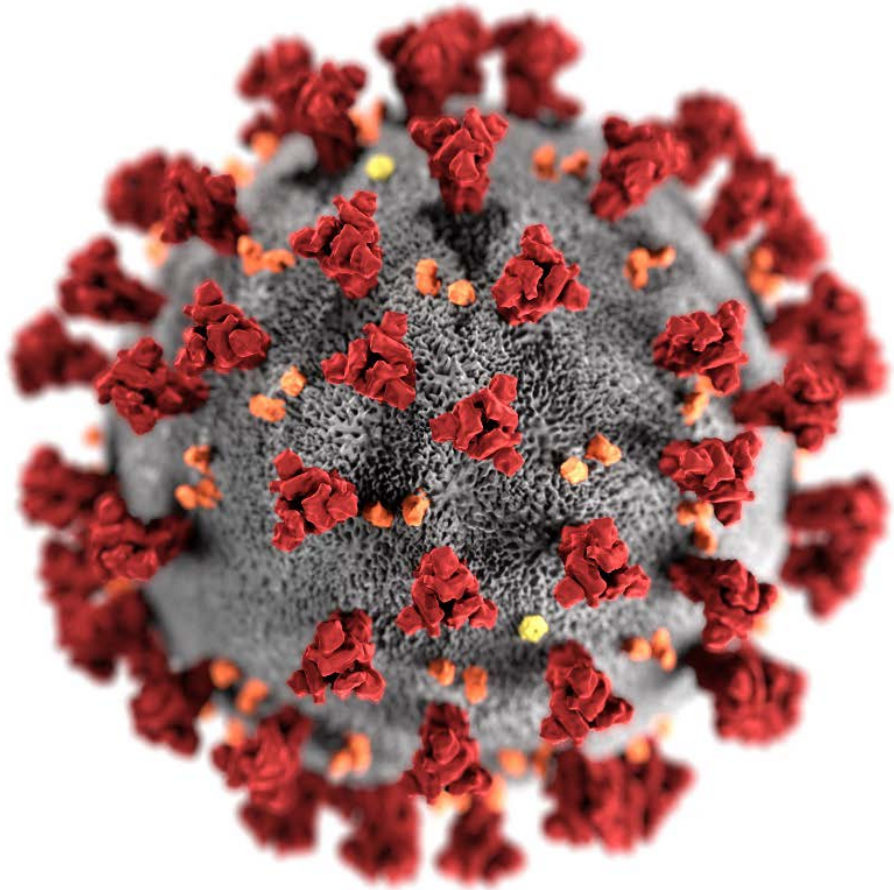
Overview of Vaccine Equity and Prioritization Frameworks



Sara Oliver MD, MSPH

ACIP Meeting
September 22, 2020

Background

- ACIP has discussed inclusion of ethics and equity principles as part of the process to identify proposed groups for early COVID-19 vaccination
- As a first step, the Work Group reviewed frameworks and published literature related to 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


WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination

14 September 2020

World Health Organization

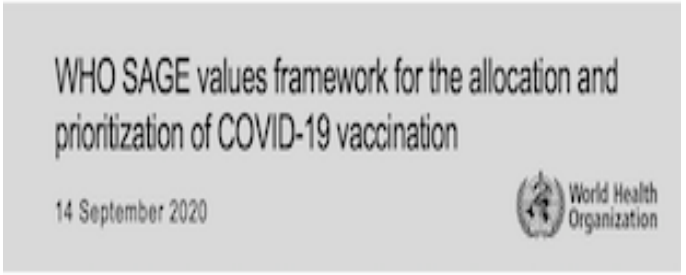
Executive Summary

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 advisors 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.

https://apps.who.int/iris/bitstream/handle/10665/334299/WHO-2019-nCoV-SAGE_Framework-Allocation_and_prioritization-2020.1-eng.pdf

