Vaccines National Strategic Plan

2021–2025

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Acronyms

ACIP	Advisory Committee on Immunization Practices
CDC	Centers for Disease Control and Prevention
COVID-19	Coronavirus disease, formerly: 2019 novel coronavirus
DTaP	diphtheria, tetanus, and acellular pertussis
EHR	electronic health record
FDA	Food and Drug Administration
HHS	U.S. Department of Health and Human Services
HIV	human immunodeficiency virus
HPV	Human papilloma virus
IID	Immunization and Infectious Disease
IIS	Immunization Information Systems
IVWG	Interagency Vaccine Working Group
MMR	measles, mumps, and rubella
NAIP	National Adult Immunization Plan
NVAC	National Vaccine Advisory Committee
NVPO	National Vaccine Program Office
OASH	Office of the Assistant Secretary for Health
OIDP	Office of Infectious Disease and HIV/AIDS Policy
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
STI	sexually transmitted infection
VAERS	Vaccine Adverse Event Reporting System
VFC	Vaccines for Children
VPD	Vaccine preventable disease
VSD	Vaccine Safety Datalink
WHO	World Health Organization

Executive Summary

The Vaccines National Strategic Plan 2021–2025 (Plan) provides a vision for the U.S. vaccine and immunization enterprise for the next five years. The Plan articulates a comprehensive strategy to enhance all aspects of vaccines and vaccination including research and development, safety, vaccine knowledge and confidence, increased access and use of routinely recommended vaccines, and global cooperation. The actions contained in the strategies of the Plan are conditional and are subject to the availability of resources.

The vision of the Plan is that the United States will be a place where vaccine-preventable diseases are eliminated through safe and effective vaccination over the lifespan. The Plan consists of the following 5 overarching goals and 19 objectives:

Goal 1: Foster innovation in vaccine development and related technologies.

- Objective 1.1 Support the development of innovative, safe, and effective vaccines to prevent infectious diseases of public health significance.
- Objective 1.2 Support the development and uptake of technologies to improve vaccine manufacturing, storage, distribution, and delivery mechanisms.

Goal 2: Maintain the highest possible levels of vaccine safety.

- Objective 2.1 Minimize preventable vaccine-related adverse events.
- Objective 2.2 Improve the timely detection and assessment of vaccine safety signals to inform public health policy and clinical practice.
- Objective 2.3 Increase awareness, understanding and usability of the vaccine safety system for providers, policymakers, and the public.

Goal 3: Increase knowledge of and confidence in routinely recommended vaccines.

- Objective 3.1 Counter vaccine mis- and disinformation and increase public support for the individual and societal benefits of vaccination.
- Objective 3.2 Increase provider capacity to promote knowledge of the benefits of immunization and increased vaccine acceptance by the public.
- Objective 3.3 Ensure key decision- and policy-makers receive accurate and timely information on vaccines and strategies to promote vaccine uptake
- Objective 3.4 Reduce disparities and inequities in vaccine confidence and acceptance.

Goal 4: Increase access to and use of all routinely recommended vaccines.

- Objective 4.1 Increase the availability of vaccines in a variety of settings.
- Objective 4.2 Reduce disparities and inequities in access to and use of routinely recommended vaccines across the lifespan.

- Objective 4.3 Strengthen data infrastructure, including Immunization Information Systems, to track vaccine coverage in the United States and conduct surveillance of vaccine-preventable diseases.
- Objective 4.4 Reduce financial and systems barriers for providers to facilitate delivery of routinely recommended vaccines.
- Objective 4.5 Reduce financial and systems barriers for the public to facilitate access to routinely recommended vaccines.
- Objective 4.6 Promote public-private partnerships to increase the capacity of the health system to deliver vaccines for routine use and protection during outbreaks.

Goal 5: Protect the health of the nation by supporting global immunization efforts.

- Objective 5.1 Support vaccine research and development to address vaccine-preventable diseases of global public health importance.
- Objective 5.2 Support global partners in efforts to combat vaccine misinformation, disinformation, and hesitancy worldwide.
- Objective 5.3 Support global partners to strengthen immunization systems.
- Objective 5.4 Increase coordination of global immunization efforts across federal agencies and with global partners.

Under each of these objectives is a set of strategies that further articulate the actions that are required to accomplish each objective. The Plan also specifies indicators to be used to measure progress toward goals and lays out suggested next steps to guide coordinated implementation by stakeholders across and outside of the federal government.

1. Introduction

The Vaccines National Strategic Plan 2021–2025 (Plan) provides a five-year roadmap for the coordination of vaccine development and use in the United States. It builds on the 2010 National Vaccine Plan (2010 Plan),[1] two Mid-Course Reviews of the 2010 Plan,[2] and the 2016 National Adult Immunization Plan (NAIP)[3] and addresses challenges that have emerged since the publication of these plans. Led by the Office of Infectious Disease and HIV/AIDS Policy (OIDP), Office of the Assistant Secretary for Health (OASH), Department of Health and Human Services (HHS), the Plan has been developed in collaboration with federal partners with significant input from stakeholders and the public. The Plan articulates an overarching vision and set of goals then defines specific objectives and strategies to achieve those goals. It also lays out specific indicators with which to measure progress and quantitative targets for each indicator. This plan focuses on policies related to vaccines that are used to prevent infectious diseases in the United States, including vaccines for routine use as well as for preventing and responding to pandemics. It does not address the use of therapeutic vaccines, e.g., vaccines that are used to treat cancer (immunotherapy), nor does it focus on the uniquely accelerated vaccine development process following the 2019 emergence of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and its associated illness, COVID-19. The Plan is intended to provide a roadmap for strengthening vaccination infrastructure across public and private sectors to prevent vaccine-preventable diseases (VPDs) and maintain the highest levels of vaccine safety in the United States.

A. The Need for the Vaccine Plan

1. The Vaccine and Immunization Landscape

Since the release of the 2010 Plan, vaccination rates have remained above 90 percent for the majority of routinely recommended pediatric vaccines in the United States,[4,5] translating into reduced disease burden and societal costs. Influenza vaccination coverage in children is one notable exception, with rates of only 64% during the 2019-2020 season.[6] For children born between 1994 and 2013, childhood vaccinations averted 322 million illnesses, prevented 732,000 premature deaths from VPDs, and saved $1.38 trillion in costs to society.[7] Within a decade following introduction of the human papillomavirus (HPV) vaccine in 2006, prevalence of vaccine-preventable HPV infections decreased 86% among females aged 14–19 years and 71% among those aged 20–24 years.[8]

In contrast, adult vaccination rates remain low overall[9] and continue to lag well behind those for children. For instance, during the 2018–2019 season, influenza vaccination coverage among adults was only 45%.[10] The annual burden of VPDs is particularly high among adults, with

approximately one million cases of herpes zoster each year,[11] over 3,000 cases of acute hepatitis B infections,[12] and about 40,000 cases and 4,000 deaths from invasive pneumococcal disease.[13] Large and prolonged outbreaks of hepatitis A in 2016–2018 among people experiencing homelessness highlight the need to redouble efforts to protect at-risk populations from VPDs.[14] While influenza and pertussis vaccines are safe during pregnancy[15,16] and can reduce the risk for severe complications of these illnesses in pregnant women and infants who are too young to be vaccinated, only about one-third of pregnant women received both recommended vaccines in 2018.[17] To address the persistently low vaccination coverage rates among adults, the National Vaccine Advisory Committee (NVAC) published the Standards for Adult Immunization Practices in 2014[18] and released the NAIP in 2016, which is discussed in Section A.2 below.[19]

Furthermore, disparities in vaccination coverage by race, ethnicity, gender, and other demographic characteristics reflect underlying health inequities in the United States that contribute to the gap between vaccination targets and actual rates. Structural racism, employment, housing, education, and transportation, among other social determinants of health, contribute to these health inequities. Coverage rates are lower among children living in poverty, Medicaid-enrolled children, and African-American children.[20] Among adults, vaccination coverage is generally lower among non-Hispanic blacks, Hispanics, and non-Hispanic Asians compared with non-Hispanic whites.[21]

In recent years there have been important changes to the vaccination landscape. A growing challenge is increasing the public's knowledge of and confidence in vaccines in the United States and worldwide as growing anti-vaccine sentiment threatens to erode progress that has been made on VPDs. As a result of geographic pockets of parental refusal of routine childhood vaccines, several recent outbreaks of VPDs[22] have caused significant morbidity and mortality in areas of the country with insufficient levels of population-level immunity, also referred to as community immunity.[23]

Another challenge is that the United States is increasingly vulnerable to endemic and emerging infectious diseases. This vulnerability is due, in part, to an increasingly globalized world with urbanization in low and middle income countries, climate change, political instability, and other forces. One of the most dramatic recent developments that has impacted the vaccine landscape is the emergence of SARS-CoV-2 in 2019 and the coronavirus disease (COVID-19) it causes. Given inequities in the U.S. populations most affected by COVID-19, as well as anticipated challenges with overcoming hesitancy specific to rapidly-developed COVID-19 vaccines, ensuring that safe and effective SARS-CoV-2 vaccines are widely available *and* broadly accepted by the population will be critically important to controlling the pandemic. In addition, given the precipitous decline in routine vaccination rates that occurred in the early months of the pandemic,[24-26] plans to ensure the timely administration of routine vaccines to children and adults are needed as part of emergency preparedness, response, and recovery strategies to prevent and control VPD epidemics.

