

The State of the National Vaccine Plan 2014 Annual Report Preview

NVAC February 10, 2015



Program Establishment

“The Secretary shall establish... a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines.”

--Title XXI Public Health Service Act
(P.L. 99-660, Section 2102)

PUBLIC LAW 101-166—NOV. 21, 1989

103 STAT. 1167

VACCINE INJURY COMPENSATION

For payments from the Vaccine Injury Compensation Trust Fund, such sums as may be necessary for claims associated with vaccine-related injury or death resolved during the current fiscal year with respect to vaccines administered after September 30, 1988, pursuant to subtitle 2 of title XXI of the Public Health Service Act as amended by Public Law 100-203.

For compensation of claims resolved by the United States Claims Court related to the administration of vaccines before October 1, 1988, \$74,500,000, of which such sums as may be necessary shall be used to reimburse the Vaccine Injury Compensation Trust Fund for any payment of such claims made from the Trust Fund prior to the current fiscal year: *Provided*, That necessary expenses of the Department of Health and Human Services under the National Childhood Vaccine Injury Act of 1986, not to exceed \$1,500,000, shall be reimbursed from the Trust Fund.

CENTERS FOR DISEASE CONTROL

DISEASE CONTROL, RESEARCH, AND TRAINING

To carry out titles III, XVII, XIX, and section 1102 of the Public Health Service Act, sections 101, 102, 103, 201, 202, and 203 of the Federal Mine Safety and Health Act of 1977, and sections 20, 21, and 2 of the Occupational Safety and Health Act of 1970; including insurance of official motor vehicles in foreign countries; and hire, maintenance, and operation of aircraft, \$1,101,559,000, of which 2,000,000 shall remain available until expended for equipment and construction and renovation of facilities: *Provided*, That training of private persons shall be made subject to reimbursement or advances to this appropriation for not in excess of the full cost of such training: *Provided further*, That funds appropriated under this heading shall be available for payment of the costs of medical care, related expenses, and burial expenses hereafter incurred by or on behalf of any person who had participated in the study of untreated syphilis initiated in Tuskegee, Alabama, in 1932, in such amounts and subject to such terms and conditions as prescribed by the Secretary of Health and Human Services and for payment, in such amounts and subject to such terms and conditions, of such costs and expenses hereafter incurred by or on behalf of such person's wife or offspring determined by the Secretary to have suffered injury or disease from syphilis contracted from such person: *Provided further*, That collections from user fees may be credited to this appropriation: *Provided further*, That amounts received by the National Center for Health Statistics from reimbursable and interagency agreements and the sale of data tapes may be credited to this appropriation and shall remain available until expended: *Provided further*, That in addition to amounts provided herein, up to 19,000,000 shall be available from amounts available under section 513 of the Public Health Service Act, to carry out the National Center for Health Statistics surveys: *Provided further*, That employees of the Public Health Service, both civilian and Commissioned Officer, detailed to States or municipalities as assignees under authority of section 214 of the Public Health Service Act in the instance where in excess of 50 per centum of salaries and benefits of the assignee is paid directly or indirectly by the State or municipal-



Program Responsibilities

- Vaccine research
- Vaccine development
- Safety and efficacy testing of vaccines
- Licensing of vaccine manufacturers and vaccines
- Production and procurement of vaccines
- Distribution and use of vaccines
- Evaluating vaccine effectiveness and safety



