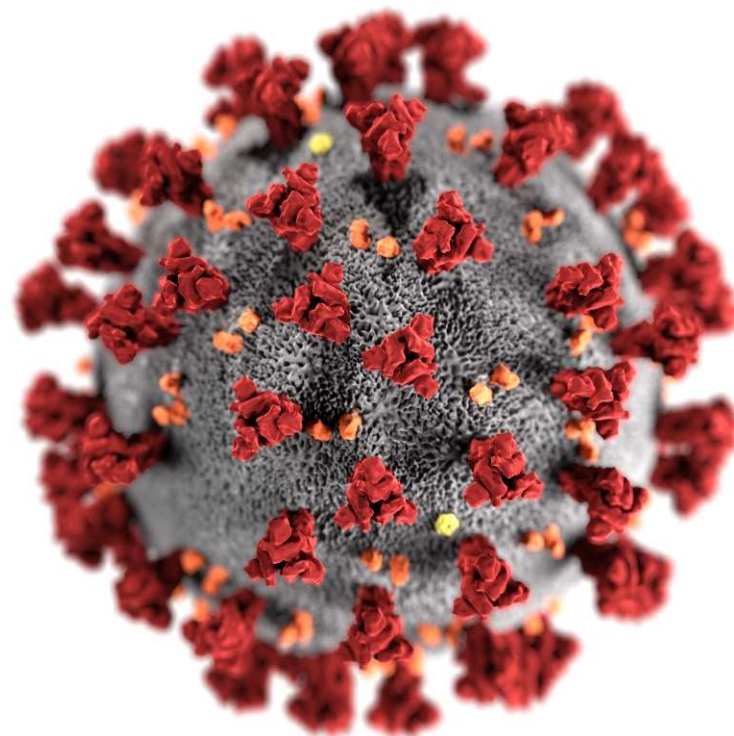


# Overview of Ethical Framework and Phased Allocation of COVID-19 vaccine



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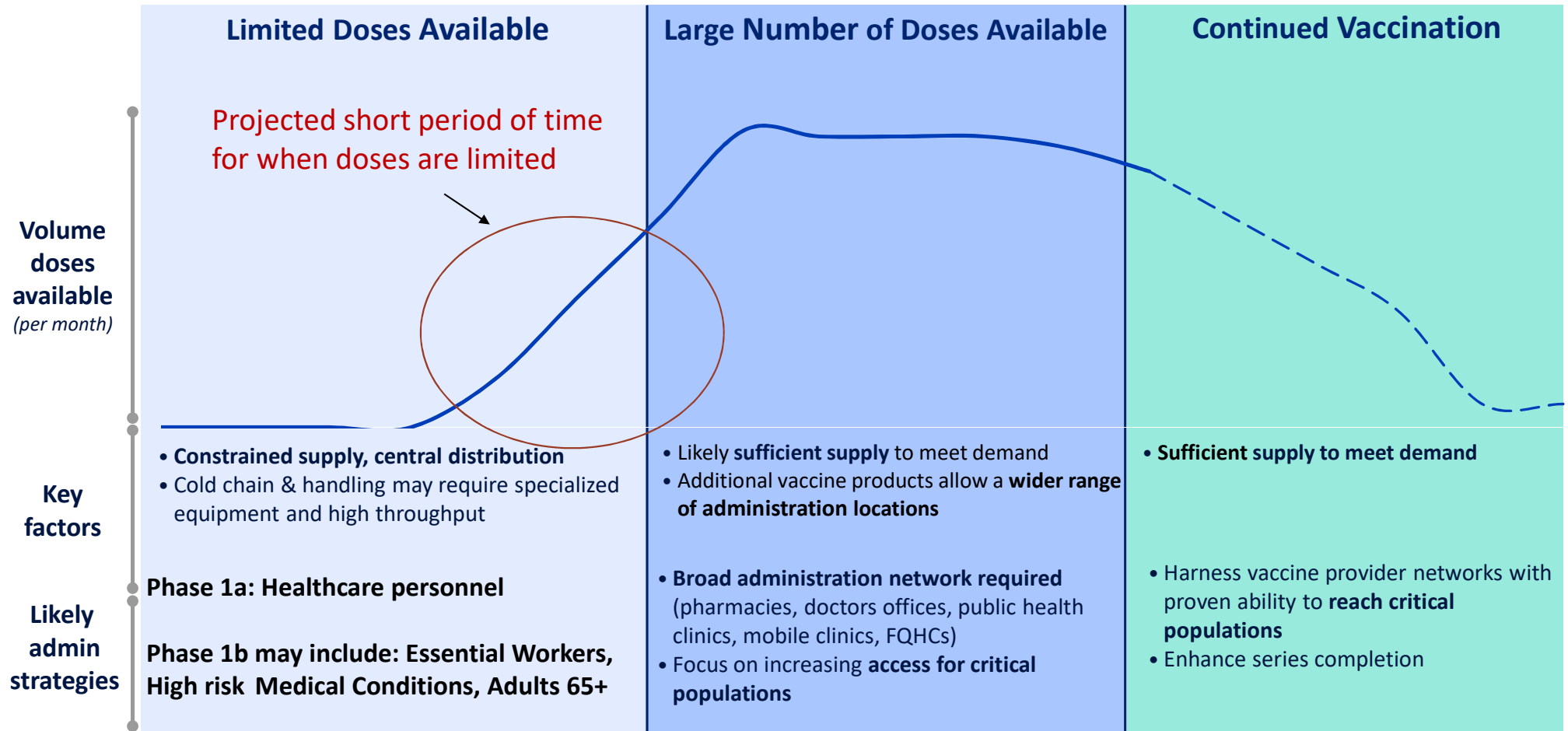
WHO Regional webinar on  
Preparedness for COVID-19 Vaccination  
October 8, 2020