2. *Previous Plans: The 2010 National Vaccine Plan and the National Adult Immunization Plan 2016*

The 2010 Plan provided a vision for the United States for the decade that began in 2010. It articulated a comprehensive strategy to improve and enhance the use of vaccines in the United States. It was organized around five overarching goals to mobilize diverse stakeholders to prevent infectious diseases and improve the public's health through vaccination: (1) develop new and improved vaccines; (2) enhance the vaccine safety system; (3) support communications to enhance vaccine decision-making; (4) ensure a stable supply of, access to, and better use of recommended vaccines in the United States; and (5) increase global prevention of death and disease through safe and effective vaccination. The 2010 Plan expanded these goals with 34 supporting objectives and nearly 150 strategies. In 2012, the National Vaccine Implementation Plan was released.[27] It described the specific activities federal partners committed to conduct in support of the priorities for the first five years of the 2010 Plan. Two separate mid-course reviews by the National Vaccine Program Office (NVPO)[1] and the National Vaccine Advisory Committee (NVAC) assessed progress of the 2010 Plan, identified areas of focus for the remaining time horizon, and suggested additional indicators to measure progress.

In 2016, HHS released a separate National Adult Immunization Plan (NAIP) that focused on priorities and strategies to improve immunization rates for adults in the United States.[28] The NAIP set forth four goals, 15 objectives, and 78 strategies, and included indicators that could be used to monitor progress. It was accompanied by an implementation guide that identified implementation priorities for the four goals of the NAIP and suggested potential activities that stakeholders could undertake to implement the NAIP.[19]

3. *Updates in the Plan*

The Plan covers the same five broad goal areas as the 2010 Plan. It differs from the 2010 Plan in three areas: (1) the 2020 Plan combines the scopes of the 2010 Plan and the NAIP into a single strategic document for vaccination across the lifespan; (2) the 2020 Plan has a five-year time horizon for more flexibility and agility given the rapid evolution of the immunization landscape; and (3) the 2020 Plan contains indicators and quantitative targets for the five-year period 2021-2025 and includes ten-year targets as benchmarks for the longer term.

[1] In June 2019, NVPO and the Office of HIV/AIDS and Infectious Disease Policy (OHAIDP) were merged to become the Office of Infectious Disease and HIV/AIDS Policy (OIDP).

B. Progress Since the 2010 National Vaccine Plan including Ongoing Challenges and Opportunities

This section reviews innovations and progress that have been made in the five major goals areas of the 2010 Plan since its release: vaccine development, safety, confidence, access and use, and global immunization. It also discusses ongoing challenges and opportunities for continued progress in each of the goal areas.

1. Vaccine Research, Development, and Innovation

Since the publication of the 2010 Plan, significant progress has been made in knowledge of the host immune response, development of new vaccines and new indications for vaccines already in use, and innovations in vaccine delivery mechanisms. Improved understanding of the pathogen-host interaction and the human immune system have led to innovations in vaccine design (e.g., advances in nucleic acid vaccine development), novel antigen delivery platforms (e.g., liposomes, nanoparticles, and novel protein expression systems such as plant-based systems), and promising vaccine delivery mechanisms (e.g., microneedle patch).[29] Other advances include structure-based vaccine design, machine-learning to identify and design antigens; novel adjuvants; and alternative routes of vaccine administration (e.g., transdermal).

Since the release of the 2010 Plan, several new vaccines have been licensed by the U.S. Food and Drug Administration (FDA) and are recommended by the Advisory Committee on Immunization Practices (ACIP) for routine use in the United States, including the 9-valent HPV, serogroup B meningococcal, recombinant zoster vaccine, and hexavalent combination (diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B, and *Haemophilus influenzae* type b) vaccines. Novel vaccines of public health importance have also been licensed (e.g., cholera,[30] dengue disease and Ebola virus disease[31]), and several vaccines are currently in development, including universal influenza vaccines, and those for malaria,[32] Group B Streptococcus during pregnancy,[33] and respiratory syncytial virus.[34] The development of a human immunodeficiency (HIV) vaccine and vaccines for sexually transmitted infections (STIs) are covered in the HIV National Strategic Plan and the STI National Strategic Plan respectively, both planned for release in 2020.

Vaccine development and commercialization are complex, requiring large, expensive clinical trials to generate data pertaining to safety and effectiveness. Initial capital investments that are needed to develop and manufacture vaccines can range from $700 million to over $1 billion,[35] with uncertain return on investment.[35] Financial incentives and other market forces (e.g., potential for significant, predictable demand; prices paid) help drive improvements in existing vaccines for diseases such as influenza and development of vaccines against pertussis, but additional incentives are needed to support vaccine development for diseases such as tuberculosis and malaria, as these vaccines would not be recommended for routine use and

therefore, the U.S. market is much smaller. With the emergence of the COVID-19 pandemic, an international alliance of government, academia, and the private sector[36] substantially accelerated the process of development, manufacturing, and distribution of COVID-19 vaccines, by conducting critical steps in this process simultaneously, where possible, and working collaboratively to develop many potential solutions to various technical challenges that could impede the process. The COVID-19 pandemic highlights the potential for substantial social returns on investment, despite the high costs associated with vaccine development. Vaccines for routine use and for use during pandemics prevent morbidity and mortality and reduce costs to society. There is a need for strategies to foster and support vaccine development that ensure industry incentives align with broader societal needs and objectives. It is essential that a pipeline of vaccine candidates with innovative designs, delivery platforms and technologies, and administration routes be maintained.

2. Vaccine Safety

The United States has an extensive safety monitoring system that ensures the highest level of vaccine safety.[37] Vaccine-related adverse events, particularly serious events, are exceedingly rare.[38,39] FDA is the regulatory authority that has oversight of the safety, effectiveness and quality of vaccines that are used in the United States. FDA evaluates the results of clinical trials conducted by vaccine manufacturers and other information to determine whether the safety and effectiveness of the vaccine has been demonstrated for licensure. After a vaccine is licensed and recommended for use, safety monitoring continues with post licensure studies and ongoing data collection and analysis, including through data safety monitoring boards that independently assess safety data. In addition, several systematic vaccine safety monitoring programs are in place that continue to evolve and improve over time.

The Vaccine Adverse Event Reporting System (VAERS) is a passive data collection system that allows the Centers for Disease Control and Prevention (CDC) and FDA to monitor safety signals associated with vaccines and conduct safety evaluations.[40] Anyone can report an adverse event to VAERS. Health care providers are required to report certain adverse events and vaccine manufacturers are required to report all adverse events that come to their attention to VAERS. Since 1990, VAERS served as a national early warning system for vaccine safety and CDC and FDA have continued to advance its capability by updating the VAERS reporting form, improving electronic reporting, and transitioning vaccine manufacturers to reporting using standardized messages through electronic data exchange.

