

A Guide to COVID-19 Vaccination Deployment for State and Local Governments

How to Plan, Execute, Evaluate, and Adjust Effectively



Introduction

Operationalizing constantly evolving plans with the goal of vaccinating hundreds of millions of Americans will be one of the largest coordination projects the country has undertaken in peacetime. The timing of COVID-19 vaccines and ramping up to widespread availability means that states, counties, and cities will need to simultaneously respond to ongoing prevention, testing, and treatment of COVID-19 and stand up a COVID-19 vaccination effort.

State and local governments are likely to face challenges in the following areas.

- **Supply Chain and Distribution:** Multi-dosage requirements, vaccine storage and delivery, and the potential for spoilage, fraud, and abuse will require a tight distribution effort.
- **Program and Project Management:** A vaccination effort of this scale has not taken place in generations, and will require extensive coordination across the public, private, nonprofit, and healthcare sectors.
- **Governance Under Uncertainty:** Information is moving quickly, and decisions need to be made without perfect data; having a streamlined process to govern the vaccination effort will be critical.
- Technology and Data: Achieving the necessary public health outcomes will require outreach and tracking, and governments will need to adapt existing technology, or stand up new platforms, quickly to meet process and data demands.
- **Communication and Confidence:** Misinformation is already rampant and building public confidence around the vaccine will be critical to community health; listening to, and tailoring messages for, the public will require a nimble public relations and marketing capability.
- Equity and Inclusion: Communities must engage partners that represent their communities, as these partnerships will build trust across the most at-risk populations, enabling a closing, rather than widening, of already present disparities due to cost and access issues.
- **Financial Management and Funding:** States, counties, and cities are already dealing with unprecedented financial strain, and the cost to distribute the vaccine will involve more than just the medicine itself; keeping accurate records and tapping all available funding streams will help support this massive effort financially.

This fact sheet includes a detailed discussion of these dynamics and offers potential solutions to plan for and execute an effective vaccine rollout.



Mastering the Coordination Challenge

What We Know So Far: CDC and State Roles

With the announcement of promising results from the early vaccine studies, the importance of developing the capacity of state and local governments to fulfill their role in the distribution of COVID-19 vaccines has become more pressing. The Centers for Disease Control and Prevention (CDC) has released the "**COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations.**" In this playbook, the CDC outlines a phased distribution approach, balancing limited vaccine doses available with the prioritized populations eligible to receive the vaccine at each phase.

COVID-19 Vaccination Program Phased Approach

Max •	Phase 1 Potentially Limited Doses Available	Phase 2 Large Number of Doses Available	Phase 3 Continued Vaccination, Shift to Routine Strategy
Volume doses available (per month)	Projected short period of time for when doses may be limited		
Key factors Likely admin strategies	 Supply may be constrained Tightly focus vaccine administration Administer vaccine in closed settings best suited for reaching initial critical populations (workplaces, other vaccination sites) specific to Phase 1-A populations 	 Likely sufficient supply to meet demand Expand beyond initial populations Use a broad provider network and settings including: Healthcare settings (doctors' offices, clinics) Commercial sector settings (retail pharmacies) Public health venues (public health clinics, mobile clinics, FQHCs, community settings) 	 Likely sufficient supply Open access to vaccination Administer through additional private partner sites Maintain public health sites where required
	Populations of Focus*		
	Phase 1	Phase 2	Phase 3
	 Phase 1-A: Paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials and are unable to work from home. 	 Remainder of Phase 1 populations Critical populations General population 	Remainder of Phase 1 populationsCritical populationsGeneral population
9/4/20	 Phase 1-B: Other essential workers People at higher risk of severe COVID-19 illness, including people 65 years of age and older 		

*Planning should consider that there may be initial age restrictions for vaccine products.

