Guidance for the Allocation of Phase 1A Tier 1 COVID-19 Vaccine for Acute Care Hospitals

Purpose of this Guidance

These guidelines will assist in the effective and equitable allocation of COVID-19 vaccine in Los Angeles (LA) County.

During the initial phases of vaccine allocation, the supply of vaccine is expected to be limited while the need is high. Until sufficient supply becomes available, vaccine eligibility will be determined by phases of prioritization developed by the Centers for Disease Control and Prevention (CDC) through the Advisory Committee of Immunization Practices (ACIP) as well as guidance developed by the California Department of Public Health (CDPH). Local planning is essential to further refine these broad categories and assist in implementation based on the current status and trends in transmission in LA County. This guidance is specific to vaccine doses under FDA Emergency Use Authorization (EUA) and includes those doses made available to Acute Care Hospitals (ACH) during the initial allocations of Phase 1A of vaccine roll-out when the supply/demand challenges will be at their highest.
Importance of vaccination against the virus that causes COVID-19

COVID-19 vaccination using a safe and effective product will be critical to preventing the transmission of SARS-CoV-2 and thus prevent illness and death due to COVID-19 disease. Vaccination will help reduce the disruption to our society and economy, including the maintenance of essential healthcare capacity.

Goals and principles guiding the allocation of vaccine in Phase 1A

The following are goals and principles guiding the vaccine allocation strategy based on CDC, ACIP, and CDPH recommendations:

Goals:
- Decrease death and serious disease.
- Preserve functioning of necessary healthcare services and the larger society
- Reduce the additional burden the disease is having on people already facing healthcare and income disparities.

Principles:
- Maximize benefits and minimize harms — Respect and care for people using the best available data to promote public health and minimize death and severe illness.
- Mitigate health inequities — Reduce health disparities in the burden of COVID-19 disease and death, and make sure everyone has the opportunity to be as healthy as possible.
- Promote justice — Treat affected groups, populations, and communities fairly. Remove unfair, unjust, and avoidable barriers to COVID-19 vaccination.
- Promote transparency — Make a decision that is clear, understandable, and open for review. Allow and seek public participation in the creation and review of the decision processes.

In addition to these guiding values, additional operational considerations are necessary:
- Efficient targeting — criteria to improve implementation feasibility.
- Maximum coverage — criteria that maximizes actual recipients among intended recipients.
- Minimum leakage — criteria that minimizes unintended recipients among actual recipients.

Los Angeles County Specific Considerations

LA County specific data can help ensure the effective and equitable use of the FDA EUA vaccine doses in Phase 1 priority populations. Key considerations include:

1. Epidemiology of cases and deaths among healthcare workers (HCW)
   a. Healthcare workers constitute a large, diverse group of occupations and work in a variety of settings.
   b. Healthcare worker data is complicated due to the difficulty in determining exact denominators, self-reported roles, self-reported workplace setting, and ascertaining the source of exposure.
   c. HCW risk of infection due to SARS-CoV-2 varies depending on the availability of adequate personal protective equipment (PPE) and its correct and consistent use.
   d. The majority of healthcare worker infections occurred among those working in congregate living facilities, acute care hospitals, outpatient settings, and EMS/first response. Adjusted for the
estimated number of workers at-risk, HCW working in congregate living facilities and EMS/first response were most affected consistent with the risk of transmission in close, less controlled settings.

e. The largest affected group of healthcare workers was nurses consistent with their risk of prolonged, close contact.

**Phase 1A Details**

**Target Populations**

The general definition and rationale for Phase 1A target groups as given in the ACIP phased approach framework consists of these two groups:

1) Healthcare workers (HCW)
2) Staff and residents of long-term care facilities

Using the above principles and data, CDPH and LA County Department of Public Health (DPH) have further defined priorities within the Phase 1A populations under the assumption of a limited initial vaccine supply that does not meet demand.

**Sub-prioritization for HCWs within Acute Care Hospitals**

Given limited vaccine supply, the above populations will need to undergo further sub-prioritization. The following considerations should be used to determine which healthcare workers should be prioritized for vaccine during the initial allocations:

**Within Facility Sub-Prioritization**

Within a facility, individuals should be designated by exposure risk and by clinical risk assessed by the facility. Within a particular area of exposure risk, if vaccine is limited, healthcare workers who are clinically at high-risk for COVID-19 should be prioritized. (See the definition section below for additional details regarding who is considered clinically at high risk). Given initial vaccine constraints, employees that are classified as low-risk for exposure should not be vaccinated in Phase 1A and will align with Phase 1B essential workers.

Table 2. LA County DPH Phase 1A within Facility Cascade Based on Exposure Risk

<table>
<thead>
<tr>
<th>Tier</th>
<th>Order</th>
<th>Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>I-III</td>
<td>1</td>
<td>Highest-risk units: e.g. ER, COVID designated med/surg, stepdown, ICUs</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>High Risk Employees (defined as the number of employees who come in direct contact with and/or provide care to patients)</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th></th>
<th>Moderate Risk Employees (defined as number of employees (not counted in the previous question) who have indirect or limited contact with patients in their current job duties and work arrangements)</th>
</tr>
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<tbody>
<tr>
<td>3</td>
<td>Due to no patient contact, Low Risk Employees (defined administrative support staff with no routine patient contact) are to be vaccinated with other essential workers (ACIP Proposed Phase 1b), NOT in Phase 1A.</td>
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### Definitions

1. **Healthcare and EMS workers** are those involved in direct patient care, as well as those working in transport, environmental services, registration, or other healthcare services who risk daily exposure to bodily fluids or aerosols from patients or other individuals. HCW who work in less controlled environments and who have prolonged close exposure are prioritized first.
   - a. **Unit wise approaches** are preferred for operational ease and to provide equitable opportunity for vaccination to HCWs in different roles. However, a unit may be covered over several days, see clinical considerations below for more information. HCWs’ designation to a unit is defined by location of regular work. This may be difficult in certain facilities or among certain categories of staff.
   - b. **Limited vaccine** will be allocated pro rata by facility size.
   - c. **HCWs should not be differentiated** by permanent vs contract, or paid vs unpaid, or directly employed vs consulting status if they are providing regular care.

