Vaccine Safety
Introduction

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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

CDC 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

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