

VACCINES

National Strategic Plan

for the United States | 2021–2025



VISION

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

Acknowledgments: The Vaccines National Strategic Plan: 2021–2025 (Vaccine Plan) was developed through a robust process that included gathering feedback from stakeholders across health care and related fields. Partners throughout the federal government, as well as hundreds of nonfederal stakeholders, including state, tribal, territorial, and local governments, researchers, health plans and providers, community groups, and national and local organizations, have helped shape the goals, objectives, and strategies contained in the Vaccine Plan. The Office of the Assistant Secretary for Health (OASH) and its Office of Infectious Disease and HIV/AIDS Policy (OIDP) of the U.S. Department of Health and Human Services, sincerely thank all those who contributed to developing the Vaccine Plan.

Additional information regarding the Vaccine Plan and associated activities may be accessed at hhs.gov/vaccines.

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EXECUTIVE SUMMARY

Although significant progress against vaccine-preventable diseases has been made in the United States, there remain significant gaps in vaccination coverage that contribute to preventable morbidity and mortality each year. The Vaccines National Strategic Plan 2021–2025 (Vaccine Plan) provides a vision for the U.S. vaccine and immunization enterprise for the next 5 years as the nation seeks to eliminate vaccine-preventable diseases.

The Vaccine Plan articulates a comprehensive strategy to promote vaccines and vaccination including research and development, vaccine safety monitoring, increase public knowledge and confidence in vaccines, increase access and use of recommended vaccines across the lifespan, and global cooperation. The Vaccine Plan builds on previous plans to guide vaccine policy to address vaccine confidence and disparities in vaccination coverage.

The Vaccine Plan establishes the following vision for the nation:

VISION

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

This vision is accompanied by five high-level goals, which frame the Plan's more specific objectives. Under each objective is a set of strategies that further articulate the actions that are recommended to accomplish each objective. The order of goals and objectives does not indicate any prioritization, and many are intertwined. In the goals and objectives, the terms *routinely used* or *routinely recommended* include vaccines that are used in routine non-outbreak settings, including those that are recommended for general populations and for specific or at-risk populations. The five goals and their associated objectives are as follows:



Goal 1: Foster innovation in vaccine development and related technologies

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



Goal 2: Maintain the highest levels of vaccine safety

- 2.1 Minimize preventable vaccine-related adverse events
- 2.2 Improve the timely detection and assessment of vaccine safety signals to inform public health policy and clinical practice
- 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

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



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

- 4.1 Increase the availability of vaccines in a variety of settings
- 4.2 Reduce disparities and inequities in access to and use of routinely recommended vaccines across the lifespan
- 4.3 Strengthen data infrastructure, including Immunization Information Systems, to track vaccine coverage and conduct surveillance of vaccine-preventable diseases
- 4.4 Reduce financial and systems barriers for health care providers to facilitate delivery of routinely recommended vaccines
- 4.5 Reduce financial and systems barriers for the public to facilitate access to routinely recommended vaccines
- 4.6 Promote public-private partnerships to increase the capacity of the health system to deliver vaccines for routine use during outbreaks



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

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

The Vaccine Plan also includes indicators for measuring progress and quantitative targets for each indicator. There are 10 core indicators, each with associated quantitative targets; additional targets specific to reducing disparities in vaccine coverage and promoting health equity will be included in the implementation of the Vaccine Plan. Although focused on the years 2021–2025, the Plan includes both 5- and 10-year targets that align with *Healthy People 2030*. To ensure implementation and accountability, a Federal Implementation Plan will be released after the release of the Vaccine Plan to document the specific actions that federal partners will take to achieve its goals and objectives.

The vision, goals, objectives, and other components of the Vaccine Plan were developed and approved by the federal Interagency Vaccine Working Group, composed of subject matter experts from across the federal government, with substantial input from public comment from numerous and varied stakeholders and the public, and recommendations from the National Vaccine Advisory Committee to the Assistant Secretary for

Health in his role as the Director of the National Vaccine Program. The Vaccine Plan is aligned with other national strategic plans including those for viral hepatitis, HIV, and sexually transmitted infections, all of which have been released in late 2020 or are expected to be released in early 2021.

The Vaccine Plan is intended to be implemented by a broad mix of stakeholders at all levels and across many sectors, both public and private. Implementation includes federal partners in collaboration with other governmental and non-governmental partners and stakeholders including those working in public health, health care, government, community-based organizations, research, manufacturing, and academia. The Vaccine Plan serves as a roadmap for all stakeholders at all levels to guide development of policies, initiatives, and actions to reduce the burden of and work toward eliminating vaccine-preventable diseases. Stakeholders are encouraged to customize their implementation of the plan for the communities they serve.

I. INTRODUCTION

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 Vaccines National Strategic Plan 2021–2025 (Vaccine Plan) is intended to provide a roadmap for federal and non-federal partners and stakeholders for strengthening vaccination infrastructure across public and private sectors, including improving immunization and health equity. Its aim is 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 National Vaccine Plan, vaccination rates have remained above 90% for the majority of recommended pediatric vaccines in the United States,^{1,2} reducing the burden and economic impact of the diseases they prevent. Influenza vaccination coverage in children is a notable exception, with rates of only 64% during the 2019–2020 season.³ 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.⁴ Within a decade following introduction of the human papillomavirus (HPV) vaccine in 2006, prevalence of vaccine-preventable HPV infections decreased by 86% among females aged 14–19 years and by 71% among those aged 20–24 years.⁵ However, despite this impact, HPV vaccination rates remain low among adolescents. In 2019, only 54% of adolescents completed the HPV vaccination series.⁶

In contrast, adult vaccination rates remain low overall⁷ and continue to lag well behind those for children. For instance, during the 2019–2020 season, influenza vaccination coverage among adults was only 48%.³ The annual burden of VPDs is particularly high among adults, with approximately 1 million cases of herpes zoster each year,⁸ more than 3,000 cases of acute hepatitis B infections,⁹ and about 40,000 cases and 4,000 deaths from invasive pneumococcal disease.¹⁰ Large and prolonged outbreaks of hepatitis A in multiple states in 2016–2018 among people experiencing homelessness highlight the need to redouble efforts to protect at-risk populations from VPDs.¹¹ Although influenza and pertussis vaccines are safe during pregnancy^{12,13} 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 2018.¹⁴ To address the persistently low vaccination coverage rates among adults, the National Vaccine Advisory Committee (NVAC) made recommendations to HHS on the Standards for Adult Immunization Practices in 2014,¹⁵ and HHS released the National Adult Immunization Plan in 2016, which is discussed in Section A.2.¹⁶

Disparities in vaccination coverage by race, ethnicity, gender, geography, and other demographic characteristics reflect underlying health inequities in the United States that contribute to the gaps in vaccination efforts and rates. Racism, employment, housing, education, and transportation, among other social determinants of health, contribute to these health inequities. Immunization rates are lower among children living in poverty, Medicaid-enrolled children, and Black children.¹⁷ Among adults, vaccination coverage is generally lower among non-Hispanic Blacks, Hispanics, and non-Hispanic Asians compared to non-Hispanic whites.¹⁸

The United States is vulnerable to epidemic and emerging infectious diseases at home and abroad. 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. The United States was a part of the global public health response to outbreaks of infections such as the Ebola virus outbreaks in Africa in 2014 and 2018, the Zika virus outbreaks in the Americas in 2015–2016, the H1N1 influenza pandemic in 2009–2010, the emergence of severe acute respiratory syndrome (SARS) in China in 2003, and the ongoing HIV global

epidemic since 1981. The most dramatic recent development is the emergence of SARS coronavirus 2 (SARS-CoV-2) in 2019 and the global 2019 coronavirus disease (COVID-19) pandemic it has caused.

