

COVID-19 Vaccines: Planning for Equitable Distribution and Access

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Introduction

The successful development and regulatory authorization or approval of a vaccine for COVID-19 is only the first critical step in vaccinating Americans. Stakeholders at all levels of government and the private sector, particularly state and local officials, must aggressively plan for equitable distribution and timely administration of vaccines. Undertaking a mass vaccination campaign of this scale, speed, and complexity will require an unprecedented level of national cooperation informed by lessons learned in past vaccination campaigns, the underlying scientific details and requirements of the available vaccine, and the unique populations and public health capacity across each state.

As part of Operation Warp Speed, initial planning is already underway for a staged distribution of an eventual vaccine. Under the leadership of the Centers for Disease Control (CDC) and the Department of Defense (DOD), the Federal government has <u>outlined a process</u> by which a centralized distribution system will support allocation of vaccines to critical and high-risk populations across all states and territories. As with any routine or seasonal vaccine, states and territories have responsibility for the "last mile" of vaccine distribution and administration—managing state systems for vaccine allocation, ordering, distribution, and inventory management, as well as working with providers across the state to deliver vaccines to the public across a wide variety of settings.

COVID-19 vaccine distribution will present significant logistical and planning challenges due to the unprecedented speed and complexity of a mass vaccine campaign required to vaccinate the entire U.S. population. This issue brief outlines the key challenges that governors and other state health officials face in designing and implementing distribution plans, as well as considerations for how they can partner with health systems, providers, payers, and organizations at the local and community level to promote widespread access to and acceptance of a COVID-19 vaccine.

Key Considerations for Equitable Distribution of a COVID-19 Vaccine

To support COVID-19 vaccine distribution, state, territorial, and six local jurisdictions receiving Vaccines for Children Funding from the Centers for Disease Control and Prevention (CDC) were required to develop and submit a COVID-19 vaccine plan addressing requirements outlined in the CDC's COVID-19 Vaccination Program Interim <u>Playbook</u> for Jurisdictional Operations by October 16, 2020. These plans, however, are initial drafts that states will continue to amend and refine in



the coming weeks and months as Federal planning efforts continue and more information is known regarding vaccine efficacy profiles and supply.

On October 18, the National Governors Association published a list of <u>questions</u> submitted by governors from across the country, seeking additional clarity from Federal leaders on information required to support state planning, including funding to support vaccine program activities, allocation methodology, supply chain challenges, Federal reporting requirements, and communication with state partners. In particular, governors and other state officials continue to highlight the need for Federal funding to support under-resourced immunization programs and public health agencies executing an extended mass vaccination campaign. Additional Federal financial support will be critical to scale state data systems and vaccination infrastructure, build additional workforce capacity, and support strong public health communications and community engagement.

Goal #1: Support a coordinated, cross-agency planning process that engages external partners

The CDC Playbook and Early COVID-19 Vaccination Program Action Items for Jurisdictions document outline requirements that states develop 1) statewide coordination and planning committees, and 2) external-facing vaccine implementation committees that can engage a wide variety of partners in planning and addressing emerging challenges. Governors can ensure that planning and coordination teams convene appropriate leadership from the governor's office, public health, immunization programs, emergency management, legal counsels, communications specialists, and other critical public health and safety officials. Likewise, incorporating a wide variety of health care and community partners in planning and implementation—including partners with expertise in serving critical populations and marginalized communities—will help address potential barriers in reaching these populations, support greater public transparency into the decision-making process, and enable states to quickly adapt to evolving challenges.

Considerations for State Officials

- Ensure that vaccine implementation committees include representation from sectors
 across the state, including traditional vaccine partners, health care systems, congregate
 living facilities, businesses, educational institutions, religious and community leaders,
 tribal leaders, and organizations serving the Black, Latinx, and Indigenous communities
 and other populations at increased risk of severe outcomes from COVID-19.
- Leverage statewide committees to support planning and preparedness by reviewing the state's pandemic preparedness plans and lessons learned from previous pandemics, staging exercises to test operational plans, and coordinating responses to ongoing challenges.
- Coordinate with local public health departments and tribes to understand local conditions, avoid duplication of efforts, and ensure that populations can receive vaccines at convenient locations. For states with Indigenous communities, while some distribution will occur directly through the Indian Health Service (IHS), state leaders should engage with both Federally-recognized and non-recognized tribes to ensure that the vaccines will



be accessible for hard-to-reach populations at their usual sources of care, including urban settings.