The Vaccine Safety Datalink (VSD) is a collaboration between CDC and a network of nine managed care organizations with nearly 10 million patient base that monitors adverse events associated with vaccines.[41] Through this collaboration, VSD also enables studies to be conducted on rare and serious adverse events associated with vaccine use. VSD data are updated weekly, which allows the detection of vaccine-associated adverse events, particularly on the safety of newly introduced vaccines and safety of vaccines given to women during pregnancy, to inform

the public in near real time. The ability to incorporate new sources of data and develop and apply innovative analytic methods is critical to continued progress. Over the past decade, VSD has pioneered advanced analytic methods, such as machine learning, applied to large integrated datasets to rapidly detect vaccine safety signals for further investigation.[42]

FDA's Sentinel Initiative is an extensive public-private collaborative that monitors the safety of FDA-regulated medical products, including vaccines, to detect potential safety signals.[43,44] Taking advantage of advances in machine learning and other analytic methods with large integrated datasets over the past decade, the sentinel program has increasingly become more effective in detecting potential vaccine safety signals.[43]

One of the major challenges facing the U.S. vaccine safety system is improving communication of its strengths to the public and increasing confidence in the efforts that are continuously in place to ensure the safety of the U.S. vaccine system. One way to overcome these challenges is to improve the transparency of the vaccine safety system to policy makers, the public, and providers.[1]

Opportunities to further strengthen vaccine safety monitoring systems include continuing to reduce the reporting burden on providers, identifying new data sources including those that allow data to be stratified by race/ethnicity, and improving analytic methodologies to increase sensitivity of detecting potential safety signals.

3. Vaccine Knowledge, Confidence, and Acceptance

The World Health Organization (WHO) considers vaccine hesitancy to be one of the ten most critical public health challenges the world currently faces.[45,46] The spread of non-scientific and false information by individuals who oppose vaccines is eroding vaccine confidence, vaccine acceptance, and progress towards reducing the burden of VPDs in the United States and globally.[47,48] Since the release of the 2010 Plan, a range of strategies to improve vaccine confidence and acceptance have been implemented, but challenges remain.

Despite the unequivocal benefit of vaccines in preventing disease and promoting healthy communities, a minority of the population that opposes the routine use of vaccines has grown and become more vocal in recent years. Amplified by social media and other channels to disseminate false and deliberately misleading information, antagonism to vaccines threatens to reverse the gains that have been made over decades. Although some social media outlets began rejecting baseless claims about vaccines and removing false content on their platforms,[49] more aggressive countermeasures are called for by vaccine advocates. Presently, there is a need for creative and impactful communication strategies to inform the public, and increase vaccine confidence and counter hesitancy.[50]

Health care providers have repeatedly been identified as the most trusted sources of information regarding vaccines for parents of children and for adults.[51,52] However, while resources and tools are available to guide vaccination discussions,[53,54] and NVAC has published

the standards for adult immunization practice,[18] some health care providers still feel ill-equipped to have difficult and time-consuming conversations with vaccine-hesitant patients and parents.[55,56] Evidence-based approaches that promote uptake of vaccines include patient reminder-recall, standing orders, and other systems-based methods and incentives to overcome hesitancy.[57] Health care providers' strong and clear recommendations are central to promoting vaccine uptake and reducing vaccine hesitancy. Thus, there is a need to address system barriers to providing this information to patients, and to emphasize during medical training and continuing education the importance of vaccination and recent advances in vaccinations.[55]

With the increase in vaccine hesitancy in recent years, there has also been a gradual increase in the proportion of children entering kindergarten with nonmedical exemptions to school vaccination requirements.[58,59] These exemptions leave children and their communities more vulnerable to VPDs. The measles outbreaks in 2014–2015 and in 2019, which primarily involved unvaccinated children, prompted policy actions at the state level to limit nonmedical exemptions to school vaccination laws. Shortly after the 2014–2015 outbreak, California eliminated personal belief exemptions.[59] Similarly, after the 2019 measles outbreak, which was large enough that the United States nearly lost its measles elimination status, Washington, Maine, and New York enacted legislation to remove personal and religious exemptions.[59] Several other states also tried to remove nonmedical exemptions but were not successful.[59] Removing such exemptions are associated with higher coverage rates with the diphtheria, tetanus, and acellular pertussis vaccine (DTaP) and the measles, mumps, and rubella vaccine (MMR).[60] There continues to be a need for additional resources for policy makers (e.g., model legislation that promotes the use of vaccines) to inform them about key issues in vaccination policy debates and decisions.

Public health officials and researchers need more evidence and understanding around sources of vaccine hesitancy to develop effective strategies to counter it.[50] There is a need to integrate input from a wider range of disciplines, such as anthropology, sociology, and behavioral economics, to study nuanced drivers of vaccine hesitancy and how they vary by geography, sociodemographics, cultural norms and beliefs, and other characteristics.[61] In addition, there is a need to develop methods and measures to monitor vaccine hesitancy.[62-64] With a better understanding of these data, and with a more inclusive engagement of community leads and organizations, more effective interventions to address hesitancy and its drivers can be developed.[61]

4. Access to and Use of Routinely Recommended Vaccines

Since the release of the 2010 Plan, access to and use of routinely recommended vaccines have improved, such as influenza vaccination among pregnant women[65] and HPV vaccination for adolescents.[66] Several factors have contributed to improved access to vaccines over the past decade—expanding availability of vaccines in non-traditional settings, addressing financial barriers for patients and providers, and modernizing health information systems to more

accurately track vaccine administration and coverage. However, coverage rates for many vaccines remain stagnant, particularly among adults.[67]

The availability of vaccination in non-traditional settings, such as workplaces, pharmacies, retail locations, and schools, has improved access.[68] Including vaccination as a part of workplace wellness program benefits employers and employees.[69,70] Workplace influenza vaccination can reduce employee absenteeism. Among full time employees in the United States, nearly three days of work is lost per episode of influenza-like illness.[71] Pharmacies are an important setting through which access to vaccines have been greatly expanded.[72]

Pharmacists have delivered vaccination services for over two decades, and policy changes at the state and federal levels have enabled pharmacists to significantly expand their scope of practice and administer more vaccines to broader age groups. Pharmacists emphasize the importance of meeting people where they are and offering recommended vaccinations at every opportunity. However, ongoing administrative and financial barriers, such as the exclusion of pharmacists from provider networks in many health care plans, prevent them from assuming a greater role as immunization service providers.

There are opportunities to identify and address challenges with finance, payment and reimbursement processes for vaccination services.[73] Continuing to address financial barriers for patients and providers will accelerate progress in vaccination coverage rates and reduce disparities by socioeconomic status, race and ethnicity. Since the release of the 2010 Plan, over 20 million Americans have gained access to health insurance,[74,75] generally without copayments for routinely recommended vaccinations. However, 27.5 million people (8.5% of the population), which includes 4.3 million children (5.5%), did not have health insurance coverage in 2018, and millions more lost health insurance by the end of 2020 due to COVID-19-related job losses.[76,77]

For children, Vaccines for Children (VFC) is a federal entitlement program that provides free vaccines for children whose families are un- or underinsured.[78] For adults, the Public Health Service Act Section 317 Immunization Program allows limited discretionary funding for state and local immunization programs to provide vaccines for adults who are un- or underinsured.[79] However, much remains to be done to eliminate financial barriers for adults, such as the rising numbers of uninsured individuals and cost-sharing for those with Medicare Part D prescription drug coverage that includes several vaccines routinely recommended for adults.[67] Financial barriers for health care providers often include insufficient reimbursement rates for immunization services under Medicaid.[80]

Health care providers require up-to-date, accurate, and complete vaccination records for their patients. Routine use of Immunization Information Systems (IIS), also known as vaccine registries, is a proven strategy to improve vaccination coverage rates.[57] IIS can be used to remind health care providers to recall patients for vaccinations and compile vaccination data to validate their quality of health care delivery for payment incentive programs. For immunization programs, IIS are used to monitor vaccination coverage rates and trends and assist them in developing program strategies and priorities. Presently, state and local immunization programs

do not have the legal authority to share individual vaccination data across state jurisdictions, despite the technological capacity for IIS to do so, which limits the use of IIS. Efforts to improve interoperability and data exchange between electronic health records (EHRs) and IIS, as well as efforts to modernize legal and policy standards, are needed to optimize the use of IIS in the United States.[81]

5. Global Immunization

The United States supports efforts to vaccinate children and adults around the world in many ways.[73] Global immunization efforts help protect the United States, given that a person with an infectious disease can travel from one part of the world to any other part of the world within 24 hours. This has been underscored by the COVID-19 pandemic. The United States' global immunization activities include providing tailored technical assistance to help countries prepare for new vaccine introduction, conducting research and evaluation, strengthening integrated disease surveillance and responses to VPDs, developing immunization policy, and improving the quality and frequency of media reporting on vaccines. The United States has also focused on global public health capacity-building to support the immunization enterprise and has made significant investments in Gavi, the global public-private vaccine alliance, to improve access to vaccines for children living in low income countries, and to governments as they introduce and manage vaccination programs.[82]

Over the past decade, there has been progress in global vaccination coverage and associated reductions in VPDs. In 2019, the global coverage rate for the diphtheria, tetanus, and pertussis vaccine was 85 percent, which is the highest level ever reported.[83] In 2018, 142 countries offered pneumococcal conjugate,[84] 101 countries offered rotavirus,[85] and 90 countries offered HPV vaccines; and the use of yellow fever and Japanese encephalitis vaccines is increasing. Maternal and neonatal tetanus remains endemic in only 12 countries, and two of three strains of wild-type polio have been eradicated with vaccines. Additionally, innovative methods of delivering vaccines to difficult-to-reach populations are making an impact, including the use of mobile technologies, drone delivery, needle-free administration, and solar-powered vaccine storage.

