

## **COVID-19 Vaccine Operations**

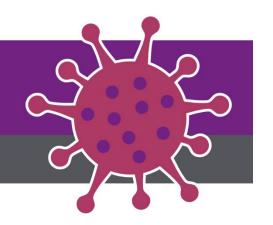
A Guidebook for Health Ministries

Version: 1.0

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# **CO**RONA**VI**RUS **DI**SEASE 2019 (COVID-19)

## **VACCINE OPERATIONS GUIDEBOOK**





Audience: Covid-19 Vaccine Task Force

Revision Date: 12/9/2020

Version: Version #1

## INTRODUCTION

#### **Purpose of Guidebook**

The purpose of this Guidebook is to align and support our Health Ministries as we work together to become *vaccine ready* for the first approval of a COVID-19 vaccine.

FDA approval not only releases the vaccine for distribution but endorses the vaccine's safety and effectiveness, which means we can confidently encourage our community to receive the vaccine. As the nation eagerly awaits the FDA's decision for EUA approval of Pfizer's vaccine, our teams are quickly mobilizing to prepare to administer the first vaccine.

Please review this document in detail. It includes critical information and guidance that ensures we are leveraging our capability and assets as one system, yet it is purposefully not overly prescriptive so that each Health Ministry responds to its community's needs as they see best.

Many of the details and processes continue to be finalized at the federal and state levels and as we learn new information, expect this Guide to be updated often.

Thank you for all that you continue to do to serve our communities.

#### Questions / Escalations:

Submit through local Incident Command to the Trinity Health Incident Command mailbox.

## **Need to Know Info & Actions**

required items and requests. Note: Defer to local and state requirements & direction.		
<b>Colleagues will follow the patient process for vaccination</b> : Receiving the vaccine is voluntary for colleagues and will be offered to those who meet the prioritization criteria for receiving the vaccine and wish to receive the vaccine.		
<b>No internal tracking of colleagues' vaccine status</b> : Colleagues who receive vaccinations as a patient are protected under HIPAA. We are only able to track vaccine status for colleagues who <a href="mailto:choose">choose</a> to upload their vaccine status to the HR4U portal.		
<b>Stand up local Vaccine Task Force and identify accountable lead:</b> Assign lead and stand up a task force that sits within your local COVID Response Team.		
<b>Preferred EMR is MGPS/Ambulatory:</b> Unless there are state requirements, or there are know operational deficiencies.		
Start with a paper process that is entered into the EMR within 24 hrs.		
<b>Identify vaccination sites:</b> Identify two to four sites within the region ( <i>unless the state has dictated where sites will be located</i> ) where vaccination will occur:		

- Two (2) outside large-scale and two clinic-like settings
- o Plan to launch two on December 15 (*unless otherwise directed by the state*)
- o Evaluate the need for additional tents similar to the ones used for COVID-19 testing
- Identify staffing needs for sites refer to the <u>People section > Reporting Relationships</u>
   <u>& Roles</u>

## **Status & Background Info**

#### Pfizer & Moderna — Phase III Trial Results

Results demonstrate ~95% efficacy for both Moderna and Pfizer vaccines.

	Pfizer (44,000 participants)	Moderna (30,000 participants)
Dosing	2 doses 21days apart	2 doses 28 days apart
COVID-19 Cases: at least two weeks out from last shot who developed COVID symptoms and tested positive	170 cases -162 placebo -8 vaccine	196 -185 placebo -11 vaccine
COVID -19 severe cases	10 -9 placebo -1 vaccine	30 -30 placebo -0 vaccine
Efficacy	95%	94.1%
Subpopulations*	No difference in efficacy by age, race, ethnicity	No difference in efficacy by age, race, ethnicity
Ultra-cold storage	Yes	No

<sup>\*</sup> No specific numbers yet but likely to be too small to make anything but a very general conclusion. Unpublished data as presented on National Academy of Medicine call.

