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

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BACKGROUND

As part of the overall study, the Committee on Equitable Allocation of Vaccine for the Novel Coronavirus is releasing a discussion draft of its framework for public comment. This discussion draft outlines a preliminary framework for equitable allocation of COVID-19 vaccine. Please note that this is a discussion draft of only the framework. Other aspects of the Statement of Task, including risk communication, steps to mitigate vaccine hesitancy, and global considerations will be addressed in the final report.

STATEMENT OF TASK

An ad hoc committee of the National Academies of Sciences, Engineering, and Medicine will develop an overarching framework for vaccine allocation to assist policy makers in the domestic and global health communities in planning for equitable allocation of vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The expectation is that such a framework would inform the decisions by health authorities, including the Advisory Committee on Immunization Practices (ACIP), as they create and implement national and/or local guidelines for SARS-CoV-2 vaccine allocation. As part of this effort, the committee will consider the following:

- 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 do we take into account factors such as:
  - Health disparities and other health access issues
  - Individuals at higher risk (e.g., elderly, underlying health conditions)
  - Occupations at higher risk (e.g., health care workers, essential industries, meat packing plants, military)
  - Populations at higher risk (e.g., racial and ethnic groups, incarcerated individuals, residents of nursing homes, individuals who are homeless)
  - Geographic distribution of active virus spread
  - Countries/populations involved in clinical trials
- 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?

COMMITTEE SPONSORS

Centers for Disease Control and Prevention and National Institutes of Health

A Note from the Committee Co-Chairs

The Committee on Equitable Allocation of Vaccine for the Novel Coronavirus has produced a *Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine* for comment. The committee believes it is critical to hear from the public on the draft framework and welcomes the public's input.

It is important to note that this is a preliminary draft and only one part of the full and final report. This draft addresses the committee's initial thoughts on how to allocate COVID-19 vaccine in the United States. This discussion draft includes:

- An exploration of lessons learned from past allocation frameworks;
- A discussion of the foundational principles that inform the committee's framework;
- A presentation of and rationale for the overarching goal of the framework;
- A discussion of the criteria for determining an equitable allocation framework;
- An outline of the vaccine allocation phases and the rationale for prioritizing each group included in each phase as informed by the goal and criteria; and
- An examination of the vaccine allocation framework's application under various scenarios.

Critically, per the committee's Statement of Task, the final report will include a final vaccine allocation framework informed by public comments and will also include additional content that grounds it in the realities of the COVID-19 pandemic.

Introductory sections will describe the health, social, and economic impacts of COVID-19 in the United States, including data-driven observations of health inequity and the disproportionate effects of COVID-19 on particular communities. The committee is monitoring evolving data and evidence to ensure an accurate understanding and description of the impact of COVID-19 across the United States.

Concluding sections will focus primarily on implementation of the framework. Topics to be covered include the committee's considerations and recommendations on issues related to vaccination program administration, evaluation, and assessment (to ensure effectiveness and equity); vaccine hesitancy, demand, and promotion; and risk communication and strategies for community engagement. Last, the committee will briefly address global considerations and the United States' role in vaccine allocation in the global arena. While some of these topics may be mentioned at a cursory level in the *Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine*, the committee acknowledges the importance of these orbiting topics and will expand on them in the final report.

Members of the public are invited to provide feedback on the preliminary framework during a 4-day public comment period that begins at 12:00 p.m. ET on Tuesday, September 1, 2020, and concludes at 11:59 p.m. ET on Friday, September 4, 2020. In addition to the written

public comment period, the committee will host an online public listening session from 12:00 p.m. to 5:00 p.m. ET on Wednesday, September 2, 2020, to solicit feedback from interested members of the public.

Thank you for taking the time to read the committee's *Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine*. We look forward to receiving and reviewing public feedback to inform the committee's work.

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Lessons Learned from Other Allocation Efforts

In response to the COVID-19 pandemic and the societal disruption it has brought, national governments and the international community have invested vast sums in the development of a safe and effective vaccine. Although subject to myriad uncertainties, mass vaccination against this novel coronavirus offers the possibility to significantly reduce transmission and severe morbidity and mortality beyond what might be accomplished through non-pharmaceutical interventions, better diagnostic tests, and improved therapies. The goal of protecting the public's health is intertwined with the goal of protecting society's socioeconomic well-being, which in turn has an impact on the public's overall health. Even if one or more safe and effective COVID-19 vaccines under development are tested and quickly approved for use, they are unlikely to be available immediately in amounts sufficient to vaccinate the whole population, despite plans to begin large-scale production of promising vaccines even before trials are completed. As a result, at the outset and in the months to follow, vaccines will almost certainly be available only in limited supplies. In this context, a scarce vaccine or vaccines will need to be allocated in ways that reduce virus transmission and/or reduce morbidity and mortality in order to protect the public's health and its socioeconomic well-being.

This is not the first time the nation, nor the world, has been faced with the issue of allocating scarce resources in the midst of a public health emergency. In developing a framework for equitable COVID-19 vaccine allocation, the committee's deliberations were informed by practical lessons from previous efforts to allocate vaccines for pandemic influenza and Ebola virus disease, as well as by the goals, ethical principles, and prioritization strategies set forth in other allocation frameworks—including several that have recently been developed to distribute scarce inpatient medications for COVID-19. The committee also reflected on the guiding

principles and prioritization criteria established by concurrent efforts being led by the World Health Organization (WHO), the Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP), and others to develop frameworks for allocating COVID-19 vaccines.

LESSONS FROM MASS VACCINATION CAMPAIGNS FOR PRIOR INFECTIOUS DISEASE OUTBREAKS

A mass vaccination campaign for an infectious disease outbreak is a complex enterprise that requires balancing different strategies for allocation, distribution, administration, access, and other considerations. Each infectious disease outbreak differs in terms of its clinical characteristics and impact across various populations, thus each outbreak requires a tailored mass vaccination approach. Although the committee was tasked with developing a framework specifically for allocation, looking back at some of the broader successes and challenges of previous mass vaccination campaigns is instructive from both operational and ethical perspectives. For instance, prior campaigns can illustrate how distribution systems can make different allocation schemes more or less feasible and how the choice of distribution system can support or impede choices regarding allocation. The committee identified several key lessons learned from prior mass vaccination campaigns that relate to or impact on vaccine allocation, which are outlined in Box 1 later in this section.

H1N1 Influenza Vaccination Campaign (2009)

The development of the U.S. plan for vaccine allocation and distribution in response to the 2009 H1N1 influenza A pandemic illustrated some of the fundamental challenges involved in implementing a mass national vaccination campaign at the local level, where many jurisdictions have limited resources and capacity (Rambhia et al., 2010). CDC's ACIP began planning an ambitious vaccination program shortly after the first cases were detected in the United States in June 2009 and vaccine development was under way (IOM, 2010). Based on epidemiological data from the first wave in the United States, ACIP recommended that vaccination efforts should target five groups: (1) pregnant women, (2) people who lived with or cared for infants <6 months old, (3) health care and emergency medical service personnel, (4) people aged >6 months to 24

years, and (5) adults aged 25–64 years with chronic health disorders or compromised immune systems. At that time, the number of vaccine doses that would be required was unknown. To facilitate centralized distribution of the forthcoming H1N1 vaccine, the national vaccine distribution plan leveraged the existing federal Vaccines for Children program, through which state and local health departments supplied providers with recommended pediatric vaccines. Vaccines funded by the federal government were allocated to states based on their population size, regardless of disease burden or number of people who fell into ACIP's priority categories. In September 2009, the U.S. Food and Drug Administration (FDA) approved four monovalent H1N1 influenza vaccines, including one intranasal and three injectable forms.[1] CDC created a centralized distribution system for shipping vaccines to states for the national vaccine campaign that began the next month (IOM, 2010). State and local health departments were left to develop and implement their own distribution plans, with some states choosing to closely follow ACIP's recommendations for priority groups and others choosing to adapt them (Rambhia et al., 2010).

The H1N1 vaccine program benefited from prior planning and funding to support vaccine production, as well as the use of a central distribution mechanism. It also provided state and local jurisdictions with flexibility and autonomy in developing their own distribution plans. However, major challenges began to emerge in the early months of the rollout. The vaccine supply schedule that was projected by manufacturers and accepted by the U.S. government was much faster than could actually be achieved, which severely limited the supply when demand was high. The initial supply was insufficient even to cover ACIP's target populations, which undermined the government's credibility when the promised number of vaccine doses could not be delivered (GAO, 2011). By the time supply was more ample, it was clear that the virus rarely caused severe illness and demand crashed; thus, there was far too little vaccine until there was far too much. Furthermore, the ability of state and local authorities to choose their own distribution methods (e.g., health care providers, local health departments, pharmacies) led to confusion and communication challenges. Health authorities struggled with dilemmas, such as deciding whether to turn away patients who were not part of initial priority groups, determining when to allow broader immunization to occur, and coordinating across jurisdictions about their decisions. Furthermore, the 100-dose minimum vaccine order required for shipment was a barrier for

[1] A fifth injectable monovalent vaccine was later approved by FDA in November 2009. More information about the H1N1 influenza vaccines is available at https://www.fda.gov/vaccines-blood-biologics/vaccines/influenza-h1n1-2009-monovalent (accessed August 18, 2020).

localities that did not need that many doses (GAO, 2011). Conflicts also emerged regarding certain priority groups—including children—that were established without a clear system to track high-priority individuals. Consequently, vaccinators had to develop ad hoc relationships with local providers and other stakeholders to ensure that they reached individuals designated as having priority (Rambhia et al., 2010). The distribution of vaccines was not fully tracked from manufacturers to individuals, undercutting the ability to efficiently administer the vaccine to those most in need and to monitor supplies (IOM, 2010). Ancillary supplies, such as syringes, were distributed separately, but in some cases they were inappropriate for their intended use and some were of varying quality. Although the shortage of vaccine was hugely problematic at the outset, the demand had decreased by January 2010 and many vaccine doses were left unused. Of note is that the demand for influenza vaccine generally drops around that time of year, even as seasonal influenza peaks.

The Texas Department of State Health Services (DSHS) conducted an after-action assessment of its response to the H1N1 pandemic, which identified successes and challenges with respect to vaccine distribution (Litaker et al., 2010). A major success was the use of a public-private partnership, led by the DSHS, to allocate and distribute the vaccine to local jurisdictions, supported by the rapid implementation of a vaccine management system. Availability of the vaccine was identified as a major challenge. Due to the timing of when the vaccine became available, the H1N1 strain could not be included in the seasonal influenza vaccine, so two separate vaccines had to be produced.

CDC's Roadmap to Implementing Pandemic Influenza Vaccination of Critical Workforce

As part of the U.S. Department of Health and Human Services' (HHS's) 2017 Pandemic Influenza Plan, CDC built on lessons learned in vaccine allocation during the 2009 H1N1 pandemic to develop a Roadmap to Implementing Pandemic Influenza Vaccination of Critical Workforce. This framework provides guidance for state and local level efforts to target and allocate pandemic influenza vaccine in scenarios in which vaccine demand exceeds supply (CDC, 2019). For an influenza pandemic of high or very high severity, the roadmap identifies five tiers of population groups, stratified by priority for vaccination:

- Tier 1: the highest priority target groups who serve important societal needs (e.g., health care providers, emergency services personnel, pandemic vaccine and antiviral drug manufacturers) and vulnerable populations,[2] such as pregnant women and infants;
- Tier 2: groups critical to national security (e.g., National Guard, intelligence services), critical community support personnel (e.g., pharmacists), other critical infrastructure (e.g., just-in-time utility services), high-risk children aged 3–18 years old, and household contacts of infants <6 months old;
- Tier 3: other critical infrastructure groups (e.g., those that maintain transportation, financial infrastructure), other health care, critical government personnel, and children aged 3–18 years without a high-risk condition;
- Tier 4: adults aged 19–64 years with high-risk conditions and adults aged >65 years; and
- Tier 5: healthy adults aged 19–64 years not included in other groups.

Vaccination Campaign During Ebola Epidemic in West Africa (2013–2016)

WHO developed an operational plan for the allocation and distribution of Ebola vaccines in response to the Ebola epidemic in West Africa (2013–2016) (Costa, n.d.). The goal was to make the best possible use of limited vaccine supplies in accordance with guiding principles of equity and transparency. The vaccine would be deployed using clear, pre-established criteria for allocation based on appropriate scientific and ethical foundations, with information shared equitably and decision making by consensus. The plan proposed that vaccines be deployed first to a qualified subset of health care workers, given that this population comprised the highest number of cases and had the greatest risk of infection; they could also be feasibly vaccinated and would likely be most amenable to data collection efforts (Gostin, 2014). After all health care workers in designated countries were vaccinated, a public vaccination strategy would be implemented in the most affected districts in Sierra Leone, Guinea, and Liberia (Costa, n.d.). Phase 2 and 3 trial results were available to inform the strategy, including data on vaccine efficacy, impacts of vaccination, feasibility of vaccination, and vaccination policies for various

[2] These populations also have substantially greater morbidity and mortality associated with influenza than other population groups.

age groups, sexes, and pregnant women. Proposed vaccination strategies included both mass vaccination in each affected nation and a ring vaccination approach.[3] Important data and legal considerations included ownership, WHO donations, countries' requests for vaccines, legal liability, informed consent, authorization by national regulatory authorities for vaccine use, and data collection and sharing.

In the early months of the Ebola outbreak in West Africa, lack of effective community engagement was among the barriers that delayed a rapid and effective response; it also contributed to fear and stigma around the disease and potential vaccine among community members. The design and delivery of the Ebola vaccine trials in Sierra Leone during and after the outbreak sought to address this through engagement strategies that included local community liaison teams. A qualitative study looked at these strategies for engaging communities and building trust to encourage vaccine trial participation (Dada et al., 2019). The study found that four principles were critical for building trust with community members: (1) ensuring reciprocal communication; (2) communicating using relatable examples; (3) fostering interpersonal relationships; and (4) respecting community members and their culture.