# **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



# Administration of COVID-19 vaccine will require a phased approach



# Published ethical frameworks for COVID-19 vaccine allocation

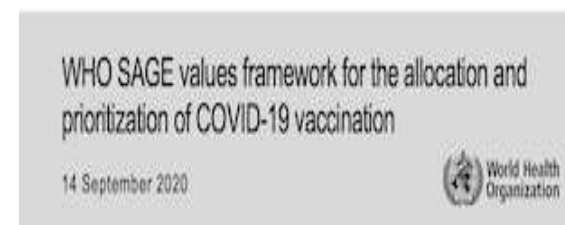


## Selected published frameworks for early COVID-19 vaccine allocation

- World Health Organization (WHO) Strategic Advisory Group of Experts (SAGE)
- Johns Hopkins Bloomberg School of Public Health
- The National Academies of Sciences, Engineering, and Medicine

# WHO SAGE: Values Framework for the Allocation and Prioritization of COVID-19 Vaccination

- Both national and global considerations
- Six core values principles
  - Human well-being
  - Equal respect
  - Global equity
  - Reciprocity
  - Legitimacy
  - National equity



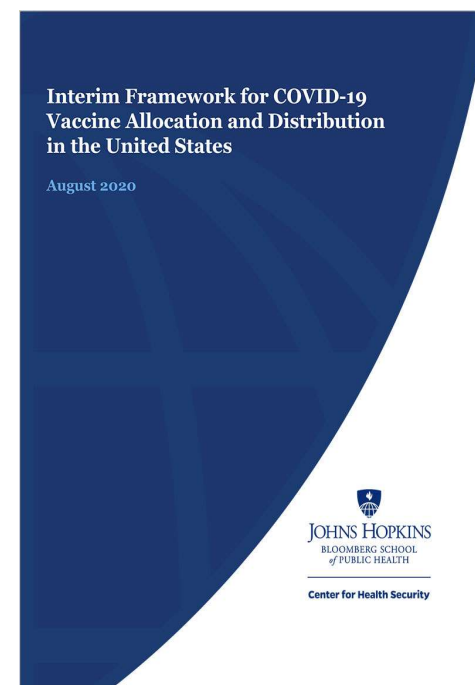
## [Executive Summary](#)

This Values Framework offers guidance globally on the allocation of COVID-19 vaccines between countries, and to offer guidance nationally on the prioritization of groups for vaccination within countries while supply is limited. The Framework is intended to be helpful to policy makers and expert advisers at the global, regional and national level as they make allocation and prioritization decisions about COVID-19 vaccines. This document has been endorsed by the [Strategic Advisory Group of Experts on Immunization \(SAGE\)](#).

