U.S. Department of Health & Human Services

National Vaccine Plan
Implementation

Protecting the Nation's Health through Immunization

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Background

2010 National Vaccine Plan

The 2010 National Vaccine Plan[1] provides strategic direction and coordination for the nation's immunization program. The scope of the Plan is broad, describes the end-to-end activities of the National Vaccine Program, and addresses the range of vaccine and vaccine-related issues for the United States (U.S.) and global communities. A ten-year horizon was set for the Plan to align with Healthy People 2020 goals.

The Plan is built around five broad goals:

Goal 1: Develop new and improved vaccines.

Goal 2: Enhance the vaccine safety system.

Goal 3: Support informed vaccine decision-making.

Goal 4: Ensure a stable supply of, access to, and better use of recommended vaccines in the United States.

Goal 5: Increase global prevention of death and disease through safe and effective vaccination.

For more information about the scope and vision for the National Vaccine Plan, please refer to the Purpose and Background section of the 2010 National Vaccine Plan.

Implementation Plan Development and Structure

The National Vaccine Plan Implementation was developed by an interagency working group representing U.S. Department of Health and Human Services (HHS) agencies involved in all aspects of vaccines and immunizations. This working group additionally consulted with partner government agencies outside of HHS, including the U.S. Agency for International Development, the Department of Veterans Affairs (VA), and the Department of Defense (DOD). Individual stakeholder input was obtained through a series of meetings, and is described further below.

The Implementation Plan follows the architecture of the National Vaccine Plan, is organized by the five goals (above), and focuses on the objectives and strategies related to achieving the 10 priorities described in the Plan (following). These priorities were established with input from the Institute of Medicine, the National Vaccine Advisory Committee, and the interagency working group. They provide strategic action steps to ensure the national has a robust immunization program. The priorities can relate to more than one goal in the National Vaccine Plan, but are presented with the most relevant goal within the Implementation Plan.

[1] http://www.hhs.gov/nvpo/vacc_plan/2010%20Plan/nationalvaccineplan.pdf

National Vaccine Plan 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 (VPDs), 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)

The 2010 National Vaccine Plan is a national, not federal, plan that acknowledges the many areas where stakeholder actions are needed to achieve a specific goal. The activities that are described in this Implementation Plan are those that will be undertaken by federal departments and agencies for the years 2010-2015 in line with their respective missions to achieve the specific objectives described for each goal. The scope of work outlined in the Implementation Plan will depend on the availability of future funds and other resources.

Implementation Monitoring and Evaluation

The National Vaccine Program Office (NVPO) will regularly track and annually summarize progress on achieving the goals and priorities in the National Vaccine Plan, identify areas where progress is lagging, and propose corrective action where needed.

In 2015, a formal mid-course review of the 2010 National Vaccine Plan and Implementation will be undertaken with guidance from the National Vaccine Advisory Committee. Results of the mid-course review will guide the development of implementation plans for 2015-2020.

The Appendix cross-walks the goals, objectives, and strategies of the 2010 National Vaccine Plan with the 10 priorities.

Stakeholder Input

In conjunction with the development of the National Vaccine Plan Implementation, NVPO worked with the Association of State and Territorial Health Officials (ASTHO), the HHS Regional Offices, and other partner organizations to convene a series of regional stakeholder meetings in the summer and fall of 2011. These meetings provided a forum for stakeholders to give individual input on best practice examples and barriers and challenges toward meeting the goals in the 2010 National Vaccine Plan. Each meeting focused on specific topics or populations of interest for the region, such as health information technology and immunization information systems, billing for vaccines, and immunization issues for American Indians, Alaska Natives, and populations along the U.S.-México border. The individual findings from these meetings have informed the development of the National Vaccine Plan Implementation as partners work together to make progress in the immunization enterprise, and will be described in a companion document published by ASTHO in 2012.

Goal 1: Develop new and improved vaccines

Vaccine development is a complex process that includes inputs from researchers, manufacturers, regulators, the public health community, and purchasers. Vaccines are increasingly developed through partnerships. These efforts have been successful at bringing new vaccines to licensure for broad use. Through targeted investments in science and technology, hundreds of vaccine candidates at various stages of maturity are now in the development pipeline.

Because vaccine development is time- and resource-intensive, establishing and understanding priorities for development and fostering collaboration among stakeholders is essential in addressing the challenges of developing new and improved vaccines.

In addition, expanding scientific knowledge, coupled with advances in biotechnology and manufacturing platforms, provides many possibilities for new and improved vaccines. Continued investments from all sectors will be increasingly important as technological opportunities expand and the costs to develop, license, and deliver vaccines increases.

Priority A: Develop a catalogue of priority vaccine targets of domestic and global health importance.

Timeframe	Lead Agency	Actions to be Performed
By the end of 2012	NVPO	NVPO will support the development of a framework to prioritize preventive vaccines and convene a workshop to obtain input from key partners on this framework through a contract with the Institute of Medicine (IOM).[2]
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 IOM.
By the end of 2015	NVPO	NVPO will support the production of a catalogue of priority vaccine targets of domestic and international importance through a contract with the IOM.

Priority B: Strengthen the science base for the development and licensure of new vaccines.

Timeframe	Lead Agency	Actions to be Performed
Ongoing through the end of 2015	National Institutes of Health (NIH)	NIH will fund a broad range of basic and clinical research studies on topics including mechanisms of host-pathogen interaction, host immune response, new vaccine targets, and vaccines against bacterial, viral, and parasitic microbes. Information about these projects will be included on publicly available websites, such as NIH RePORT[3] (Research Portfolio Online Reporting Tools) and ClinicalTrials.gov, as well as in scientific publications.

[2] http://www.iom.edu/Activities/PublicHealth/VaccineTargets.aspx
[3] http://report.nih.gov/

Priority B: Strengthen the science base for the development and licensure of new vaccines *(continued)*.		
Timeframe	**Lead Agency**	**Actions to be Performed**
Beginning in 2006 and ongoing	Assistant Secretary for Preparedness and Response (ASPR)	ASPR will support the advanced development of next-generation cell-based and recombinant influenza vaccines with the goal of making more influenza vaccine available faster during influenza pandemics.
Beginning in 2011	ASPR	ASPR will coordinate and support efforts to optimize production and testing of influenza vaccines with the goal of decreasing the time needed to make vaccine available in an influenza pandemic.
Beginning in 2011 and annually thereafter	Food and Drug Administration (FDA)	FDA will develop and implement a research agenda that focuses on expanding the development of applied research with the goal of enhancing the safety and effectiveness of vaccines and facilitate product development.
By the end of 2012	ASPR	ASPR will fund cooperative agreements with U.S.-based universities to support Advanced Biomanufacturing Training Programs for scientists from manufacturers in developing countries.
By the end of 2013	ASPR	ASPR will fund development of clinical trial and laboratory infrastructure in developing countries for the evaluation of candidate influenza vaccines in preclinical research.
By the end of 2015	NIH	NIH will fund product development research on 15 vaccines for infectious diseases and related conditions.
By the end of 2015	NIH	NIH will evaluate five new formulations/technologies with potential to improve vaccine immunogenicity, safety, delivery, and/or dosing.
By the end of 2015	NIH	NIH will fund preclinical services for investigators to develop and evaluate five candidate vaccines.
By the end of 2015	NIH	NIH will fund multifunctional clinical research sites to expand the range of studies conducted among diverse populations in the U.S. and international settings.