Source: CDC COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations

Along with the phased approach to vaccine recipients, there will be a phased rollout of multiple COVID-19 vaccines, each with different transportation and storage requirements, and likely many with different eligible populations (some, for example, have yet to undergo clinical trials with children). These various phases create a complex logistical challenge for both the CDC and the immunization programs run by states and other jurisdictions.

States drafted CDC-mandated plans in mid-October describing their approach to vaccine management, including inventory management, storage, distribution, and recipient tracking. The interim plans, however, are far from complete, and will need to evolve as more is learned about vaccine supplies, supply chain requirements, and demand.

Supply Chain and Distribution: The Federal Role

The CDC, working in coordination with the Department of Defense, has announced plans to serve as the central distributor for COVID-19 vaccines. The CDC will manage the purchase and distribution of the vaccine from the manufacturers to the relevant jurisdiction (such as a state), which is then responsible for distribution to primary end-user sites in an equitable manner.

Distribution of Pandemic Vaccine and Supplies



*https://www.cdc.gov/vaccines/hcp/admin/storage/index.html

† The Vaccine Tracking System (VTrcks) is CDC's management and ordering systems for publicly-funded vaccines. ‡ Immunization Information System (IIS)

Source: CDC Pandemic Vaccine Program Distribution, Tracking, and Monitoring Infographic

Supply Chain and Distribution: The State and Local Role

What's currently unclear is how the federal government will assist states in preparing for their downstream vaccine distribution functions. At the beginning of the pandemic, the sourcing of critical supplies such as PPE resulted in states competing against each other for supplies required to respond to the pandemic. There is the potential for a similar situation to arise in vaccine handling and distribution at the state level, as states seek the freezers, syringes, and other materials necessary to ready their part of the vaccine distribution chain. As a result, state and local governments should begin immediately to ensure that their supply chain for PPE and other necessary supporting materials is fortified, and work with the CDC to confirm the supplies coming from the strategic national stockpile.

Managing the Distribution Effort

Program and Project Management: Standing Up an Implementation Team

State interim COVID-19 vaccine distribution plans are only the first step in the massive management challenge states and other jurisdictions face with the COVID-19 vaccine. State and local departments of public health, already overworked, will not be able to bear this burden alone, and states' COVID-19 vaccine implementation committees/boards will need extensive resources to provide the necessary data to drive decisions and then to operationalize those decisions.

A team will need to be created for each jurisdiction to:

- Drive effective program management and execution governance at a cross-agency, public-private level.
- Gather, analyze, and report on data that will track the progress of the vaccination effort and its ability to reach at-risk populations.
- Listen to feedback from, and share critical messages with, community groups and the public, and proactively craft and distribute messages to the community.
- Constantly update and revise key planning and guidance documents based on the latest information.
- Serve as a liaison/information conduit between elected officials, public health agencies, information technology, emergency management, finance and management, education, regulatory and licensing boards, departments of correction, and the legislature, for mass vaccination issues.
- Develop and assign tasks for completion and set task deadlines that operationalize the state's vaccine distribution plan.
- Engage and communicate with external stakeholders and residents key to facilitating the COVID-19 mass vaccination activities as necessary, including mass vaccination marketing plans, local/regional health departments, healthcare providers, and federal agencies and associations.

Governance: Planning and Adapting Amid Uncertainty

As with the original COVID-19 outbreak earlier this year, perfect information will not be available to decision-makers all at once. Information about the vaccine itself (dosage requirements, storage needs, delivery requirements, etc.) will change frequently, and these changes will have material effects on how to effectively vaccinate the population. This will require nimble governance across agencies perhaps even beyond that which may have been stood up for the initial COVID-19 response.