The Framework articulates the overall goal of COVID-19 vaccine deployment, provides six core principles that should guide distribution and twelve objectives that further specify the six principles (Table 1). To provide recommendations for allocating vaccines between countries and prioritizing groups for vaccination within each country, the Values Framework needs to be complemented with information about specific characteristics of available vaccine or vaccines, the benefit-risk assessment for different population groups, the amount and pace of vaccine supply, and the current state of the epidemiology, clinical management, and economic and social impact of the pandemic. Hence, the final vaccination strategy will be defined by the characteristics of vaccine products as they become available.

# Johns Hopkins Bloomberg School of Public Health: Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States

Ethical values	Ethical principles
I. Promote the common good	<ul style="list-style-type: none"><li>• Promote public health</li><li>• Promote economic &amp; social well being</li></ul>
II. Treat people fairly and promote equality	<ul style="list-style-type: none"><li>• Address inequities</li><li>• Prioritize the worst-off</li><li>• Reciprocity</li></ul>
III. Promote legitimacy, trust, and sense of ownership in a pluralistic society	<ul style="list-style-type: none"><li>• Respect diversity of views</li><li>• Engage community</li></ul>



# Johns Hopkins Framework: Tier 1

## Priority Groups

- 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

## Examples

- Frontline HCP caring for COVID-19 patients
- Frontline emergency medical services personnel
- Vaccine manufacturing/supply chain personnel
- COVID-19 diagnostic and immunization teams
- Public health workers in critical, frontline intervention work
- Adults  $\geq 65$  years of age and those who care for them
- Others at increased risk of serious disease, e.g. medical conditions, pregnant, social groups with disproportionately high fatality rates
- Frontline long-term care facility providers
- HCP caring for pts with high-risk conditions
- Frontline public transportation workers
- Food supply workers
- Teachers and school workers (pre-K through 12<sup>th</sup> grade)



# Johns Hopkins Framework: Tier 2

## Priority Groups

- Those involved in broader health provision
- Those who face greater barriers to access care if they become seriously ill
- Needed to maintain other essential services
- Those whose living or working conditions give them elevated risk of infection

## Examples

- HCP & staff with direct, non-COVID patient contact
- Pharmacy staff
- Remote locations with substandard infrastructure and healthcare access (Native American reservations, isolated rural communities)
- Frontline workers: electricity, water, sanitation, fuel, financial, information (cannot work remotely)
- Warehouse, delivery workers (including postal workers)
- Deployed military (including National Guard)
- Police & fire workers with frequent public contact
- TSA & border security with direct public contact
- Unable to safely distance (e.g. high-density/high-contact jobs; shelters; incarcerated persons; prison workers)
- Others (TBD)

