

The National Vaccine Plan Implementation

February 6, 2013

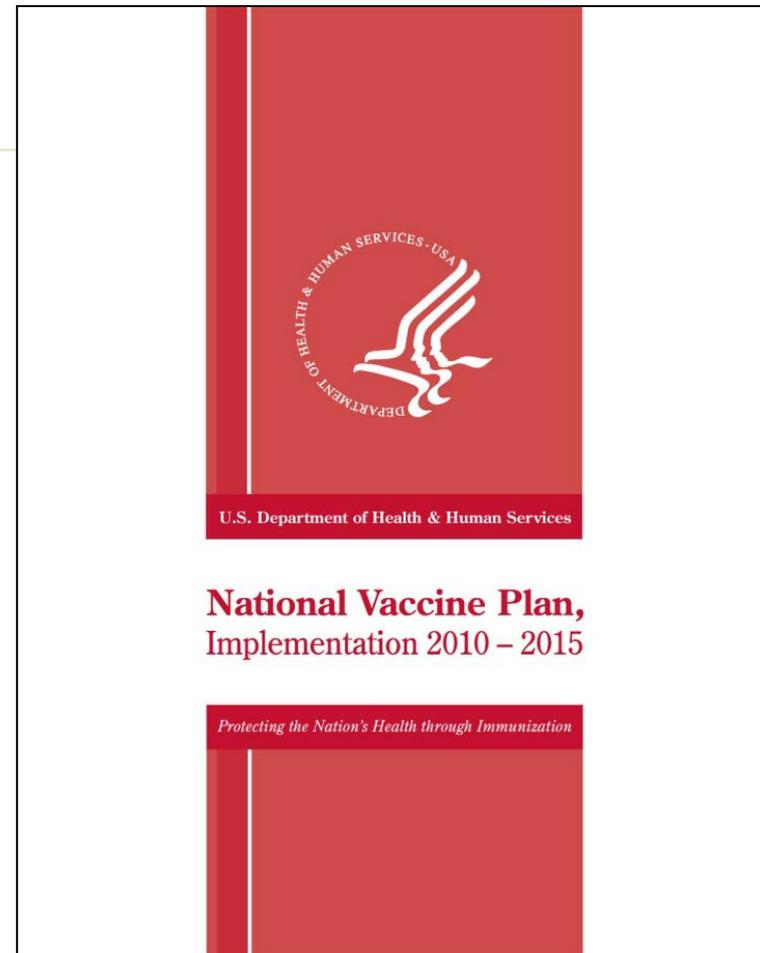
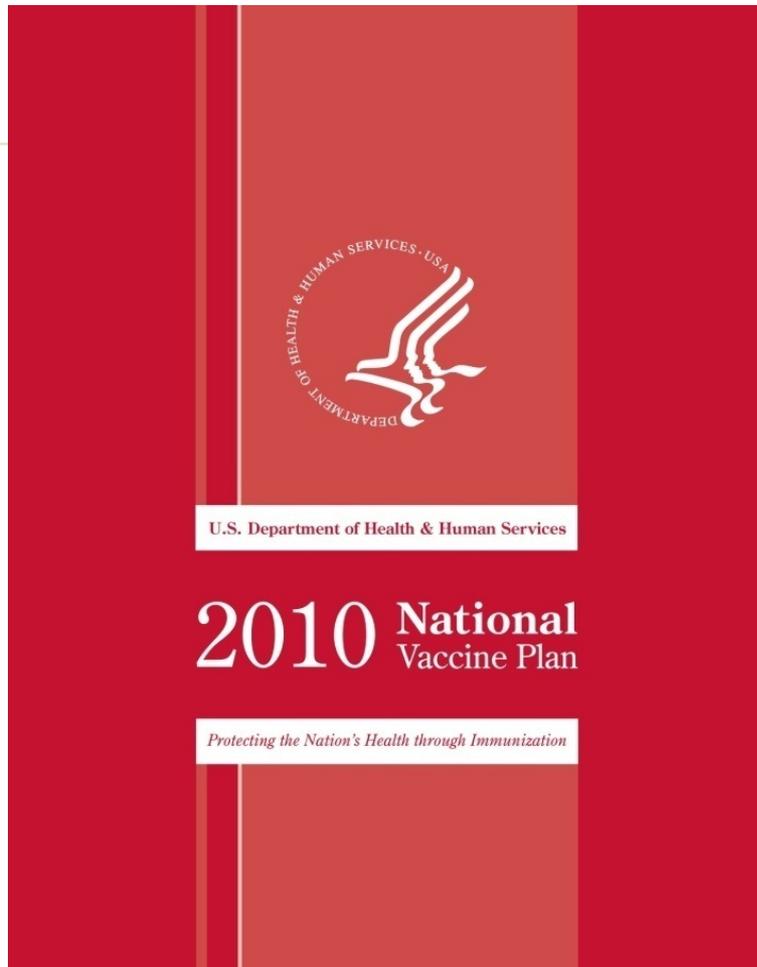
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Strategic Plan

