

# VACCINES

**Federal Implementation 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 throughout the lifespan.*

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# INTRODUCTION

In January 2021, the Office of Infectious Disease and HIV/AIDS Policy (OIDP) in the Office of the Assistant Secretary for Health released the [Vaccines National Strategic Plan 2021–2025](#) (VNSP) under the authority of the Public Health Service Act Section 2103. The VNSP provides a broad framework for goals, objectives, and strategies to advance vaccine development and increase vaccine use and safety. It has five goals:



**Goal 1:** Foster Innovation in Vaccine Development and Related Technologies



**Goal 2:** Maintain the Highest Levels of Vaccine Safety



**Goal 3:** Increase Knowledge of and Confidence in Routinely Recommended Vaccines



**Goal 4:** Increase Access to and Use of All Routinely Recommended Vaccines



**Goal 5:** Protect the Health of the Nation by Supporting Global Immunization Efforts

The VNSP also identifies 10 indicators and associated quantitative targets to be maintained or achieved by 2025 (Appendix A). These indicators and targets will measure progress, address gaps, and inform future implementation and quality improvement efforts.

The VNSP was developed in collaboration with the Federal Interagency Vaccine Work Group (IVWG), which consists of senior leadership from 11 U.S. Department of Health and Human Services (HHS) agencies and 3 additional federal Departments, with coordinating support from OIDP (Appendices B and C). The federal agencies represented in the IVWG have distinct responsibilities in vaccine development, administration, safety monitoring, and policy. Synergistic collaboration and coordination among federal partners are crucial to administering and galvanizing national and international policies and programs that aim to eliminate vaccine-preventable diseases.

This *Vaccines Federal Implementation Plan* is a companion document to the VNSP. It is a compilation of coordinated immunization activities by federal agencies that collectively advance the goals of the VNSP. The *Vaccines Federal Implementation Plan* reports on vaccine development, administration, and policy based on the IVWG agencies' missions, priorities, regulatory and legislative directives, resources, and capacities. The activities were self-reported by agencies, identified through other plans, and informed by stakeholder engagement and public comments. Each activity corresponds with objectives and strategies identified in the VNSP.

While the VNSP is broad in scope, the *Vaccines Federal Implementation Plan* focuses on specific federal agency actions. The activities are not intended to be a comprehensive listing of federal agency vaccine programs and operations. Instead, this document highlights a selection of activities that demonstrate the agencies' commitment to reducing the burden of vaccine-preventable diseases.

Achieving the goals of the VNSP relies on public-private partnerships and stakeholders championing vaccine uptake. Although many activities identified in the *Vaccines Federal Implementation Plan* are agency-specific, they may also be suitable for implementation by state and local immunization programs, health care management systems, health care providers, professional organizations, academic institutions, vaccine advocacy organizations, and community organizations. Some activities are broad in scope, while others are specific. Each activity represents a commitment to achieving the goals identified in the VNSP.

In 2021, the coronavirus disease 2019 (COVID-19) became a vaccine-preventable disease in the United States. Although the *Vaccines Federal Implementation Plan* was developed while the COVID-19 public health emergency declaration was in effect,<sup>1</sup> it generally does not consider agency activities related to the COVID-19 vaccines presently in use in the United States. Future iterations of both the VNSP and the *Vaccines Federal Implementation Plan* may include COVID-19 vaccines more extensively.

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<sup>1</sup> Pursuant to Section 319 of the Public Health Service Act (42 U.S.C. § 247d), the Secretary of the Department of Health and Human Services (HHS) issued a *Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak* on January 31, 2020, and most recently renewed the declaration on July 15, 2021.

# PURPOSE AND AUDIENCE

The *Vaccines Federal Implementation Plan* is intended to inform the program planning processes for federal agencies to promote interagency collaboration and achieve optimal prevention of diseases through vaccinations. The target audience for the *Vaccines Federal Implementation Plan* is federal agencies engaged in vaccine development and use.

Non-federal partners in vaccine development and use, as well as members of the public, may be interested in the *Vaccines Federal Implementation Plan* as a report on how federal agencies work synergistically to coordinate their efforts. This document does not provide consumer information or advocate for vaccine policy changes. It does not mandate vaccination.

All activities included in the *Vaccines Federal Implementation Plan* are subject to budgetary constraints and other approvals, including the weighing of priorities and availability of authorized resources.

# FEDERAL ACTIVITIES<sup>2</sup>



## Goal 1: Foster Innovation in Vaccine Development and Related Technologies

### Objective 1.1: Support the development of innovative, safe, and effective vaccines to prevent infectious diseases of public health significance

*Strategy 1.1.1 Build upon prior efforts to prioritize new vaccine targets of global public health importance to guide research and development efforts.*

Action	Lead	Support
Convene scientific meetings and/or facilitate collaborative efforts among federal agencies to support the development of vaccines against infectious diseases of public health significance.	NIH	BARDA, CDC, FDA, IHS, OGA, ODP, USAID, VA
Support basic research on mechanisms of host-pathogen interaction and host immune response and preclinical studies to develop candidate vaccines and vaccine-related products.	NIH	BARDA, CDC, USAID

*Strategy 1.1.2 Identify and reduce market barriers to developing new vaccines.*

Action	Lead	Support
Evaluate and, where appropriate, enhance policies that support strengthening manufacturing and supply chains for vaccines in the United States.	ASPR	
Develop and implement sustainable investment strategies with the private sector that allow flexibility in financing for advanced development, licensure, and manufacturing of current and promising vaccine candidates and vaccine production platforms.	BARDA	
Evaluate incentives for the development and production of vaccines by private manufacturers and public-private partnerships to ensure adequate domestic pandemic manufacturing capacity and capability in the event of a public health emergency or disaster, such as a pandemic.	ASPR	

<sup>2</sup> Appendix D provides a list of acronyms.