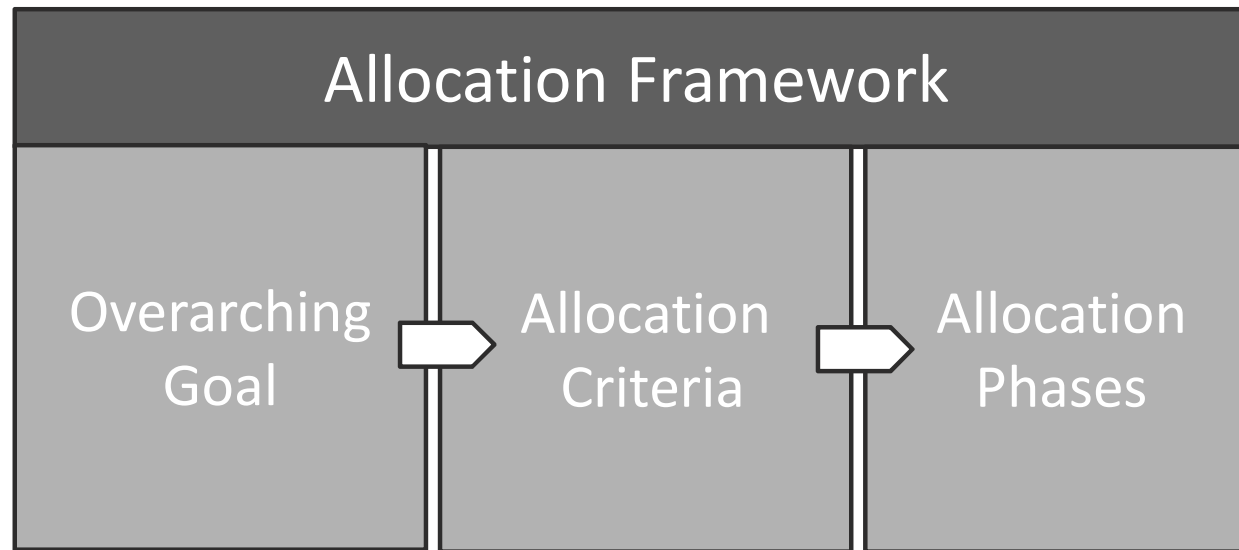
# National Academies of Medicine

## Framework for Equitable Allocation of COVID-19 Vaccine

- Purpose
  - Develop an overarching framework for vaccine allocation to assist policy makers in domestic and global health communities in planning for equitable allocation of vaccines against SARS-CoV-2
  - Expectation that framework will inform decisions by health authorities, including the ACIP, as they create and implement national/local guidelines for vaccine allocation
- Asked to consider
  - Criteria for setting priorities for equitable allocation
  - How to apply criteria to determine 1<sup>st</sup> tier of recipients

See: <https://www.nap.edu/catalog/25914/discussion-draft-of-the-preliminary-framework-for-equitable-allocation-of-covid-19-vaccine>

# National Academics of Medicine Framework:



## Foundational Principles

Maximize benefits \* Equal regard \* Mitigate health inequities \* Fairness \* Evidence-based \* Transparency

# National Academies of Medicine Framework:

- Overarching goal

Maximize societal benefit by reducing morbidity and mortality caused by transmission of novel coronavirus

- Allocation criteria are risk based

*Individuals have higher priority to the extent of their:*

- Risk of acquiring infection
- Risk of severe morbidity and mortality
- Risk of negative societal impact
- Risk of transmitting disease

# National Academies of Medicine Framework: Vaccine allocation phases

- **Phase 1a “Jumpstart phase”**

- High-risk workers in health care facilities
- First responders (EMS, police, fire)

- **Phase 1b**

- People of all ages with comorbid/underlying conditions that put them at significantly higher risk, i.e.  $\geq 2$  CDC designated medical conditions
- Older adults living in congregate or overcrowded settings, e.g. nursing homes, residential care facilities

# National Academies of Medicine Framework: Vaccine allocation phases

## ■ Phase 2

- Critical risk workers in industries essential to functioning of society and at substantially high risk of exposure
- Teachers and school staff
- People of all ages with comorbid/underlying conditions that put them at moderately higher risk, i.e. 1 CDC designated medical condition
- All older adults not in Phase 1
- People in homeless shelters or group homes for individuals with physical or mental disabilities or in recovery
- People in prisons, jails, detention centers, and similar facilities as well as staff

# National Academies of Medicine Framework: Vaccine allocation phases

- **Phase 3**

- Young adults (18-30 years)
- Children (0-19 years)
- Workers in industries essential to the functioning of society and at increased risk of exposure not included in Phases 1 or 2

