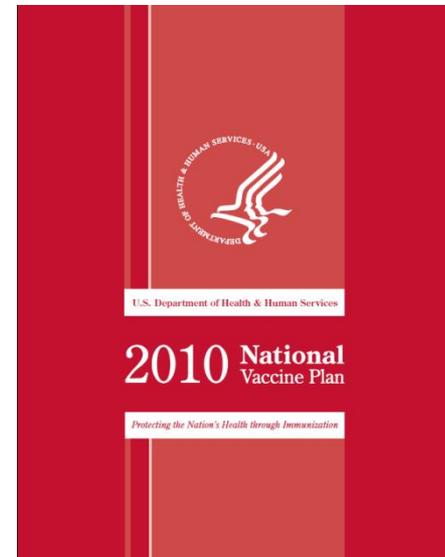
**NVPO coordinates and leads the ISTF:** Ensures that all federal efforts relevant to immunization safety are coordinated and integrated and that opportunities to enhance synergies across the federal government in immunization safety are identified



# NVAC and Vaccine Safety: The State of the U.S Vaccine Safety System



<http://www.hhs.gov/nvpo/nvac/reports/index.html>



# Vaccine Safety & the National Vaccine Plan

## Goal 2: Enhance the vaccine safety system

- Ensure a robust vaccine safety scientific system that focused on high priority areas
- Facilitate the timely integration of advances in manufacturing sciences and regulatory approaches relevant to manufacturing, inspection, and oversight to enhance product quality and patient safety
- Enhance timely detection and verification of vaccine safety signals
- Improve timeliness of the evaluation of vaccine safety signals
- Improve causality assessments of vaccines and related AEFIs
- Improve scientific knowledge about why and among whom vaccine adverse reactions occur
- Improve clinical practice to prevent, identify and manage vaccine adverse reactions
- Enhance collaboration of vaccine safety activities





# The National Vaccine Plan Implementation

Priority: Enhance timely detection and verification of vaccine safety signals and develop a vaccine scientific agenda

<b>LEAD AGENCY</b>	<b>ACTION</b>
NVPO	Fund independent literature review of vaccine safety
ISTF	Will use the literature review to inform a vaccine safety scientific agenda
CDC	Redesign the online electronic reporting form for VAERS
FDA and CDC	Enhance reporting on VAERS by improving the ability to submit reports electronically
CDC	Support VSD contractors in rapid assessments of all vaccine safety signals of significance

# Updates on Vaccine Safety Findings

- Safety of vaccines used for routine immunization in the U.S.: a systematic review
  - By Ms. Margaret Maglione (RAND)
- Updates to the vaccine adverse event reporting system (VAERS): VAERS reporting form version 2.0 (proposed)
  - By Dr. Tom Shimabukuro (CDC)



# Acknowledgements

## **CDC**

Rita Helfand  
Cindy Weinbaum

## **HRSA**

Melissa Houston  
Tamara Overby

## **NIH**

Barbara Mulach  
Charles Hackett  
Claire Schuster  
Andrew Ford

## **FDA**

Steven Anderson  
Marion Gruber  
Karen Midthun  
Peter Marks  
Scott Winiecki  
Phil Krause

## **BARDA**

Jo Schweinle

## **DOD**

Jorge Carrillo  
Catherine Witkop  
Ava Conlin  
Amy Costello

## **VA**

Fran Cunningham

## **IHS**

Amy Groom

