COVID-19: Vaccination Primer for California Hospitals

November 24, 2020

Overview

The first COVID-19 vaccine could be available for front-line health care workers as early as mid-December. Pfizer released its first set of complete results on November 18 from a late-stage vaccine trial that showed 95% effectiveness for mild and severe forms of COVID-19. Pfizer’s emergency use authorization (EUA) was submitted to the Food and Drug Administration on November 20 and will take about three weeks to review. The company states it could have up to 50 million doses available by the end of the year and as many as 1.3 billion by the end of next year. However, only half the doses would be allocated to the U.S., which would be enough to vaccinate 12.5 million people this year in the U.S. with the required two doses per person.

Hospitals will play a pivotal role in administering the vaccine during the first phase, referred to as Phase 1-A by the California Department of Public Health (CDPH), when front-line health care workers will be prioritized. This is in part because the Pfizer candidate requires storage at an ultra-low temperature (-80 degrees Celsius) or repacking with dry ice, both of which many settings do not have access to, and given the large amounts shipped (975 doses are in a shipment). Hospitals will offer the vaccine to their employees and staff, and many hospitals are volunteering to serve as closed points of dispensing for skilled-nursing facility staff, paramedics, and other health care workers who are expected to be prioritized.

Moderna announced a 94.5% effectiveness rate for its vaccine candidate in a recent clinical trial and is also expected to receive EUA soon. It does not require storage at ultra-low temperatures, and CDPH might offer this vaccine to non-hospital settings given its less-challenging storage and handling requirements.

AstraZeneca announced on November 23 that a preliminary analysis of its Phase 3 trial revealed the vaccine was up to 90% effective, depending on the dosage. The vaccine requires refrigerated versus ultra-cold storage.

CHA has compiled information on the following topics to assist California hospitals in preparing to administer COVID-19 vaccination:

- Communications from CDPH
- Allocation to Multi-County Entities
- Provider Enrollment
- Safe Storage and Transportation
- IT and Data Reporting
- Vaccine Prioritization

Communications from CDPH

CDPH will host two all-hospitals calls — on December 4 and December 18 — both from 9 to 10 a.m. (PT). CDPH will distribute the call-in number and meeting materials via the California Health Alert Network, and CHA will distribute it via its Coronavirus Response email newsletter (to be added to the distribution, email info@calhospital.org). CDPH is also posting information on two areas of its website: the California COVID-19 Vaccination Program and the COVID-19 Vaccine Planning sections. Hospitals can direct questions on these upcoming calls to CDPH or their local health departments.
In addition, CDPH has established a Community Vaccine Advisory Committee, on which CHA is represented by President & CEO Carmela Coyle. The committee will provide input and feedback for CDPH’s ongoing planning and engagement efforts to ensure equitable vaccine distribution and allocation. According to CDPH, it will build on the Scientific Safety Review Workgroup and California’s COVID-19 Drafting Guidelines Workgroup. Information on how to listen to the meetings will be posted here.

**Allocation to Multi-County Entities**
CDPH is currently considering allowing health systems with hospitals in three or more counties to be designated as multi-county entities (MCEs). CDPH would determine the doses for MCEs, while local health officers would determine the number of doses for all other hospitals and health systems. All doses would be distributed directly to hospitals from a vaccine distributor or manufacturer. Once it has determined which entities will be designated MCEs, CDPH (rather than local health officers) will work directly with them on their allocations.

**Provider Enrollment**

**Vaccine Provider Enrollment and Agreements**
Hospitals that administer COVID-19 vaccines are required to register online with CDPH and submit a Provider Agreement issued by the Centers for Disease Control and Prevention (CDC). In addition, a hospital that will accept a shipment of vaccines and share/redistribute some of them with another administration site must sign a Redistribution Agreement. The CDPH COVIDRead system launched the week of November 16 for general acute care hospitals. Providers that are likely to be Phase 1A vaccinators, which includes hospitals, should have received an invitation to enroll, instructions, and a link to the website.

Hospitals are encouraged to review the draft provider agreement now and start preparing to fulfill the requirements if they wish to administer and/or redistribute the vaccine. All providers that plan to receive and administer COVID-19 vaccines must be enrolled. To assist with the multi-step enrollment process, CDPH has provided these instructions and a step-by-step guide. Questions can be directed to COVIDCallCenter@cdph.ca.gov.

