COVID-19 Vaccine Development and Distribution

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Vaccine Licensure and Recommendations

ACIP

Advises

CDC recommendations

- Recommendation for use of licensed vaccines guided by label and other considerations

Pharma submits to FDA for Emergency Use Authorization (EUA)

Advises

FDA Licensure

- PHS Act (Sec 351a), FD&C Act (PREA, FDASIA...)
- National Regulatory Agency, has enforcement authority
- Licensure for interstate commerce
- Label content restricted to stated intended use in studied population and supported by data from adequate and well controlled studies provided by manufacturer.

Advises

Vaccines and Related Biological Products Advisory Committee (VRBPAC)
Efficient Distribution. During a pandemic, efficient, expeditious and equitable distribution and administration of authorized vaccine is critical.

Flexibility. Within national guidelines, state and local jurisdictions should have flexibility to administer vaccine based on local epidemiology and demand.
COVID-19 Vaccine Distribution and Initiation

As of January 8, 2021

Total Number of People Initiating Vaccination (1st Dose Received) Reported to the CDC by State/Territory and for Selected Federal Entities per 100,000


<table>
<thead>
<tr>
<th>Total Doses Distributed</th>
<th>22,137,350</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Number of People Initiating Vaccination (1st Dose Received)</td>
<td>6,668,231</td>
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</tbody>
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Updated: Jan 8, 2021 as of 9:00am ET
Differences Between Moderna and Pfizer COVID-19 Vaccines

**Moderna**
- Age 18
- 28 - day dose interval
- Arrives in a thermal shipping container at between -25 °C and -15°C (-13°F to 5°F)

**Pfizer**
- Age 16
- 21 - day dose interval
- Arrives in a thermal shipping container at between -80°C and -60°C (-112°F to -76°F)
Distribution will adjust as volume of vaccine doses increases

**Limited Doses Available** (Phase 1: Priority Populations)
- Constrained supply
- Highly targeted administration required to achieve coverage in priority populations

**Larger Number of Doses Available** (Phase 2: General Public)
- Likely sufficient supply to meet demand
- Supply increases access
- Broad administration network required, including surge capacity

**Example populations**
- Healthcare personnel
- Residents of long-term care facilities
- Non-healthcare essential workers
- People with high-risk medical conditions
- Older adults (65+)

**Example population**
- All others in the US who did not have access in previous phases

Illustrative scenario for planning purposes; will be adapted based on clinical / manufacturing information on all OWS candidates & vaccine prioritization

1/11/21
Essential Workers

Frontline Essential Workers (~30M)
- First Responders (Firefighters, Police)
- Education (teachers, support staff, daycare)
- Food & Agriculture
- Manufacturing
- Corrections workers
- U.S. Postal service workers
- Public transit workers
- Grocery store workers

Other Essential Workers (~57M)
- Transportation and logistics
- Food Service
- Shelter & Housing (construction)
- Finance
- IT & Communication
- Energy
- Media
- Legal
- Public Safety (Engineers)
- Water & Wastewater

Frontline Essential Workers: workers who are in sectors essential to the functioning of society and are at substantially higher risk of exposure to SARS-CoV-2

Distribution and Administration

In early-phase distribution: COVID-19 vaccines will be administered in focused areas for priority groups

- Healthcare Personnel
- Long-Term Care Facility Residents
- Public Health Clinics

Later in distribution: vaccines will be administered to broader populations through many different administration sites, with focus on ensuring equity and expanding access

- Pharmacies
- Doctor's Offices
- LTC Providers
- Home Bound
- Mobile Units
- Public Health Clinics / FQHCs
- Indian Health Service
- Other federal entity sites (DOD)
- Hospitals
- Mass Vx – large outpatient clinics
Complexities and Additional Considerations for Early Phase Implementation of COVID-19 Vaccine

- Varying cold-chain requirements
- Need for socially distanced vaccination practices
- Sub-prioritization may be required with initial limited supply
- One vs. two dose series
  - Products not interchangeable
- Vaccine efficacy and adverse event profile in different populations
  - Implementation of vaccination programs for healthcare personnel will need to consider **reactogenicity** post-vaccination
- **Safety monitoring** of all populations in early phases, especially LTCF residents, will be critical post-authorization
- **Communication and education critical to success** of vaccination program
v-safe™
after vaccination health checker

active surveillance

CDC + FDA

passive surveillance

VAERS
Vaccine Adverse Event Reporting System

DoD VAECs
US Department of Defense

VA ADERS
VA

NHSN
National Healthcare Safety Network

individual case consults

CISA
Clinical Immunization Safety Assessment (CISA) Project

active surveillance, passive surveillance, case consults

safety monitoring timeline

1/11/21

VA EHR & data warehouse

VSD
Vaccine Safety Datalink

FDA Vaccine Surveillance Program

Federal Partners
CMS, VA

BEST Initiative
Acumen, IBM, IQVIA/DHHS

PRISM
Harvard Pilgrim Healthcare Institute

DoD DMSS
Defense Medical Surveillance System

large-linked database monitoring
The Problem: Need to Instill Vaccine Confidence

- Overall acceptability of a COVID-19 vaccine is moderate\(^1\)
  - Proportion intending to receive vaccine ranged across surveys: 42-86% (as of Nov-Dec 2020 polls)

Factors weighing on acceptance:

- Concern about side effects
- Efficacy
- Risk perception
- Associated costs

COVID-19 vaccine more acceptable if:

- Healthcare provider said it was safe
- There are no costs to the individual
- It would help get back to school and work
- They could get it easily


# A National Strategy to Reinforce Confidence in COVID-19 Vaccines

## Reinforce Trust
Objective: Regularly share clear and accurate COVID-19 vaccine information and take visible actions to build trust in the vaccine, the vaccinator, and the system.

## Empower Healthcare Providers
Objective: Promote confidence among healthcare personnel in their decision to get vaccinated and to recommend vaccination to their patients.

## Engage Communities & Individuals
Objective: Engage communities in a sustainable, equitable and inclusive way—using two-way communication to listen, increase collaboration and build trust in COVID-19 vaccine.
COVID-19 Vaccine Implementation

- This is an **exciting and historic time**, but the work is far from over.
- There will be **unanticipated challenges**, but CDC will continue to work closely with you, our partners, to **find solutions and overcome obstacles**.
- Vaccines are an important tool to control the pandemic, but we need to continue to message the importance of **masks, social distancing, and hand washing**.
- **Community engagement** is critical to vaccination implementation success
  - Engage in conversations in your community, choose to get vaccinated when it’s your turn, share CDC resources and toolkits
  - [https://www.cdc.gov/vaccines/covid-19/index.html](https://www.cdc.gov/vaccines/covid-19/index.html)
Thank you

For more information, contact CDC
1-800-CDC-INFO (232-4636)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.