National Adult Immunization Plan

National Vaccine Program Office

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Executive Summary

Vaccination is considered one of the most important public health achievements of the 20th century and continues to offer great promise in the 21st century. Vaccines save lives and improve the quality of life by preventing serious infectious diseases and their consequences. However, the benefits of vaccination are not realized equally across the U.S. population. Adult vaccination rates remain low in the United States, and significant racial and ethnic disparities also exist.

The U.S. Department of Health and Human Services National Vaccine Plan (NVP), released in 2010, is a road map for vaccines and immunization programs for the decade 2010–2020. While the NVP provides a vision for improving protection from vaccine-preventable diseases across the lifespan, vaccination coverage levels among adults are not on track to meet Healthy People 2020 targets. The National Vaccine Advisory Committee and numerous stakeholder groups have emphasized the need for focused attention on *adult vaccines and vaccination*.[1] The National Adult Immunization Plan (NAIP) outlined here results from the recognition that progress has been slow, and there is a need for a national adult immunization strategic plan.

The NAIP is a five-year national plan. As a national plan, it will require engagement from a wide range of stakeholders to achieve its full vision. The plan emphasizes collaboration and prioritization of efforts that will have the greatest impact. The NAIP also aims to leverage the unique opportunity presented by the implementation of the Affordable Care Act.

The NAIP is intended to facilitate coordinated action by federal and nonfederal partners to protect public health and achieve optimal prevention of infectious diseases and their consequences through vaccination of adults. The NAIP includes indicators to draw attention to and track progress against core goals. These indicators will measure progress against set standards and inform future implementation and quality improvement efforts. The plan establishes four key goals, each of which is supported by objectives and strategies to guide implementation through 2020:

Goal 1: Strengthen the adult immunization infrastructure.
Goal 2: Improve access to adult vaccines.
Goal 3: Increase community demand for adult immunizations.
Goal 4: Foster innovation in adult vaccine development and vaccination-related technologies.

Achieving the goals of the NAIP is facilitated by agreement on plan priorities and coordination of the wide range of programs that support them. The Assistant Secretary for Health serves as the director of the National Vaccine Program and will lead the NAIP and its implementation. In support of this mission, NVPO will facilitate collaboration and coordinate the monitoring of progress for the NAIP.

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Abbreviations

ACF	Administration for Children and Families
ACIP	Advisory Committee on Immunization Practices
ACL	Administration for Community Living
AHRQ	Agency for Healthcare Research and Quality
AITF	Interagency Adult Immunization Task Force
ASH	Assistant Secretary for Health
ASPE	Assistant Secretary for Planning and Evaluation
ASPR	Assistant Secretary for Preparedness and Response
BARDA	Biomedical Advanced Research and Development Authority
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
DHS	U.S. Department of Homeland Security
DoD	U.S. Department of Defense
DOH	Department of Health
EHRs	Electronic health records
FDA	U.S. Food and Drug Administration
FOH	Federal Occupational Health
HHS	Department of Health and Human Services
HPV	Human papilloma virus
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
IID	Immunization and Infectious Diseases
IIS	Immunization information systems
IT	Information technology
NAIP	National Adult Immunization Plan
NIH	National Institutes of Health
NVAC	National Vaccine Advisory Committee
NVP	National Vaccine Plan
NVPO	National Vaccine Program Office
OASH	Office of the Assistant Secretary for Health
OMH	Office of Minority Health
ONC	Office of the National Coordinator for Health Information Technology
OWH	Office on Women's Health
RHA	Regional Health Administrator
Tdap	Tetanus, diphtheria, and pertussis
VA	Department of Veterans Affairs
VAERS	Vaccine Adverse Event Reporting System
VFC	Vaccine for Children Program
VICP	National Vaccine Injury Compensation Program

Introduction

Despite the widespread availability of safe and effective vaccines, adult vaccination rates remain low in the United States and far below Healthy People 2020 targets.[2,3] Vaccine-preventable diseases take a heavy toll on adults age 18 and older. The health and productivity costs of influenza alone are estimated to be as high as $87 billion per year.[4] The Centers for Disease Control and Prevention (CDC) estimates that among US adults each year there are roughly 40,000 cases and 4,000 deaths attributable to invasive pneumococcal disease,[5] between 3,000 and 50,000 deaths due to seasonal influenza,[6] 9,000 cases of pertussis,[7] approximately 3,000 cases of acute hepatitis B,[8] and about one million cases of herpes zoster.[9] Adults have also been affected in recent outbreaks of other vaccine-preventable diseases such as measles. With the aging of the U.S. population, the public health impact of vaccine-preventable diseases and their complications in adults is likely to grow. The diminishing function of the aging immune system reduces the immune response to vaccination and underscores the need to develop more effective products for older adults.[10]

The CDC and its Advisory Committee on Immunization Practices (ACIP) currently recommends 13 different vaccines for adults age 18 and older to prevent a host of diseases (Appendix 1).[10] The adult vaccine schedule, which was first published in 2002, now includes vaccines that are universally recommended (e.g., influenza), those that are recommended for certain age groups (e.g., human papilloma virus [HPV]), and those that are targeted to individuals with specific risk factors (e.g., hepatitis A and B).[1,10] The adult schedule also includes catch-up vaccinations for those adults who never initiated or did not complete a multi-dose series when vaccination was first recommended during childhood. Catch-up vaccinations include vaccines such as measles, mumps, rubella and varicella, which are routinely recommended for administration during childhood.

As shown in Table 1, despite the health benefits that result from implementation of ACIP recommendations, adults continue to be vaccinated at low and variable rates. In contrast, childhood vaccination rates in the United States typically exceed 90 percent. The success of childhood vaccination can be attributed to many factors unique to pediatric vaccination, such as state laws requiring vaccination for school entry and the coordinated public health infrastructure established by the Vaccines for Children Program (VFC), a federally funded program to provide free vaccines to children who are Medicaid eligible, uninsured, underinsured, or American Indian or Alaskan Native.[11] Another reason for the high rates of vaccination among children is that pediatricians and family physicians, the primary providers of health care and preventive health services for children, have long been committed to making immunization a core part of well-child care. For adults, chronic diseases and screenings for cancer, blood pressure, and cholesterol have historically been the primary focus of acute medical and preventive health care, respectively.[1] As a result, vaccinations have been given less emphasis and are underutilized in the adult population.

Table 1. Healthy People Objectives Specific to Adult Vaccination, 2012 Coverage, and 2020 Targets

Objective: IID-12: Increase the percentage of children and adults who are vaccinated annually against seasonal influenza.	**2012 Percentage**	**2020 Target Percentage***
Adults age ≥18 years	39†	70
Health care personnel	62†	90
Pregnant women	52‡	No target, in development

Objective: IID-13: Increase the percentage of adults who are vaccinated against pneumococcal disease.	**2012 Percentage**	**2020 Target Percentage***
Noninstitutionalized adults age ≥65 years	60§	90
Noninstitutionalized high-risk adults age 18–64 years	20§	60
Institutionalized adults age ≥18 in long-term care or nursing homes	66‖	90

Objective: IID-14: Increase the percentage of adults age ≥60 who are vaccinated against zoster (shingles).	**2012 Percentage**	**2020 Target Percentage***
Adults age ≥60 years	20§	30

Objective: IID-15: Increase hepatitis B vaccine coverage among high-risk populations.	**2012 Percentage**	**2020 Target Percentage***
Health care personnel age ≥19 years	64¶	90

*Sources: *Healthy People 2020[2]; †National Health Interview Survey as Reported by Healthy People 2020[2]; ‡ Most recent published statistics for 2013-2014 influenza season; This estimate is from an Internet panel survey. The study sample did not include women without Internet access; results might not be generalizable to all pregnant women in the United States. Also, the estimate might be biased if the selection processes for entry into the Internet panel and a woman's decision to participate in this survey were related to receipt of vaccination; Ding (2014)[12]; §National Health Interview Survey (2012)[3]; ‖ Minimum Data Set data from 2005-2006 as reported by Healthy People 2020[2]; ¶National Health Interview Survey data from 2008 as reported by Healthy People 2020[2]*

Notes: IID = Immunization and Infectious Diseases. The objective for influenza vaccination for pregnant women is developmental, and no target has been set. Some, but not all, of the ACIP-recommended vaccines are included among Healthy People 2020 objectives.

In addition to achieving higher vaccination rates, the childhood vaccination program in the United States has been largely successful at reducing or eliminating racial and ethnic disparities in vaccination coverage. As a

result of multiple interventions and programs implemented over the past two decades, including the VFC, disparities in vaccination coverage have dramatically declined between non-Hispanic white children and children of other racial and ethnic groups.[11] In contrast, African-American and Latino adults receive recommended vaccinations at rates far below those of whites for most vaccines.[13] Appendix 2 shows the disparities in immunization rates for several racial and ethnic groups.