Health systems with a consolidated management structure, with a chief medical officer (CMO) and CEO (or chief fiduciary/legal official) who will oversee multiple locations, must complete the enrollment and sign the CDC provider agreement. The individual locations will then have to complete their own section of the provider enrollment form. Through this process, the organization’s leadership does not have to sign enrollment agreements multiple times for all sites under their umbrella.

For hospitals that are independently managed, each site will need to be enrolled individually, as an organization, with leadership from each hospital (CMO and CEO) completing and agreeing with the participation agreement.

**Additional Resources From CDPH**
- COVID-19 Vaccination Program Participation Requirements
- Immunization Information System Participation

**Safe Storage and Transportation**
Any vaccine is likely to require refrigeration. It appears there will be more than one vaccine, and they likely will have different properties. For example, the Moderna candidate will require cold storage while the Pfizer candidate requires storage at ultra-cold temperatures. It is important for hospitals to understand all potential requirements of vaccine storage and transportation to ensure their organization has the necessary equipment and supplies to execute vaccination plans. Hospitals and health systems should work with materials managers, engineers, and risk managers to establish facility guidelines for what is possible and establish what is not possible. This should
include ensuring that receiving teams understand the process for receiving vaccine deliveries, including performing a temperature check.

For additional details, see CDPH’s COVID-19 Vaccine Planning PowerPoint presentation (Nov. 13) and CDPH’s Responses to Questions from hospitals about that presentation.

**Pfizer Vaccine Storage**

- Requires ultra-low temperature storage (-80 degrees Celsius)
- Shipped from Pfizer administration sites in Pfizer’s Ultra-Low Temperature Thermal Shipper container with dry ice
- Upon receipt, follow specific receipt instructions
- Three storage options: 1) ultra-cold temperature storage (-80 degrees Celsius), 2) storage in shipping container with dry ice, or 3) refrigerate immediately and use in five days
- For vaccine viability, explicitly follow specific instructions for each of the storage options
- For health systems with multiple locations, CDPH reports that Pfizer does not recommend distribution to one central location within the health system and then distributing to the individual medical centers/administration sites. Reasons include:
  - There are no guidelines for re-packing the ultra-cold vaccine at -80 degrees Celsius.
  - It can be stored at 2-8 degrees Celsius for 120 hours, so could be shipped directly by the manufacturer or distributor to other sites and administered within five days.
  - The minimum shipment is 975 doses, which also creates logistics challenges.
  - The company is recommending that the vaccine be shipped to the site where it will be administered. Each site that will be administering the Pfizer vaccine can order vaccine to be shipped directly to the administration site.

**Moderna Vaccine Storage**

- Requires frozen storage (-20 degrees Celsius)
- Shipped from McKesson administration sites requiring frozen storage (-20 degrees Celsius)
- If using refrigerated storage, must be at 2–8 degrees Celsius, for up to seven days
- Thaw times: Two hours in refrigerator, then 15 minutes at room temperature; or one hour at room temperature
- Can be used up to 12 hours at room temperature before administration, but the vial must be used within six hours after first entry/puncture

**First and Second Dose Distributions**

In all cases, according to CDPH, the initial shipment is to be used solely for the first dose and should not be reserved for the second dose. If a facility receives a certain amount of vaccine, the same amount will be held in reserve for the second dose. If all the vaccine is used by the facility, the full amount held in reserve will be sent to the facility. Re-distribution might be easier with a vaccine — such as the Moderna candidate — that does not require ultra-cold storage.

**Scientific Safety Review Workgroup**

California, Washington, Nevada, and Oregon are jointly convening a Scientific Safety Review Workgroup, which will review the vaccine candidates for their safety prior to a vaccine being distributed in California or these other Western states.
IT and Data Reporting

Hospitals must plan to address several IT and data reporting considerations to track vaccination doses and report adverse events. Below are several steps California hospitals can take to prepare their IT systems for vaccination data reporting.

Reporting Doses

Hospitals and providers administering COVID-19 vaccination doses will be required to report this information to the California Immunization Registry (CAIR). Providers can submit dose administration information to CAIR through several established methods, including data interface with the provider’s electronic health record (EHR); PrepMod vaccine management software, which will be made available to COVIDReadi enrollees; CAIR2 Mass Vax online tools (effectively an online spreadsheet); or manual data entry into one of California’s CAIR software applications.