*Strategy 1.1.3 Support research that advances vaccine development and enhances vaccine safety and effectiveness.*

Action	Lead	Support
Support investigator-initiated research to advance the development of innovative, safe, and effective vaccines to prevent infectious diseases of public health significance.	BARDA, NIH	
Conduct research related to pathogenesis and vaccine development.	FDA, NIH	CDC

*Strategy 1.1.4 Maximize efficiency in the vaccine development process.*

Action	Lead	Support
Support clinical trials to evaluate the effectiveness of adjuvanted influenza vaccines and reduce the dose of antigen required for the influenza vaccine.	BARDA	DOD, NIH, VA
Facilitate the use of advanced technologies and relevant scientific discoveries (e.g., newly identified clinical biomarkers or adaptive clinical trial designs).	FDA	BARDA

*Strategy 1.1.5 Undertake a systematic process to evaluate and apply lessons learned from the development of COVID-19 vaccines and vaccination planning.*

Action	Lead	Support
Support the development of more broadly protective vaccines for coronaviruses.	BARDA, NIH	CDC, FDA



## Objective 1.2: Support the development and uptake of technologies to improve vaccine manufacturing, storage, distribution, and delivery mechanisms

*Strategy 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.*

Action	Lead	Support
Develop domestic modernization strategies to manufacture vaccines efficiently and rapidly scale up production.	BARDA	CDC, FDA, OIDP
Ensure that a modern manufacturing base is flexible enough to support next-generation vaccine technologies.	BARDA	
Distribute vaccines for use in a pandemic or against other emerging vaccine-preventable disease threats.	CDC	DOD, HRSA, VA
Encourage innovations to improve storage and handling technologies.	CDC	BARDA, DOD, FDA, NIH

*Strategy 1.2.2 Encourage research and development of novel vaccine delivery mechanisms to increase safety and effectiveness.*

Action	Lead	Support
Support research and development of novel vaccine administration technologies (e.g., micro-patches) and vaccine adjuvants.	NIH	BARDA
Support training and capacity building programs for U.S.-based and international scientists for vaccine development, manufacturing, and distribution.	CDC	OGA, NIH, USAID

*Strategy 1.2.3 Disseminate best practices in vaccine development and administration.*

Action	Lead	Support
Provide best practices and guidelines about vaccine administration, storage, and handling to health care providers, including those in the Vaccines for Children (VFC) program.	CDC	CMS, DOD, HRSA, IHS, VA
Encourage health care providers to follow best practices in vaccine administration by providing vaccine refresher trainings regularly.	CDC, DOD, VA	HRSA, IHS

Strategy 1.2.4 Encourage expansion of the vaccine supply chain capacity, including ancillary resources needed to administer vaccines (e.g., syringes, vials).

Action	Lead	Support
Ensure implementation of best practices for rapid and effective distribution of vaccines.	CDC	DOD, VA
Provide guidance on storage, handling, and transportation of vaccines to support access in remote sites while maintaining the safety and integrity of the vaccine for use.	CDC	DOD, VA
Expand domestic surge capacity to ensure sufficient supplies to manufacture and administer vaccines (e.g., sterile injectables) while minimizing disruption to other commercial products.	BARDA	



## Goal 2: Maintain the Highest Levels of Vaccine Safety

### Objective 2.1: Minimize preventable vaccine-related adverse events

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

Action	Lead	Support
Support preclinical and clinical research related to the development of safe and effective vaccines, including studies among healthy adults, pregnant people, infants and children, older adults, immunocompromised persons, people with disabilities, racial and ethnic minority populations, and other disadvantaged populations.	NIH	BARDA, CDC, DOD, FDA, ODP, VA
Support research on biological mechanisms of adverse events associated with vaccines and vaccinations.	CDC, FDA	NIH
Update a systematic review of vaccine safety literature to inform vaccine safety monitoring.	AHRQ	DOD, ODP

*Strategy 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.*

Action	Lead	Support
Continue to improve and update education and training for vaccination service providers on proper vaccine administration practices in order to recognize, manage, and prevent vaccine-related adverse events.	CDC	DOD, FDA, HRSA, IHS, ODP, VA
Provide ongoing trainings for health care providers and other service providers who handle vaccines to maintain viability and safe vaccine administration, and monitoring and reporting for adverse events.	DOD, HRSA, IHS, VA	CDC

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

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

Action	Lead	Support
Continue to develop and improve vaccine safety monitoring systems (e.g., surveillance tools and data transfer technologies), investigate suspected vaccine safety signals, and disseminate vaccine safety data and recommendations for vaccine policy considerations.	CDC, FDA	CMS, DOD, VA
Promote and strengthen vaccine safety surveillance systems in IHS federal, tribal, and urban programs.	IHS	CDC

*Strategy 2.2.2 Develop innovative algorithms to detect safety signals associated with vaccines and vaccination in the vaccine tracking system.*

Action	Lead	Support
Continue to implement the “v-safe after vaccination health checker” that allows COVID vaccine recipients to use their smartphones to report post-vaccination adverse events to CDC directly.	CDC	

*Strategy 2.2.3 Facilitate the timely exchange of vaccine safety information between federal, state, tribal, territorial, and local public health authorities and vaccine manufacturers.*

Action	Lead	Support
Educate providers and consumers about vaccine safety information, including how to submit a report to the Vaccine Adverse Event Reporting System (VAERS).	CDC	CMS, DOD, FDA, HRSA, IHS, VA
Educate VA vaccinators on the importance of the adverse drug event reporting system (VA-ADERS), including through training that is specific to COVID-19.	VA	

*Strategy 2.2.4 Develop and enhance processes to facilitate and simplify health care provider reporting of adverse events associated with vaccines and vaccinations.*

Action	Lead	Support
Develop and implement systems to capture adverse events and/or medical errors, including vaccine administration errors.	CDC	DOD, VA
Ensure early reporting of adverse events through telehealth for the active-duty military population.	DOD	

**Objective 2.3: Increase awareness, understanding, and usability of the vaccine safety system for providers, policymakers, and the public**

*Strategy 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.*

Action	Lead	Support
Collaborate with professional and advocacy organizations to conduct vaccine safety outreach, engagement, and training activities.	CDC	FDA, HRSA, OIDP
Inform and support health care providers in reporting adverse vaccine events across established IHS passive and active vaccine safety surveillance systems.	IHS	

*Strategy 2.3.2 Improve access to current vaccine safety data to enable informed clinical decision-making.*

Action	Lead	Support
Continue to monitor vaccine safety data and disseminate findings to providers and the public.	CDC, FDA	CMS, HRSA, ONC, VA
Monitor and assess VAERS data on vaccine safety issues associated with DOD-affiliated individuals.	DOD	CDC



### Goal 3: Increase Knowledge of and Confidence in Routinely Recommended Vaccines

#### Objective 3.1: Counter vaccine mis- and disinformation and increase public support for the individual and societal benefits of vaccination

*Strategy 3.1.1 Promote vaccination as a social norm through coordinated traditional and social media campaigns.*

Action	Lead	Support
Disseminate immunization information through agency updates and channels on research, development, safety and effectiveness, licensure, recommended use, payment, legislation, policy, and other topics.	CDC, OIDP	CMS, DOD, FDA, HRSA, IHS, NIH, OGA, USAID, VA
Develop and disseminate regularly updated communication products in formats designed to reach specific target audiences such as racial and ethnic minority populations, people with limited English proficiency, people with disabilities, and veterans and active-duty military personnel.	CDC, DOD, HRSA, IHS, VA	FDA, OIDP
Develop and disseminate regularly updated communication products about vaccines and vaccine safety to Medicare beneficiaries, their providers, and state Medicaid agencies.	CMS	CDC
Utilize metrics to evaluate the effectiveness of communication on vaccine development and vaccination programs.	CDC	CMS, OIDP, VA
Track vaccination coverage rates, via dashboards, in the VA system to identify Veteran sub-populations that have low vaccine coverage rates and develop strategies to increase vaccine acceptance and access.	VA	
Promote vaccination as a routine, standard element of preventive care throughout the lifespan, including for pregnant people.	CDC, DOD, HRSA, IHS, OIDP, VA	CMS, OGA