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

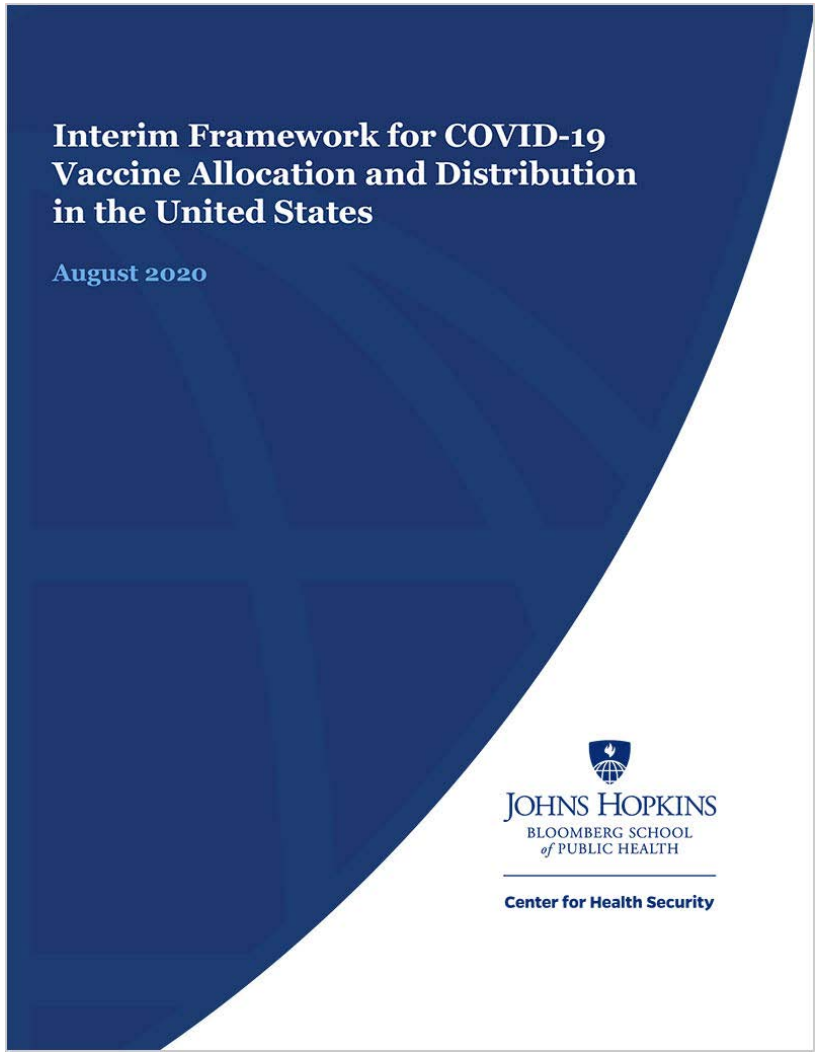


- Priority groups not ranked
- Include:
  - Populations with significantly elevated risk of being infected
    - Health workers at high risk
    - Employment categories unable to physically distance
    - Social groups unable to physically distance
    - Groups in dense urban neighborhoods or living in multigenerational housing
  - Populations with significantly elevated risk of severe disease/death
    - Older adults
    - Groups with comorbidities
    - Sociodemographic groups at disproportionately higher risk of severe disease and death

https://apps.who.int/iris/bitstream/handle/10665/334299/WHO-2019-nCoV-SAGE_Framework-Allocation_and_prioritization-2020.1-eng.pdf

