COUNTY OF LOS ANGELES
Public Health

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November 2, 2020

TO: Each Supervisor

FROM: Barbara Ferrer, Ph.D., M.P.H., M.Ed.
Director Barbara Ferrer

SUBJECT **COVID-19 VACCINATION PLAN FOR LOS ANGELES COUNTY (ITEM 19, BOARD AGENDA OF SEPTEMBER 15, 2020)**

This is in response to your Board's September 15, 2020, motion requesting that the Department of Public Health (Public Health) follow the Centers for Disease Control and Prevention's guidance and develop a COVID-19 vaccination plan for Los Angeles County and report back in 45 days. The Board also directed Public Health to include in the report back a campaign designed to increase vaccine acceptance rates.

Attached is the "Interim COVID-19 Vaccination Plan" (Plan) for Los Angeles County which describes a comprehensive and flexible approach that outlines targeted strategies and potential courses of action to vaccinate persons susceptible to infection with COVID-19. The Plan outlines a variety of planning assumptions based on the best available information and acknowledges that these assumptions and the recommended strategies may change over time as more information becomes available. The document anticipates that vaccine supply will change over time, beginning with constrained supply, then a large supply, followed by continued vaccination. The Plan outlines priority populations that will likely be vaccinated during each phase and describes the roles of various organizations as well as the necessity of coordinating with a wide range of community partners.

The Plan also describes communications planning for vaccine awareness and acceptance including plans to target specific audiences including communities highly impacted by COVID, frontline workers, communities with low coverage rates, and communities of color.

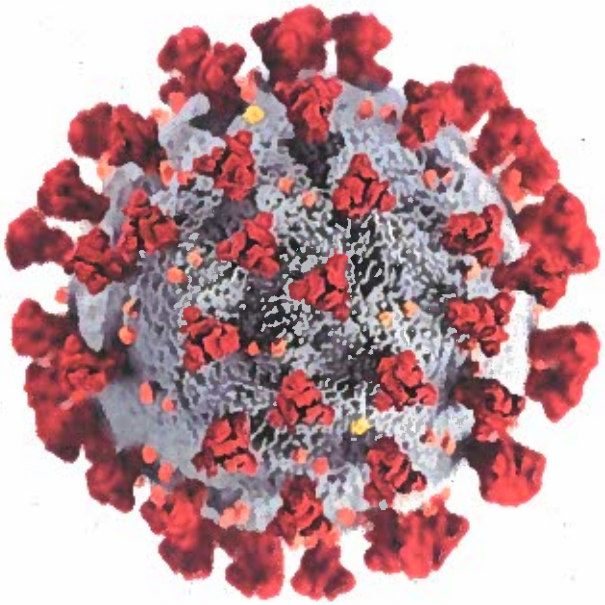
Public Health anticipates that information on upcoming available COVID-19 vaccines will be continuously changing and will keep your Board informed regularly of these changes as well updated information on our most current plan for vaccination.

If you need any additional information, please let me know.

BF:jdg

Attachment

c: Chief Executive Officer
County Counsel
Executive Officer, Board of Supervisors



INTERIM COVID-19 Vaccination Plan

LOS ANGELES COUNTY

Los Angeles County Department of Public Health
10-27-20 |

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Record of Changes

This page captures any substantive changes made to this document including the date, description, and rationale, and the name of the person who made the change.

Date of original version:

Date Reviewed	Change Number	Date of Change	Description of Change	Name of Author

Approval and Implementation

This plan applies to all agencies, departments, divisions and programs assigned emergency responsibilities herein, is hereby approved for implementation, and supersedes any previous editions.

11/2/2020
Date

Barbara Ferrer
Barbara Ferrer, PhD, MPH, MEd
Director
Los Angeles County Department of Public Health

11/2/2020
Date

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Background

The speed at which candidate vaccines against SARS-CoV-2 have been developed globally is unprecedented. In the U.S., one company, Moderna, in association with the National Institutes of Health (NIH), went into early clinical testing just 63 days after scientists first sequenced the viral genome. Now, more than 210 vaccine candidates are in development around the world, and the U.S. has four that have advanced to the final stages of clinical trials in which each vaccine's ability to safely protect recipients from infection is evaluated. The clinical trials are also being conducted simultaneously with large-scale manufacturing.

In addition, government agencies have worked with pharmaceutical manufacturers and regulatory agencies to accelerate the development process given that the benefits of expediting targeted aspects of this process outweigh potential concerns. Processes to accelerate the development include combining research phases, beginning later phases before initial ones are complete, building manufacturing capacity before trials are complete, providing guidance from the Federal Drug Administration (FDA) to assist in the development and licensure of vaccines, and issuing Emergency Use Authorizations (EUA) for successful candidates for use in healthcare workers or other essential workers before all studies have been completed.

Much of this work has occurred under the federal initiative, *Operation Warp Speed* (OWS), whose principal objective is to deliver safe and effective vaccine to every American who wants one. With multi-billion-dollar support provided through emergency supplemental and flexible discretionary funding, OWS has made considerable progress. 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. A successful COVID-19 vaccination program will require historic coordination across all levels of governments as well as with a wide range of public and private partners to ensure efficient, effective, and equitable access to COVID-19 vaccines.

Situational Overview

As of October 1, 2020, over 210 vaccines for COVID-19 are in various stages of development across the globe. As of the writing of this plan, more than 50 are in human trials. In the U.S., HHS has funded six pharmaceutical companies to develop and manufacture vaccine under OWS. It is not known which vaccines will be approved. Therefore, this plan is an interim and working document that will evolve over time based on the best information available at the time.

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

Purpose

To prevent COVID-19 cases, hospitalizations, and deaths through a safe and effective vaccine

Goals

- Reduce transmission, morbidity, and mortality of COVID-19 disease
- Help minimize disruption to society and economy, including maintaining healthcare capacity
- Ensure equity in access to vaccine

Scope

The scope of this document is to provide targeted strategies and potential courses of actions to be activated in order to vaccinate persons susceptible to COVID-19. Administering COVID-19 vaccine as a preventive medication is expected to minimize morbidity and mortality and preserve healthcare, workforce, and infrastructure functions in our community.

Role

The role of Los Angeles County Department of Public Health (Public Health) in the National COVID-19 Vaccine Program is to:

- Oversee and coordinate the federally-supported centralized vaccine distribution system administered through the State of California in Los Angeles County to public and private partners;
- Provide vaccine to the eligible uninsured, underinsured, undocumented, those lacking a medical home, and anyone experience challenges accessing vaccine administered through any other means;
- Maintain flexibility and responsiveness for the use of vaccine based on local conditions including available supply, local impacts, and epidemiology of the pandemic;
- Track and report doses administered;
- Present recommendations on target groups for vaccine administration and update them based on local disease epidemiology and vaccine demand;
- Develop plans for the allocation, distribution, and administration of vaccine for LA County;
- Determine how to strategically allocate doses based on optimizing reach of targeted groups;
- Conduct public information campaigns on vaccine eligibility and safety; and
- Provide guidance to partners to ensure appropriate safety measures while undertaking vaccination efforts (e.g., use of personal protective equipment [PPE], physical distancing, etc.)