However, progress has stalled in other areas over the last decade due to armed conflicts,[86] political instability, climate change, and other crises. In addition, increasing vaccine hesitancy has become a significant threat to efforts to vaccinate children and adults around the world.[48,87] Measles outbreaks and circulating vaccine-derived polio virus are proof that sustaining disease eradication and elimination goals require strong immunization programs and investments in public health infrastructure. In 2019, 13.5 million infants did not receive any vaccines worldwide and over 1.5 million people died from diseases that could have been prevented by vaccines.[83] Health systems have been severely weakened in many countries such as Venezuela, Syria, and Yemen due to conflicts and poverty. In 2017, over 1 million people in Yemen were affected by cholera, almost 60 percent of them children.[88] Displaced and migrating populations, climate change, and other factors have led to extension of vector-borne diseases into new areas.[89] The

rapid worldwide spread of COVID-19 is evidence that infectious diseases are not bound by geopolitical boundaries and the United States has an obligation to be an active participant in and a leader of the global community to ensure its own national health security. Supporting global partners to vaccinate children and adults, strengthen immunization systems and infrastructure, overcome barriers to access to vaccines, and promote vaccine confidence among immunization service providers and the patients they serve, at home and abroad, are immediate and long-term goals of the Plan.

C. Scope and Development of the Plan

A strategic national plan is needed to sustain and renew progress, address persistent and newly identified gaps, and proactively respond to the changing vaccine landscape. The Plan outlines priority issues for vaccination in the United States, defines objectives and strategies to address those issues, and sets forth specific indicators to measure progress. It focuses on policies related to vaccines that are used to prevent infectious diseases across the lifespan. The Plan's intent is to guide and coordinate efforts across a complex system that involves many public and private stakeholders, including policymakers, public health officials, payers, health care providers, vaccine manufacturers, researchers, and the public.

The Plan uses the following definitions:[90]

- **Goals:** Broad initiatives that enable a plan's mission and vision to be realized
- **Objectives:** Changes, outcomes, and impact a plan is trying to achieve
- **Strategies:** Choices about how to best accomplish objectives

The Vaccine Plan was developed by subject matter experts throughout the federal government, with significant input from stakeholders, including NVAC. Stakeholders provided input through public comments in response to a Request for Information and individual and small group discussions (Appendix A). The NVAC formally reviewed and submitted its recommendations for the Plan (Appendix B). The Interagency Vaccine Working Group (IVWG), consisting of vaccine experts across different agencies in the federal government, worked through an iterative, structured process to refine, prioritize, and finalize the components of the Plan (Appendix C). Throughout the Plan's development, OIDP and the IVWG considered other relevant federal and global initiatives and aligned the priorities of the Plan with other published or proposed national strategic plans for HIV, viral hepatitis, and sexually transmitted infections; Healthy People 2030; WHO's Immunization Agenda 2030 and Research and Development Blueprint; and the Global Health Security Agenda.

The next section lays out the vision for the Plan, the five overarching goals, objectives and strategies for each goal, and key indicators and targets to measure progress. The success of the Plan detailed in Section 2 relies on the active engagement and participation of public and private

stakeholders. Section 3 discusses mechanisms to ensure accountability of the Plan's implementation.

2. 2020 Vaccines National Strategic Plan

Vision

The United States will be a place where vaccine-preventable diseases are eliminated through safe and effective vaccination over the lifespan.

Goals, Objectives, and Strategies

Each goal of the Plan is presented below with a brief introduction including discussion of its objectives and associated strategies.

Goal 1: Foster innovation in vaccine development and related technologies.

The aim of Goal 1 is to foster innovation in vaccine development and related technologies. As described in Section 1, there has been much progress in recent years with the development of many new and improved vaccines and related technologies. Continued focus and investment is needed to sustain this progress and build upon it. For example, there is a significant need for new vaccines including, in particular, a universal influenza vaccine, aligning with the President's 2019 Executive Order on Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health;[91] maternal immunizations; and vaccines against vector-borne diseases. There is also a need to make improvements to existing vaccines, including improving effectiveness, manufacturing speed and capacity, and delivery mechanisms. Challenges throughout the product development pathway can hinder progress. These challenges need to be addressed to further promote innovation in the development of vaccines and related technologies.

The two objectives under this goal complement one another to support modernizing development, manufacturing, storage, distribution, and delivery across the entire vaccine enterprise. The first objective focuses on the development of innovative, safe, and effective vaccines through prioritizing new vaccine targets; reducing market barriers and supporting research that advances vaccine development; and optimizing efficiency in the vaccine development process. The final strategy under this objective is aimed at systematically documenting and applying lessons learned from the rapidly accelerated process for developing COVID-19 vaccines. The second objective addresses the need for technologies to improve vaccine manufacturing, storage, distribution, and delivery mechanisms through public-private partnerships, continued research and development, and dissemination of best practices.

Objectives and Strategies

Objective 1.1

Support the development of innovative, safe, and effective vaccines to prevent infectious diseases of public health significance.

Strategies:

1.1.1 Build upon prior efforts to prioritize new vaccine targets of global public health importance to guide research and development efforts.
1.1.2 Identify and reduce market barriers to developing new vaccines.
1.1.3 Support research that advances vaccine development and enhances vaccine safety and effectiveness.
1.1.4 Maximize efficiency in the vaccine development process.
1.1.5 Undertake a systematic process to document and act on lessons learned from the development of COVID-19 vaccines.

Objective 1.2

Support the development and uptake of technologies to improve vaccine manufacturing, storage, distribution, and delivery mechanisms.

Strategies:

1.2.1. Promote public-private partnerships that enable flexible vaccine manufacturing processes and ensure safe and efficient vaccine storage and distribution for routine and emergency use.
1.2.2. Encourage research and development of novel vaccine delivery mechanisms to increase safety, effectiveness, and tolerability.
1.2.3. Disseminate best practices in vaccine development and administration.

Goal 2: Maintain the highest possible levels of vaccine safety.

The aim of Goal 2 is to maintain the highest possible levels of vaccine safety, and more effectively communicate the strengths of the U.S. vaccine safety system to providers, policymakers, and the public. As already noted, VAERS, VSD, and the Sentinel Initiative provide a strong foundation for the vaccine safety monitoring infrastructure in the United States, and prior vaccine safety reviews have shown, for example, that serious side effects from vaccines are extremely rare.[39] Since the publication of the 2010 Plan, additional capabilities have been developed using machine learning and other advanced analytic methods applied to large integrated datasets to rapidly detect vaccine safety signals to investigate further.

The first objective under Goal 2 seeks to minimize preventable vaccine-related adverse events by better understanding the mechanisms of adverse events associated with vaccination and promoting education and training for health care providers on vaccine-and vaccination-related adverse events. The second objective aims to improve the timely detection and assessment of vaccine safety signals, leveraging data sources that track vaccine administration and adverse events and developing innovative algorithms to detect near real-time safety signals. The third objective aims to improve the transparency of the vaccine safety system to various stakeholders in order to promote public confidence in vaccines and support implementation of successful immunization programs.

Objectives and Strategies

Objective 2.1
Minimize preventable vaccine-related adverse events.

Strategies:

2.1.1 Identify gaps in knowledge and support research on mechanisms of adverse events associated with vaccines and vaccinations.

2.1.2 Promote education and training for health care providers on recognizing, managing, and preventing vaccine- and vaccination-related adverse events.

Objective 2.2
Improve the timely detection and assessment of vaccine safety signals to inform public health policy and clinical practice.

Strategies:

2.2.1. Strengthen integration of systems that track vaccine administration and adverse events associated with vaccines.

2.2.2. Develop innovative algorithms to detect safety signals associated with vaccines and vaccination in the vaccine tracking system.
2.2.3. Facilitate timely exchange of vaccine safety information between federal, state, and local public health authorities and vaccine manufacturers.