*Strategy 3.1.2 Strengthen efforts to limit the spread of misleading and/or false information, including on social media, that can create discord and disrupt public trust in vaccines.*

Action	Lead	Support
Develop vaccine confidence messaging and multimedia materials.	CDC	CMS, DOD, FDA, HRSA, IHS, OIDP, VA
Provide messaging and multimedia materials to health care providers and trusted messengers in the community to enable them to address misleading or false information about vaccines.	CDC	CMS, DOD, FDA, HRSA, OIDP, VA

*Strategy 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.*

Action	Lead	Support
Develop and implement outreach activities that target hard-to-reach populations (e.g., racial and ethnic minority populations, rural communities, people with disabilities, older adults, persons with limited English proficiency, immigrants, and refugees) to increase awareness of and confidence in vaccines.	CDC, HRSA, IHS	CMS, DOD, NIH, OIDP, VA
Support health care providers in educating patients on recommended vaccines and collaborate with community leaders and organizations.	CDC, CMS, HRSA, IHS, VA	DOD, OIDP
Assess vaccine information statements for different target audiences and revise or translate the statements as needed.	CDC	DOD, HRSA, VA

*Strategy 3.1.4 Maintain evidence-based, transparent processes for vaccine development, the regulatory process, distribution, and recommendations for use.*

Action	Lead	Support
Ensure that decisions on vaccine approvals and recommended use of vaccines are evidence-based and transparent and that the information is publicly available.	CDC, FDA	

*Strategy 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.*

Action	Lead	Support
Support research to better understand vaccine hesitancy and to develop vaccine confidence best practices through the use of available funding mechanisms.	CDC, NIH	OIDP

*Strategy 3.1.6 Work with federal partners and state, tribal, territorial, and local school agencies to support the development and dissemination of culturally and linguistically appropriate health education curricula that foster vaccine knowledge and confidence from an early age.*

Action	Lead	Support
Promote efforts to analyze, select, or develop culturally competent materials for local education agencies, and community- and faith-based organizations.	CDC	

**Objective 3.2: Increase provider capacity to promote knowledge of the benefits of immunization and increase vaccine acceptance by the public**

*Strategy 3.2.1 Strengthen vaccine curricula in medical, nursing, pharmacy, and allied health education, with an emphasis on immunization throughout the lifespan.*

*Strategy 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.*

Action	Lead	Support
Partner with professional organizations to strengthen clinician knowledge and increase capacity to deliver vaccination services.	CDC, HRSA, IHS, VA	DOD, OIDP

*Strategy 3.2.3 Scale up implementation of best practices among health care providers to effectively promote vaccine confidence and vaccination uptake.*

Action	Lead	Support
Establish and expand effective, evidence-based immunization counseling (e.g., motivational interviews, presumptive recommendations) programs and train health care providers to promote vaccine acceptance.	CDC, HRSA, IHS, VA	DOD
Promote catch-up immunizations with effective, evidence-based communication strategies in a variety of settings, including community health centers.	CDC, HRSA, IHS	DOD, OIDP, VA
Provide technical assistance to health center program staff on how to improve vaccination rates in health centers and free clinics, including discussion of the factors leading to a decline in vaccination rates and some actionable strategies for improving vaccination rates.	HRSA	CDC

*Strategy 3.2.4 Simplify immunization practice guidelines where possible to make them easier to implement in practice.*

Action	Lead	Support
Simplify childhood, adolescent, and adult vaccine recommendations, where possible, for better adherence by the public.	CDC	
Improve vaccination workflow in DOD facilities based on input from vaccination service providers and share best practices that may be applicable in civilian settings.	DOD	

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

*Strategy 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.*

Action	Lead	Support
Identify and address systemic barriers to vaccination, including those related to equitable availability of vaccine and vaccination supplies among vaccination service providers and the scope of vaccination practice by different types of health care providers.	CDC	CMS, DOD, HRSA, IHS, OIDP, VA



*Strategy 3.3.2 Educate legislators, executive officers, and policymakers in jurisdictions on policies that increase vaccine use.*

Action	Lead	Support
Educate policymakers and partners about policies that increase vaccine uptake and confidence and that promote pandemic preparedness and recovery.	OIDP	CDC, CMS, DOD, FDA, HRSA, IHS, NIH, VA
Share vaccine information with legislators and their staff that benefits Veterans (e.g., the Strengthening and Amplifying Vaccination Efforts to Locally Immunize All Veterans and Every Spouse Act [SAVE LIVES Act], H.R.1276), which authorizes the VA to provide COVID-19 vaccination to persons previously not eligible for the vaccine in Veteran facilities, including Veterans not eligible for care under the Veterans Health Administration, spouses, caregivers, and the beneficiaries of Civilian Health and Medical Program of the U.S. Department of Veteran Affairs).	VA	

**Objective 3.4: Reduce disparities and inequities in vaccine confidence and acceptance**

*Strategy 3.4.1 Reduce barriers to data sharing between public health and the community (e.g., schools) to identify under-vaccinated populations.*

Action	Lead	Support
Provide and maintain databases that use U.S. Census data to identify socially vulnerable communities that may need additional support during public health emergencies and natural disasters through the Geospatial Research, Analysis & Services Program of the Agency for Toxic Substances and Disease Registry (ATSDR).	CDC	
Maintain up-to-date immunization data that are publicly available from CDC's VaxView website, which provides vaccination coverage data for all ages.	CDC	

*Strategy 3.4.2 Support research in local communities to identify causes of vaccine hesitancy and develop and implement targeted interventions to address them.*

Action	Lead	Support
Support research in local communities to identify causes of vaccine hesitancy and develop and implement targeted interventions.	CDC, NIH	OIDP
Engage and support pharmacists as vaccinators; equip pharmacists with the tools to educate and counsel their patients.	CDC	CMS, HRSA, OIDP
Conduct community outreach to reduce vaccination inequities and promote vaccine confidence and acceptance.	CDC	CMS, HRSA, OIDP

*Strategy 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.*

Action	Lead	Support
Develop measures and tools to evaluate vaccine confidence.	CDC	NIH
Evaluate vaccine confidence strategies to ensure that they are culturally appropriate and reflect health literacy, language proficiency, and/or the functional and access needs of the specific populations they serve.	CDC, CMS	

*Strategy 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.*

Action	Lead	Support
Support partners to prioritize vaccination equity among populations who experience health disparities.	CDC	CMS, HRSA, IHS, OGA, VA
Support tribal communities and tribal organizations to develop and disseminate culturally and linguistically appropriate messages and strategies to address vaccine hesitancy.	IHS	CDC, NIH