Section 1: COVID-19 Vaccination Preparedness Planning

Pandemic vaccination response planning requires collaboration among a wide range of public and private sector partners, including immunization and public health emergency preparedness programs, emergency management agencies, healthcare organizations, industry groups that include critical infrastructure sectors, policy makers, and community vaccination providers (e.g., pharmacies, occupational health settings, doctors' offices). Many of these partners are engaged regularly in seasonal influenza and other outbreak vaccination campaigns, and many served as vaccination providers during the 2009 H1N1 influenza pandemic. However, significant additional planning is needed to operationalize a vaccination response to COVID-19, which is much larger in scope and complexity than seasonal influenza or other previous outbreak-related vaccination responses.

Planning Assumptions

Vaccine

- At the end of September 2020, the CDC told public health agencies that "limited doses of a vaccine may be available beginning in late October or November, although that would only be if a vaccine is shown to be safe and effective."
- All Phase II/III trials in the U.S. are trying to recruit participants that closely align with the U.S. population demographics.
- According to OWS, Vaccine A may have two million doses available by the end of October, with 10 to 20 million doses possibly available by end of November, and 20 to 30 million by the end of December. Vaccine B could have about 1 million doses available by October, 10 million by November, and 15 million by December.
- Two (2) doses of COVID-19 vaccine, separated by ≥21 or ≥28 days, will be needed for immunity for some vaccine candidates; both doses will need to be with the same product. This will require tracking vaccine administered, personal vaccination profiles, and patient reminders.
- Some vaccine candidates will require an ultra-low cold (ULC) chain.
- Cold chain storage and handling requirements for each COVID-19 vaccine product will vary from refrigerated (2°C to 8°C) to frozen (-15°C to -25°C) to ultra-cold (-60°C to -80°C) temperatures, and ongoing stability testing may impact these requirements. These temperatures are based on information available as of September 15, 2020. Updated information will be provided as it becomes available and may lead to varied stability profiles necessitating changes in cold chain requirements.
- Some COVID-19 vaccine products will likely require reconstitution with diluent or mixing adjuvant at the point of administration.
- Because of uncertainty, planning needs to include high demand and low demand scenarios.
- Dose level accountability and daily reporting for ordering, distribution, and administration of two-dose vaccine series will be required.
- Communications and public perception may be challenging given adverse events documented in the trials and because people will be getting COVID-19 after vaccination that may not be related.

Approval

- The FDA is responsible for approving and regulating vaccines in the U.S. It has previously stated that any vaccine would have to be 50 percent more effective than a placebo.
- If the clinical trial data shows efficacy and safety, the vaccine developer may apply to the FDA to license for a formal Biologics License (BL) or an EUA.
- The BL must provide the FDA reviewer team with the efficacy and safety information necessary to make a risk/benefit assessment and to recommend or oppose the approval of a vaccine. A pre-approval inspection is conducted during which production of the vaccine as it is in progress is examined in detail.

- The EUA can be sought and issued to facilitate the availability of an unapproved product only after several statutory requirements, including a determination by the FDA that the "known and potential benefits of an unapproved product, when used to prevent a serious or life-threatening disease or condition, outweigh the known and potential risks of the unapproved product."
- Initial doses of COVID-19 vaccine may be authorized for use under an EUA issued by the FDA.
- At any stage, if data raise significant concerns about either safety or effectiveness, FDA may request additional information or studies, or may halt ongoing clinical studies.
- The NIH hosts an independent Data and Safety Monitoring Board (DSMB) that reviews data and has the authority to end the trials early if the results are overwhelmingly positive or negative.

Distribution

- COVID-19 vaccine distribution will be managed centrally, although vaccines may be handled through more than one distributor.
- Distribution may be expanded to include additional healthcare organizations and vaccination providers who can provide pandemic vaccination to targeted groups. Vaccine will be sent directly to some vaccination providers (e.g., pharmacies, physician's offices, the Veterans Administration) or designated receiving sites for secondary distribution to administration sites (e.g., public health departments, chain drug stores central distribution).
- Vaccine providers must enroll with California Department of Public Health's (CDPH's) provider system to receive vaccine, administered locally by Public Health's Vaccine Preventable Disease Control Program's system.
- Multi-jurisdictional providers may have agreements with federal and state governments for distribution and will need to establish channels for communication and coordination with Public Health.
- COVID-19 vaccine and ancillary supplies (including needles and syringes for vaccine reconstitution and administration and appropriate PPE) will be provided and distributed to providers by the federal government at no cost to enrolled pandemic vaccination providers.

Allocation

- COVID-19 vaccine will be allocated to each jurisdiction and selected commercial and federal partners.
- The amount of COVID-19 vaccine allocated to each jurisdiction will be based on several factors, including population size and final priority group selection.
- Enrolled vaccination providers receiving vaccine through their jurisdiction allocations will order COVID-19 vaccine from the County's allocation.
- Allocations may shift over time based on supply, demand, and disease epidemiology.

Prioritization

- Once a vaccine is FDA-approved for use, it will take several months to be produced in sufficient quantities to immunize large numbers of people. Therefore, CDC's Advisory Committee on Immunization Practices (ACIP) is developing a prioritization plan, in consultation with the NIH and the National Academies of Sciences, Engineering, and Medicine.
- Initial populations recommended for COVID-19 vaccination will likely be healthcare workers, followed by some combination of essential workers, those with high-risk medical conditions, older adults, and staff and residents in long-term care facilities.
- Recommendations for groups to target will likely change after vaccine is available, depending on characteristics of each vaccine, vaccine supply, and disease epidemiology.
- ACIP has stated that they will finalize the prioritization plan once final clinical trial data is independently reviewed for safety and efficacy, and the FDA authorizes or approves vaccine(s) for use.

Vaccine Requirements

- There will be multiple types of vaccine available with different contraindications, cold chain requirements, and ancillary supplies.
- Phase I distribution under EUA will require active surveillance in early recipients and most likely be shipped directly to states and local health jurisdictions as well as a handful for multi-jurisdictional healthcare partners.
- The vaccine will become available in phases, increasing over time. These are the current projections as of mid-October:
    - Phase 1: Limited doses available- estimated for December 2020
    - Phase 2: Large number of doses available- estimated increase of supply in February 2021
    - Phase 3: Continued vaccination- sufficient supply to meet demand by mid-2022

Phase 1: Constrained Supply

- COVID-19 vaccine authorized for use under an EUA
- ACIP recommends specific groups of the population for priority receipt of the vaccine
- Anticipated prioritized population:
    - Healthcare personnel: All paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials. This includes persons not directly involved in patient care but potentially exposed to infectious agents while working in a healthcare setting.
    - Essential workers: Workers who are essential to continue critical infrastructure and maintain the services and functions Americans depend on daily and who cannot perform their duties remotely and must work in close proximity to others.
    - National Security population
    - Long Term Care Facility residents
- As more vaccine supply and data becomes available, these are the anticipated additional prioritized populations:
    - Adults with medical conditions at higher risk for severe illness, including those with medical conditions such as cancer, chronic kidney disease, chronic obstructive pulmonary disease, immunocompromised state from solid organ transplant, obesity, serious heart conditions, sickle cell disease, and type 2 diabetes mellitus
    - Adults 65 years of age and older
- Expected COVID-19 Vaccine:
    - Two (2) mRNA-based vaccines available with different cold chain management requirements and ancillary/mixing supplies that are shipped separately
    - Two (2) dose series administered, one requires 21 and other is 28 days from the first dose

Phase 2: Large Number of Supply

- Anticipated prioritized population:
    - Adults with Medical Conditions at Higher Risk for Severe COVID-19: medical conditions include cancer, chronic kidney disease, chronic obstructive pulmonary disease, immunocompromised state from solid organ transplant, obesity, serious heart conditions, sickle cell disease, and type 2 diabetes mellitus
    - Under-resourced/disproportionately impacted communities
    - Adults 65 years and older
    - As supply increases, ensure equity of access to all population
- Expected COVID-19 Vaccine:
    - Anticipated to have up to 4 different vaccines available

Phase 3: Continued Vaccination

With sufficient supplies, continue to make vaccine available through existing healthcare structure and vaccine provider networks

H1N1 Lessons Learned

Over the years, LA County has engaged in numerous table-top exercises for pandemic planning and has taken a consistent approach for improvement-related activities each year during seasonal flu exercises. There are many unknowns and unanswered questions at this time. For example, it is not yet known which vaccines will be available, in what volumes, at what time, with what efficacy, and with what storage and handling requirements. However, LA County is reviewing planning assumptions and building out different scenarios. In addition to current situational awareness, Public Health reviewed our 2009 H1N1 pandemic vaccination response After Action Report and Improvement Plans.