Goal 2: Enhance the vaccine safety system.

The U.S. has a robust vaccine safety system. The goal of this system is to identify in a timely manner and minimize the occurrence of adverse events from vaccines. Past successes and challenges offer insights into areas where the existing vaccine safety system can be enhanced. Advances in information technology enhance the ability to conduct active surveillance. Improvements in the understanding of immunology and genomics create opportunities to better comprehend the immune response and biological mechanisms important for understanding the safety of vaccines.

Vaccine safety science is often challenging because it may require studying very rare, but serious outcomes. New tools have been developed that help detect and quantify rare events, elucidate biological mechanisms and subpopulations at increased risk for adverse events, and help address these scientific challenges.

Priority B: Strengthen the science base for the development and licensure of new vaccines.

Timeframe	Lead Agency	Actions to be Performed
Beginning in 2011 and annually thereafter	FDA	FDA will develop and implement a research agenda focusing on enhancement of vaccine safety evaluation; including laboratory research, bioinformatics for exchanging information, overseeing the safety of vaccine products, and new epidemiological methods.
By the end of 2015	NIH	NIH will fund preclinical and clinical research related to the development of safe and effective vaccines, including studies among healthy adults as well as specific populations such as infants and children, the elderly, and people with weakened immune systems.

Priority C: Enhance timely detection and verification of vaccine safety signals and develop a vaccine safety scientific agenda.

Timeframe	Lead Agency/ies	Actions to be Performed
Beginning in 2012	NVPO	NVPO will fund a literature review of vaccine safety to inform development of a vaccine safety scientific agenda.
By the end of 2012	Federal Immunization Safety Task Force (ISTF): CDC, FDA, VA, Indian Health Service (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 [e.g., Vaccine Adverse Events Reporting System (VAERS), VA, IHS, DOD] in the U.S. to 90 million.

Priority C: Enhance timely detection and verification of vaccine safety signals and develop a vaccine safety scientific agenda *(continued)*.		
Timeframe	**Lead Agency/ies**	**Actions to be Performed**
By the end of 2012	FDA	FDA will contract with private health care data systems to access claims based information for vaccine safety surveillance in the Post-licensure Rapid Immunization Safety Monitoring (PRISM) program under FDA's Mini-Sentinel initiative. This will allow FDA to assess whether vaccine exposure might be associated with health outcomes of interest.
By the end of 2012	FDA and Centers for Medicare and Medicaid Services (CMS)	FDA and CMS will monitor the safety of seasonal influenza vaccines in Medicare beneficiaries using Medicare databases.
Beginning in 2013	ISTF	The ISTF will use the information from the NVPO-funded literature review of vaccine safety and develop a vaccine safety scientific agenda. (This item is related to Priority C, Action Item 1.)
By the end of 2013	ISTF	The ISTF will increase the number of infants, children, adolescents, and adults enrolled in active surveillance systems for adverse events following immunizations [e.g., Vaccine Adverse Events Reporting System (VAERS), VA, IHS, DOD] in the U.S. to 100 million. (This item is related to Priority C, Action Item 2.)
By the end of 2013	Centers for Disease Control and Prevention (CDC)	CDC will redesign the online electronic reporting form for the Vaccine Adverse Events Reporting System (VAERS) to include new fields that capture additional demographic information and implement web-based features to expedite complete and accurate online reporting.
By the end of 2015	FDA and CDC	FDA and CDC will enhance reporting by improving the ability to submit reports to VAERS electronically, to facilitate efficient, complete, and accurate reporting of adverse events following immunization.
By the end of 2015	CDC	CDC will conduct research and development for technologies to facilitate reporting to VAERS from hand held devices such as application software and to incorporate technologies into electronic health records to facilitate VAERS reporting, such as provider prompts.

Priority C: Enhance timely detection and verification of vaccine safety signals and develop a vaccine safety scientific agenda *(continued)*.		
Timeframe	**Lead Agency/ies**	**Actions to be Performed**
By the end of 2015	FDA	FDA will take steps toward providing patients, providers, and manufacturers with a single reporting portal for adverse events by recommending VAERS data structure modifications to allow compatibility with adverse event reporting systems used for other medical products.
By the end of 2015	CDC	CDC will ensure that health plans with the capacity to rapidly and regularly provide complete, privacy-protected medical records and chart review data for immunization participate in vaccine safety surveillance through the Vaccine Safety Datalink (VSD).
By the end of 2015	CDC	CDC will support VSD contractors in rapid assessments of all vaccine safety signals of significance.
By the end of 2015	FDA and CDC	FDA and CDC will receive manufacturer reports of vaccine adverse events electronically in accordance with International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) E2B(R3) standards.

Goal 3: Support communications to enhance informed vaccine decision-making

Vaccines have the unique quality of protecting both individuals and communities. However, given their effectiveness and wide use for many years in preventing and eliminating a number of serious infectious diseases, their significant contributions to public health may have faded from public consciousness.

A myriad of enhanced tools are available for communicating accurate information about the effectiveness and safety of the vaccines that we use. Communication tools and channels used to disseminate immunization and vaccine information span a broad spectrum: publication of evidence-based recommendations; use of mass media and new media; provider education and training; and support of partner organizations and state immunization programs through provision of resources, trainings, updates, and announcements.

Communications materials target many audiences including the public, health care providers and media with timely and accurate information about the safety of vaccines. Communication materials come in a variety of formats, including talking points or key messages, summaries of scientific articles, Web content (e.g., notices to clinicians, fact sheets for consumers), clinician videos, as well as responses to media and public inquiries. Cultural and linguistic appropriateness for the intended audience are also considered in the development of communications materials, as well as their accessibility to persons with disabilities.

Priority D: Increase awareness of vaccines, vaccine-preventable diseases, and the benefits/risks of immunization among the public, providers, and other stakeholders.

Timeframe	Lead Agency	Actions to be Performed
Beginning in 2011 and ongoing	FDA	FDA will enhance communication to stakeholders by utilizing social media (including Twitter) to distribute FDA-specific news and content about vaccines (e.g., new approvals, safety issues, etc).
By the end of 2011	NVPO	NVPO will launch a comprehensive government website on vaccines and immunization.
Beginning in 2012	Office of the National Coordinator for Health Information Technology (ONC)	ONC will promote consumer engagement projects to allow parents access to vaccination history data from immunization information systems, including clinical decision support tools.
By the end of 2012	NVPO	NVPO will launch a Spanish language comprehensive government website on vaccines and immunization.