Goal #2: Promote health equity, engage at-risk communities, and address barriers to access

Black, Latinx, Indigenous communities, and other communities of color have suffered a disproportionate impact of COVID-19 cases, hospitalizations, and deaths. Promoting health equity and reducing the burden of disease for these populations is a key principal underlying Federal and state planning frameworks, as well as other planning efforts to date. As such, effective strategies to distribute a COVID-19 vaccine in an equitable manner must actively mitigate the structural inequalities that have contributed to health disparities by ensuring that a vaccine is available in a variety of convenient community settings, building trust in communities, delivering vaccine information in ways that is culturally responsive, and addressing barriers related to cost and access to care. State leaders must also acknowledge past trauma that communities may have experienced related to vaccines and public health, and partner with community, religious, and tribal leaders to provide linguistically and culturally responsive information that responds to potential concerns.

Considerations for State Officials

- Ensure that promoting health equity is a guiding principal for planning efforts and that external engagement committees engage leaders from high-risk and historically marginalized communities.
- Leverage data and tools such as the CDC's <u>Social Vulnerability Index</u>, the <u>Mapping Medicare Disparities</u>, or existing state data to identify disparities in health outcomes by populations or geographies. Ensure that vaccine administration data includes critical demographic information, including race and age, to guide decision-making and track progress in reaching high-risk populations and supporting an equitable distribution.
- Evaluate and build on successful efforts to promote influenza vaccines in convenient community settings with appropriate social distancing. Where possible, leverage existing infrastructure such as drive-through testing sites, food drives, outreach to homeless populations, and harm reduction organizations, among others.
- Provide convenient access to vaccination for hard-to-reach communities through mobile vaccination facilities, neighborhood clinics, and other nontraditional but trusted administration sites such as faith-based organizations, grocery stores, community centers, senior citizen centers, barber shops, schools, and businesses.
- Partner with health providers and payers to eliminate financial barriers (such as co-pays for vaccine administration) for anyone who has difficulty in paying.

Goal #3: Develop a transparent, collaborative process for identifying and allocating early vaccine to critical populations

Once authorized or approved, a COVID-19 vaccine will be initially available in limited quantities, necessitating a <u>phased roll-out</u> that maximizes protection to public health while protecting high-



risk populations and critical workforces. One of the most pressing challenges for states will be to outline a process for prioritizing and allocating limited vaccine to populations most at risk for exposure or severe effects from COVID-19.

The National Academy of Science and Medicine's (NASEM) Framework for Equitable Allocation of Vaccine for the Novel Coronavirus was recently developed to inform policymakers as they determine initial allocations for limited vaccine supply. It outlines priority groups for distribution based on factors that include a population's risk of acquiring infection, community social risk according to CDC's Social Vulnerability Index, risk of severe morbidity and mortality, risk of negative social impact, and risk of transmitting infection to others. NASEM's framework will help inform the CDC's Advisory Committee on Immunization Practices (ACIP), which will recommend priority groups based on these principles, in addition to available evidence on COVID-19 epidemiology, disease burden, and current information on the vaccine's safety and effectiveness in different populations.

While ACIP and NASEM will provide broad guidance on populations that should be included in each distribution phase, states will need to identify, quantify, prioritize, and allocate to critical populations within these categories when initial vaccine supply is limited. For example, while NASEM has identified high-risk health workers, individuals with co-morbid and underlying conditions that put them at significantly higher risk, and older adults living in congregate care facilities as being included in Phase 1a and 1b of distribution, there are approximately 20 million health care workers and 100 million people with high risk medical conditions. States will need to work with health systems and other partners to identify, quantify, and prioritize within these sub groups, as well as develop plans for efficiently distributing to these populations.