Objective 2.3

Increase awareness, understanding and usability of the vaccine safety system for providers, policymakers, and the public.

Strategies:

2.3.1. Develop and disseminate effective messages for policymakers, health care providers, and the public on the systems in place to monitor vaccine safety.
2.3.2. Improve access to current vaccine safety data to enable informed clinical decision-making.
2.3.3. Simplify processes for health care providers to report adverse events associated with vaccines and vaccinations.

Goal 3: Increase knowledge of and confidence in routinely recommended vaccines.

The aim of Goal 3 is to improve vaccination coverage by increasing knowledge of and confidence in routinely recommended vaccines. There is growing concern that the spread of mis- and disinformation as well as a growing mistrust of science and institutions is eroding vaccine confidence and leading to lower vaccination coverage rates. In the case of the recent measles outbreaks in the United States, insufficient community immunity has already contributed to increases in the burden of VPDs. Prominent public health scientists and researchers believe that growing vaccine hesitancy and the related decline in vaccine confidence is a significant public health crisis with potentially devastating impacts.

Addressing this crisis will require a multifaceted approach. Therefore, the objectives under Goal 3 and their associated strategies focus on increasing knowledge and confidence among patients, providers, and policymakers. The first objective focuses on countering the mis- and disinformation and using effective communication strategies to build understanding and support for the individual and societal benefits of vaccination.

The second objective focuses on health care providers and the need to strengthen their capacity to make strong vaccination recommendations and promote vaccine acceptance.

The third objective focuses on policy- and decision-makers who play an important role in promoting vaccination. To be effective, they need accurate and timely information about vaccines and effective strategies to promote vaccine uptake.

The fourth objective recognizes that there are differences across communities and cultures that influence vaccine confidence and acceptance. The objective aims to reduce disparities and inequities by developing a better understanding of these differences and working collaboratively to tailor messages and strategies to address the specific issues and concerns within a community.

Objectives and Strategies:

Objective 3.1

Counter vaccine mis- and disinformation and increase public support for the individual and societal benefits of vaccination.

Strategies:

3.1.1. Promote vaccination as a social norm through coordinated traditional and social media campaigns.
3.1.2. Strengthen efforts to limit the spread of misleading and/or false information, including on social media, that creates discord and disrupts public trust in vaccines.
3.1.3. Invest in communication sciences and community engagement to delivery compelling messages on vaccines and vaccinations by trusted messengers.
3.1.4. Maintain an evidence-based, transparent process for developing recommendations for vaccine use.

3.1.5. Advance research on societal, cultural, behavioral, and other factors that affect confidence in and use of vaccines and develop interventions to address these factors.
3.1.6. Work with federal partners and state and local school boards to support development and dissemination of modules for school health curricula that foster vaccine knowledge and confidence from an early age.

Objective 3.2

Increase provider capacity to promote knowledge of the benefits of immunization and increased vaccine acceptance by the public.

Strategies:

3.2.1. Strengthen vaccine curricula in medical, nursing, pharmacy, and allied health education.
3.2.2. Develop partnerships with health professional societies, health professional training programs, and licensing and certification boards to strengthen communications and training of health care professionals about the importance of vaccines and best practices for vaccine counseling and administration.
3.2.3. Improve dissemination and implementation of best practices among health care providers to effectively promote vaccine confidence and vaccination uptake.

Objective 3.3

Ensure key decision- and policy-makers receive accurate and timely information on vaccines and strategies to promote vaccine uptake.

Strategies:

3.3.1. Support development of state-level communities of practice to facilitate implementation of evidence-informed strategies to increase vaccine uptake.
3.3.2. Inform and engage legislators and executive officers in governments on policies that increase vaccine use.

Objective 3.4

Reduce disparities and inequities in vaccine confidence and acceptance.

Strategies:

3.4.1. Reduce barriers to data sharing between public health and the community (e.g., schools) to identify under-vaccinated populations.
3.4.2. Support research in local communities to identify causes of vaccine hesitancy and develop targeted interventions to address them.

3.4.3. Further develop, implement, and evaluate metrics to better understand vaccine confidence by age, race/ethnicity, geography, education and socioeconomic status over time.
3.4.4. Engage trusted community members and organizations (e.g., faith-based leaders) within targeted communities to develop effective messages and strategies in those communities.

Goal 4: Increase access to and use of all routinely recommended vaccines.

This goal is focused on increasing access to and use of all routinely recommended vaccines. Access to vaccines is a complex and multifaceted challenge that is part of much broader issues with health care access in the United States. In addition to patient-level barriers to vaccination, providers also face financial and systems barriers. While Goal 1 focuses on developing vaccines and Goal 3 centers on increasing public demand for vaccination, Goal 4 bridges the two. Specifically, this goal aims to ensure that the public can access and afford the vaccines they need and that providers are able to administer them. For providers to vaccinate their patients, they must invest time and money to stock vaccines, have access to a steady supply of vaccines at reasonable cost, and have an administrative system in place for payments. They also need access to reliable information to determine if a vaccine is indicated for the patient, require adequate time and reimbursement for counseling, and must document vaccines administered in the IIS.

The first objective under Goal 4 focuses on making vaccines available in a variety of settings and seize every opportunity to offer vaccines to those who need them. The second objective emphasizes the need to reduce disparities and inequities in access to and use of routinely recommended vaccines. The third objective highlights the continued need to strengthen data infrastructure to track vaccination coverage in real-time, and conduct surveillance for VPDs and use this information to improve coverage and reduce disparities. The fourth and fifth objectives aim to reduce financial and systems barriers for providers and patients, respectively. The last objective under Goal 4 calls out the need to promote public-private partnerships to increase the capacity of the health system to deliver vaccines for routine use and, as highlighted by the Covid-19 pandemic, during outbreaks. These partnerships, (e.g., the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership among multiple federal agencies, biopharmaceutical companies, and non-profit organizations such as foundations and research organizations) are needed to improve vaccine ordering, distribution, and tracking during routine use and public health emergencies; and to develop and practice plans to deliver routine vaccinations as well as conduct mass vaccination during public health emergencies.

Objectives and Strategies

Objective 4.1
Increase the availability of vaccines in a variety of settings.

Strategies

4.1.1. Remove barriers to and incentivize vaccination in non-health care settings such as schools, workplaces, places of worship, community centers, and pharmacies, as well as in specialty health care settings (e.g., cancer treatment centers).
4.1.2. Scale-up implementation of evidence-based systems-level strategies that increase vaccine uptake (e.g., centralized reminder-recall system, standing orders).

4.1.3. Expand the number of Vaccines for Children sites and reduce barriers to provider enrollment.

Objective 4.2

Reduce disparities and inequities in access to and use of routinely recommended vaccines across the lifespan.

Strategies

4.2.1. Support continued research on racial and ethnic, age, social, economic, cultural, and other factors that contribute to disparities in vaccination rates, and develop targeted interventions to address them.
4.2.2. Support state and local health departments' efforts to study local immunization disparities and strengthen their community engagement efforts.
4.2.3. Increase use of data by public health departments and health care systems to identify and address disparities in vaccination rates in their jurisdictions and patient populations.

Objective 4.3

Strengthen data infrastructure, including Immunization Information Systems, to track vaccine coverage in the United States and conduct surveillance of vaccine-preventable diseases.

Strategies

4.3.1. Improve Immunization Information System reporting, its interoperability across state lines, and bidirectional communication with other health data systems.
4.3.2. Use interoperable health information technology including electronic health records, electronic case reporting, and health information exchange networks to characterize and improve monitoring of vaccine-preventable diseases.
4.3.3. Increase data analytics capacity to conduct disease surveillance and increase enrollment of adult health care providers in immunization information systems.
4.3.4. Provide additional resources, training, and incentives to improve IIS reporting by adult vaccine providers.

Objective 4.4

Reduce financial and systems barriers for providers to facilitate delivery of routinely recommended vaccines.

Strategies

4.4.1. Support adequate payments for vaccine counseling and administration to providers under public sector and private health plans.

4.4.2. Encourage development and implementation of best business practices to improve vaccination services at the practice level.
4.4.3. Encourage state Medicaid programs to continue implementing evidence-based policies to improve vaccination rates among Medicaid beneficiaries..
4.4.4. Promote the use of vaccination as a quality measure in value-based payment models.
4.4.5. Adequately reimburse and remove system barriers to implementation of innovative services such as the use of mobile vans and telehealth.