Priority D: Increase awareness of vaccines, vaccine-preventable diseases, and the benefits/risks of immunization among the public, providers, and other stakeholders *(continued)*.		
Timeframe	**Lead Agency**	**Actions to be Performed**
By the end of 2013	FDA	FDA will use specified metrics to evaluate use of Twitter as a means to communicate with stakeholders.
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.

Goal 4: Ensure a stable supply of, access to, and better use of recommended vaccines in the United States.

The incidence in the U.S. of most diseases against which children are routinely immunized is at or near record-low levels, and infant and child vaccination rates are approaching or exceeding record levels. However, coverage levels are below Healthy People 2020 targets for many vaccines targeted to adolescents and adults, and substantial disparities exist among racial and ethnic groups in adult and adolescent vaccination levels.

A robust vaccine delivery system relies on multiple interrelated components, including ensuring a reliable and steady supply of vaccines in the U.S., where shortages of several commonly used vaccines have occurred since 2000 (e.g., Haemophilus influenza type b, hepatitis A, and influenza). Financial barriers and lack of health care access also contribute to vaccination disparities and need to be addressed in strategies moving forward.

Strong public health surveillance to monitor and evaluate vaccine-preventable diseases (VPDs) and the effectiveness of licensed vaccines provides the link between vaccination policy and health outcomes. Such public health surveillance is a key component of strategies to overcome barriers and improve use of existing vaccines.

Immunization information systems (IIS) and electronic health records (EHRs) may become increasingly important components of immunization programs, allowing for better immunization recordkeeping for children and adults.

Priority E. Use evidence-based science to enhance vaccine-preventable diseases surveillance, measurements of vaccine coverage, and measurement of vaccine effectiveness.

Timeframe	Lead Agency	Actions to be Performed
Ongoing	CDC	CDC will increase the number of virus specimens received and characterized annually from global National Influenza Centers for use in determining vaccine strain selection.
Ongoing	CDC	CDC will continue to monitor the number of indigenous cases of paralytic polio, rubella, congenital rubella syndrome, measles, Haemophilus influenza type b (Hib), diptheria, tetanus, mumps, pertussis (in persons <7 years), and varicella (in persons <18 years) to evaluate the impact of vaccine policy and programs.
Beginning in 2012 and ongoing	CDC	Within one year of a disease becoming newly vaccine-preventable CDC will implement a plan for documenting and reporting vaccine impact.
Beginning in 2012 and annually thereafter	CMS	CMS will track and publicly report the percentage of nursing home residents that are assessed and appropriately given influenza vaccine.

Priority E. Use evidence-based science to enhance vaccine-preventable diseases surveillance, measurements of vaccine coverage, and measurement of vaccine effectiveness *(continued)*.		
Timeframe	**Lead Agency**	**Actions to be Performed**
By the end of 2013	CDC	CDC will increase the number of public health laboratories monitoring influenza virus resistance to antiviral agents to 15.
By the end of 2015	CDC	CDC will increase the percentage of Pandemic Influenza Collaborative Agreement grantees (state, local, territorial, and tribal project areas) that meet the standard for surveillance and laboratory capability criteria.

Priority F: Eliminate financial barriers for providers and consumers to facilitate access to routinely recommended vaccines.		
Timeframe	**Lead Agency**	**Actions to be Performed**
Beginning in 2010 and annually thereafter	NVPO	NVPO will provide an annual update to the National Vaccine Advisory Committee on progress toward strengthening and improving the vaccine financing system in the U.S. to facilitate access to routinely recommended vaccines.
Beginning in 2012 and annually thereafter	Health Resources and Services Administration (HRSA)	HRSA will measure the percentage of children seen at HRSA-funded health centers who receive all-age appropriate routinely recommended vaccines by their second birthday.
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.
Beginning in 2013	CDC	CDC will provide guidance to immunization grantees to not use Section 317 vaccines for routine vaccination of fully-insured patients. Section 317 is a discretionary federal program distributed to the states to provide money for vaccine purchase and to develop vaccine infrastructure.

Priority G: Create an adequate and stable supply of routinely recommended vaccines and vaccines for public health preparedness.		
Timeframe	**Lead Agency**	**Actions to be Performed**
Ongoing	CDC	CDC will continue to track the status of vaccine supplied in the U.S. and maintain a strategic national stockpile of vaccines that are available to state and local health departments during public health emergencies and when local supplies are depleted or unavailable.
Ongoing	ASPR	ASPR will continue to support, through public-private partnerships, the development of domestic influenza vaccine manufacturing capacity to address seasonal and pandemic influenza vaccine needs.
Beginning in 2011	FDA	FDA will convene/co-sponsor three scientific meetings to facilitate the development of an effective vaccine against a number of preventable infectious diseases for which there is not a vaccine currently available.

Priority H: Increase and improve the use of interoperable health information technology and electronic health records (EHRs).		
Timeframe	**Lead Agency**	**Actions to be Performed**
Beginning in 2010 and annually thereafter	ONC	ONC will certify national standards for EHRs to ensure that eligible professionals and hospitals may be assured that the systems they adopt are capable of performing the required functions.
Beginning in 2011	ONC	ONC will collect information on barriers to implementing meaningful use requirements for immunization through the CRM (Sales Force) tool. The CRM (Sales Force) is a milestone management tool which tracks the progress of Regional Extension Centers (RECs) towards meeting their goals of enrolling providers and getting providers to achieve meaningful use.
Beginning in 2012 and annually thereafter	ONC	ONC will perform surveys of select providers enrolled to receive services from RECs to determine issues/barriers with immunization information systems and compatibility with EHRs.
By the end of 2012	ONC	ONC will register 100,000 primary care providers to receive services from RECs and ensure that 60 percent of those have adopted the use of EHRs.

Goal 5: Increase global prevention of death and disease through safe and effective vaccination.

In the era of global pandemics and mass travel, the public health of U.S. citizens is closely related to disease prevalence in other countries. Even though many VPDs such as polio, measles, and rubella have been eliminated in this country, the U.S. remains vulnerable to importations as long as these diseases continue to persist elsewhere. Support for developing new vaccines to address diseases in other countries and assisting with their immunization programs contributes toward providing a domestic "umbrella of protection" and fulfilling the U.S. government's broader commitment to support global public health.

Success in global immunization requires action by a broad range of stakeholders involved in the vaccine and immunization enterprise: research and development, regulation and manufacturing, procurement, distribution and delivery, program implementation, and monitoring. The Pan American Health Organization's "revolving fund" and new partnerships such as the GAVI Alliance have led to increased support for immunization worldwide, spurring introduction of new vaccines in low income countries and expanded vaccination coverage. U.S. governmental and non-governmental organizations have contributed to progress through vaccine research and development, participation in multilateral and bilateral partnerships, technical assistance, and program support.