In recent years, notable changes have been observed in the vaccination landscape. Growing anti-vaccine sentiment threatens to erode progress that has been made by vaccines. In the United States, communities with widespread mistrust of vaccines and vaccination programs have resulted in outbreaks of preventable diseases, particularly among children.^{19,20} The development of COVID-19 vaccines has prompted open discussions in health care and public health communities and in public forums on the importance of ensuring the public's confidence in vaccine safety and effectiveness. Developing and making available a safe and effective vaccine is not enough, particularly in minority and disenfranchised communities. A key component of the effort to control the COVID-19 pandemic is an effective communication strategy to overcome vaccine hesitancy, including populations that are disproportionately impacted by COVID-19.

In addition, there have been precipitous declines in numbers of vaccines routinely administered to children and adults in the early months of the COVID-19 pandemic.^{21,22,23} These declines have put further stress on the health care and public health systems in the United States and may lead to outbreaks of diseases that vaccines would prevent. The rapid development and distribution of the COVID-19 vaccine also presents and will continue to present many lessons to be incorporated into the strategies to reach the Vaccine Plan's goals.

2. PREVIOUS VACCINE PLANS

The 2010 National Vaccine 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 and interconnected goals to mobilize diverse stakeholders to prevent VPDs and improve public 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; and (5) increase global prevention of death and disease through safe and effective vaccination. The 2010 National Vaccine Plan expanded these goals with 34 supporting objectives and nearly 150 strategies.²⁴ In 2012, the National Vaccine Implementation Plan was released.²⁵ It described the specific activities that federal partners committed to conduct in support of the priorities for the first 5 years of the 2010 National Vaccine Plan. Two separate mid-course reviews, conducted by the National Vaccine Program Office²⁶ and informed by recommendations to HHS by the National Vaccine Advisory Committee (NVAC),²⁷ assessed progress on meeting the goals of the 2010 National Vaccine Plan, identified areas of focus for the remaining years covered by it, and suggested additional indicators to measure progress.

In 2016, the U.S. Department of Health and Human Services (HHS) released a separate National Adult Immunization Plan that focused on priorities and strategies to improve immunization rates for adults in the United States.²⁸ The National Adult Immunization Plan 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 and suggested potential activities that stakeholders could undertake to implement the Vaccine Plan.¹⁶

3. UPDATES IN THE VACCINE PLAN

This Vaccine Plan covers the same five broad goal areas as the 2010 National Vaccine Plan but differs from the previous plan in three areas: (1) it combines the scopes of the 2010 National Vaccine Plan, which focused primarily on childhood vaccinations, and the 2016 National Adult Immunization Plan into a single strategic document across the lifespan; (2) it has a 5-year time frame, to provide more flexibility for a mid-course correction in 5 years given the rapid evolution of the immunization landscape; and (3) it contains indicator measures with 5- and 10-year quantitative targets as benchmarks for the duration of the Vaccine Plan and the longer term.

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

This section reviews innovations and progress that have been made in the five major goals in the 2010 National Vaccine Plan: vaccine development, safety, confidence, access and use, and global immunization. It also discusses challenges and opportunities in each goal area.

1. VACCINE RESEARCH, DEVELOPMENT, AND INNOVATION

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 since the release of the 2010 National Vaccine Plan. 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 National Vaccine 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, and hexavalent combination (diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B, and *Haemophilus influenzae* type b) vaccines.³⁰ New vaccines of public health importance have also been licensed (e.g., cholera,³¹ dengue disease,³² and Ebola virus disease³³), and several vaccines are currently in development, including universal influenza vaccines and vaccines for group B streptococcus,³⁴ respiratory syncytial virus,³⁵ and malaria.³⁶ The development of vaccines to prevent sexually transmitted infections (STIs) and human immunodeficiency virus (HIV) are covered in the [STI National Strategic Plan](#), which was released in December 2020, and the [HIV National Strategic Plan](#), which is expected to be released in early 2021.

However, there remains a significant need for new and improved vaccines and vaccination strategies, such as the development of new vaccines against vector-borne diseases, a more broadly protective (universal) influenza vaccine, and improved strategies for maternal immunization. Developing new vaccines includes modernizing the domestic vaccine enterprise to be highly responsive, flexible, and scalable; improving capacity for agile and rapid responses to emerging influenza threats; and developing more broadly protective vaccines.³⁷

Vaccine development and commercialization are complex, requiring large, expensive clinical trials to generate data pertaining to safety and effectiveness. The initial capital investments needed to develop and manufacture vaccines can range from \$700 million to more than \$1 billion, with uncertain return on investment.³⁸ Financial incentives and other market forces (e.g., potential for significant, predictable demand; balancing development costs and pricing) help drive improvements in existing vaccines for diseases such as influenza and pertussis. However, additional incentives are needed to support vaccine development for diseases such as tuberculosis and malaria because in the United States target populations for these vaccines are small in numbers. With the emergence of the COVID-19 pandemic, an alliance of government, academia, and the private sector³⁹ accelerated the timeline for development, manufacture, and distribution of COVID-19 vaccines by conducting critical steps simultaneously where possible, and working collaboratively to overcome technical, administrative, and financial challenges.

Despite enormous costs associated with the development and distribution of COVID-19 vaccines, they represent substantial social and economic returns on investment. Similarly, vaccines in routine use yield proven and substantial social and economic returns by preventing disease, protecting people and communities, and saving health care costs.⁴⁰ There is a need for continued support both for developing new

vaccines and improving existing vaccines that align incentives 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.⁴¹ Vaccine-related adverse events, particularly serious events, are exceedingly rare.^{42,43} The Food and Drug Administration (FDA) is the regulatory authority with oversight of the safety, effectiveness, and quality of vaccines that are used in the United States. Vaccine development programs include studies conducted by manufacturers according to FDA standards to evaluate safety and effectiveness in the target population. Clinical trials are conducted according to plans that reflect FDA's expertise in clinical trial design. FDA evaluates the results of clinical trials conducted by vaccine manufacturers and other information to determine whether the safety and efficacy of the vaccine have 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 conducted by vaccine safety surveillance.

