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FRAMEWORK FOR
EQUITABLE
ALLOCATION OF
COVID-19
VACCINE

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Study Sponsors

- Centers for Disease Control and Prevention (CDC)
- National Institutes of Health (NIH)

Committee Membership

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- **Helene Gayle (Co-Chair)**, The Chicago Community Trust
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- **Alison Buttenheim**, University of Pennsylvania School of Nursing
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- **Abigail Echo-Hawk (Citizen of the Pawnee Nation)**, Urban Indian Health Institute, Seattle Indian Health Board
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- **Arthur Reingold**, Berkeley School of Public Health
- **Reed Tuckson**, Tuckson Health Connections, LLC
- **Michael R. Wasserman**, California Association of Long Term Care Medicine

Statement of Task

Charge to the Committee

- Develop an overarching framework for vaccine allocation to assist policy makers in the domestic and global health communities in planning for equitable allocation of COVID-19 vaccine.
- Will inform the decisions by national health authorities and decision-making bodies, including the Advisory Committee on Immunization Practices (ACIP), as they create and implement national and/or local guidelines for COVID-19 vaccine allocation.

Charge to the Committee, Cont.

The committee was asked to specifically consider the following questions:

- What criteria should be used in setting priorities for equitable allocation of vaccine?
- How should the criteria be applied in determining the first tier of vaccine recipients? As more vaccine becomes available, what populations should be added successively to the priority list of recipients?
- How will the framework apply in various scenarios (e.g., different characteristics of vaccines and differing available doses)?
- If multiple vaccine candidates are available, how should we ensure equity?
- How can countries ensure equity in allocation of COVID-19 vaccines?
- For the United States, how can communities of color be assured access to vaccination?
- How can we communicate to the American public about vaccine allocation to minimize perceptions of lack of equity?
- What steps should be taken to mitigate vaccine hesitancy, especially among high-priority populations?

Study Approach

Study Methods

- Iterative review of current and relevant literature
- 8 virtual committee meetings held between mid-July and September 2020
- 3 public meetings, including one workshop and a public listening session (coinciding with draft comment period)
- Release of *Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine* and overlapping 4-day public comment period
- Final draft incorporated revisions from public comment and National Academies peer review process
- Appendix A of the report describes how public comments were considered

Report Organization

- **Chapter 1:** Introduction
- **Chapter 2:** Lessons Learned from Other Allocation Efforts
- **Chapter 3:** A Framework for Equitable Allocation of COVID-19 Vaccine
- **Chapter 4:** Applying the Framework for Equitable Allocation of COVID-19 Vaccine in Various Scenarios
- **Chapter 5:** Administering and Implementing an Effective and Equitable National COVID-19 Vaccination Program
- **Chapter 6:** Risk Communication and Community Engagement
- **Chapter 7:** Achieving Acceptance of COVID-19 Vaccine
- **Chapter 8:** Ensuring Equity in COVID-19 Vaccine Allocation Globally

**Discussion
Draft**

Background

Impact of COVID-19

- Current evidence shows that COVID-19 disproportionately affects racial and ethnic minority groups including Black, Hispanic or Latinx, American Indian and Alaska Native, and Native Hawaiian and Pacific Islander communities
- Much of the increased risk of COVID-19 in these communities and others is tied to social risk and structural inequality, e.g., disproportionate representation in high-risk jobs in essential industries
- Advanced age, specific comorbid conditions, and other factors also put individuals and communities at higher risk for severe COVID-19 morbidity and mortality

COVID-19 Vaccine Landscape

- Per WHO, 149 vaccine candidates are currently in preclinical development, and 38 are being tested in clinical trials
- U.S. Operation Warp Speed currently has a portfolio of 6 candidates, with 4 candidates in Phase 3 trials
- OWS candidates in Phase 3 are either mRNA or replication-defective vectored vaccines