Key strengths

Strengths identified during the H1N1 response included the following:

- **Efficient and innovative use of anti-viral resources.** Public Health performed targeted ring prophylaxis with Tamiflu on household contacts of first 60 confirmed and probable cases.
- **Effective collaboration with County response partners**. With Department of Health Services, Emergency Medical Services Agency partners, pre-staged over 10,000 antiviral courses.
- **Real world operationalization of Pandemic Influenza Plan.** While the overall severity of the disease proved to be relatively mild for the first wave, the emergence of H1N1 provided a real-world opportunity to utilize, test and refine Public Health's Pandemic Influenza Operational Plan. The H1N1 response also represented the first comprehensive and protracted application of the Department's emergency response structure to handle a global public health event.
- **Facilitating local declaration of emergency.** Following the declaration of a national public health emergency by the CDC and the imminent spread to Los Angeles County, the Los Angeles County Public Health Officer requested that the Board of Supervisors proclaim a local emergency on April 27, 2009. This declaration eased logistical and fiscal requirements, greatly improving the Department's response capacities.
- **Successful activation of emergency response plans.** This incident marked the first high level and sustained real-world activation of the Public Health Department Operations Center (DOC), as well as the first sustained utilization of the plans, policies, and procedures that support such efforts.
- **Effective coordination of events by** Public Health. The DOC activation underscores the effectiveness of the ongoing ICS/Standardized Emergency Management System (SEMS)/National Incident Management System (NIMS) training courses that Public Health staff members have completed over the past several years.
- **Nimble investigation and effective communication.** Public Health Programs and Units conducted solid and comprehensive disease investigation and surveillance utilizing staff and tools from various programs, which were critical for public health emergency response of the H1N1 incident.
- **Unique position on non-pharmaceutical interventions**. Although CDC and CDPH recommendations for pandemic response included school closures and other social distancing measures, Public Health reviewed the science supporting the measures and determined that they would not be effective unless implemented early, widely, and for the duration of the pandemic. Given that cases remained moderate, that the impact of the measures if implemented improperly was negligible, and the high societal and economic costs, Public Health did not implement these measures.

The after-action report from H1N1 noted the following areas in need of improvement. Public Health has successfully operationalized and updated all of these plans and structures in the years since H1N1, and they have been in use during our pandemic response to COVID-19.

- **Development and coordination of response plans.** Public Health activated the DOC in response to the H1N1 incident in Spring 2009. A formal and comprehensive DOC Plan has not been fully developed and integrated into Public Health preparedness and response efforts. Public Health should complete a DOC Plan to include ICS compliant Job Action Resource Guides (JARGS) and position checklists. Public Health should ensure that all key response staff are familiar with the Plan and the Plan is trained and exercised.
- **Utilization of ICS.** Public Health implemented the ICS for its DOC activation. It is acknowledged that there are opportunities for continued understanding and utilization of DOC and ICS principles. In some cases, the DOC organization chart was created by replacing ICS units with Public Health programs, rather than reorganizing staff into "true" ICS structure. An integrated functional command and control structure within all areas of the DOC ICS should be included in the training and incorporated into the DOC Plan.
- **Enhanced understanding of response strategies and responsibilities.** Shared understanding among DOC staff of (1) the role and capabilities of each Public Health program and (2) the overlap and coordination between Public Health programs could streamline strategic planning efforts during DOC activation. Public Health should arrange for training meetings that provide Public Health staff with such familiarization.
- **Improved use of COOP.** Public Health responded to the H1N1 incident as directed by previously developed plans, preparedness training and exercises. A Continuity of Operations Plan was developed in 2007-2008. In the spirit of building on these efforts, additional measures should be taken to ensure the continuity of Public Health core services and programs.

Section 2: COVID-19 Organizational Structure and Partner Involvement

Planning and Coordination Team (Internal)

Public Health COVID-19 Vaccine Response Organizational Structure has been established through a reorganization of the current ICS structure with key personnel moving out of their current roles into new roles and additional staffing. Public Health currently has an internal COVID-19 Vaccination Program Leadership Team and a COVID Vaccine Planning and Coordination Team made up of Emergency Preparedness and Vaccine Preventable Disease Control subject matter experts. The larger structure is being developed and will include additional staff from legal affairs, media/public affairs, Bureau of Disease Control, and crisis and emergency risk communications. In addition, there will be a team with clinical expertise from programs that serve the early populations of focus (e.g., Healthcare Workers, Emergency services, those 65+ years and older living in congregate settings, HIV/AIDS program, Persons Experiencing Homelessness, etc.).

External Planning and Coordination Workgroups

Reaching intended vaccine recipients is essential to achieving desired levels of COVID-19 vaccination coverage. To ensure equitable access to vaccinations, we will need to strategically overlay detailed demographic information of key priority populations within a jurisdiction with logistical and safety considerations. This will require extensive collaboration with external entities and community partners who are familiar with how these key priority populations obtain healthcare, how to best meet communities where they are in terms of attitudes and behaviors toward immunizations, and other essential services.

Public Health is working with its key partners and will build those out into strategic workgroups for the various phases of the roll-out. The External Phase 1 Implementation Workgroup will consist of all local partners that will be distributing COVID-19 vaccine in Phase 1, regardless of who the allocating partner is; federal, state, or local. This will likely include the public health departments from the cities of Pasadena and Long Beach, the VA, Public Health, and a handful of multi-jurisdictional healthcare partners.

Public Health will also establish a variety of committees and coalitions to enhance development of plans, reach of activities, enhance feedback from communities, and risk/crisis response communication messaging and delivery. Committee membership will include leadership from the jurisdiction's COVID-19 planning and coordination team as well as representatives from key COVID-19 vaccination providers to and community members in priority population groups identified by ACIP. These priority population groups will be voted on and finalized immediately following the issuance of an Emergency Use Authorization to the first vaccine.

The development of these committees and coalitions guidelines and application/appointment process are under development but will be very helpful in advocating for and developing strategies to ensure equitable access to COVID- 19 vaccination services.

State-Local Coordination

Pandemic vaccination planning is a combined state and local responsibility that requires close collaboration between public health, external agencies, and community partners. It is imperative that the State and Public Health combine and coordinate efforts. Coordination will be necessary to ensure equitable access to COVID-19 vaccination across geographies. CDPH and Public Health's VPDC program have been holding weekly calls with the State's Immunization Branch for a month to align areas of responsibility as well as specific tasks to complement rather than duplicate efforts at either level, maximizing the efficient use of resources and overall quality of the COVID-19 Vaccination Program.