Implementation Plan, 2010-2015



Session Objectives

- Describe the overarching HHS philosophy and guiding principles to the development of the Implementation Plan
- Describe the development and structure of the Implementation Plan
 - Cross-agency collaborative efforts
 - Linkages to HHS and Agency priorities
- Describe future plans for reporting progress
- NVAC discussion



Title XXI Public Health Service Act

National Vaccine 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 the need for, the effectiveness, and adverse effects of vaccines and immunization activities
 - Coordinating governmental and non-governmental activities
 - Funding of federal agencies
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2010 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**
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2010 National Vaccine Plan

- 5 Goals
 - 34 Objectives
 - 150 Strategies
- How do we build an implementation strategy focused on the highest priority items?
 - Identified 10 Priorities for implementation



Priorities for Implementation

- | | |
|----|--|
| A. | Develop a catalogue of priority vaccine targets of domestic and global health importance (Goal 1). |
| B. | Strengthen the science base for the development and licensure of new vaccines (Goals 1 and 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, vaccine-preventable diseases, and the benefits/risks of immunization among the public, providers, and other stakeholders (Goal 3). |
| E. | Use evidence-based science to enhance vaccine-preventable disease 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 and 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 vaccine-preventable diseases and strengthen global health information systems to monitor vaccine coverage, effectiveness, and safety (Goal 5). |
| J. | Support global introduction and availability of new and under-utilized vaccines to prevent diseases of public health importance (Goal 5). |



Priorities for Implementation – Short Name

Priority A	Catalogue of priority vaccine targets
Priority B	Science base for developing and licensing new vaccines
Priority C	Vaccine safety signals and safety scientific agenda
Priority D	Vaccine communications
Priority E	Surveillance, vaccine coverage and effectiveness measurement
Priority F	Eliminate financial barriers and increase access
Priority G	Vaccine supply
Priority H	Health information technology
Priority I	Global surveillance and information systems
Priority J	Global introduction and supply of new and under-utilized vaccines