The Ebola vaccine campaign also illustrates the stark consequences of allocation decisions to exclude certain groups from potentially life-saving vaccination. Although the proposed criteria for deployment according to vaccine availability considered including pregnant women (Costa, n.d.), WHO ultimately recommended against vaccinating pregnant and breastfeeding women against Ebola, even if they were registered as contacts of known cases (Soucheray, 2019).[4] This decision was contentious from both ethical and public health perspectives (Faden et al., 2018). Limited evidence of the safety of the live vaccine in pregnant and lactating women was a rationale, but this group was largely excluded from the clinical trials to establish the vaccine's safety profile and potential fetal risk (Gomes et al., 2017). Evidence soon emerged that pregnancy is associated with increased risks of infection, high risk of maternal death (>90 percent), and even greater risk of neonatal death related to Ebola virus disease (Bebell

[3] A ring vaccination strategy focuses on vaccinating the social networks of people with laboratory-confirmed disease, including household contacts, contacts of contacts (e.g., neighbors, friends, workplace contacts, extended family). A vaccination ring typically includes an average of 150 individuals. Source: https://www.who.int/emergencies/diseases/ebola/frequently-asked-questions/ebola-vaccine (accessed August 24, 2020).

[4] Children were also excluded from the vaccination deployment at the early stages, although they were included in the Ebola vaccine trials conducted in East Africa.

et al., 2017; Black et al., 2015). Women of childbearing age are also more likely to be caregivers for relatives who are sick (Faden et al., 2018). Despite this mounting evidence suggesting that the benefit of vaccination outweighed the risk for pregnant and lactating women, WHO did not reverse the decision until February 2019, during a subsequent outbreak in the Democratic Republic of the Congo (UN News, 2019).

BOX 1

Key Lessons Learned from Prior Mass Vaccination Efforts

- Leverage relationships with professional medical societies and other key downstream stakeholders from the outset.
- When cost, insurance and other policies create barriers, consider the issue of rationing at the state, local, and practice levels.
- Develop effective systems for tracking distribution.
- Ensure that ancillary supply distribution is timely and appropriate.
- "Under-promise and over-deliver" in planning and communication efforts.
- Ensure up-to-date information on vaccine production, inventory, and projections via stronger and more formal partnerships between federal entities and vaccine producers.
- Plan for a range of vaccine supply scenarios.
- Continue to use the Vaccines for Children program infrastructure as a basis for emergency vaccination distribution programs; consider something similar for adults.
- Deploy limited vaccine supplies equitably and transparently using pre-established, evidence-based criteria to prioritize allocation.
- Promote global regulatory harmonization and standardization in vaccine development to improve speed, flexibility, and efficiency.
- Consistent, respectful, accurate communication to earn, secure, and maintain trust.

Frameworks for Allocating Pandemic Influenza Vaccines

Many countries have developed national plans and frameworks to prepare for the allocation of limited vaccine supply during an outbreak of pandemic influenza, which are distinct from vaccination campaigns conducted outside of outbreak or pandemic scenarios in terms of

goals and operationalization. These national plans are tailored to countries' own systems and resources and each influenza outbreak will differ in terms of specific clinical characteristics and distribution of the burden of disease across populations (Williams and Dawson, 2020). However, a review of pandemic vaccine prioritization strategies in 31 countries[5] found some commonalities. For instance, more than 80 percent had at least one vaccine priority group (Straetemans et al., 2007). All of those countries prioritized health care workers and almost all prioritized essential service providers and people at high risk. The authors noted that most of the public plans did not feature clear criteria for prioritization, which are critical for garnering public acceptance of a prioritization framework.

A more recent review looked at ethical arguments used to justify the prioritization of vaccine during an influenza pandemic based on literature published between 2005–2015,[6] much of which was informed implicitly or explicitly by interest in the ethics of vaccine allocation spurred by the severe acute respiratory syndrome (SARS) (2003–2004) and H1N1 (2009) pandemics (Williams and Dawson, 2020). In this literature, the most commonly proposed group for priority was health care workers, followed by vaccine manufacturers, emergency service workers, and basic infrastructure workers (e.g., utility, transportation, food, law enforcement). Some literature prioritized certain age groups, people who are medically vulnerable or otherwise at "high risk," or socially vulnerable groups—noting that the concept of vulnerability is employed frequently, but it is rarely defined or explained sufficiently. The most commonly cited goal of vaccination was to prevent illness or save lives, which was framed variously as benefiting the most individuals, maximizing quality-adjusted life years or minimizing years of life lost, or saving particular groups, including people who are vulnerable and stigmatized, people who are most likely to recover, younger people, or people most likely to contribute to minimizing the pandemic's impact or to contribute to society more broadly. A much less common approach was to prioritize vaccination of those most likely to be significant transmitters of infection. The ethics arguments used in the literature were largely focused on outcomes, in terms of maximizing a good or minimizing a harm. Many appealed to justice—which is sometimes framed as fairness or equity—and reciprocity. For instance, arguments based on distributive justice often called for

[5] The 27 European Union (EU) member states and the four non-EU countries of the Global Health Security Action Group.
[6] One of the 40 articles was published in 2017.

giving priority to vulnerable groups, while appeals to reciprocity were used to justify priority given to health care workers.

LESSONS FROM GUIDANCE AND FRAMEWORKS FOR ALLOCATING SCARCE RESOURCES DURING THE COVID-19 PANDEMIC

In addition to lessons learned from prior mass vaccination campaigns, the committee's deliberations were informed by the goals, principles, and prioritization strategies set forth in guidance and frameworks recently developed for the allocation of scarce resources during the COVID-19 pandemic. Some of these frameworks are vaccine-specific, some are focused on in-patient treatments, and others address the allocation of scarce medical resources more broadly. This section provides an overview of these frameworks' guiding ethical principles and (when available) the criteria for prioritizing allocation of the vaccine to specific groups. Box 2 summarizes key guiding principles gleaned by the committee from these efforts.

Ethical Frameworks for Allocating Scarce Medical Resources

Fair Allocation of Scarce Medical Resources in the Time of COVID-19

In May 2020, a publication in the *New England Journal of Medicine* proposed a set of ethical values to underpin recommendations for allocating scarce medical resources during the COVID-19 pandemic (Emanuel et al., 2020).[7] Drawing on previous proposals about how to allocate resources during scenarios of absolute scarcity, such as pandemics, the authors identify four fundamental ethical values: (1) maximize benefit, (2) treat people equally, (3) promote and reward instrumental value (i.e., providing benefit to others), and (4) give priority to the worst off. Importantly, the authors maintain that none of these values should be used in isolation to determine the allocation of resources; instead, fair allocation requires a multi-value framework that can be tailored to specific settings and resources. Each of these values could be operationalized in different ways in the context of the COVID-19 pandemic. In a pandemic, the most important ethical value is maximizing benefits of scarce resources, which could aim to save

[7] This publication builds on the "complete lives system" for allocation of scarce medical interventions that was proposed by a subset of the authors in a 2009 publication. The system "prioritizes younger people who have not yet lived a complete life, and also incorporates prognosis, save the most lives, lottery, and instrumental value principles" (Persad et al., 2009).

the greatest number of lives or to save the most life-years (e.g., by prioritizing people with the best prognosis). The authors recommend that both of these factors should receive the highest priority. They suggest that treating people equally would be best operationalized by random selection among people with similar prognoses, because a first-come, first-served system is inappropriate for a pandemic. Instrumental value can be promoted retrospectively by giving priority to people who have saved other's lives—for example, research participants and health care workers—or prospectively by giving priority to people who are likely to save others in the future, such as health care workers. Giving priority to the worst off could either be operationalized by priority to the sickest patients or to younger patients who stand to lose the most life-years. The authors use these four values to generate six recommendations for fair allocation of resources during the COVID-19 pandemic:

- To maximize the benefit of limited resources, prioritization should balance two aims: saving the greatest number of lives and maximizing improvements in people's length of life after treatment.
- By virtue of their instrumental value in the pandemic response, health care workers and others who maintain critical infrastructure should be prioritized.
- For patients with similar prognoses, equality should be operationalized by random allocation.
- Criteria for prioritization should be tailored to the specific resource that is scarce and responsive to changing evidence.
- Research participants should be recognized by receiving some priority, but only as a tiebreaker among those with similar prognoses.
- The same criteria for allocation should apply to people with and without COVID-19.

Ethics of Creating a Resource Allocation Strategy During the COVID-19 Pandemic

In a July 2020 article for *Pediatrics*, a group of bioethicists reviewed the fundamental ethical principles that frequently underpin scarce resource allocation frameworks and interpreted those principles in the context of the COVID-19 pandemic (Laventhal et al., 2020). They found broad agreement that such frameworks should seek to provide "the greatest benefit to the greatest number of individuals while the fewest resources are used" (Laventhal et al., 2020). Systems for

allocation should be fair, transparent, consistently applied, and mindful of socially vulnerable populations without making allocation decisions based solely on sociodemographic factors. Furthermore, allocation frameworks should integrate criteria from across multiple moral dimensions. The authors categorize five principles of allocation drawn from different frameworks with specific relevance to COVID-19:

1. Allocation frameworks should optimize the likelihood of benefit by allocating resources to those most likely to survive.
2. For people with similar likelihood of benefit, resources should be allocated to those with the greatest urgent or acute need.
3. Consider the absolute number of people who can be helped by available resources and maximize opportunities to help more people.
4. People who perform vital functions (e.g., health care workers, first responders) are prioritized for resource allocation as a tiebreaker in decisions between people with similar likelihood of survival.
5. When all other factors are equal, randomization should be used to prioritize the allocation of resources rather than a first-come, first-served process that can compound inequities.

When creating new resource allocation guidance during the COVID-19 context, the authors suggest the following guiding principles: (1) short-term survival (i.e., survival to discharge) is a reasonable criterion for prioritization; (2) first-come, first-serve systems should not be used to determine who receives scarce resources, and (3) to make decisions between people of equal priority with respect to other factors, people who perform vital functions should be prioritized to receive resources.

WHO Policy Brief on Ethics and COVID-19: Resource Allocation and Priority Setting

A policy brief by WHO's Working Group on Ethics and COVID-19 was developed to provide guidance on scarce resource allocation and priority setting, with the caveat that the allocation of different types of resources will likely be ethically justified by different principles or values (WHO Working Group on Ethics and COVID-19, 2020). This brief is distinct from the

WHO's forthcoming guidance on the allocation of vaccine described in the next section. Broadly, the brief suggests that a fair process for allocating scarce resources should promote certain ethical values, including transparency of allocation decisions and prioritization criteria, inclusiveness of affected groups in the decision making process, consistent treatment of all persons in the same categories, and accountability of decision makers. In making decisions about prioritization, they highlight four key ethical considerations. The principle of equality can be used in allocating scarce resources to individuals or populations expected to derive the same benefit (e.g., to justify a lottery system). The principle of best outcomes (i.e., utility) can guide the allocation of scarce resources according to their potential to maximize good or minimize harm. Maximizing utility should be balanced with the principle of prioritizing the worst off; the latter can be used to justify the allocation to treat those in greatest medical need or protect those at greatest risk. Finally, the principle of prioritizing those "tasked with helping others" can apply to allocating resources to health care workers, for example. In the context of COVID-19 vaccine allocation specifically, the brief recommends prioritizing three categories of individuals or populations, with greater priority for those who are included in multiple categories: (1) people at greatest risk of becoming infected and seriously ill, (2) people who would prevent the greatest spread of the virus if vaccinated, and (3) people who have volunteered to participate in research to develop the vaccine. The first two categories are prioritized to maximize the benefit of the vaccine. The rationale for the third category is "reciprocal obligation to those who were voluntarily put at risk to aid in this effort," although this group should not be prioritized over those at greatest risk.

Nuffield Council on Bioethics Policy Brief on Fair and Equitable Access to COVID-19 Treatments and Vaccines

The Nuffield Council on Bioethics has developed a policy brief that identifies key factors that determine fair and equitable access to COVID-19 treatments and vaccines (Nuffield Council on Bioethics, 2020). These factors include how research is prioritized and funded; how the burdens and benefits of that research is distributed between low- and high-income countries; structural and health inequalities that pose barriers to access, and public engagement and trust in the development and deployment of treatments and vaccines. In making difficult decisions about the allocation of resources that affect access, the authors suggest hewing to an ethical compass of

three broadly shared values: (1) ensuring equal respect, dignity, and human rights, (2) helping to reduce suffering of those who are sick or otherwise in need, and (3) maintaining fairness through both non-discriminatory treatment of others and equitable distribution of benefits and burdens.

Ethical Frameworks for Allocating Scarce In-Patient Treatments for COVID-19

After FDA issued an Emergency Use Authorization for the use of the antiviral remdesivir for patients with severe COVID-19 in May 2020, decisions about how to allocate remdesivir have been largely delegated to state health departments. However, many hospitals are operating without clear guidance about how to ethically allocate limited supplies of the medication to eligible patients (White and Angus, 2020). This issue will likely be compounded as more treatments for COVID-19 become available, but demand exceeds supply. In some states, such as New Jersey, advisory committees have recommended that remdesivir should be allocated to eligible patients on a first-come, first-served basis. However, other states and research groups are developing various types of ethical frameworks and policies to guide the fair allocation of scarce medications to treat COVID-19. Many of these allocation plans provide for some type of independent decision maker. Controversy has already emerged around some of these plans—particularly regarding the allocation of ventilators—with regard to their disparate impact based on patients' race or disability status (Schmidt, 2020; Truog et al., 2020). Some plans have subsequently been revised to address these types of critiques.

