



From the Factory to the Frontlines

The Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine

What This Strategy Aims to Do

This report to Congress details a strategy to achieve the principal purpose and objective of Operation Warp Speed (OWS): ensuring that every American who wants to receive a COVID-19 vaccine can receive one, by delivering safe and effective vaccine doses to the American people beginning January 2021.

The leadership of OWS has committed to being transparent with Congress, the media, and the American people. OWS has provided regular briefings on topics of interest to Congress and the media and will continue to provide updates and announcements as OWS reaches new milestones. Congress has been a vital partner in the all-of-America response to the COVID-19 pandemic.

With support provided through emergency supplemental and flexible discretionary funding, OWS has now made strong progress toward a safe and effective COVID-19 vaccine, with multiple candidates in Phase 3 clinical trials.

Simultaneously, OWS and partners are developing a plan for delivering a safe and effective product to Americans as quickly and reliably as possible. Experts from the Department of Health and Human Services (HHS) are leading vaccine development, while experts from the Department of Defense (DoD) are partnering with the Centers for Disease Control and Prevention (CDC) and other parts of HHS to coordinate supply, production, and distribution of vaccines.

Successful implementation of the national COVID-19 vaccination program requires precise coordination across federal, state, local, tribal, and territorial governments and among many public and private partners. Cooperation on each of these fronts has already begun, as detailed throughout this strategy document.

OWS is harnessing the strength of existing vaccine delivery infrastructure while leveraging innovative strategies, new public-private partnerships, and robust engagement of state, local, tribal, and territorial health departments to ensure efficient, effective, and equitable access to COVID-19 vaccines.

Some variables that will impact the planning of this vaccination program are unknown until a vaccine is authorized or approved by the Food and Drug Administration (FDA), such as populations for whom a given vaccine is most appropriate, distribution and storage requirements, dosage requirements, and other variables. This document lays out a flexible strategy that can accommodate a range of scenarios.

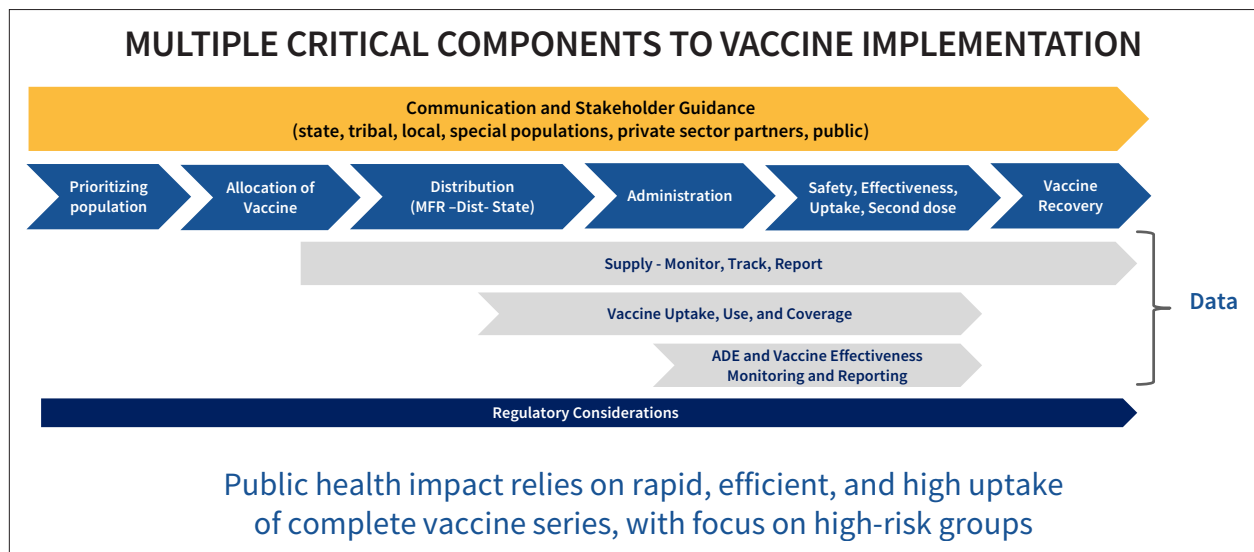
Through the COVID-19 vaccination program, OWS seeks to achieve maximum uptake of the vaccine across all population groups. The eventual objective of the vaccination program is to leave the U.S. government and commercial infrastructure better able to respond to pandemics and public health crises in the future.