Considerations for State Officials

- Develop a public, transparent process for allocation and distribution to critical
 populations that incorporates input from affected communities. A number of states have
 developed advisory committees for this purpose, incorporating input from organizations
 that provide care to critical populations into the development of state-based frameworks,
 as well as planning for the distribution of the vaccine to these populations.
- Adapt and refine NASEM and ACIP guidance on priority groups for early allocation, tailoring planning efforts to meet unique challenges and population needs across states based on factors such as demographics, health care infrastructure, disease transmission, and burden of disease.
- Build on existing partnerships and communications channels to develop processes for efficiently identifying and targeting populations for Phase 1 distribution. As an example, to identify Phase 1a populations (critical health care personnel at high risk for exposure), some states are surveying health systems to determine estimated populations of professions that meet these qualifications (e.g., nurses, physicians, EMT/paramedics, respiratory therapists, home health aides, long-term care staff), while others will rely on health system providers themselves to prioritize limited access.



Goal #4: Address physical distribution challenges based on state needs, infrastructure, and conditions

Operation Warp Speed's <u>plan</u> for centralized distribution of a COVID-19 vaccine includes three main components:

- A centralized distributor contract with McKesson (with an option for back-up distributors) that will deliver vaccines and ancillary supplies directly to states or other authorized partners.
- A web-based information technology (IT) tracking system, which will leverage the existing Vaccine Tracking System (VTrckS), to integrate vaccine allocation, ordering, uptake, and management.
- Partnerships for allocation and distribution with states, territories, and local and tribal health departments, as well as direct distribution to commercial pharmacies.

As outlined in the CDC Playbook and Jurisdictional Checklist, states are charged with identifying critical populations for early vaccine administration, enrolling and training providers, and identifying vaccination settings that can serve high volumes of individuals targeted during the phased roll out that can meet social distancing requirements and can meet potential storage and handling requirements. Planning guidance from the CDC advises that states prepare for a number of scenarios accounting for potential variability in product availability, cold or ultra-cold storage requirements, required number of doses, and requirements for mixing or reconstitution at the site of administration.

Considerations for State Officials

- Engage with health system leaders, including providers serving high-risk communities, to
 identify populations most likely to be included in early distribution (e.g., health care
 providers at high risk of exposure, individuals at high risk for severe outcomes, among
 others), support provider enrollment, and begin planning for distribution sites based on
 state population, infrastructure, and potential vaccine storage and handling needs.
- Begin planning with hospitals, health care systems, and long-term care facilities to stand
 up centralized points of distribution (PODs) that can support high-volume vaccine
 administration while maintaining social distancing requirements. In states with large rural
 populations, special considerations should be made for efficiently distributing vaccines
 (often packaged in doses of 1,000) to key populations while avoiding waste.
- As vaccine supply increases and targets for vaccination for priority groups are met, broaden provider participation in a wide variety of public- and private-sector settings, using "push" strategies to make the vaccine widely available in health care centers, school-based settings, workplaces, pharmacies, and temporary/mobile clinics.



Goal #5: Develop targeted and evidence-based communications strategies to promote vaccine confidence

Recent surveys indicate that as many as half of Americans would not get vaccinated if a vaccine were available today, with rising public concerns that a vaccine may be rushed through an approval process without meeting the rigorous standards for safety and efficacy. Additionally, organized misinformation campaigns have also contributed to what the World Health Organization (WHO) has dubbed an "infodemic" of false information related to COVID-19 circulating on social media, further undermining the public health response and fueling troubling levels of vaccine hesitancy in the United States. Ensuring that the public understands and has confidence in the FDA's process for evaluating the safety and efficacy of a vaccine is critical to the success of a vaccination campaign. Robust, multi-faceted communications strategies are needed to provide the public with clear, transparent information about the safety, efficacy, and availability of a vaccine, while engaging communities with targeted, culturally-responsive messages tailored to community concerns.

Considerations for State Officials

- Communicate with the public in clear terms about the integrity of the FDA's vaccine approval process, established standards for safety and efficacy, and how the vaccine will be distributed when availability is limited. A companion Duke-Margolis <u>issue brief</u> serves as a resource for understanding the FDA's well-established evaluation and approval process for vaccines.
- Partner with trusted messengers, including community and religious leaders as well as health care providers, to engage communities and respond to potential concerns with evidence-based public health messages.
- Develop culturally and linguistically responsive materials in partnership with organizations serving racial and ethnic minority communities and focus-group test messages.
- Continue to emphasize the importance of effective public health measures to reduce the spread of COVID-19, including mask-wearing, handwashing, and appropriate social distancing.