Minnesota's Ethical Framework for Distributing Remdesivir

In June 2020, the state of Minnesota developed an ethical framework for distributing remdesivir to facilities statewide and for prioritizing specific patients within each facility who are at greatest risk of mortality and serious morbidity, as well as those who would benefit from access to the drug (Lim et al., 2020).[8] The framework's guiding ethical principles are to (1) responsibly allocate the scarce resource to reduce risk while providing benefit, (2) save the most lives possible while respecting rights and fairness, (3) promote the common good through transparency, accountability, and trustworthiness, and (4) use the best available evidence while addressing uncertainty. To ensure that the framework protects the rights and interests of all, the

[8] The Ethical Framework to Allocate Remdesivir in the COVID-19 Pandemic (updated August 2020) is available at https://www.health.state.mn.us/diseases/coronavirus/hcp/remdesivir.pdf (accessed August 17, 2020).

approach rejected allocation based on race, ethnicity, gender or gender identity, citizenship or immigration status, socioeconomic status, or ability to pay for treatment. Age, disability status, and comorbid conditions are disallowed as criteria unless relevant to clinical prognosis and likelihood of survival. To protect those at greatest risk while also maximizing remdesivir's benefit, it is allocated to patients based both on need and on likelihood of survival to hospital discharge. The framework focuses on short-term rather than longer-term prognosis to avoid disadvantaging people based on age, comorbid conditions, disabilities, or systemic health inequities. The framework highlights the importance of obtaining patient consent, because remdesivir was not FDA approved when the framework was developed and the drug has the potential to cause serious adverse events. It is important to note that this framework is a living document that will likely be updated as better data are available to guide the use of remdesivir.

Pennsylvania's Weighted Lottery System for Allocating Scarce Medications for COVID-19

The Commonwealth of Pennsylvania has endorsed a weighted lottery system for ethically allocating medications for COVID-19 to eligible patients in cases of shortage. This lottery system is part of a model hospital policy,[9] developed by a multidisciplinary team at the University of Pittsburgh, which is guided by the ethical duties to steward scarce resources in the interest of public health and to mitigate the impact of social inequities on COVID-19 outcomes in disadvantaged communities. This model policy recommends that hospitals create an allocation team to unburden treating clinicians of the responsibility and potential moral distress of making decisions about the allocation of scarce medications to their patients. The weighted lottery system is designed to fairly allocate the supply of a medication for treating COVID-19 if it is insufficient for the number of eligible patients, with certain groups receiving heightened priority: (1) individuals who reside in disadvantaged areas, as defined by an address with an Area Deprivation Index score of 8–10; and (2) individuals who are essential workers, as defined by the state's list of businesses required to continue physical operations during the pandemic. The latter group includes health care workers, but also lower-paid workers who tend to be socially and economically vulnerable (e.g., people employed in grocery stores, public transportation,

[9] The Model Hospital Policy for Fair Allocation of Medications to Treat COVID-19 is available at https://ccm.pitt.edu/sites/default/files/2020-05-28b%20Model%20hospital%20policy%20for%20allocating%20scarce%20COVID%20meds.pdf (accessed August 17, 2020).

agriculture, and custodial work). Individuals who are expected to die within a year from an end-stage condition are not excluded from the lottery but receive lower priority than individuals without such conditions. Others have argued that lottery systems to allocate scarce medications for COVID-19 should be centralized and run by state health departments—rather than by individual hospitals—in order to expedite distribution and allow for the collection of larger volumes of pooled clinical data about the effectiveness of remdesivir or other scarce medications (White and Angus, 2020).

Ethical Framework for Allocating Therapies to Hospitalized Patients with COVID-19

Another ethical framework for allocating scarce inpatient medications for COVID-19 was developed by a group at the University of California, San Francisco, in May 2020. This framework was developed as a practical guide for clinicians and health care facilities faced with decisions about how to ethically allocate therapies to hospitalized patients with COVID-19, including existing therapies such as remdesivir, as well as novel treatments under development (e.g., monoclonal antibodies) (DeJong et al., 2020). The aims of this framework are to maximize benefit to patients, mitigate disparities, adhere to ethical principles, and revise allocation policies as more evidence becomes available. The guiding ethical principles of this framework are that reducing mortality provides benefit to the community as a whole and benefit should be assessed using the best available evidence. The framework holds that during a shortage, medications should be prioritized for indications with demonstrated efficacy and safety, ideally from randomized controlled trials. Patient preferences should be respected to the extent that the drug supply allows, and scarce medications should be allocated in a way that is fair, avoids discrimination, and mitigates health disparities. Allocation policies should be made transparent, accountable, responsive to the concerns of the affected population, and proportionate to the epidemiological situation and the drug supply relative to need. Prioritization in this framework does not exclude people based on age, disability, religion, race or ethnicity, national origin, gender, sexual orientation, or perceived quality of life or comorbid conditions. Random allocation (e.g., lottery) is deemed the fairest way to allocate scarce supplies among *eligible* patients—although workers in essential jobs may be assigned some priority—because a "first-come, first-serve" system is not random and puts people who face barriers to care at a disadvantage. An additional advantage of random lottery system is the potential for knowledge

generation, because a randomized sample could potentially be used to causally evaluate the effect of being vaccinated on relevant outcomes. The authors also outline five goals that can be derived from the ethical framework for allocating scarce therapies for COVID-19: (1) to save the most lives in the short/near term, with additional goals of preventing new cases and reducing the durations of hospitalization and mechanical ventilation; (2) to decrease disparities in COVID-19 case-fatality proportions that disproportionately affect racial and ethnic minority communities; (3) to strengthen the community's pandemic response ability; (4) to preserve a supply of existing medications for non-COVID-19 indications that patients with chronic conditions may depend on; and (5) to reserve enough of the therapy to conduct RCTs and develop a stronger evidence base for effective therapies.

BOX 2

Guiding Principles from Allocation Frameworks Developed for the COVID-19 Pandemic

- Ensure that allocation maximizes benefit to patients, mitigates inequities and disparities, and adheres to ethical principles.
- Promote the common good through fairness, transparency, accountability, and trustworthiness.
- Save the greatest number of lives possible—while respecting rights and fairness—to maximize benefit to the community as a whole.
- Use the best available evidence to assess benefit to communities and address uncertainty.
- Allocate scarce resources responsibly to reduce risk while providing benefit.
- Provide clear and transparent criteria for prioritization strategies.
- Ensure that allocation policies are flexible, responsive to the concerns of the affected population, and proportionate to the epidemiological situation and the vaccine supply relative to need.

Allocation Frameworks Developed for Vaccine Allocation During the COVID-19 Pandemic

This section outlines ethical frameworks developed specifically for vaccine allocation during the COVID-19 pandemic, including an interim framework developed by a group at Johns

Hopkins University and forthcoming efforts from WHO and CDC. Table 1 summarizes the goals, ethical principles, and prioritization approaches of these vaccine-specific allocation frameworks. It is important to note that these frameworks were developed in the context of rapidly changing goals for vaccination (e.g., as schools began to reopen in August 2020) and evolving data about the SARS coronavirus 2 (SARS-CoV-2) virus and vaccine candidates.

Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States

In August 2020, Johns Hopkins University's Center for Health Security released an interim framework for COVID-19 vaccine allocation and distribution in the United States that is framed by three broad ethical values: (1) promoting the common good, (2) treating people fairly and equally, and (3) promoting legitimacy, trust, and sense of ownership in a pluralistic society. In this framework, the ethical value of promoting the common good includes the more specific ethical principles of promoting public health (e.g., preventing illness and death and protecting health systems) as well as promoting economic and social well-being, which includes protection of essential services, supporting economic activity, and enabling children to return to school and childcare. Ethical principles falling under the broader value of treating people fairly and equitably include addressing background and emerging inequities experienced by disadvantaged and marginalized groups, giving priority to the worst off people at greatest risk of severe illness and death, and ensuring reciprocity to protect those who provide essential services and advance the development of treatments and vaccines. The third ethical value calls for respecting the diversity of views in a pluralistic society and engaging with communities to strengthen vaccine campaigns. Based on this ethical foundation, the framework suggests that the following groups should be candidates for high priority access to scarce vaccine, including provisional examples of the groups in each tier.

Tier 1 priority groups include:

- Those most essential in sustaining the ongoing COVID-19 response (e.g., frontline health workers, emergency services personnel, and public health workers; pandemic vaccine manufacturing and supply chain personnel; COVID-19 diagnostic and immunization teams)

- Those at greatest risk of severe illness and death, and their caregivers (e.g., adults aged ≥65 years; others at elevated risk of serious COVID-19 and complications; frontline long-term care providers and health care workers providing direct care to patients with high-risk conditions)
- Those most essential to maintaining core societal functions (e.g., workers in frontline public transport, food supply, and schools)

Tier 2 priority groups include:

- Those involved in broader health provision (e.g., health workers and staff with direct but non-COVID-19-specific patient contact; pharmacy staff)
- Those who face greater barriers to access care if they become seriously ill (e.g., people living in remote locations with substandard infrastructure and health care access)
- Those contributing to maintenance of core societal functions (e.g., frontline infrastructure workers who cannot work remotely; warehouse and delivery workers; deployed military involved in operations; police and fire personnel with frequent public contact; Transportation Security Administration and border security personnel with direct public contact)
- 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 (e.g., people who are unable to maintain safe physical distance in their home or work environments, including people living in shelters, people who are incarcerated, and people who work in prisons)

Multi-Value Ethical Framework for Fair Global Allocation of a COVID-19 Vaccine

A group of authors from Vanderbilt University have developed a multi-value ethical framework for fair global allocation of a COVID-19 vaccine to different countries by analyzing

four types of allocation paradigms[10] and synthesizing their ethical principles into a model for the COVID-19 pandemic (Liu et al., 2020). To promote fair vaccine allocation across countries of different resource levels, the authors propose stratifying countries into groups for prioritization based on three guiding ethical principles: (1) ability to provide care, (2) ability to implement, and (3) reciprocity. The rationale for the first principle is that vaccines are the only effective intervention in low-income countries lacking in capacity to treat people with severe COVID-19, so those countries should receive priority. The rationale for the second principle is that vaccines should not be allocated if they cannot be used, so low-income countries' capacities for distribution and implementation should be supported. The third principle, reciprocity, prioritizes countries based on their level of contribution and participation in developing and testing vaccines.

WHO's Ongoing COVID-19 Vaccine Allocation Efforts

WHO has several related global planning efforts under way for vaccine allocation, including COVAX, guiding principles for immunization activities during the COVID-19 pandemic, and a global framework to ensure equitable and fair allocation of COVID-19 products, including vaccines (see Table 1). COVAX[11] is the vaccines pillar of the Access to COVID Tools Accelerator,[12] a global initiative bringing together governments, health organizations, scientists, businesses, civil society, and philanthropists to accelerate the development and deployment of the key countermeasures needed to respond to the COVID-19 pandemic, including COVID-19 tests, therapeutics, and vaccines. The COVAX pillar's primary goal is to accelerate the development and manufacture of vaccines and ensure equitable access worldwide. COVAX is co-led by the Global Alliance for Vaccines and Immunizations (GAVI), the Coalition for Epidemic Preparedness Innovations (CEPI), and WHO. As of August 19, 2020, GAVI, CEPI, and WHO were seeking representatives from civil society and community

[10] The allocation paradigms considered include a country's ability to develop or purchase vaccine, reciprocity in prioritizing countries that contribute samples or have participants in research trials, countries' ability to deploy vaccine to its population, and distributive justice for developing countries.
[11] More information about COVAX is available at https://www.who.int/initiatives/act-accelerator/covax (accessed August 25, 2020).
[12] More information about the Access to COVID Tools Accelerator is available at https://www.who.int/initiatives/act-accelerator#:~:text=The%20Access%20to%20COVID%2D19%20Tools%20(ACT)%20Accelerator%2C,tests%2C%20treatments%2C%20and%20vaccines (accessed August 25, 2020).

organizations (CSOs) to participate in COVAX and help to foster the necessary support at both political and community-engagement levels to ensure equitable access and delivery of future COVID-19 vaccines.[13] The plan is for these CSOs to advocate for civil society and community perspectives and help build public trust and capacity across health care systems for COVID-19 vaccination programs.

Within the COVAX pillar,[14] CEPI is leading the development and manufacturing of a portfolio of vaccine development partnerships. GAVI is leading the work on global procurement and financing through the COVAX Facility, which is designed to provide all countries with an opportunity to participate in securing initial access to vaccine supply sufficient to cover 20 percent of their populations (per WHO's allocation guidance). WHO leads the efforts pertaining to policy and vaccine allocation guidance, which informs the COVAX Facility's procurement schemes. As of August 2020, WHO was working with its member states and the Strategic Advisory Group of Experts—which is the apical vaccine advisory body within WHO—to finalize the allocation framework for distribution of vaccines from COVAX between countries. The Strategic Advisory Group of Experts (SAGE) on Immunization, was established to serve as WHO's principal advisory group on global policies and strategies for immunization and its link to other health interventions for all vaccine-preventable diseases. Their preliminary estimate is that distribution of enough vaccines for 20 percent of the population should be sufficient for each member state to immunize frontline health care workers, other essential workers, older adults, and those with significant comorbidities that increase the risk of serious COVID-19 illness in most countries. The current plan is to initially distribute enough vaccine for countries to cover 3 percent of their respective populations, followed by vaccine to cover the additional 17 percent of the populations later. Within-country allocation decisions remain under the authority of each individual Member State. However, WHO/SAGE is developing an interim guidance on guiding principles for immunization activities during the COVID-19 pandemic, which is a values

[13] See https://www.who.int/news-room/articles-detail/covax-seeks-civil-society-representatives-to-contribute-to-ensuring-equitable-global-access-to-covid-19-vaccines (accessed August 25, 2020).
[14] Background information on the COVAX pillar is available at https://www.gavi.org/sites/default/files/covid/COVAX-Pillar-background.pdf (accessed August 13, 2020).

framework for within-country prioritization and other country-level decision making related to the provision of COVID-19 immunization.[15]

WHO's global framework to ensure equitable and fair allocation of COVID-19 products aims to reduce mortality due to COVID-19, protect health systems, improve the well-being of populations, and reduce the impact of the pandemic on societies and economies.[16] The framework has prioritized three populations: (1) health care system workers, who represent about 1 percent of the global population (50 million people) and would require about 115 million doses;[17] (2) adults aged ≥65 years, who represent roughly 8 percent of the population (650 million people) and would requires about 1,500 million doses; and (3) other high-risk adults, who represent about 15 percent of the population (around 1.15 billion people) and would require about 2.65 billion doses. Additional prioritized groups would be based on risk assessment of the country's vulnerability and an estimated burden or threat of COVID-19. The guiding principles of the WHO allocation framework include transparency, ethical values, public health needs, collaboration with stakeholders, flexible and robust regulatory approaches, good governance and the "open scientific collaboration, transparency, and sharing of data and biological samples" that will be critical to the success of global vaccination efforts (Bollyky et al., 2020). Although WHO has shared the forthcoming framework's overarching principles for allocating COVID-19 products, its detailed ethical justification for the vaccine allocation guidance had not yet been shared as of August 2020.