Governor Gavin Newsom established a Scientific Safety Review Workgroup to advise the state on COVID-19 vaccines that includes a variety of clinicians from local health jurisdictions, academia, and public health. Dr. Erica

Pan, Acting State Public Health Officer, named a group of California immunization, geriatrics, ethics, epidemiology, health equity, and pharmacy practice experts to the state's COVID-19 Drafting Guidelines Workgroup. This Workgroup will develop California-specific guidance for the prioritization and allocation of a COVID-19 vaccine and includes Public Health's Director of Vaccine Preventable Disease Control.

Tribal Communities

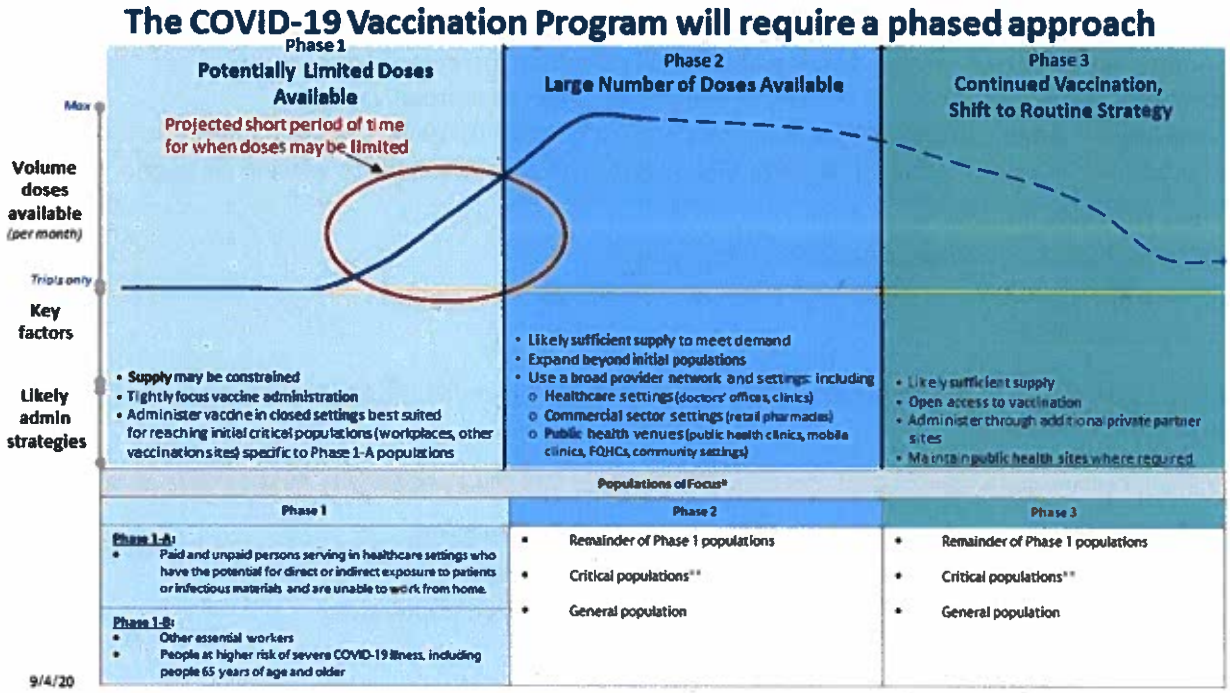
CDC is working directly with the Indian Health Service (IHS) at the federal level and CDPH is reaching out to various tribal communities throughout California to ensure these communities are included in the planning stages. Los Angeles County is home to more Native Americans/ Alaska Natives than any other county in the United States, totaling more than 140,000 people. While there are no federally recognized Native American Indian tribal lands within LA County boundaries, we are home to three Native American Indian tribes that predate the establishment of California Missions: the Ventureño, Gabrieleño, and Fernandeño. Although IHS may provide vaccination services to the populations they serve, plans are currently in development regarding vaccine distribution to tribal health facilities, including urban facilities, that are not officially connected to IHS. Public Health will work with leaders in the non-federally recognized tribes in their area to ensure they have access to vaccination services, since these groups may not be served by IHS.

Section 3: Phased Approach to COVID-19 Vaccination

Due to changing vaccine supply levels at various points during the COVID-19 Vaccination Program, planning needs to be flexible but as specific as possible to accommodate a variety of scenarios. Although vaccine supply will be limited at the beginning of the program, the vaccine supply is projected to increase quickly over the succeeding months, allowing vaccination efforts to be expanded to additional critical populations and the general public. It is important to note that recommendations on the various population groups to receive initial doses of vaccine could change after vaccine is available, depending on each vaccine's characteristics, vaccine supply, disease epidemiology, and local community factors.

Final decisions at the federal level are being made about use of initially available supplies of COVID-19 vaccines. These decisions will be partially informed by the proven efficacy of the vaccines coming out of Phase 3 trials.

The following graph illustrates the three phases of the COVID-19 Vaccine Program and populations of focus in each phase.



Phase 1: Constrained Supply

Initial doses of vaccine will likely be distributed in a limited manner, with the goal of maximizing vaccine acceptance and public health protection while minimizing waste and inefficiency. COVID-19 vaccine administration efforts must concentrate on the initial populations of focus to achieve vaccination coverage in those groups. Inventory, distribution, and any repositioning of vaccine will be closely monitored through daily reporting to ensure end-to-end visibility of vaccine doses.

Priority populations will likely include:

- Frontline Healthcare Personnel (examples – hospitals, outpatient, pharmacies, EMS, public health)
- Essential Workers (examples – transportation, education, energy, law enforcement, water and wastewater, food and agriculture)
- National Security population

- Long Term Care Facility residents and staff, Skilled Nursing Facility residents and staff, assisted living facilities and staff, home health care aids

The limitations of the EUA eligibility and specialized cold chain and handling may determine the best courses of action for administering the COVID-9 vaccine.

- Activate Closed Medical Points of Dispensing (MPODSs) with partners
- Activate Emergency School Located Vaccination with partners
- Partner with the occupational health programs
- Partner with DHS and EMS agency
- Partner with pharmacies to make vaccine available to prioritized population
- Partner with clinics to make vaccine available to prioritized population
- Activate team(s) to conduct mobile vaccinations at sites that do not have licensed vaccinators

Phase 2: Large Number of Supply

COVID-19 vaccine supply will likely be sufficient to meet demand for critical populations as well as the general public. Additional COVID-19 vaccine doses available will permit an increase in vaccination providers and locations. A surge in COVID-19 vaccine demand is possible, so a broad vaccine administration network for surge capacity will be necessary while a low COVID-19 vaccine demand is also a possibility, so supply monitoring should be routinely adjusted as necessary to minimize vaccine wastage.

Priority populations will likely include:

- Under-resourced/disproportionately impacted communities
- Adults with medical conditions at higher risk for severe COVID-19
- Adults 65 years and older

The availability of vaccine supply and prioritization of populations may determine the best courses of action for administering the COVID-19 vaccine.

- Activate Closed MPODs with partners
- Partner with pharmacies to make vaccine available to prioritized population
- Partner with clinics to make vaccine available to prioritized population
- Partner with healthcare entities to make vaccine available to prioritized population
- Activate Public MPODs with city partners
- Activate a team to conduct mobile vaccinations

Phase 3: Continued Vaccination- sufficient supply

Ultimately, COVID-19 vaccine will be widely available and integrated into routine vaccination programs, run by both public and private partners. With sufficient supplies, continue to make vaccine available through existing healthcare structure and vaccine provider networks.