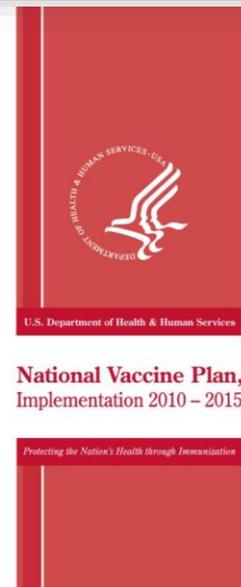
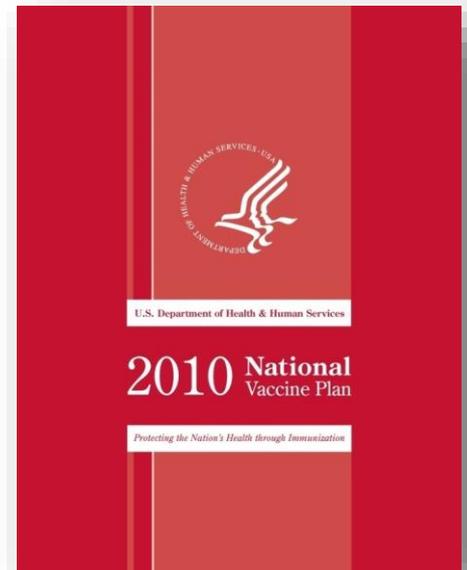
2010 National Vaccine Plan

Strategic Plan

- Vision for the US vaccine and immunization enterprise for **decade** 2010-2020
- 5 goals; 34 objectives; 150 strategies

Implementation Plan

- Focuses on the objectives and strategies **described** in the strategic plan
- 10 priorities (A-J)



National Vaccine Plan Goals

1. Develop new and improved vaccines
2. Enhance the vaccine safety system
3. Support communications to enhance informed vaccine decision-making
4. Ensure a stable supply of recommended vaccines and achieve better use of existing vaccines to prevent disease, disability and death in the United States
5. Increase global prevention of death and disease through safe and effective vaccination



Implementation Plan Priorities

A	Develop a catalogue of priority vaccine targets of domestic and global importance (goal 1)
B	Strengthen the science base for the development and licensure of new vaccines (goals 1 & 2)
C	Enhance timely detection and verification of vaccine safety signals and develop a vaccine safety scientific agenda (goal 2)
D	Increase awareness of vaccines, VPD and the benefits/risks if immunization among the public, providers and other stakeholders (goal 3)
E	Use evidence-based science to enhance VPD surveillance, measurement of vaccine coverage and measurement of vaccine effectiveness (goal 4)
F	Eliminate financial barriers for providers and consumers to facilitate access to routinely recommended vaccines (goal 4)
G	Create an adequate and stable supply of routinely recommended vaccines for public health preparedness (goal 4)
H	Increase and improve the use of interoperable health information technology and electronic health records (goal 4)
I	Improve global surveillance for VPD and strengthen global health information systems to monitor vaccine coverage, safety and effectiveness (goal 5)
J	Support global introduction and availability of new and under-utilized vaccines to prevent diseases of public health importance (goal 5)

National Vaccine Plan-Stakeholders

F E D E R A L	H H S	ACF
		AHRQ
		ASPR (BARDA)
		CDC
		CMS
		FDA
		HRSA
		IHS
	NIH	
	NVPO	
	ONC	
	DHS	
	DoD	
	DoJ	
Dept. of State		
USAID		
VA		

N O N - F E D E R A L	Health care providers
	Health care system
	Public & private health care plans
	State, local, tribal govt.
	Academia
	Advocacy organizations
	Philanthropic organizations
	Vaccine manufacturers
	UNICEF
	WHO

Stakeholders - Goal 2 Example

[Accessible version on last page of the document](#)

Objective	Federal															
	HHS										DHS	DoD	DoJ	Dept. of State	USAID	VA
	ACF	AHRQ	ASPR (BARDA)	CDC	CMS	FDA	HRSA	IHS	NIH	NVPO						
Goal 2: Enhance the vaccine safety system																
2.1				✓		✓	✓		✓	✓			✓			✓
2.2						✓							✓			
2.3				✓	✓	✓	✓	✓		✓			✓			✓
2.4			✓	✓	✓	✓	✓	✓		✓			✓			✓
2.5				✓	✓	✓	✓	✓		✓			✓			✓
2.6				✓		✓	✓	✓	✓				✓			✓
2.7				✓	✓	✓		✓		✓			✓			✓
2.8		✓		✓	✓	✓	✓			✓			✓		✓	✓