What Is the Strategy?

Once a vaccine has received approval or authorization from the FDA, the four key tasks to achieve the primary objective of ensuring vaccine access for every American who wants it are to:

- ✓ Continue engaging with state, tribal, territorial, and local partners, other stakeholders, and the public to communicate public health information, before and after distribution begins, around the vaccine and promote vaccine confidence and uptake.
- ✓ Distribute vaccines immediately upon granting of Emergency Use Authorization/ Biologics License Application, using a transparently developed, phased allocation methodology.
- ✓ Ensure safe administration of the vaccine and availability of administration supplies.
- ✓ Monitor necessary data from the vaccination program through an information technology (IT) system capable of supporting and tracking distribution, administration, and other necessary data.

This report lays out the requirements for each of these tasks and how OWS has taken action and is planning future actions to execute on them.



Distribution

What is required: A distribution plan must be able to deliver vaccines immediately upon FDA authorization or licensure to all possible administration endpoints, while remaining flexible enough to accommodate a variety of factors, including varying product requirements and manufacturing timelines and volumes. Any distribution effort must ensure safety of the products, maintain control and visibility, manage uptake and acceptance, ensure traceability of product, and maximize coverage, which requires a centralized solution as well as close local partnerships.

What we are doing: OWS is developing a cooperative plan for centralized distribution that will be executed in phases by the federal government, the 64 jurisdictions CDC works with (all 50 states, six localities, and territories and freely associated states), Tribes, industry partners, and other entities.

Distribution has three key components:

- ✓ Partnerships with state, local and tribal health departments, territories, Tribes, and federal entities to allocate and distribute vaccines, augmented by direct distribution to commercial partners.
- ✓ A centralized distributor contract with potential for back-up distributors for additional storage and handling requirements.
- ✓ A flexible, scalable, secure web-based IT vaccine tracking system for ongoing vaccine allocation, ordering, uptake, and management.

State, Tribal, and Local Partnerships

CDC is working with state, local and tribal health departments to hone existing plans for vaccine distribution and administration. CDC has worked for decades with these partners, including under cooperative agreements, to ensure public health systems are prepared with plans, trained personnel, strategic relationships and partnerships, data systems, and other resources needed for sustaining a successful routine immunization infrastructure, and these plans will be adapted for this vaccine program.

CDC awarded grants as part of the Coronavirus Aid, Relief, and Economic Security (CARES) Act and the Families First Coronavirus Response Act that can help immunization programs begin preparation for vaccine distribution and administration. The funding will be used to enhance capacity to support staffing, communication and stakeholder engagement, pandemic preparedness, and mass vaccination.

A multi-agency federal team has worked with five pilot jurisdictions—California, Florida, Minnesota, North Dakota, and Philadelphia—to utilize a basic plan for administration and adapt it to create jurisdiction-specific plans that will serve as models for other jurisdictions. Jurisdiction planning will cover coordination with federal facilities in their jurisdiction, coordination with national chain partners, vaccination of critical work forces, and reaching underserved populations.

Each jurisdiction will be required to develop a “microplan,” based on their existing plans as well as outputs from the first five jurisdictions supported, with CDC providing technical assistance. These microplans will identify vaccination sites and necessary logistical considerations and lay out how the sites will be onboarded into the necessary IT system. The microplans will need to be flexible to allow adaptation as more information about the specific characteristics of the vaccines becomes available.

Under their cooperative agreements with CDC through which CARES Act awards were made, jurisdictions will then onboard providers to the IT system and identify and plan for the necessary vaccination workforce. Jurisdictions will also be responsible for laying specific groundwork for vaccinating high-risk and prioritized populations through various outreach efforts, including a work group or stakeholder groups, and forming a vaccination committee.

Jurisdictions will be expected to incorporate planning for distribution of vaccines to members of Tribes into their microplans. In addition, CDC and OWS are working with the Indian Health Service (IHS) to develop a plan for direct IHS distribution of vaccine to Tribes that desire that option.