CDC's Ongoing COVID-19 Vaccine Allocation Efforts CDC's ACIP is currently developing a plan for the allocation of COVID-19 vaccine in the United States. As a CDC federal advisory committee, ACIP provides recommendations on the use of vaccines in the United States civilian population and provides guidance on the optimal use of vaccines for the CDC and the Secretary of HHS. ACIP does not traditionally play a role in implementation (Lee

[15] WHO's interim guidance on guiding principles for immunization activities during the COVID-19 pandemic (updated March 26, 2020) is available at https://www.who.int/publications/i/item/guiding-principles-for-immunization-activities-during-the-covid-19-pandemic-interim-guidance (accessed August 13, 2020).

[16] The WHO Member States Briefing on a global framework to ensure equitable and fair allocation of COVID-19 products and potential implications for COVID-19 vaccines (June 18, 2020) is available at https://apps.who.int/gb/COVID-19/pdf_files/18_06/Global%20Allocation%20Framework.pdf?utm_source=POLITICO.EU&utm_campaign=18fd118248-EMAIL_CAMPAIGN_2020_06_22_04_52_COPY_01&utm_medium=email&utm_term=0_10959edeb5-18fd118248-189787901 (accessed August 13, 2020).

[17] The estimates of doses needed to vaccinate in this framework assume two doses per person and a 15 percent wastage rate.

et al., 2020). An ACIP COVID-19 Vaccine Workgroup was established in April 2020 to provide overarching guidance and vaccine-specific recommendations to CDC. The workgroup will evaluate available evidence and make recommendations, evaluate the likelihood that vaccines will reduce COVID-19 transmission, morbidity and mortality, and minimize disruption to society, and explore approaches to ensure equity in allocation. The ACIP workgroup has established three guiding principles to inform decision making: (1) safety, (2) diversity in clinical trials, which is necessary for diversity in vaccine allocation, and (3) efficient and equitable vaccine distribution. ACIP focuses on vaccine recommendations, rather than implementation; the latter will depend on partnerships with state and local public health entities. During their initial deliberations, proposed groups for prioritized allocation included health care workers, essential workers, adults aged ≥65 years, long-term care facility residents, and persons with high-risk medical conditions (Splete, 2020). More information about ACIP's efforts is provided in Table 1 below.

DRAFT TABLE 1 Overview of Ongoing COVID-19 Vaccine Allocation Efforts *(To be updated as more information becomes available.)*

Effort	Leaders	Goals	Guiding Principles	Prioritized Groups
COVAX	WHO CEPI GAVI	• Provide a process mechanism for between-country coordination and allocation. • Offer advance purchase agreements to vaccine candidates meeting technical threshold criteria.	• Mitigate economic damage. • Accelerate availability of vaccine. • Ensure globally fair allocation and access for Low- and Middle- Income Countries.	Groups likely to be prioritized in first round of vaccination: 1. Health care system workers 2. Adults aged ≥65 years 3. Other high-risk adults with underlying conditions (e.g., hypertension, diabetes)
Guiding principles for immunization activities during the COVID-19 pandemic	WHO SAGE	• Provide a values framework for within-country prioritization and decision making about immunization services.	• Ensure continuity of routine immunization services during the COVID-19 pandemic (where feasible) to prevent outbreaks of vaccine-preventable diseases.	
Global Allocation Framework for COVID-19 Products	WHO	• Ensure equitable and fair allocation of COVID-19 products. • Issue policy recommendations to inform optimal use of scarce resources as more product-specific information becomes available.	• Reduce COVID-19 mortality and protect health systems to improve population well-being and reduce societal and economic impact. • Ensure flexibility to adapt to each new product, evolving epidemiology, and risk. • Use transparent criteria for allocating doses as they become available.	1. Health care workers 2. Adults aged≥65 years 3. Other high-risk adults
ACIP COVID-19 Vaccine Workgroup	ACIP	• Develop plan for allocation of vaccine in the United States	• Monitor effectiveness and safety in real time to revise recommendations based on the risk/benefit balance in different populations. • Ensure diversity in vaccine clinical trials to ensure that recommendations are based on safety and efficacy data across all populations who may benefit.	

			• Distribute vaccines efficiently and equitably; avoid compounding inequities and disparities.	
Interim Framework for COVID-19 Vaccine Allocation in the United States: Assisting Policy Maker, Stakeholder and Public Deliberation	Johns Hopkins Center for Health Security	• Provide an interim framework for COVID-19 vaccine allocation and distribution in the United States	• Promote the common good • Treat people fairly and equally • Promote legitimacy, trust, and sense of ownership in a pluralistic society	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

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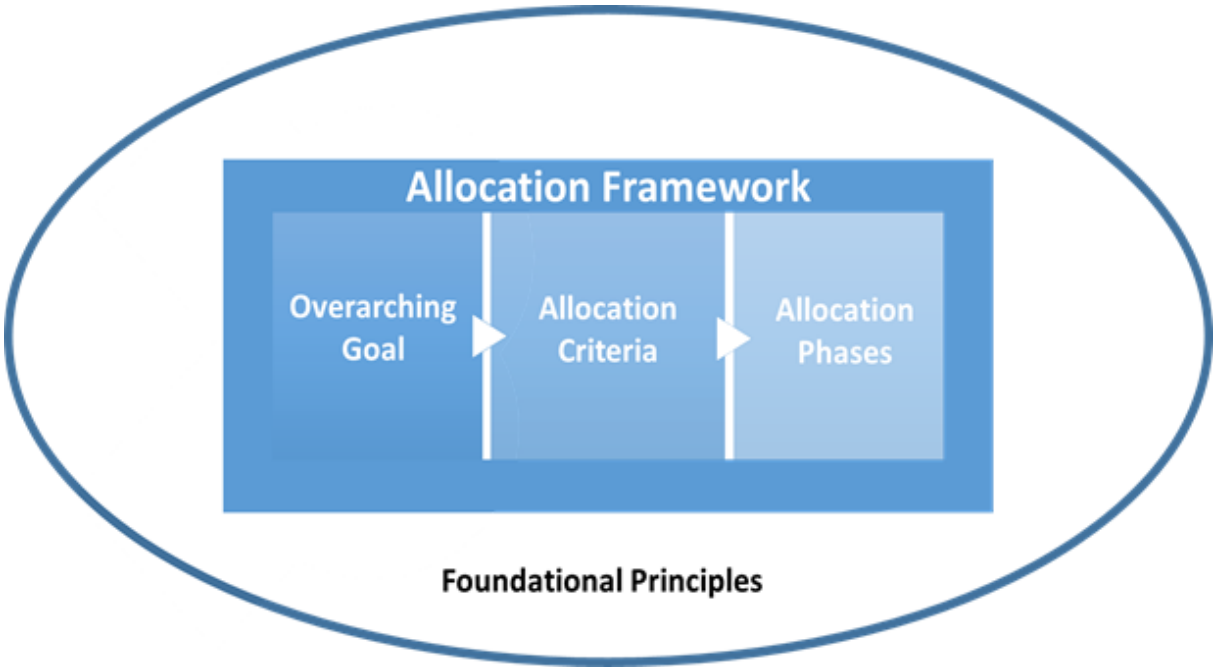
A Framework for Equitable Allocation of COVID-19 Vaccine

In this chapter—drawing from the lessons learned from other allocation frameworks outlined in the prior chapter—the committee lays out the foundational principles that inform its recommended COVID-19 vaccine allocation framework, and describes the primary goal of its framework, the risk-based allocation criteria used to apply the principles, and the resulting allocation phases (see Figure 1). The chapter concludes with an in-depth description and discussion of the phases, including the rationale behind the inclusion of groups listed in each phase.



DRAFT FIGURE 1 Major elements of the framework for equitable allocation of COVID-19 vaccine

Numerous uncertainties about COVID-19 vaccine still exist that must eventually be addressed, and allocation and prioritization will likely depend on certain key vaccine characteristics. These uncertainties include the safety and efficacy of the vaccines in certain populations (such as children, pregnant women, older adults, and individuals previously infected with COVID-19); the effective use of vaccines in tandem with existing preventive measures; public confidence in the vaccine; the ability to adapt plans based on pharmacovigilance; and others.

Such uncertainties require the framework to be adaptable to a variety of circumstances, including the state of the pandemic when a vaccine becomes available. Designing the framework to be adaptable to a range of possible circumstances means that the committee must consider how the framework would operate ethically and effectively in a range of plausible scenarios. Planning is crucial, but a rigid framework is unlikely to match the specific circumstances that actually emerge, and will likely change depending on the goal of the vaccination program, the state of the pandemic, the state of the science, and the extent to which people are engaging in social distancing and other preventive measures. The following chapter describes several such scenarios and their implications for the framework. Likewise, the framework must be implementable. To be able to guide policy makers in planning for vaccine allocation, it must be feasible to put the framework into operation. For example, for individuals or groups prioritized to receive the vaccine, it must be possible to identify them accurately and quickly.

One-third or more of the U.S. population may decline a free and U.S. Food and Drug Administration (FDA-approved) vaccine for the novel coronavirus (Mullen O'Keefe, 2020). Concerns about inclusion and diversity in COVID-19 vaccine trials (Jaklevic, 2020) and uncertainties like those previously noted compound the already significant doubts that some members of the public have about the vaccine. The committee's framework for vaccine allocation cannot address the general lack of confidence in vaccination. A mass vaccination program for public health will fail if there is widespread public mistrust. The committee believes that the equitable allocation framework that it recommends, if properly implemented and communicated, can secure public trust by being based on foundational principles that are simple, clear, coherent, and consistent in their application. The hope is that an equitable allocation

framework will gain public trust, by providing benefit to individuals and communities, thereby mitigating the damage caused by the pandemic and aggravated by existing health inequities.

FOUNDATIONAL PRINCIPLES OF THE FRAMEWORK

The committee was charged with developing an overarching framework for the equitable allocation of COVID-19 vaccine. This framework is intended to assist and guide policy makers in planning for vaccine allocation under conditions of scarcity that will necessitate vaccinating persons in phases over time. In presenting the sponsor's charge at the committee's first meeting on July 24, 2020, the director of the National Institutes of Health (NIH), Dr. Francis Collins, stressed that the overarching framework should include "foundational principles." Such principles, which are summarized and explicated below, informed the committee's deliberations about allocation criteria.

The committee recognizes that its proposed framework must not only be equitable but also be *perceived* as equitable by audiences who are socioeconomically, culturally and educationally diverse, and who have distinct historical experiences with the health system. As a result, the framework's public face must do justice to its scientific and ethical foundations. Therefore, the committee has designed the framework so that it:

- Can be easily and equally well understood by the diverse audiences whose concerns the vaccine allocation scheme must address;
- Reflects widely accepted social and ethical principles;
- Can be reliably translated into operational terms;
- Distinguishes scientific and ethical judgments in their application; and
- Does not perpetuate discrimination and inequities.

Foundational Principles

The foundational principles for the equitable allocation framework for COVID-19 vaccine include ethical and other principles embedded in U.S. social institutions and culture (see Box 3). The committee recognized that the principles required for its deliberations had to be

686 solid and broad enough to urgently address a pandemic of a magnitude not seen in a century with
687 disastrous effects not only on the public's health for persons with COVID-19 and other health
688 problems and their communities but also on the economy, education, and other central aspects of
689 society.

690 The committee immediately invoked a principle of *maximization of benefits* that sets an
691 primary goal of maximizing societal benefit through the reduction of morbidity and mortality
692 caused by the transmission of the novel coronavirus. While spread throughout the society, the
693 pandemic's damage has more significantly harmed some populations more than others,
694 particularly causing higher rates of infection, serious illness, hospitalization, and death among
695 people of color. This reality led the committee to formulate a principle of *mitigation of health*
696 *inequities* to address the higher risks faced by such persons in certain work environments and
697 living arrangements which correspond to higher risk of transmitting and acquiring infection and
698 with having a higher prevalence of certain health problems that make it more likely that they will
699 suffer severe outcomes and even die from COVID-19. In tragic choices about vaccine allocation,
700 the principle of *equal regard* directs attention to the equal worth and value of every person,
701 protecting each one from discrimination, while the principle of *fairness* requires impartiality and
702 the engagement and participation of affected populations in setting allocation criteria and
703 determining priority groups. Furthermore, the principle of *transparency* ensures the disclosure of
704 the principles, criteria, and priority groups that will determine people's chances of getting a
705 vaccine sooner rather than later. Finally, none of these principles can accomplish its goals
706 without the principle that all decisions must be *evidence-based.*

707 Not unexpectedly, these principles overlap substantially with those in other frameworks
708 for the allocation of scarce medical and public health goods, including vaccines for pandemic
709 influenza (Williams and Dawson, 2020). Virtually every such framework has a principle like the
710 committee's on the maximization of benefits. Most frameworks also include principles like the
711 committee's relating to equality and to equity, fairness, and justice (Emanuel et al., 2020;
712 Nuffield Council on Bioethics, 2020; Persad et al., 2009; Toner et al., 2020; Williams and
713 Dawson, 2020). These frameworks vary in how clusters of ethical considerations are combined
714 into primary principles and the weight assigned to those principles.

In seeking a set of foundational principles to guide its deliberations, the committee identified the following principles as both necessary and sufficient for formulating vaccine allocation criteria and their implementation in phases of vaccine allocation. These principles, which are unranked, do not reflect any specific ethical theory, but are consonant with many and grounded in U.S. social values and cultural discourse.