Objective 4.5

Reduce financial and systems barriers for the public to facilitate access to routinely recommended vaccines.

Strategies

4.5.1. Remove co-pays, cost sharing, and other financial barriers by health care plans for all routinely recommended vaccines.
4.5.2. Promote adequate payments for vaccines and vaccinations by public and private health plans to incentivize providers to vaccinate, thereby promoting access.
4.5.3. Expand systems that provide access to free vaccines for uninsured adults.

Objective 4.6

Promote public-private partnerships to increase the capacity of the health system to deliver vaccines for routine use and protection during outbreaks.

Strategies

4.6.1. Strengthen public-private partnerships to improve vaccine ordering, distribution, and tracking for routine use and during public health emergencies.
4.6.2. Develop and practice plans to continue delivering routine vaccinations during public health emergencies.
4.6.3. Develop and practice plans to expand capacity to conduct mass vaccination during public health emergencies.

Goal 5: Protect the health of the nation by supporting global immunization efforts.

Goal 5 aims to protect the health of the nation by supporting global immunization efforts. While the Plan is a national plan, the United States is firmly committed to continuing to collaborate with and support partners in global immunization efforts as a critical element of the nation's broader health security agenda. As COVID-19 has demonstrated, the success of the United States' national vaccine strategy will continue to be inextricably linked with the success of global immunization activities. The United States has demonstrated long-standing leadership in these activities, including building an effective influenza laboratory surveillance network around the world and assisting other countries to develop surveillance systems; supporting global polio eradication; contributing financial resources to Gavi; leading tuberculosis and malaria vaccine development efforts; deploying a vaccine against Ebola virus disease; and working to develop vaccines to prevent pandemics. Across the U.S. government, funding for and expertise in surveillance, collaborative research, vaccine deployment, understanding and addressing vaccine confidence globally, advancing regulatory science, and other activities are leveraged every day in support of global immunization.

However, as discussed in Section 1, several emerging issues are threatening the global uptake of vaccinations, including violent conflict, political instability, population displacement, and a growing mistrust of science. In our global economy, in which people and information can circle the globe quickly and easily, the United States will most effectively protect the health of its population by supporting global immunization efforts. The first objective aligns with Goal 1 of the Plan and expands the focus to global vaccine research and development to address vaccine-preventable diseases, including those that do not yet have a licensed vaccine but are of significant public health importance. The second objective aligns with Goal 3 and is focused on supporting global partners in their efforts to counter vaccine misinformation and disinformation through strategies such as working with immunization programs in other countries to disseminate evidence-based vaccine information. The third objective aligns with Goal 4 of the Plan, seeking to support global partners' efforts to strengthen their immunization systems, including through the use of digital and data tools to conduct vaccination campaigns more efficiently, manage supply chains, and monitor vaccine coverage. The fourth objective calls for improved coordination across federal agencies and with global partners, through strategies aimed at harmonizing global regulatory processes where possible and increasing collaboration with international partners on global vaccine advocacy.

Objectives and Strategies

Objective 5.1

Support vaccine research and development to address vaccine-preventable diseases of global public health importance.

Strategies:

5.1.1. Support development of technologies that improve vaccine access, distribution, and equity in low-resource countries during a public health emergency.
5.1.2. Provide technical assistance to developing country vaccine manufacturers to support development and production of safe and effective vaccines.
5.1.3. Work with global partners to establish an international system that facilitates rapid response to emerging infections through the development of vaccine reference strains, candidate vaccines, and reagent standards for vaccine evaluation.
5.1.4. Explore new avenues, including through multilateral organizations and engaging with health economists and ministers of finance, to develop strong investment cases and secure sustainable financing to foster innovation in vaccine development and delivery mechanisms.

Objective 5.2

Support global partners in efforts to combat vaccine misinformation, disinformation, and hesitancy worldwide**.**

Strategies:

5.2.1. Work with immunization programs in other countries to disseminate evidence-based information on vaccines through traditional and social media.
5.2.2. Identify and address knowledge gaps on societal, cultural, behavioral, and other factors that affect vaccine hesitancy worldwide, especially among populations at risk of under-immunization.

Objective 5.3

Support global partners to strengthen immunization systems.

Strategies:

5.3.1 Develop tools and technology for real-time global surveillance of vaccine-preventable disease patterns, adverse events following immunization, and emerging infectious diseases.
5.3.2 Leverage digital and data tools to more efficiently target vaccination campaigns, more effectively manage supply chains, and more accurately monitor vaccine coverage.
5.3.3 Support countries to maintain a stable vaccine supply through secure and reliable vaccine finance, ordering, and distribution systems.
5.3.4 Support global efforts to increase vaccine delivery to underserved populations.
5.3.5 Continue to support multilateral organizations focused on eradicating and eliminating endemic and emerging vaccine-preventable diseases.

Objective 5.4

Increase coordination of global immunization efforts across federal agencies and with global partners.

Strategies:

5.4.1. Enhance collaboration with the global regulatory community to enhance regulatory convergence, where feasible.

5.4.2. Increase collaboration with international partners on global vaccine advocacy including promoting vaccine confidence.

3. Implementation and Accountability

Achieving the goals of the Plan requires the collaboration of federal and non-federal stakeholders around a shared vision and coordination of activities. Meaningful progress can be made if governments at all levels, health care delivery systems, health care providers, vaccine manufacturers, vaccine advocates and community leaders, and other stakeholders work together.

Federal Implementation

Federal partners will collaborate to develop an implementation plan to support the Vaccine Plan goals, objectives, and strategies. The federal implementation plan will set forth federal partners' commitments to policies, initiatives, and activities to meet the goals of the Plan, and will be published for transparency and accountability.

As part of their ongoing commitment to reduce vaccine-preventable diseases in this nation, federal partners have committed to serve on a vaccine plan implementation working group, continuing to provide their expertise and guidance. This implementation working group will meet regularly to coordinate activities across agencies and departments, implement lessons learned from epidemiological data and research findings, monitor progress toward the indicator targets, course correct as needed, and report on national progress. As scientific, medical, and public health advances and challenges emerge, new and innovative policies will be developed to complement the existing plan.

Non-Federal Stakeholder Implementation

Each community and stakeholder brings a unique perspective and plays a critical role in implementing the Plan. Stakeholders are encouraged to use the Plan to build their own roadmap to improve uptake of vaccines and reduce VPDs in their communities. Stakeholders can consider adopting the vision and goals of the Plan; implementing the objectives and strategies relevant to their role, populations, and communities; applying other evidence-based objectives and strategies; using available data to identify where their resources will have the most impact; and identifying indicators and targets to measure their progress. A data-driven strategy will help stakeholders focus and effectively use limited resources.

Accountability

The Plan includes ten indicators and associated quantitative targets to be achieved by 2025 (Table 1). The indicators will be used to measure progress and inform future implementation and quality improvement efforts. In selecting indicators, preference was given to

those that measure an important outcome or aspect of progress, are well defined, have face validity and construct validity, and have sources of data that are nationally representative and collected on a regular basis. The selected indicators reflect the Plan's focus on vaccination over the lifespan, with five focused on pediatric populations, four focused on adult populations, and one that covers all populations. Where available, existing targets for the indicators, such as from Healthy People 2030, were adopted. The other targets were informed by analysis of trends and expert opinion. Both 5- and 10-year targets are included, and they are considered ambitious but achievable. The Plan also recommends development of three additional developmental indicators that align with the developmental indicators in the Immunization and Infectious Disease (IID) objective for Healthy People 2030 (Table 1).[92] Nationally representative data for these developmental indicators are not currently collected and doing so would fill critical gaps in measuring the nation's efforts to address vaccination across the lifespan.

Successful implementation of the Plan will require monitoring and periodic evaluation. A detailed federal implementation plan will be released in 2021, subsequent to the release of the Vaccine Plan.