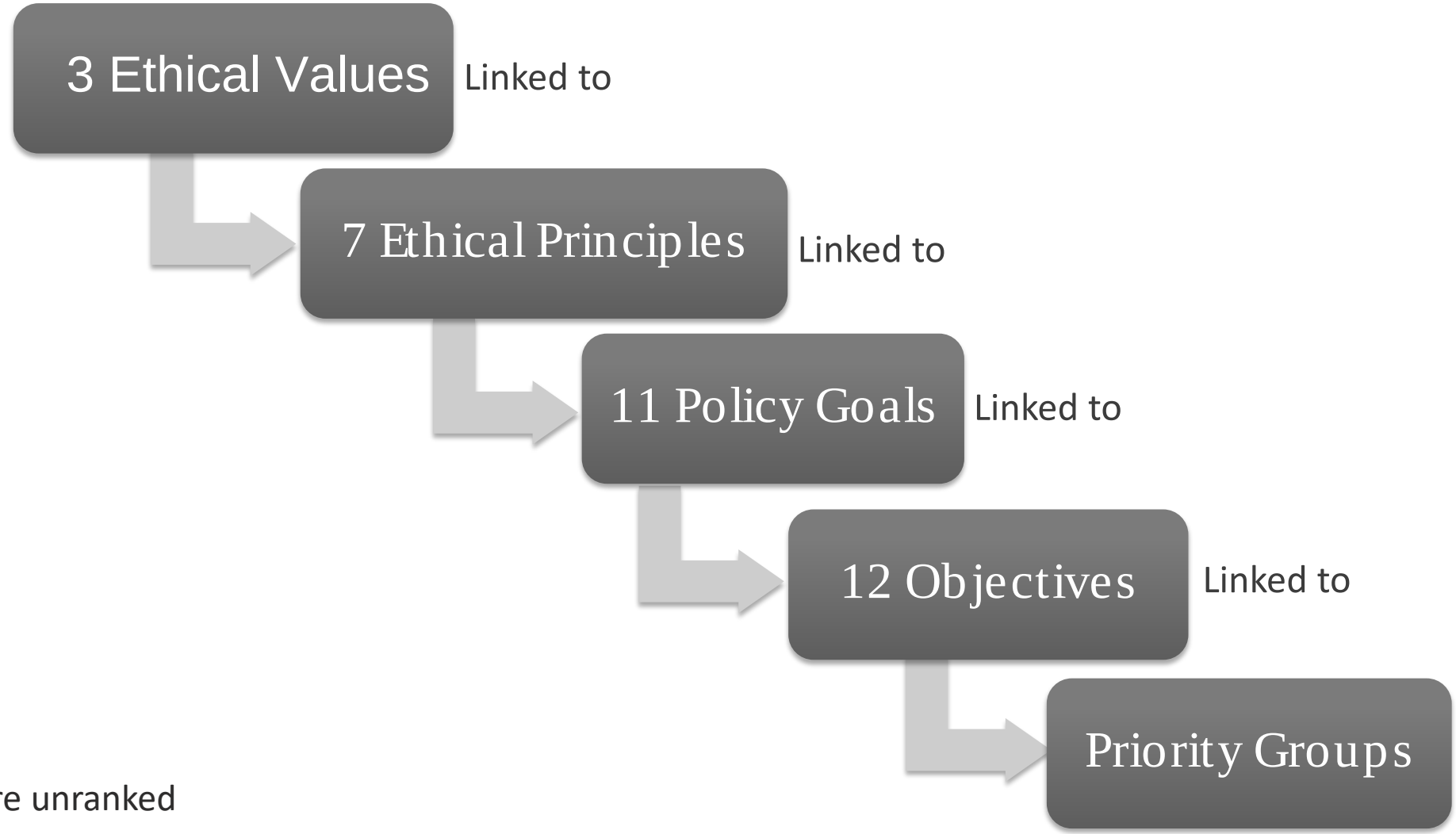
Johns Hopkins Bloomberg School of Public Health: Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States

- Purpose
  - Identify candidate groups for serious consideration as priority groups
  - Demonstrate how ethical principles and objectives can be integrated to produce an ethically defensible list of candidate groups
- Authors note importance of:
  - Transparency and a fair process
  - Equity, including access to healthcare
  - Community outreach and engagement



See: https://www.centerforhealthsecurity.org/our-work/publications/interim-framework-for-covid-19-vaccine-allocation-and-distribution-in-the-us