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.⁴⁴ 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 has served as a national early warning system for vaccine safety. CDC and FDA have continued to advance VAERS' capability by updating the VAERS reporting form, improving electronic reporting, and transitioning vaccine manufacturers to 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 a patient base of nearly 10 million that monitors adverse events associated with vaccines.⁴⁵ Through this collaboration, studies on rare and serious adverse events associated with vaccine use can be conducted. VSD data are updated weekly, which allows for the detection of vaccine-associated adverse events, particularly on the safety of newly introduced vaccines and vaccines given to women during pregnancy, to inform the public in near real time. The ability to incorporate new data sources 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.⁴⁶

The Sentinel Initiative is an extensive public-private collaborative that allows the FDA to monitor the safety of its licensed medical products, including vaccines, to detect potential safety signals.^{47,48} Taking advantage of advances in analytic methods with large integrated datasets over the past decade, the sentinel program has increasingly become more effective including through detecting potential vaccine safety signals.⁴⁸ In addition, other large-linked database monitoring systems from the Department of Defense and Veterans Administration are in place to monitor vaccine safety.

For monitoring COVID-19 vaccine safety, in addition to the systems above, CDC added the V-safe active vaccine health checker, a smart phone-based active monitoring program for COVID-19 vaccine recipients.

To strengthen confidence in vaccines by health care providers, policymakers, and the public, it is important to develop effective and transparent communication strategies on vaccine safety, from clinical trials to post-licensure safety monitoring to post-marketing surveillance.⁴⁹ Mechanisms to further strengthen vaccine safety monitoring systems include continuing to reduce the vaccine safety reporting burden on health care providers, identifying new data sources including those that allow for stratification of data by race and 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 10 most critical public health challenges the world currently faces.^{50,51} The spread of non-scientific and false information by individuals who oppose vaccines is eroding vaccine confidence, vaccine acceptance, and progress toward reducing the burden of VPDs in the United States and globally.^{52,53} Since the release of the 2010 National Vaccine Plan, in 2015, NVAC issued recommendations to HHS in a report on National Vaccine Confidence, *Assessing the State of Vaccine Confidence in the United States*, which provided advice on setting the groundwork to approach this issue and helped inform the confidence-related recommendations in this Vaccine Plan. A follow-up to the 2015 report is currently in development by NVAC. As awareness of the threat posed by vaccine hesitancy has grown, a range of strategies to improve vaccine confidence and acceptance has been implemented, but challenges remain.

Despite the unequivocal benefit of vaccines in preventing disease and promoting healthy individuals and communities, a minority of the population opposes routine use of vaccines and has grown and become more vocal in recent years. Amplified by social media and other channels disseminating deliberately misleading and false information, antagonism to vaccines threatens to reverse the gains that have been made over decades. Some social media outlets are rejecting baseless claims about vaccines and removing false content on their platforms,⁵¹ but vaccine advocates are calling for more aggressive countermeasures. Creative and impactful communication strategies are needed to inform the public and increase vaccine confidence and address vaccine hesitancy.⁵⁴

Health care providers have repeatedly been identified as the most trusted sources of information regarding vaccines for parents and guardians of children and for adults.^{55,56} Although resources and tools are available to guide vaccination discussions,^{57,58} some health care providers feel ill-equipped to engage in sometimes difficult and time-consuming conversations with vaccine-hesitant patients and parents and guardians.^{59,60} Evidence-based approaches that promote uptake of vaccines include patient reminders-recalls, standing orders, other systems-based methods, and incentives to patients and families to overcome hesitancy.⁶¹ Health care providers' strong and clear recommendations, as described in the standards for adult immunization practice,¹⁵ for example, are central to promoting vaccine uptake and reducing vaccine hesitancy. Thus, there is a need to emphasize the importance of vaccination and recent advances in vaccinations as an integral component of medical training and continuing education programs.⁶¹

A gradual increase in the proportion of children entering kindergarten with nonmedical exemptions to school vaccination requirements also threatens to undermine the gains made in childhood vaccination rates.^{62,63} These exemptions leave children and their communities more vulnerable to VPDs. The measles outbreaks in 2014–2015 and in 2019 (Table 1), which primarily involved unvaccinated children, prompted policy actions at the state level to limit nonmedical exemptions in school vaccination requirements. Shortly after the 2014–2015 outbreak, California eliminated personal belief exemptions.⁶⁵ Similarly, after the 2019 measles outbreak (see Table 1), which brought the United States close to losing its WHO measles elimination status, the states of Washington, Maine, and New York enacted legislation to remove personal and religious exemptions.⁶⁵ (See Figure 1.) Several other states also tried to remove nonmedical exemptions but were not successful.⁶⁵ Removal of such exemptions is associated with higher coverage rates of the diphtheria, tetanus, and acellular pertussis vaccine (DTaP) and the measles, mumps, and rubella vaccine (MMR) in children.⁶⁴

Table 1. Number of Reported Cases of Measles, 2015–2020, United States

Year	Number of Cases
2015	188
2016	86
2017	120
2018 ^a	375
2019 ^a	1,282
2020 ^b	13

^a From October 2018 through July 2019, outbreaks of measles in New York City and New York state accounted for 1,101 (75%) of the 1,459 reported cases in the United States. Most of the cases occurred in children who were not vaccinated against measles.

^b Through November 30, 2020.

Source: [Centers for Disease Control and Prevention](https://www.cdc.gov/).

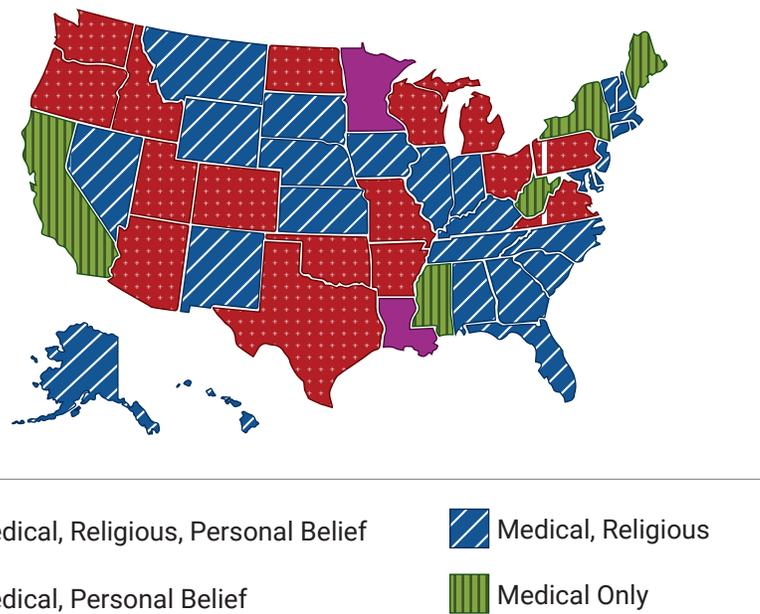


Figure 1. Exemptions permitted to school and child-care immunization requirements, United States, June 2019. Source: [Immunization Action Coalition](https://www.immunizationactioncoalition.org/).