Barriers to Adult Immunization

Numerous barriers must be addressed to make significant progress in adult vaccination, meet Healthy People 2020 coverage goals, and eliminate disparities. Barriers that are consistently highlighted by stakeholder groups and the research community include the following:

- Lack of coordination of adult immunization activities across all stakeholders, including multiple health care providers for adults[1]
- Lack of integration of vaccines into adult medical care[1]
- Lack or underuse of administrative systems for documenting vaccination histories and identifying patients who are due for vaccinations in medical records[14,15]
- Skepticism regarding vaccine safety and effectiveness[1]
- Inability to pay for vaccination as a result of lack of insurance or variable coverage for recommended vaccinations across health plans[1,14]
- Provider concerns about reimbursement and vaccine administration fees paid by health insurers, which discourages some providers from stocking all adult vaccines[14,16,17]
- Lack of public knowledge regarding the adult immunization schedule and the risks and consequences of vaccine-preventable diseases; lack of awareness that adults are supposed to receive more than influenza vaccines[1]
- Lack of and/or weak recommendations by health care providers[1,14]
- Limited use of evidence-based strategies to improve vaccine uptake, such as reminder-recall and related systems[18]
- Conflicting and inaccurate information about immunizations in mass media[1,19]

The National Adult Immunization Plan (NAIP) was developed to help address these barriers, as well as other persistent challenges, through coordinated action.

Opportunities in the Changing Policy Landscape

The NAIP builds on work that has been completed, or is under way, for adult immunization and advances priorities that reflect the changing landscape of medical care and preventive health services as a result of Affordable Care Act implementation.

There have been several important developments in recent years that provide context for the development and implementation of the NAIP at this time.

- In 2012, the National Vaccine Advisory Committee (NVAC) published *A Pathway to Leadership for Adult Immunization*, which outlined three recommendations to support a NAIP: national leadership, allocation of resources, and the development of a strategic plan for the adult immunization program.[1]
- In 2014, NVAC published updated Standards for Adult Immunization Practice to emphasize that all providers who care for adults are responsible for assessing immunization needs at every clinical encounter, strongly recommending needed vaccines, administering recommended vaccines, and documenting receipt in a state immunization information system. The standards also instruct providers who do not vaccinate to refer adult patients to a vaccinating provider.[20]
- In 2012, the first annual National Adult and Influenza Immunization Summit was convened. The Summit brings together public and private stakeholders involved in adult immunization and provides a forum to share new ideas and information and identify actions to increase adult vaccination rates.[21]

In addition, passage of the Affordable Care Act in 2010 was an important milestone for adult vaccination in the United States. The Affordable Care Act expands access to health insurance to millions of previously uninsured or underinsured Americans and requires that recommended clinical preventive services, including vaccines, be provided without cost-sharing in most health insurance plans, except for Medicare and traditional Medicaid plans in non-expansion states. A study published in the *New England Journal of Medicine* estimated that 10 million Americans gained health insurance between January 2012 and June 2014 through employer-sponsored insurance, the health insurance marketplaces, and Medicaid expansion.[22] Furthermore, more than 71 million individuals in private plans have gained expanded access to vaccinations and other preventive services coverage without cost-sharing under the Affordable Care Act.[23] At the state level, the Affordable Care Act also authorizes use of funds for purchase of vaccines for adults at federally negotiated prices. Although the full impact of this legislation is yet to be determined, it is anticipated that the Affordable Care Act will eliminate some of the financial barriers to adult vaccination.

While the Affordable Care Act represents an important step forward for adult vaccination, some challenges remain. For example, people who continue to lack health insurance (e.g., uninsured non-U.S. citizens, low- income individuals in states that do not elect to expand Medicaid to cover people with annual incomes of up to 138 percent of the federal poverty level) will continue to have difficulty accessing and paying for needed vaccinations.

Furthermore, some Medicare beneficiaries may encounter financial barriers when accessing vaccines covered by Medicare Part D (e.g., herpes zoster vaccine and tetanus, diphtheria, and pertussis [Tdap] vaccine). Medicare Part B covers select vaccines without cost-sharing; however, cost-sharing for vaccines covered under Medicare Part D varies widely from plan to plan and may be cost-prohibitive for some patients. In a 2011 report, the U.S. Government Accountability Office noted that many stakeholders have raised concerns about the administrative challenges associated with Part D and have recommended actions

to improve access to Part D vaccinations.[24] The Centers for Medicare & Medicaid Services (CMS) has issued guidance on a number of approaches to help address administrative challenges, but stakeholders report that additional steps are needed.

Purpose and Leadership of the National Adult Immunization Plan

To address ongoing barriers as well as new challenges, the NAIP is intended to promote coordinated planning and action across all stakeholder groups, including those within and outside the U.S. federal government. It provides direction by establishing a vision, four goals, 16 strategic objectives, and numerous strategies to promote action over the next five years.

The vision for adult immunization is *to protect the public health and achieve optimal prevention of infectious diseases and their consequences through vaccination of all adults.*

The goals are as follows:

Goal 1: Strengthen the adult immunization infrastructure.

Goal 2: Improve access to adult vaccines.

Goal 3: Increase community demand for adult immunizations.

Goal 4: Foster innovation in adult vaccine development and vaccination-related technologies.

Under each goal is a set of strategic objectives to steer improvement efforts within functional areas critical to achieving the goal. Within those objectives, the NAIP identifies key strategies to guide implementation through 2020. The strategies encourage focused attention on areas that can have the greatest impact toward achieving the vision of a robust immunization system that will improve adult health by protecting adults against vaccine-preventable diseases and their complications.

While there is recognition of the challenges facing adult vaccination, plan goals can be achieved with national leadership and collaboration among the many stakeholders who comprise the adult immunization enterprise. National leadership is critical to support our nation's focus on disease prevention and to catalyze action to strengthen vaccination delivery across the country. The Office of the Assistant Secretary for Health (ASH), within the Department of Health and Human Services (HHS), has been a strong advocate for the importance of adult immunization. The ASH serves as the director of the National Vaccine Program and will lead the NAIP and its implementation. In support of this mission, the National Vaccine Program Office (NVPO) within HHS will facilitate collaboration and coordinate the monitoring of progress for the NAIP, which will be reviewed annually by ASH and the National Vaccine Advisory Committee (NVAC).

While federal leadership and the alignment of federal activities are critical to implementing this plan, participation by diverse stakeholders is necessary for the NAIP to realize its potential. The NAIP is a national rather than federal plan and thus calls for the coordinated action of governmental and nongovernmental partners. The success of this plan will depend on the synergies between state, local, territorial, and tribal governments; health care providers; advocacy groups; vaccine manufacturers; academia and research organizations; payers and health plans; employers; and the general public to work

together to overcome barriers and improve access to adult vaccinations. Table 2 outlines some of the stakeholder groups that will be a part of plan implementation.

Table 2. National Adult Immunization Plan: Federal and Nonfederal Stakeholders

Stakeholder Category	Agency/Entity
Federal government, HHS agencies	Administration for Community Living, Administration for Children and Families, Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, Centers for Medicare & Medicaid Services, U.S. Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, Assistant Secretary for Public Affairs, Assistant Secretary for Planning and Evaluation, Assistant Secretary for Preparedness and Response, Office of Global Affairs, Office of Minority Health, Office of the National Coordinator for Health Information Technology, Partnership Center, Office of Assistant Secretary for Health, Office of Disease Prevention and Health Promotion, Office of Women's Health, Office of Adolescent Health, Regional Health Administrators
Federal government, other departments/ agencies	U.S. Department of Defense, Department of Homeland Security, Department of Veterans Affairs, Department of Justice, Federal Occupational Health, Personnel Management Office
Government, nonfederal	State, territorial, tribal, and local public health agencies and governments
Nongovernmental stakeholders	Vaccine industry, academia/research organizations, health care providers, health care systems, community immunizers, professional associations, payers and plans, employers, foundations, community and patient advocacy organizations, philanthropic organizations, and the general public

Development of the National Adult Immunization Plan

Lack of progress in meeting adult immunization objectives coupled with NVAC's recommendation led to the development of the NAIP.[1] The plan is the product of deliberation, analysis, and input from a broad range of stakeholders, including health care providers; professional and advocacy organizations; federal, state, and local governments; researchers; insurers; employers; vaccine manufacturers; and members of the general public. RAND Corporation was enlisted to review historic literature, interview stakeholders, and collect data to identify plan priorities and key indicators.

Literature Review

The first step in developing the plan was to develop a comprehensive environmental assessment and review all prior recommendations and reports on adult vaccination over the past decade. Numerous stakeholder groups have issued reports in recent years calling for action to improve adult vaccination.[14-16,25-31] These reports inventory past successes, ongoing barriers, and potential opportunities to improve adult vaccination and recommend actions to be taken by government agencies, health insurers, community vaccinators, and others to raise adult vaccination rates. Through this environmental scan, both best practices and potential actions for strengthening adult vaccination were identified. These actions were assessed for continued relevance in the current policy environment, and the chosen actions were organized by plan goal and objective.