The availability of vaccine coverage data may determine the best courses of action for administering the COVID-19 vaccine.

- Monitoring COVID-19 vaccine uptake and coverage in critical populations and enhancing strategies to reach populations with low vaccination uptake or coverage
- Continue to focus on equity of access and uptake
- Partner with commercial and private entities to ensure COVID-19 vaccine and vaccination services are widely available
- Monitoring supply and reposition refrigerated vaccine products to minimize vaccine wastage

Section 4: Critical Populations

Planning Considerations

The federal government will issue guidance on which groups to prioritize for initial COVID-19 vaccination once safety and efficacy data have been released and an application for an EUA has been submitted. Allocation of COVID-19 vaccine to jurisdictions will be based on multiple factors, including:

- Populations recommended by the ACIP (with input from the National Academy of Sciences, Engineering, and Medicine)
- Current local spread/prevalence of COVID-19
- COVID-19 vaccine production and availability

Public Health anticipates allocations may shift during the response based on supply, demand, and risk. Due to the need to be prepared and respond to these eventualities, Public Health is outlining specific planning scenarios for both high-demand and low-demand scenarios.

Public Health is currently working with CDPH on (1) identifying, (2) estimating the numbers of, and (3) the location of the critical populations listed below:

- Healthcare personnel
- Other essential workers
- Long-term care facility residents (e.g., nursing home and assisted living facility residents)
- People with underlying medical conditions that are risk factors for severe COVID-19 illness
- People 65 years of age and older
- People from racial and ethnic minority groups
- People from tribal communities
- People who are incarcerated/detained in correctional facilities
- People experiencing homelessness/living in shelters
- People attending colleges/universities
- People living and working in other congregate settings
- People with disabilities
- People who are under- or uninsured

Section 5: COVID-19 Provider Recruitment and Enrollment

An adequate network of trained, technically competent COVID-19 vaccination providers in accessible settings is critical to COVID-19 Vaccination Program success.

Planning Considerations

To receive and administer COVID-19 vaccine and ancillary supplies, vaccination providers must enroll in the United States Government (USG) COVID-19 vaccination program, coordinated through Public Health's VPDC Program, by signing and agreeing to conditions outlined in the COVID-19 Vaccination Program Provider Agreement. Public Health will be required to maintain these agreements on file for a minimum of three years.

- Public Health will be required to collect and submit to CDC information on each enrolled vaccination provider/site, including provider type and setting, patient population (i.e., number and type of patients served), refrigerated/frozen/ultra-cold temperature storage capacity, and logistical information for receiving COVID-19 vaccine shipments.
- Some multijurisdictional vaccination providers (e.g., select large drugstore chains, VA, large HMOs, and other federal providers) will enroll directly with CDC to order and receive COVID-19 vaccine. These directly enrolled partners will be required to report vaccine supply and uptake information back to Public Health.
- CDC will share additional information when available on these procedures to ensure Public Health has full visibility for planning and documentation purposes.
- Public Health may choose to partner with commercial entities to reach the initial populations of focus.
- Routine immunization programs will continue.

COVID-19 Vaccination Provider Training

Training of COVID-19 vaccination providers is vital to ensure the success of the COVID-19 Vaccination Program. Public Health will utilize CDC educational resources currently being developed, but Public Health may use CDPH or other additional resources.

COVID-19 vaccination providers must understand the following:

- ACIP COVID-19 vaccine recommendations, when available
- How to order and receive COVID-19 vaccine
- COVID-19 vaccine storage and handling (including transport) requirements
- How to administer vaccine, including reconstitution, use of adjuvants, appropriate needle size, anatomic sites for vaccine administration, avoiding shoulder injury with vaccine administration, etc.
- How to document and report vaccine administration via the jurisdiction's Immunization Information System (IIS) or other external system
- How to manage vaccine inventory, including accessing and managing product expiration dates
- How to report vaccine inventory
- How to manage temperature excursions
- How to document and report vaccine wastage/spoilage
- Procedures for reporting moderate and severe adverse events as well as vaccine administration errors to VAERS
- Providing EUA fact sheets or VISs to vaccine recipients
- How to submit facility information for COVID-19 vaccination clinics to CDC's VaccineFinder (particularly for pharmacies or other high-volume vaccination providers/settings)

Section 6: COVID-19 Vaccine Administration Capacity

Occupational health settings, temporary vaccination clinics, and closed PODs will be particularly useful for the vaccination of critical infrastructure workers and other select critical populations early in the COVID-19 vaccination response when vaccine supply may be limited. Once vaccine supply increases, leveraging a wide variety of potential community COVID-19 vaccination providers and settings is essential to providing equitable access to COVID-19 vaccination for all people in all communities.

Public Health is currently assessing the overall potential COVID-19 vaccine administration capacity in the County, using a variety of COVID-19 vaccination provider types and settings. "Vaccine administration capacity" is defined as the maximum achievable vaccination throughput regardless of public demand for vaccination. We are working to generate rough estimates of COVID-19 vaccine administration capacity and our ability to reach various COVID-19 vaccination coverage goals

Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management

Planning Considerations

- COVID-19 vaccine and ancillary supplies will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers.
- Administration fees may become reimbursable.
- CDC will use its current centralized distribution contract to fulfill orders for most COVID-19 vaccine products as approved by CDPH and Public Health. Some vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer.
- Enrolled vaccination providers will follow the CDPH and Public Health's vaccine ordering procedures.
- COVID-19 vaccination providers will be required to report ongoing COVID-19 vaccine inventory.
- Vaccine orders will be approved and transmitted in CDC's Vaccine Tracking System (VTrckS) by Public Health for vaccination providers they enroll.
- Vaccine (and adjuvant, if required) will be shipped to provider sites within 24 hours of order approval by Public Health, if supply is available. Ancillary supply kits and diluent (if required) will ship separately from the vaccine due to different cold chain requirements, but shipment will be timed to arrive with or before the vaccine.
- Ancillary supply kits will include needles, syringes, alcohol prep pads, COVID-19 vaccination record cards for each vaccine recipient, and a minimal supply of personal protective equipment (PPE), including surgical masks and face shields, for vaccinators.
- Each kit will include supplies needed to administer 100 doses of vaccine.
- Public Health may need to plan for additional PPE, depending on vaccination site needs.
- For COVID-19 vaccines that require reconstitution with diluent or mixing adjuvant at the point of administration, these ancillary supply kits will include additional necessary syringes, needles, and other supplies for this purpose.
- Sharps containers, gloves, bandages, and other supplies will not be included.
- Minimum order size for CDC-centrally distributed vaccines will be 100 doses per order for most vaccines. Minimum order size for direct-ship vaccines may be much larger (~4,800).
- Vaccine will be sent directly to vaccination provider locations for administration or designated depots for secondary distribution to administration sites (e.g., chain drugstores' central distribution).
- Once vaccine products have been shipped to a provider site, the federal government will not redistribute product.
- Public Health will be allowed to redistribute vaccines while maintaining the cold chain. However, with the challenge of meeting cold chain requirements for frozen or ultra-cold vaccines, Public Health will be judicious and limit any redistribution to refrigerated vaccines only.