Public health officials and researchers need more evidence and understanding of origins and proponents of vaccine antagonism to develop effective strategies to counter them.⁵⁶ Study of the nuanced drivers of vaccine hesitancy and how they vary by geography, socio-demographics, cultural norms and beliefs, and other characteristics would benefit from input from a wider range of disciplines, such as anthropology, sociology, and behavioral economics.⁶⁵ Development of methods and measures to monitor vaccine hesitancy is also needed.^{66,67,68} With a better understanding of these data, and with a more inclusive engagement of community leaders and organizations, more effective interventions to address hesitancy and its drivers can be developed.⁶⁷

4. ACCESS TO AND USE OF ROUTINELY RECOMMENDED VACCINES

Since the release of the 2010 National Vaccine Plan, access to and use of routinely recommended vaccines have improved, such as influenza vaccination among pregnant women⁶⁹ and HPV vaccination for adolescents (although HPV vaccination rates are still low).^{6,70} In the 2010 National Vaccine Plan and this Vaccine Plan, the terms *routinely used* or *routinely recommended* include vaccines that are used in routine non-outbreak settings, including those that are recommended for general populations and for specific or at-risk populations. Several factors have contributed to improved access to vaccines over the past decade—expanding availability of vaccines in nontraditional 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, and disparities by age, socioeconomic status, geography, race and ethnicity persist.⁷¹ Recent data indicate:

- Black and Hispanic adults have lower vaccination rates than white for all recommended adult vaccines, and Asian adults have lower rates than whites for all but three vaccines, hepatitis A, hepatitis B, and influenza;⁷
- Rural adolescents are less likely to receive their first dose of the HPV or meningococcal conjugate vaccines than those living in urban areas;⁷²
- People without health insurance have vaccination rates that are significantly lower than people with health insurance for influenza, shingles, HPV, and other diseases;⁷² and
- Black and Hispanic health care professionals have lower vaccination rates than white health care professionals for influenza, hepatitis B, and Tdap.⁷



BOX 1

A SNAPSHOT OF VACCINATION COVERAGE IN THE UNITED STATES

Young children (age 2 years): Among children born during 2016–2017, greater than 90% have completed the vaccination series for polio, hepatitis B, MMR, and varicella (chickenpox), but only 58% received ≥ 2 doses for influenza (most children are recommended to receive three doses of influenza vaccine by age 24 months).⁷³

Adolescents (age 13–17 years): In 2019, 89% of adolescents received a meningococcal vaccine, but only 54% completed HPV vaccination series.⁶

Pregnant women: During the 2019–2020 season, only 40% of pregnant women received both the recommended influenza vaccine and the tetanus, diphtheria, and pertussis (Tdap) vaccine.⁷⁴

Adults (age 18 years or older): During the 2019–2020 season, less than one-half of adults received an influenza vaccine. In 2017, less than one-quarter of adults age 65 years or older received all recommended vaccines for their age.⁷

A growing awareness of the impact of social determinants of health—a complex interplay of factors such as poverty, stigma, housing and food insecurity, discrimination, racism, medical mistrust, violence/trauma, access to care, and education—has reshaped the understanding of disparities in vaccination rates as health inequity arising from underlying systemic barriers. An NVAC subcommittee report on immunization equity is currently in development for consideration by the full NVAC, and if the NVAC votes to adopt it as its recommendations after public deliberation, it may provide further guidance for the federal government’s approach to this disparity issue.

The availability of vaccination services in nontraditional settings, such as workplaces, pharmacies, retail locations, and schools, has improved access.⁷⁵ Including vaccination as a part of workplace wellness programs benefits employers and employees.^{76,77} Workplace influenza vaccination can reduce employee absenteeism. Among full-time employees in the United States, nearly 3 days of work is lost per person-episode of influenza-like illness.⁷⁸

Pharmacies are an important setting through which access to vaccines has been greatly expanded.⁷⁹ Pharmacists have delivered vaccination services for more than two decades. Policy changes at the state and federal levels have enabled pharmacists to expand significantly their scope of practice and administer more vaccines to broader age groups. Pharmacists offer vaccinations at times and locations that often are convenient to most people in their communities. Pharmacists who administer vaccines can also link patients to or coordinate with their patient-centered medical home or primary care provider and are critical members of the local health care community. Pharmacists have been key participants in pandemic planning in all states and have a critically important role in COVID-19 vaccination efforts in local communities.

Opportunities exist to identify and address challenges associated with payments for vaccination services.²⁸ Continuing to address financial barriers for patients and providers will accelerate progress in vaccination coverage rates and help reduce disparities by socioeconomic status, race, and ethnicity. Since the release of the 2010 National Vaccine Plan, more than 20 million Americans have gained access to health insurance, which generally covers routinely recommended vaccinations without copayments.^{80,81} However, 27.5 million people, or 8.5% of the population in the United States, including 4.3 million children, did not have health insurance in 2018.^{82 83}

Vaccines for Children (VFC) is a federal entitlement program that provides free vaccines for children whose families are un- or underinsured, children eligible for Medicaid, and American Indian/Alaskan Native children.⁸⁴ 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.⁸⁵ However, challenges remain for many children whose access to vaccines may be limited due to other barriers such as a lack of transportation and limited vaccination service locations in their communities.⁷⁵ Much remains to be done to eliminate financial barriers for adults and their health care providers. For example, Medicare Part B does not cover all routinely recommended vaccines for adults age 65 years or older. Under Medicare Part D, individuals who are enrolled in a prescription drug plan may access vaccines that are not covered under Medicare Part B. In general, Part D prescription drug plans are required to cover all commercially available vaccines unless they are covered under Part B.⁷³ Cost-sharing for these vaccines varies based on the Part D plan. For health care providers, Medicaid reimbursement for adult vaccination services may not provide incentives to promote vaccines as a part of their routine patient care.⁸⁶

Health care providers seek 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.⁶³ 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. Immunization programs use IIS to monitor vaccination coverage rates and trends and support development of program strategies and priorities. State immunization programs do not have the legal authority to share individual vaccination data across jurisdictions, despite the technological capacity for IIS to do so, which limits the use of IIS. To optimize the use of IIS, improvements in interoperability and data exchange between electronic health records (EHRs) used by health care providers and IIS, interconnecting IIS across jurisdictions, and modernizing legal and policy standards are needed.⁸⁷

5. GLOBAL IMMUNIZATION

The United States supports efforts to vaccinate children and adults around the world.²⁸ Global immunization efforts help protect the United States, given that a person with an infectious virus or disease can travel from

one part of the world to any other part regardless of geopolitical borders, as evidenced 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 assist governments in managing vaccination programs.⁸⁸

Over the past decade, progress has been made toward global vaccination coverage and associated reductions in VPDs. In 2019, the global coverage rate for the diphtheria, tetanus, and pertussis vaccine (DTaP) was 85%, which is the highest level ever reported.⁸⁹ In 2018, 142 countries offered pneumococcal conjugate,⁹⁰ 101 countries offered rotavirus,⁹¹ and 90 countries offered HPV vaccines.⁹² Maternal and neonatal tetanus remains endemic in only 12 countries, and two of three strains of wild-type polio have been eradicated through the use of vaccines. In addition, innovative methods to deliver 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, over the past decade, progress has stalled in other areas because of armed conflicts,⁹³ 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.^{55,94} Measles outbreaks and circulating vaccine-derived polio virus are proof that sustaining disease eradication and elimination goals requires strong immunization programs and investments in public health infrastructure. In 2019, 13.5 million infants worldwide did not receive any vaccine and more than 1.5 million people died from VPDs.⁹¹ Conflicts and poverty have severely weakened health systems in many countries such as Venezuela, Syria, and Yemen.^{95,96} The rapid worldwide spread of COVID-19 demonstrated yet again 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. Therefore, the need to support global partners to vaccinate children and adults, strengthen immunization systems and infrastructure, overcome barriers to access to vaccines, and promote vaccine confidence is an important goal of the Vaccine Plan.