Focus Groups, Surveys, and Interviews

The second step in the process was robust stakeholder engagement. First, a survey was fielded to 96 respondents representing a range of stakeholder groups such as health departments, payers, employers, research organizations, professional associations, and healthcare providers. Then, eight focus groups with a total of 90 participants were convened to review survey results. Lastly, in-depth interviews were conducted with dozens of governmental and nongovernmental subject matter experts. Stakeholders were asked to assess and prioritize actions identified in the environmental scan, as well as to identify any new actions.

Measuring Progress: Indicator Development

Once a final set of actions was identified, stakeholders were also asked to identify and prioritize indicators to track progress on plan goals and objectives and set ambitious yet attainable milestones for 2020, using a target-setting method consistent with Healthy People 2020. If a target was already set by an existing policy or program, that target was adopted. In cases where no target existed, stakeholders discussed trend data and determined target levels by consensus.

Following a number of stakeholder engagements, a draft plan was released for public comment through a notice in the Federal Register. The final NAIP is meant to reflect the input of the full range of stakeholders in the adult vaccine enterprise in the United States.

Alignment with Existing HHS Programs

In developing the plan, care was taken to align with numerous HHS initiatives and programs, including the NVP, Healthy People 2020, the National Prevention Strategy, and the HHS Strategic Plan. These initiatives all contain specific objectives and indicators related to strengthening adult vaccination and include the following:

- Healthy People 2020: Healthy People 2020 includes four objectives related to improving vaccination coverage among adults within the topic of immunizations and infectious diseases and one within the topic of older adults. The NAIP is designed to achieve the adult vaccination targets specified in Healthy People 2020.
- National Prevention Strategy: The National Prevention Strategy emphasizes the importance of adult vaccination and other preventive services for increasing the number of Americans who are healthy at every stage of life.
- HHS Strategic Plan: One of the objectives of the HHS Strategic Plan is to reduce the occurrence of infectious diseases, including vaccine-preventable diseases. The HHS Strategic Plan includes a specific strategy to remove financial and other barriers to routine vaccination for adults, which is also a major focus of the NAIP.
- National Quality Strategy: Established as part of the Affordable Care Act, the National Quality Strategy focuses nationwide quality improvement and measurement efforts on six priorities, including working with communities to promote wide use of best practices to enable healthy living. This priority encourages the adoption of clinical preventive services for adults, such as vaccination.
- HHS Action Plan to Reduce Racial and Ethnic Health Disparities: The HHS Action Plan to Reduce Racial and Ethnic Health Disparities includes a measure to increase the percentage of the minority population who receive the seasonal influenza vaccination.
- National Vaccine Plan: The NVP, released in 2010, provides a guiding vision for vaccination for the decade 2010–2020 and strategic direction for coordination of the immunization enterprise in the United States. While the NVP provides an overarching plan for immunization, it does not focus specifically on adults. This is why a distinct plan was created to address those gaps. Many issues raised in the NVP are also identified in the NAIP. For example, both the NAIP and NVP highlight the need to increase awareness of vaccines and the benefits and risks of vaccination, reduce financial barriers for consumers and providers, and increase and improve the use of interoperable health information technology (IT) and electronic health records (EHRs). However, within these broad categories (e.g., financing), this plan draws attention to specific issues that affect adults (e.g., high

cost-sharing for some beneficiaries with Medicare Part D). The NAIP supports and can be described as being nested within the NVP, which is the road map for the broader set of efforts seeking to prevent serious infectious diseases and their complications through vaccination.

The NAIP was also designed to highlight areas of adult immunization that are addressed in a more focused and detailed manner by other efforts. While the NAIP provides a framework for approaching adult vaccination, there are unique issues for certain populations such as pregnant women that require focused attention:

- The NVAC Standards for Adult Immunization Practice, released in 2014, provide guidance for health care providers representing both traditional and complementary settings for vaccination of adults on how to implement many of the priorities in the plan.[20]
- The Community Guide to Preventive Services is a website that reviews the evidence for potential interventions and strategies to promote the use of screening, counseling, and other preventive services typically delivered in primary care settings. The Community Guide includes 13 recommendations on vaccination strategies and identifies five areas where there is insufficient evidence.[32]
- NVAC also is working to strengthen vaccination for specific subgroups of adults, such as health care workers and pregnant women, by offering evidence-based strategies for overcoming patient and provider barriers that continue to hinder uptake of recommended vaccines in this population. In addition, NVAC provides forward-looking analyses to identify barriers and challenges to research and development of new vaccines specifically for pregnant women.[33] These analyses and resulting recommendations help guide department efforts to expand the potential of vaccines to protect pregnant women and their infants.

NAIP Goals, Objectives, and Strategies

This section presents the goals, objectives, and strategies that comprise the NAIP. The activities outlined here will guide federal adult immunization efforts in collaboration with nonfederal partners over the next five years to advance strategic goals and supporting objectives. Key agencies with specific roles and responsibilities for each strategy are identified in Appendix 4.

Goal 1: Strengthen the Adult Immunization Infrastructure

The adult immunization infrastructure in the United States is complex and multifaceted, consisting of numerous components with unique functions. While all the goals of the NAIP feature objectives that impact critical aspects of the infrastructure or interdependencies among system components, Goal 1 of the NAIP focuses on high-level issues with the potential to have significant impact on adult vaccination rates in the next five years. One example is the increasing importance of health IT and the need for systems and providers to be able to exchange accurate, timely information. Goal 1 represents a commitment to strengthen the adult immunization infrastructure by improving and leveraging elements that already exist, rather than creating new systems, programs, and entities.

Goal 1 includes six objectives to strengthen the adult immunization infrastructure:

> Objective 1.1: Monitor and report trends in adult vaccine-preventable disease levels and vaccination coverage data for all ACIP-recommended vaccines. In cases where there are associated Healthy People 2020 goals, measure progress toward established targets.
>
> Objective 1.2: Enhance current vaccine safety monitoring systems and develop new methods to accurately and more rapidly assess vaccine safety and efficacy in adult populations (e.g., pregnant women).
>
> Objective 1.3 Continue to analyze claims filed as part of the National Vaccine Injury Compensation Program (VICP) to identify potential causal links between vaccines and adverse events.
>
> Objective 1.4: Increase the use of electronic health records (EHRs) and immunization information systems (IIS) to collect and track adult immunization data.
>
> Objective 1.5: Evaluate and advance targeted quality improvement initiatives.
>
> Objective 1.6: Generate and disseminate evidence about the health and economic impact of adult immunization, including potential disease burden averted and cost-effectiveness with the use of current vaccines.

Objective 1.1:

Monitor and report trends in adult vaccine-preventable disease levels and vaccination coverage data for all ACIP-recommended vaccines. In cases where there are associated Healthy People 2020 goals, measure progress toward established targets.

Translating vaccination policy into health outcomes depends on strong public health surveillance to evaluate the impact of adult vaccinations on vaccine-preventable diseases. Surveillance also provides needed data to assess progress on plan indicators, including the impact of activities on racial and ethnic disparities.

1.1.1 Evaluate the impact of adult vaccination on morbidity and mortality, with special emphasis on vulnerable populations (e.g., frail older adults and adults with chronic conditions, such as diabetes, heart disease, and stroke).

1.1.2 Highlight coverage gaps and disparities among racial and ethnic groups and develop targeted strategies to reduce disparities.

1.1.3 Improve methods to verify vaccination coverage status.

1.1.4 Identify efficiencies to improve adult immunization delivery by encouraging greater use and increased functionality of existing systems (e.g., state IIS).

Objective 1.2:

Enhance current vaccine safety monitoring systems and develop new methods to accurately and more rapidly assess vaccine safety and effectiveness in adult populations (e.g., pregnant women).

Vaccines have a long track record of safety and effectiveness in adults, yet there is a need to ensure that when recommended and used broadly, vaccines perform as would be expected from the clinical trials that led to their licensure. In addition, there is a need to rapidly assess vaccine safety and effectiveness in adult populations when new vaccines are approved, when vaccines are recommended for new populations, or when vaccines are used as part of the response to a public health emergency (e.g., influenza pandemic). Vaccine safety and effectiveness monitoring is not only important for public health, but also to ensure public confidence in vaccines.

1.2.1 Increase awareness of the vaccine safety systems among adult health care providers who vaccinate the public (e.g., CDC Vaccine Adverse Event Reporting System [VAERS], VSD and the Clinical Immunization Safety Assessment, FDA's Post-Licensure Rapid Immunization Safety Monitoring system, and DoD and VA efforts).