Most methods – except for manual entry – allow for real-time submission of dose information via standard HL7 VXU messages directly into CAIR. However, as Phase 1-A of COVID-19 vaccine administration will be primarily limited to health care workers, it is important for hospitals to consider how to reconcile and transmit data from employee health records to the CAIR. CHA members have reported a number of methods, including building an interface from employee health records that transmits to CAIR, creating a separate system for employee health records within their EHRs, or manual data entry for employee immunizations.

In addition, hospitals should consider how their IT systems can support second dose reminders for vaccines that require two doses. Hospitals using PrepMod or another vaccination administration management system will also be required by the state to use the second dose reminder functionality in these applications.

Reporting and Requesting Vaccine Inventory

Initial vaccine orders will be placed on behalf of new and existing providers by local health departments. Vaccine re-orders will be submitted by enrolled providers through COVIDReadi. Provider re-orders for COVID-19 vaccines will require reporting on-hand inventory at the time of the vaccine order, and a summary of vaccine doses administered. Any vaccine waste or authorized transfer must be reported through the same system. Vaccine re-order requested by enrolled providers will be forwarded to the respective local health department for review, reallocation, and approval.

Reporting Adverse Events

To enroll for receipt of COVID-19 vaccines, providers must agree to the provisions of the CDC’s COVID-19 Vaccination Program Provider Agreement, which requires providers’ organizations to report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS).

Hospitals can report to VAERS at https://vaers.hhs.gov/index. For further assistance reporting to VAERS, hospitals can contact VAERS directly at info@VAERS.org or (800) 822-7967.

Additional Resources From CDPH

- Reporting Requirements
**Vaccine Prioritization**

Since vaccine supply will likely be limited at the beginning of the distribution program, it will be necessary to prioritize access until enough doses become available to meet demand, which will likely be several months. Prioritization will need to occur both on a statewide and hospital-by-hospital basis.

**California’s COVID-19 Drafting Guidelines Workgroup** is currently developing guidelines for how the state will best equitably distribute the vaccine, taking into account the populations to be targeted and how to most effectively use the initially scarce vaccine. The workgroup will distribute drafts publicly for review and comment. CHA will review these drafts and determine whether and how to comment.

According to **California’s COVID-19 Vaccination Plan Version 1.0**, submitted to the CDC, as well as subsequent CDPH presentations, the state of California will focus its efforts on first vaccinating its critical populations in two subphases (Phase 1-A and Phase 1-B), including:

**Phase 1-A**
- Health care personnel likely treating patients with COVID-19
- Health care personnel likely to be exposed to COVID-19

**Phase 1-B**
- People at increased risk for severe illness or death from COVID-19
- Other essential workers

Within these broad parameters, and informed by the resources identified below, hospitals should develop their own vaccine allocation plans, taking into account their own types and numbers of health care personnel falling into each category for purposes of Phase 1-A. For purposes of Phase 1-B, the demographics of their community that put people at higher risk of acquiring COVID-19 and suffering severe morbidity and mortality should be considered. Even as further guidance is issued, it will continue to be necessary for hospitals to apply these frameworks to their health care personnel and within their communities. The National Academies of Sciences, Engineering, and Medicine (NASEM) has proposed the following framework for equitable allocation of the COVID-19 vaccine:

![Allocation Framework](image)

**Allocation Framework**

**Goal**
Reduce severe morbidity and mortality and negative societal impact due to the transmission of SARS-CoV-2

**Allocation Criteria**
Risk of (1) acquiring infection, (2) severe morbidity and mortality, (3) negative societal impact, and (4) transmitting infection to others

**Four Allocation Phases**

**Foundational Principles**
- Ethical Principles: Maximum Benefit; Equal Concern; Mitigation of Health Inequities
- Procedural Principles: Fairness; Transparency; Evidence-Based


Additionally, the CDC’s Advisory Committee on Immunization Practices (ACIP) is in the process of developing an ethical framework and proposed strategy for early COVID-19 vaccine allocation. ACIP’s extensive materials reflecting its development process and interim conclusions are available here.