*Strategy 3.4.5 Support efforts to strengthen the diversity of the health care workforce to increase vaccine confidence and acceptance across diverse communities.*

Action	Lead	Support
Expand activities in recruitment and pipeline programs to support diversity, equity, and inclusion in the public health workforce to increase awareness and interest in public health among underrepresented groups.	CDC	HRSA, NIH



## Goal 4: Increase Access to and Use of All Routinely Recommended Vaccines

### Objective 4.1: Increase the availability of vaccines in a variety of settings

*Strategy 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.*

Action	Lead	Support
Increase access to vaccines by expanding the number of immunization sites.	CDC	ASPR, CMS, DOD, HRSA, IHS, VA
Link vaccination records from pharmacies, specialty care practices, and non-healthcare settings with the patient's primary care doctor.	CDC	DOD, HRSA, ONC, VA
Promote assessments for and, if not up-to-date, recommend vaccinations at every patient encounter (e.g., in-person or virtual, routine or complaint-specific, primary or specialty care, in- or out-patient, and office-based or mobile facility).	CDC, VA	DOD, IHS, HRSA

*Strategy 4.1.2 Scale-up implementation of evidence-based systems-level strategies that increase vaccine uptake (e.g., centralized reminder-recall system, standing orders).*

Action	Lead	Support
Promote evidence-based practices for improving vaccine uptake among specific populations, e.g., persons in rural communities, persons with disabilities, pregnant people, older adults, and people with limited English proficiency.	CDC	
Increase the percentage of children at HRSA-funded health centers who receive recommended, age-appropriate vaccines by age 2 years.	HRSA	CDC

*Strategy 4.1.3 Expand the number of VFC sites and reduce barriers to provider enrollment in the program.*

Action	Lead	Support
Assess barriers in pharmacy enrollment in VFC and explore options to reduce barriers while maintaining sufficient quality assurance oversight and requirements.	CDC	CMS
Assess VFC provider recruitment and retention efforts in areas where access to vaccines is limited or at risk of becoming limited to ensure that VFC-eligible children receive needed services.	CDC	CMS, HRSA

**Objective 4.2: Reduce disparities and inequities in access to and use of routinely recommended vaccines throughout the lifespan**

*Strategy 4.2.1 Support continued research on race and ethnicity, age, disability, social, economic, cultural, and other factors that contribute to disparities in vaccination rates, and develop targeted interventions to address them.*

Action	Lead	Support
Identify and implement evidence-based intervention strategies that reduce disparities in vaccination rates.	CDC	CMS, HRSA, IHS, NIH, VA
Increase access to and use of vaccinations in the medically vulnerable and underserved communities, including racial and ethnic minority, rural, and/or low-income communities.	CDC	ASPR, HRSA, NIH

*Strategy 4.2.2 Support state, tribal, territorial, and local health departments' efforts to study local immunization disparities and strengthen their community engagement efforts.*

Action	Lead	Support
Support immunization grantees to develop and implement plans to enable billing for vaccine services provided by public health clinics.	CDC	CMS

*Strategy 4.2.3 Increase the 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.*

Action	Lead	Support
Measure progress of vaccination uptake using Healthy People 2030 targets.	CDC	CMS, DOD, HRSA, IHS, ODP, VA
Track vaccination rates and develop interventions to build trust and reduce disparities in key populations, e.g., Veterans, people with disabilities, older adults, rural communities, and racial and ethnic minorities.	CDC, HRSA, IHS, VA	CMS, ONC
Establish data use agreements with state public health departments to retrieve vaccination data from their immunization information systems (IIS) in order to identify and address disparities in vaccination rates among various local jurisdictions and patient populations.	CDC	

*Strategy 4.2.4 Scale up implementation of evidence-based practices to improve immunization equity.*

Action	Lead	Support
Prepare and release a report “Advancing Immunization Equity: Recommendations from the National Vaccine Advisory Committee” that presents system-wide recommendations for reducing disparities and gaps in coverage.	ODP	
Provide vaccination support to health centers in underserved communities. Through its annual Uniform Data Systems reporting, HRSA captures data on immunizations such as, but not limited to, childhood immunizations and flu vaccinations.	HRSA	CDC
Develop “Vaccinate with Confidence” strategies to maximize immunization equity among VA beneficiaries.	VA	CDC

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

*Strategy 4.3.1 Improve Immunization Information System reporting, its interoperability across jurisdictions, and bidirectional communication with other health data systems.*

Action	Lead	Support
Strengthen data management infrastructure and IIS standards of practice, including inter-jurisdictional data sharing and bi-directional data flow, between IIS and electronic health records and health information exchanges.	CDC	CMS, DOD, HRSA, ONC, VA
Work to include IIS within federal data modernization efforts.	CDC, FDA, ONC	CMS, DOD, HRSA, IHS, OIDP, VA

*Strategy 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.*

Action	Lead	Support
Implement a plan for documenting and reporting vaccine impact within 1 year of a disease becoming vaccine-preventable.	CDC	CMS
Advance the interoperable access, exchange, and use of health information and data where appropriate, and provide consultation and/or technical assistance to lead agencies on health data standards, exchange protocols, and technologies.	ONC	CDC, CMS, DOD, HRSA, IHS, OIDP, VA

*Strategy 4.3.3 Increase data analytics capacity to conduct disease surveillance and increase enrollment of adult health care providers in immunization information systems.*

Action	Lead	Support
Monitor the number of cases of paralytic polio, rubella, congenital rubella syndrome, measles, Hemophilus influenza type b, diphtheria, tetanus, mumps, pertussis (in children younger than age 7 years), and varicella (in children younger than age 18 years) to evaluate the impact of vaccine policy and programs.	CDC	
Monitor the number of cases of vaccine-preventable diseases that affect adults to evaluate the impact of vaccine policy and programs.	CDC	
Remove barriers for adult health care providers to enroll in IIS.	CDC	CMS, HRSA IHS, ONC, VA

*Strategy 4.3.4 Provide additional resources, training, and incentives to improve Immunization Information System reporting by adult vaccination service providers.*

Action	Lead	Support
Monitor and evaluate the impact of funds awarded to states that are dedicated to improving IIS reporting by adult vaccination service providers.	CDC	

*Strategy 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.*

Action	Lead	Support
Develop approaches for adults, parents, and guardians to electronically access and view vaccination IIS data and use clinical decision support tools to identify needed vaccines.	CDC	ONC
Strengthen and expand the use of health information networks as well as electronic health records to support responses to public health emergencies.	ONC	CDC

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

*Strategy 4.4.1 Support adequate payments for vaccine counseling and administration.*

