

# Overview of 2009 H1N1 Influenza Vaccine Safety Monitoring

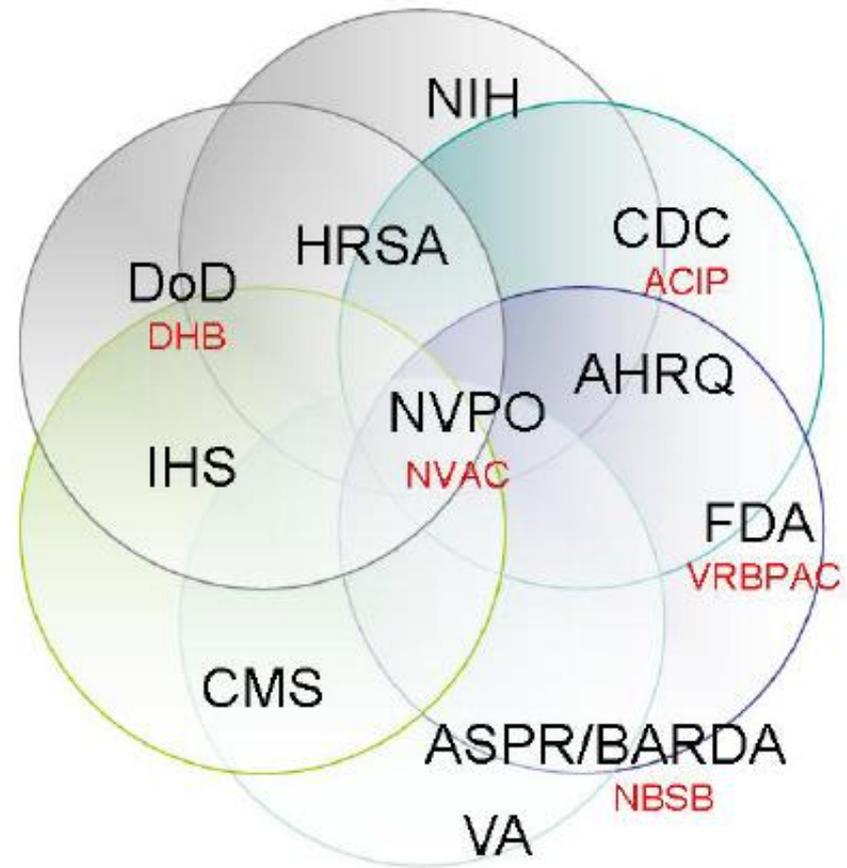
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# Federal Plans to Monitor Immunization Safety for the Pandemic 2009 H1N1 Influenza Vaccination Program

Federal Immunization Safety Task Force

U.S. Department of Health and Human Services  
 Agency for Healthcare Research and Quality  
 Centers for Disease Control and Prevention  
 Food and Drug Administration  
 Health Resources and Services Administration  
 Indian Health Service  
 National Institutes of Health  
 Department of Defense  
 Department of Veterans Affairs



<http://www.flu.gov/professional/federal/fed-plan-to-mon-h1n1-imm-safety.pdf>

Advisory Committees in Red

# Monitoring H1N1 Vaccine Safety: Existing Monitoring System Infrastructure

Data Source	Agency/Dept.	Pop. Covered	Attributes
Clinical Trials	NIH and BARDA	14,200 (healthy adults, children, pregnant women)	Optimal study design, limited size
<b>Rapid Signal Detection Systems</b>			
Vaccine Adverse Event Reporting System (VAERS)	CDC/FDA	300 million (general population)	Stimulated Passive
Real Time Immunization Monitoring System	CDC	Tens of thousands (health care workers, children, pregnant women)	Active surveillance

# Monitoring H1N1 Vaccine Safety: Existing Monitoring System Infrastructure (cont)

<b>Hypothesis Testing Systems</b>			
<b>Vaccine Safety Datalink (VSD)</b>	CDC	9 million (managed care population)	Active surveillance
Veteran Patients & VA Employee and Volunteers	VA	1 million (veterans and feds)	Active surveillance
Defense Medical Surveillance System	DoD/FDA/CDC	2.6 million (uniformed military)	Active surveillance
National Claims History File & Enrollment Database	CMS/FDA	46 million (elderly and disabled)	Active surveillance
<b>Long-Term Studies</b>			
Clinical Immunization Safety Assessment	CDC	Clinical investigation	Understanding adverse events at the individual level

# Monitoring H1N1 Vaccine Safety: Enhancements to the Current System

Data Source	Agency/Dept.	Pop. Covered	Attributes
<b>Hypothesis Testing Systems</b>			
Post-licensure Rapid Immunization Safety Monitoring (PRISM)	NVPO/ FDA/CDC	14 million (persons in health plans in 8 states)	Active surveillance
GBS Surveillance	CDC	45 million (general population)	Active surveillance
Indian Health Service Resource & Patient Management Database	IHS/FDA	1.4 million (Native Americans)	Active surveillance
<b>Long-Term Studies</b>			
Vaccines and Medicine Pregnancy Surveillance System	BARDA	~2500 (pregnant women)	Special studies (Distal Outcomes)

# **Assessing H1N1 Vaccine Safety- The Big Picture**

## **Federal Immunization Safety Task Force**

- Cross-government coordination of vaccine safety activities (HHS Agencies, DoD, VA)
- Led by ASH and ASPR
- Data sharing: Regular review of safety data & analysis from all sources

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