Objective	Federal																Non-federal										
	HHS											DHS	DoD	DoJ	Dept. of State	USAID	VA	Health care providers	Health care system	Public and private health care plans	State, local, and tribal governments	Academia	Advocacy organizations	Philanthropic organizations	Vaccine manufacturers	UNICEF	WHO
	ACF	AHRQ	ASPR (BARDA)	CDC	CMS	FDA	HRSA	IHS	NIH	NVPO	ONC																
Goal 1: Develop new and improved vaccines																Goal 1: Develop new and improved vaccines											
1.1			✓	✓		✓		✓	✓				✓		✓	✓				✓							✓
1.2			✓	✓		✓							✓							✓			✓	✓			
1.3			✓	✓									✓							✓			✓	✓			
1.4				✓		✓							✓							✓			✓	✓			
1.5			✓	✓					✓				✓							✓			✓	✓			
1.6				✓		✓		✓					✓		✓					✓			✓	✓			
Goal 2: Enhance the vaccine safety system																Goal 2: Enhance the vaccine safety system											
2.1				✓		✓	✓		✓	✓			✓			✓			✓		✓			✓			
2.2						✓		✓					✓						✓		✓			✓			
2.3				✓	✓	✓	✓	✓		✓			✓			✓			✓		✓			✓			✓
2.4			✓	✓	✓	✓	✓	✓		✓			✓			✓			✓		✓			✓			✓
2.5				✓	✓	✓	✓	✓		✓			✓			✓			✓		✓			✓			✓
2.6				✓	✓	✓	✓	✓	✓				✓			✓			✓		✓			✓			✓
2.7				✓	✓	✓	✓	✓		✓			✓			✓			✓		✓			✓			✓
2.8		✓		✓	✓	✓	✓	✓		✓			✓		✓				✓		✓			✓			✓
Goal 3: Support communications to enhance informed vaccine decision-making																Goal 3: Support communications to enhance informed vaccine decision-making											
3.1	✓			✓	✓	✓		✓	✓	✓			✓			✓			✓		✓			✓			
3.2	✓			✓	✓	✓	✓	✓	✓	✓			✓			✓			✓		✓			✓			
3.3	✓			✓	✓	✓	✓	✓	✓	✓			✓			✓			✓		✓			✓			
3.4	✓			✓	✓	✓	✓	✓	✓	✓			✓			✓			✓		✓			✓			
3.5	✓			✓	✓	✓	✓	✓	✓	✓			✓			✓			✓		✓			✓			
Goal 4: Ensure a stable supply of, access to and better use of recommended vaccines in the United States																Goal 4: Ensure a stable supply of, access to and better use of recommended vaccines in the United States											
4.1			✓	✓		✓	✓	✓		✓			✓			✓			✓		✓			✓			
4.2			✓	✓		✓	✓	✓		✓			✓			✓			✓		✓			✓			
4.3				✓	✓		✓	✓		✓			✓			✓			✓		✓			✓			
4.4				✓	✓		✓	✓		✓			✓			✓			✓		✓			✓			
4.5				✓	✓	✓	✓	✓	✓				✓			✓			✓		✓			✓			
4.6			✓	✓	✓	✓	✓	✓		✓			✓			✓			✓		✓			✓			
4.7			✓	✓		✓	✓	✓		✓			✓			✓			✓		✓			✓			
4.8	✓		✓	✓		✓	✓					✓	✓	✓		✓			✓		✓			✓			
4.9	✓			✓								✓		✓		✓			✓		✓			✓			
Goal 5: Increase global prevention of death and disease through safe and effective vaccination																Goal 5: Increase global prevention of death and disease through safe and effective vaccination											
5.1				✓				✓				✓	✓	✓					✓		✓			✓			✓
5.2				✓								✓	✓	✓					✓		✓			✓			✓
5.3				✓		✓		✓				✓	✓	✓					✓		✓			✓			✓
5.4				✓								✓	✓	✓					✓		✓			✓			✓
5.5			✓	✓		✓						✓	✓	✓					✓		✓			✓			✓
5.6				✓		✓		✓				✓	✓	✓					✓		✓			✓			✓

HHS Philosophy and Guiding Principles for Strategic and Implementation Plans

Sarah Potter

Strategic Planner

Office of the Assistant Secretary for Planning and Evaluation

Department of Health and Human Services



Development of the National Vaccine Plan Implementation

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Development of an Implementation Plan

- Interagency National Vaccine Plan Working Group
- Input from VA, DOD, USAID
- Guidance from Assistant Secretary for Planning and Evaluation (ASPE)
 - Focus on years 2010-2015
 - Ensure outcomes are measurable
- Stakeholder meetings



VA – U.S. Department of Veterans Affairs
DOD – U.S. Department of Defense
USAID – U.S. Agency for International Development



Philosophy for Implementation Plan

- Build items around the 10 priority areas
 - NVAC, IOM, and HHS agencies input on priorities
- Ensure items are actionable and measurable
- Ensure specific HHS agencies are responsible for carrying out and tracking progress on actions
- Include items that focus on collaborative efforts and align with agency priorities



NVAC – National Vaccine Advisory Committee
IOM – Institute of Medicine



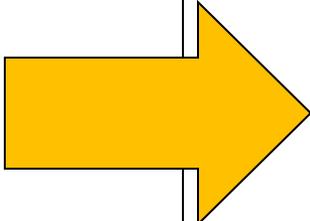
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National Vaccine Plan, Implementation 2010 – 2015



Is the Implementation Plan comprehensive and inclusive?

62 action items total across five goals and 10 priorities

Goal 1	Priorities A & B	13 action items
Goal 2	Priorities B & C	15 action items
Goal 3	Priority D	6 action items
Goal 4	Priorities E, F, G, & H	17 action items
Goal 5	Priorities I & J	11 action items



Structure of Action Items



Priority C. Vaccine Safety

Timeframe	Lead Agency	Action to be Performed
By the end of 2013	Federal Immunization Safety Task Force (ISTF): CDC, FDA, VA, IHS, and DOD	The ISTF will increase the number of infants, children, adolescents, and adults enrolled in active surveillance systems for adverse events following immunizations in the U.S. to 100 million.



FDA – Food and Drug Administration
IHS – Indian Health Service



Priority C. Vaccine Safety

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Aligns with HHS Strategic Plan

HHS is encouraging health care providers to become meaningful users of health information technology (IT) by accelerating health IT adoption and promoting electronic health records to help improve the quality of health care, reduce costs, and ultimately, improve health outcomes.