Table 1. Indicators and Targets for the 2020 Vaccine Strategic National Plan

Indicator	Baseline (Year)	2025 Target	2030 Target	Data Source
Pediatric populations				
Percentage of children aged <6 years whose immunization records are in a fully operational, population-based IIS	95 percent (2017)	95 percent	95 percent	IISAR, CDC/NCIRD; Population Estimates, Census
Proportion of children enrolled in kindergarten who received 2 or more doses of MMR	95 percent (2017-2018)	95 percent	95 percent	Annual School Assessment Reports, CDC/NCIRD
Proportion of children who received 4 or more doses of DTaP by their 2nd birthday	80.6 percent of children born in 2016-2017	85 percent	90 percent	NIS-Child, CDC/NCIRD
Proportion of kindergarten population with a nonmedical exemption from school vaccination requirements	2.2 percent (2018-19)	2 percent	2 percent	Annual School Assessment Reports, CDC/NCIRD
Proportion of adolescents aged 13 to 17 years who receive recommended doses of HPV vaccine	46 percent (2017)	80 percent	85 percent	NIS-Teen, CDC/NCIRD
Adult populations, including pregnant women and older adults				
Percentage of adults aged >=19 years who have one or more immunizations recorded in an IIS	56 percent (2018)	80 percent	90 percent	IISAR, CDC/NCIRD; Population Estimates, Census
Percentage of non-institutionalized high risk adults aged 18-64 years vaccinated against pneumococcal disease	24.3 percent (2017)	60 percent	70 percent	(NHIS, CDC/NCHS
Percentage of non-institutionalized adults aged ≥65 years and older vaccinated against pneumococcal disease	69.0 percent (2017)	90 percent	95 percent	NHIS, CDC/NCHS
Percentage of pregnant women who report receiving	53.5 percent (2016-2017)	80 percent	95 percent	NHIS, CDC/NCHS

influenza immunization during pregnancy				
All populations				
Proportion of persons aged ≥6 months who are vaccinated annually against seasonal influenza	51.8 percent (2019-20)	60 percent	70 percent	NHIS, CDC/NCHS
Developmental Indicators				
Proportion of pregnant women who receive 1 dose of the tetanus-diphtheria-acellular pertussis (Tdap) vaccine during pregnancy				
Proportion of Immunization Information Systems that track adult immunizations across the lifespan				
Proportion of adults age 19 years or older who receive recommended age-appropriate vaccines				

CDC: Centers for Disease Control and Prevention; DTaP: diphtheria, tetanus, and acellular pertussis vaccine; HPV: human papillomavirus; IIS: Immunization Information System; IISAR: Immunization Information Systems Annual Report; MMR: measles, mumps, and rubella vaccine; NCIRD: National Center for Immunization and Respiratory Diseases; NCHS: National Center for Health Statistics; NHIS: National Health Interview Survey; NIS-Child: National Immunization Survey–Child; NIS-Teen: National Immunization Survey–Teen

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Appendix A: Detailed Methodology

The process for developing the Plan included engaging federal leadership, experts, and nonfederal partners to compile subject matter evidence and recommendations to enhance all aspects of vaccines and vaccination including research and development, safety, vaccine knowledge and confidence, increased access and use of routinely recommended vaccines, and global cooperation. These data were then synthesized and developed into the vision, goals, objectives, strategies, indicators, and quantitative targets that are the core of the Plan. This process also included aligning the components of the Plan with strategic national plans for HIV, viral hepatitis, and sexually transmitted infections. The Plan included aligning the indicators and quantitative targets with *Healthy People 2030* objectives. The process was facilitated by the Office of Infectious Disease and HIV/AIDS Policy (OIDP), Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (HHS).

Interagency Vaccine Working Group

The federal Interagency Vaccine Work Group (IVWG) was convened to set the vision, goals, objectives, and strategies for the Plan. Development of the Plan components was an iterative process with OIDP developing proposals based on a synthesis of stakeholder input as a starting point for discussion and updating based on feedback from the IVWG. Revised versions were then voted on and continued to be revised until approved by the IVWG. The IVWG consists of senior representatives from 3 federal Departments and 9 HHS agencies and offices (Appendix C) and met regularly from July 2019 to October 2020.

National Vaccine Advisory Committee

The National Vaccine Advisory Committee (NVAC) is a federal advisory group that provides advice to the Assistant Secretary for Health on prevention of infectious diseases through vaccination. In March 2019, the Assistant Secretary for Health requested that the NVAC develop recommendations to guide the development of the 2020 Vaccine Plan. The NVAC released its recommendations in September 2019 (Appendix B).[1]

[1] Approved by the National Vaccine Advisory Committee on September 17, 2019. 2020 National Vaccine Plan Development: Recommendations From the National Vaccine Advisory Committee. *Public Health Rep*. 2020 Mar/Apr;135(2):181-188. doi: 10.1177/0033354920904074. Epub 2020 Feb 14. PMID: 32058834; PMCID: PMC7036602.

Public Input

Public input was gathered through an announcement in the Federal Register that solicited input from the public on the plan to develop a national strategy on vaccination and individual and small group interviews with leading experts in vaccine science, program management, policy, and advocacy.

Request for Information

OIDP solicited public comments through a Request for Information (RFI) published in the Federal Register on September 24, 2019.[93] The purpose of the RFI was to gather input from stakeholders and the general public on the priorities, goals, and objectives for the Plan. During the 30-day comment period, OIDP received 1,334 responses, including those from organizations in Table A1.

Table A1. Selected Organizations that Submitted Comments in Response to the RFI

American Academy of Family Physicians (AAFP)
American Academy of Pediatrics (AAP)
America's Health Insurance Program (AHIP)
American Immunization Managers (AIM)
American Nursing Association (ANA)
Association of State and Territorial Health Officials (ASTHO)
Big Cities Health Coalition (BCHC)
Biotechnology Innovation Organization (BIO)
Global Health Technologies Coalition (GHTC)
Glaxo Smith Kline (GSK)
The Hepatitis B Foundation (HBF)
National Association of City and County Health Officials (NACCHO)
National Association of Nutrition and Aging Services Programs (NANASP)
National Committee for Quality Assurance (NCQA)
National Association of Chain Drug Stores (NACDS)
PATH
Statewide Parental Advocacy Network and NJ Family Voices (SPAN/NJ FV)
Trust for America's Health (TFAH)
Walgreens
West Virginia Immunization Network (WIN)

All comments were uploaded to Dedoose for qualitative analysis (Version 8.2.14, SocioCultural Research Consultants, LLC, Los Angeles, CA). After excluding documents that were deemed not relevant, such as a copy of the RFI or a news release, the remaining 1,326 comments were analyzed. Each submission was categorized as from an individual or an organization and whether it included specific feedback on one or more goals in the Plan or reflected general concerns about vaccines. All comments were analyzed using a qualitative descriptive approach to sort comments, identify patterns and synthesize them into salient themes and sub-themes.

Of the 1,326 comments, 24 provided input that directly aligned with the five goal areas of the Plan (Table A.2). The remainder, 1,302 expressed concerns about vaccines, including a large number with identical or nearly-identical content.

Table A.2. Number of comments directly addressing each of the five proposed goals

2020 Vaccine Plan Proposed Goal	Number of comments (organizations or individuals)
Goal 1: Vaccine Research and Development	8
Goal 2: Vaccine Safety	4
Goal 3: Vaccine Knowledge and Confidence	17
Goal 4: Vaccine Delivery and Access	24
Goal 5: Global Immunization	7

Responses to the RFI provided overarching and goal-specific comments. The overarching comments primarily focused on the value of having a strong plan that can serve as a roadmap for all stakeholders and inform allocation of resources. To build a strong plan, the commenters encouraged OIDP to engage a broad range of stakeholders, including those that are new or currently underutilized, in the development of the Plan to promote wider and more active implementation of the Plan. A summary of goal-specific input is as follows:

- **Goal 1. Vaccine Research and Development:** Responses emphasized the complex nature of vaccine development and commercialization as a challenge and asked that the Plan address it. The focus was primarily on the unfavorable economics due to the high investment costs and uncertainties of the products in the commercial market.
- **Goal 2. Vaccine Safety:** Responses described a robust vaccine safety monitoring system currently in place, and identified a need to inform the public of its strengths.
- **Goal 3. Vaccine Knowledge and Confidence:** Responses identified vaccine hesitancy as a top priority for the Plan.
- **Goal 4. Vaccine Delivery and Access:** Responses highlighted several key challenges to optimizing access to and use of recommended vaccines, including variation and fragmentation within the health care system, financial barriers for providers and patients, challenges with data integration and a need for local data, strained public health resources, and the need to expand the use of vaccine-related quality measures.
- **Goal 5. Global Immunization:** Responses expressed support for the inclusion of a goal focused on global immunization.

Stakeholder Interviews

OIDP solicited input from leading experts on the subject of vaccines through individual and small group interviews. Twenty-six semi-structured individual and group discussions were conducted by telephone with 65 vaccine experts in October 2019. Their expertise spanned 13 topic areas and perspectives (Table A.3).