Learning from Other Efforts

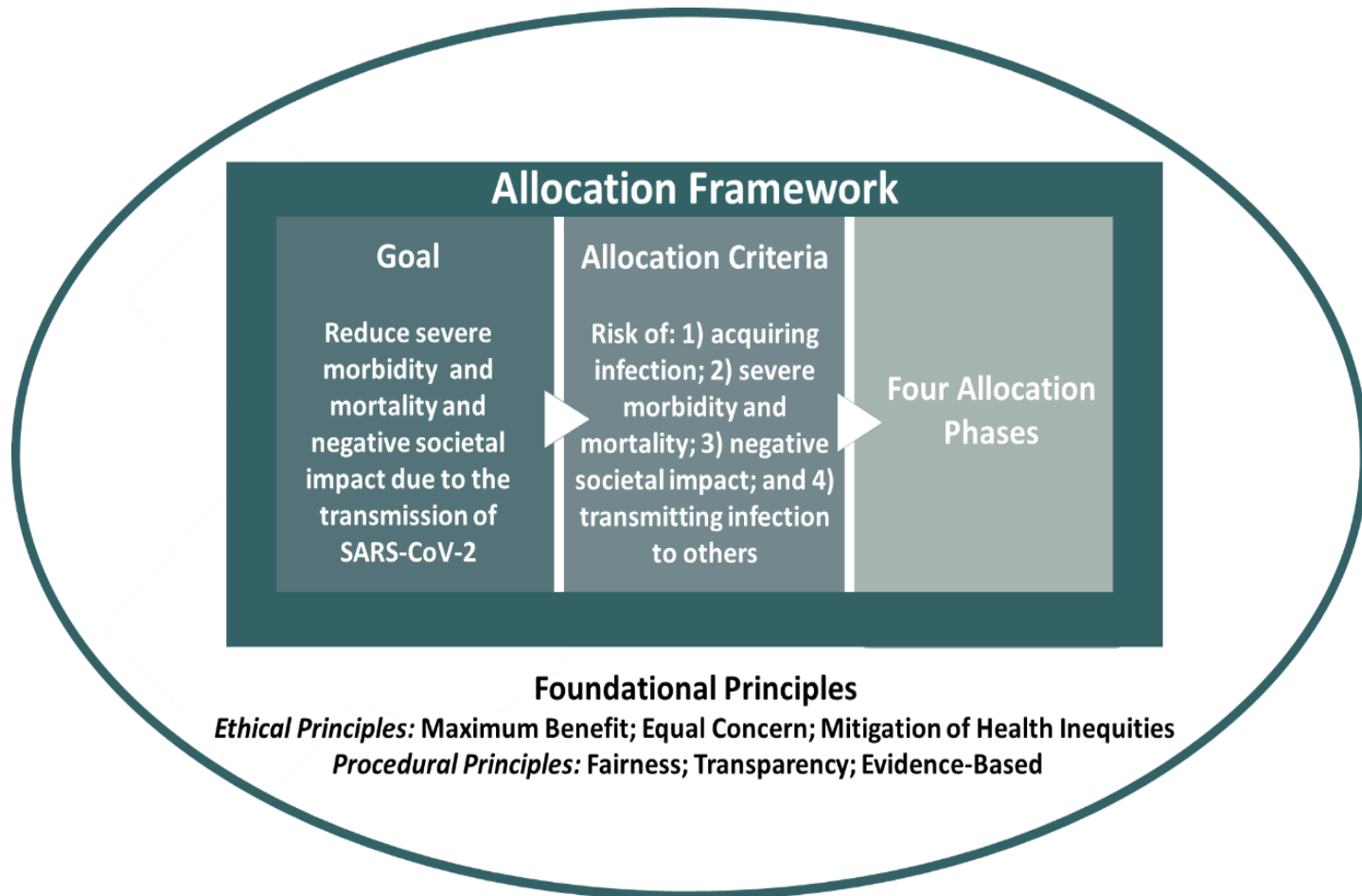
- The committee reviewed past mass vaccination campaigns, including for H1N1 and Ebola
- The committee reviewed current efforts around allocation for COVID-19, including for scarce medical resources and vaccine
- Other groups working on vaccine allocation include: Advisory Committee on Immunization Practices (ACIP), Johns Hopkins Center for Health Security, and the World Health Organization (WHO)

Unknowns Affecting Vaccine Allocation

- Number and timing of available vaccine doses
- Vaccine efficacy (overall and in different groups)
- Vaccine safety (overall and in different groups)
- Vaccine uptake (population acceptance, overall and in different groups)
- Number of available vaccine types
- Epidemic conditions when vaccine becomes available
- Vaccine distribution and administration
- Social, economic, and legal contexts

Framework on Equitable Allocation

Elements of the Framework



Ethical Principles

- **Maximum benefit** encompasses the obligation to protect and promote the public's health and its socioeconomic well-being in the short and long term.
- **Equal concern** requires that every person be considered and treated as having equal dignity, worth, and value.
- **Mitigation of health inequities** includes 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.