1.2.2 Increase the percentage of adult vaccination providers and patients that report adverse events into VAERS.

1.2.3 Support improved online reporting interfaces (e.g., VAERS) to facilitate the electronic submission of adverse event reports that occur after the administration of vaccines.

1.2.4 Enhance vaccine efficacy assessments in adults through improved reporting of vaccine-preventable diseases and more precise determination of immunization coverage rates.

1.2.5 Encourage use of clinical research and population-based epidemiologic studies for vaccine safety and efficacy monitoring among vaccinated adults.

1.2.6 Encourage increasing the use of electronic health data and national immunization registries to more rapidly detect vaccine safety concerns and to assess their potential to measure efficacy in the adult population.

1.2.7 Determine the data needs to evaluate vaccine safety and monitor efficacy in pregnant women and newborns and the ability of these systems to capture relevant data.

Objective 1.3:
Continue to analyze claims filed as part of the National Vaccine Injury Compensation Program (VICP) to identify potential causal links between vaccines and adverse events.

The VICP was established in 1988 to provide compensation to individuals found to be injured by certain vaccines. It provides a no-fault alternative to the traditional tort system for resolving vaccine injury claims. This program is instrumental in helping to ensure an adequate supply of vaccines, encourage innovation, and stabilize vaccine costs by establishing and maintaining an accessible and efficient forum for individuals found to be injured by select vaccines.

1.3.1 Review the latest medical and scientific literature for evidence of causal links between vaccines and adverse events when reviewing claims.

Objective 1.4:
Increase the use of electronic health records (EHRs) and immunization information systems (IIS) to collect and track adult immunization data.

While IIS may act as a centralized repository of adult vaccination records, EHRs also play a critical role in ensuring coordination of adult vaccination activities and improving coverage.[34] A centralized source of vaccination information is especially critical for adults, who see a variety of providers and receive vaccinations in a variety of settings (e.g., medical settings, workplaces, schools, retail pharmacies). Many adult vaccination improvements are dependent upon or would be accelerated by better data exchange, and interoperability between EHRs and IIS facilitates better health outcomes.

In order to achieve these outcomes, EHRs must be able to electronically send data to IIS and to receive consolidated histories and forecasts from IIS. EHRs also must be able to reconcile the patient's history and forecast what might be needed to ensure that the appropriate vaccines are given at the right times. IT enhancements can lead to better recordkeeping and submission to IIS that addresses the barrier of unknown vaccination history, avoids the administration of duplicate doses of vaccine, and helps ensure that opportunities for vaccination are not missed. EHR and IIS-related strategies include the following:

1.4.1 Increase the ability of EHRs to generate a query using nationally accepted standards and accept a standardized immunization history and forecast.

1.4.2 Increase the ability of IIS to accept a query using nationally accepted standards and respond with a standardized immunization history and forecast to inform providers of needed vaccinations.

1.4.3 Increase adoption of standardized transport methods by IIS and by EHRs to allow for more consistent information exchange across all in the health care system who provide vaccine services for adults

1.4.4 Expand IIS and EHR functionality to generate a query to support "data hub"–type pilot projects that facilitate interstate immunization data exchange.

1.4.5 Develop and disseminate "model agreements" to address the documented legal and policy barriers that preclude data sharing between states and systems.

1.4.6 Expand consumers' access to their own vaccination data through IIS and EHR consumer portals.

1.4.7 Develop and encourage adoption of standardized clinical decision support tools for adult vaccination.

1.4.8 Encourage evaluation of IIS and EHR usage for adult vaccinations among providers, facilities, and organizations delivering vaccines to adults.

1.4.9 Promote automation strategies for documenting adult vaccines, such as EHRs capturing 2D barcodes on vials and syringes.

1.4.10 Promote automation strategies for documenting adult vaccines, such as the inclusion of 2D barcodes on vials and syringes, and by building IIS capacity to accept barcode data.

1.4.11 Encourage bi-directional exchange between EHRs and IIS for adult vaccinations among clinics/health systems already entering pediatric data (e.g., federally qualified health center–funded clinics, health maintenance organizations).

1.4.12 Increase participation of federal agencies in IIS, and the connectivity between IIS and EHR in these organizations (e.g., federal occupational health clinics, VA health systems, DoD-run clinics).

Objective 1.5:
Evaluate and advance targeted quality improvement initiatives.

Targeted quality improvement efforts, such as the development and use of clinical performance measures, play an important role in helping providers set priorities and establish practice patterns, and thus can motivate providers to improve adult vaccination rates. To ensure progress on plan goals and objectives, it is helpful to encourage and incentivize providers to recommend, provide, and maintain records of adult vaccinations. Many future quality improvements projects will be facilitated by addressing critical IT gaps outlined in objectives 1.3 and 1.4.

1.5.1 Evaluate impact of current adult vaccination quality measures in federal programs and the feasibility of future quality measure development projects.

1.5.2 Disseminate best practices and lessons learned from successful and also unsuccessful adult quality measure and adult quality improvement pilot projects.

1.5.3 Develop and validate new metrics to track progress towards NAIP objectives.

Objective 1.6:
Generate and disseminate evidence about the health and economic impact of adult immunization, including potential disease burden averted and cost-effectiveness with the use of current vaccines.

Generating information on the economic impact of adult immunization is a critically important element of the plan. While economic evaluations of the childhood immunization program in the United States have assessed the impact of all routinely recommended vaccines on both direct and societal costs, no parallel research has been published on adult immunization. Economic evaluations are critically important because they help to inform policymakers, health insurance plans, providers, and the public about the value and importance of adult immunizations and can inform decisions regarding promotion as well as reimbursement for adult immunization services.

1.6.1 Encourage the development and evaluation of models to estimate the cost-effectiveness of adult immunization programs.

1.6.2 Encourage employers to offer and promote adult immunization using evidence on economic impact.

Goal 2: Improve Access to Adult Vaccines

The passage of the Affordable Care Act marked an important opportunity for adult vaccination, with more consumers having access to preventive services. However, despite the Affordable Care Act's impact, critical challenges remain in achieving access to low-cost, high-quality vaccination services, and there will likely continue to be an uninsured or underinsured adult population. The NAIP aims to leverage the full potential of the Affordable Care Act to improve access to adult vaccinations and to identify solutions to ongoing challenges.

Goal 2 includes four objectives to improve access to adult vaccines:

> Objective 2.1: Reduce financial barriers for individuals who receive vaccines routinely recommended for adults.
>
> Objective 2.2: Assess and improve understanding of providers' financial barriers to delivering vaccinations, including stocking and administering vaccines.
>
> Objective 2.3: Expand the adult immunization provider network.
>
> Objective 2.4: Ensure a reliable supply of vaccines and the ability to track vaccine inventories, including during public health emergencies.

Objective 2.1:
Reduce financial barriers for individuals who receive vaccines routinely recommended for adults.

The inability of some individuals to pay for vaccines is a commonly cited barrier to increasing adult vaccination. There is no adult program comparable to the Vaccines for Children Program, which offers free vaccines to eligible populations and supports a robust delivery infrastructure including provider education. While the Affordable Care Act has reduced financial barriers to vaccination for millions of Americans, large proportions of the population will continue to have significant out-of-pocket costs for recommended vaccines. Thus, understanding and reducing financial barriers is an important objective of the NAIP.

- 2.1.1 Evaluate the impact of different cost-sharing approaches and co-pays on adult vaccination uptake.
- 2.1.2 Advance efforts to have consistency in the individual state Medicaid benefit for ACIP recommended vaccines for adults.
- 2.1.3 Evaluate the impact of no-cost-sharing policies for recommended adult vaccines within state Medicaid programs that decide to make the benefit the same for the traditional and expansion populations; evaluate the impact of the Federal Medical Assistance Percentage bump.[35]
- 2.1.4 Evaluate the impact of novel state vaccine financing pilot programs that provide vaccines to adults.

Objective 2.2:
Assess and improve understanding of providers' financial barriers to delivering vaccinations, including stocking and administering vaccines.

Providers need to be educated about the importance of routinely assessing the vaccine needs of their patients, strongly recommending needed vaccines, and either vaccinating or referring patients to others who administer vaccinations. They also must be empowered to pursue these activities with tailored guidance, education, and tools. Currently, many factors prevent providers from consistently vaccinating all patients who could benefit. The Affordable Care Act does not address providers' financial barriers to maintaining a vaccine inventory; thus, other policies and programs need to focus on understanding these issues and work toward improving providers' business practices when providing vaccination services.

2.2.1 Research the cost of providing vaccination services in a provider setting to improve understanding of costs associated with the range of activities that are needed to ensure efficient and effective immunization services (e.g., ordering, handling, storage, administration, patient recall/reminders, and counseling).

2.2.2 Encourage the development of tools to improve immunization business practices, including practice efficiency and inventory management, and assess the impact of these tools on adult vaccination rates at the practice level.