Centralized Distribution

Centralized distribution allows the government full visibility, control, and ability to shift assets and use data to optimize vaccine uptake. On August 14, CDC announced its centralized distributor contract by executing an existing contract option with McKesson, which distributed the H1N1 vaccine during the H1N1 pandemic in 2009–2010. The current contract with McKesson, awarded as part of a competitive bidding process in 2016, includes an option for the distribution of vaccines in the event of a pandemic.

Once vaccines are allocated to a given jurisdiction or authorized partner, McKesson will deliver a specific amount of vaccine to a designated location. In many instances, delivery locations will be sites where vaccine will be administered. Alternatively, vaccines can be delivered to locations in jurisdictions to be further distributed to administration sites within health department networks. Vaccines can also be delivered to locations integrated into national retail pharmacy networks for distribution to individual pharmacies.

This system will be scalable to meet demand. Some vaccine with ultra-cold storage requirements may be shipped directly from the manufacturer to the administration sites, but all distribution will be managed by this centralized system.

If necessary, the McKesson contract can cover rapid distribution of doses of refrigerated (2–8°C) and frozen (–20°C) vaccines.

The COVID-19 pandemic has likely accelerated a trend towards different ways of engaging with the healthcare system, and successful delivery of this vaccine will need to incorporate new types of sites and approaches for vaccine delivery. For example, during H1N1, once vaccines became widely available pharmacies played an important role in the vaccine distribution; pharmacies' role is even more critical to vaccinations today and will be fully integrated into the distribution plan.

Ordering and Tracking Systems

Vaccine allocation and centralized distribution will utilize HHS's Vaccine Tracking System (VTrckS), which is a secure, web-based IT system that integrates the entire publicly funded vaccine supply chain from purchasing and ordering through distribution to participating state, local, and territorial health departments and healthcare providers.

VTrckS is being scaled for distribution of pandemic vaccines, to include the onboarding of new providers under each jurisdiction's microplan. For the COVID-19 vaccination program, additional providers, including private partners (e.g., pharmacy chains) and other federal entities (e.g., the Indian Health Service), will be onboarded to enable allocation to and ordering directly by these partners, in addition to the state, local, and territory allocations.

Through the linkage of a number of systems, information technology will also help direct people to where to get vaccinated using web-based "finder" systems.

A Potential Phased Structure

Phase 1: Upon FDA authorization or approval, initial vaccine doses will be distributed in a focused manner, with the goal of maximizing vaccine acceptance and public health protection while minimizing waste and inefficiency.

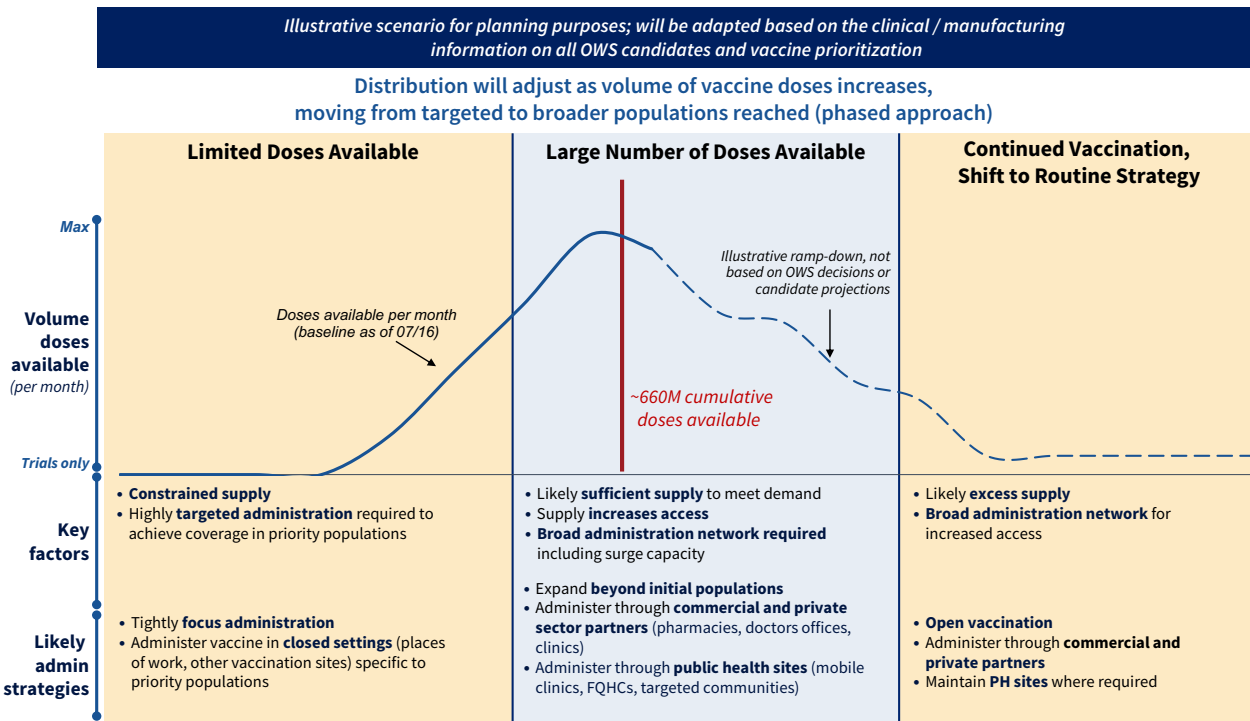
Although final decisions about prioritization will not be made until closer to implementation, select scenarios have been developed to assist with state and local planning. State and local health departments have been given specific scenarios to plan for during this stage, while scenario planning for distribution and administration plans specific to focused populations has begun at the federal level.