Johns Hopkins Framework:
Structural organization*



*All elements are unranked

Johns Hopkins Framework: Linking ethical values to ethical principles

Ethical values	Ethical principles
I. Promote the common good	• Promote public health • Promote economic & social well being
II. Treat people fairly and promote equality	• Address inequities • Prioritize the worst-off • Reciprocity
III. Promote legitimacy, trust, and sense of ownership in a pluralistic society	• Respect diversity of views • Engage community

Johns Hopkins Framework: Tier 1

Priority Groups	Examples
Those most essential in sustaining the ongoing COVID-19 response	• 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
Those at greatest risk of severe illness and death, and their caregivers	• Adults ≥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
Those most essential to maintaining core societal functions	• Frontline public transportation workers • Food supply workers • Teachers and school workers (pre-K through 12th grade)

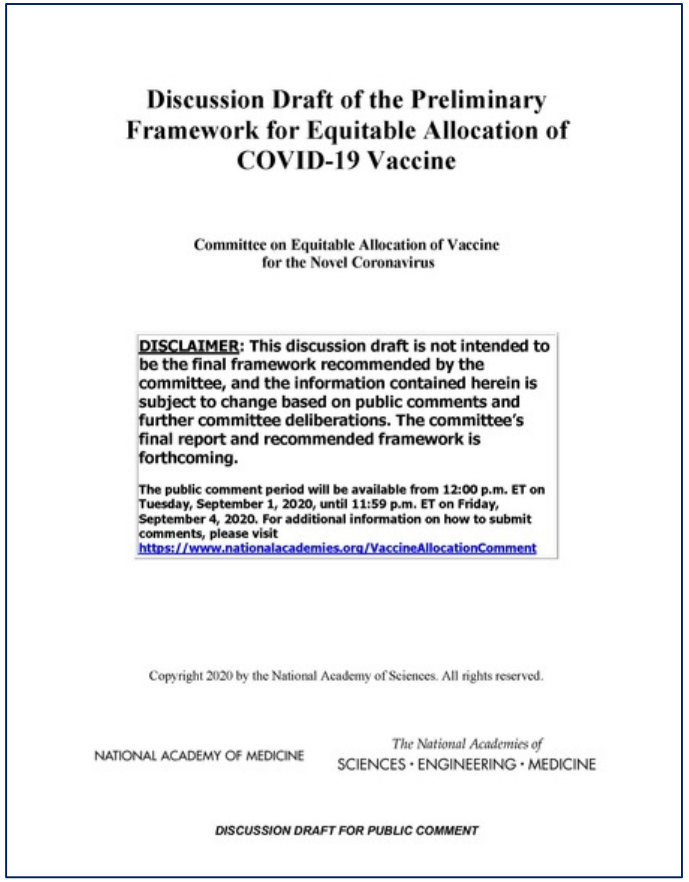
Johns Hopkins Framework: Tier 2

Priority Groups	Examples
▪ **Those involved in broader health provision**	• HCP & staff with direct, non-COVID patient contact • Pharmacy staff
▪ **Those who face greater barriers to access care if they become seriously ill**	• Remote locations with substandard infrastructure and healthcare access (Native American reservations, isolated rural communities)
▪ **Needed to maintain other essential services**	• 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
▪ **Those whose living or working conditions give them elevated risk of infection**	• Unable to safely distance (e.g. high-density/high-contact jobs; shelters; incarcerated persons; prison workers) • Others (TBD)

National Academies of Medicine

Discussion Draft of the Preliminary 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 1st tier of recipients



Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine

Committee on Equitable Allocation of Vaccine for the Novel Coronavirus

DISCLAIMER: This discussion draft is not intended to be the final framework recommended by the committee, and the information contained herein is subject to change based on public comments and further committee deliberations. The committee's final report and recommended framework is forthcoming.