Priority I: Improve global surveillance for vaccine-preventable diseases and strengthen global health information systems to monitor vaccine coverage, effectiveness, and safety.

Timeframe	Lead Agency	Actions to be Performed
Ongoing	CDC	CDC will continue to serve as a global reference lab for polio, measles, and rubella.
By the end of 2013 and ongoing	CDC	CDC will provide surveillance and laboratory capacity to monitor progress in reaching global polio eradication, guide programmatic response, and implement the polio eradication end-game strategy.
By the end of 2013 and annually thereafter	CDC	CDC will provide a descriptive report of progress on immunization activities in the Field Epidemiology and Laboratory Training Program.

[4] http://www.cdc.gov/globalhealth/FETP/

Priority J: Support global introduction and availability of new and under-utilized vaccines to prevent diseases of public health importance.		
Timeframe	**Lead Agency**	**Actions to be Performed**
Ongoing	CDC	CDC will continue to provide surveillance, laboratory, and vaccine program implementation capacity to support national decision-making on new vaccine introduction, and to enable introduction of new vaccines including pneumococcal vaccine, rotavirus vaccine, meningococcal vaccine, and human papillomavirus vaccine in GAVI eligible countries.
Beginning in 2006 and annually thereafter	ASPR	ASPR will provide financial and technical support for the World Health Organization (WHO) Global Action Plan to Increase Pandemic Influenza Vaccines, including capacity building for vaccine production at developing country manufacturers, royalty-free adjuvant production, specialized training in advanced biomanufacturing skills, and clinical/laboratory infrastructure building.
Beginning in 2010 and annually thereafter	FDA	FDA will develop and implement a research agenda to facilitate the development of vaccines against tropical and neglected diseases.
Beginning in 2010	FDA	FDA will participate in international collaborative studies to establish and maintain international reference materials and standards for biologics.
Beginning in 2010	FDA	FDA will help build regulatory capacity in developing countries, which may include training, participation in WHO assessments, and other international activities.
By the end of 2015	ASPR	ASPR will provide technical support in vaccine manufacturing, including training on vaccine production, analytical evaluation, laboratory techniques, and clinical evaluation, to developing country manufacturers for the WHO Global Action Plan to Increase Pandemic Influenza Vaccines. This training may take place on-site in developing countries and at established educational institutions in the U.S.

Priority J: Support global introduction and availability of new and under-utilized vaccines to prevent diseases of public health importance *(continued)*.

Timeframe	Lead Agency	Actions to be Performed
By the end of 2015	Office of Global Affairs (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.
By the end of 2015	OGA	OGA will facilitate development of new partnerships across HHS, across the U.S. government, and with other international partners not previously engaged for support of the WHO Action Plan to Increase Pandemic Influenza Vaccines.

Note: ASPR's technical assistance and OGA's policy activities are collaborative and leverage support with international stakeholders for in-country influenza vaccine manufacturing and adoption of influenza vaccine policies.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies[5]

Priority	Related Goal(s)	Related Objectives and Strategies
A. Develop a catalogue of priority vaccine targets of domestic and global health	**Goal 1: Develop new and improved vaccines**	
		Objective 1.1: Prioritize new vaccine targets of domestic and global public health importance. **1.1.1** Develop and implement a process for prioritizing and evaluating new vaccine targets of domestic and global public health importance. This catalogue of vaccine targets (including improved vaccines) should include an analysis of barriers to development **1.1.2** Conduct and improve disease surveillance of existing pathogens and optimize methods to detect new pathogens to continuously inform the priorities for potential new vaccines

