

Overview of H1N1 Vaccine Safety Monitoring

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H1N1 Vaccine Safety: Microcosm of the Vaccine Safety Challenge

- Response to H1N1 is the largest mass vaccination program in recent US history
- Public concern regarding vaccine safety
- Many reluctant to receive H1N1 vaccine because of “safety” concerns
 - Vaccine production was “rushed”
 - Vaccine “inadequately tested”
 - 1976 experience with Guillain-Barré Syndrome



National Vaccine Advisory Committee (NVAC) Recommendations for H1N1 Safety Monitoring

- 1) Assemble background rates of adverse events that occur in the general population
- 2) Develop and disseminate a federal plan
- 3) Enhance active surveillance for signal detection, assessment and confirmation of possible associations between vaccines and adverse events
- 4) Establish a transparent and independent review of vaccine safety data as it accumulates
- 5) Develop, and where possible test in advance, a strong and organized response to scientific and public concerns about vaccine safety



ESTIMATES OF COINCIDENT, TEMPORALLY-ASSOCIATED EVENTS

Coincident events	Number of coincident events since a vaccine dose:			Baseline incidence rate used for estimate
	<i>Within 1 day</i>	<i>Within 7 days</i>	<i>Within 6 weeks</i>	
Guillain-Barré Syndrome (per 10 million vaccinated people)	0.51	3.58	21.50	1.87 per 100,000 person-years (all ages; UK Health Protection Agency data)
Optic Neuritis (per 10 million female vaccinees)	2.05	14.40	86.30	7.5 per 100,000 person-years in US females
Spontaneous abortions (per 10 million vaccinated pregnant women)	3,970	27,800	166,840	Based on data from the USA (12% of pregnancies)
Sudden death within 1 hour of onset of any symptoms (per 10 million vaccinated people)	0.14	0.98	5.75	Based upon UK background rate of 0.5 per 100,000 person-years



Black *et al.* Importance of background rates of disease in assessment of vaccine safety during mass immunisation with pandemic H1N1 influenza vaccines; Table 6. *Lancet* 2009; 374; Oct. 30 [Epub.]



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Medical events following vaccination will occur

- Important to differentiate between coincidental events and events causally related to vaccination
 - 2,500 miscarriages and 3,000 heart attacks each day in US
- Important to rapidly identify and follow-up vaccine safety signals
- Robust Scientific follow up takes time



http://www.flu.gov/professional/federal/fed-plan-to-mon-h1n1-imm-safety.pdf - Windows Internet Explorer provided by Comcast

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

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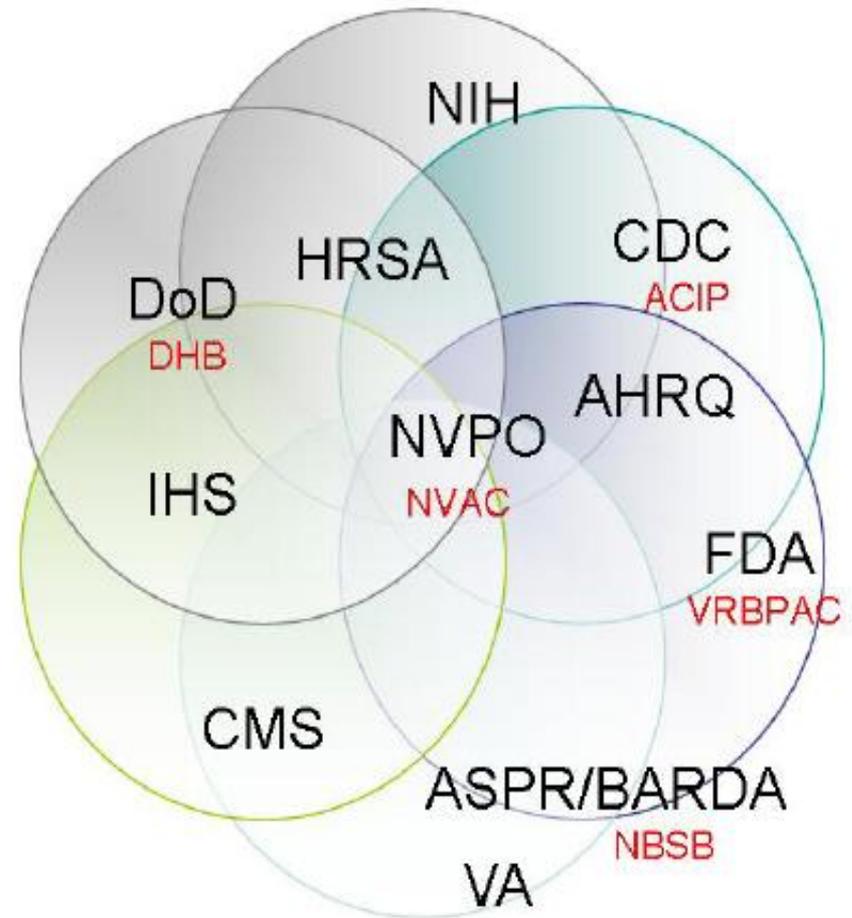
Federal Plans to Monitor Immunization Safety for the Pandemic 2009 H1N1 Influenza Vaccination Program

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

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<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
Rapid Signal Detection Systems			
Vaccine Adverse Event Reporting System (VAERS)	CDC/FDA	300 million (general population)	Stimulated Passive
Real Time Immunization Monitoring System	CDC	Several million (health care workers, children, pregnant women)	Active surveillance



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

Hypothesis Testing Systems			
Vaccine Safety Datalink (VSD)	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
Long-Term Studies			
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
Hypothesis Testing Systems			
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
Long-Term Studies			
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



Assessing H1N1 Vaccine Safety-The Big Picture

NVAC H1N1 Vaccine Safety Risk Assessment Working Group

- Independent, expert review of safety data & analysis from many sources
- Assess if adverse outcomes are associated with vaccine
- Representatives from existing federal vaccine advisory committees
- Review data biweekly
- Monthly reports to ASH through National Vaccine Advisory Committee
- Weak signals for GBS, ITP/thromb, BP



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