Action	Lead	Support
Evaluate payments for vaccine counseling with or without vaccine administration under private and public health care plans (e.g. Medicare and Medicaid).	CMS	CDC, OIDP
Evaluate costs and benefits gained from administering the COVID-19 Coverage Assistance Fund by beneficiary age, sex, race, disability, ethnicity, geographic region, provider type, and vaccination site setting.	HRSA	OIDP

*Strategy 4.4.2 Encourage the development and implementation of best business practices to improve vaccination services at the health care provider practice level.*

Action	Lead	Support
Share strategies and best practices to improve vaccinations through the Title V Maternal and Child Health Block Grant program, which serves women, children, and adolescents in 59 states and jurisdictions.	HRSA	OIDP
Monitor the performance of vaccination sites for the Veteran population and evaluate the data in comparison to community benchmark standards, including for influenza and pneumococcal vaccines.	VA	

*Strategy 4.4.3 Encourage state Medicaid programs to continue implementing evidence-based policies to improve vaccination rates among Medicaid beneficiaries.*

Action	Lead	Support
Work with state Medicaid agencies to improve knowledge of and information to Medicaid providers and beneficiaries about how to access recommended vaccine.	CMS	CDC, OIDP



*Strategy 4.4.4 Promote the use of vaccination as a quality measure in value-based payment models.*

Action	Lead	Support
Promote the use of vaccination data for children and adults as quality measures in value-based payment models.	CMS	CDC, OIDP, VA
Promote the adoption of the Adult Immunization Status and Prenatal Immunization Status measures by plans and providers as tools to promote quality improvement and increase vaccination rates.	CMS	CDC, OIDP, VA

*Strategy 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.*

Action	Lead	Support
Conduct mass vaccination, mobile, and drive-through clinics for COVID-19 and routine vaccination efforts.	CDC, DOD, HRSA, VA	ASPR
Provide personnel for vaccination efforts outside of the immediate department or agency during public health emergencies.	ASPR	CDC, DOD, NIH, OIDP, VA

**Objective 4.5: Reduce financial and systems barriers for the public to facilitate access to routinely recommended vaccines**

*Strategy 4.5.1 Remove co-pays, cost sharing, and other financial barriers for all routinely recommended vaccines.*

Action	Lead	Support
Review the vaccine payment system in Medicare, Medicaid, CHIP, and commercial insurance to identify opportunities to improve payment to vaccination service providers, if appropriate.	CMS	CDC, OIDP
Reduce financial barriers to health care and vaccine services for Veteran populations served by the VA.	VA	

*Strategy 4.5.2 Improve access to free vaccines for uninsured adults.*

Action	Lead	Support
Implement activities that expand or develop systems that provide access to free vaccines for uninsured adults.	CDC	CMS, HRSA, VA
Maintain access to vaccines through the community care network for Veterans who lack private or public health insurance and ensure access to vaccines within Veterans Health Administration facilities.	VA	

**Objective 4.6: Promote public-private partnerships to increase the capacity of the health system to deliver vaccines for routine use during outbreaks**

*Strategy 4.6.1 Strengthen public-private partnerships to improve vaccine ordering, distribution, and tracking for routine use, outbreak control, and during public health emergencies.*

Action	Lead	Support
Monitor the status of vaccine supplies and purchase or maintain a supply of vaccines that are available to state and local health departments during public health emergencies and when local supplies are depleted or unavailable.	CDC	ASPR
Foster and strengthen public-private partnerships to promulgate surge vaccine production capability as part of pandemic preparedness.	BARDA	

*Strategy 4.6.2 Develop and practice strategies to continue to deliver routine vaccinations during public health emergencies.*

Action	Lead	Support
Develop systems and networks for rapid and efficient vaccine distribution and administration for active-duty military personnel.	DOD	
If the Stafford Act is activated, provide services and facilities as needed during public health emergencies.	VA	

Strategy 4.6.3 Review and practice plans to expand capacity to conduct mass vaccination during public health emergencies.

Action	Lead	Support
Review and update vaccination concepts of operation included in the HHS All-Hazards Plan and exercise plans to ensure that Primary Mission Essential Functions, including vaccination, continue to be performed during large-scale accidental, natural, man-made, or other emergencies.	ASPR	OIDP



## Goal 5: Protect the Health of the Nation by Supporting Global Immunization Efforts

### Objective 5.1: Support vaccine research and development to address vaccine-preventable diseases of global public health importance

Strategy 5.1.1 Support the development of technologies that improve vaccine access, distribution, and equity in low-resource countries during a public health emergency.

Action	Lead	Support
Support a National Academies of Sciences, Engineering, and Medicine study on how scientific advances in vaccine development, technological advances in vaccine manufacturing, and social and behavioral science in promoting vaccine uptake learned from the COVID-19 response can inform and improve pandemic influenza preparedness.	OGA	
Coordinate HHS engagement around the G7 Clinical Trials Charter, which includes building clinical research capacity in lower- and middle-income countries as a core principle.	OGA	FDA, NIH

Strategy 5.1.2 Provide technical assistance to developing country vaccine manufacturers to support development and production of safe and effective vaccines.

Action	Lead	Support
Support and maintain a global reference laboratory for polio, measles, and rubella.	CDC	

Action	Lead	Support
Support the World Health Organization (WHO) Influenza Prevention and Response Team's efforts to develop and improve tools for global influenza monitoring and expand influenza vaccine manufacturing capacity in developing countries.	OGA	CDC
Support international vaccine development to address existing and emerging infectious diseases.	FDA	OIDP, OGA, USAID
Support clinical trials and laboratory infrastructure in developing countries to evaluate candidate vaccines.	NIH	CDC, OGA, USAID

*Strategy 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.*

Action	Lead	Support
Work with global partners to strengthen and expand international systems that facilitate rapid response to emerging infections, such as the Global Influenza Surveillance and Response System (GISRS), a system fostering global confidence and trust for over half a century through effective collaboration and sharing of viruses, data, and benefits based on Member States' commitment to a global public health model.	OGA	CDC, NIH, USAID
Engage with international partner countries to participate in the Phase 3 clinical trials for U.S. government-supported COVID-19 vaccines.	OGA	CDC, NIH
Conduct research to facilitate the development of vaccines against tropical and neglected diseases.	FDA	
Participate in international collaborative studies to establish and maintain international reference materials and standards for biologics.	FDA	NIH

*Strategy 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**

*Strategy 5.2.1 Work with immunization programs in other countries to disseminate evidence-based information on vaccines through traditional outlets and social media.*

Action	Lead	Support
Collaborate with lower- and middle-income countries (LMICs) to provide access to updates on research and policy through implementing partners and support to National Immunization Technical Advisory Groups.	USAID	CDC