2.2.3 Encourage vaccine manufacturers and third-party vaccine distributors to build on existing work with providers to reduce the financial burden of maintaining vaccine inventories.

2.2.4 Evaluate the impact of various methods to encourage and incentivize provider recommendations for, provision of, and recordkeeping related to adult vaccination (e.g., standing orders, IIS).

2.2.5 Evaluate the impact of third-party billing and other business models that address financial risks associated with providing adult vaccination services and providers' ability to bill and receive payment from Medicare Part D plans.

Objective 2.3:
Expand the adult immunization provider network.

Adults frequently obtain needed vaccinations in complementary, nonclinical settings, such as workplaces, schools, and retail pharmacies, so it is especially important for these providers to have the capability to exchange information and document administration in collaboration with physicians and the patients' medical homes. Moreover, it is important for pharmacists and others to be able to offer vaccinations because they are well-positioned to offer convenience to patients and to bill for Medicare Part D vaccines, and they have the potential to expand the capacity of the health care system in administering vaccines. More than 250,000 pharmacists have been trained to administer vaccines in the United States, and nearly 95 percent of Americans live within five miles of a community pharmacy.

The Affordable Care Act established an immunization coverage standard that requires qualified health plans on the health insurance marketplaces to cover immunizations recommended by the ACIP without cost-

sharing when administered by an in-network provider. This has led to questions about which providers are considered in and out of network and whether the network is adequate to meet demand in all geographic settings. Therefore, within the plan's goal of improving access to adult vaccination services, is the objective of collecting data to better understand and evaluate reported insurance network provider adequacy concerns.

Another important element of the plan is expanding access through employers to improve employee health and wellness and create healthier workplaces. The most immediate impact from an employer perspective may be with seasonal influenza immunization campaigns, but efforts here offer the possibility of expanding to other vaccines recommended for adults.

2.3.1 Encourage in-network coverage of adult vaccinations administered in accessible health care delivery settings (e.g., public health clinics, pharmacies).
2.3.2 Identify and promote effective collaborative models, best practices (e.g., among physicians and other immunizers).
2.3.3 Collect more data to evaluate reported in-network adequacy concerns.
2.3.4 Strengthen the capacity of public health departments and federally qualified health centers to provide all adult vaccines by sharing effective practices for billing private insurance issuers for vaccination services provided to plan enrollees.
2.3.5 Continue to identify the barriers that prevent or discourage pharmacists and other providers in complementary settings from accessing and entering vaccinations into state IIS and reporting vaccinations to the patients' primary care providers.
2.3.6 Clearly articulate the legal, practical, and policy barriers that remain so that the challenges are well understood by partners (e.g., legislators, lawyers) necessary to advance solutions.
2.3.7 Assess the impact of providing vaccination services in accessible and complementary settings (e.g., pharmacies and community health centers) on vaccination coverage, cost-effectiveness, and care.
2.3.8 Increase the number of community health centers that routinely administer vaccinations to adults and report vaccinations to immunization information systems and primary care providers.
2.3.9 Encourage on-site, occupational health vaccination clinics and involvement of employers to increase employee vaccination rates.

Objective 2.4:
Ensure a reliable supply of vaccines and the ability to track vaccine inventories, including during public health emergencies.

Many of the priorities described in the plan, if implemented, could result in increased demand for adult vaccines and vaccination services. Thus, a reliable and steady supply of adult vaccines is needed to realize the full benefit of the actions described in the plan. In addition, ensuring the functioning of routine systems will be critical in monitoring the response to public health emergencies requiring vaccines, such as an influenza pandemic.

2.4.1 Assess current tracking systems' ability to rapidly monitor the supply of adult vaccines for use during shortages and public health emergencies.

2.4.2 Develop and evaluate the impact of pilot projects designed to improve supply tracking and innovative inventory management (e.g., the use of 2D bar coding to improve pandemic preparedness and response).

2.4.3 Evaluate strategies that encourage multiple suppliers of vaccines for adults.

Goal 3: Increase Community Demand for Adult Immunizations

As described in the NVP, HHS is committed to providing accurate, timely, transparent, complete, and audience-appropriate information about vaccinations. Furthermore, communication activities concerning vaccination should be strategic, evidence-based, and culturally-appropriate and should reflect the health literacy, language proficiency, and functional and access needs of specific target populations. While the NVP includes a goal to support communications to enhance informed vaccine decision-making more broadly, Goal 3 of the NAIP is intended to address the needs of adults and providers of adult vaccination services specifically. Further, because adults make decisions for their children regarding vaccination, education of adults and their health care providers is likely to have impacts beyond this population.

Goal 3 includes three objectives to increase community demand through communications and outreach strategies:

> Objective 3.1: Educate and encourage *individuals* to be aware of and receive recommended adult immunizations.
>
> Objective 3.2: Educate, encourage, and motivate *health care professionals* to recommend and/or deliver adult vaccinations.
>
> Objective 3.3: Educate and encourage *other groups* (e.g., community and faith-based groups, tribal organizations) to promote the importance of adult immunization.

Objective 3.1:
Educate and encourage *individuals* to be aware of and receive recommended adult immunizations.

Communications and outreach to the public are critical to address a lack of knowledge, as well as common misconceptions and skepticism about adult vaccinations. Frequent outreach raises awareness that vaccination is recommended across the lifespan and helps establish vaccination as a routine part of preventive services and as a societal norm. Although education alone is insufficient to increase vaccination rates, it can have significant impact as a part of a number of broader, evidence-based strategies. Adults are often unaware of their potential risk of acquiring diseases that can be prevented by vaccination and of the availability of specific vaccines. This lack of knowledge may be particularly acute among populations with limited English proficiency and persons with disabilities.[36-38] While there are many existing materials that can be used to educate the public and health care providers about adult vaccination, innovative strategies are needed to address the lack of knowledge regarding the risk of vaccine-preventable diseases and their consequences and the benefits of vaccines in preventing these infections. In a digital age in which information travels rapidly and misinformation can reach millions, novel outreach strategies that take into account patients' preferences, cognitive styles, literacy level, preferred sources of information, and cultural background should be tested and deployed. Furthermore, these strategies should recognize competing

demands in providers' office-based practices that limit the length of provider-patient interactions about vaccination.

3.1.1 Conduct research on public awareness and acceptance of adult vaccines (including vaccine financing, vaccine effectiveness, and vaccine safety concerns) among the public, with a focus on racial, ethnic, and economic disparities.

3.1.2 Conduct research on effective messaging and outreach strategies (e.g., social media) for different adult populations to inform communication efforts.

Objective 3.2:
Educate and encourage *health care professionals* to recommend and/or deliver adult vaccinations.

Health care providers are a highly influential source of information and advice about vaccinations, and a strong recommendation about the importance of immunizations can exert a strong influence over the vaccination decisions of patients, including those patients who may have reservations about some or all vaccines.[39,40] However, adult immunization status is not routinely assessed, and the rationale for evidence-based vaccine recommendations is not always articulated from providers to patients. This is one reason why NVAC issued the updated Standards for Adult Immunization Practice to encourage assessment of vaccination needs at every patient encounter.

Many health care providers stock some, but not all, adult vaccines. Cost and reimbursement concerns; competing clinical priorities, such as the management of acute medical issues; and the complexities of vaccine storage and handling continue to be reported barriers to providing office-based immunization services. While educational outreach targeted at the public is important, health care providers also require the knowledge and tools to recommend and either deliver vaccinations or to refer their adult patients to others who administer vaccinations. Furthermore, increasing consumer demand without simultaneously addressing health care provider vaccination barriers could have a detrimental effect on efforts to improve adult immunization.

The NAIP communications and education strategy is to focus on activities that will have the most meaningful impact, while also recognizing the existence and importance of addressing provider barriers that may hinder uptake.

3.2.1 Encourage all providers, including providers in complementary settings, to implement the NVAC Standards for Adult Immunization Practice, which include assessing patients' vaccination status at every clinical encounter, strongly recommending needed immunizations, and either administering vaccines (including documentation in an IIS) or referring patients to others who administer vaccinations.

3.2.2 Educate providers about implementing proven strategies (e.g., standing orders and reminder/recall) to increase vaccination coverage.

3.2.3 Encourage the incorporation of adult vaccine education into the training of health professionals (e.g., medical, nursing, and pharmacist education curricula; post-graduate training, certification, and board examinations; and required continuing education credits).

3.2.4 Enlist professional medical societies to support ongoing education of their trainees and members about the value and importance of adult vaccination (e.g., NVAC's Standards for Adult Immunization Practice), the importance of clear provider recommendations, and ways to assess patients' needs and adequately document receipt of vaccinations.

3.2.5 Encourage integration of vaccination into the provision of other adult preventive care services and chronic care management.