BOX 3

Foundational Principles for Equitable Allocation

- Maximization of benefits
- Equal Regard
- Mitigation of health inequities
- Fairness
- Evidence-based
- Transparency

Maximization of Benefits

This principle encompasses the obligation to protect and promote the public's health and its socioeconomic well-being in the short- and long-run. In this pandemic, it entails the obligation, as previously noted, to *maximize societal benefit by reducing morbidity and mortality caused by transmission of the novel coronavirus*. Meeting this obligation constitutes the overarching goal of the committee's proposed allocation framework. Societal benefit is broadly understood in this context (public's health and socioeconomic well-being). While it includes individuals' health and well-being, the committee recognizes that conflicts may emerge between the society's and the individuals' needs and risks and require resolution. The framework the committee proposes seeks to combine them to the extent possible**.**

The vaccine allocation framework thus seeks to reduce the risks of severe morbidity and mortality caused by transmission due to the novel coronavirus for those (a) most at risk of infection and serious outcomes, (b) in roles considered to be essential for societal functioning, and (c) most at risk of transmitting the coronavirus to others. Individuals in these roles include:

- Those whose work puts them at additional risk of infection; and
- Those whose absence from their societal roles or work puts others and the society at risk of loss of needed goods and services if they become infected (e.g., physicians, nurses, other health care providers, first responders, workers employed in the food supply system, transportation workers, teachers, etc.).

The interconnection between protecting and promoting the public's health and socioeconomic quality of life is generally understood and appreciated. However, it can be difficult scientifically to determine the best way to achieve both aims through vaccine allocation and other measures. Given present scientific knowledge, it is also difficult to determine the most effective combination of focusing vaccine allocation on reducing morbidity and mortality versus reducing transmission of COVID-19. Making those determinations wisely will require accurate, evidence-based assessments of the state of the pandemic and the available vaccine.

Equal Regard

The government's obligation to express equal regard to residents should both guide and constrain its allocation and distribution of goods, such as vaccines, and burdens, such as delays in the provision of vaccines. This fundamental obligation requires that everyone be considered and treated as having equal dignity, worth, and value. It presupposes that no one person is intrinsically more valuable or worthy of regard than another. It entails treatment as an equal rather than, automatically, an equal share (several versions of an egalitarian principle appear in Emanuel et al., 2020; Persad et al., 2009; and Nuffield Council on Bioethics, 2020).

The principle of equal regard retains its force even when it is necessary and ethically justifiable to ration vaccines and other health related goods under conditions of scarcity. It requires allocation and distribution by criteria that are non-discriminatory in design and impact. It excludes rationing based on criteria such as religion, race, ethnicity, national origin, etc. The moral right to equal regard and concern requires that allocation of vaccine proceed impartially according to fair criteria as will be further specified below. Moreover, the requirement of equal regard does not preclude consideration of people's social roles in such allocations. Some social

roles are essential in this pandemic to ensure the provision of necessary goods and services to the community and to individuals, including but not limited to medical care. This means that the people filling those roles may legitimately gain priority (e.g., clinicians, emergency responders, food processors) in those circumstances.

If the supply of vaccine is too limited to provide it to everyone in a particular priority population group at the same time, the principle of equal regard supports random selection (e.g., lottery) within that population group. It can also support a weighted lottery[18] for vaccine allocation as it has for the allocation of COVID-19 therapies such as remdesivir (White et al., 2020).

Mitigation of Health Inequities

The obligation to mitigate health inequities and their effects has become particularly salient in this pandemic. COVID-19 infections and deaths are strongly associated with race, ethnicity, occupation, and socioeconomic status. A significantly higher burden is experienced by Black, Hispanic or Latinx, and American Indian and Alaska Native populations. Currently there is no evidence that this is biologically mediated, but rather the impact of systemic racism leading to higher rates of comorbidities that increase the severity of COVID-19 infection and the socioeconomic factors that increase likelihood of acquiring the infection (front line jobs, crowded living conditions, lack of access to personal protective equipment (PPE), inability to work from home, etc.). A significantly higher burden is also experience by individuals who hold jobs with high transmission risk that cannot be done from home and often are poorly paid. These groups also experience disproportionately large burdens of other adverse health conditions. Many factors contribute to these health inequities, defined as "systematic differences in the health status of different population groups" (WHO, 2017) (see Box 4). Fundamental health inequities in COVID-19 and in other health conditions are rooted in structural inequalities, racism, and residential segregation. Any vaccine allocation scheme designed to reduce COVID-19 risk must explicitly address the higher burden of COVID-19 experienced by the populations affected most heavily, given their exposure and compounding health inequities. Mitigating those

[18] A weighted lottery system could be used to fairly allocate the scarce supply of vaccine with certain groups receiving heightened priority.

health inequities is, therefore, a moral imperative of an equitable vaccine allocation system. In addition, any vaccine allocation plan implemented at the federal and state levels must respect the tribal sovereignty of American Indian and Alaska Native nations.

BOX 4

Health Inequities

The World Health Organization defines health inequities as "*systematic differences in the health status of different population groups […] which have significant social and economic costs both to individuals and societies*" (WHO, 2017). Health inequities arise from social, economic, environmental, and structural disparities that contribute to intergroup differences in health outcomes both within and between societies. A 2017 report of the National Academies of Sciences Engineering and Medicine identified two root causes of health inequities:

- ***Structural inequities***, or the "*systemic disadvantage of one social group compared to other groups with whom they coexist, and which encompasses policy, law, governance, and culture and refers to race, ethnicity, gender or gender identity, class, sexual orientation, and other domains*" (NASEM, 2017).
- ***Social determinants of health***, or the " *conditions in the environments in which people live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality of-life outcomes and risks*" (NASEM, 2017).

The interplay between these two root causes can lead to systematic differences in the opportunities certain communities have to achieve optimal health, leading to unfair and avoidable differences in health outcomes (Braveman, 2006; WHO, 2017)

Thus, the vaccine allocation criteria should mitigate the negative effects of existing health inequities on the transmission of and harms from the novel coronavirus. The committee's allocation criteria do so in part by taking into account to the "vulnerability" of

- People at increased risk of infection because of social conditions, such as working conditions and living in multigenerational homes[19]; and
- People at increased risk of severe outcomes because of comorbid conditions that often result from or are worsened by social determinants, limited access to health care, etc.

These allocation criteria identify people who are considered to be the most disadvantaged or the "worst off" because of conditions of ill health or social deprivation or both that could make them more susceptible to infection or severe outcomes. Such criteria are often called "prioritarian" because of the primary place assigned to the "worst off" (Emanuel et al., 2020; Toner et al., 2020). A further way to mitigate the effects of health inequities is to incorporate some metric of social disadvantage, such as the Centers for Disease Control and Preventions (CDC's) Social Vulnerability Index[20], into the prioritization of vaccine recipients by making it an additional consideration within the phases.

Ultimately, the mitigation of health inequities includes development and deployment of distribution systems that ensure that people who are allocated a vaccine actually receive it (e.g., by taking it to where they are) and can afford it, even if they are hard to reach.

Fairness

The principle of fairness includes the obligation to develop allocation criteria based only on relevant non-discriminatory characteristics, already noted under the principle of equal regard, to apply these criteria impartially, and to employ fair procedures in allocation and distribution. The principle of fairness here entails formulating criteria focused on individual, community, and social needs and risks, and vigilantly avoiding the sometimes conventional practices that create and sustain discrimination.

Questions often arise about fair rationing when age is involved. This committee has been clear that it does not use age as a criterion of allocation, but only as a predictor of heightened (1) risk of acquiring infection, (2) risk of severe outcomes of infection, or (3) risk of transmission to

[19] Multigenerational homes consist of more than two generations living under the same roof.

[20] CDC's Social Vulnerability Index was developed for local preparedness for public health emergencies such as natural disasters and disease outbreaks, identifies geographic areas of vulnerability based on 15 census variables. These variables capture many recognized social determinants of health, indicators of access, infection transmission, increased risk of adverse COVID-19 outcomes (ATSDR, 2018).

847 others. Given the currently available evidence about the pandemic's behavior, priority for older
848 adults in certain phases, if warranted, would probably be based mainly on risk of severe
849 outcomes of infection, whereas priority for young adults, if warranted, would probably be based
850 mainly on risk of transmission to others.. The conflict is not so direct between these two
851 populations in the current pandemic because children who are infected with the novel
852 coronavirus and can transmit it tend not to have such severe outcomes as older adults. If such a
853 direct conflict existed because of widespread severe outcomes among children, there would be
854 strong arguments for prioritizing children over older adults on the basis of severe outcomes.
855 Children would be "worse off" because of the years of life they would lose, older adults have had
856 their "fair innings," and so forth (Daniels, 2008; Emanuel and Wertheimer, 2006; Emanuel et al.,
857 2020; Kamm, 1993; Williams, 1997). In the current context, the more difficult conflict to resolve
858 is between reducing transmission among children in order to make it more likely that they can
859 attend school in person and to reduce transmission to others in the community, on the one hand,
860 and reducing severe illness and death among older adults, on the other hand.
861 A related debate about age concerns the loss of life years versus the loss of life. Older
862 adults in their eighties, for instance, generally lose fewer life years if they die than children or
863 young adults who die. However, given the large numbers of older adults who die from COVID-
864 19, those numbers multiplied by fewer life years can still end up being quite substantial.
865 Resolving these conflicts depends on evidence about the relative effectiveness of different
866 vaccine strategies at particular stages in the pandemic give available supplies of vaccine, as will
867 be examined later in this chapter.
868 Fairness should guide not only the formulation of allocation criteria, but also their
869 application, which should be impartial and evenhanded, and avoid arbitrary exceptions and
870 gaming. Implementation should be as uniform as possible across the country, consistent with
871 allowing discretion to state, local, tribal, and territorial (SLTT) authorities to address specific
872 patterns of COVID-19 transmission, extent of spread, and severity of outcomes. Unless clearly
873 communicated and justified, extreme variation in applying the criteria can evoke charges of
874 unfairness.
875 Procedural fairness is also crucial. This means that decisions about allocation,
876 distribution, and access to vaccine should incorporate input from affected groups, especially

those disproportionately affected. Decisions about whether a group has heightened risk and which individuals fall in that particular group should be data-driven and made by impartial decision makers, such as public health officials. Ideally, affected individuals and communities should be able to appeal decisions, and in doing so, the committee believes that the transparency of its principles will help adjudicate those subsequent debates.

Reciprocity, defined as rewarding people for their past contributions, is sometimes presented as an additional ethical principle, in part to account for common intuitions about certain situations, particularly giving priority to vaccine clinical trial participants who received a placebo or an ineffective vaccine. The committee agrees with the common practice of post-trial access for research participants but believes that this is covered by the principle of fairness.

Evidence-Based

Vaccination phases—who receives the vaccine when—should be based on the best available evidence and models for identifying the populations most likely to become seriously ill or die without vaccination, for determining when slowing the pandemic is best accomplished with a focus on those most likely to spread the infection, and for estimating the added effect of vaccination on transmission in public and crowded settings. The framework must be adaptive, capable of being changed as the understanding of the disease and its risk factors deepens, and as vaccines become available, especially if some are more useful for particular populations than others. Models and their inputs will be revised as the pandemic and available information evolves. The criteria used to identify categories of individuals or groups for each phase will evolve accordingly but will at all times be stated clearly and applied in a neutral fashion.

Transparency

The principle of transparency includes the obligation to communicate with the public openly, clearly, accurately, and straightforwardly about the vaccine allocation criteria and framework, as they are being developed and deployed. Central to this process is clear articulation and explanation of the allocation criteria. Those explanations must include the principles underlying these criteria, as grounded in widely accepted societal institutions and culture, as well as the procedures for ensuring their faithful implementation.

Sometimes governments present vaccine allocation criteria without explicitly or adequately explaining their grounding in principles. This is a mistake in at least two ways. First, the public has a legitimate reason to expect such a justification when criteria affect when they can receive a vaccination, especially when their government funds the vaccine program. Second, such communication is essential to generating and sustaining public trust in the vaccine allocation criteria and program.

Transparency should also extend to other aspects of procedural fairness. Individuals (or their trusted surrogates) must be able to observe, understand, and monitor how the program's procedures are formulated and applied. That will require simple, clearly defined, and comprehensibly communicated rules. It will also require accessible documentation of how the allocation system performs and how it responds to the unanticipated consequences inevitable with such a complex human enterprise.

Without transparency regarding the allocation criteria, their ethical rationale, the deliberative process used to formulate them, and fair procedures, it will be difficult to generate and maintain the trust that is indispensable for the public's cooperation with a mass vaccination program.

To achieve transparency, it is necessary to ensure that the program's principles and operations are accessible and comprehensible to all those affected by it. This cannot be done without empirically testing proposed communications in two essential ways: Can people find a program's procedures and guiding principles easily, following their normal search patterns? Can they interpret them in ways that inform their evaluations regarding the legitimacy of the program and their own vaccination choices?

Using the Principles

Each pandemic has what Yale historian Frank Snowden calls its distinctive "personality" (Snowden, 2019), that is, its distinctive characteristics of disease and rates of infection, its modes of transmission, the groups and individuals most susceptible to infection, ages most affected, varying rates of severity and mortality, etc. Determining the specific criteria for vaccine allocation will require attention to up-to-date scientific information about the pandemic, on the one hand, and to foundational principles, on the other. These principles need to be specified and applied in the process of developing vaccine allocation criteria and phases to match the features

of the pandemic, along with the characteristics, supply, safety, and efficacy of any available vaccines.

This is evident, to take just one example, in applications of the principle of *maximization of benefits* and the primary goal it sets for vaccine allocation. Determining how best to protect and promote the public's health and socioeconomic well-being, both immediate and long-term, while the vaccine is being phased in before becoming available to everyone in the society requires solid scientific evidence (principle of *evidence-based*) in the several ways previously noted. Similar points apply to the principles of *mitigation of health inequities*, *equal regard*, and *fairness* as well as to *transparency*. In the final analysis, each proposed allocation criterion and its proposed weight or strength must pass scrutiny in light of all of these principles. To be sure, conflicts may appear and require resolution, even necessitating trade-offs. Possible conflicts notwithstanding, these principles provide the foundation for the allocation criteria and the phases in vaccine allocation derived from them. The overall allocation framework reflects the committee's best judgment about how to balance sometimes conflicting aims as the pandemic evolves and vaccine becomes incrementally available over time.