Coronavirus Vaccine Tracker



Source: The New York Times Coronavirus Vaccine Tracker https://www.nytimes.com/interactive/2020/science/coronavirusvaccine-tracker.html

As an example of the critical nature of a fast and flexible response, we have already seen the need for immediate adaptation in vaccine plans. States were told in mid-October to prepare to receive the first of the COVID-19 vaccines for Phase 1a distribution and the first vaccine announced Phase 3 trial results on November 9, 2020. The requirements for this vaccine, the first of four vaccines in Phase 3 trials to announce promising results, include storage and handling practices maintaining "ultra-cold" temperatures. Given the timing of the vaccine's temperature requirements, many state plans (also released in mid-October) do not address the ultra-cold supply chain needs and will have to be adapted for this requirement.

The other three vaccines currently in Phase 3 trials do not require "ultra-cold" supply chains, but as of November 16, 2020, only one other has results demonstrating large-scale efficacy or safety. The ultimate mix of approved vaccines, their specific supply chain needs, and the CDC Vaccination Program Phase that they will be available for, will be an evolving process over the next months and year(s). States must be prepared for differing allocations from different vaccines and scale up or down appropriate supply chains as necessary.

Many jurisdictions simply don't have the resources available for this level of flexibility.

Constantly adapting project plans takes a huge amount of time to maintain, manage dependencies, identify and monitor risks, and perform the levels of outreach necessary.

Technology and Data Management: Opportunities for Modern Vaccine Tracking Systems and Advanced Data Analytics

Technology can significantly advance a jurisdiction's ability to meet the challenges of the COVID-19 vaccine. Beyond the critical task of safely and effectively transporting the various COVID-19 vaccines, states and other jurisdictions are responsible for significant reporting and tracking related to the administration of the vaccines. Moreover, simply determining who has been vaccinated, either at the individual or community levels, will be critical to determining the overall progress of the effort to eradicate the disease.

The CDC mandates certain data elements for each dose administered to be reported within 24 hours of administration. In addition, states and other jurisdictions have additional responsibilities, including:

- Assessing the capability of COVID-19 vaccination providers to meet federal and jurisdiction-specific reporting requirements before or upon enrollment.
- Facilitating and monitoring reporting to the CDC's Immunization Information Systems (IIS) by enrolled vaccination providers.
- Establishing processes to match first and second doses, including addressing the need to exchange data with or query other jurisdictions' systems and/or the Immunization Data Lakes to obtain immunization history, if applicable.
- Confirming that redundant measures and procedures are in place for recording vaccine administration data in instances of connectivity problems or failures in the jurisdiction's IIS or other system.
- Collecting, reporting, and submitting data directly to CDC's Immunization Data Lake.

Most states implemented their reporting systems, their IIS, more than 20 years ago. As many states with older unemployment insurance systems discovered during this past spring and summer, these systems are often ill-prepared for the unprecedented demands brought on by COVID-19. For example, many jurisdictions currently manage supplies of seasonal flu vaccines by having vaccine administration sites notify the state when they are running low on vaccine doses. This approach limits the ability of jurisdictions to reposition unused doses to areas of greater need and may result in some sites storing unused vaccines while others consistently run out. Especially for vaccines requiring ultra-cold supply chains, this longer-term storage is risky and expensive. Other critical issues that create the need for real-time tracking include the possibility of a recall. If there is a recall of certain vaccines or batches of vaccines, knowing the exact location of all vaccine doses in the recall will be critical.

Jurisdictions should leverage modern tools that maintain real-time inventory and holding-capacity data, making it easier to match demand to supply, preventing potential spoilage, and quickly vaccinating as many eligible residents as possible. States need to prepare for such difficulties early in the process and consider supplementing their existing IIS with a more modern system that will allow significantly more functionality than legacy systems. Although replacing an IIS entirely is likely not feasible during the vaccine effort, supplementing the IIS is a lower-impact step that states can take to substantially increase their ability to meet the demands of the COVID-19 vaccination effort.