*Strategy 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.*

Action	Lead	Support
Support increased demand and acceptance of immunization throughout the lifespan in LMICs by fostering the improved capacity of health providers and partnerships at national, regional, and global levels.	USAID	
Support improved quality and effectiveness of behavior change and vaccine confidence interventions in LMICs.	USAID	
Represent the United States and engage with international multilateral fora (e.g., WHO, G7, and Five Eyes) on policy efforts to combat vaccine misinformation and disinformation.	OGA	CDC

**Objective 5.3: Support global partners to strengthen immunization systems**

*Strategy 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.*

Action	Lead	Support
Coordinate HHS/U.S. government engagement with the WHO Research and Development Blueprint, which seeks to better coordinate international research preparedness and response to epidemic and pandemic threats for which there are no licensed medical countermeasures.	OGA	ASPR, CDC, FDA, NIH

Action	Lead	Support
Provide surveillance and laboratory capacity to monitor progress in reaching global polio eradication, guide programmatic response, and implement the polio eradication end-game strategy.	CDC, USAID	
Provide technical assistance to support surveillance, laboratory, and vaccine program implementation to facilitate global decision-making on new vaccine introduction, and enable introduction of new vaccines (e.g., pneumococcal, rotavirus, meningococcal, and human papillomavirus vaccines) in GAVI-eligible countries.	CDC	
Provide a descriptive report of progress on immunization activities in the Global Field Epidemiology and Laboratory Training Program.	CDC	

*Strategy 5.3.2 Leverage digital and data tools to target vaccination campaigns effectively and efficiently manage supply chains, and accurately monitor vaccination coverage.*

Action	Lead	Support
Support the strengthening of country data systems, including optimizing digital systems, data use at all levels, quality improvement, and capacity for adaptive management, and evidence-based decision-making for strengthening immunization programs in LMICs.	USAID	CDC, OGA

*Strategy 5.3.3 Support countries to maintain a stable vaccine supply through secure and reliable vaccine finance, ordering, and distribution systems.*

Action	Lead	Support
Support analysis of financial flows and strengthen the public financing systems to ensure sustained access and delivery of routine vaccines in LMICs.	USAID	

*Strategy 5.3.4 Support global efforts to increase vaccine distribution in underserved populations.*

Action	Lead	Support
Support reaching all eligible populations with vaccines, especially marginalized communities, to reduce inequities in access to and use of routine vaccines at each stage of life, with particular focus on zero-dose children and under-immunized individuals who are concentrated in urban, remote rural, hard-to-reach, or conflict settings in LMICs.	USAID	CDC, OGA

*Strategy 5.3.5 Continue to support multilateral organizations focused on eradicating and eliminating endemic and emerging vaccine-preventable diseases.*

Action	Lead	Support
Promote strengthening of immunization systems, access to new and underutilized vaccines in lower-income countries, and support for elimination and eradication of vaccine-preventable diseases, including through financial and technical support to GAVI, the Vaccine Alliance, and the Global Polio Eradication Initiative.	USAID	CDC, OGA

**Objective 5.4: Increase coordination of global immunization efforts across federal agencies and with global partners**

*Strategy 5.4.1 Improve collaboration with the global regulatory community to enhance regulatory convergence, where feasible.*

Action	Lead	Support
Build regulatory capacity in LMICs, including support for WHO benchmarking of national regulatory authorities using the Global Benchmarking Tool and other international activities.	FDA	CDC

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

Action	Lead	Support
Support the goals of the global immunization agenda related to the eradication of measles, polio, and other vaccine-preventable diseases.	CDC, USAID	OGA
Increase collaboration with global partners on vaccine advocacy including promoting vaccine confidence (e.g., WHO, G7, Five Eyes Intelligence Oversight and Review Council [FIORC]).	OGA	CDC, USAID

*Strategy 5.4.3 Facilitate data sharing to advance how vaccine coverage, safety, and effectiveness are monitored globally.*

Action	Lead	Support
Improve communication and coordination among federal agencies and global partners, including WHO, Gavi, the Vaccine Alliance, and the Coalition for Epidemic Preparedness Innovations (CEPI), to support global vaccine development partnerships and build immunization infrastructure.	CDC, OGA, ODP, USAID	FDA, NIH



# NEXT STEPS

Following the release of the *Vaccines Federal Implementation Plan*, the federal departments and agencies that comprise the IVWG will report on the progress of their activities. The progress reports will highlight the work done by federal departments and agencies and will monitor the activities and indicators outlined in Appendix A.

Each report will describe achievements across the vaccine landscape, both national and international, as they relate to vaccine innovation, safety, confidence, access, and support of global immunization efforts. ODP will collaborate and coordinate with the IVWG to document successes, challenges, and barriers identified throughout the evaluation period. Once finalized, a progress report will be shared with partner agencies, external stakeholders, and the public. The release of the first VNSP progress report is expected to occur in 2023.

# APPENDIX A: INDICATORS AND TARGETS IN VACCINES NATIONAL STRATEGIC VACCINE PLAN 2021–2025

Indicator	Baseline (%) (Year)	2025 Target (%)	2030 Target (%)	Data Source
<b>Pediatric populations</b>				
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 received recommended doses of HPV vaccine	54 (2019)	80	85	NIS-Teen
<b>Adult populations, including pregnant women and older adults</b>				
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 people who received influenza immunization during pregnancy	53.5 (2016–2017)	80	95	NHIS
<b>All populations</b>				
Percentage of persons aged ≥6 months who are vaccinated annually against seasonal influenza	51.8 (2019–2020)	60	70	NHIS

# APPENDIX B: INTERAGENCY VACCINE WORK GROUP (IVWG)

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Office of Infectious Disease and HIV/AIDS Policy

## *Staff Lead*

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Col Tonya Rans, MD, FACAAI  
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# APPENDIX C: IVWG DEPARTMENTS' AND AGENCIES' ROLES IN VACCINES AND VACCINATIONS

This appendix includes the descriptions of federal departments and agencies who support the *Vaccine National Strategic Plan 2021–2025* and the *Vaccines Federal Implementation Plan*.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

HHS is the Cabinet-level agency charged with improving the health, safety, and well-being of the Nation by providing effective health and human services and fostering sound, sustained advances in the sciences underlying medicine, public health, and social services. HHS programs are administered by the Office of the Secretary Staff Divisions, Operating Divisions, and Regional Offices. Vaccinations are a key priority across all of HHS's Operating Divisions. The HHS Operating Divisions and Staff Divisions that have contributed to the *Vaccines Federal Implementation Plan* are as follows:

- Agency for Healthcare Research and Quality
- Administration for Strategic Preparedness and Response and the Biomedical Advanced Research and Development Authority
- Centers for Disease Control and Prevention
- Centers for Medicare & Medicaid Services
- Food and Drug Administration
- Health Resources and Services Administration
- Indian Health Service
- National Institutes of Health
- Office of Global Affairs
- Office of Infectious Disease and HIV/AIDS Policy, National Vaccine Program
- Office of the National Coordinator for Health Information Technology

### ***Agency for Healthcare Research and Quality (AHRQ)***

AHRQ is charged with improving the safety and quality of America's health care system. AHRQ supports health services research initiatives that seek to improve the quality of health care in America. AHRQ's mission is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within HHS and with other partners to ensure that the evidence is understood and used. AHRQ works to fulfill its mission by conducting and supporting health services research, both within AHRQ and in leading academic institutions, hospitals, physicians' offices, health care systems, and other settings across the country. The agency has a broad research portfolio that touches on nearly every aspect of health care. AHRQ funds research on vaccine safety and has developed best practices and recommendations related to immunization, including guidance on increasing COVID-19 vaccine confidence.