Allocation

Allocation of initial doses of COVID-19 vaccine distributed under an EUA will arrive into LA County via federal allocation to their direct partners (VA, Chain pharmacies CVS and Walgreens, etc.), through state allocation to a few multi-jurisdictional healthcare partners, and to LAC, LB, and Pasadena DPHs.

Ordering

Phase 1 will be a constrained supply and thus an allotment. An ordering and management system is being developed at the state level. All federally qualified health centers (FQHCs), pharmacies, and other community clinics and healthcare partners wanting to distribute vaccine will be able to sign up via the state registration system that will entail ensuring they meet the criteria to be an administration partner.

Distribution

During Phase 1, distribution is expected to be a mixture between direct ship to the federal and state allocation to a handful of pre-certified partners as well as direct ship to Public Health. All FQHCs, pharmacies, and other community clinics and healthcare partners wanting to distribute vaccine in Phase 2 will need to register. Public Health is running various POD scenarios based on planning assumptions to identify the most strategic allocation of resources across the county while meeting priority group allocation and ensuring equitable access given the NASEM and other frameworks.

Inventory Management

Inventory management will be run our logistics and planning teams. CDC, the manufacturers, and McKesson, the distributor, have a system of QR codes that will be used to mainly manage inventory operations. A large warehouse will house doses in the appropriate cold chain and in proximity to the ancillary supplies will be maintained through Phase 2 and potentially longer based on necessity. Current assessments are underway by CDPH to understand the clinical cold chain and storage capacity. Satellite, temporary, and off-site clinic storage and handling considerations have been drafted and will be finalized when we know which vaccines meet the safety and efficacy criteria to apply for an EUA.

Section 8: COVID-19 Vaccine Storage and Handling

Planning Considerations

- The planning scenarios described below will be used by Public Health to develop operation plans for early COVID-19 vaccination when vaccine supply may be constrained.
- The scenarios describe potential COVID-19 vaccine requirements, early supply estimates after vaccine product approvals, and populations that may be recommended for vaccination during this early period. They are designed to support planning, but are hypothetical, and may evolve as more information is available.
- Assume that by January 2021 significantly more COVID-19 vaccine will be available for distribution and plans will need to evolve to address additional vaccine availability.

Scenario 1: Vaccine A demonstrates sufficient efficacy/safety for EUA in 2020

Availability Assumptions

	Vaccine availability by			
Candidate	**End of Oct 2020**	**End of Nov 2020**	**End of Dec 2020**	**Notes**
Vaccine A	~2M doses	10–20M doses	20–30M doses	Ultra-cold (-70 °C), for large sites only

Distribution, Storage, Handling, and Administration Assumptions

Vaccine A	
SHIPMENT ***3 separately acquired components (mixed on site)*** 1. Vaccine • Direct to site from manufacturer (on dry ice) • Multidose vials (5 doses/vial) 2. Diluent • Direct to site from USG (at room temperature) 3. Ancillary supply kits • Direct to site from USG (at room temperature)	**ON-SITE VACCINE STORAGE** ***Frozen (-70 °C ± 10 °C)*** • Must be used/recharged within 10 days • Storage in shipping container OK (replenish dry ice as needed) ***Thawed but NOT reconstituted (2–8 °C)*** • Must use within 24-48 hours ***Reconstituted (room temperature)*** • Must use within 6 hours
ORDERS ***Large quantities, to large administration sites only*** • Minimum order: ~1000 doses • Maximum order: ~5,000 doses	**ADMINISTRATION** ***2-dose series (21 days between doses)*** • On-site mixing required; reconstitute with diluent just prior to administration • Administer by intramuscular (IM) injection
PRIORITIZED POPULATIONS AND ANTICIPATED VACCINE ADMINISTRATION SITES ***Health care professionals (incl. LTCF staff)*** – public health closed temporary mass vaccination clinics + potential for mobile clinics ***Essential workers (specifics TBA)*** – public health closed temporary mass vaccination clinics + potential for mobile clinics ***National Security populations*** – public health closed temporary mass vaccination clinics + DoD sites ***LTCF residents & staff*** – potential for mobile clinics to facilities	

Scenario 2: Vaccine B demonstrates sufficient efficacy/safety for EUA in 2020

Availability Assumptions

Candidate	Vaccine availability by End of Oct 2020	End of Nov 2020	End of Dec 2020	Notes
Vaccine B	~1M doses	~10M doses	~15M doses	Central distro capacity required (-20 °C)

Distribution, Storage, Handling, and Administration Assumptions

Vaccine B

SHIPMENT

2 separately shipped components

1. Vaccine
   - To central distributor (at -20 °C)
   - Multidose vials (10 doses/vial)
2. Ancillary supply kits
   - Direct to site from USG (at room temperature)

ON-SITE VACCINE STORAGE

Frozen (-20 °C)

- Storage in shipping container OK (replenish dry ice as needed)

Refrigerated (2–8 °C)

- Must use within 7-14 days

Room temperature

- Must use within 6 hours

ORDERS

Central distribution capacity required

- Required by Dec 2020
- Maintained at -20 °C

ADMINISTRATION

2-dose series (28 days between doses)

- No on-site mixing required
- Administer by intramuscular (IM) injection

PRIORITIZED POPULATIONS AND ANTICIPATED VACCINE ADMINISTRATION SITES

Health care professionals (incl. LTCF staff) – health care clinics + health care occupational health clinics + public health closed temporary mass vaccination clinics + mobile clinics

Essential workers (specifics TBA) – hospital occupational health + hospital clinics + public health closed temporary mass vaccination clinics

National Security populations – DoD + closed temporary mass vaccination clinics + mobile clinics

LTCF residents & staff – commercial pharmacy partners + mobile clinics

Additional Considerations for Early Vaccination Planning

- Jurisdictions should plan for real-time shipment of doses.
- Administration sites (during Phase 1) will not be required to store vaccine products beyond the period of Vaccine B can be stored at 2–8 °C.
- Vaccine will be free of cost, but administration fees may not be reimbursable while a vaccine product is administered under an EUA.
- Given the challenging storage, handling, and administration requirements, early vaccination should focus on administration sites that can reach prioritized populations with as much throughput as possible.
- Stability testing is ongoing for Vaccine B; the storage and handling requirements presented here may shift. The requirements in these scenarios are likely the strictest set of requirements for which planning is needed.
- Jurisdictions should consider partnering with the private sector and with local hospital systems to provide vaccine in closest proximity to the prioritized populations as possible, given the limitations with the product.