3.2.6 Promote increased attention to vaccine-specific recommendations in disease-specific clinical practice guidelines (e.g., diabetes, heart disease, lung disease, and stroke).

3.2.7 Highlight best clinical practices that could be adopted by providers and health systems: standing orders, reminder and recall systems, clinical decision support for immunizations into EHRs, and other tools.

3.2.8 Reduce vaccine storage and handling errors by improving provider education and awareness of vaccine delivery best practices and the need for standardized vaccine management plans.

3.2.9 Improve provider awareness of the Affordable Care Act's impact on adult vaccine insurance coverage in Medicare, Medicaid, and private health insurance plans, both off and on the marketplaces.

3.2.10 Educate individuals and health care providers about the National Vaccine Injury Compensation Program.

Objective 3.3:
Educate and encourage *other groups* (e.g., community- and faith-based groups) to promote the importance of adult immunization.

While health care providers are critical to promoting vaccination, they are not the only influential source of vaccine-related information. Education through social and community networks may help to increase adults' knowledge of the risks of vaccine-preventable diseases and the benefits of vaccination. A variety of networks can be leveraged, including faith-based and community organizations and individual trusted leaders.

Prior research has shown that outreach on preventive services, through faith-based organizations and individual faith communities, is effective in increasing uptake of these services.[1] Community and faith-based organizations are likely to play an especially important role in reducing racial and ethnic disparities in adult immunization, as they can deliver education that is culturally sensitive and tailored to specific subpopulations.

3.3.1 Engage community leaders in reaching the public with information about the importance of adult information.

3.3.2 Encourage the development of adult immunization champions across all sectors.

Goal 4: Foster Innovation in Adult Vaccine Development and Vaccination-Related Technologies

One of the five goals of the NVP is to develop new and improved vaccines. The NVP, as well as myriad other policy documents, recognizes that vaccines have led to enormous reductions in the incidence and impact of several once-widespread infectious diseases.

Goals 1 through 3 in the NAIP focus on enhancing vaccine delivery. However, achieving these goals is dependent on the existence of safe and effective vaccines. Goal 4 recognizes that there are opportunities for the development of new vaccines, more effective versions of existing vaccines for adults, and technological advancements to improve vaccine delivery.

Goal 4 includes two objectives to foster innovation and future advancements in both adult vaccine development and new technology:

Objective 4.1: Develop new vaccines and improve the effectiveness of existing vaccines for adults.

Objective 4.2: Encourage new technologies to improve the distribution, storage, and delivery of adult vaccines.

Objective 4.1:
Develop new vaccines and improve the effectiveness of existing vaccines for adults.

While most existing vaccines are highly effective in children, vaccines recommended for adults are generally less effective, especially older adults and those with immune systems compromised by underlying diseases or medications. In general, the immune response of currently recommended vaccines declines with advancing age and the onset of chronic diseases. The perception that vaccines may have limited effectiveness in some adults may in turn negatively influence demand and contribute to low vaccination rates. However, the changing demographics of an aging society highlight the importance of improving our understanding of the aging immune system and the development of next-generation vaccines that can protect against serious infections that occur in this population.

There are numerous challenges that must be overcome in developing new vaccines. Bringing a new product to market can take ten or more years in development and require a significant financial investment on the part of manufacturers. The market is also limited for special populations that are smaller in size than the general population of adults, suggesting the need for targeted efforts to develop vaccines for use in pregnant women and in immunocompromised individuals.

4.1.1 Encourage ongoing efforts to develop and license new and improved vaccines, including support for research, development, and licensure of vaccines; improved effectiveness; and longer duration of immunity.

4.1.2 Encourage ongoing efforts to support the discovery, validation, development, standardization and distribution of specialized reagents, assays, technologies (i.e., genomic sequencing, bioinformatics, and systems biology tools), and animal models needed to facilitate basic, preclinical, and clinical research programs aimed at developing and testing vaccine candidates.

4.1.3 Encourage ongoing efforts to support research and advanced development of vaccine adjuvants and formulations in order to enhance the immune response.

4.1.4 Develop internationally adopted standards for evaluating vaccine efficacy and effectiveness that take into account diagnosis, study design, and correlates of protection.

4.1.5 Optimize predictive values of vaccine efficacy in animal models, and develop and validate new analytical methods and biomarkers that will establish early-phase correlates of protection.

4.1.6 Evaluate the use of incentives like those in place to stimulate drug development to accelerate vaccine development.

Objective 4.2:
Encourage new technologies to improve the distribution, storage, and delivery of adult vaccines.

Numerous studies have highlighted the challenges that providers face in storing and managing their vaccine inventories. New technologies are in development to address these challenges and reduce the administrative burden on providers. New technologies are also being developed to change the ways that vaccines are administered (e.g., needle-free jet injector). These developments may further reduce barriers to adult immunization by offering new solutions that appeal to both providers and consumers. The NAIP encourages innovation in the realm of both new drug development and new technologies to facilitate the management and administration of vaccines.

4.2.1 Encourage ongoing efforts to support vaccine technologies that ease vaccine delivery, storage, and distribution and/or enhance immune response.

Monitoring and Evaluation

Achieving the goals of the NAIP requires the collaboration of partners around a shared vision and coordination of activities through focused implementation efforts. Meaningful progress will be achieved only if stakeholders are engaged in shared, sustained, focused, and coordinated actions. The actions noted above operationalize the objectives, goals, and strategies laid out in the plan. However, these activities are not intended to be a comprehensive list of all activities related to adult vaccination; rather, they are focused on the *priority* activities. The actions described in the plan are conditional and are subject to engagement by all stakeholders and to the availability of resources to achieve them. To foster action and accountability, federal stakeholders with leading or supporting roles have been identified for each objective in the NAIP. Stakeholders are also invited to review these materials and identify novel ways that they can contribute.

An Adult Immunization Implementation Plan, which reflects available resources and agency priorities, will be developed by the Adult Interagency Task Force (AITF). The AITF was created to help improve coordination and collaboration across HHS agencies and other federal groups during the 2009 H1N1 pandemic. The AITF membership is composed of core federal stakeholders with a vested interest in adult immunization.

Implementing the NAIP will require not just federal action, but also national action. The success of the plan will require states, tribal and local governments, components of the health care delivery system, communities, manufacturers, and other stakeholders to work together to ensure a coordinated and comprehensive adult immunization program. The strategies identified here are intended to serve as a catalyst for other stakeholders to develop their own plans for participation in adult immunization activities.

The implementation of this plan demands regular monitoring and documentation of progress, challenges, and opportunities—all of which provide transparency to policymakers and the public. NVPO, in partnership with the HHS Interagency Adult Immunization Task Force, will regularly track and annually summarize progress on achieving the goals and priorities in the NAIP and present them to NVAC and ASH in an effort to highlight the impact of the implementation of strategies outlined here, as well as to identify areas where progress is lagging and propose corrective action where needed. An update on plan progress also will be presented at an NVAC meeting, which is open to the public and is attended by many stakeholders.

A key feature of the NAIP is the indicators (Table 3) and accompanying milestones for specific improvements to be achieved by 2020. These indicators reflect the priorities within each goal of the plan. The indicators will be used to measure progress and inform future implementation and quality improvement efforts. While many things could be measured, a limited number of indicators—one or more for each plan goal—will be tracked to monitor progress on priority issues. Indicators were selected to draw attention to some of the most critical challenges within each goal of the plan and were drawn

primarily from existing measurement and data collection efforts, such as Healthy People 2020 and annual national surveys. In most cases, required data are already being collected by partner agencies. A small number of developmental indicators have also been included to shed light on key aspects of adult vaccination programs where ongoing attention and improved data collection may be needed. NVPO has chosen to include the developmental indicators to draw attention to these important areas of opportunity. Research is planned to identify baseline levels for the developmental measures. The data sources for the full set of indicators are listed in Appendix 3.

Target milestones for most indicators were identified by subject matter experts or adapted from previously published goals. Certain developmental measures do not have target milestones because trend data are not available to inform the target-setting process. As data sources and indicators are developed or enhanced, the NAIP indicators and accompanying milestones will be updated.