Instilling Public Confidence

Technology and Data Management: Beyond Mandatory Data Reporting

States should not aim to collect just the minimum vaccine information required by the CDC. Many newer vaccine management systems exist that allow states to integrate the pre-qualification of recipients into priority groups, schedule initial and second-dose appointments, automate appointment reminders, track vaccine doses tied to recipients, allow recipients to log adverse reactions, and collect the data needed for more advanced mapping, demographic analysis, and other advanced and predictive data analytics.

The ability of these systems to automatically link the recipient, their demographic information, their specific vaccine type and batch, and any adverse effects is critical to the ongoing vaccination evaluation effort by the CDC.

Although the CDC has the Vaccine Adverse Event Reporting System (VAERS), this system often results in incomplete or unreliable information manually reported. Jurisdictions can improve the quality of data submitted to VAERS and help improve COVID-19 vaccine safety information much more quickly and efficiently by rolling out a modern, application-based integrated tool.

Further, significant risk of limited demand exists with the COVID-19 vaccines. The unprecedented speed to market of these vaccines, the existing lack of trust of the vaccination program in some communities, and the concerns over misinformation spreading through social media, may depress demand. The CDC is asking states to prepare for both high and low demand scenarios. Advanced data analytics, however, can help jurisdictions identify areas with anomalous vaccine demand, and specifically target those areas with information campaigns, listening sessions, and other efforts to increase vaccine uptake.

The Guidehouse team of data analytics experts has identified actions that public sector chief data officers and leaders can take to maximize the usefulness of data to drive informed, evidence-based decision-making throughout and beyond the Covid-19 pandemic. Moving into the next phase of the pandemic, sharing accurate and current data on vaccine distribution and administration to communicate government actions and keep the public informed, will be vital to shape a more effective response.

Communication and Confidence: The Need for Public Education and Community Engagement

Public opinion polls reveal a declining percentage of Americans would take the vaccine if it were available today, down to 50% in September from 72% in May.

This trend, and the overall skepticism of the vaccine, highlight the importance of effective public education and community engagement campaigns for a state's vaccine program. These efforts should focus on connecting with the underserved, hard to reach, vulnerable, and vaccine-hesitant populations, as well as communities at highest risk of COVID-19.

State and local government public education and community engagement approaches should be viewed through a health equity lens that leaves no community behind. Components of the approach should include:

- Outreach and engagement to communities at highest risk of COVID-19.
- · Close coordination with community-based organizations to disseminate information.
- · Digital media promotion with easy-to-access information about vaccine eligibility and FAQs.
- A consistent presence by trusted healthcare experts delivering messages to build public confidence about the vaccine, and proactive communication efforts to combat disinformation.

Addressing Equity and Inclusion

COVID-19 has disproportionately impacted low-income and communities of color, deepening a health crisis for the most vulnerable. As part of a phased approach for vaccine distribution, equity and inclusion considerations should be central in vaccine operations for state and local health departments. Based on rapidly changing circumstances, oversight and monitoring functions play a key role in identifying adjustments necessary to ongoing equitable allocation.

Health equity and inclusion activities critical for states and cities include:

- · Listening to a diverse range of stakeholders and perspectives.
- · Welcoming transparency in data-driven analysis of prioritization and allocation across and within communities.
- · Offering flexible and affordable provisions for uninsured, underinsured, and other vulnerable populations.



Bracing for Financial Impact

The economic impacts of COVID-19 have hit state budgets hard. States have, to date, been funding COVID-19 response and recovery efforts with funding from the Federal Emergency Management Agency (FEMA) Public Assistance (PA) Program and other federal sources, primarily the Coronavirus Relief Fund (CRF). Unfortunately, the CRF is only permitted to cover costs incurred through December 30, 2020; while some of those funds therefore may be able to cover early vaccine costs, longer-term planning, systems for monitoring and tracking, and the vast majority of jurisdictions' vaccine efforts will be outside the scope of CRF funds.

Funding for the initiative at the state and other jurisdictional levels is likely to come from two sources: 1) an additional COVID-19 response and recovery bill passed by Congress in the next few months, and 2) FEMA PA.