The public comment period will be available from 12:00 p.m. ET on Tuesday, September 1, 2020, until 11:59 p.m. ET on Friday, September 4, 2020. For additional information on how to submit comments, please visit https://www.nationalacademies.org/VaccineAllocationComment

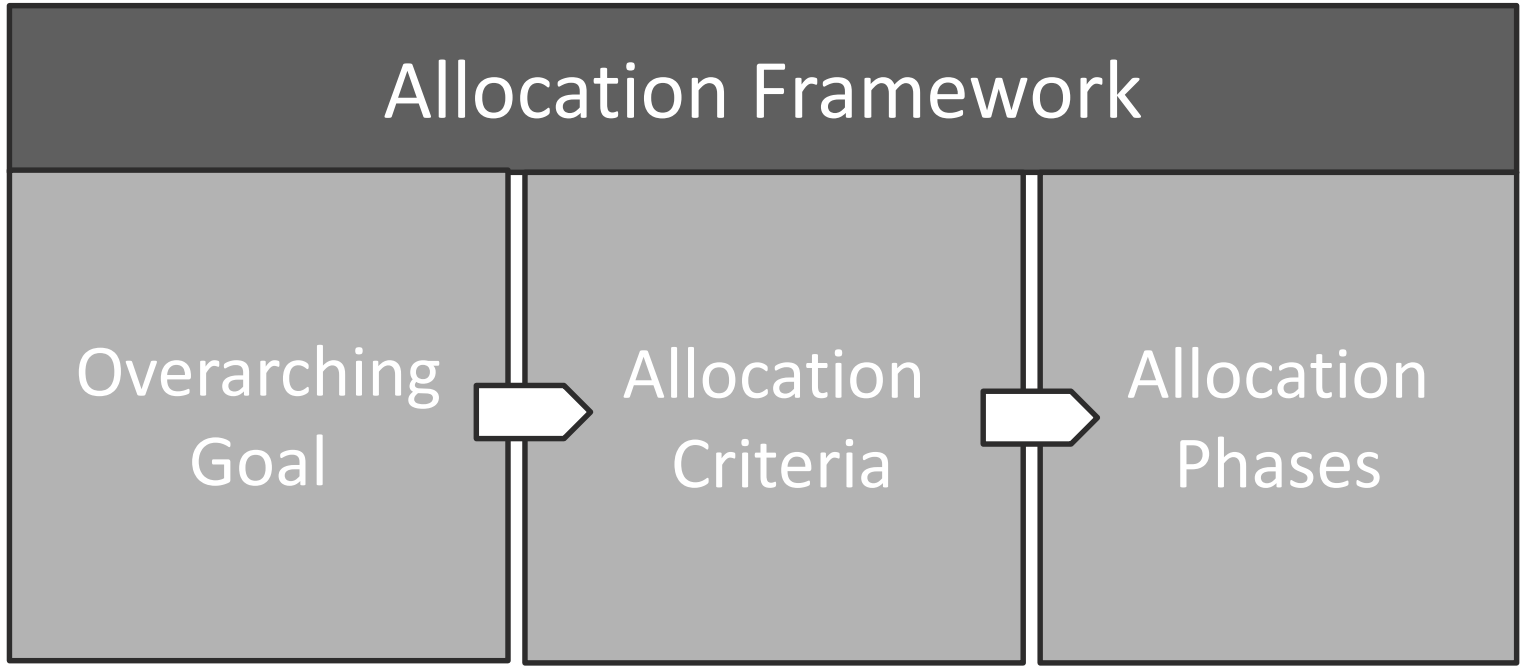
NATIONAL ACADEMY OF MEDICINE

The National Academies of SCIENCES · ENGINEERING · MEDICINE

DISCUSSION DRAFT FOR PUBLIC COMMENT

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: Structure



Foundational Principles

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

National Academies of Medicine Framework: Components

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

Work Group interpretation

- Published frameworks all identify **healthcare personnel** important for early phase vaccine allocation
  - After HCP, all frameworks have large population size for next doses
  - “Tier 1” or “Phase 1” population size 50+ million individuals

- Many identified populations contain operational/implementation difficulties:
  - Essential workers in different “Tiers”/”Phases”
  - Identification and delivery of vaccine to only those with ≥2 underlying medical conditions

- Epidemiology of COVID-19 disease among HCP demonstrates cases extend beyond “frontline” healthcare personnel

ACIP's Ethics/Equity Framework

Equity is a crosscutting consideration

- **Johns Hopkins:** “Promoting equity and social justice requires addressing higher rates of COVID-19 related severe illness and mortality among systematically disadvantaged or marginalized groups.”

