COVID-19 vaccine prioritization: Work Group considerations

Kathleen Dooling, MD MPH
August 26, 2020
Work Group Considerations: Goals of the COVID-19 Vaccine Program

- Ensure safety and effectiveness of COVID-19 vaccines
- Reduce transmission, morbidity, mortality of COVID-19 disease
- Help minimize disruption to society and economy, including maintaining healthcare capacity
- Ensure equity in vaccine allocation and distribution
Identifying groups for allocation of initial doses COVID-19 vaccine: critical for program planning

Strengthen vaccine distribution networks to reach target groups

Engage partners and stakeholders

Develop state and local microplans for vaccine implementation

Create communications strategies to promote vaccination in target groups

Plan evaluations to rapidly monitor vaccine safety, effectiveness, and coverage
Administration of COVID-19 vaccine will require a phased approach

**Limited Doses Available**
- Constrained supply
- Cold chain & handling may require specialized equipment and high throughput
- Highly targeted administration

**Large Number of Doses Available**
- Likely sufficient supply to meet demand
- Additional vaccine products allow a wider range of administration locations
- Broad administration network required (pharmacies, doctors offices, public health clinics, mobile clinics, FQHCs)
- Focus on increasing access for critical populations

**Continued Vaccination**
- Sufficient supply to meet demand
- Harness vaccine provider networks with proven ability to reach critical populations
- Enhance series completion
Administration of COVID-19 vaccine will require a phased approach

<table>
<thead>
<tr>
<th>Volume doses available (per month)</th>
<th>Key factors</th>
<th>Likely admin strategies</th>
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Projected short period of time for when doses are limited
**Proposed scenarios for planning for D&A initial phase (Q4 2020)**

Does not represent decisions; preliminary scenarios for planning

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Cumulative Doses available</th>
<th>Distribution requirements</th>
<th>Administration</th>
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<tbody>
<tr>
<td>1. <strong>Vaccine candidate A</strong> is the first to demonstrate safety &amp; efficacy</td>
<td></td>
<td><strong>Shipped direct at --70-80°C on dry ice, to be used within 10 days</strong></td>
<td><strong>Vaccine can be stored at 2-8°C for 24 hours</strong>&lt;br&gt;<strong>6 hour shelf life at room temperature</strong>&lt;br&gt;<strong>Unique diluent / kit requirements</strong>&lt;br&gt;<strong>Only shippable to large admin sites</strong></td>
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<td>2. <strong>Vaccine candidate B</strong> is the first to demonstrate safety &amp; efficacy</td>
<td></td>
<td><strong>Central distro capacity at -20°C, may be stored for months at -20°C</strong></td>
<td><strong>Vaccine can be stored at 2-8°C for 7 days</strong>&lt;br&gt;<strong>6 hour shelf life at room temperature</strong></td>
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<td>3. <strong>Vaccine candidates A and B</strong> demonstrate safety &amp; efficacy</td>
<td></td>
<td><strong>As above</strong></td>
<td><strong>Administration site considerations as above</strong>&lt;br&gt;<strong>Complexity increases significantly if sites are administering 2 products with different requirements and differing dose schedules</strong></td>
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</tbody>
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CDC Activities to Support Implementation Planning

- Microplanning
- Critical population focus
- Federal entity planning
- Development of IT tools
- Communications and engagement materials
# Recap of ACIP discussions early phase COVID-19 vaccination

<table>
<thead>
<tr>
<th>Meeting</th>
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| **June** | - Support for identification of groups for allocation of initial vaccine to aid implementation planning  
- Recognition of disparity in COVID-19 impact on race/ethnic groups, essential workers, low income families, etc.  
- Need to build on existing vaccine infrastructure to meet challenges of the COVID-19 vaccination | |
| **July** | - Support for **healthcare personnel and other essential workers** to receive initial vaccine allocation | |
Objective for today’s ACIP discussion: Focus on the Work Group’s proposed groups for early phase vaccination

- Healthcare personnel
- Essential workers
- Persons with high risk medical conditions
- Older adults (≥65 years)

ACIP considerations for sequence of groups

September: Possible vote on interim allocation of initial vaccine doses
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

- Includes persons not directly involved in patient care but potentially exposed to infectious agents while working in a healthcare setting

Estimated Population ~17-20M

Examples:
- Hospitals
- Long term care facilities (assisted living facilities & skilled nursing facilities)
- Outpatient
- Home health care
- Pharmacies
- EMS
- Public health

https://www.bls.gov/ooh/healthcare/home.htm
Composition of healthcare workforce varies widely by setting

Hospitals
- Registered nurses: 27.7%
- Physicians & surgeons: 5.93%
- Medical & health services managers: 3.76%
- Diagnostic-related technologists & technicians: 3.41%
- Licensed practical & licenced vocational nurses: 3.11%

Skilled Nursing Facilities
- Nursing assistants: 30.5%
- Personal care aides: 4.64%
- Cooks: 3.39%
- Recreational workers: 1.64%
- Janitors & building cleaners: 1.58%

Essential Workers (non Healthcare)

- Workers who are essential to continue critical infrastructure and maintain the services and functions Americans depend on daily.

- Workers who cannot perform their duties remotely and must work in close proximity to others should be prioritized.

- Sub-categories of essential workers may be prioritized differently in different jurisdictions depending on local needs.