Phase 2: As the volume of available vaccine increases, distribution will expand, increasing access to the larger population. When larger quantities of vaccine become available, there will be two simultaneous objectives: 1) to provide widespread access to vaccination and achieve coverage across the United States population and 2) to ensure high uptake in target populations, particularly those who are at high risk for severe outcomes from COVID-19.

Phase 3: If the risk of COVID-19 persists such that there remains a public health need for an ongoing vaccination program, COVID-19 vaccines will ultimately be universally available and integrated into routine vaccination programs, run by both public and private partners.

Based on the timeline associated with FDA regulatory decision-making, increasing quantities of produced vaccines may be stockpiled as manufacturing proceeds before a regulatory decision has been made, which would mean that distribution may begin directly with Phase 2 or Phase 3.

Allocation: Allocations in the early phases will be based in part on methodology previously developed and reviewed by public health experts as part of pandemic planning. This methodology will be adjusted based on experience from COVID-19, real-time data on the virus and its impact on populations, performance of each vaccine, and the ongoing needs of the essential workforce.



To develop and update populations to target in settings with limited doses of vaccine, the National Institutes of Health (NIH) and CDC requested that the National Academies of Sciences, Engineering, and Medicine and the National Academy of Medicine (NAM) develop an overarching framework to assist policymakers in the U.S. and global health communities in planning for equitable allocation of vaccines against COVID-19.

NAM established a committee to consider the criteria that should be used to set priorities for equitable distribution of potential vaccine and released a discussion draft of a preliminary allocation framework on September 1. The findings from the NAM committee will be shared with the CDC's Advisory Committee on Immunization Practices (ACIP), to help inform the committee's deliberations related to vaccine priority groups and ensuring equity in vaccination in the United States.

ACIP will review evidence on COVID-19 epidemiology and burden, vaccine safety, vaccine efficacy, evidence quality, and implementation issues to inform recommendations for COVID-19 vaccine policy, including priority groups for vaccination, which are submitted to the CDC director for adoption. ACIP meetings are open to the public, and committee records are required to be made available to the public, ensuring transparency and visibility for this recommendation-making process.

ACIP formed a COVID-19 Vaccine Work Group to help inform its evidence-based approaches to COVID-19 vaccination policy, including the initial vaccine prioritization strategy to be presented to the full ACIP for deliberation at public ACIP meetings, development of recommendations, and eventual presentation of these recommendations to the CDC for consideration in determining population prioritization.

ACIP embarked on early planning for these efforts. The framework developed during, and the lessons learned from, the H1N1 influenza vaccine implementation are being used to guide COVID-19 vaccine prioritization. CDC learned several lessons from the H1N1 response and vaccine distribution, including the real possibility of uncertainties in the pharmaceutical manufacturing process, which requires the distribution plan to anticipate delays and respond to changing circumstances. Further, demand is likely to vary regionally and in diverse populations within a given geographic area. Nimble delivery and allocation strategies will be essential.