- **Phase 4**

- Everyone not previously vaccinated

## COVID-19 vaccine priority group comparison

Group	Johns Hopkins	National Academies	WHO
Healthcare personnel	<p><b>Tier 1:</b> Frontline healthcare personnel including LTCF providers; EMS</p> <p><b>Tier 2:</b> HCP &amp; staff with direct, non-COVID patient contact; pharmacy workers</p>	<p><b>Phase 1a:</b> Frontline healthcare personnel including LTCF providers; EMS</p> <p><b>Phase 2:</b> Other healthcare personnel</p>	Priority groups unranked
Other essential workers	<p><b>Tier 1:</b> Public transport, food supply workers; <b>teachers &amp; school workers</b>. Workers necessary for pandemic support: (e.g. vaccine manufacturers; public health workers/support)</p> <p><b>Tier 2:</b> Frontline infrastructure; warehouse/delivery/postal; deployed military; <b>police &amp; fire</b>; TSA and border security; high-density or high-contact jobs</p>	<p><b>Phase 1a:</b> <b>Police, fire</b></p> <p><b>Phase 2:</b> Critical infrastructure at risk of exposure; <b>teachers and school staff</b> incl childcare workers</p>	
Underlying medical conditions	<p><b>Tier 1:</b> Those with elevated risk of serious disease; members of social groups experiencing disproportionately high fatality rates</p>	<p><b>Phase 1b:</b> Significantly higher risk (≥2 CDC designated conditions)</p> <p><b>Phase 2:</b> Moderately higher risk (1 CDC condition)</p>	
Adults ≥65 years of age	<p><b>Tier 1:</b> Adults ≥65 years including those living with or providing care to them</p>	<p><b>Phase 1b:</b> Older adults in congregate settings</p> <p><b>Phase 2:</b> All older adults not in Phase 1</p>	



## Work Group interpretation

- Published frameworks all identify **healthcare personnel** important for early phase vaccine allocation
- Many identified populations contain operational/implementation difficulties:
  - After HCP, all frameworks have large population size for next Phase
  - Essential workers types split into in different “Tiers” or “Phases”
  - Identification and delivery of vaccine to only those with  $\geq 2$  underlying medical conditions
- Epidemiology of COVID-19 disease among HCP demonstrates cases extend beyond those traditionally classified “high risk” or “frontline”

# ACIP's Interim Ethical Framework for Initial Phase Allocation of COVID-19 Vaccine



# ACIP interim ethical framework

- **Purpose:** Assist ACIP in the identification of early recipients for allocation of COVID-19 vaccine in the setting of a constrained supply
- **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

# ACIP interim ethical framework: Proposed ethical principles

- Maximize benefits and minimize harms
- Equity
- Justice
- Fairness
- Transparency

# ACIP proposed ethical principles

- Maximize benefits and minimize harms
  - Minimize death and serious disease
  - Addresses our obligation to promote public health and promote the common good
  - Balanced with our obligation to respect and care for persons
  - Based on best available science
- Equity
  - Vaccine allocation reduces rather than increases health disparities
  - Ensure that everyone has a fair and just opportunity to be as healthy as possible

# ACIP proposed ethical principles

## ■ Justice

- Commitment to remove unfair, unjust, and avoidable barriers to good health and well-being that disproportionately affect the most disadvantaged populations
- Interventions must intentionally ensure that groups, populations, and communities affected by a policy are being treated fairly

## ■ Fairness

- Commitment to fair stewardship in the distribution of a scarce resource
  - Equitable distribution of benefits and burdens
  - Not exacerbate existing disparities in health outcomes
  - Equal opportunity to access vaccine to those within the agreed groups of early recipients
  - Consistency in implementation