Table A.3. Stakeholder categories represented in individual and group discussions

Stakeholder group	Number of individuals
Professional medical organizations or health care providers	2
Pharmacy organizations or pharmacists	5
Pharmaceutical companies	6
Public health entities	3
Immunization information system or electronic health record vendors	3
Advocacy organizations	8
School/adolescent health-related organizations	2
Occupational health experts	4
Policy organizations	10
Organizations representing historically marginalized populations	2
Global health organizations	5
Academia/researchers	11
Health care services payers (e.g., health insurance plans)	4
Total	65

Interviewers used a semi-structured discussion guide to solicit input. The guide consisted of questions and accompanying probes that were asked of all stakeholders, as well as questions tailored to the particular stakeholder groups. The interviews were recorded and transcribed for analysis. A qualitative descriptive approach was used to sort comments, identify patterns in the comments, and synthesize them into the most salient themes and sub-themes.

Feedback received through these discussions largely aligned with responses to the RFI. A summary of goal-specific input is as follows:

- **Goal 1. Vaccine Research and Development:** Stakeholders emphasized that the uncertain return on investment when developing vaccines was an important barrier or

challenge to innovation and research and development. Several stakeholders described the vaccine development process as very slow and identified "valleys of death" where vaccines fall out of the development pipeline. There are vaccine candidates that could be further developed but are not pursued because there is no business case that can be made from the industry's perspective.

- **Goal 2. Vaccine Safety:** The dominant theme from stakeholders was that the vaccine safety monitoring system is robust, but it can be further strengthened. Four areas for improvement were highlighted: (1) improve communication on the vaccine safety monitoring system to patients, (2) invest additional resources and guidance for frontline health care providers, (3) leverage new data sources and analysis techniques to improve vaccine safety monitoring, and (4) conduct additional research on the safety of powerful adjuvants and recombinant DNA technologies.
- **Goal 3. Vaccine Knowledge and Confidence:** Stakeholders identified vaccine hesitancy as a top priority for the Plan. They identified four challenges related to vaccine hesitancy: (1) growing anti-vaccine sentiment and spread of misinformation, (2) varied reasons for vaccine hesitancy across communities and populations, (3) complacency and growing hesitancy among some health care providers, and (4) lack of tools and resources for health care providers to address hesitancy.
- **Goal 4. Vaccine Delivery and Access:** Stakeholders identified several challenges to improved vaccine delivery and access: 1) variation and fragmentation within the health care system, 2) financial barriers for providers and patients, 3) challenges with data integration and locally relevant data, 4) strained public health resources, and 5) a need to expand uses of vaccine-related quality measures.
- **Goal 5. Global Immunization:** Stakeholders identified the following broad themes around global immunization priorities and challenges: 1) challenges with ensuring continued U.S. leadership on global immunization; 2) the need to communicate the value of global immunization efforts for ensuring national health security; 3) the need to combat the spread of misinformation around the globe that fuels vaccine hesitancy and refusals; and 4) challenges within the research and development pipeline, including market pressures and perceived regulatory hurdles.

Through the RFI process and individual and small group interviews, stakeholders suggested approaches to address these challenges. Their recommendations are reflected in the Plan's objectives and strategies.

Public Comment on Draft Vaccines National Strategic Plan 2021-2025

OIDP posted a draft of the Vaccines National Strategic Plan 2021-2025 for public comment on [date]. X comments were received during the comment period…

Developing Indicators and Quantitative Targets

Indicators

The IVWG was tasked to review and approve indicators and quantitative targets for the Plan. OIDP compiled a list of existing vaccine--related measures and used the following criteria to select a set of the indicators to recommend to the IVWG. To be considered in the Plan, an indicator must:

- relate to at least one goal in the Plan;
- reflect current vaccine science and policy;
- represent measurements of outcomes that, if changed for the positive, would be an indication of better health for the nation;
- have sources of data that are nationally representative, collected routinely, and allows stratification by demographic and other variables; and
- have a national impact.

A set of 10 indicators was presented to the IVWG for review and approval along with three developmental indicators. Developmental indicators in the Plan are indicators that are included as developmental measures related to vaccines in Healthy People 2030. If these developmental measures in Healthy People 2030 mature and become core measures, the Plan will consider incorporating them as indicators in future updates. The IVWG discussed these indicators and developmental indicators and unanimously approved them to be included in the Plan.

Targets

Several different approaches were used to develop targets for the indicators, depending on the type of indicator and the source of data for the indicator. Eight of the 10 indicators are taken from either Healthy People 2030 or Healthy People 2020. For those that align with Healthy People 2030, the 2030 target was adopted. For indicators adopted from Healthy People 2020 where the most recent data did not reach the Healthy People 2020 targets, analyses of trends were used to determine 5- and 10-year targets. For two indicators where a quantitative target has not been previously determined, a review of existing data and expert input were used to establish targets.

Appendix B. NVAC Recommendations for the Vaccine Plan

The National Vaccine Advisory Committee (NVAC) put forth the following recommended goals and objectives for the Plan. The full report describing their methods, analysis, and recommendations was published in *Public Health Reports*.[1]

Goal 1: Foster innovation in vaccine development and related technologies

Objective 1: Prioritize the development of innovative vaccines to prevent infectious diseases of population health significance.

Objective 2: Enhance systems for vaccine production, storage, and delivery.

Objective 3: Identify and optimize current vaccines in need of improved effectiveness.

Goal 2: Continue to leverage the vaccine safety system

Objective 1: Sustain and enhance current tools, standards, and approaches used to assess vaccine safety.

Objective 2: Develop new methods to rapidly and accurately assess the safety of all recommended vaccines.

Objective 3: Disseminate lessons learned from the vaccine safety system.

Goal 3: Enhance knowledge of and confidence in routine vaccines and the immunization system

Objective 1: Research effective communication strategies to reach underimmunized populations and address vaccine hesitancy, including messaging, outreach strategies, and cultural and linguistic approaches.

Objective 2: Unify and promote vaccination standards across the lifespan.

[1] Approved by the National Vaccine Advisory Committee on September 17, 2019. 2020 National Vaccine Plan Development: Recommendations From the National Vaccine Advisory Committee. *Public Health Rep*. 2020 Mar/Apr;135(2):181-188. doi: 10.1177/0033354920904074. Epub 2020 Feb 14. PMID: 32058834; PMCID: PMC7036602.

Objective 3: Enhance the delivery of vaccine safety and effectiveness messages to providers and to the public.

Goal 4: Optimize access to and utilization of all routinely recommended vaccines across the lifespan

Objective 1: Eliminate geographic, racial/ethnic, and socioeconomic barriers to vaccine access across the lifespan and improve care through quality improvement initiatives

Objective 2: Increase the use of, and data exchange within, electronic health records and immunization information systems to collect and track immunization data, support clinical decision making, assist with vaccine forecasting, and identify areas of need

Objective 3: Strengthen public, private, and community-based partnerships and the public health infrastructure to improve manufacturing capabilities and delivery of immunizations for routine use and for protection during outbreaks

Goal 5: Promote global immunization

Objective 1: Improve global surveillance for vaccine preventable diseases and track progress against goals

Objective 2: Support international vaccine research and development and delivery programs to ensure vaccines are available to address global disease prevention

Objective 3: Sustain partnerships to prepare for emerging diseases and ongoing vaccine-preventable challenges

Appendix C. Members of the Inter-Agency Vaccine Working Group

Name	Affiliation
Justin Mills	AHRQ
Rick Bright	BARDA
Yuliya Deibes	BARDA
Linda Lambert	BARDA
Brooke Barry	CDC
Jillian Doss-Walker	CDC
Nancy Messonnier	CDC
Carla Miles	CDC
Kristin Pope	CDC
Melinda Wharton	CDC
Mary Beth Hance	CMS
Jeffrey Kelman	CMS
Tonya Sue Rans	DoD
Steven Anderson	FDA
Marion Gruber	FDA
Maureen Hess	FDA
Peter Marks	FDA
Manette Niu	FDA
Gregory Pappas	FDA
Glenton Atwell	HRSA
Jannette Dupuy	HRSA
Corette Taylor	HRSA
Jeffrey McCollum	IHS
Barbara Mulach	NIH
Emily Erbelding	NIH
Tammy Beckham	OIDP
Anthony Mounts	USAID
Carmen Tull	USAID
Troy Knighton	VA
Sophia G. Califano	VA