Procedural Principles

- **Fairness** requires engagement with the public, particularly those most affected by the pandemic, and impartial decision making about and even-handed application of allocation criteria and priority categories.
- **Transparency** includes the obligation to communicate with the public openly, clearly, accurately, and straightforwardly about the allocation framework as it is being developed, deployed, and modified.
- **Evidence-based** expresses the requirement to base the allocation framework, including its goal, criteria, and phases, on the best available and constantly updated scientific information and data.

Comparison with Other Frameworks

Committee's Foundational Principles	Johns Hopkins Interim Framework for COVID-19 Vaccine Allocation in the United States	WHO SAGE Values Framework for the Allocation and Prioritization of COVID-19 Vaccination	ACIP Proposed Ethics/Equity Framework
Maximum benefit	Promote public health and economic and social well-being	Human well-being	Maximize benefits and minimize harms
Equal concern		Equal respect	
Mitigation of health inequities	Address inequities Give priority to the worse off	Global and national equity	Equity Justice
Fairness	Respect diversity of views in a pluralistic society Engage community members	Legitimacy	Fairness
Transparency			Transparency
Evidence-based			
	Reciprocity	Reciprocity	

Goal of the Committee's Framework

Reduce severe morbidity and mortality and negative societal impact due to the transmission of SARS-CoV-2

Risk-Based Criteria

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

Phases

Phase 1

Phase 1a “Jumpstart Phase”

- High-risk health workers
- First responders

Phase 1b

- People of all ages with comorbid and underlying conditions that put them at *significantly* higher risk
- Older adults living in congregate or overcrowded settings

Phase 2

- K–12 teachers and school staff and child care workers
- Critical workers in high-risk settings—workers who are in industries essential to the functioning of society and at substantially higher risk of exposure
- People of all ages with comorbid and underlying conditions that put them at *moderately* higher risk
- People in homeless shelters or group homes for individuals with disabilities, including serious mental illness, developmental and intellectual disabilities, and physical disabilities or in recovery, and staff who work in such settings
- People in prisons, jails, detention centers, and similar facilities, and staff who work in such settings
- All older adults not included in Phase 1

Phase 3

- Young adults
- Children
- Workers in industries and occupations important to the functioning of society and at increased risk of exposure not included in Phase 1 or 2

Phase 4

- Everyone residing in the United States who did not have access to the vaccine in previous phases

Equity is a crosscutting consideration:

In each population group, vaccine access should be prioritized for geographic areas identified through CDC’s Social Vulnerability Index or another more specific index.

Ensuring Equity

- The committee's framework focuses on the underlying causes of racial/ethnic inequity
- Within phases, the committee recommends the application of a vulnerability index such as SVI or CCVI to consider the disproportionate impact of COVID-19 on particular communities
- SVI identifies geographic areas of vulnerability based on Census variables that help to capture social determinants of health

Phase 1a “Jumpstart Phase”

- Includes high-risk health workers and first responders
- Inclusion based on maintenance of health system and broader functioning, high risk of exposure to COVID-19, and transmission to at-risk individuals

Phase 1b

- Includes people with 2+ comorbidities that put them at significantly higher risk and older adults in congregate/overcrowded settings
- Inclusion based on high vulnerability to severe morbidity and mortality due to COVID-19

Phase 2

- Includes K-12 teachers, school staff, child care workers; critical workers in high-risk settings; people with comorbid conditions that put them at moderately higher risk; people in homeless shelters, group homes, staff; people in prisons, jails, detention centers, staff; all older adults
- Inclusion based on morbidity/mortality risk and transmission (dependent on group)

Phase 3

- Includes young adults (18-30); children; workers in industries important to functioning of society and at moderate risk of exposure
- Inclusion based primarily on transmission prevention and restoration of social and economic activity

Phase 4

- Includes everyone residing in the United States who did not have access to the vaccine in prior phases

Additional Considerations

- STLT authorities should remain flexible when applying the framework between and within phases
- Vaccine safety and efficacy still must be tested and proven in certain populations, including children and pregnant women
- Key limitations: Overlap between population groups and demographic data counts
- Emphasis of COVID-19 vaccine as part of a larger toolbox of COVID-19 response tools (e.g., social distancing, mask wearing, etc.)

Recommendation 1

Adopt the committee's framework for equitable allocation of COVID-19 vaccine.