[5] Priorities may relate to objectives and strategies within multiple National Vaccine Plan goals. Within the National Vaccine Plan, Implementation 2010-2015, priorities are presented the most relevant goal.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
B. Strengthen the science base for the development and licensure of new vaccines	**Goal 1: Develop new and improved vaccines** **Goal 2: Enhance the vaccine safety system**	**Objective 1.2:** Support research to develop and manufacture new vaccine candidates and improve current vaccines to prevent infectious diseases. **1.2.1** Conduct and support expanded vaccine research to meet medical and public health needs. Establish surveillance systems or studies to better assess disease burden in specific target populations including neonates, infants, children, older adults, pregnant women, immunocompromised individuals, and other at-risk individuals. **1.2.2** Advance research and development toward new and/or improved vaccines that prevent infectious diseases and their sequelae, including those that protect against emerging, re-emerging, and important biodefense-related pathogens. **1.2.3** Advance the science of neonatal and maternal immunity including immunization and the development of immunological models to study maternal immunization and effects on offspring. **1.2.5** Develop new approaches to vaccine manufacturing (e.g., rapid, flexible, and cost-effective) to meet demands for efficient, expandable vaccine production capacity while also meeting needs related to other public health emergency threats such as international emerging diseases.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
		Objective 1.3: Support research on novel and improved vaccine delivery methods.
		1.3.1 Develop and evaluate new and improved alternate delivery methods of vaccine administration to optimize the protective immune response, safety, effectiveness, and/or efficiency (e.g., number of doses).
		1.3.2 Expand knowledge regarding the induction and maintenance of vaccine immune responses via different routes of administration (e.g., mucosal surfaces).
		Objective 1.4: Increase understanding of the host immune system.
		1.4.1 Define the capacity and quality of innate and adaptive human immune response to infections among diverse gender, ethnic, racial, age (childhood, adolescence, and adulthood), and health condition status (e.g., autoimmune compromised individuals) populations in order to advance the understanding of immune protection.
		1.4.2 Gain a better understanding of how induction and recall of immune memory may inform the development of vaccines that provide life-long protection.
		1.4.3 Support development of immunomodulators including vaccine adjuvants that facilitate the appropriate cell-mediated and antibody responses for protection against pathogens with distinct effector requirements.
		1.4.4 Expand knowledge of host-related factors that impact severity of disease and vaccine-induced host immune response, and use this information to inform vaccine development.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
		1.4.5 Develop a database of gene-expression and immunologic responses to selected currently licensed vaccines with a focus on signals that correlate with mechanism of action, protection, safety, and adverse events. Utilize this compendium to inform development of new candidate vaccines and adjuvants.
		1.4.6 Study mucosal immunity following vaccination in order to better understand vaccine mechanisms and to provide new, potentially more relevant, correlates of protection against respiratory, enteric, genital, and urinary pathogens.
		Objective 1.5: Support product development, evaluation, and production techniques of vaccine candidates and the scientific tools needed for their evaluation.
		1.5.1 Support applied research to develop rapid and cost-efficient production, and optimize formulations and stability profiles of currently available vaccines.
		1.5.2 Support research on and development of more flexible and agile approaches to product development, manufacturing production techniques including multi-use technologies such as platforms, and quality testing procedures (e.g., potency and safety testing).
		1.5.3 Improve access to pilot lot manufacturing facilities that produce clinical grade material for evaluating promising vaccine candidates.
		1.5.4 Support translational research that accelerates the development of information that can be used in the evaluation and licensure process.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
		1.5.5 Establish and strengthen public and private partnerships to address urgent needs in vaccine research and development.
		Objective 1.6: Improve the tools, standards, and approaches to assess the safety, efficacy, and quality of vaccines.
		1.6.1 Improve assay development for characterization of novel cell substrates.
		1.6.2 Improve efforts to develop, refine, and validate new biomarkers and correlates of immunity.
		1.6.3 Develop and improve methods to better assess vaccine efficacy and safety including assessment of new technologies and development of better animal models.
		1.6.4 Improve methods for assessing and evaluating vaccine quality, potency, safety, and effectiveness.
		Objective 2.1: Ensure a robust vaccine safety scientific system that focuses on high priority areas.
		2.1.1 Develop, prioritize, and regularly update a national vaccine safety scientific agenda.
		2.1.2 Retain current and recruit additional highly trained vaccine safety scientists and clinicians.
		2.1.3 Improve laboratory, epidemiological, and statistical methods used in Vaccine safety research.
		Objective 2.2: 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.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies	
		2.2.1	Facilitate the enhancement of vaccine manufacturing sciences and quality systems, including production technologies, in-process controls and testing, and identification of best practices in preventive quality systems and oversight.
		2.2.2	Develop, implement, and periodically reassess risk-based scientific approaches to identify inspectional priorities and best practices.
		2.2.3	Develop new scientific methods for both industry and the Food and Drug Administration (FDA) for product quality testing.
		2.2.4	Assure that regulations, guidance documents, policies, and procedures that are relevant to vaccine manufacturing, laboratory testing, and quality control incorporate the most current relevant scientific information to promote and enhance product safety.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
C. Enhance timely detection and verification of vaccine safety signals and develop a vaccine safety scientific agenda	**Goal 2: Enhance the vaccine safety system**	**Objective 2.1:** Ensure a robust vaccine safety scientific system that focuses on high priority areas. **2.1.1** Develop, prioritize, and regularly update a national vaccine safety scientific agenda. **2.1.2** Retain current and recruit additional highly trained vaccine safety scientists and clinicians. **2.1.3** Improve laboratory, epidemiological, and statistical methods used in vaccine safety research. **Objective 2.3:** Enhance timely detection and verification of vaccine safety signals. **2.3.1** Improve the effectiveness and timeliness of signal identification and assessment through coordinated use of passive and active surveillance systems, and from providers and the public. **2.3.2** Improve the process for assessing adverse event following immunization (AEFI) signals to determine which signals should be evaluated further in epidemiological and clinical studies.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
		Objective 2.4: Improve timeliness of the evaluation of vaccine safety signals, especially when 1) a high-priority new vaccine safety concern emerges or 2) when a new vaccine is recommended, vaccination recommendations are expanded, or during public health emergencies such as in an influenza pandemic or other mass vaccination campaign. **2.4.1** Expand collaboration with clinical, laboratory, genetic, statistical, and bioinformatics experts to conduct clinical research studies to investigate the role of host genetics in AEFIs. **2.4.2** Increase the size, representativeness, and utility of the population under active surveillance for serious AEFIs that can be included in timely, high quality, rigorously conducted epidemiological studies to assess vaccine safety questions. **Objective 2.5:** Improve causality assessments of vaccines and related AEFIs. **2.5.1** Build upon new scientific developments in areas such as genetics, systems biology and bioinformatics, and immunology to develop and validate tools which aid in (or enable) the identification of individual risk factors for AEFIs for which a causal relationship has been established. **2.5.2** Assess the evidence for a causal relationship between certain vaccines and specific clinically important AEFIs and, as the need arises, conduct an independent review of available evidence. **Objective 2.6:** Improve scientific knowledge about why and among whom vaccine adverse reactions occur.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
		2.6.1 Identify host risk factors that may be associated with increased risk for specific vaccine adverse reactions through basic, clinical, or epidemiological research.
		2.6.2 Identify the biological mechanism(s) for vaccine adverse reactions.
		2.6.3 Assess whether the risk of specific AEFIs is increased in specific populations such as pregnant women, premature infants, older adults, those with immunocompromising or other medical conditions, based on gender or race/ethnicity, or other at-risk individuals.
		2.6.4 Develop a robust system to enhance collection of medical histories and biological specimens from selected persons experiencing serious AEFIs to enhance study of biological mechanisms and individual risk factors.
		Objective 2.8: Enhance collaboration of vaccine safety activities.
		2.8.1 Improve collaboration, such as data sharing arrangements, across federal agencies, departments, and with non-federal partners.
		2.8.2 Improve information and data sharing with international partners (e.g., national vaccine safety programs) consistent with ethical and human subjects protections and applicable law, including confidentiality protections.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
		2.8.3 Develop additional standard case definitions for AEFIs for use in immunization safety surveillance and research, vaccine safety standards such as concept definitions, standardized abbreviations, and standardized study designs.
D. Increase awareness of vaccines, vaccine-preventable diseases, and the benefits/risks of immunization among the public, providers, and other stakeholders	**Goal 3: Support informed vaccine decision-making**	
		Objective 3.1: Utilize communication approaches that are based on ongoing research. **3.1.1** Conduct research regularly to understand the public's knowledge, beliefs, and concerns about vaccines and VPDs. **3.1.2** Conduct research on factors that affect decision-making about vaccination for individuals and families, providers, and policy-makers. **3.1.3** Identify, develop, and test educational strategies that better enable policy-makers to read, understand, and use information about vaccine benefits and risks. **3.1.4** Evaluate the effectiveness of messages and materials in addressing the information needs and concerns of the public and under-immunized populations.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
		3.1.5 Develop evidence-based tools to assist individuals, parents, and providers with relevant information to make informed decisions regarding vaccination.
		Objective 3.2: Build and enhance collaborations and partnerships for communication efforts.
		3.2.1 Strengthen existing partnerships and coalitions and build relationships with new partners to support relevant immunizations across the lifespan.