Goal #6: Build a robust data infrastructure for reporting, tracking, and monitoring vaccine information

States have existing Immunization Information Systems (IIS) that record immunization histories and have a range of other capabilities for ordering, tracking inventory, issuing reminders/recalls, and integrating with electronic health records (EHRs). Many states are leveraging additional software and/or adding IIS capacity to manage mass vaccination clinics, including appointment scheduling, online consent and insurance forms, follow-up surveillance, and clinic planning (supply and staffing needs based on number of appointments scheduled).



CDC is providing one such mass vaccination software solution, the Vaccine Administration Management System (VAMS). To meet Federal data reporting requirements, states will either need to submit data through the IZ Gateway, a centralized technical infrastructure that can support bi-directional exchange of immunization data between state IISs as well as large national and non-traditional vaccinators (e.g., large pharmacy chains or Federal agencies receiving vaccine directly from CDC), or directly to CDC's Clearinghouse. Data from the Clearinghouse will be deidentified and sent to the Immunization Data Lake, which is a cloud-hosted data repository that will receive, store, and manage COVID-19 vaccine data.

Considerations for State Leaders

- Assess whether state IISs are capable of supporting activities such as enrolling providers, ordering vaccines, managing inventory (including reporting wastage), and sending second dose reminders; or whether supplemental systems may be needed to augment these capabilities.
- In exploring supplemental systems (such as VAMs or other technology), identify options
 to address interoperability (such as connecting to EHRs and/or health information
 exchanges).
- Leverage mobile technologies to ensure that temporary or mobile vaccine administration sites can efficiently schedule and plan staffing for clinics, and can meet reporting requirements.
- Determine pathway for sharing data with CDC, either through the IZ Gateway (requiring
 a data use agreement and MOU) or through the CDC Clearinghouse (requiring a data use
 agreement that has not yet been provided by CDC). Assess whether legal or regulatory
 actions are needed to share personal health information with the Clearinghouse.

Conclusion

Executing a mass vaccination plan of this size and complexity—with remaining unknown and evolving information on vaccine availability, handling requirements, and efficacy across different subgroups—will require a dynamic planning process and coordination of all stakeholders involved in vaccinating the public. However, even before a vaccine is available, state and local officials can begin laying the groundwork for the timely and equitable distribution of a COVID-19 vaccine by investing in public health infrastructure, developing frameworks and decision-making processes for identifying and allocating to critical communities, and building coordination structures to respond to evolving challenges. Strategies for engaging communities, building public trust, and communicating the value of vaccines will also be critical to success of a vaccination campaign and—ultimately—moving beyond the pandemic to resume social and economic activities.



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Appendix: Additional COVID-19 Vaccine Planning Resources

Distribution Planning

- Early COVID-19 Vaccination Program Action Items for Jurisdictions
- COVID-19 Vaccination Program Interim Playbook for Jurisdictional Operations
- Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine
- CDC COVID-19 Vaccination Scenarios for Jurisdictional Planning
- National Governors Association Preparing for the COVID-19 Vaccine and Considerations for Mass Distribution
- <u>Kaiser Family Foundation Distributing a COVID-19 Vaccine Across the U.S. A Look at Key Issues</u>

Allocating to Critical Populations

- National Academy of Science and Medicine's (NASEM) Framework for Equitable Allocation of Vaccine for the Novel Coronavirus
- <u>Johns Hopkins Center for Health Security Interim Framework for COVID-19 Vaccine</u> Allocation and Distribution in the United States
- ACIP Meeting Information Upcoming Meetings and Past Meeting Materials

Building a Robust Data Infrastructure

- American Immunization Registry Association (AIRA) IIS Policies to Support Pandemic and Routine Vaccination
- The Immunization Gateway, Presentation to AIRA, August 11th, 2020

Communications and Community Engagement

- COVID-19 Vaccines: Ensuring Regulatory and Scientific Integrity During the Approval Process
- Vaccinate Your Family Understanding the Difference Between COVID-19 and Normal Vaccine Approval Process
- Association of Immunization Managers Vaccine Confidence Toolkit
- CDC COVID Communications Resources
- Johns Hopkins University Center for Health Security The Public's Role in COVID-19
 Vaccination: Planning Recommendations Informed by Design Thinking and the Social,
 Behavioral, and Communication Sciences