HHS and STLT authorities should adopt the equitable allocation framework set out in the committee's report in the development of national and local guidelines for COVID-19 vaccine allocation. The guidelines should adhere to the foundational principles, goal, allocation criteria, and allocation phases described in the committee's report and seek to maximize benefit, mitigate health inequities, manifest equal regard for all, be fair and transparent, and build on the best current evidence. Important considerations include:

- This framework can also inform the decisions of other groups, such as the Advisory Committee on Immunization Practices and those in the global health community.
- STLT authorities will have to make final decisions on refining and applying the framework and should plan for situations when prioritization has to be adapted mid-process. In doing so, they should refer to the principles and allocation criteria that guided the formulation of the phases.

Coordination and Cost Considerations

Coordination and Cost

- Federal agencies, with CDC in a leading role, should provide guidance and resources to STLT authorities who will manage local allocation and distribution.
- To promote equity in vaccine allocation, STLT authorities will need to work with community-based partners to identify members of priority populations and ensure there are no out-of-pocket costs to the public.
- Effective, authentic, and meaningful engagement with community-based organizations is crucial in order to build effective vaccine delivery systems that are convenient for priority populations.

Recommendation 2

Leverage and expand the use of existing systems, structures, and partnerships across all levels of government and provide the necessary resources to ensure equitable allocation, distribution, and administration of COVID-19 vaccine.

HHS should commit to leveraging and expanding the use of existing systems, structures, and partnerships across all levels of government and provide the resources necessary to ensure equitable allocation, distribution, and administration of COVID-19 vaccine. Equitable allocation must be supported by equitable distribution and administration.

Recommendation 2, Cont.

Specific action steps to implement this recommendation are as follows:

- Provide resources (including resources for staff) to STLT authorities and their implementation partners and adequately fund indirect assets (e.g., needles, syringes, personal protective equipment for vaccinators, resources for ultra-cold chain management, and so forth) necessary for effective vaccine allocation, distribution, and administration.
- To ensure identification and delivery of COVID-19 vaccine to priority population groups, develop the capacity and systems to collect and integrate the necessary data (digital and other) from public health and private providers of care to facilitate the identification and monitoring of people with preexisting conditions and other high-risk characteristics.

Recommendation 2, Cont.

Specific action steps to implement this recommendation are as follows:

- Establish a robust and comprehensive surveillance system to monitor, detect, and respond to identified problems, gaps, inequities, and barriers. Monitoring should encompass equitable vaccine allocation and distribution, vaccine delivery, adverse events following immunization, promotion and communication, and uptake and coverage.
- Ensure that a rigorous COVID-19 vaccine safety monitoring program, built on existing systems, is in place, with an emphasis on rapid reporting and timely and transparent assessment of adverse events to determine whether events are associated with receipt of vaccine or occurring by chance.

Recommendation 3

Provide and administer COVID-19 vaccine with no out-of-pocket costs for those being vaccinated.

HHS should coordinate across agencies so that (1) COVID-19 vaccine is available at no cost to the public health and health care sectors and thus free to the individual; (2) providers are assured that they have the ability to submit for reimbursement of allowable and reasonable administration fees to a third party but with no costs shared by the individual being vaccinated; and (3) public health mass vaccination clinics are federally supported and funded to provide vaccinations at no cost to individuals being vaccinated, which is particularly important for reaching populations that do not have insurance.

Recommendation 3, Cont.

Specific action steps to implement this recommendation are as follows:

- Apply Patient Protection and Affordable Care Act regulations regarding no cost-sharing for preventive services for COVID-19 vaccinations for insured individuals, while addressing instances where these regulations fail to protect the beneficiary from out-of-pocket costs. Require health insurance providers and self-insured employers to waive co-pays and deductibles for vaccine administration based upon a reasonable nationally determined administrative rate set by the Centers for Medicare & Medicaid Services for all providers, irrespective of site of care or network participation status.
- To reach uninsured individuals, federal support and funding should be provided for mass vaccination clinics and for reimbursement for providers serving uninsured directly. In all cases, a billing code of some kind will be needed to monitor uptake, for pharmacovigilance, and to monitor disparities.
- Keep barriers to provider participation in administration of the vaccine as low as possible, especially for those providers who are in communities that are disproportionately impacted by COVID-19 by assuring vaccines are available at no cost and that administration of the vaccine is adequately reimbursed even if there is no cost sharing for the patient.

Communication and Community Engagement Considerations

Communication and Community Engagement

- Coordinated, evidence-based risk communication and community engagement are essential to COVID-19 vaccination strategies, and should feature continuous engagement across multiple channels, timeliness, and trustworthiness.
- These efforts should begin immediately in order to foster community trust in any vaccine allocation plan.
- STLT authorities must demonstrate respect for diverse audiences, forming partnerships with community organizations that can provide the two-way communication channels needed to hear public concerns and deliver messages from trusted sources in an accessible way.