- **National Academies:** “The committee recommends that vaccine access should be prioritized for geographic areas identified as vulnerable through CDC’s Social Vulnerability Index”

- **World Health Organization**: “The overarching goal is for COVID-19 vaccines to contribute significantly to the equitable protection and promotion of human well-being among all people of the world.”

ACIP ethics/equity framework for COVID-19 vaccine allocation

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

- Goals
  - Minimize death and serious disease
  - Preserve functioning of society
  - Reduce disproportionate burden on those with existing disparities
  - Increase equity of opportunity to enjoy health and well-being

ACIP ethics/equity 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 recommendations for COVID-19 vaccines

- Ethically principled
- Evidence based
- Feasible for implementation

ACIP recommendations for COVID-19 vaccines

- Ethically principled
- Evidence based → GRADE, EtR framework
- Feasible for implementation → Upcoming presentation

Application of ethical principles to potential early COVID-19 vaccine recipient groups

Evidence Based

Group	Maximize benefits	Equity	Justice	Fairness
Healthcare personnel				
Other essential workers				
High-risk medical conditions				
Older adults (≥65 years of age)				
Transparency				

Application of ethical principles to potential early COVID-19 vaccine recipient groups

Evidence Based

Group	Maximize benefits	Equity	Justice	Fairness
Healthcare personnel (~20M)	Essential for response May decrease transmission to patients, coworkers, community[1] Decrease COVID-19 morbidity and mortality in some HCP • ~40% have high risk condition or ≥65 years of age[2] May be in low redundancy jobs where absenteeism may compromise/stop care	Overrepresentation of some racial or ethnic minority groups and lower income earners • Seroprevalence of SARS-CoV-2 higher among Hispanic and non-Hispanic Black HCP[3] • Larger proportion of staff at LTCF female and non-Hispanic Black persons; disproportionately lower-wage workers[4]	HCP recommended for early phase vaccination have an equal opportunity to access vaccine Definition of HCP includes “paid and unpaid persons serving in healthcare settings”	Can help reduce disparities in health outcomes Acknowledges increased risk of COVID-19 exposure due to essential nature of work
Transparency Engagement with partners and key stakeholders; Discussion at public meetings				

[1]Slayton. Modeling allocation strategies for the initial COVID-19 Vaccine Supply. ACIP meeting Aug 26, 2020
[2]Gibson. J Gen Int Med 2020 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7314425/?report=reader
[3]Self et al MMWR: https://www.cdc.gov/mmwr/volumes/69/wr/mm6935e2.htm?s_cid=mm6935e2_w
[4]Oliver. Epidemiology of COVID-19 in essential workers, including healthcare personnel. ACIP meeting July 29, 2020

Application of ethical principles to early potential COVID-19 vaccine recipient groups

Evidence Based

Group	Maximize benefits	Equity	Justice	Fairness
Other essential workers (~60M)	Essential for response and/or functioning of society May decrease transmission to work and community contacts May decrease outbreaks in some work settings/sectors[1] • Food/agricultural processing plants • Correctional facilities	Overrepresentation of minority groups in subsets of essential workers[1] • Accounted for 87% of cases in meat and poultry processing plants[1] • 73% of cases in workplace outbreaks in Utah[2]	Essential workers recommended for early phase vaccination have an equal opportunity to access vaccine	Can help reduce disparities in health outcomes Acknowledges increased risk of COVID-19 exposure due to high density workplaces; frontline nature of work; and inability to work remotely
Transparency Engagement with partners and key stakeholders; Discussion at public meetings				