		3.2.2 Use cross-agency and intra-agency collaboration to inform development of communication research agendas, protocols, campaigns and messages.
		3.2.3 Collaborate with partners and stakeholders to communicate vaccine benefits, risks, and recommendations in accessible formats and in culturally appropriate languages, methods, and literacy levels.
		3.2.4 Utilize state and local venues to educate on vaccine and immunization issues to expand the reach of messages outside of the traditional clinical setting.
		Objective 3.3: Enhance delivery of timely, accurate, and transparent information to public audiences and key intermediaries (such as media, providers, and public health officials) about what is known and unknown about the benefits and risks of vaccines.
		3.3.1 Enhance communication of new findings about vaccine effectiveness, safety, and administration studies to the public, partners and providers in a clear, transparent and timely manner.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
		3.3.2 Respond in a rapid, coordinated, consistent, and effective manner to emerging vaccine issues and concerns (e.g., supply, safety, or public health emergencies).
		3.3.3 Rapidly and effectively disseminate communications research findings through peer-reviewed journals, conferences, media, and partner communications to facilitate implementation of evidence-based strategies.
		Objective 3.4: Increase public awareness of the benefits and risks of vaccines and immunization, especially among populations at risk of under-immunization.
		3.4.1 Develop, implement, and evaluate a long-term strategic communications plan and program aimed at educating parents, caregivers of children, adolescents, and adults about VPDs; the benefits and risks of vaccines; and vaccine recommendations.
		3.4.2 Maintain current, easily accessible, evidence-based online information on VPDs and vaccines, including benefits and risks and the basis of immunization recommendations, for all audience groups.
		3.4.3 Evaluate new media (such as mobile technologies and social media) and utilize it appropriately to reach target audiences with accurate and timely information about vaccines and to respond to emerging concerns and issues.
		3.4.4 Enhance awareness of the importance of immunization as part of preventive health care among parents, adolescents, and adults.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
		3.4.5 Collaborate with the education community to assess opportunities to integrate information on VPDs, recommended vaccines, preventive health care, and public health in existing educational curricula.
		3.4.6 Develop and disseminate vaccine communication tools/ materials that are accessible and culturally and literacy-level appropriate for groups at risk of under-immunization.
		Objective 3.5: Assure that key decision- and policy-makers (e.g., third-party payers, employers, legislators, community leaders, hospital administrators, health departments) receive accurate and timely information on vaccine benefits and risks; economics; and public and stakeholder knowledge, attitudes, and beliefs.
		3.5.1 Develop, disseminate, and evaluate broad-based education tools for key groups on the value, risks, and cost-effectiveness of vaccines; the basis of immunization recommendations; business case evidence and guidance; vaccine policy development; the standards of immunization practice and administration; and vaccines as a component of preventive health care.
		3.5.2 Select and implement a model for sustained community engagement to inform vaccine policy and program activities.
		3.5.3 Provide vaccine program managers and policy-makers information on the direct and indirect costs and benefits of vaccination. This includes, but is not limited to, information on federal and state programs that offer low-cost vaccines.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
		3.5.4 Provide policy-makers with data necessary to make informed decisions on the utilization of vaccines in mass vaccination programs for public health emergencies.
E. Use evidence-based science to enhance vaccine-preventable disease surveillance, measurement of vaccine coverage, and measurement of vaccine effectiveness	**Goal 1: Develop new and improved vaccines** **Goal 2: Enhance the vaccine safety system** **Goal 4: Ensure a stable supply of, access to, and better use of recommended vaccines in the U.S.**	
		Objective 1.1: Prioritize new vaccine targets of domestic and global public health importance. **1.1.2** Conduct and improve disease surveillance of existing pathogens and optimize methods to detect new pathogens to continuously inform the priorities for potential new vaccines. **Objective 1.2:** Support research to develop and manufacture new vaccine candidates and improve current vaccines to prevent infectious diseases. **1.2.1** Conduct and support expanded vaccine research to meet medical and public health needs. Establish surveillance systems or studies to better assess disease burden in specific target populations including neonates, infants, children, older adults, pregnant women, immunocompromised individuals, and other at-risk individuals.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
		Objective 1.6: Improve the tools, standards, and approaches to assess the safety, efficacy, and quality of vaccines.
		1.6.1 Improve assay development for characterization of novel cell substrates.
		1.6.2 Improve efforts to develop, refine, and validate new biomarkers and correlates of immunity.
		1.6.3 Develop and improve methods to better assess vaccine efficacy and safety including assessment of new technologies and development of better animal models.
		1.6.4 Improve methods for assessing and evaluating vaccine quality, potency, safety, and effectiveness.
		Objective 2.8: Enhance collaboration of vaccine safety activities.
		2.8.1 Improve collaboration, such as data sharing arrangements, across federal agencies, departments, and with non-federal partners.
		2.8.2 Improve information and data sharing with international partners (e.g., national vaccine safety programs) consistent with ethical and human subjects protections and applicable law, including confidentiality protections
		2.8.3 Develop additional standard case definitions for AEFIs for use in immunization safety surveillance and research, vaccine safety standards such as concept definitions, standardized abbreviations, and standardized study designs.
		Objective 4.2: Ensure consistent and stable delivery of vaccines for the U.S.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
		4.2.7 Implement, monitor, and evaluate evidence-based interventions designed to raise and sustain high vaccination coverage across the lifespan.
		4.2.8 Monitor and evaluate the impact of state immunization laws and regulations on vaccine coverage, including childcare, pre-school, school, college prematriculation requirements, employer requirements, and the role of exemptions, insurance mandates, and immunization information systems requirements.
		Objective 4.4: Maintain and enhance the capacity to monitor immunization coverage for vaccines routinely administered to all age groups.
		4.4.1 Identify, implement, and evaluate cost-effective and rapid methods, such as the use of IIS or internet panel surveys, for assessing vaccination coverage by categories, including age groups, groups at risk of under immunization, by type of vaccine, and type of financing.
		4.4.2 Improve the completeness of, use of, and communication between, IIS and EHR to monitor vaccination coverage.
		4.4.3 Support the adoption of national certified, interoperable health information technology and EHR for immunization.
		4.4.4 Support and improve existing surveys assessing immunization coverage (e.g., the National Immunization Survey and the Behavioral Risk Factor Surveillance System), to include more representative samples and timely reporting of data.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
		Objective 4.5: Enhance tracking of VPDs and monitoring of the effectiveness of licensed vaccines.
		4.5.1 Strengthen epidemiologic and laboratory methods and tools to diagnose VPDs, assess population susceptibility, and characterize vaccine effectiveness and the impact of vaccination coverage on clinical and public health outcomes.
		4.5.2 Monitor circulating strains of relevant vaccine-preventable and potentially vaccine-preventable pathogens, including emerging and re-emerging diseases.
		4.5.3 Improve monitoring of disease burden and determine epidemiologic and clinical characteristics of cases of VPDs and potential VPDs by supporting traditional surveillance and use of health information technology, interoperable data standards, and new data resources.
		4.5.4 Develop and maintain capacity to rapidly estimate the effectiveness of new vaccines, such as pandemic and pre-pandemic influenza vaccines.
		4.5.5 Assure rapid and comprehensive identification, investigation, and response to vaccine- preventable disease outbreaks.
		4.5.6 Assure timely evaluation to assess vaccine effectiveness, duration of protection, and indirect (community and herd) protection by current and newly recommended vaccines.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
		Objective 4.9: Enhance immunization coverage for travelers. **4.9.1** Define the populations at risk for acquiring international travel-related VPDs, and identify and address barriers to their receiving immunizations. **4.9.2** Assess overall immunization status during travel-related immunization clinics.
F. Eliminate financial barriers for providers and consumers to facilitate access to routinely recommended vaccines	**Goal 4: Ensure a stable supply of, access to, and better use of recommended vaccines in the U.S.**	
		Objective 4.3: Reduce financial barriers to vaccination. **4.3.1** Identify and regularly monitor financial barriers to receipt of Advisory Committee for Immunization Practices (ACIP)-recommended and CDC-adopted vaccines. **4.3.3** Strengthen the ability of states to purchase, and expand access to, ACIP-recommended and CDC-adopted vaccines for those who qualify for publicly supported vaccinations. **4.3.4** Develop, implement, and evaluate strategies to reduce the financial burden on vaccination providers for purchase of initial and ongoing vaccine inventories. **Objective 4.6:** Educate and support health care providers in vaccination counseling and vaccine delivery for their patients and themselves.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies	
			4.6.4 Promote and support educational and technical assistance to improve business practices associated with providing immunizations, such as educating providers and enrolling new providers into the Vaccines for Children program, including non-traditional providers.
			4.6.6 Support adequate reimbursement for vaccine counseling, administration, storage and handling by providers under public sector and private health plans.
			4.6.7 Support research to evaluate the capacity (accommodating the increased number of patient visits required to receive recommended vaccines) of health care providers to implement vaccine recommendations for all age groups.
		Objective 4.8:	Strengthen the National Vaccine Injury Compensation Program (VICP) and Countermeasures Injury Compensation Program (CICP).
			4.8.3 Continue to ensure fair and efficient compensation for vaccine-related injuries.
			4.8.4 Examine alternative approaches, and evaluate and implement those deemed optimal, for adjudication of VICP claims for illnesses not included in the Vaccine Injury Table to the extent permitted by applicable law.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
G. Create an adequate and stable vaccine supply routinely recommended vaccines and vaccines for public health preparedness	**Goal 1: Develop new and improved vaccines** **Goal 4: Ensure a stable supply of, access to, and better use of recommended vaccines in the U.S.**	