Administration

What is required: Successful administration requires identifying prioritized populations and working cooperatively with state, local and tribal public health departments and other key partners to ensure individuals in targeted groups safely receive vaccines when limited doses initially become available.

What we are doing: Through collaborative planning with states and private sector provider partners such as pharmacies, vaccine administration sites will be selected to optimize access to vaccines throughout the distribution process.

Administration tasks within each distribution phase will include:

- ✓ Delivery of vaccine to sites, with the goal of no upfront costs to providers and no out-of-pocket cost to the vaccine recipient.
- ✓ Ensuring administration sites, as covered in the jurisdiction's microplans, have the capabilities for storing, handling, and administering vaccine products with specific distribution and administration requirements.
- ✓ Supporting reliable distribution of ancillary supplies that may be necessary for vaccine administration.
- ✓ Engagement of traditional and non-traditional administration sites and approaches in vaccination planning to allow for flexibility to accommodate vaccine requirements.

Delivery and Cost

The federal government is procuring hundreds of millions of doses of safe and effective vaccines, and has contracted with McKesson for purposes of vaccine distribution, such that no American will be charged for either the COVID-19 vaccine or its distribution. Various plans, supported by the CARES Act and the Families First Coronavirus Response Act, are under development with the objective of ensuring no one will be charged any out-of-pocket expenses for the administration of the vaccine either. The objective is to ensure no one desiring vaccination will face an economic barrier to receiving one.

Section 3203 of the CARES Act (P.L. 116-136) requires health insurance issuers and plans to cover any ACIP-recommended COVID-19 preventive service, including vaccines, without cost-sharing within 15 days of such recommendation to the CDC. Once a licensed COVID-19 vaccine is recommended by ACIP, and the recommendation is adopted by the CDC Director, required coverage for vaccines as preventative services for Medicaid Early and Periodic Screening, Diagnostic and Treatment beneficiaries and the Affordable Care Act provisions for most private insurance coverage and for the Medicaid expansion populations will also apply.

Ancillary Supplies

Supporting and securing an adequate quantity of ancillary supplies needed for administration has been a collaborative, interagency effort. OWS has aimed to procure and assemble 6.6 million ancillary supply kits, including pediatric, adult, and mixed-use kits, which would support the vaccination of up to 660 million doses of vaccine. These kits will include needles, syringes, alcohol pads, vaccination cards, and limited PPE for vaccinators.

HHS's Biomedical Advanced Research and Development Authority (BARDA) has awarded four large task orders for needles and syringes. BARDA will support additional solicitations, in coordination with the Strategic National Stockpile, to maximize the availability of needles

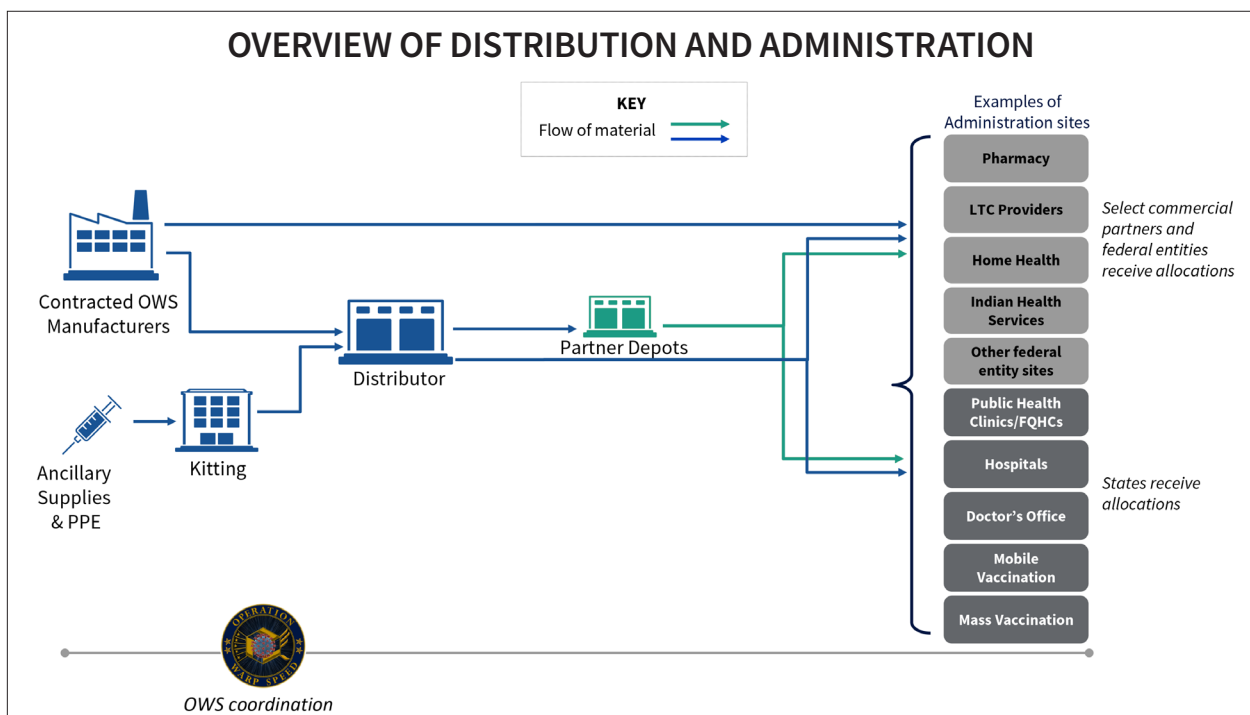
and syringes toward the end of 2020. BARDA and the DoD Joint Program Executive Office for Chemical, and Biological, Radiological, and Nuclear Defense (JPEO-CBRND) have awarded three agreements to increase needle and syringe capacity in the U.S. for the future, some of which will be available in time to support the COVID-19 vaccination in early 2021. BARDA and the JPEOCBRND have also awarded agreements with two domestic manufacturers of vials to increase capacity necessary to support multiple vaccine candidates.