Table 3. Indicators for the Goals of the NAIP

Goal 1: Strengthen the Adult Immunization Infrastructure

Key Indicator**	**Baseline (Year)***	**2020 Milestone**	**Entity Responsible for Data Collection (Data Source)**
Adult vaccination coverage for Healthy People 2020 measures	For additional information, see link to AHRQ-developed adult immunization rate dash board (in development)		CDC (National Health Interview Survey, CMS Minimum Data Set, Internet Panel Surveys of Pregnant Women and Healthcare Providers)
Racial/ethnic disparities in adult vaccination coverage for Healthy People 2020 measures	For additional information, see link to AHRQ-developed adult immunization rate dash board (in development)		CDC (National Health Interview Survey, CMS Minimum Data Set, Internet Panel Surveys of Pregnant Women and Healthcare Providers)
Percentage of surveyed primary care physicians who record information on adult vaccinations in state or regional IIS	8% of internists; 36% of family physicians	50%	CDC (Survey conducted by research institution under contract with HHS)
Percentage of surveyed pharmacists who submit adult vaccination data to IIS	28% (2013)	60%	CDC and NVPO (American Pharmacists Association Survey)
Developmental measure: Percentage of adult health care providers who have identified an adverse event following immunization and reported it to VAERS[41]	*17%*	*In development*	*NVPO (Future research carried out under contract with HHS)*

* The baseline year is 2012 unless otherwise specified. ** Items in italics are developmental

Goal 2: Improve Access to Adult Vaccines

Key Indicator**	Baseline (Year)*	2020 Milestone	Entity Responsible for Data Collection (Data Source)
Percentage of states and territories that allow pharmacists to administer all routinely recommended vaccines for adults 19+	85% (2013)	100%	American Pharmacists Association
Percentage of surveyed primary care providers who stock vaccines routinely recommended for adults†	20% of internists; 31% of family physicians	60%	NVPO and CDC (Survey conducted by research institution under contract with HHS)
Developmental measure: Percentage of state Medicaid programs that include all recommended vaccinations for adults as a preventive benefit for existing patients and prohibit cost-sharing	*33%*	*100%*	*CDC and CMS (Supported in part by CDC-funded research with George Washington University)*

Goal 3: Increase Community Demand for Adult Vaccinations

Key Indicator**	Baseline (Year)*	2020 Milestone	Entity Responsible for Data Collection (Data Source)
Percentage of surveyed adults who believe that they are recommended to receive a flu vaccine	45%	75%	CDC (Survey conducted by research institution under contract with HHS)
Percentage of surveyed adults who report receiving a provider recommendation for flu vaccine	45%	90%	CDC (Survey conducted by research institution under contract with HHS)

* The baseline year is 2012 unless otherwise specified. ** Items in italics are developmental

† The survey will capture stocking behavior for different adult vaccines, as well as provider-reported rationale for not stocking some products. This will help to inform Goal 2 of the plan.

Developmental measure: Percentage of surveyed adult health care providers who report assessing vaccination status at every visit	*29% of internists; 32% of family physicians*	*60%*	*CDC (Survey conducted by research institution under contract with HHS)*
Developmental measure: Percentage of surveyed adults aware of selected routinely recommended adult vaccines that they are supposed to receive‡	*In development*	*In development*	*NVPO (No existing data source)*
Developmental measure: Percentage of pregnant women who reported receiving the following immunizations during pregnancy: *1) Influenza* *2) Tdap*	*In development*	*In development*	*CDC (Internet panel survey conducted by research institution under contract with HHS)*

Goal 4: Foster Innovation in Adult Vaccine Development and Vaccination-Related Technologies

Key Indicator**	**Baseline (Year)***	**2020 Milestone**	**Entity Responsible for Data Collection (Data Source)**
Developmental measure: Number of vaccines in clinical development (Phase II or Phase III clinical trials) with an expected adult indication	*In development*	*In development*	*Biotechnology Industry Organization (No existing data source)*
Developmental measure: Number of vaccines on CDC contracted vaccine pricelist that include a 2D barcode	*38*	*All*	*CDC*

‡ Research will capture data for different subsets of the adult population. However, this research is not meant to be inclusive of every group, but to provide an estimate of adult vaccine consumer awareness and areas of opportunity.

* The baseline year is 2012 unless otherwise specified. ** Items in italics are developmental

Appendix 1: 2014 Adult Immunization Schedule*

1. Adult Immunization Schedule and Tools (CDC): http://www.cdc.gov/vaccines/schedules/hcp/adult.html

2. Advisory Committee on Immunization Practices Recommended Immunization Schedules for Adults Aged 19 Years or Older—United States, 2014 (*Morbidity and Mortality Weekly Report*): http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6305a7.htm

*Note that the published immunization schedule does not include 2014 ACIP recommendations related to the use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine among adults aged ≥65 years.[42]

Appendix 2: Disparities in Adult Immunization Coverage by Race/Ethnicity

Vaccine and Age Group	White (%)	Black (%)	Hispanic (%)	Asian (%)	Other (%)
Pneumococcal vaccination, ever (Age 19–64, high risk)*	21.4	19.7	13.8	13.2	20.2
Pneumococcal vaccination, ever (Age ≥65)*	64.0	46.1	43.4	41.3	44.7
Tetanus vaccination, past 10 years (Age19–49)*	69.7	56.1	53.9	54.3	71.9
Tetanus vaccination, past 10 years (Age 50–64)*	67.5	52.3	52.3	48.2	69.9
Tetanus vaccination, past 10 years (Age ≥65)*	57.7	44.6	44.8	45.8	50.2
Tetanus vaccination including pertussis vaccine, past 7 years (Age ≥19)*	16.1	9.8	8.7	14.7	21.4
Hepatitis A vaccination (≥2 doses), ever (Age 19–49)*	12.2	11.3	10.5	18.7	16.1
Hepatitis B vaccination (≥3 doses), ever (Age 19–49)*	37.5	34.2	27.1	39.7	37.4
Herpes zoster (shingles) vaccination, ever (Age≥60)*	22.8	8.8	8.7	16.9	19.7
HPV vaccination among females (≥1 dose), ever (Age19–26)*	42.2	29.1	18.7	15.6	41.2
Influenza vaccination, 2013–2014 season (Age ≥18)**	47.4	41.5	44.3	51.3	47.3

* National Health Interview Survey (2012).[3]

** National Immunization Survey-Flu and Behavioral Risk Factor Surveillance System (2013–2014).[43]

Appendix 3: Federal Partner Efforts

Agencies across HHS support a host of efforts that directly or indirectly support adult immunization. The table below lists just a small sampling of agency efforts. These select activities highlight how agencies across HHS advance adult immunization within their respective organizations.

Agency	**Activities**
Agency for Healthcare Research and Quality (AHRQ)	AHRQ has developed a data management tool, or dashboard, to depict Healthy People 2020 immunization data in a clear, easy-to-view format. This dashboard highlights ongoing racial and ethnic disparities in adult immunization and brings more attention to key gaps in coverage.
Assistant Secretary for Preparedness and Response (ASPR)	ASPR, in conjunction with DoD, has supported the development of Centers for Innovation in Advanced Development and Manufacturing. These centers help to bolster the nation's existing manufacturing surge capacity and flexible manufacturing of vaccines for pandemic influenza and other therapeutic products in a health emergency.
Centers for Disease Control and Prevention (CDC)	CDC has advanced new contracts with academic institutions and health systems for vaccine safety and ongoing surveillance; annually collects, analyzes, and disseminates influenza and adult vaccination coverage estimates and conducts economic evaluations for new vaccine recommendations; promotes immunization information system improvements; expands public and private sector partnerships; conducts research and disseminates materials to increase awareness of adult immunization; annually updates the ACIP adult immunization schedule; and works with state immunization programs to improve adult immunization infrastructure.
Centers for Medicare and Medicaid Services (CMS)	CMS is working with partners including the Assistant Secretary for Planning and Evaluation and NVPO to identify and resolve medical coverage issues through the Affordable Care Act and its impact on adult vaccination. Moreover, CMS continues to work with partners including the Assistant Secretary for Planning and Evaluation and NVPO to identify and resolve outstanding Affordable Care Act questions. The CMS Quality Improvement Initiatives also encourage regions to promote adult immunization projects.
Health Resources and Services Administration (HRSA)	HRSA has announced the Health Center Patient-Centered Medical Home and Quality Improvement Awards to recognize health centers that have focused on practice transformation and quality improvement, including efforts to strengthen adult immunization. HRSA administers VICP jointly with the Department of Justice and the U.S. Court of Federal Claims. The VICP provides compensation to individuals, including adults, who are injured or die after receiving VICP-covered vaccines.