Scenario 3: Vaccines A and B demonstrate sufficient efficacy/safety for EUA in 2020

Availability Assumptions

Candidate	Vaccine availability by End of Oct 2020	End of Nov 2020	End of Dec 2020	Notes
Vaccine A	~2M doses	10–20M doses	20–30M doses	Ultra-cold (-70 °C), for large sites only
Vaccine B	~1M doses	~10M doses	~15M doses	Central distro capacity required (-20 °C)
Total	**~3M doses**	**20–30M doses**	**35–45M doses**	

Distribution, Storage, Handling, and Administration Assumptions

Vaccine A

SHIPMENT

3 separately acquired components (mixed on site)

1. Vaccine
   - Direct to site from manufacturer (on dry ice)
   - Multidose vials (5 doses/vial)
2. Diluent
   - Direct to site from USG (at room temperature)
3. Ancillary supply kits
   - Direct to site from USG (at room temperature)

ON-SITE VACCINE STORAGE

Frozen (-70 °C ± 10 °C)

- Must be used/recharged within 10 days
- Storage in shipping container OK (replenish dry ice as needed)

Thawed but NOT reconstituted (2–8 °C)

- Must use within 24-48 hours

Reconstituted (room temperature)

- Must use within 6 hours

ORDERS

Large quantities, to large administration sites only

- Minimum order: ~1,000 doses
- Maximum order: ~5,000 doses

ADMINISTRATION

2-dose series (21 days between doses)

- On-site mixing required; reconstitute with diluent just prior to administration
- Administer by intramuscular (IM) injection

PRIORITIZED POPULATIONS AND ANTICIPATED VACCINE ADMINISTRATION SITES

Health care professionals (incl. LTCF staff) – public health closed temporary mass vaccination clinics + potential for mobile clinics

Essential workers (specifics TBA) – public health closed temporary mass vaccination clinics + potential for mobile clinics

National Security populations – public health closed temporary mass vaccination clinics + DoD sites

LTCF residents & staff – potential for mobile clinics to facilities

Vaccine B

SHIPMENT

2 separately shipped components

1. Vaccine
   - To central distributor (at -20 °C)
   - Multidose vials (10 doses/vial)
2. Ancillary supply kits
   - Direct to site from USG (at room temperature)

ON-SITE VACCINE STORAGE

Frozen (-20 °C)

- Storage in shipping container OK (replenish dry ice as needed)

Refrigerated (2–8 °C)

- Must use within 7-14 days

Room temperature

- Must use within 6 hours

ORDERS

Central distribution capacity required

- Required by Dec 2020
- Maintained at -20 °C

ADMINISTRATION

2-dose series (28 days between doses)

- No on-site mixing required
- Administer by intramuscular (IM) injection

PRIORITIZED POPULATIONS AND ANTICIPATED VACCINE ADMINISTRATION SITES

Health care professionals (incl. LTCF staff) – health care clinics + health care occupational health clinics + public health closed temporary mass vaccination clinics + mobile clinics

Essential workers (specifics TBA) – hospital occupational health + hospital clinics + public health closed temporary mass vaccination clinics

Section 9: COVID-19 Vaccine Administration Documentation and Reporting

Planning Considerations

Public Health will be required to report CDC-defined data elements related to vaccine administration each day to the state who will in turn report it daily to CDC. Table 1 includes each data element that Immunization Information System (IIS) will be required to report to CDC. Table 2 includes each data element that will be optional for IIS to report to CDC at this time.

Table 1. Required Data Elements

Required Data Element *Data elements required for IIS to report*	Mass Vaccination or Standard *Mass Vaccination = may require mass vaccination module or enhancement* *Standard = IIS Core Data Element commonly collected during routine vaccination*
Administered at location: facility name/ID	Standard
Administered at location: type	Standard
Administration address (including county)	Standard
Administration date	Standard
CVX (Product)	Standard
Dose number	Standard
IIS Recipient ID*	Standard
IIS vaccination event ID	Standard
Lot Number: Unit of Use and/or Unit of Sale	Standard
MVX (Manufacturer)	Standard
Recipient address*	Standard
Recipient date of birth*	Standard
Recipient name*	Standard
Recipient sex	Standard
Sending organization	Standard
Vaccine administering provider suffix	Standard
Vaccine administering site (on the body)	Standard
Vaccine expiration date	Standard
Vaccine route of administration	Standard
Vaccination series complete	Mass Vaccination

**Identifiable Information*

Table 2. Optional Data Elements

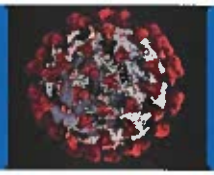
Optional Data Element *Data elements optional for IIS to report (e.g., state mass vaccination tool collects this information)*	Mass Vaccination or Standard *Mass Vaccination = may require mass vaccination module or enhancement* *Standard = IIS Core Data Element commonly collected during routine vaccination*
Comorbidity status (Y/N)	Mass Vaccination
Recipient ethnicity	Standard
Recipient race	Standard
Recipient missed vaccination appointment (Y/N)	Mass Vaccination
Serology results (Presence of Positive Result, Y/N)	Mass Vaccination
Vaccination Refusal (Y/N)	Standard

**Identifiable Information*

All vaccination providers may be required to report and maintain their COVID-19 vaccination information on CDC's Vaccine Finder.

CDC's Vaccine Administration Management System (VAMS) will be available to Public Health and provider sites that need assistance in patient registration and scheduling, clinic flow, supply management, patient record management, and reporting.

Data Use Agreements (DUAs) will be required for data sharing via the IZ Gateway and other methods of vaccine administration data sharing with CDC, and will be coordinated by Public Health.

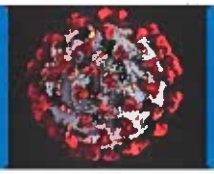


Section 10: COVID-19 Vaccination Second-Dose Reminders

For most COVID-19 vaccine products, two doses of vaccine, separated by 21 or 28 days, will be needed. Because different COVID-19 vaccine products will not be interchangeable, a vaccine recipient's second dose must be from the same manufacturer as their first dose. Second-dose reminders for vaccine recipients will be critical to ensure compliance with vaccine dosing intervals and achieve optimal vaccine effectiveness. Public Health will develop guidance and strategies to help COVID-19 vaccination providers schedule a patient's second-dose appointment when they get their first dose.

COVID-19 vaccination record cards will be provided as part of vaccine ancillary kits. Public Health will develop guidance for vaccination providers on how to complete these cards with accurate vaccine information (i.e., vaccine manufacturer, lot number, date of first dose administration, and second dose due date), and give them to each patient who receives vaccine to ensure a basic vaccination record is provided. Public Health is looking into various automated reminder systems to increase the likelihood that individuals will return on the day determined for their second dose.

Public Health will work with occupational health providers, pharmacies, and healthcare partners to consider the most appropriate and effective method of issuing second-dose reminders. These may range from a third-party SMS vendor to a functionality within a healthcare partners' electronic health record (EHR) system, or an automated patient phone call ("robocalls"), and scheduled emails.

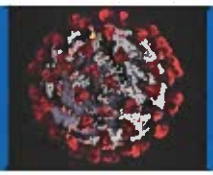


Section 11: COVID-19 Requirements for IISs or Other External Systems

Immediate data reporting priorities for Public Health include:

- Determine and implement a solution for documenting vaccine administration in temporary or high-volume settings (e.g., CDC mobile app, IIS or module that interfaces with the IIS, or other jurisdiction-based solution)
- Ensure access to the State system with the system capacity for data exchange, security, storage, and reporting
- Enroll vaccination provider facilities/organizations anticipated to vaccinate essential workers
- Establish required data use agreements
- Assess and improve data quality
- Ensure data are available, secure, complete, timely, valid, accurate, consistent, and unique

Once systems are built out at the State level, we will be able to ascertain what type of system we need at the LA County level in order to manage this work. We will be able to assess systems infrastructure, data management, and interoperability which are all key to ensuring any systems we set up are both functional from a front-end user perspective as well as from a back-end user for data analysis and reporting.

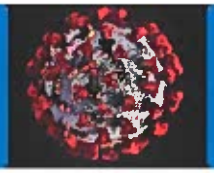


Section 12: COVID-19 Vaccination Program Communication

Public Health will develop a comprehensive communications campaign that will include messages targeting specific audiences: communities highly impacted by COVID-19, frontline healthcare and other workers, communities with low immunization coverage rates, and communities of color. Part of the campaign will include tailoring messaging from the CDC and state level, and some will be original content developed specifically for LA County, depending on needs identified by the listening and community collaboration work.