### ***Administration for Strategic Preparedness and Response (ASPR) and Biomedical Advanced Research and Development Authority (BARDA)***

ASPR leads the Nation's medical and public health preparedness for, response to, and recovery from disasters and public health emergencies. ASPR collaborates with hospitals; health care coalitions; biotech firms; community members; state, tribal, territorial and local governments; and other partners across the country to improve readiness and response capabilities. BARDA, within ASPR, uses a comprehensive portfolio approach to develop and acquire a broad array of medical countermeasures for pandemic influenza, including vaccines, therapeutics, diagnostics, and non-pharmaceutical countermeasures and to build and sustain their domestic manufacturing infrastructure. BARDA promotes the advanced development of medical countermeasures to

protect Americans and respond to 21st-century health security threats. For example, BARDA supported the advanced development and scale-up of manufacturing of candidate COVID-19 vaccines.

The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) coordinates federal efforts to enhance chemical, biological, radiological, and nuclear threats, and emerging infectious diseases preparedness from the medical countermeasures perspective. The PHEMCE is led by ASPR and includes three primary HHS internal agency partners (CDC, FDA, NIH), as well as several interagency partners (DOD, VA, the Department of Homeland Security, and the U.S. Department of Agriculture).

### ***Centers for Disease Control and Prevention (CDC)***

CDC has primary responsibility for reducing the occurrence and spread of infectious diseases in the U.S. population. Within CDC, the National Center for Immunization and Respiratory Diseases (NCIRD) seeks to prevent disease, disability, and death through immunization and control of respiratory and related diseases. NCIRD is charged with planning, coordinating, and implementing a comprehensive portfolio of vaccination activities in the United States, including the administration of the Vaccines for Children program, which offers vaccines at no cost to eligible children. In addition, NCIRD provides leadership, expertise, and service in laboratory and epidemiological sciences and immunization program delivery; conducts applied research on disease prevention and control; translates research findings into public health policies and practices; and provides diagnostic and reference laboratory services to relevant partners. CDC's Immunization Safety Office communicates timely and transparent information about the safety of vaccines to public health officials, health care providers, and the public through passive and active vaccine safety surveillance systems.

### ***Centers for Medicare & Medicaid Services (CMS)***

CMS provides health coverage to more than 100 million people through Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and the Health Insurance Marketplace, including health coverage to low-income people, older persons, and persons with disabilities. These programs are among the largest payers for health care in the United States. Medicaid covers Advisory Committee on Immunization Practices (ACIP)-recommended vaccines and vaccine administration for beneficiaries up to age 21 years as a basic component of the Early and Periodic Screening, Diagnostic, and Treatment benefit, as well as those enrolled in Alternate Benefit Plans. CHIP carries a similar immunization coverage requirement. Medicaid and CHIP bar cost-sharing for immunizations for children through age 18 years. CMS provides states with strategies on ways to design services to increase vaccine uptake among its beneficiaries. CMS data are used for numerous vaccine safety studies.

### ***U.S. Food and Drug Administration (FDA)***

FDA is responsible for protecting the public health by ensuring the safety, effectiveness, and security of human and veterinary drugs, biological products, and medical devices. FDA is the regulatory authority that has oversight of the safety, effectiveness, and quality of vaccines that are used in the United States. The Center for Biologics Evaluation and Research (CBER), within FDA, ensures that FDA's rigorous scientific and regulatory processes are followed by those who pursue the development of vaccines. CBER's scientific and regulatory advice to vaccine developers, as well as FDA's evaluation to determine the safety and effectiveness of vaccines, are among the most robust in the world. CBER provides rigorous regulatory and scientific oversight throughout the vaccine development life cycle. For vaccines approved or authorized for emergency use, CBER may require additional studies to evaluate vaccines further to address specific questions about a vaccine's safety, effectiveness, or possible side effects. CBER is also charged with monitoring the safety of licensed (approved) and authorized vaccines through passive and active vaccine safety surveillance systems. Research is fundamental to CBER's ability to provide effective scientific and regulatory evaluation of vaccines, and CBER has a robust vaccine research program that broadens FDA's knowledge of the evolving technical and scientific issues concerning the safety, potency, and effectiveness of vaccines.



### ***Health Resources and Services Administration (HRSA)***

HRSA is the primary federal agency responsible for improving access to health care and enhancing health systems of care for the tens of millions of people who are geographically isolated and/or economically or medically vulnerable. HRSA achieves its mission through a range of programs and initiatives designed to improve health equity, increase the number of health care access points, enhance the quality and breadth of health services, and safeguard the health and well-being of the Nation's most vulnerable populations. Immunization is an integral component of HRSA's primary health care services. To ensure that underserved communities and those disproportionately affected by COVID-19 are equitably vaccinated against COVID-19, HRSA and CDC launched a program to directly allocate COVID-19 vaccine to HRSA-supported health centers. HRSA also collects data on several patient-related metrics that inform immunization policy.

### ***Indian Health Service (IHS)***

IHS is responsible for providing federal health services to American Indians and Alaska Natives. IHS is the principal federal health care provider and health advocate for Indian people, and its goal is to raise their health status to the highest possible level. IHS provides a comprehensive health service delivery system for Indian people, and immunization is a priority. IHS supports improved immunization coverage through electronic health records, staff training, quality measures, and incentives.

### ***National Institutes of Health (NIH)***

NIH is the Nation's biomedical research agency. Within NIH, the National Institute of Allergy and Infectious Diseases (NIAID) conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. One of the primary goals of NIAID research is to develop new vaccines against infectious diseases. Research conducted and supported by NIAID has led to new or improved vaccines for various infectious diseases, including COVID-19, influenza, hepatitis A and B, shingles, rabies, meningitis, whooping cough, chickenpox, and pneumococcal pneumonia. NIAID supports multiple networks for the clinical evaluation of new and improved vaccines and vaccine technologies, including the Infectious Diseases Clinical Research Consortium (IDCRC) with associated Vaccine and Treatment Evaluation Units (VTEUs), the HIV Vaccine Trials Network (HVTN), and the COVID-19 Prevention Trials Network (COVPN). These networks conduct research in domestic and international research locations, including resource-poor settings. Many vaccines are currently under development in NIAID intramural labs, including vaccines to prevent HIV/AIDS, pandemic influenza, childhood respiratory diseases, dengue, and malaria. NIH also supports research strategies and interventions to address vaccine hesitancy and issues of vaccine equity.