[1]Oliver. Epidemiology of COVID-19 in essential workers, including healthcare personnel. ACIP meeting July 29, 2020
[2]Bui et al. MMWR: https://www.cdc.gov/mmwr/volumes/69/wr/mm6933e3.htm?s_cid=mm6933e3_w

Application of ethical principles to potential early COVID-19 vaccine recipient groups

Evidence Based

Group	Maximize benefits	Equity	Justice	Fairness
Adults with high-risk medical conditions (>100M)	Reduce risk of COVID-19 morbidity and mortality • 60% of hospitalized adults and 80% of hospitalized adults who died had ≥3 high-risk conditions[1]	Racial and ethnic minority groups have increased prevalence of high-risk conditions • Non-Hispanic Black adults have highest prevalence of obesity (39.8%), followed by Hispanic adults (33.8%) and non-Hispanic White adults (29.9%)[2] Prevalence of underlying medical conditions higher in counties in the Southeastern United States and in rural counties[3]	Persons recommended for early phase vaccination have an equal opportunity to access vaccine	Can help reduce disparities in health outcomes
Transparency Engagement with partners and key stakeholders; Discussion at public meetings				

[1]McClung. Epidemiology of COVID-19 in essential workers, including healthcare personnel. ACIP meeting August 26, 2020
[2]Combined data from 2017-2019, BRFSS https://www.cdc.gov/obesity/data/obesity-and-covid-19.html
[3]Razzaghi et al. MMWR. https://www.cdc.gov/mmwr/volumes/69/wr/mm6929a1.htm?s_cid=mm6929a1_w

Application of ethical principles to potential early COVID-19 vaccine recipient groups

Evidence Based

Group	Maximize benefits	Equity	Justice	Fairness
Adults ≥65 years of age (~53M)	Reduce risk of COVID-19 morbidity and mortality • Adults ≥65 years of age represent 16% of cases, but nearly 80% of deaths[1]	Hispanic and non-White decedents under-represented among COVID-19 deaths in adults ≥65 years of age[2]	HHS Office for Civil Rights says age not recommended for use in ventilator/resource allocation[3]	"Healthy older person who can shelter in place is at different risk from a medically vulnerable older person in crowded housing"[4] "Age should never be used to exclude someone categorically from a standard of care, nor should age 'cut-offs' be used in allocations"[5]
Transparency Engagement with partners and key stakeholders; Discussion at public meetings				

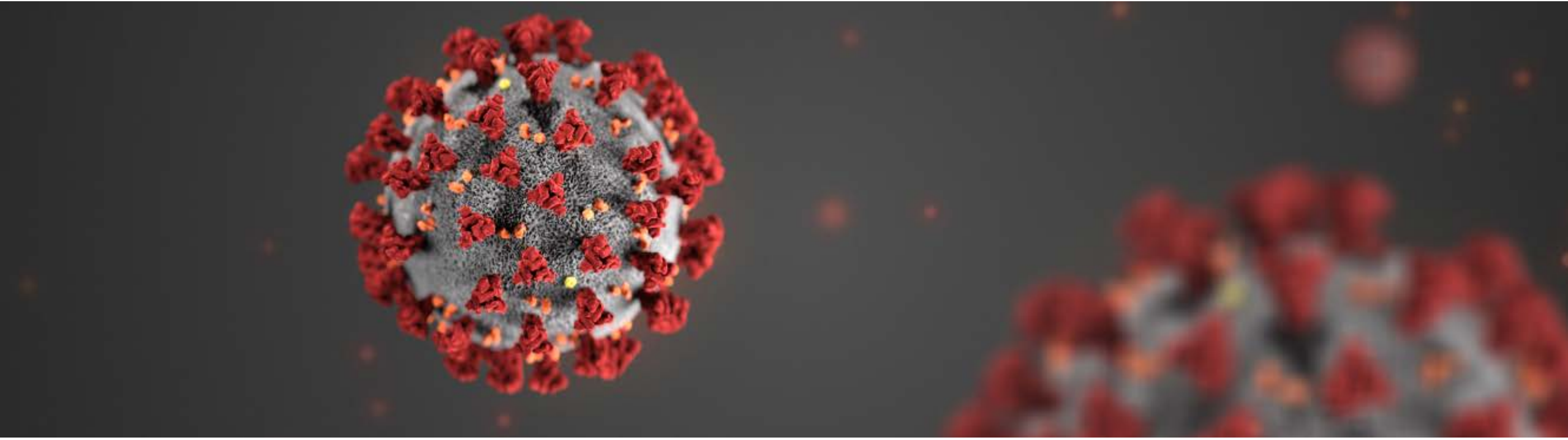
[1]McClung. Epidemiology of COVID-19 in essential workers, including healthcare personnel. ACIP meeting August 26, 2020
[2]Wortham et al. MMWR https://www.cdc.gov/mmwr/volumes/69/wr/mm6928e1.htm?s_cid=mm6928e1_w
[3] https://www.hhs.gov/sites/default/files/ocr-bulletin-3-28-20.pdf
[4]Persad G, Peek MS, Emanuel EJ. JAMA. See https://jamanetwork.com/journals/jama/fullarticle/2770684.
[5]American Geriatric Society Public Comment to National Academics of Science, Engineering and Medicine