Listening sessions completed to inform Public Health's Influenza communications campaign will be built out to target communities voted on and confirmed as priority populations for the COVID-19 Vaccination roll-out by ACIP, expected to occur at the end of November. Public Health is operationalizing the high-level frontline worker and "high-risk" group classifications and overlaying the Social Vulnerability Index as outlined by the Framework for that and used for work on listening to feedback from these key communities.

- Work is underway on guidelines and an appointment process for a few coalitions and workgroups to give feedback into the process to ensure equity issues are addressed and communications campaigns are tailored to the needs of specific priority groups.
- CDPH will work to develop a state-wide media campaign that Public Health will build on.
- Communication and educational materials about COVID-19 vaccination provider enrollment, COVID-19 vaccine ordering, COVID-19 vaccine storage, handling, administration (i.e., reconstitution, adjuvant use, administration techniques), etc., will be available in a variety of formats.
- When vaccine supply is available for expanded groups among the general population, a national COVID- 19 vaccine finder will be available on the public-facing Vaccine Finder.
- Public Health will develop a dedicated website with information, resources, and either link to the State screening tools to help individuals determine their own eligibility for COVID-19 vaccine or develop our own depending on the details of the Phase 2 roll-out.
- All information will need to be translated into threshold languages to ensure access to all of our community members.



Section 13: Regulatory Considerations for COVID-19 Vaccination

Initially available COVID-19 vaccines may be authorized for use under an EUA issued by FDA or approved as licensed vaccines.

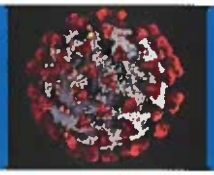
Emergency Use Authorization Fact Sheets

The EUA authority allows FDA to authorize either (a) the use of an unapproved medical product (e.g., drug, vaccine, or diagnostic device) or (b) the unapproved use of an approved medical product during an emergency based on certain criteria. The EUA will outline how the COVID-19 vaccine should be used and any conditions that must be met to use the vaccine. FDA will coordinate with CDC to confirm these "conditions of authorization." Vaccine conditions of authorization are expected to include distribution requirements, reporting requirements, and safety and monitoring requirements. The EUA will be authorized for a specific time period to meet response needs (i.e., for the duration of the COVID-19 pandemic). Additional information on EUAs, including guidance and frequently asked questions, is located on the FDA website.

Product-specific EUA fact sheets for COVID-19 vaccination providers will be made available that will include information on the specific vaccine product and instructions for its use. An EUA fact sheet for vaccine recipients will also be developed, and both will likely be made available on the FDA website and through the CDC website. Jurisdictions should ensure providers know where to find both the provider and recipient fact sheets, have read and understand them, and are clear on the requirement to provide the recipient fact sheet to each client/patient prior to administering vaccine.

Vaccine Information Statements

Vaccine Information Statements (VISs) are required only if a vaccine is added to the Vaccine Injury Table. Optional VISs may be produced, but only after a vaccine has been licensed (e.g., such as with zoster vaccines). Plans for developing a VIS for COVID-19 vaccine are not known at this time but will be communicated as additional information becomes available.



Section 14: COVID-19 Vaccine Safety Monitoring

An "adverse event following immunization" is an adverse health problem or condition that happens after vaccination (i.e., a temporally associated event). It might be truly caused by the vaccine or it might be purely coincidental and not related to vaccination.

Planning Considerations

- Safety is a priority during all phases of vaccine development, approval, and use
- Post-licensure/post-authorization safety monitoring is an established part of the vaccine life cycle
- Pre-licensure trials are not optimal for:
  - Detecting rare adverse events (numbers enrolled too small)
  - Monitoring vaccine safety in a real-world environment
  - Assessing safety in special populations (e.g., pregnant women and people with certain pre-existing medical conditions often excluded)
  - Evaluating adverse events with delayed onset
- Monitoring COVID-19 vaccine safety will be a coordinated effort by multiple federal agencies (public safety) and manufacturers (individual products)
- Clinically important adverse events following any vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).
- Adverse events will also be monitored through electronic health record (EHR)- and claims-based systems (e.g., Vaccine Safety Datalink).
- Additional vaccine safety monitoring may be required under the EUA, including:
  - Requiring manufacturers to follow participants in late-stage clinical trials for a median of at least two months, starting after they receive a second dose; and
  - Reporting at least five severe cases of COVID-19 in the placebo group for each trial, as well as some cases of the disease in older people.

Logistics of how we will integrate reporting to the Vaccine Adverse Event Reporting System, the Vaccine Safety Datalink, and the Clinical Immunization Safety Assessment Project are being worked on with the Public Health and the CDPH immunization teams.

Appendices

Appendix 1: Countermeasures Injury Compensation Program

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of covered countermeasures identified in and administered or used under a PREP Act declaration. The CICP also may provide benefits to certain survivors of individuals who die as a direct result of the administration or use of such covered countermeasures. The PREP Act declaration for medical countermeasures against COVID-19 states that the covered countermeasures are:

- Any antiviral, any other drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine, used:
    - To treat, diagnose, cure, prevent, mitigate, or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or
    - To limit the harm that COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, might otherwise cause; or
- Any device used in the administration of any such product, and all components and constituent materials of any such product.

Covered Countermeasures must be "qualified pandemic or epidemic products," or "security countermeasures," or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the Federal Food, Drug, and Cosmetic Act (FD&C Act), and the Public Health Service Act, or a respiratory protective device approved by National Institute for Occupational Safety and Health (NIOSH) under 42 CFR part 84, or any successor regulations, that the Secretary of the Department of Health and Human Services determines to be a priority for use during a public health emergency declared under section 319 of the Public Health Service Act.

Appendix 2: Liability Immunity for Covered Persons

The Declaration Under the Public Readiness and Emergency Preparedness Act (PREP Act) for Medical Countermeasures Against COVID-19 provides liability immunity to covered persons. The third amendment to the declaration defines "covered persons" as follows:

"V. Covered Persons

42 U.S.C. 247d–6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability immunity under this Declaration are "manufacturers," "distributors," "program planners," "qualified persons," and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States.

In addition, I [the Secretary] have determined that the following additional persons are qualified persons:

a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an emergency;

b) any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act;

c) any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act; and

d) a State-licensed pharmacist who orders and administers, and pharmacy interns who administer (if the pharmacy intern acts under the supervision of such pharmacist and the pharmacy intern is licensed or registered by his or her State board of pharmacy), vaccines that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule.

Such State-licensed pharmacists and the State-licensed or registered interns under their supervision are qualified persons only if the following requirements are met:

- The vaccine must be FDA authorized or FDA-approved.
- The vaccination must be ordered and administered according to ACIP's standard immunization schedule.
- The licensed pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.

- The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period.
- The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary- care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine.
- The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregiver accompanying the child of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate.

Nothing in this Declaration shall be construed to affect the National Vaccine Injury Compensation Program, including an injured party's ability to obtain compensation under that program. Covered countermeasures that are subject to the National Vaccine Injury Compensation Program authorized under 42 U.S.C. 300aa–10 et seq. are covered under this Declaration for the purposes of liability immunity and injury compensation only to the extent that injury compensation is not provided under that Program. All other terms and conditions of the Declaration apply to such covered countermeasures."