# ACIP proposed ethical principles

## ■ Transparency

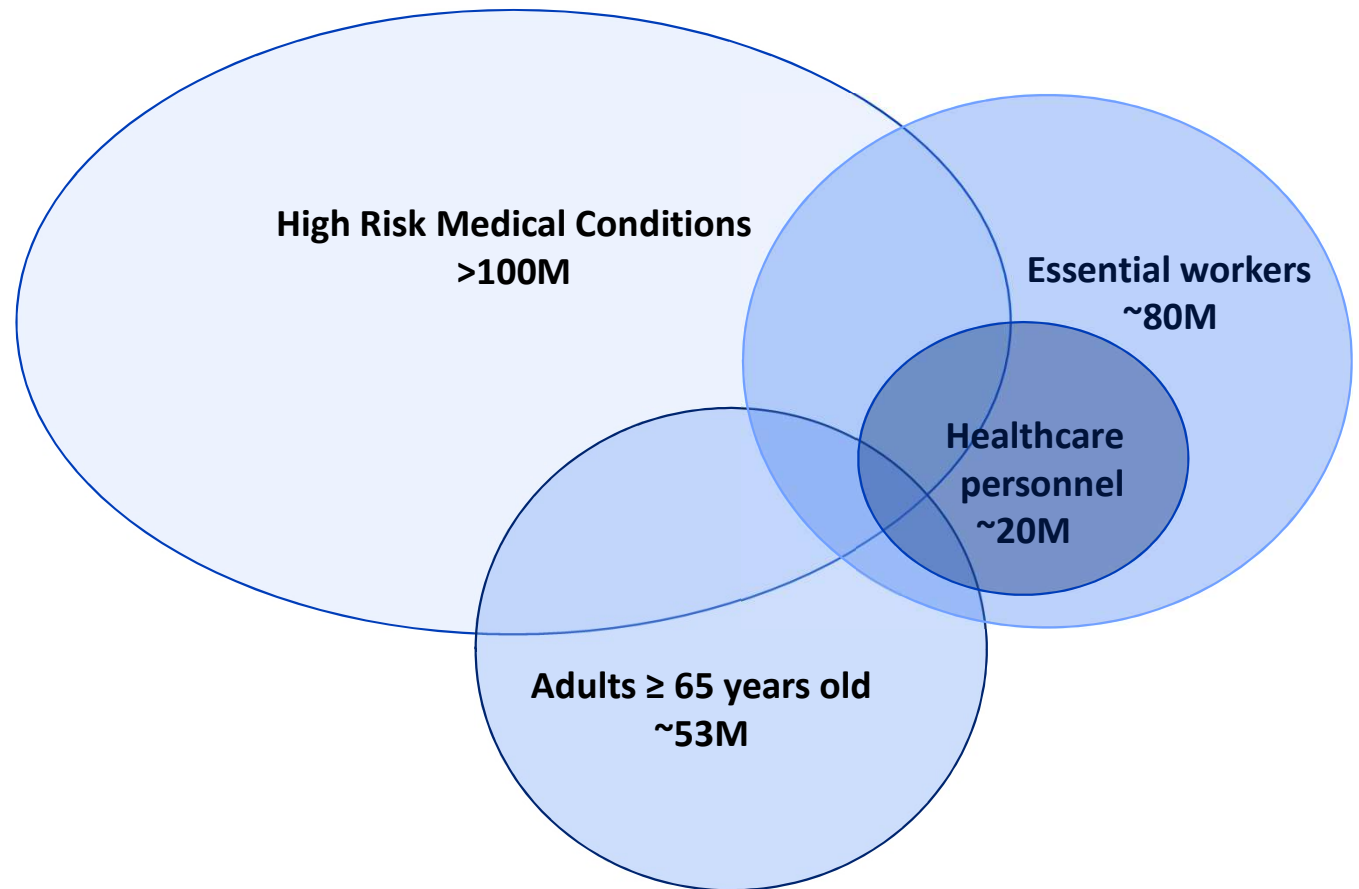
- Supporting principles and process for allocation decisions are clear, understandable, and open for review
- To the degree possible, given the urgency of the response, public participation in the creation and review of processes should be recognized and honored
- Essential to build and maintain public trust during planning and implementation
- All recommendations are evidence based, with information used to make recommendations made publicly available