2. **Exposure risk** refers to high-risk, moderate-risk, and low-risk workplace exposure to SARS-COV-2 by HCW as defined by the CDPH survey to acute care facilities and outlined in Appendix 1 below. Exposure risk may not reflect disease incidence as the latter is modifiable, but not eliminated, by workplace interventions and individual behavior.

3. **Clinical risk** refers to the risk of severe COVID-19 illness, these individuals are defined as having two (2) or more criteria defined by CDC based on data from COVID-19 Associated Hospitalization Surveillance Network. These include:
   - Age ≥ 65
   - Cancer
   - Chronic kidney disease
   - Chronic obstructive pulmonary disease
   - Immunocompromised state from solid organ transplant
   - Obesity (body mass index ≥30)
   - Serious heart conditions (e.g., heart failure, coronary artery disease, cardiomyopathies)
   - Sickle cell disease
   - Type 2 diabetes mellitus
Additional clinical considerations from [CDC](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/clinical-considerations.html)

1. If supplies are insufficient to fully vaccinate those in a risk subgroup, the facility could consider vaccinating HCWs or LTCF residents with a documented lab positive test for SARS-CoV-2 within 90 days later, as evidence suggests reinfection is uncommon within this time interval. Prior SARS-CoV-2 infection, symptomatic or asymptomatic, is not a contraindication to vaccination, and serologic testing for SARS-CoV-2 antibodies is not recommended prior to vaccination.

2. The number of HCW who are pregnant or breastfeeding are substantial and are at higher risk for severe COVID-19. Currently, we do not have vaccine safety and efficacy data in this population so guidance will have to await additional trial data and/or EUA conditions.

3. While zero serious adverse events have been reported in the large, Phase 3 clinical trials for COVID-19 vaccines, local and systemic symptoms are expected. In Phase 2 vaccine trials from which detailed data is available, COVID-19 vaccination produced symptoms such as local pain, fatigue, and headache. Other recipients experienced fever, chills or myalgias. Most symptoms were graded as mild or moderate in intensity. Symptoms were more common after the second dose and among younger participants. While further data is needed to determine the incidence, timing, and duration of post-vaccination symptoms, facilities should stagger vaccinations so that staff from a single shift, single specialized function, or single unit are not all vaccinated at the same time to mitigate against potential absenteeism due to post-vaccination symptoms. Facilities should plan for personnel to potentially need time off work if they develop post-vaccination symptoms.

Additional Considerations

1. Simultaneous vaccination of priority groups (high and moderate risk groups together for example) should not be conducted if vaccine supply is limited to prevent low coverage of higher priority groups and to facilitate logistics and improvement in the vaccine delivery process as larger group sizes are encountered.

2. Each group should be targeted with sufficient outreach and mobilization before proceeding to the next group. However, exceptions may be made in order to prevent any vaccine wastage. Individuals assigned to a priority group who initially decline vaccination may opt in anytime thereafter.

3. Initial allocation will only be for the 1st dose as planning for 2nd dose for those recipients will be contingent upon the size and timing of subsequent shipments. Second dose of the vaccine must be the same manufacturer as the first dose.

4. Subsequent shipments of vaccine will undergo the same triage process starting at the group where prior supplies were exhausted or from the beginning of the list if enough time has elapsed for the group to be eligible for the 2nd dose.

Vaccine Accountability and Reporting

Vaccine allocation to facilities by DPH is contingent upon the conditions of the federal provider agreement in addition to local expectations of accountability. Key to accountability is timely and complete reporting. All doses administered must be entered into the State Immunization Information System (IIS), named CAIR2, the same day the dose is administered. Daily reporting to LACDPH is also required. Additionally, mandated serious adverse events, must be reported to VAERS. The data elements and workflows for data entry will be communicated fully through other channels. In addition to reporting, facilities are expected to adhere to
the phased guidance provided by DPH. While within facility flexibility exists within this framework, gross departures from it may constitute grounds for cessation of further dose allocations in order to ensure a fair and transparent allocation process central to public health aims and public trust. Each receiving facility should designate a coordinator for vaccine distribution. This individual should have a clinical background to assess medical history and be involved with COVID-19 control within the facility. They must oversee completion of vaccine recipient lists and be the designated arbiter for review of any vaccination requests or questions to ensure a fair, transparent process.

Resources

● National Academies Phased Approach  
● CDC Clinical Considerations for COVID-19 Vaccine  
● CDC COVID-19 Vaccine Recommendations Process  
● CDPH Essential Workforce  
● LACDPH Healthcare Worker Surveillance Report  
● CDPH COVID-19 Vaccine Playbook  
● LAC DPH COVID-19 Surveillance Dashboard  
● ACIP Meeting Slides Dec 3, 2020
Appendices

Appendix 1. Risk Stratification according the CDPH AFL COVID-19 Vaccine Survey

Highest-risk employee: front-line clinical staff who care for patients in high risk settings or for patients with unknown COVID-19 status (e.g. ED, ICU, urgent care, respiratory therapists, anesthesiologists, etc)

High-risk employee: front-line clinical staff who provide direct patient care and support staff with risk of exposure to bodily fluids or aerosols (e.g. EVS staff)

Moderate-risk employee: staff who have indirect or limited patient contact (e.g. food services, medical records, front desk staff)

Low-risk employee: administrative support staff with no routine patient contact.