Administration Sites

Administration site options will vary depending on the nature of the vaccine and the phase of the vaccination program. During Phase 1, administration sites may be more limited to settings that can optimize reaching the target population while meeting the early requirements for storage and handling of vaccine product. During Phase 2, an expanded administration network would, for instance, likely include adult and pediatric healthcare providers and pharmacies. These considerations will be part of planning done by the jurisdictions discussed in the Distribution section.

As part of efforts to make administration sites easily accessible, the program will make maximum use of all healthcare professionals licensed to administer vaccines, including allied health professionals such as pharmacists.

HHS is also committed to ensuring rural populations can receive the vaccine, and has decades of experience working with public health partners addressing the needs of hard-to-reach populations. CDC will work with local communities, governments, and other partners to identify the best places and times to reach this population and utilize strategic distribution points via community health centers, schools, workplaces, mobile clinics, and pharmacies.



Monitoring

What is required: The vaccination program requires extensive data monitoring infrastructure, including appropriate IT architecture, to incorporate claims and payment processes, to identify when a person needs a potential second dose, to monitor outcomes and adverse events, and to account for products the U.S. government is spending billions of dollars to research, develop, and produce. Data will need to be available both federally and at the state, local, and tribal level to ensure efficient management of the vaccination program.

What we are doing: OWS will construct and integrate an IT architecture that achieves this objective, building off of existing IT infrastructure and filling gaps with new IT solutions.

CDC has already been working to improve the data infrastructure needed to better track vaccines, vaccination, and related information. The COVID-19 vaccination program requires significant enhancement of the IT that will support enhancements and data exchange that are critical for a multi-dose candidate to ensure proper administration of a potential second dose.

Immunization Information Systems used by state, territory, and city entities that deliver public vaccinations will be central to this IT infrastructure. Major pharmaceutical retailers have proven and reliable dispensing record systems, while healthcare systems, hospitals, and private providers employ Electronic Health Record systems to store, monitor, and track patient information. Points of administration with undeveloped infrastructure—such as ad hoc mobile clinics and other rapidly mobilized mass vaccination sites—will be provided with free access and training for purpose-built web-based applications to support vaccine data administration and tracking, with an array of options available to make these accessible.

Together, this data will be reported into a common IT infrastructure that will support analysis and reporting. The IT infrastructure will support partners with a broad range of tools for record-keeping, data on who is being vaccinated, and reminders for second doses.

In all cases, administration records will be aggregated, anonymized, and de-identified to protect personally identifiable, private health information to the maximum extent possible.