COVID-19 VACCINE ALLOCATION FRAMEWORK

Primary Goal of the Framework

Previous proposals for allocation of scarce resources in pandemics and other settings articulate various overarching goals to guide allocation that are focused on aspects of reducing morbidity and mortality, reducing disease transmission, minimizing societal disruptions, maintaining national security, and mitigating health inequities. For example, the 2018 CDC guidance document, *Allocating and Targeting Pandemic Influenza Vaccine During an Influenza Pandemic* states that its overarching goals are to reduce the impact of the pandemic on health and minimize the disruption to society and the economy.

Emanuel and colleagues (2020) recommended that in the context of a pandemic, such as COVID-19, the principle of maximization of benefits is most important and reflects the importance of responsible stewardship of scarce, valuable resources. Therefore, the primary goal of the committee's framework on equitable allocation of COVID-19 vaccine derives from the ethical principle of maximization of benefits, which is:

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

The primary goal of the committee's allocation framework has a dual focus: maximization of benefit through prevention of morbidity and mortality and through reduction in transmission. Moreover, the framework attempts to mitigate health inequities and is informed by the current evidence. In the early phases, prevention of morbidity and mortality, and maintenance of health and emergency services to aid prevention of morbidity and mortality is emphasized more than the reduction in transmission;[21] with an increased focus on transmission in later phases.

There are multiple reasons for this approach.

- Morbidity and mortality are clearly identified and provide a logical and understandable start to selecting the first vaccine recipients.
- Any substantive impact of vaccination on reducing transmission would require a critical mass of individuals to be vaccinated. Even if this critical mass is lower than the nominal herd immunity threshold, in the early phases of vaccine deployment, there will not be sufficient courses of the vaccine available for an effective transmission-focused strategy.
- The ongoing COVID-19 vaccine trials are not designed to estimate the impact of the vaccine candidates on transmission and evidence of the vaccines' impact on transmission might not be available for some time after approval or authorization.
- While data on all aspects of COVID-19 are emerging, data on transmission risk groups (e.g., by age, profession etc.) is particularly limited.
- There are legitimate claims for many groups (such as school children, "non-essential" workers important for the economy) to be in earlier phases as damage could occur if these groups are not prioritized. For example, there might be a substantial impact on

[21] For clarification, the committee considered transmission in terms of transmitting infection to others and not acquiring infection.

the economy if a primarily transmission focused strategy is not employed from the outset. However, while the non-trivial effects of an economic downturn or an online semester can at least be partially reversed, death is the most irreversible outcome.

- Preventing severe morbidity and mortality indirectly protects the health care system (i.e., an overwhelmed health care may have an impact on excess morbidity and mortality).

A focus on preventing mortality and severe morbidity in the initial phases does not mean vaccinating only groups at a direct risk of these outcomes. Prevention of transmission to groups at a high risk of morbidity and mortality should also be a part of the early phases of the vaccine program. For example, vaccinating nursing home workers would protect the high-risk residents of these facilities—particularly if the vaccine efficacy is lower among the elderly compared to younger individuals. Moreover, as more courses of vaccines become available, an increasing focus on reducing transmission, starting with high transmission settings and moving to the general population, would ensure sustainable long-term control of COVID-19. Focusing on health care and emergency workers in the initial phases will help mitigate the pandemic's impact on morbidity and mortality due to disruptions in the health care system.

Ultimately, the U.S. COVID-19 vaccination program should aim to vaccinate all who choose to be vaccinated and are without medical contraindications to the vaccine.

Allocation Criteria

The ethical principle of transparency, as well as the practical requirement of efficient, consistent administration of the framework have led the committee to develop risk-based criteria for operationalizing the foundational principles to achieve its primary goal (see Box 5). After presenting these criteria briefly, this section discusses their compatibility with the foundational principles, practical aspects of implementation, and their likely implications for allocation as vaccines becomes increasingly available. The committee notes that the fidelity of the allocation process to these foundational principles and criteria depends on the availability of data, as well as the resolution of the uncertainties discussed earlier. Achieving this goal requires comprehensive, consistent data collection that includes the needed variables of race/ethnicity, age, gender, and

social status. The section below on the allocation framework provides operational definitions of these criteria, suiting to current and emerging evidence regarding the disease, the vaccine, and their impact on society.

BOX 5

Risk-Based Criteria

- Risk of acquiring infection: Individuals have higher priority to the extent that they have a greater probability of being in settings where COVID-19 is circulating and exposure to a sufficient dose of the virus.
- Risk of severe morbidity and mortality: Individuals have higher priority to the extent that they have a greater probability of severe disease or death if they acquire infection.
- Risk of negative societal impact: Individuals have higher priority to the extent that societal function and other individuals' lives and livelihood depend on them directly and would be imperiled if they fell ill.
- Risk of transmitting disease to others: Individuals have higher priority to the extent that there is a higher probability of their transmitting the disease to others.

Risk of Acquiring Infection

Individuals have higher priority to the extent that they have a greater probability of being in settings where COVID-19 is circulating and exposure to a sufficient dose of the virus to become infected.

Risk of Severe Morbidity and Mortality

Individuals have higher priority to the extent that they have a greater probability of severe disease or death should they acquire infection.

Risk of Negative Societal Impact

Individuals have higher priority to the extent that societal function and other individuals' lives and livelihood depend on them directly and would be imperiled if they fell ill. This risk is interpreted through the number of other people potentially affected. It does not consider their

wealth, income, or other factors. It does not consider how readily an individual could be replaced in a work setting, given labor market conditions.

Risk of Transmitting Infection to Others

Individuals have higher priority to the extent that there is a higher probability of their transmitting the infection to others. This risk reflects individuals' interactions with others, given their normal course of life and their material, physical, and social resources. It is important to note that there is limited data on differential transmissibility.

Compatibility of Allocation Criteria with Foundational Principles

Maximization of Benefits

Each of the four types of risk reflects a threat to the public's health and socioeconomic well-being. Reducing each risk would bring such benefits in the short and long run. These risk-based criteria expressed the foundational principles in terms that are further specified in the allocation phases that follow.

Equal Regard

These criteria treat all people equally. They make no reference to who people are, just to their circumstances, what social roles they fill and what personal challenges they face (e.g., health). If more vaccine goes to members of one population group than another, it will not reflect who they are, but what they do, and what has happened in their lives.

Mitigation of Health Inequities

Although the criteria do not directly address health inequities, the first criterion addresses them indirectly insofar as those inequities have increased individuals' risk of disease (e.g., social disadvantage is linked to having more disease and more severe disease). The second criterion addresses them indirectly insofar as workers who have been subject to health inequities play essential roles in jobs with greater exposure. The third criterion addresses them indirectly insofar as those individuals are more likely to live in dense settings. A measure such as CDC's Social Vulnerability Index could identify people in geographic areas who have suffered health inequities that put them at greater risk.

Fairness

These criteria focus solely on four forms of risk, with no explicit recognition of any other individual characteristics. The committee anticipates that the criteria will, in practice, tend to give higher priority to lower-income individuals (because it is they who more frequently live in high-density settings, work in jobs that cannot be done without having personal contact with others, and have multiple comorbidities due to their circumstances and their relative lack of access to health care) and Black, Hispanic or Latinx, and American Indian and Native Alaskan communities given the ways in which these risks disproportionately affect people in these groups.

Evidence-Based

These three risk-based criteria apply well-understood analytical procedures to the best available scientific evidence (NRC, 1983, 1994, 2009). They can readily incorporate new evidence as it becomes available and characterize uncertainties in ways that can guide future data collection. Their application in the allocation phases reflects the committee's assessment of the evidence regarding how vaccines can best maximize benefits to individuals and communities and the health inequities that must be mitigated in that process (NRC, 2009).

Transparency

There are explicit, auditable procedures for defining risk and applying those definitions. The guidance provided by various reports of the National Academies of Sciences, Engineering, and Medicine can achieve transparency, including the procedural fairness that it requires (NRC, 1996).

The committee notes that it **chose not to consider three issues**:

- **Political context:** The committee appreciates that decisions about the public's health are made in the context of existing political realities and those are not static. However, the committee believes that regardless of the political context, officials at all levels will administer these principles faithfully, considering the wellbeing of all members of the communities that they are elected or appointed to serve. The

committee also acknowledges, as stated earlier, that other groups are working to inform allocation strategies as well.

- **Regulatory and public health changes:** The committee recognizes that there are settings where risks could be changed by regulatory or public health requirements (e.g., mask mandates, greater spacing of workers in food processing facilities). Recommending such changes is beyond the committee's statement of task. However, should they occur, they will affect some individuals' risks of getting sick or transmitting infection if they do. As a result, they will affect the operation of the allocation procedure, and require adaptive implementation, which the proposed framework is designed to make possible. However, it is crucial that these other protective measures not be prematurely abandoned.
- **Advances in medical treatment and therapeutic agents:** The committee recognizes the vast, creative efforts made to improve medical treatment and develop therapeutic agents. As they succeed, they should reduce the risk of disease severity and may reduce the risk of transmission of infection. Here, too, the adaptability of the allocation procedure can accommodate changes in risk.

Allocation Phases

Major efforts are being made by the federal government through Operation Warp Speed (OWS) to have enough COVID-19 vaccine available for everyone in the United States as soon as possible. However, even with this commitment, the length of time to develop enough vaccine is unknown, and the committee has been tasked with considering the difficult choices that will need to be made for allocating the tightly constrained initial supply of vaccine (e.g., 10–15 million courses, enough to vaccinate approximately 3–5 percent of the U.S. population). The supply of vaccine, as it increases, will be incrementally phased in so that some persons or groups of persons will receive it earlier than others. The committee here uses the term "phases," suggesting successive deployments, rather than the hierarchical, and static term "tiers." As vaccine supplies are phased in, it will be necessary to have in place an equitable framework to determine who will receive a vaccine first, second, and so forth. In this committee's judgment, an equitable—that is, just and reasonable—framework for these phases should follow the proposed foundational principles.

It should be noted that the guidance offered through the committee's allocation framework is intended to inform the work of the Advisory Committee on Immunization Practices (ACIP) and that of SLTT authorities in their COVID-19 vaccine allocation planning. There are certain communities (such as the U.S. military) that may handle vaccine allocation separate from this proposed framework.. If the federal government were to provide states with an allotment of COVID-19 vaccine, in the interest of speed and workability, federal allocation to states could be conducted based on these jurisdictions' population size.[22] While there is obviously variation among SLTT communities in disease burden and demography, these differences are not large enough to justify the delay and deliberation that would be required to decide on customized allocations to each location. Speed is essential because many difficult choices need to be made at the state and local levels.

One exception to a straightforward population-based approach would be to withhold a percentage (e.g., 10 percent) of available vaccine supply at the federal level as a reserve for deployment by CDC for use in areas of special need or epidemiological "hot spots."[23] If by the time COVID-19 vaccines become available, the United States. has achieved the success seen in other countries in stopping widespread community transmission with non-pharmaceutical interventions and test, trace, isolate, quarantine approaches, a more focused outbreak response will be feasible.

Specific to tribal nations, it is important to acknowledge that the federal government would allocate vaccine to tribal, urban Indian, and Indian Health Service (IHS) facilities directly through the existing IHS system. Federal trust responsibility for health care to Native people mandates that. To do so successfully, IHS allocation will require additional funding and external oversight. While separate from state allocation, it may also be in states' best interest to supplement IHS allocation with a portion of their own supply in order to protect the public's health. Even in this scenario, states would not oversee how tribal governments allocate vaccine in order to ensure tribal sovereignty.

[22] There remains uncertainty as to whether private entities, such as healthcare systems or businesses, will be able to access allotments of COVID-19 vaccines outside of a federal-to-state allotment system.

[23] Planning for whether an epidemiological "hot spot" reserve would be valuable and make a difference also depends on the characteristics of the vaccine (e.g., how long it takes for immunity to develop, etc.).

Operationalizing the Criteria to Determine Allocation Phases

Data will not be available to characterize each individual in terms of these criteria. Even were those data available, an allocation system based on individual priority scores would be technically impractical for delivering millions of courses of vaccine to geographically distributed individuals. To determine the population groups that comprise each allocation phase, the committee operationalized the above criteria by characterizing certain population groups in terms of the risks faced by their typical members and the ability of a vaccine to reduce those risks (see Table 2). The committee also considered the role mitigating factors such as access to PPE and the ability to social distance / isolate or telework when applying the risk-based criteria and determining the priority population groups.

1158 **DRAFT TABLE 2** Applying the Allocation Criteria to Specific Population Groups

Phases	Population Group	Criterion 1: Risk of Acquiring Infection	Criterion 2: Risk of Severe Morbidity and Mortality	Criterion 3: Risk of Negative Societal Impact	Criterion 4: Risk of Transmitting Infection to Others	Mitigating Factors for Consideration
1a	High risk workers in health care facilities	H	M	H	H	High risk of acquiring infection due to no choice in setting but may have access to personal protective equipment. Essential to protecting the health care system.
1a	First responders	H	M	H	H	High risk of acquiring infection due to no choice in setting but may have access to personal protective equipment. Essential to protecting the health care system.
1b	People with significant comorbid conditions	M	H	M	L	High risk of severe morbidity and mortality, but may be able to social distance and isolate.
1b	Older adults in congregate or overcrowded settings	H	H	L	L	High risk of acquiring infection due to lack of choice in setting.
2	Critical risk workers (part 1)	H	M	H	M	High risk of acquiring infection due to no choice in setting, but may have access to personal protective equipment.
2	Teachers and school staff	H	M	H	H	High risk of loss to an essential service, but there are alternative choices such as online schooling (lower grades should be given priority).
2	People with moderate comorbid conditions	M	M	M	L	Moderate risk of severe morbidity and mortality, but may be able to social distance and isolate.
2	All older adults	M	H	L	L	High risk of severe morbidity and mortality, but may be able to social distance and isolate.