# ACIP's Interim Proposed Groups for Initial Phase Allocation of COVID-19 Vaccine





# Possible groups for Phase 1 vaccination



## ACIP support for:

### Phase 1a:

-HCP

### Phase 1b:

- Essential Workers
- High Risk Med Conditions
- Adults ≥ 65 years old

# 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 ~20M

## Examples:

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

# 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

Estimated  
Population ~60M

## Examples:

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

# 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

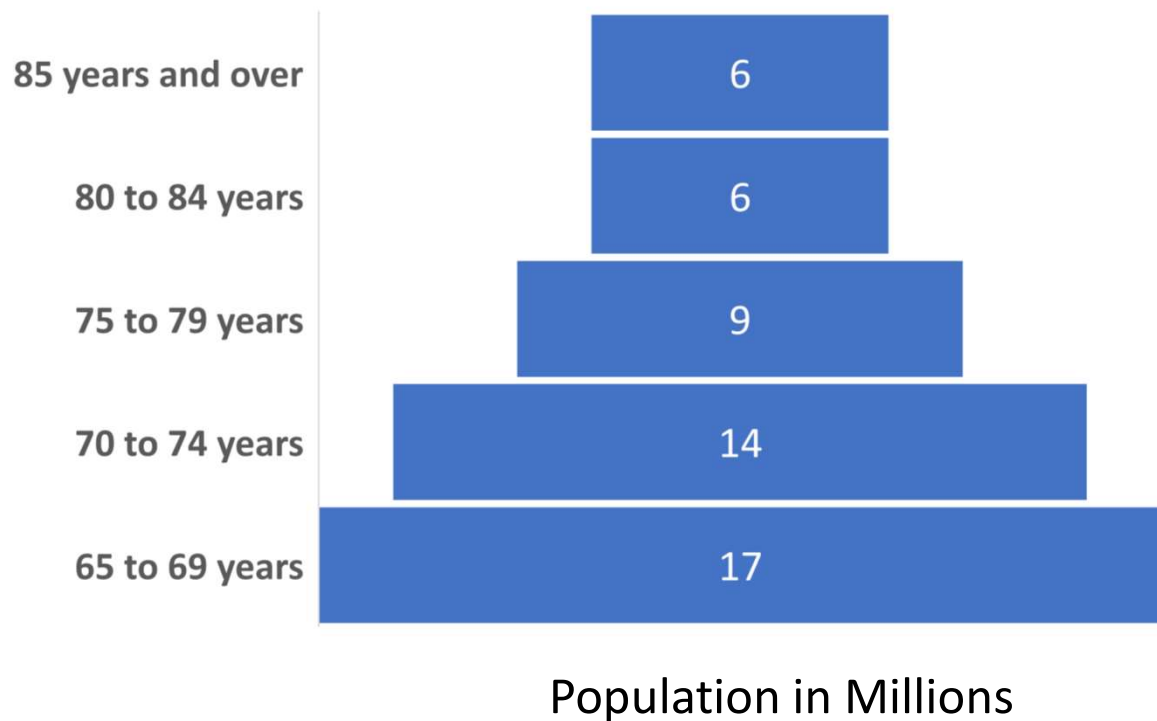
Estimated Population >100M

Examples†	% Population
■ Obesity	31%
■ Diabetes	11%
■ COPD	7%
■ Heart Condition	7%
■ Chronic kidney	3%

\* [https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html?CDC\\_AA\\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fneed-extra-precautions%2Fgroups-at-higher-risk.html](https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fneed-extra-precautions%2Fgroups-at-higher-risk.html)

† [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



United States Census Bureau <https://www.census.gov/topics/population/older-aging.html>  
<https://www.cdc.gov/nchs/fastats/nursing-home-care.htm>

**Estimated  
Population** ~53M

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

# Key Unknowns

- Vaccine characteristics
  - Magnitude and balance of benefits and potential risks
  - Storage/distribution/handling cold chain requirements
  - Vaccine efficacy/immunogenicity in younger and older adult
- The pathway to approval
  - Emergency Use Authorization (all adults vs younger adults)
  - Licensure
- The number of doses available at time of approval and rate of scale-up



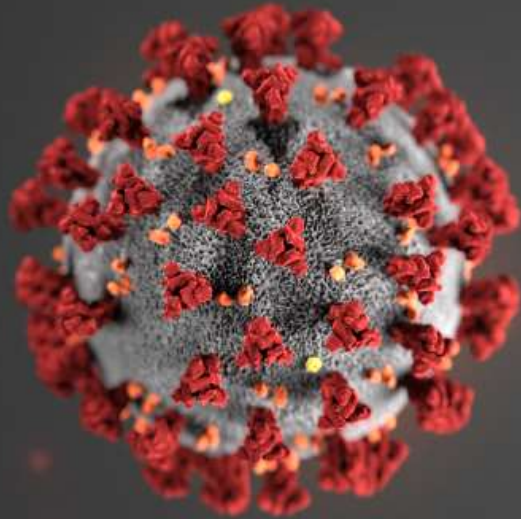
## ACIP recommendations for COVID-19 vaccines

- Ethically principled
- Evidence based
- Feasible for implementation

## ACIP recommendations for COVID-19 vaccines

- Ethically principled → Development of Ethical Framework
- Evidence based → EtR framework, GRADE
- Feasible for implementation → Continued feedback from stakeholders





For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

# Thank you

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.