Next steps

- Continue to progress development of an ACIP ethics/equity framework
  - Receive input from ACIP regarding the 5 proposed ethical principles
- Further discussions to apply ethical/ethics framework to “Phase 1” allocation discussions
- Consider how ethics and equity can be incorporated into the Evidence to Recommendations (EtR) Framework for COVID-19 vaccines

Acknowledgements

- Mary Chamberland
- Kathy Kinlaw
- Dayna Bowen Matthew



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 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.

National Academies: 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. ≥2 CDC designated medical conditions
  - Older adults living in congregate or overcrowded settings, e.g. nursing homes, residential care facilities

Comments

- Frontline HCWs in hospitals, nursing homes, home care who i) work where transmission is high or ii) at increased risk of transmitting to pts at high risk of severe morbidity and mortality
- Includes clinicians; environmental services; nursing assistants; staff in assisted living, long term care and group care; and home caregivers if meet 1a risk criteria
- CDC/ACIP best positioned to assess and refine applicable medical conditions and age

National Academies: Vaccine allocation phases

Comments

- **Phase 2**
  - Critical risk workers in industries essential to functioning of society and at substantially high risk of exposure
    - Excludes workers who can telework or are not at high risk of exposure; includes HCWs not in Phase 1a
  - Teachers and school staff
    - Includes childcare workers, administrative, environmental services, school bus drivers
  - 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
    - Defers to CDC to determine specific age guidance as health and vaccine safety data become available
  - 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: Vaccine allocation phases

- **Phase 3**
  - Young adults (18-30 yrs.)
  - Children (0-19 yrs.)
  - Workers in industries essential to the functioning of society and at increased risk of exposure not included in Phases 1 or 2

Comments

- Examples include workers in restaurants; bars; hotels; libraries; hair and nail salons; exercise facilities; factories or other goods producing facilities

- **Phase 4**
  - Everyone not previously vaccinated

Johns Hopkins: COVID-19 vaccine priority groups

Tier 1

- Essential in sustaining the ongoing COVID-19 response
- Greatest risk of severe illness and death, and their caregivers
- Most essential to maintaining core societal functions

Tier 2

- Essential to broader health provision
- Least access to health care
- Needed to maintain other essential services
- Elevated risk of infection due to living or working conditions

Johns Hopkins Framework:

Structural organization*

3 **Ethical Values**

Values linked to 7 **Ethical Principles** (2-3 per Value)

Principles linked to 11 **Policy Goals** (1-3 per Principle)

Goals linked to 12 **Objectives** for vaccine allocation

Objectives linked to **Priority Groups** & examples

*All elements are unranked