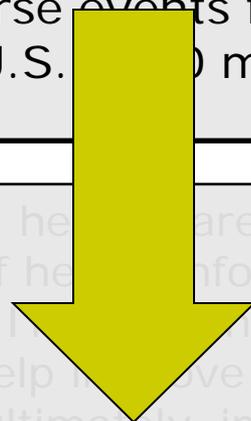
Aligns with Agency Priorities

CDC National Center for Emerging and Zoonotic Infectious Diseases Strategic Plan: Objective 2.2 Promote improved healthcare quality and patient safety - Strengthen monitoring and evaluation of adverse events following immunization in order to enhance vaccine safety.

The IHS continues to collect information on possible adverse events related to seasonal influenza vaccine and PCV13.

Priority C. Vaccine Safety

Timeframe	Lead Agency	Action to be Performed
By the end of 2012	Federal Immunization Safety Task Force (ISTF): CDC, FDA, VA, IHS, and DOD	The ISTF will <u>increase the number of infants, children, adolescents, and adults enrolled in active surveillance systems</u> for adverse events following immunizations in the U.S. 10 million.



Actionable

Aligns with HHS Priorities

HHS is encouraging health care providers to become meaningful users of health information technology (IT) by accelerating health information and promoting electronic health records to help improve the quality of health care, reduce costs, and ultimately, improve health outcomes.

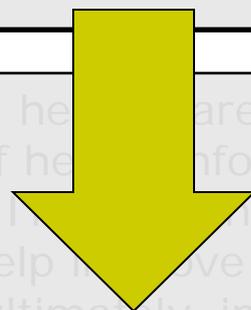
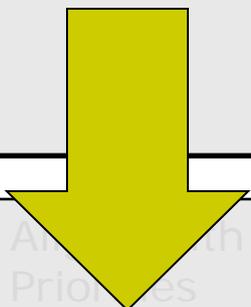
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Measurable

Aligns with Agency Priorities

CDC NCEZID Strategic Plan: Objective 2.2 Promote improved healthcare quality and patient safety - Strengthen monitoring and evaluation of adverse events following immunization in order to enhance vaccine safety.

The IHS continues to collect information on possible adverse events related to seasonal influenza vaccine and PCV13.

Selected Action Items



Priority A. Vaccine Prioritization

Timeframe	Lead Agency	Action to be Performed
By the end of 2013	NVPO	NVPO will support the development of a methodology for identifying priority vaccine targets for domestic and global health priorities through a contract with the Institute of Medicine.

Cross-Agency Collaboration	Comments and input from agency partners across HHS
Aligns with Agency Priorities	Office of the Assistant Secretary for Health – NVPO priority: Develop a catalogue of priority vaccine targets of domestic and global health importance.



Priority B. Vaccine Research

Timeframe	Lead Agency	Action to be Performed
By the end of 2015	NIH	NIH will evaluate five new formulations/technologies with potential to improve vaccine immunogenicity, safety, delivery, and/or dosing.

Aligns with Agency Priorities

National Institute of Allergy and Infectious Diseases (NIAID) Planning for the 21st Century: 2008 Update (pages 7-8)

Priority 1: Conduct basic research to elucidate mechanisms of host-pathogen interaction, to better understand and enhance immune response, and to identify promising new vaccine targets.

Priority 2: Design new or improved vaccines that are safe and effective, with particular emphasis on multivalent and cross-protective vaccine strategies.

Priority 3: Use advanced technologies to rapidly determine safety and immunogenicity of candidate vaccine products and to streamline manufacturing.

NIAID Biodefense Strategic Plan-2007 Update

Priority D. Communications

Timeframe	Lead Agency	Action to be Performed
By the end of 2015	CDC	CDC will assess the accessibility and usability of Vaccine Information Statements (VIS) for different target audiences. CDC will use this information to revise VIS as needed.

Aligns with Agency Priorities

Use of Vaccine Information Statements (VIS) is required by the National Childhood Vaccine Injury Act (section 2126 of the Public Health Service Act, 42 U.S.C. Section 300aa-26). As part of overall efficiency goals, CDC is working to review and finalize VIS on a consistent schedule.



Priority E. Measurement

Timeframe	Lead Agency	Action to be Performed
By the end of 2015	CDC	CDC will continue to monitor the number of indigenous cases of paralytic polio, rubella, congenital rubella syndrome, measles, <i>Haemophilus influenzae</i> type b (Hib), diphtheria, tetanus, mumps, pertussis (in persons <7 years), and varicella (in persons <18 years) to evaluate the impact of vaccine policy and programs.