C. Scope, Approach, and Development of the Vaccine Plan

The Vaccine Plan provides a 5-year roadmap for the coordination of vaccine development and use in the United States. The Vaccines Plan is intended to provide a roadmap for strengthening vaccination infrastructure across public and private sectors, including addressing immunization and health equity, to prevent VPDs across the lifespan and maintain the highest levels of vaccine safety in the United States. The Vaccine Plan does not address the use of therapeutic vaccines, such as vaccines that are used to treat cancer (immunotherapy). It also does not focus on the uniquely accelerated vaccine development process for COVID-19, although it does recognize that lessons learned from the COVID-19 vaccine development will need to be incorporated into future strategies.

The COVID-19 pandemic has been a catalyst for immunization infrastructure improvements and vaccine innovation. The Vaccine Plan seeks to capture and capitalize upon the strides made during the pandemic to ensure that lessons learned and best practices are not lost. Applying these lessons learned will require sustained investment in public health and immunization programs, as well as vaccine research and development. Doing so will ultimately put the United States in a better position to respond to the next public health crisis and further address VPDs.

The Vaccine Plan sets forth an overarching vision and set of interconnected goals and provides specific objectives and recommended strategies to achieve its goals. Implicit in all of its goals is promotion,

coordination and mobilization of vaccine development and use, and associated activities among federal agencies and relevant stakeholders. It also provides specific indicators with which to measure progress and quantitative targets for each indicator. These components—vision, goals, objectives, strategies, indicators, and targets—are all set forth in Section II of the Plan. The methodology for developing the Vaccine Plan, including extensive stakeholder input, is detailed in Appendix A.

The Vaccine Plan focuses on policies, initiatives, and activities related to vaccines that are used routinely to prevent infectious diseases in the United States across the lifespan. Its success relies on the active engagement and participation of public and private stakeholders. Section III discusses implementation of the Vaccine Plan and mechanisms to ensure accountability for its implementation.

II. VACCINES NATIONAL STRATEGIC PLAN

The goals, objectives, strategies, and indicators are cross-cutting, and the order in which they are presented does not indicate any prioritization among them.

A. Vision

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

B. Goals

In pursuit of this vision, the Vaccines Plan establishes five goals:



1. Foster innovation in vaccine development and related technologies



2. Maintain the highest levels of vaccine safety



3. Increase knowledge of and confidence in routinely recommended vaccines



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



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

C. Objectives and Strategies

The Vaccine Plan sets forth objectives for each goal, and strategies for each objective (see Table 2 for definitions). These objectives and strategies are designed to guide federal partners and other stakeholders in achieving the Vaccine Plan's vision and goals. The objectives provide direction for the attainment of each goal. The strategies recommend approaches to achieve the objectives. The objectives and strategies offered in the Vaccine Plan are intertwined and overlapping and may be used to make progress toward more than one goal; many objectives and strategies may fit under more than one goal. However, each one has been placed under the goal in which it most closely aligns. The objectives and associated strategies for each goal of the Vaccine Plan are presented below with a brief introduction.

Table 2. Definitions Included in the Vaccine Plan^a

Vaccine Plan	Federal Implementation Plan
<p>Goals: Broad aspirations that enable a plan’s vision to be realized</p> <p>Objectives: Changes, outcomes, and impact a plan is trying to achieve</p> <p>Strategies: Choices about how best to accomplish objectives</p>	<p>Action Steps: Specific activities that will be performed to implement the strategies and achieve the goals of the plan</p> <p>Progress Reports: Reports on progress, successes, and challenges</p>

^a Adapted from the HHS Office of the Assistant Secretary for Planning and Evaluation.



GOAL 1: FOSTER INNOVATION IN VACCINE DEVELOPMENT AND RELATED TECHNOLOGIES

The aim of Goal 1 is to promote the development of new vaccines and improvements to existing vaccines. As described in Section I, recent years have seen much progress in the development of many new and improved vaccines and related technologies. Continued focus and investment is needed to sustain and build upon this progress. For example, the need for new vaccines is significant including a universal influenza vaccine, maternal immunizations, and vaccines against vector-borne diseases. Also needed are improvements to existing vaccines to improve their effectiveness, manufacturing speed and capacity, and delivery mechanisms. Challenges throughout the product development pathway can hinder progress and must be addressed to further promote innovation in the development of vaccines and related technologies. In addition, to ensure confidence in these vaccines, the development and approval process must be rigorous and transparent before they are approved and recommended for use.

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.



GOAL 1: FOSTER INNOVATION IN VACCINE DEVELOPMENT AND RELATED TECHNOLOGIES

Objectives

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

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 evaluate and apply lessons learned from the development of COVID-19 vaccines and vaccination planning.

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 and effectiveness.
- 1.2.3 Disseminate best practices in vaccine development and administration.
- 1.2.4 Encourage expansion of the vaccine chain supply capacity, including ancillary resources needed to administer vaccines (e.g., syringes, vials).



GOAL 2: MAINTAIN THE HIGHEST LEVELS OF VACCINE SAFETY

The aim of Goal 2 is to maintain the highest levels of vaccine safety and effectively communicate the strengths of the U.S. vaccine safety system to providers, policymakers, and the public. As noted in the challenges and opportunities section of the Vaccine Plan, VAERS, VSD, and the Sentinel Initiative provide a strong foundation for the vaccine safety monitoring infrastructure in the United States. Prior vaccine safety reviews have shown that serious side effects from vaccines are extremely rare.⁹⁷ Continued innovation in vaccine technology and safety monitoring systems is necessary to maintain high levels of vaccine safety. Since the publication of the 2010 National Vaccine Plan, additional capabilities have been developed with advanced analytic methods applied to large integrated datasets to rapidly detect vaccine safety signals.



GOAL 2: MAINTAIN THE HIGHEST LEVELS OF VACCINE SAFETY

Objectives

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

The first objective under Goal 2 seeks to minimize preventable vaccine-related adverse events by better understanding the mechanisms of these adverse events and providing education and training for health care providers on their prevention and treatment. 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 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, training, and expert consultation resources 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, tribal, territorial, and local public health authorities and vaccine manufacturers
- 2.2.4 Develop and enhance processes to facilitate and simplify health care provider reporting of adverse events associated with vaccines and vaccinations.

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.



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 and vaccines under development. The terms routinely used and routinely recommended refer to vaccines that are used in routine, non-outbreak settings, including those that are recommended for specific portions of the population as well as the general population. The increasing spread of mis- and disinformation and mischaracterization of science and institutions erode confidence and sow

hesitancy in the use of vaccines. 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.