Recommendation 4

Create and appropriately fund a COVID-19 vaccine risk communication and community engagement program.

HHS should create and appropriately fund a COVID-19 vaccination risk communication and community engagement program to support STLT authorities as an integral part of an effective and equitable national COVID-19 vaccination program.

Recommendation 4, Cont.

The program should:

- Ensure public understanding of the foundational principles, procedures, expected outcomes, and performance of vaccination efforts, including changes in response to research, experience, and public input.
- Be informed by the concerns and beliefs, as revealed by surveys, news media, public discourse, and social media channels, with special attention to information gaps and misinformation.
- Support STLTs in their engagement and partnership with community-based organizations, local stakeholders, and others to provide two-way communication with their constituencies and most effectively reach diverse populations.
- Be grounded on scientific foundations, incorporating the expertise of individuals with the cultural competency to hear and speak to diverse communities that have a stake in successful vaccination efforts.
- Rely on transparent, trustworthy assessments of vaccine safety and efficacy, as reviewed by the federal government and independent external scientists.

Vaccine Acceptance Considerations

Vaccine Acceptance

- Vaccine hesitancy is common in the U.S. and is on the rise, with prominent ant-vaccine messaging and concerns about the speed of COVID-19 vaccine development contributing to this skepticism.
- Particularly for minority communities, histories of medical research exploitation fuel understandable skepticism of vaccination.
- There is no “one size fits all” solution to vaccine hesitancy, and addressing it will require a combination of interventions, including the engagement of community leaders, mass media campaigns, health care professional training, and innovative behavioral and social sciences research.

Recommendation 5

Develop and launch a COVID-19 vaccine promotion campaign.

CDC should rapidly develop and launch a national, branded, multi-dimensional COVID-19 vaccine promotion campaign, using rigorous, evidence-informed risk and health communication, social marketing, and behavioral science techniques.

Recommendation 5, Cont.

The COVID-19 vaccine promotion campaign should:

- Be consistent in its messaging but also flexible and modular to allow state, tribal, local, and territorial authorities to tailor it to specific communities and audiences, similar to the truth campaign against tobacco use.
- Partner with diverse stakeholders (e.g., health care providers, Historically Black Colleges and Universities research centers, Hispanic Association of Colleges and Universities, Tribal Colleges and Universities research centers, social marketing firms and other groups with specific expertise reaching underserved communities) and prioritize promoting the vaccine to Black, Hispanic or Latinx, American Indian and Alaska Native, Hawaiian Native and Pacific Islander, and other communities in which vaccine hesitancy and skepticism have been documented.
- Engage thought and opinion leaders, such as celebrities, to help promote COVID-19 vaccination acceptance and uptake.

Recommendation 5, Cont.

The COVID-19 vaccine promotion campaign should:

- Incorporate messaging (in a variety of languages) and graphical elements that increase motivation, counter misinformation, and overcome perceived or actual practical barriers to vaccination.
- Include print, radio, television, and social media formats; incorporate toolkits, educational materials, and guidebooks to support community discussion about the COVID-19 vaccine; and make materials available in multiple languages.
- Be incorporated into broader messaging that provides consistent information on COVID-19 public health strategies that include nonpharmaceutical interventions, such as mask usage, physical distancing, hand washing, and so forth; expanded and accessible diagnostic testing linked to contact tracing, isolation, and quarantine strategies aimed at containing transmission, suppressing outbreaks, and interrupting super-spreading events; and the deployment of therapeutic measures that mitigate morbidity and mortality.

Recommendation 6

Build an evidence base for effective strategies for COVID-19 vaccine promotion and acceptance.

CDC and NIH should invest in rapidly building an evidence base for effective strategies for COVID-19 vaccine promotion and acceptance, acknowledging the unique circumstances around COVID-19 vaccination and the knowledge gaps related to understanding community needs and perceptions and effective promotion and delivery strategies.

Recommendation 6, Cont.

Specific action steps to implement this recommendation include:

- Support innovation in vaccine promotion at the state, tribal, local, and territorial levels and among community-based organizations through existing and expanded program grant mechanisms, with an emphasis on supporting existing entities, programs, and infrastructure with community knowledge and expertise; and on expanding CDC's existing Vaccinate with Confidence programs.
- Support a new rapid response research grant mechanism to advance the science of COVID-19 vaccine acceptance through grants that:
 - Foster partnership among research entities, public health agencies, and community-based organizations;
 - Evaluate existing or novel theory-driven strategies and interventions to decrease COVID-19 vaccine hesitancy, increase COVID-19 vaccine uptake, and eliminate social, cultural, logistic, and legal barriers to COVID-19 vaccination in focal populations; and
 - Support research grounded in diverse theoretical and methodological approaches, with an emphasis on novel approaches and data sources.