Aligns with Agency Priorities

CDC-RFA-IP13-1301 and the Immunization Program Operations Manual require all 64 grant recipients to assure adherence to CDC's Manual for the Surveillance of Vaccine-preventable Diseases including Vaccine Adverse Events Reporting. CDC Subject Matter Experts review reports and use the information to monitor impact and revise vaccine policy, as needed.

Priority F. Financing

Timeframe	Lead Agency	Action to be Performed
By the end of 2013	CDC	CDC will support 28 immunization grantees to develop plans and 14 immunization grantees to implement plans to enable billing for vaccine services provided by public health clinics.

Aligns with Agency Priorities

Billing for vaccine service provided by public health clinics is a priority for CDC and is included in CDC's Quarterly Program Review (QPR) to CDC Senior Leadership.

The "Billables" project is designed to improve reimbursement in public health department clinics for immunization services and vaccine administration to fully insured patients. Currently, 38 of 64 Immunization grantees have received funds for planning, or implementing billables, or have received funding for both planning and implementation.



Priority H. Health IT

Timeframe	Lead Agency	Action to be Performed
Beginning in 2012 and annually thereafter	ONC	ONC will perform surveys of select providers enrolled to receive services from regional extension centers (RECs) to determine issues/barriers with immunization information systems and compatibility with electronic health records (EHRs).
Aligns with Agency Priorities	<p>HHS Strategic Plan: HHS is encouraging health care providers to become meaningful users of health IT by accelerating health IT adoption and promoting electronic health records to help improve the quality of health care, reduce costs, and ultimately, improve health outcomes.</p> <p>ONC Priorities:</p> <ul style="list-style-type: none">-Support health IT adoption and information exchange for public health and populations with unique needs.-Ensure public health agencies are able to receive and share information with providers using certified EHR technology.-Lead the creation of a learning health system to support quality, research, and public and population health.	

Priority J. Global Use of Vaccines

Timeframe	Lead Agency	Action to be Performed
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Beginning in 2012	FDA	FDA will participate in international collaborative studies to establish and maintain international reference materials and standards for biologics.
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Aligns with Agency Priorities

FDA Center for Biologics Evaluation and Research (CBER) Strategic Plan July 2011
Goal 2- Improve global public health through international collaboration including research and information sharing.

CBER Strategic Plan for Regulatory Science and Research 2012-2016, Issued May 2012
Section I. Increase the nation's preparedness to address threats as a result of terrorism and pandemic influenza and emerging infectious diseases.



Priority J. Global Use of Vaccines

Timeframe	Lead Agency	Action to be Performed
By the end of 2015	OGA	OGA will provide policy and diplomatic support for the WHO Global Action Plan to Increase Pandemic Influenza Vaccines by co-organizing and facilitating workshops to bring together supporting infrastructures in influenza vaccine development in developing countries, including ministers of health, ministers of finance, vaccine manufacturers, non-governmental organizations, regulatory authorities, and policy-makers.
Aligns with Agency Priorities	<p data-bbox="517 858 1238 901"><u>National Health Security Strategy</u></p> <p data-bbox="517 908 1760 1051">Objective 9 – Work with cross-border and global partners to enhance national, continental, and global health security</p> <p data-bbox="517 1110 1116 1153"><u>HHS Global Health Strategy</u></p> <p data-bbox="517 1160 1798 1203">Obj 2: Prevent infectious diseases and other health threats</p> <p data-bbox="517 1210 1541 1303">Obj 3: Prepare for and respond to public health emergencies</p> <p data-bbox="517 1310 1580 1405">Obj 4: Increase the safety and integrity of global manufacturing and supply chains</p>	

Evaluation and Monitoring

- Annual reports
- Mid-course review in 2015
 - With guidance from NVAC
 - Priorities may change
- Implementation plan for 2015-2020



Annual Report Ideas

- Annual National Vaccine Program Report – The Year in Review
 - Focus on topic areas/chapters of interest
 - Each chapter presents the Program perspective along with expert commentaries
 - Chapters feature tie-ins to Plan goals and implementation items
- Appendix
 - Progress on Healthy People 2020 immunization goals
 - Progress on National Vaccine Plan Implementation items



NVAC Discussion

- Are there areas of importance not included in the Implementation Plan we should consider?
- Are there suggestions for the Annual Report structure? Ideas for topics for this year's report?



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- National Vaccine Plan
Implementation, 2010-2015
 - www.hhs.gov/nvpo/vacc_plan