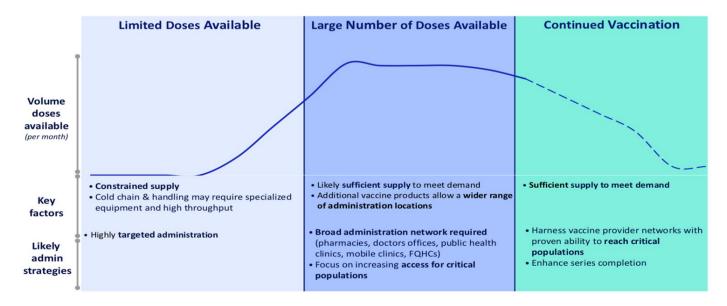
## **Projected Vaccine Availability**

105 million courses by end of March with FDA EUA approval for both vaccines.

Month	Pfizer	Moderna
December	25 million	15 million
January	30 million	20 million
February	35 million	25 million
March	35 million	25 million
TOTAL	125 million	85 million

- 200 million more after March
- Distribution to states based on population
- Projections are that supplies will be sufficient by the end of March to vaccinate all in Phase 1a and 1b categories

### **COVID-19 Vaccination Phases**



## **CHA's Six Principles**

To effectively and justly develop and allocate COVID-19 vaccines:

- 1. Vaccines should be demonstrably safe and adequately tested
- 2. Vaccines should be demonstrated to be scientifically effective
- 3. Vaccines development must respect human dignity
- 4. Vaccines should be equitably distributed with priority to those at most risk
- 5. Efforts to develop and distribute an effective vaccine should emphasize solidarity
- 6. Consistent with the principle of Subsidiarity, the distribution of effective vaccines should involve local communities

### The National Academy of Medicine Framework

View Source

Major elements of the framework for Equitable Allocation of COVID-19 Vaccine

#### **Foundational Ethical Principles**

**Maximum benefit:** The obligation to protect and promote the public's health and its socioeconomic well-being in the short and long term.

**Equal concern:** The obligation to consider and treat every person as having equal dignity, worth, and value.

Mitigation of health inequities: The obligation to explicitly address the higher burden of COVID-19 experienced by the populations affected most heavily, given their exposure and compounding health inequities.

#### **Foundational Procedural Principles**

**Fairness:** Decisions should incorporate input from affected groups, especially those disproportionately affected by the pandemic. Once informed by public input, decisions should be data-driven and made by impartial decision makers, such as public health officials.

**Transparency:** The obligation to communicate with the public openly, clearly, accurately, and straightforwardly about the vaccine allocation criteria and framework, as they are being developed and deployed.

**Evidence-based:** Vaccination phases, specifying who receives the vaccine when, should be basked on the best available scientific evidence, regarding risk of disease, transmission, and societal impact.

#### 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

#### Prioritization for distribution

#### Phase 3 Phase 4 Phase 1 Phase 2 Everyone residing in the United States Phase 1a "Jumpstart Phase" Young adults High-risk health child care workers Children who did not have workers Workers in industries First responders settings—workers who are in access to the and occupations vaccine in previous Phase 1b important to the phases People of all ages functioning of society higher risk of exposure with comorbid and and at increased risk o • People of all ages with comorbid and underlying conditions exposure not included underlying conditions that put them at moderately higher risk that put them at in Phase 1 or 2 significantly higher risk People in homeless shelters or group homes for individuals with Older adults living in congregate or disabilities, including serious mental illness, developmental and intellecovercrowded settings tual disabilities, and physical disabilities or in recovery, and staff People in prisons, jails, detention centers, and similar facilities, and • All older adults not included in Phase 1 Equity is a In each population group, vaccine access should be prioritized crosscutting for geographic areas identified through CDC's Social Vulnerability Index or another more specific index. consideration:

NOTE: The CDC-ACIP revised to include residents in long term care in Phase 1a

MATIONAL ACADEMY of MEDICINE FIGURE: A Phased Approach to Vaccine Allocation for COVID-19

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