Additional Federal Aid to States for Vaccine Operations

As control of the Senate remains in doubt due to the Georgia runoff elections, it's difficult to predict what a new COVID-19 response and recovery bill will look like. State and local administrators should work with the Congressional delegations, however, to explain the vaccine distribution plans, challenges, and likely costs. These conversations will help leaders in Congress understand the vaccination-related needs for states and localities working to get the pandemic under control.

Potential FEMA Funding

Guidehouse expects that FEMA will pay for a portion of the costs that jurisdictions will incur related to the vaccination effort. While FEMA headquarters has not yet issued guidance on eligible costs, regional office proposals include the following potentially FEMA-eligible expenses.

- Equipment, and supplies for storing, handling, distributing/transporting, and administering COVID-19 vaccinations
 - PPE includes masks, face shields, and gloves for proper handling and administration of vaccinations, as well as handling dry ice for storage needs
 - Equipment including coolers/freezers, thermometers, and portable units for transportation
 - Supplies including alcohol pads, emergency medical kits, and dry ice
- Facility support costs, including leasing space for storage and/or administration of the vaccine, utilities, maintenance, and security
- Additional staff if necessary, including medical and support staff, consistent with public assistance labor policies in FEMA regulations
- Onsite infection control measures, including PPE for staff, as well as extra masks/cloth facial coverings for patients, disinfection of the facility and equipment in accordance with CDC guidance, temperature scanning, and physical barriers (e.g., plexiglass dividers)
- Eligible medical care and related costs including onsite emergency medical care and medical waste disposal
- · Communications to disseminate public information regarding vaccinations



We recommend government entities embed FEMA specialists at all phases of the procurement, management, and closeout process for these goods and services. With complete, FEMA-compliant documentation developed and collected throughout the project life cycle, government entities can more readily ensure FEMA obligation and thus be able to more quickly draw down funds.

FEMA PA funding is contingent on successful application of a Project Worksheet (PW). PW preparation is normally very time intensive, but it does not have to be. Administrators tasked with managing recovery efforts, usually in addition to their operational responsibilities, must spend a lot of time gathering evidence, resolving issues, or addressing gaps in documentation.

An embedded FEMA specialist involved in each step of the process will allow a state to file PWs with fully compliant and complete documentation much earlier than normal. Potential roles for these embedded FEMA specialists include:

- Consulting on how operational decisions may impact FEMA eligibility and review procurement/contracts/invoices as needed
- Answering questions related to FEMA PA eligibility as necessary
- Assisting with operational requirements as needed (invoicing support, vendor management)
- · Compiling and organizing documentation for PWs

If FEMA eligibility rules are announced as expected, the costs associated with contracting FEMA support specialists would fall under FEMA Category Z or Management Costs, and therefore would also be eligible for federal funding. A state could contract with FEMA specialists for vaccine support immediately, to begin the procurement and planning process, knowing these costs will be covered by federal funding.

Conclusion

The global COVID-19 pandemic is a massive challenge for states and cities. The virus has gravely impacted our governments, the economy, healthcare, and our lives. We must now simultaneously respond to the ongoing mitigation and treatment challenges while ramping up a massive supply chain, public education efforts, and reporting processes for the vaccine. An event with this level of complexity and urgency requires, more than ever, innovative, collaborative, and rapid responses.

Since the arrival of COVID-19, Guidehouse has assembled a team of experts and insights from public health, clinical medicine, disaster preparedness, supply chain resilience, economic development, and other areas to help our communities and people thrive. We stand ready to help states, local governments, healthcare providers, life sciences companies, and other organizations operationalize their vaccine deployment plans.

Contacts

Chris O'Brien Partner cobrien@guidehouse.com

Nini Donovan Partner ndonovan@guidehouse.com

Hillary Thompson Associate Director hthompson@guidehouse.com

Jordan Reisner Managing Consultant jreisner@guidehouse.com

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