Ensuring accuracy of vaccine information will require a multifaceted approach. The objectives under Goal 3 and their associated strategies focus on increasing knowledge and confidence among health care providers, policymakers, and the public. The first objective focuses on increasing public support for vaccination by countering mis- and disinformation. This objective promotes using effective communication strategies to increase transparency about the vaccine development and regulatory process, and builds understanding and support for the individual and societal benefits of vaccination through educational awareness. The messages should be plain, and linguistically and culturally appropriate, and use auxiliary aids (e.g., close captioning, sign language).

The second objective focuses on health care providers across the spectrum, including physicians, nurses, nurse practitioners, physician assistants, pharmacists, medical and pharmacy technicians, and allied health care providers. Its aim is to strengthen their capacity to make strong vaccination recommendations and promote vaccine acceptance.

The third objective focuses on policy 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 differences across communities and cultures influence vaccine confidence and acceptance. The objective aims to reduce disparities in immunization rates and promote health equity by developing a better understanding of these differences and by stakeholders working collaboratively to tailor messages and strategies to address the specific issues and concerns in communities. Enhancing the health care workforce to be reflective of populations served may also increase communities' confidence in recommended vaccines.

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 deliver compelling messages on vaccines and vaccinations by trusted messengers in plain language and using auxiliary aids and services.



GOAL 3: INCREASE KNOWLEDGE OF AND CONFIDENCE IN ROUTINELY RECOMMENDED VACCINES

Objectives

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

- 3.1.4 Maintain evidence-based, transparent processes for vaccine development, the regulatory process, distribution, and recommendations for 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, tribal, territorial, and local school boards to support development and dissemination of culturally and linguistically appropriate 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, with an emphasis on immunization across the lifespan.
- 3.2.2 Develop partnerships with health professional organizations, health professional training programs, and licensing and certification boards to strengthen communications and training of health care providers about the importance of vaccines and best practices for vaccine counseling and administration.
- 3.2.3 Scale up implementation of best practices among health care providers to effectively promote vaccine confidence and vaccination uptake.
- 3.2.4 Simplify immunization practice guidelines where possible to make them easier to implement in practice.

Objective 3.3: Ensure key decision- and policymakers receive accurate and timely information on vaccines and strategies to promote vaccine uptake

Strategies:

- 3.3.1 Support development of state, tribal, territorial, and local communities of practice to facilitate implementation of evidence-based strategies to increase vaccine uptake.
- 3.3.2 Educate legislators, executive officers, and policymakers in jurisdictions 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 and implement targeted interventions to address them.
- 3.4.3 Further develop, implement, and evaluate metrics to better understand vaccine confidence by age, race, ethnicity, disability, 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 culturally and linguistically appropriate messages and strategies in those communities.
- 3.4.5 Support efforts to strengthen the diversity of the health care workforce to increase vaccine confidence and acceptance across diverse 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 a part of much broader issues with health care access in the United States. Challenges include patient-level barriers to vaccination, as well as the financial and systems barriers that providers face in providing vaccinations. 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 enabled to administer them.

Achieving this goal requires addressing the social determinants of health, which contribute to disparities in access to routinely recommended vaccines. In addition, expanding the number and types of health care settings, such as obstetrics-gynecology practices, specialty clinics, substance use and mental health treatment facilities, and occupational health clinics, that provide vaccinations can increase opportunities for people to be vaccinated. In addition, expanding community-based points of access to vaccines, such as pharmacies, schools, and community-based organizations, are necessary.

For health care 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 to access reliable information to determine whether a vaccine is indicated for the patient and be adequately reimbursed for vaccination services including counseling. Payments for vaccination services should be adequate and standardized, and barriers to payment for vaccination services should be addressed.

The first objective under Goal 4 focuses on making vaccines available in a variety of settings and seizing 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 disparities in vaccination coverage for program improvement. 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 to manufacture vaccines to meet demands created by routine use and, as highlighted by the COVID-19 pandemic, during outbreaks. Such partnerships are critically important in vaccine allocation, distribution, tracking, and accountability.



GOAL 4: INCREASE ACCESS TO AND USE OF ALL ROUTINELY RECOMMENDED VACCINES

Objectives

- 4.1 Increase the availability of vaccines in a variety of settings
- 4.2 Reduce disparities and inequities in access to and use of routinely recommended vaccines across the lifespan
- 4.3 Strengthen data infrastructure, including Immunization Information Systems, to track vaccine coverage and conduct surveillance of vaccine-preventable diseases
- 4.4 Reduce financial and systems barriers for health care providers to facilitate delivery of routinely recommended vaccines
- 4.5 Reduce financial and systems barriers for the public to facilitate access to routinely recommended vaccines
- 4.6 Promote public-private partnerships to increase the capacity of the health system to deliver vaccines for routine use during outbreaks

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 pharmacies, obstetrics-gynecology practices, other specialty health care settings, and non-health care settings such as schools, workplaces, places of worship, and community 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, disability, 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, tribal, territorial, 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.
- 4.2.4 Scale up implementation of evidence-based practices to improve immunization equity.

Objective 4.3: Strengthen data infrastructure, including Immunization Information Systems, to track vaccine coverage and conduct surveillance of vaccine-preventable diseases

Strategies

- 4.3.1 Improve Immunization Information System reporting, its interoperability across jurisdictions, 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 Immunization Information System reporting by adult vaccination service providers.
- 4.3.5 Increase data sharing and collaboration across public health, health care systems, and payers to better assess and improve vaccine coverage and disparities and increase data analytics capacity.

Objective 4.4: Reduce financial and systems barriers for health care providers to facilitate delivery of routinely recommended vaccines

Strategies

- 4.4.1 Support adequate payments for vaccine counseling and administration.
- 4.4.2 Encourage development and implementation of best business practices to improve vaccination services at the health care provider 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 Remove system barriers to implementation of innovative services such as the use of mobile vans and telehealth and support adequate reimbursement for these services.

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 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 Improve 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 during outbreaks

Strategies

- 4.6.1 Strengthen public-private partnerships to improve vaccine ordering, distribution, and tracking for routine use, outbreak control, and during public health emergencies.
- 4.6.2 Develop and practice strategies to continue to deliver routine vaccinations during public health emergencies.
- 4.6.3 Review 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. Although the Vaccine Plan is a national plan, the United States is firmly committed to continued collaboration with and support of partners in global immunization efforts as a critical element of the nation’s broader health security agenda. The success of the United States’ national vaccine strategy will remain 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, advancing regulatory science, and other activities are leveraged every day in support of global immunization.

However, as discussed in Section I, several emerging issues are threatening the global uptake of vaccinations, including conflicts, political instability, population displacement, and the spread of mistrust of science. In a 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 in Goal 5 aligns with Goal 1 and expands the focus to global vaccine research and development to

address VPDs. The second objective aligns with Goal 3 and is focused on supporting global partners in their efforts to counter vaccine mis- and disinformation by working with immunization programs in other countries to disseminate evidence-based vaccine information and other strategies. The third objective aligns with Goal 4, seeking to support global partners' efforts to strengthen their immunization systems, including through digital and data tools to conduct vaccination campaigns more efficiently, manage supply chains, and monitor vaccine coverage. The fourth objective calls for improved coordination by U.S. federal agencies and global partners on global vaccine advocacy and to harmonize global regulatory processes where possible.