Before a vaccine is authorized for use, evidence of its safety and efficacy is limited to the results from clinical trials, where patients are selected carefully and followed up very closely under controlled conditions. Because some technologies have limited previous data on safety in humans, the long-term safety of these vaccines will be carefully assessed using pharmacovigilance surveillance and Phase 4 (post-licensure) clinical trials.

The key objective of pharmacovigilance is to determine each vaccine's performance in real-life scenarios, to study efficacy, and to discover any infrequent and rare side effects not identified in clinical trials. OWS will also use pharmacovigilance analytics, which serves as one of the instruments for the continuous monitoring of pharmacovigilance data. Robust analytical tools will be used to leverage large amounts of data and the benefits of using such data across the value chain, including regulatory obligations. Pharmacovigilance provides timely information about the safety of each vaccine to patients, healthcare professionals, and the public, contributing to the protection of patients and the promotion of public health.

Engagement

What is required: To support vaccine distribution, administration, and monitoring, as well as promote vaccine uptake, vaccine confidence, and reporting of adverse events, a successful vaccination program requires engaging a nationwide network of partners. Working with established partners—especially those that are trusted sources for target audiences—is critical to advancing public understanding of, access to, and acceptance of eventual vaccines.

What we are doing: To build partnerships as part of the vaccination program and deliver an effective communications strategy, OWS is engaging public, nonprofit, and private partners, while leveraging the government's longstanding relationships with state health departments, tribal nations and organizations, healthcare systems, the vaccine industry, health insurance issuers and plans, and non-traditional partners.

Partnerships

State, local and tribal health departments have conducted pandemic vaccination planning with immunization and preparedness funding from CDC for over a decade. Rapidly updating these vaccination response plans for COVID-19 will ensure readiness for timely administration of COVID-19 vaccines.

This work builds on existing successful partnerships: Each year, CDC safely distributes more than 80 million doses of vaccines to approximately 40,000 public and private health providers across the country, in addition to the tens of millions of other vaccines distributed through other channels. During the 2009 H1N1 pandemic, more than 70,000 provider sites participated in the expanded vaccination program. This represents strong baseline capacity and partnerships for distribution and administration.

HHS's Office of Intergovernmental and External Affairs has established communication channels with almost 30 private sector organizations representing hospitals, physicians, nurses, nursing homes, community health centers, health insurance issuers and plans, drug stores, influencers, foundations, patients, and seniors' groups to provide regular updates on the work of OWS, including the distribution program.

HHS has also been holding regular calls with intergovernmental partners at the state, local, tribal, and territorial levels, with robust dialogue on how the federal government will successfully partner with them on the vaccination program.

Further, work has begun with organizations representing minority populations and vulnerable communities, with consultation already occurring with more than 150 organizations dedicated to addressing health disparities. Faith-based and other trusted community organizations can also be critical in addressing vaccine hesitancy, and HHS's Center for Faith and Opportunity Initiatives is working with minority-serving faith and community groups to enlist their help in educating Americans and encouraging participation in the vaccination program.

Communications

Strategic communications and public messaging are critical to ensure maximum acceptance of vaccines, requiring a saturation of messaging across the national media.

An information campaign led by HHS's public affairs department—developed using human-centered design, extensive public and stakeholder engagement, and research on message development and delivery—will focus on vaccine safety and efficacy, and target key populations and communities to ensure maximum vaccine acceptance.

CDC and other HHS components are working collaboratively within OWS to ensure that consistent and accurate information is at the foundation of the communications effort. The plan will also help inform the American people about the OWS strategy of delivering faster results while still following the same processes for safety and effectiveness that Americans expect with any other vaccine.

Identifying the right messages to promote vaccine confidence, countering misinformation, and targeting outreach to vulnerable and at-risk populations will be necessary to achieve high coverage. CDC will build on its existing relationships with local public health partners and health departments to effectively implement communications, and CDC is also working to develop innovative approaches to improve vaccine uptake among hard-to-reach critical populations.

Understanding that public confidence in vaccines is necessary for vaccine uptake and acceptance, CDC will make use of its strategic framework, *Vaccinate with Confidence*, which it has used successfully to strengthen public trust in vaccines and prevent vaccine-preventable disease outbreaks. This framework emphasizes three key priorities: protect communities, empower families, and stop myths. Within this framework, CDC is already working with local partners and using trusted messengers to establish new partnerships and contain the spread of misinformation.