Objective 1.2: Support research to develop and manufacture new vaccine candidates and improve current vaccines to prevent infectious diseases.

1.2.5 Develop new approaches to vaccine manufacturing (e.g., rapid, flexible, and cost-effective) to meet demands for efficient, expandable vaccine production capacity while also meeting needs related to other public health emergency threats such as international emerging diseases.

Objective 1.5: Support product development, evaluation, and production techniques of vaccine candidates and the scientific tools needed for their evaluation.

1.5.1 Support applied research to develop rapid and cost-efficient production, and optimize formulations and stability profiles of currently available vaccines.

1.5.2 Support research on and development of more flexible and agile approaches to product development, manufacturing production techniques including multi-use technologies such as platforms, and quality testing procedures (e.g., potency and safety testing).

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
		1.5.3 Improve access to pilot lot manufacturing facilities that produce clinical grade material for evaluating promising vaccine candidates.
		1.5.4 Support translational research that accelerates the development of information that can be used in the evaluation and licensure process.
		1.5.5 Establish and strengthen public and private partnerships to address urgent needs in vaccine research and development.
		Objective 4.1: Ensure consistent and adequate supply of vaccines for the U.S.
		4.1.1 Determine barriers to having multiple suppliers for each vaccine licensed and recommended for routine use in the U.S.
		4.1.2 Promote harmonization of international vaccine regulatory standards for licensure.
		4.1.3 Improve vaccine quality and availability through better manufacturing and production oversight.
		4.1.4 Optimize use, content, and distribution of vaccine stockpiles and ancillary supplies.
		4.1.5 Improve the development of, communication of, and tracking of adherence to recommended changes in vaccine use during national vaccine shortages.
		Objective 4.5: Enhance tracking of VPDs and monitoring of the effectiveness of licensed vaccines.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies	
		4.5.1	Strengthen epidemiologic and laboratory methods and tools to diagnose VPDs, assess population susceptibility, and characterize vaccine effectiveness and the impact of vaccination coverage on clinical and public health outcomes.
		4.5.2	Monitor circulating strains of relevant vaccine-preventable and potentially vaccine-preventable pathogens, including emerging and re-emerging diseases.
		4.5.3	Improve monitoring of disease burden and determine epidemiologic and clinical characteristics of cases of VPDs and potential VPDs by supporting traditional surveillance and use of health information technology, interoperable data standards, and new data resources.
		4.5.4	Develop and maintain capacity to rapidly estimate the effectiveness of new vaccines, such as pandemic and pre-pandemic influenza vaccines.
		4.5.5	Assure rapid and comprehensive identification, investigation, and response to vaccine- preventable disease outbreaks.
		4.5.6	Assure timely evaluation to assess vaccine effectiveness, duration of protection, and indirect (community and herd) protection by current and newly recommended vaccines.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
H. Increase the use of interoperable health information and electronic health records	**Goal 4: Ensure a stable supply of, access to, and better use of recommended vaccines in the U.S.**	

Objective 4.4: Maintain and enhance the capacity to monitor immunization coverage for vaccines routinely administered to all age groups.

- **4.4.1** Identify, implement, and evaluate cost-effective and rapid methods, such as the use of IIS or internet panel surveys, for assessing vaccination coverage by categories, including age groups, groups at risk of under immunization, by type of vaccine, and type of financing.
- **4.4.2** Improve the completeness of, use of, and communication between, IIS and EHR to monitor vaccination coverage.
- **4.4.3** Support the adoption of national certified, interoperable health information technology and EHR for immunization.
- **4.4.4** Support and improve existing surveys assessing immunization coverage (e.g., the National Immunization Survey and the Behavioral Risk Factor Surveillance System), to include more representative samples and timely reporting of data.