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 Support social and economic investments to 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 diseases, adverse events associated with vaccines, and emerging infectious diseases.
- 5.3.2 Leverage digital and data tools to effectively target vaccination campaigns, efficiently manage supply chains, and accurately monitor vaccination coverage.



GOAL 5: PROTECT THE HEALTH OF THE NATION BY SUPPORTING GLOBAL IMMUNIZATION EFFORTS

Objectives

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

- 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 distribution in 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 Improve collaboration with the global regulatory community to enhance regulatory convergence, where feasible.
- 5.4.2 Increase collaboration with global partners on vaccine advocacy including promoting vaccine confidence.
- 5.4.3 Facilitate data sharing to advance how vaccine coverage, safety, and effectiveness are monitored globally.

III. IMPLEMENTATION AND ACCOUNTABILITY

A. Implementation

Achieving the goals of the Vaccine Plan requires the collaboration of federal and nonfederal stakeholders around a shared vision and coordination of activities. Working toward a nation free of VPDs depends on state, tribal, territorial, and local governments; community-based and faith-based organizations; health care providers and their professional organizations; health plans; researchers; vaccine manufacturers; advocacy organizations; and the public working together. Stakeholders are encouraged to use this national plan as a reference to build or update their own plans to promote the use of vaccines and reduce VPDs.

Federal partners will collaborate to develop an implementation plan to support the Vaccine Plan goals, objectives, and strategies. The implementation plan will set forth federal partners' commitments to take action to meet the goals of the Vaccine Plan. A federal implementation working group will convene to coordinate policies, initiatives, and activities across federal agencies and departments; implement lessons learned from epidemiological data and research findings; monitor and report on national progress; and course correct as needed.

B. Accountability Including Indicators to Measure Progress

The Vaccine Plan includes 10 indicators and associated quantitative targets to be maintained or achieved by 2025 (Table 3). These indicators and targets will be used to measure progress and inform future implementation and quality improvement efforts. The selected indicators measure outcomes or progress and have data that are nationally representative and collected on a regular basis. The choice of indicators was intentionally kept simple; the indicators do not identify the use of all routinely recommended vaccines.

The selected indicators reflect the Vaccine 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. Three indicators were chosen due to their significance as indicators of pediatric immunization; they have targets that aim to maintain the high levels of baseline performance. For other indicators, where available, existing targets for the indicators, such as from *Healthy People 2030*, were adopted or were informed by analysis of trends. Five- and 10-year targets that are ambitious but achievable have been identified. Appendix A describes the methodology for choosing indicators and the targets. However, the COVID-19 pandemic may impact progress as disruptions in routinely recommended vaccinations have occurred.

The Vaccine Plan also includes three additional indicators that are developmental. Developmental indicators focus on the need to develop data sources and collect critical data to monitor vaccination rates in the United States. They do not have baseline, 5-year, or 10-year targets because data for them are not currently available. These developmental indicators are aligned with the Healthy People 2030 Immunization and Infectious Disease objectives.⁹⁸ The three developmental indicators recommended to supplement the existing indicators are:

1. Percentage of pregnant women who received one dose of Tdap during pregnancy;
2. Percentage of IIS that tracks immunizations across the lifespan; and
3. Percentage of adults age 19 years or older who receive recommended age-appropriate vaccines.

The Vaccine Plan is dynamic and data driven. The list of indicators could be enhanced by disaggregating data by race, ethnicity, gender, and other demographic characteristics related to immunization equity. In addition, the

Vaccines Plan recognizes the potential impact of immunization quality measures and calls for expansion of such measures.

Table 3. Indicators and Targets for the Vaccine National Strategic Plan 2021-2025

Indicator	Baseline (%) (Year)	2025 Target (%)	2030 Target (%)	Data Source ^a
Pediatric populations				
Percentage of children aged <6 years whose immunization records are in a fully operational, population-based IIS	96 (2019)	> 95	> 95	IISAR
Percentage of children enrolled in kindergarten who received ≥2 doses of MMR	95 (2018–2019)	> 95	> 95	ASAR
Percentage of children who received ≥4 doses of DTaP by their 2nd birthday	80.6 of children born in 2016–2017	85	90	NIS-Child
Percentage of kindergarten population with a nonmedical exemption from school vaccination requirements	2.2 (2018–2019)	2	2	ASAR
Percentage of adolescents aged 13–17 years who receive recommended doses of HPV vaccine	54 (2019)	80	85	NIS-Teen
Adult populations, including pregnant women and older adults				
Percentage of adults aged ≥19 years who have one or more immunizations recorded in an IIS	60 (2019)	80	90	IISAR
Percentage of non-institutionalized high-risk adults aged 18–64 years vaccinated against pneumococcal disease	24.3 (2017)	60	70	NHIS
Percentage of non-institutionalized adults aged ≥65 years and older vaccinated against pneumococcal disease	69.0 (2017)	90	95	NHIS
Percentage of pregnant women who received influenza immunization during pregnancy	53.5 (2016–2017)	80	95	NHIS
All populations				
Percentage of persons aged ≥6 months who are vaccinated annually against seasonal influenza	51.8 (2019–2020)	60	70	NHIS

^a ASAR = [Annual School Assessment Report](#); IISAR = [Immunization Information Systems Annual Report](#); NHIS = [National Health Interview Survey](#); NIS-Child = [National Immunization Survey–Child](#); NIS-Teen = [National Immunization Survey–Teen](#)

APPENDIX A: PROCESS/METHODOLOGY FOR DEVELOPING AND ADOPTING THE VACCINE PLAN

The process for developing the Vaccine Plan included engaging federal leadership, experts, and nonfederal partners to compile subject matter evidence and recommendations to promote vaccines and vaccination including research and development, vaccine safety monitoring, vaccine knowledge and confidence, increased access to 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. The Vaccine Plan aligned its indicators and quantitative targets with *Healthy People 2030* objectives.

Federal Leadership

The federal Interagency Vaccine Working Group (IVWG) was convened to set the vision, goals, objectives, strategies, and indicator measures for the Vaccine Plan. Development of the Vaccine Plan was an iterative process with substantial recommendations from the National Vaccine Advisory Committee (NVAC), stakeholders, and the public as a result of opportunities for public comment. Revisions and the final draft of the Vaccine Plan were approved by the IVWG. The IVWG consisted of senior representatives from four federal departments and nine HHS agencies and offices (see Table A.1 and Appendix C) and met from July 2019 through October 2020.

Development of the Vaccine Plan was facilitated by the Office of Infectious Disease and HIV/AIDS Policy (OIDP), Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services.