2	People in homeless shelters or group homes	H	H	L	H	High risk of acquiring infection due to lack of choice in setting.
2	Incarcerated/detained people and staff	H	M	L	M	High risk of acquiring infection due to lack of choice in setting.
3	Young adults	H	L	M	H	Low risk of severe morbidity and mortality, high risk of transmission, but may be able to social distance/isolate/close bars, etc.
3	Children	M	L	M	H	Low risk of severe morbidity and mortality
3	Critical risk workers (part 2)	M	L	M	L	Moderate risk of acquiring infection due to lack of choice in setting.

NOTES: Cell entries are for a typical member of each group. H = high risk, M = medium risk, L = low risk. M can indicate either a heterogeneous group or one whose typical member bear medium risk. All cell entries are relative to risks in the overall population, not measures of absolute risk, and are based on the committee's expert judgment of the evidence and the uncertainties at the time of this writing. Lastly, the committee has elected not to use the designation "essential worker." Instead, the committee refers to these workers as critical risk workers as they are both working in industries vital to the functioning of society and in occupations where they cannot avoid exposure risk by, for example, teleworking. This is described further later in this chapter.

The framework recognizes current uncertainty regarding the disease, its spread, and treatments and the possibility that new evidence may change the risks and, with them, the priorities. Achieving all of these goals requires evidence, regarding the disease, the program, treatments, and their impacts. That evidence is required by both those managing the COVID-19 vaccination program and those who depend on it. The COVID-19 vaccination program must immediately begin developing and implementing procedures that continuously collect data.

Discussion of the Allocation Phases

The committee recommends a four-phased approach to COVID-19 vaccine allocation. Within the population groups included in each of these four phases, the committee recommends that vaccine access should be prioritized for geographic areas identified as vulnerable through CDC's Social Vulnerability Index. This issue is discussed further in the ensuring equity section later in this chapter.

Included in the first phase would be "frontline" health workers—health professionals who are involved in direct patient care, as well as those in transport, environmental services staff, or other health care facility services, who risk exposure to bodily fluids or aerosols. Under conditions of such scarcity, access should not be defined by professional title, but rather by the individual's actual risk of exposure to COVID-19. The rationale for including "frontline" health workers in the first phase is manifold: their contact with patients exhibiting COVID-related symptoms puts them at obvious risk of exposure (despite the use of PPE, which is also often inadequate in supply); the fact that they work in an essential industry, but may be precluded from performing their professional duties if not adequately protected; and the reality that many are potentially important nodes in onward transmission networks given that many live in multigenerational homes and belong to communities whose opportunities for well-being have been forestalled by systemic racism and discrimination. The latter is especially true for many of those who work in nursing homes and as home health aides. In addition to frontline health care workers, first responders are included as well.

Another group to include in the first phase would be those older adults living in congregate settings—such as nursing homes or skilled nursing facilities—and other similar settings. Last, individuals with select high-risk comorbid and underlying conditions are included in Phase 1.

In Phase 2, expansion of vaccine supply would allow for the immunization of another cohort of individuals with comorbid and underlying conditions that put them at increased risk, as well as all older adults not already included in Phase 1. Health care providers and public health authorities will need to assess the risk of increased age (while morbidity and mortality begins to rise substantially with age starting around age 50, it is most prevalent above age 70), as well as the presence of comorbid conditions. Current knowledge of the relative risks stemming from specific underlying risk factors is evolving quickly and will be better known by the time vaccines actually become available. This may allow decision makers to target those at greatest risk of serious morbidity and mortality more effectively than is possible today. This could also allow the identification of younger people who are at high risk of infection or serious morbidity/mortality so that they can also be prioritized. The development of life-saving therapeutics may also alter the prioritization if early detection and treatment provide a means for averting much of the serious morbidity and mortality seen with COVID-19 today.

Recognizing the importance of education and child development, teachers and school staff are included in Phase 2. It is important to include this group relatively early to facilitate the reopening of schools, and to protect the most high-risk adults present when this occurs given current knowledge about morbidity and mortality due to COVID-19.

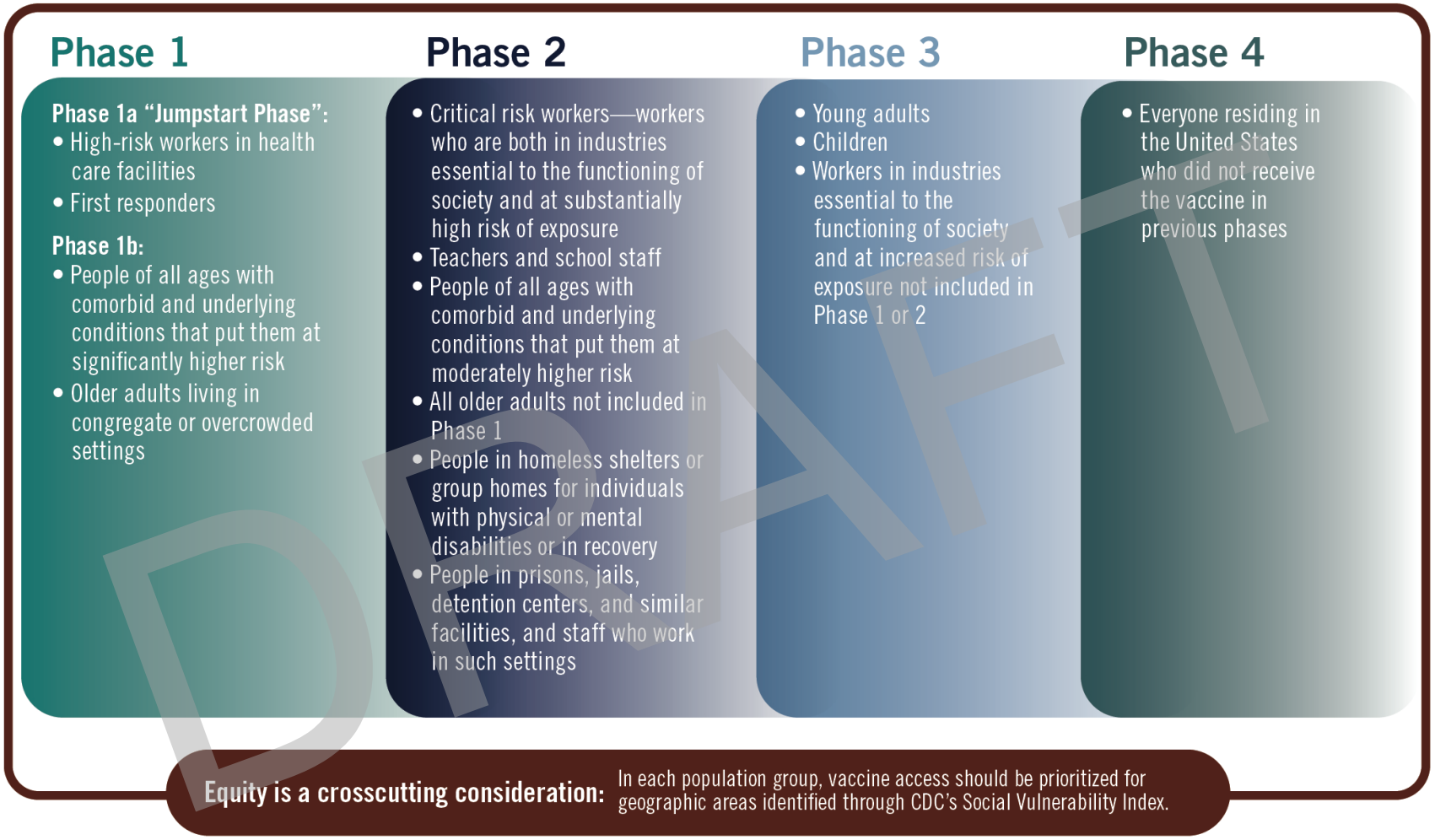
People who are incarcerated or detained and people who live in group homes and homeless shelters—congregate settings—are also included in Phase 2 along with the staff who work in such settings. With respect to these groups, the committee stressed the importance of recognizing their reduced autonomy and the recognized difficulty of preventing spread in such settings should COVID-19 be introduced. Last, the first cohort of workers who are both in industries essential to the functioning of society and at high risk of exposure are included in Phase 2.

In Phase 3, vaccine supply will become more widely available and allow the broader immunization of workers essential to restoring full economic activity. In this phase many workers will still be able to safely work from home and thus would be prioritized for later access to the vaccine. In this phase the broad immunization of children and young adults is included, given emerging evidence of the role they may play in asymptomatic transmission, especially in intrafamilial situations. An important caveat here is that broad immunization of children will

depend on whether new COVID-19 vaccines have been adequately tested for safety and efficacy in childhood age groups. Most initial trials are testing vaccines among older age groups who are known to suffer more serious morbidity and mortality.

Finally, once vaccine supply becomes more broadly available (Phase 4), vaccines would be made available to healthy adult individuals who would be interested in receiving the vaccine for personal protection. Ideally, these individuals would be willing to participate in an egalitarian process (such as a lottery) if there are persistent local or regional shortages in this phase. It is important to acknowledge that uncertainties about the COVID-19 vaccine and the nature of the pandemic itself persist, but the committee approached its framework under the best available evidence today. Under the context described, the committee's allocation approach is shown in Figure 2 and described in greater detail below—first as a description of the various phases, following by discussion of ensuring equity across all phases.

The proposed approach assumes a poorly-controlled outbreak in which the relative distribution of burden of morbidity and mortality is similar to what exists today. Given the epidemiology of COVID-19 so far, it is reasonable to assume these underlying conditions will hold around the anticipated start of the U.S. COVID-19 vaccination program. However, it is possible that the United States is able to substantially control the outbreak similar to situations in countries such as New Zealand. In that case, a prioritization approach that initially emphasizes transmission over direct protection from morbidity and mortality could be considered.



DRAFT FIGURE 2 A phased approach to vaccine allocation for COVID-19

A Phased Approach to Vaccine Allocation

Phase 1

Phase 1 includes the following groups:

- High-risk workers in health care facilities;
- First responders;
- People of all ages with comorbid and underlying conditions that put them at *significantly* higher risk; and
- Older adults living in congregate or overcrowded settings.

According to estimates provided by OWS (Slaoui, 2020), there should be sufficient courses available relatively soon after commencement of vaccine production to cover an estimated 10–15 million people. In that limited supply scenario, high-risk and high-exposure workers in health care facilities and first responders should constitute an initial "Jumpstart" Phase 1a. This would be followed by Phase 1b comprised of people with comorbid and underlying conditions that put them at *significantly* higher risk and older adults living in congregate or overcrowded settings.

Phase 1a would cover approximately 5 percent of the U.S. population, and in its entirety, Phase 1 would cover an estimated 15 percent. Such a structure could help kick off initial vaccine administration, while SLTT authorities prepare distribution procedures for the next phases.

Phase 1a

Population: High-Risk Workers in Health care Facilities

This group includes front line health care workers (in hospitals, nursing homes, or providing home care) who either: (1) work in situations where risk of SARS-CoV-2 transmission is high, or (2) are at an elevated risk of transmitting the infection to patients at high risk of mortality and severe morbidity. These individuals—who are themselves unable to avoid exposure to the virus—play a critical role in ensuring that the health system can care for COVID-19 patients.

These groups include not only clinicians (e.g., nurses, physicians, respiratory technicians, dentists and hygienists) but also other workers in health care settings who meet the Phase 1a risk criteria (e.g., nursing assistants, environmental services staff, assisted living home staff, long-term care facility staff, group home staff, and home caregivers). Situations with high risk of transmission include caring for COVID-19 patients, cleaning areas where COVID-19 patients are admitted and treated, and performing procedures with high risk of aerosolization such as endotracheal intubation, bronchoscopy, suctioning, turning the patient to the prone position, disconnecting the patient from the ventilator, invasive dental procedures and exams, invasive specimen collection, and cardiopulmonary resuscitation. The committee also includes morticians and funeral home workers involved in handling bodies as part of this high-risk group.

Rationale

Front line health care workers are particularly important in stemming the pandemic and preventing death and severe illness. From the beginning of the pandemic, many frontline workers have worked in environments where they have been exposed to the virus, often without adequate PPE. These individuals are critical to providing essential care, especially to older adults who are at greatest risk of COVID-19 disease or death. Vaccinating these individuals not only enables them to provide these services, but also reduces the risk that they will spread the infection as they work in hospitals, nursing homes, assisted living facilities, home care, and group homes, or return to their own homes.

Frontline health care workers are at significantly higher risk of becoming infected with SARS-CoV-2 compared to members of the general public. A recently cohort study using data from the United States and the United Kingdom found that frontline health care workers had nearly 12 times the risk of the general population of testing positive for COVID-19 (Nguyen et al., 2020). Protecting these workers will have a great impact on protecting older individuals, who receive a large share of health services and have borne a large share of the disease burden from COVID-19.

Nearly 80 percent of all COVID-19 deaths in the United States have occurred in people over the age of 65 (CDC, 2020e). Nursing home residents and staff have been at the center of the pandemic since the first reported cases. As of August 2, 2020, there were 286,382 confirmed or suspected COVID-19 cases and 45,958 deaths among nursing home residents, according to the

Centers for Medicare and Medicaid Services (CMS) (CMS, 2020a), and these numbers are likely to be underreported (Ouslander and Grabowski, 2020). Nursing home workers are at increased risk themselves—CMS also reports that nearly 800 nursing home staff in the United States have died from COVID-19—and play a role in infection spread within and between institutions (CMS, 2020b). Asymptomatic spread by nursing home workers is a well-established route (Lee et al., 2020), and vaccinating this group could have a significant impact on the incidence of infection in this setting. Nursing home and home care employment is low-paying, with many workers holding jobs at more than one nursing home or home care setting. Many of these workers take public transportation and live in multi-generational housing, increasing the likelihood of exposure and exposing others.