Annual Reporting Process & Structure

- Collected input, updates and progress reports from federal and non-federal stakeholders
- Developed narrative to highlight examples of progress made to achieve five goals of the Plan
- Includes progress on implementation* of the Plan-- using progress reports submitted by agencies
- Update on the National Vaccine Advisory Committee's recent work
- Progress on Healthy People 2020 immunization goals



*ASPR: 7 items, CDC: 21 items, CMS: 2 items, DOD: 3 items, FDA: 15 items, HRSA: 1 item, IHS: 3 items, NIH: 6 items, NVPO: 10 items, OGA: 2 items, ONC: 5 items, VA: 3 items

Report Highlights

Goal	Narrative Examples
1	<ul style="list-style-type: none">• Advances in vaccine research and development• Development and testing of SMART Vaccines tool• Maternal immunization progress
2	<ul style="list-style-type: none">• Vaccine safety scientific agenda• Improvements in safety monitoring and reporting• Systematic review of vaccine safety studies
3	<ul style="list-style-type: none">• HPV communication efforts focused on improving vaccination uptake• Influenza vaccination campaign pieces targeting special populations
4	<ul style="list-style-type: none">• Adult vaccination: strategic plan, standards and access• Strengthening IIS systems and improving interoperability• Immunization infrastructure reporting
5	<ul style="list-style-type: none">• Vaccine use in under-resourced areas• US strategies to protect the global population from infectious disease

While I have the floor...

Vaccine Safety Scientific Agenda (VSSA)

- Robust vaccine safety enterprise exists
 - Range of federal department/agency leads
 - Each stage of vaccine development
 - Pre-licensure, regulatory review and licensure, and post-licensure
- VSSA details federal leads, specific systems and system's contributions to scientific agenda



VSSA Pre-licensure Example

Lead	Vaccine Safety Activity	Scientific Agenda
NIH	Identification and development of vaccine candidates	Develop and provide resources to facilitate basic and applied research including the ability to assess vaccines for safety and immunogenicity
NIH	Design of novel vaccine strategies	Support research to explore novel vaccine technologies and strategies to improve the immunization profile
NIH	Investigate the variability in human immune responses	Support research to understand the range of variability in the human population that impacts responses to vaccines and potential associations with AEFIs
NIH	Improving vaccine immunomodulators, administration, and formulations	Discover and develop novel adjuvants, alternative routes of administration, and formulations
FDA	Vaccine development	Develop pre-clinical models, and vaccine efficacy and safety screening methodology
FDA	Study of pathogenicity	Study molecular mechanisms of pathogenicity and determine biomarkers of virulence that might improve the safety profile

Funding Opportunity for Vaccine Safety Research

- Partner with NVPO to strengthen the U.S. vaccine safety enterprise
- Potential for 2 awardees to receive up to \$250,000 (\$500,000 total available)
- Projects related to pregnant women and infants are of particular interest
- Closing date for proposals: April 15, 2015
- More info: <http://www.hhs.gov/nvpo/funding-opportunity-vaccine-research.html>



Stakeholders - Goal 2 Example

Objective	Federal																
	HHS											DHS	DoD	DoJ	Dept. of State	USAID	VA
	ACF	AHRQ	ASPA	CDC	CMS	FDA	HRSA	IHS	NIH	NVPO	ONC						
2.1				X		X	X		X	X			X			X	
2.2						X							X				
2.3				X		X	X	X		X			X			X	
2.4			X	X		X	X	X		X			X			X	
2.5				X		X	X	X		X			X			X	
2.6				X		X	X		X				X			X	
2.7				X		X		X		X			X			X	
2.8		X		X	X	X	X			X			X		X	X	