Agency	Activities
Indian Health Service (IHS)	IHS has implemented performance measures for adult immunizations and partnered with NVPO to evaluate the feasibility and usefulness of a composite adult immunization measure to facilitate monitoring of vaccine coverage.
National Vaccine Program Office (NVPO)	NVPO co-authored an article on the Affordable Care Act and its impact on immunization insurance coverage for health care providers, collaborated on the advancement of a vaccine safety agenda, developed a tool kit to increase influenza vaccination among health care personnel in long-term care settings, published a report and recommendations on reducing barriers to increased uptake of recommended vaccines in pregnant women, and collaborated with CMS on the development of a Medicare claims data map for influenza. Through its support of NVAC, NVPO has supported publication of the 2011 report *A Pathway to Leadership for Adult Immunization: Recommendations of the National Vaccine Advisory Committee*.
Office of Minority Health (OMH)	OMH developed and maintains a co-sponsorship agreement between HHS and Walgreens Inc. that provides 400,000 free seasonal influenza vaccines annually to uninsured individuals. Working with community and faith based organizations, this initiative has successfully vaccinated over 780,000 individuals.
Office of the National Coordinator for Health Information Technology (ONC)	ONC continues to advance pilot projects designed to improve exchange of vaccination data and improved access to vaccination data by consumers. This includes the "data hub" initiative that is being advanced in collaboration with NVPO, CDC, and state and local partners. The data hub enables state and local IIS to exchange data with each other through a centralized model utilizing existing standards. By connecting to the central hub, jurisdictions can then connect to any other jurisdiction also connected to the central hub. ONC is also working in close collaboration with CDC to specify CDC's Clinical Decision Support for Immunizations tools into sharable clinical decision support artifacts.
Department of Veterans Affairs (VA), National Institutes of Health (NIH), and the U.S. Food and Drug Administration (FDA)	VA, NIH, and FDA have supported the development of new and improved vaccines. They have engaged in activities related to zoster vaccine research, maternal vaccination, and a host of other initiatives. These agencies and other stakeholders are working to advance adult vaccination safety, research, and development needs.

Appendix 4: Federal Roles and Responsibilities by Agency

Goal and Objective	ACF	AHRQ	ASPE	ASPR/BARDA	CDC	CMS	HRSA	IHS	NIH	NVPO	ONC	OWH	FDA	RHA	ACL	DHS	DoD	DOH	FOH	VA
Goal 1: Strengthen the adult immunization infrastructure.																				
Objective 1.1: Monitor and report trends in adult vaccine-preventable disease levels and vaccination coverage data for all ACIP-recommended vaccines. In cases where there are associated Healthy People 2020 goals, measure progress toward established targets.		√√			√√			√√						√√	√√		√√	√√	√√	√√
Objective 1.2: Enhance current vaccine safety monitoring systems and develop new methods to accurately and more rapidly assess vaccine safety and efficacy in adult populations (e.g., pregnant women).		√√		√√	√√	√√	√√	√√		√√			√√				√√			√√
Objective 1.3: Continue to analyze claims filed as part of the National Vaccine Injury Compensation Program (VICP) to identify potential causal links between vaccines and adverse events.				√√	√√	√√	√√			√√	√√			√√			√√	√√	√√	√√

Goal and Objective	ACF	AHRQ	ASPE	ASPR/BARDA	CDC	CMS	HRSA	IHS	NIH	NVPO	ONC	OWH	FDA	RHA	ACL	DHS	DoD	DOH	FOH	VA
Objective 1.4: Increase the use of EHRs and IIS			√√		√√	√√	√√	√√		√√	√√	√√								√√
Objective 1.5: Evaluate and advance targeted quality improvement initiatives.		√√	√√			√√	√√	√√						√√						
Objective 1.6: Generate and disseminate evidence about the health and economic impact of adult immunization, including potential disease burden averted and cost-effectiveness with the use of current vaccines.					√√															
Goal 2: Improve access to adult vaccines.																				
Objective 2.1: Reduce financial barriers for individuals who receive vaccines routinely recommended for adults.					√√	√√	√√	√√		√√				√√	√√			√√	√√	√√
Objective 2.2: Assess and improve understanding of providers' financial barriers to delivering vaccinations, including stocking and administering					√√	√√	√√	√√		√√		√√		√√						

Goal and Objective	ACF	AHRQ	ASPE	ASPR/BARDA	CDC	CMS	HRSA	IHS	NIH	NVPO	ONC	OWH	FDA	RHA	ACL	DHS	DoD	DOH	FOH	VA
Objective 2.3: Expand the adult immunization provider network.	✓✓				✓✓	✓✓	✓✓			✓✓		✓✓						✓✓	✓✓	✓✓
Objective 2.4: Ensure a reliable supply of vaccines and the ability to track vaccine inventories, including during public health emergencies.				✓✓	✓✓					✓✓			✓✓			✓✓	✓✓			
Goal 3: Increase community demand for adult immunizations.																				
Objective 3.1: Educate and encourage *individuals* to be aware of and receive recommended adult immunizations.	✓✓			✓✓	✓✓		✓✓	✓✓		✓✓	✓✓	✓✓	✓✓	✓✓	✓✓		✓✓	✓✓	✓✓	✓✓
Objective 3.2: Educate and encourage *health care professionals* to recommend and/or deliver adult vaccinations.				✓✓	✓✓		✓✓	✓✓		✓✓		✓✓		✓✓	✓✓		✓✓	✓✓	✓✓	✓✓
Objective 3.3: Educate and encourage *other groups* (e.g., community and faith-based groups) to promote the importance of adult immunization.	✓✓				✓✓			✓✓		✓✓					✓✓					

Goal and Objective	ACF	AHRQ	ASPE	ASPR/BARDA	CDC	CMS	HRSA	IHS	NIH	NVPO	ONC	OWH	FDA	RHA	ACL	DHS	DoD	DOH	FOH	VA
Goal 4: Foster innovation in adult vaccine development and vaccination-related technologies.																				
Objective 4.1: Develop new vaccines and improve the effectiveness of existing vaccines for adults.				√√					√√	√√			√√			√√	√√			√√
Objective 4.2: Encourage new technologies to improve distribution, storage, and delivery of adult vaccines.				√√						√√						√√	√√			

Appendix 5: Non-Federal Roles and Responsibilities

Instructions: Non-federal stakeholders should indicate areas where their organization(s) can play and role, and communicate this information to NVPO. The input of non-federal stakeholders regarding their roles and responsibilities will be reflected in the final version of the plan.

Goal and Objective	**Health Care Providers**	**Professional Organizations**	**Public and Private Health Care Payers and Plans**	**State, Local, Territorial, and Tribal Governments**	**Academia and Research Organizations**	**Advocacy Organizations**	**Employers**	**Vaccine Manufacturers**
Goal 1: Strengthen the adult immunization infrastructure.								
Objective 1.1: Monitor and report trends in adult vaccine-preventable disease levels and vaccination coverage data for all ACIP-recommended vaccines. In cases where there are associated Healthy People 2020 goals, measure progress toward established targets.								

Goal and Objective	Health Care Providers	Professional Organizations	Public and Private Health Care Payers and Plans	State, Local, Territorial, and Tribal Governments	Academia and Research Organizations	Advocacy Organizations	Employers	Vaccine Manufacturers
Objective 1.2: Enhance current vaccine safety monitoring systems and develop new methods to accurately and more rapidly assess vaccine safety and efficacy in adult populations (e.g., pregnant women).								
Objective 1.3: Continue to analyze claims filed as part of the National Vaccine Injury Compensation Program (VICP) to identify potential causal links between vaccines and adverse events.								
Objective 1.4: Increase the use of EHRs and IIS to collect and track adult immunization data.								
Objective 1.5: Evaluate and advance targeted quality improvement initiatives.								

Goal and Objective	Health Care Providers	Professional Organizations	Public and Private Health Care Payers and Plans	State, Local, Territorial, and Tribal Governments	Academia and Research Organizations	Advocacy Organizations	Employers	Vaccine Manufacturers
Objective 1.6: Generate and disseminate evidence about the health and economic impact of adult immunization, including potential disease burden averted and cost-effectiveness with the use of current vaccines.								
Goal 2: Improve access to adult vaccines.								
Objective 2.1: Reduce financial barriers for individuals who receive vaccines routinely recommended for adults.								
Objective 2.2: Assess and improve understanding of providers' financial barriers to delivering vaccinations, including stocking and administering vaccines.								

Goal and Objective	Health Care Providers	Professional Organizations	Public and Private Health Care Payers and Plans	State, Local, Territorial, and Tribal Governments	Academia and Research Organizations	Advocacy Organizations	Employers	Vaccine Manufacturers
Objective 2.3: Expand the adult immunization provider network.								
Objective 2.4: Ensure a reliable supply of vaccines and the ability to track vaccine inventories, including during public health emergencies.								
Goal 3: Increase community demand for adult immunizations.								
Objective 3.1: Educate and encourage *individuals* to be aware of and receive recommended adult immunizations.								
Objective 3.2: Educate and encourage *health care professionals* to recommend and/or deliver adult vaccinations.								

Goal and Objective	Health Care Providers	Professional Organizations	Public and Private Health Care Payers and Plans	State, Local, Territorial, and Tribal Governments	Academia and Research Organizations	Advocacy Organizations	Employers	Vaccine Manufacturers
Objective 3.3: Educate and encourage *other groups* (e.g., community and faith-based groups) to promote the importance of adult immunization.								
Goal 4: Foster innovation in adult vaccine development and vaccination-related technologies.								
Objective 4.1: Develop new vaccines and improve the effectiveness of existing vaccines for adults.								
Objective 4.2: Encourage new technologies to improve distribution, storage, and delivery of adult vaccines.								

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