Examples:
- Food & Agriculture
- Transportation
- Education
- Energy
- Water and Wastewater
- Law Enforcement


Estimated Population ~60-80M
Healthcare personnel and essential worker race/ethnic composition is similar to U.S. population (self-report, NHIS)

Hispanic and non-White workers accounted for 73% of workplace outbreak-associated COVID-19 cases in Utah

Adults with medical conditions at higher risk for severe COVID-19*

- Cancer
- Chronic kidney disease
- Chronic obstructive pulmonary disease (COPD)
- Immunocompromised state from solid organ transplant
- Obesity (BMI of 30 or greater)
- Serious heart conditions (heart failure, coronary artery disease or cardiomyopathies)
- Sickle cell disease
- Type 2 diabetes mellitus


Examples‡ % Population
- Obesity 31%
- Diabetes 11%
- COPD 7%
- Heart Condition 7%
- Chronic kidney 3%

‡ [https://www.cdc.gov/mmwr/volumes/69/wr/mm6929a1.htm?s_cid=mm6929a1_w](https://www.cdc.gov/mmwr/volumes/69/wr/mm6929a1.htm?s_cid=mm6929a1_w)
Adults 65 years and older

- 65 to 69 years: 17
- 70 to 74 years: 14
- 75 to 79 years: 9
- 80 to 84 years: 6
- 85 years and over: 6

Estimated Population ~53M

- 16% of the U.S. population
- ~3M person live in long-term care facilities

United States Census Bureau [https://www.census.gov/topics/population/older-aging.html](https://www.census.gov/topics/population/older-aging.html) [https://www.cdc.gov/nchs/fastats/nursing-home-care.htm](https://www.cdc.gov/nchs/fastats/nursing-home-care.htm)
The proportion with COVID-19 high risk medical conditions is similar among younger and older adults (NHIS, self-report)

Summary: Groups for early phase vaccination

- Overlapping
- Significant heterogeneity
- Accounts for > half of U.S. adults
- Need for additional sub-grouping
Work Group Considerations

Epidemiology, Feasibility of Implementation, Equity & Ethics
Work Group Interpretation: Implementation challenges & implications for distribution of initial vaccine

- A COVID-19 vaccine that requires distribution and storage at -20°C, followed by 7 days (max) at 2-8°C, will require diligent vaccine management to minimize waste.

- The storage, distribution and handling requirements of a -70°C vaccine will make it very difficult for community clinics and local pharmacies to store and administer.
  - will necessitate most vaccine be administered at centralized sites with adequate equipment and high throughput.
  - vaccinating healthcare personnel at centralized sites with high throughput is the best allocation of initial supply.
Workers at long-term care facilities are a priority among healthcare personnel and achieving high coverage is important and may be resource intensive.

Mass vaccination clinics will be difficult to conduct in the setting of social distancing.

Healthcare homes, such as provider offices or pharmacies, could be better suited to provide vaccination if recommendations are based on individual risk factors such as age or underlying medical conditions.

Challenges to equitable vaccine administration:
- Reaching rural areas
- Racial and ethnic minorities
- Populations with limited access to vaccines
Key Unknowns:

- Vaccine performance: the magnitude of benefits and potential risks, for younger and older adults
- Possibility of multiple vaccines with differing profiles
- The pathway to approval: emergency use authorization or full licensure
- The timing of vaccine availability
- The number of doses available and rate of scale-up
Next Steps for the COVID-19 Vaccine Work Group: Develop and vote on an interim prioritization schema for initial COVID-19 vaccine

- Review clinical trial data for candidate vaccines, as they become available
  - Safety data, including plans for post-approval safety surveillance
  - Immunogenicity and efficacy data
- Review epidemiologic data for risk of COVID-19 disease and severity by race/ethnicity
- Review results of focus groups and other public engagement regarding COVID-19 vaccines
- Review equity frameworks for allocating vaccine
Tier 1:
- Those most essential in sustaining the ongoing COVID-19 response
- Those at greatest risk of severe illness and death, and their caregivers
- Those most essential to maintaining core societal functions

Tier 2:
- Those involved in broader health provision
- Those who face greater barriers to access care if they become seriously ill
- Those contributing to maintenance of core societal functions
- Those whose living or working conditions give them elevated risk of infection, even if they have lesser or unknown risk of severe illness and death

“The purpose of this report is to offer an ethics framework that can be used to make decisions about the allocation of a SARS-CoV-2 vaccine during the initial period of scarcity in the United States and make related suggestions about vaccine distribution.”

Questions:

1) Given the information presented thus far (epidemiology, values, acceptability, feasibility) do you agree that initial doses of COVID-19 vaccine should be allocated to healthcare personnel?

2) If supply remains constrained, due to vaccine or distribution limitations, do you agree with vaccinating essential workers next as supply permits?
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Background slides
Safety is paramount. Vaccine safety standards will not be compromised in efforts to accelerate COVID-19 vaccine development or distribution.

Inclusive clinical trials. Study participants should reflect groups at risk for COVID-19 to ensure safety and efficacy data are generalizable.

Efficient Distribution. During a pandemic, efficient, expeditious and equitable distribution and administration of approved vaccine is critical.

Flexibility. Within national guidelines, state and local jurisdictions should have flexibility to administer vaccine based on local epidemiology and demand.