Global Considerations

Global Equitable Allocation

- A failure to achieve equity in global distribution of vaccines would ultimately fail to eliminate the risk of new outbreaks in the future.
- Parallel to efforts by the U.S. government, international entities—including the COVAX Facility convened by CEPI and GAVI—are working to ensure COVID-19 vaccine is accessible and allocated equitably worldwide.
- United States participation in these efforts would not only provide insurance in the case that currently federally-funded vaccine projects are not successful, but would also help prevent future global outbreaks and protect national security and domestic preparedness.

Recommendation 7

Support equitable allocation of COVID-19 vaccine globally.

The U.S. government should commit to a leadership role in the equitable allocation of COVID-19 vaccine globally, including:

- Opt in to the COVAX Facility at GAVI. The U.S. government can pledge its support while still pursuing its bilateral national efforts through Operation Warp Speed and executing its own robust vaccine manufacturing and distribution plans.
- Deploy a proportion (e.g., 10 percent) of the U.S. vaccine supply for global allocation, both as a means to help contain the COVID-19 pandemic and as an effort to build global solidarity in addressing this pandemic—and the next. This deployment should be implemented through the COVAX Facility led by GAVI, which is developing a fair and equitable allocation for global distribution in concert with the member states of the World Health Assembly.
- Engage with and support the World Health Organization and its member states to optimize the fair and equitable allocation of COVID-19 vaccines both between and within all nations, regardless of their income level.

Concluding Thoughts

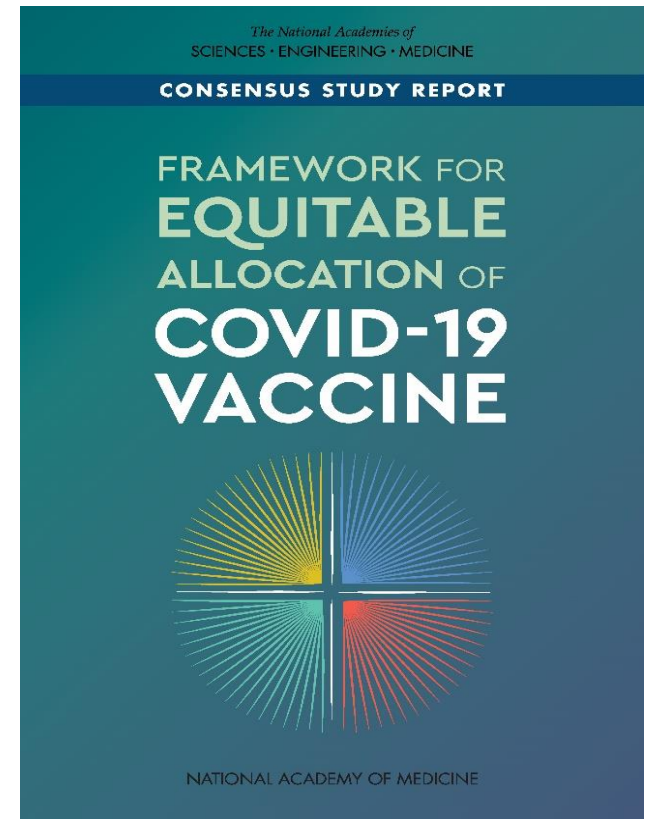
Summary of Recommendations

- Adopt the committee's framework for equitable allocation of COVID-19 vaccine.
- Leverage and expand the use of existing systems, structures, and partnerships across all levels of government and provide the necessary resources to ensure equitable allocation, distribution, and administration of COVID-19 vaccine.
- Provide and administer COVID-19 vaccine with no out-of-pocket costs for those being vaccinated.
- Create and appropriately fund a COVID-19 vaccine risk communication and community engagement program.
- Develop and launch a COVID-19 vaccine promotion campaign.
- Build an evidence base for effective strategies for COVID-19 vaccine promotion and acceptance.
- Support equitable allocation of COVID-19 vaccine globally.

Public Release

Free PDF of the report and related materials are available at:

<https://www.nationalacademies.org/our-work/a-framework-for-equitable-allocation-of-vaccine-for-the-novel-coronavirus>



Thank You!

Questions? Please email:
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