### ***Office of Global Affairs (OGA)***

OGA is HHS's diplomatic voice by fostering critical global relationships to ensure a safer, healthier world. Recognizing the vital connection between the health and well-being of Americans and that of people worldwide, HHS has had a longstanding and active engagement in global health and human services efforts. HHS's global human services work encompasses the cross-cultural educational, social, and economic support activities that promote the health, well-being, safety, and resilience of individuals and communities across the globe. OGA works to strengthen coordination of HHS-led global immunization efforts. For example, OGA represents the United States at the World Health Assembly, supports U.S. participation in International Health Regulations, and participates in other international efforts. Access to immunization is a key priority, which includes identifying gaps and opportunities for sustainable influenza vaccine manufacturing in the areas of policy, surveillance, product development and manufacturing, product approval and regulation, and communication to support vaccination programs.

### ***Office of Infectious Disease and HIV/AIDS Policy (OIDP), National Vaccine Program***

In 1986, Congress directed the Secretary to establish in the Department of Health and Human Services a National Vaccine Program to "achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines" (Public Health Service Act § 2101 [42 USC § 300aa-1]). Per the statute, the National Vaccine Program is administered by a Director selected by the Secretary. The Assistant Secretary for Health was selected by the Secretary to be the Director of the National Vaccine Program. OIDP, in the Office of the Assistant Secretary for Health, is the principal coordinating

office for the National Vaccine Program. The Vaccine National Strategic Plan under Public Health Service Act Section 2103 establishes priorities in research and the development, testing, licensing, production, procurement, distribution, and effective use of vaccines, describes an optimal use of resources to carry out such priorities, and describes how each of the various departments and agencies will carry out their vaccine functions in consultation and coordination with the National Vaccine Program and in conformity with such priorities. The *Vaccines National Strategic Plan 2021–2025* and its companion document, the *Vaccines Federal Implementation Plan*, provide strategic objectives and specific actions to fulfill the National Vaccine Program.

### **Office of the National Coordinator for Health Information Technology (ONC)**

ONC, a staff division of the HHS Office of the Secretary, is charged with formulating the federal government's health information technology strategy and promoting coordination of federal health information technology policies, technology standards, and programmatic investments.

### **U.S. DEPARTMENT OF DEFENSE (DOD)**

DOD is charged with coordinating and supervising all agencies and functions of the government directly related to national security and the U.S. Armed Forces. The Immunization Healthcare Branch promotes excellence in immunization health care practice and policy for service members and beneficiaries. It supports DOD immunization programs and provides clinical consultative services, educational support, and training resources. DOD conducts multiple activities to optimize the safety of vaccinations administered to service members, military retirees, and their family members who are health care beneficiaries of DOD. For example, DOD collaborates with federal agencies to collect and interpret safety surveillance data. In addition, DOD is a proponent of vaccine development and funds vaccine research for infectious diseases.

### **U.S. DEPARTMENT OF VETERANS AFFAIRS (VA)**

VA provides life-long health care services to eligible military Veterans. VA offers vaccinations to military Veterans through its health care systems. VA supports research across a broad spectrum of areas related to vaccines and immunizations. In response to the COVID-19 pandemic, VA launched a wide array of activities to support and advance its clinical and research missions. These efforts have spanned biomedical research, therapeutics and vaccine clinical trials, and data analyses that leverage VA's robust electronic health records system. In 2021, VA opened COVID-19 vaccination services to families of Veterans, thus substantially increasing access.

### **U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT (USAID)**

USAID leads international development and humanitarian efforts to save lives, reduce poverty, strengthen democratic governance, and help people progress beyond assistance. USAID carries out U.S. foreign policy by promoting broad-scale human progress at the same time it expands stable, free societies, creates market and trade partners for the United States, and fosters goodwill abroad. USAID supports countries to develop sound immunization programs. USAID partners with WHO, GAVI, and other large international and national groups to bring together public and private sectors and expand access to and utilization of life-saving vaccines in 73 low-income countries. USAID supports polio eradication activities through the Global Polio Eradication Initiative (GPEI), including through engagement with local and international nongovernmental organizations, with a particular focus on hard-to-reach populations, disease surveillance, and outbreak response. USAID also invests in malaria and HIV/AIDS vaccine development. The USAID Malaria Vaccine Development Program partners with other U.S. government agencies as well as private partners to accelerate the development of efficacious, durable, and affordable vaccines for use in malaria control programs in endemic areas of the developing world. USAID supports the development of effective vaccines for HIV/AIDS as part of comprehensive prevention, diagnostic, and treatment strategies. USAID works in collaboration with African and Indian partners to move the world closer to a safe and globally effective HIV vaccine through the U.S. President's Emergency Plans for AIDS Relief, and aims to ensure African scientists fully participate in a product development pathway that reflects African realities and considers key regional priorities.

# APPENDIX D: ACRONYMS

AHRQ	Agency for Healthcare Research and Quality
ASAR	Annual School Assessment Report
ASPR	Administration for Strategic Preparedness and Response
BARDA	Biomedical Advanced Research and Development Authority
CBER	Center for Biologics Evaluation and Research (FDA)
CDC	Centers for Disease Control and Prevention
CHIP	Children’s Health Insurance Program
CMS	Centers for Medicare & Medicaid Services
COVID-19	coronavirus disease 2019
DOD	Department of Defense
DTaP	diphtheria, tetanus, and acellular pertussis vaccine
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
HIV	human immunodeficiency virus
HPV	human papillomavirus
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
IIS	immunization information systems
IISAR	Immunization Information Systems Annual Report
IVWG	Interagency Vaccine Work Group
LMIC	low- and middle-income country
MMR	measles, mumps, and rubella vaccine
NCIRD	National Center for Immunization and Respiratory Diseases (CDC)
NHIS	National Health Interview Survey
NIAID	National Institute of Allergy and Infectious Diseases (NIH)
NIH	National Institutes of Health
NIS-Child	National Immunization Survey–Child
NIS-Teen	National Immunization Survey–Teen
NVAC	National Vaccine Advisory Committee

OGA	Office of Global Affairs
OIDP	Office of Infectious Disease and HIV/AIDS Policy
ONC	Office of the National Coordinator for Health Information Technology
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
USAID	US Agency for International Development
VA	Department of Veterans Affairs
VAERS	Vaccine Adverse Event Reporting System
VA ADERS	VA Adverse Drug Event Reporting System
VFC	Vaccines for Children
VNSP	Vaccines National Strategic Plan 2021–2025
WHO	World Health Organization