Table A.1. Federal Departments and Agencies Represented in the Interagency Vaccine Working Group

Federal Departments	HHS Agencies/Offices
<ul style="list-style-type: none"> • Department of Defense • Department of Health and Human Services • Department of Veterans Affairs • U.S. Agency for International Development 	<ul style="list-style-type: none"> • Agency for Healthcare Research and Quality • Biomedical Advanced Research and Development Authority • 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 • Office of the Assistant Secretary for Health

Stakeholder and Public Input

NATIONAL VACCINE ADVISORY COMMITTEE

The NVAC is a federal advisory committee, governed by the Federal Advisory Committee Act, that, pursuant to the Public Health Service Act section 2105 (42 U.S.C. 300aa–5), studies and recommends to the Assistant Secretary for Health, as Director of the National Vaccine Program, ways to encourage the availability of an adequate supply of safe and effective vaccination products in the United States, recommends research priorities and other measures the Assistant Secretary for Health should take to enhance the safety and efficacy of vaccines, advises the Assistant Secretary for Health in the implementation of his responsibilities under the National Vaccine Program and in issuing a plan for implementation, and identifies for the Assistant Secretary for Health the most important areas of government and nongovernment cooperation that should be considered in implementing National Vaccine Program responsibilities. In March 2019, the Assistant Secretary for Health requested that the NVAC develop recommendations to guide the development of the Vaccine Plan. The NVAC submitted its recommendations to the Assistant Secretary for Health in September 2019, and its full report was published in Public Health Reports.⁹⁹ The NVAC’s recommendations informed the IVWG in its development of the Vaccine Plan.

OTHER STAKEHOLDER AND PUBLIC INPUT

Stakeholder and public input was gathered through an announcement in the *Federal Register* that solicited comments on the plan to develop a national strategy on vaccination, and individual and small group interviews were conducted 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, 2019.¹⁰⁰ The purpose of the RFI was to collect input from stakeholders and the general public on the priorities, goals, and objectives for the Vaccine Plan. During the 30-day comment period, OIDP received 1,334 responses, including submissions from professional, advocacy, and other organizations (listed in Table A.2).

Table A.2. Organizations That Submitted Comments in Response to the September 24, 2019, Request for Information

- | | |
|--|--|
| <ul style="list-style-type: none">• American Academy of Family Physicians• American Academy of Pediatrics• America’s Health Insurance Plans• Association of Immunization Managers• American Nurses Association• Association of State and Territorial Health Officials• Big Cities Health Coalition• Biotechnology Innovation Organization• Global Health Technologies Coalition• GlaxoSmithKline• The Hepatitis B Foundation | <ul style="list-style-type: none">• National Association of Chain Drug Stores• National Association of City and County Health Officials• National Association of Nutrition and Aging Services Programs• National Committee for Quality Assurance• PATH (also known as Program for Appropriate Technology in Health)• Statewide Parental Advocacy Network and NJ Family Voices• Trust for America’s Health• Walgreens• West Virginia Immunization Network |
|--|--|

All submitted comments were compiled for analysis using Dedoose 8.2.14 (SocioCultural Research Consultants, LLC, Los Angeles, CA). After excluding comments that were deemed not relevant, such as a copy of the RFI without accompanying comments, the remaining 1,326 comments were sorted to identify patterns and synthesize themes, attributed to one or more goals identified in the Vaccine Plan, and analyzed for consideration.

Of the 1,326 comments, 24 provided input that directly aligned with one or more of the five goal areas of the Vaccine Plan (see Table A.3). The remainder of commenters expressed concerns about vaccines, including a large number with identical or nearly identical content.

Table A.3. Number of Commenters Who Directly Addressed Each of the Five Proposed Goals

2020 Vaccine Plan Proposed Goal	Number of Commenters (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. The commenters encouraged ODP to engage a broad range of stakeholders, including those that are new or currently underutilized, in the development of the Vaccine Plan to promote a wider and more active implementation. 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 Vaccine 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 Vaccine 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 health care 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 vaccine experts through individual and small group interviews. Twenty-six semi-structured individual and group interviews were conducted by telephone with 65 experts in October 2019. Their expertise spanned 13 topic areas and perspectives (see Table A.4).

Table A.4. Stakeholder Categories Represented in Individual and Group Interviews

Stakeholder Category	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 and adolescent health-related organizations	2
Occupational health experts	4
Policy organizations	10
Organizations representing historically marginalized populations	2
Global health organizations	5
Academia and 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 stakeholder interviewed, as well as questions tailored to 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 themes.

Feedback received from stakeholders through these interviews 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 is 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 no business case 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 Vaccine Plan. They identified four challenges related to vaccine hesitancy: (1) growing anti-vaccine sentiment and spread of misinformation; (2) varied reasons for vaccine hesitancy in different 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 overcome to improve 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 availability of 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 Vaccine Plan's objectives and strategies.

PUBLIC COMMENT ON DRAFT VACCINES NATIONAL STRATEGIC PLAN 2021–2025

OIDP published an RFI in the [Federal Register](#) on November 23, 2020, seeking public comment on the draft Vaccines National Strategic Plan: 2021–2025. Comments were received from 19 commenters. These comments were reviewed and analyzed and incorporated into the Vaccine Plan.

Developing Indicators and Quantitative Targets

INDICATORS

The IVWG was tasked to review and approve indicators and quantitative targets for the Vaccine 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 Vaccine Plan, an indicator must:

- relate to at least one goal in the Vaccine Plan;
- be consistent with current vaccination 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 3 developmental indicators. Developmental indicators in the Vaccine Plan are measures that do not currently have an identified data source but would help measure some high-priority issues. The developmental indicators adopted by the IVWG are also recommended by Healthy People 2030. The IVWG discussed these indicators and developmental indicators and approved them for inclusion in the Vaccine Plan.

INDICATOR 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: FEDERAL INTERAGENCY VACCINE WORKING GROUP AND OIDP STAFF

Development and preparation of the Vaccines National Strategic Plan: 2021–2025 was led by the U.S. Department of Health and Human Services (HHS), Office of the Assistant Secretary for Health (OASH) through the Office of Infectious Disease and HIV/AIDS Policy (OIDP).

The federal Interagency Vaccine Working Group served as the Steering Committee guiding development of the Vaccine Plan.

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Rose Li & Associates under contract HHS75N98020R0026, in particular Nancy Tuveson, and its subcontractor Blue Door Consulting.

APPENDIX C: ACRONYMS

ACIP	Advisory Committee on Immunization Practices
ASAR	Annual School Assessment Report
CDC	Centers for Disease Control and Prevention
COVID-19	2019 coronavirus disease
DTaP	diphtheria, tetanus, and acellular pertussis vaccine
EHR	electronic health record
FDA	Food and Drug Administration
HHS	U.S. Department of Health and Human Services
HIV	human immunodeficiency virus
HPV	human papillomavirus
IHS	Indian Health Service
IID	Immunization and Infectious Disease
IIS	Immunization Information Systems
IISAR	Immunization Information Systems Annual Report
IVWG	Interagency Vaccine Working Group
MMR	measles, mumps, and rubella vaccine
NAIP	National Adult Immunization Plan
NHIS	National Health Interview Survey
NIS-Child	National Immunization Survey–Child
NIS-Teen	National Immunization Survey–Teen
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
Tdap	tetanus, diphtheria, and acellular pertussis vaccine
VAERS	Vaccine Adverse Event Reporting System

VFC	Vaccines for Children
VPD	vaccine-preventable disease
VSD	Vaccine Safety Datalink
WHO	World Health Organization

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