Objective 4.6: Educate and support health care providers in vaccination counseling and vaccine delivery for their patients and themselves.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies	
		4.6.2	Expand and implement training and education of immunization providers at all levels of their education on the proper use and administration of vaccines; the proper storage and handling of vaccines; the basis of immunization recommendations; the safety of vaccines; reporting of AEFIs; understanding of the vaccine safety system; and on the standards of immunization practice (e.g., vaccine education modules in primary care and continuing medical education programs).
		4.6.5	Expand the incorporation of vaccinations and the use of IIS into quality improvement programs such as the Healthcare Effectiveness Data and Information Set.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
I. Improve global surveillance for vaccine-preventable diseases and strengthen global health information systems to monitor vaccine coverage, effectiveness, and safety	**Goal 4: Ensure a stable supply of, access to, and better use of recommended vaccines in the U.S.** **Goal 5: Increase global prevention of death and disease through safe and effective vaccination**	**Objective 4.5:** Enhance tracking of VPDs and monitoring of the effectiveness of licensed vaccines. **4.5.1** Strengthen epidemiologic and laboratory methods and tools to diagnose VPDs, assess population susceptibility, and characterize vaccine effectiveness and the impact of vaccination coverage on clinical and public health outcomes. **4.5.2** Monitor circulating strains of relevant vaccine-preventable and potentially vaccine-preventable pathogens, including emerging and re-emerging diseases. **4.5.3** Improve monitoring of disease burden and determine epidemiologic and clinical characteristics of cases of VPDs and potential VPDs by supporting traditional surveillance and use of health information technology, interoperable data standards, and new data resources. **4.5.4** Develop and maintain capacity to rapidly estimate the effectiveness of new vaccines, such as pandemic and pre-pandemic influenza vaccines.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
		4.5.5 Assure rapid and comprehensive identification, investigation, and response to vaccine- preventable disease outbreaks.
		4.5.6 Assure timely evaluation to assess vaccine effectiveness, duration of protection, and indirect (community and herd) protection by current and newly recommended vaccines.
		Objective 5.1: Support international organizations and countries to improve global surveillance for VPDs and strengthen health information systems to monitor vaccine coverage, effectiveness, and safety.
		5.1.1 Achieve sustainable WHO certification quality surveillance for eradication of targeted VPDs.
		5.1.2 Expand and improve sustainable surveillance systems for all diseases having WHO-recommended vaccines and diseases for which vaccine introduction is being considered.
		5.1.3 Strengthen all levels of global laboratory networks (including national, regional, and global reference laboratories) to sustain and improve VPD diagnosis in order to establish baseline disease burden, detect outbreaks, detect newly emerging variants of VPDs, and monitor the impact of new vaccines. This laboratory capacity should also be developed for surveillance of potential public health emergencies of international concern.
		5.1.4 Enhance assessments of emerging variants or strains of VPD agents.
		5.1.5 Develop new diagnostic tests, tools and procedures to improve both field-based and laboratory confirmation of diagnoses.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
		Objective 5.2: Support international organizations and countries to improve and sustain immunization programs as a component of health care delivery systems and promote opportunities to link immunization delivery with other priority health interventions, where appropriate.
		5.2.1 Provide technical support to countries, multilateral institutions, and other partners to strengthen key components of immunization program management and implementation, including epidemiological analysis, comprehensive planning, vaccine distribution and safe administration, monitoring, information systems, and program evaluation.
		Objective 5.6: Build and strengthen multilateral and bilateral partnerships and other collaborative efforts to support global immunization and eradication programs.
		5.6.1 Participate in establishing global immunization priorities, goals and objectives and provide technical assistance at global, regional, and national levels.
		5.6.3 Contribute to development and implementation of a plan establishing the scientific basis for VPD eradication/elimination, identifying optimal vaccination approaches, and developing strategies to minimize risks in the post-eradication period.
		5.6.4 Participate in regional immunization initiatives, such as those adopted by the Pan American Health Organization and other WHO regions.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
J. Support global introduction and availability of new and under-utilized vaccines to prevent diseases of public health importance	**Goal 1: Develop new and improved vaccines** **Goal 5: Increase global prevention of death and disease through safe and effective vaccination**	**Objective 1.1:** Prioritize new vaccine targets of domestic and global public health importance. **1.1.1** Develop and implement a process for prioritizing and evaluating new Vaccine targets of domestic and global public health importance. This catalogue of vaccine targets (including improved vaccines) should include an analysis of barriers to development. **1.1.2** Conduct and improve disease surveillance of existing pathogens and optimize methods to detect new pathogens to continuously inform the priorities for potential new vaccines. **Objective 1.2: .** Support research to develop and manufacture new vaccine candidates and improve current vaccines to prevent infectious diseases **Objective 1.3:** Support research on novel and improved vaccine delivery methods. **Objective 1.5:** Support product development, evaluation, and production techniques of vaccine candidates and the scientific tools needed for their evaluation.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
		1.5.5 Establish and strengthen public and private partnerships to address urgent needs in vaccine research and development.
		Objective 5.3: Support international organizations and countries to introduce and make available new and underutilized vaccines to prevent diseases of public health importance.
		5.3.1 Strengthen capacity at the country level, and in multilateral institutions as appropriate, to make informed decisions on introduction of new vaccines based on evaluation of epidemiology, financial sustainability, safety, and programmatic considerations, including support to national advisory committees.
		5.3.2 Collaborate with global organizations and partners to accelerate clinical testing and licensure in developing countries of vaccines already licensed in developed countries, where appropriate.
		5.3.3 Support the integration of new and underutilized vaccines into each GAVI-eligible country's multi-year national plan of action and provide training and logistical support necessary to successfully incorporate new vaccines into routine programs.
		5.3.4 Support post-licensure evaluations of new vaccines with regard to immunization programs, disease patterns, and vaccine safety.

5. Priorities may relate to objectives and strategies within multiple National Vaccine Plan goals. Within the National Vaccine Plan Implementation priorities are presented the most

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
		5.3.5 Work with global partners to establish an international system that facilitates rapid response to emerging infections through the development of vaccine reference strains and candidate vaccines.
		5.3.6 Work with global partners to secure and maintain adequate stockpiles/strategic reserves of vaccines to maintain uninterrupted supply and for emergency response to outbreaks.
		5.3.7 Support and develop mechanisms for rapidly making vaccines available to developing countries for public health emergencies such as pandemic influenza, including exploring options for sharing of vaccines and tiered pricing.
		Objective 5.5: Support the development of regulatory environments and manufacturing capabilities that facilitate access to safe and effective vaccines in all countries.
		5.5.1 Promote and support the efforts of WHO and other global partners to develop and harmonize international standards for vaccine development and licensure.
		5.5.2 Promote and support the efforts of WHO and others to improve regulatory capacity in countries with limited infrastructures to assure vaccine quality, evaluate new vaccines when appropriate, and assure that clinical trials are conducted in accordance with Good Clinical Practices.

Appendix: Priorities for Implementation and Related National Vaccine Plan Goals, Objectives, and Strategies *(continued)*

Priority	Related Goal(s)	Related Objectives and Strategies
		5.5.3 Provide technical assistance to developing country vaccine manufacturers to support development and production of safe and effective vaccines.
		Objective 5.6: Build and strengthen multilateral and bilateral partnerships and other collaborative efforts to support global immunization and eradication programs.
		5.6.1 Participate in establishing global immunization priorities, goals and objectives and provide technical assistance at global, regional, and national levels.
		5.6.2 Strengthen international collaborations for basic and applied research and related training of next generation researchers, especially in disease endemic areas, to include improving the stability and performance of current vaccines.
		5.6.3 Contribute to development and implementation of a plan establishing the scientific basis for VPD eradication/elimination, identifying optimal vaccination approaches, and developing strategies to minimize risks in the post-eradication period.
		5.6.4 Participate in regional immunization initiatives, such as those adopted by the Pan American Health Organization and other WHO regions.
		5.6.5. Strengthen vaccination of globally mobile populations through targeted programs (e.g., pre-departure vaccination of US bound refugees).