In addition to their occupational and community exposures, these workers are statistically at higher risk of COVID-19 disease and severe health effects because they come from populations with higher rates of comorbid conditions. A relatively high proportion of nursing home workers are Black (27.8 percent) as are home care workers likely to be Black (29.7 percent) or Latinx (17.5 percent) (McCormack et al., 2020). A sizable proportion of such workers are over 65 as well (Black: 9.1 percent Latinx: 11.3 percent). In the first months of the pandemic, some hospitals were unprepared for the large number of COVID-19 cases. Exposure of hospital workers was often poorly controlled, and many workers received inadequate PPE. Tens of thousands of hospital workers have been infected, and many hundreds have died, although there are no accurate data on these cases. While there is still a severe national PPE shortage, it appears that many hospitals are now better able to protect members of their workforce who directly work with COVID-19 patients. However, this is not true uniformly across the country, and, even better equipped hospitals still leave some workers exposed. Nursing homes have struggled with having adequate PPE since the beginning of the pandemic and some continue to do so (Clark, 2020). Individuals who provide home care or work in hospitals, nursing homes, and assisted and living (or similar) facilities—who are also at high risk for severe illness and death because of comorbid conditions and age—should be among the first receiving the vaccine.

Vaccination is not a substitute for non-medical or (non-therapeutic) preventive policies and equipment. All exposed workers should be, for example, provided an adequate supply of appropriate PPE. It is vitally important that the prospect of vaccination not supplant efforts to

assure adequate supply of protective equipment or continuing the use mitigation strategies after vaccination.

Estimated Group Size[24]

According to the best currently available estimates for the United States, among health care practitioners and technical staff, 6,728,000 are exposed to COVID-19 more than once per week; among health care support staff, 3,160,000 are exposed to COVID-19 more than once per week. There are also approximately 1,500,000 full-time nursing home employees, 432,000 health care practitioners who work in skilled nursing facilities, and 3,162,000 home health care workers (Baker et al., 2020; BLS, 2019b). The number of morticians, undertakers, and funeral directors in the United States is estimated to be approximately 25,000 people (Statista, 2020).

Population: First Responders

This group includes emergency medical services (EMS) personnel, police, and firefighters (including volunteer firefighters). Like health care workers, many first responders have been working in situations in which exposure to infected individuals is sometimes unavoidable. Given their public serving role, first responders who become ill can transmit infection to their families and to the broader community. While data on exposure risk for first responders are limited, initial estimates indicate high infection rates among first responders in high COVID-19 transmission settings. For example, in early April, approximately 20 percent of New York Police Department (NYPD) officers were out sick (DeStefano, 2020) and, as of May, 43 NYPD officers had died of COVID-19 (Eyewitness News, 2020).

Rationale

First responders are central to society's overall functioning, to its response to the virus, and to ensuring that others with medical emergencies receive necessary immediate care. When emergency medical personnel and fire fighters are unable to work, because of illness or when isolating because of exposure to the virus, their ability to provide badly needed, medical, rescue and fire-fighting services, is impaired. First responders who are at high risk of exposure who are

[24] Estimated group sizes across phases are not intended to be entirely cumulative, and the committee acknowledges there is overlap between the group estimates provided. Please see the discussion of limitations at the end of this chapter for additional discussion of data.

also at high risk for severe illness and death because of comorbid conditions and age should be among the first in this group receiving the vaccine.

Many of the reasons for protecting health care workers also apply to first responders. These include the social value of maintaining emergency services, reciprocity for assumption of additional risk by these groups, and—in some cases—high risk of acquisition and, potentially, transmission. Similarly, until substantial and sustained suppression of the COVID-19 outbreak is achieved, first responders are likely to need PPE for performing their responsibilities.

Estimated Group Size

An estimated 2.1 million first responders are covered by this population group comprising 262,000 EMS personnel, 701,000 police, and 1,100,000 firefighters (approximately 300,000 of whom are paid with the rest serving in a volunteer capacity, and a subset of whom provide emergency medical services) (BLS, 2019; BLS, 2020a; Evarts, 2020).

Phase 1b

Population: People of All Ages with Comorbid and Underlying Conditions That Put Them at Significantly Higher Risk

It remains unclear precisely which comorbid and underlying conditions put individuals at a significantly higher risk of severe COVID-19 disease or death. CDC continues to gather evidence on this topic, and lists the following as factors associated with an increased risk of severe COVID-19 disease: Cancer, chronic kidney disease, chronic obstructive pulmonary disease (COPD), immunocompromised state from solid organ transplant, obesity (body mass index [BMI] ≥30), serious heart conditions (e.g., heart failure, coronary artery disease, cardiomyopathies), sickle cell disease, and type 2 diabetes mellitus (CDC, 2020d). Vaccinating all individuals with the above comorbid conditions in Phase 1b would prove unmanageable, as the group includes hundreds of millions of people in the United States. In a highly constrained vaccine scenario, the initial group of recipients with comorbid and underlying conditions could focus specifically on individuals with *two or more* of these designated conditions.

It should be noted that as the relationship between severe COVID-19 disease and certain comorbid conditions becomes clearer, this list is subject to evolve. ACIP and CDC will play a key role in assessing relevant evidence on this topic, and in the process of prioritization, it will

be critical to recognize that not all comorbid conditions are equal when it comes to their placement in an allocation framework.

Rationale

According to data recently published through the Coronavirus Disease 2019 (COVID-19) Associated Hospitalization Surveillance Network (COVID-NET) from March 1 through August 15, 2020, approximately 75 percent of adults hospitalized for COVID-19 in the United States had at least two comorbid conditions. More than 60 percent of hospitalized adults had three or more underlying conditions (McClung, 2020).[25]

Multiple studies have explored a range of comorbid and underlying conditions as potential risk factors for severe COVID-19 disease. According to CDC's surveillance data for March 2020, people with COVID-19 who had underlying health conditions—most commonly hypertension, obesity, cardiovascular disease, diabetes mellitus, and chronic lung disease—were 6 times as likely to be hospitalized and 12 times as likely to die from the disease as those without underlying health conditions. A study from a large health care system in New York found that individuals below age 60 with a BMI of 30 or higher were more likely to be admitted to acute and critical care than patients in the same age categories with a BMI below 30 (Lighter et al., 2020). Another recent study suggests that, in particular, those with chronic heart failure, kidney disease, and a BMI of 40 or higher are particularly high-risk groups (Petrilli et al., 2020). Ultimately, given the high risk of adverse outcomes in individuals with select comorbid conditions and the evolving evidence on this topic, it will be critical to monitor how the nature and number of comorbid conditions affect morbidity and mortality at the individual level.

Estimated Group Size

There is currently no clear data to accurately estimate the size of this population group with multiple select comorbid conditions, which the committee acknowledges as a key limitation. A recent modeling study by Clark et al. (2020) may help to provide some insight on a general range for this population group. In the study, the authors highlighted a "high risk" group

[25] The list of comorbid conditions assessed in COVID-NET differs slightly from CDC's current list of conditions that put individuals at "increased risk" of severe illness from COVID-19 disease. The COVID-NET list includes hypertension, obesity, diabetes, cardiovascular disease, neurologic disease, chronic lung disease, renal disease, asthma, immune suppression, gastrointestinal/liver disease, and autoimmune disease.

defined as individuals who would require hospitalization if infected with COVID-19, calculated using age-specific infection-hospitalization ratios for COVID-19. The study estimated that 19–20 million people in the United States fall into this category. Given that approximately 75 percent of those hospitalized for COVID-19 based on the COVID-NET data had multiple comorbid conditions, the committee estimates that the value of 19–20 million may approximate the number of individuals with multiple comorbid conditions (from the CDC list above).

Population: Older Adults Living in Congregate or Overcrowded Settings

This group includes older individuals living in situations that increase their risk of SARS-CoV-2 infection and resultant morbidity and mortality. The scientific community's understanding of age-specific COVID-19 mortality is still emerging, and there are concerns, based on the lower efficacy of other vaccines (such as influenza vaccine) among the elderly, that COVID-19 vaccines will have a lower efficacy among older adults. For these reasons, the committee recommends that ACIP determine age guidelines as health and vaccine efficacy data become more available.

Rationale

According to CDC, the case fatality proportion for COVID-19 is substantially higher among older adults in the United States. As a result, as of August 1, 2020, approximately 80 percent of all deaths occurred in adults 65 and older (Freed, 2020). Similarly, the risk of hospitalization from COVID-19 increases with age, with rates per 100,000 significantly higher for adults 65 and older (~199 per 100,000 for 65–74 year old individuals, ~329 per 100,000 for 75–84 individuals, and ~513 per 100,000 for individuals 85 and older) (CDC, 2020b). A significant proportion of COVID-19 deaths occurred in individuals living in long-term care facilities (CMS, 2020a). Data from Canada and other countries, as well as investigative reporting in the United States, suggests that the percentage of COVID-19 deaths in long-term care facilities may be higher than indicated by CDC's database (CIHI, 2020; NYT, 2020a). Whatever the precise numbers, it is clear that directly protecting older adults—particularly those living in congregate or overcrowded settings—will have substantial impact on COVID-19-related severe outcomes. Although there is some uncertainty regarding how well the vaccine will work in older individuals, models find that prioritizing older adults will have a substantial impact

on mortality, even if the vaccine is up to 50 percent less effective among people 60 or older compared people younger than 60 (Lipsitch, 2020). In addition, adjuvanted vaccines such as the recombinant zoster vaccine (RZV; Shingrix) have been demonstrated to provide efficacy to older adults across the age spectrum (Bastidas et al., 2019; Dagnew et al., 2020).

The committee also suspects that many older adults living in overcrowded settings may live in multigenerational households. Historically, in virtually every society, people lived together in households comprised of three and even four generations (Miller and Nebeker-Adams, 2017). Although such households are less common overall in the United States today, they are still often found in lower income communities. Such households typically have relatively few bedrooms and bathrooms, with crowded sleeping arrangements and reduced opportunity to practice social distancing. Because many individuals living in multigenerational households in the United States also work in jobs that put them at elevated risk of exposure to COVID-19, it is important to vaccinate the members of those households who are most vulnerable to protect them from acquiring COVID-19 infection.

The combination of risk of severe disease due to advanced age and high risk of COVID-19 acquisition and transmission among older adults included in this population group make it among the highest priority groups for receiving the COVID-19 vaccine.

Estimated Group Size

There are approximately 1,347,000 nursing home residents in the United States and 811,000 individuals living in residential care facilities. In addition, 4,700,000 adults over the age of 65 live below the poverty line, meaning the individuals included in this group total more than 6.8 million people (CDC, 2020a,f; Cubanski, 2018).

Phase 2

Phase 2 includes the following groups:

- Critical risk workers—workers who are both in industries essential to the functioning of society and at substantially high risk of exposure;
- Teachers and school staff;

- People of all ages with comorbid and underlying conditions that put them at *moderately* higher risk;
- All older adults not included in Phase 1
- People in homeless shelters or group homes for individuals with physical or mental disabilities or in recovery; and
- People in prisons, jails, detention centers, and similar facilities, and staff who work in such settings.

Phase 2 would cover an estimated 30–35 percent of the U.S. population; combined with Phase 1, the groups included across both phases would total approximately 45–50 percent of the population.

Population: Critical Risk Workers—Workers in Both Industries Essential to the Functioning of Society and at Substantially High Risk of Exposure

Another group included in Phase 2 are people whose work is vital to the functioning of society and the economy, and whose work causes them to have a high level of exposure to persons with SARS-CoV-2 infection. The U.S. Department of Homeland Security (DHS) has identified categories of "Essential Critical Infrastructure Workers" whose functioning "is imperative during the response to the COVID-19 emergency for both public health and safety as well as community well-being" (Krebs, 2020). The list of categories of workers designated by DHS includes many groups of workers who are at high risk of exposure. Others designated by DHS, however, are either able to telework or are otherwise isolated and not at high risk of exposure. Recent work has found that 37 percent of jobs in the U.S. economy are "teleworkable." Many of these jobs are in occupations in essential industries, but they also represent "white collar" positions in industries that are generally considered "blue collar" (Dingel and Neiman, 2020). Thus, while performing "essential work," they are able to avoid the exposure risk while doing vital work. For this reason, the committee has elected not to use the designation "essential worker" in the allocation framework. Instead, the committee refers to these workers as critical risk workers as they are both working in industries vital to the functioning of society and in occupations where they cannot avoid exposure risk.

The industries in which these critical risk workers are employed are essential to keep society and the economy functioning. Since the beginning of the pandemic, millions of people

have been going to work and risking exposure to the virus to ensure there is food in markets; pharmaceutical products in drug stores; public safety and order maintained; mail and packages delivered; and buses, trains, and planes operated. This group also includes other health care workers who are not already accounted for in Phase 1a. Importantly, only those occupations in these essential industries where there is *unavoidable* high risk of exposure qualify as the critical risk workers in this group.

Rationale

Large numbers of these workers whose work is vital to the function of society and the economy have been infected with COVID-19 while on the job, although precise counts are not available (The Lancet, 2020). It is the committee's belief that those members of these sectors who are at higher risk for exposure and infection should be given priority. Many of them work without adequate protection while in close proximity with coworkers and members of the public. Groups of workers in essential industries and who are at high risk of exposure (CDC, 2020g) include workers in the U.S. food supply system who plant, harvest and package crops; slaughter and process meat; deliver food to stores and stock shelves and staff checkout lines. In many food system workplaces, inadequate protections have been provided. There are many reasons that food supply workers are at increased risk of infection and disease, including prolonged close workplace contact with coworkers, frequent community contact with fellow workers, mobility of the work force (i.e., migrant workers), shared transportation to and from the workplace, lack of paid sick leave, congregate housing (including living in employer-furnished housing and shared living quarters, and living in crowded and multigenerational homes) (Oliver, 2020). These low-paid workers may be less likely to attempt to use the health care system for care for economic or legal reasons. Workers in other sectors are at increased risk as well, including workers employed in public transportation, (such as buses, trains, car services or planes), especially in localities or situations where passengers are not required to wear masks. Also, in this population group are postal workers and workers in warehouses and fulfillment centers. Not all workers in these essential industries are U.S. citizens or green card holders; some may have come to the United States as refugees or may be undocumented. All workers in this population group need to be provided the vaccine, and special efforts must be made to reach these workers in ways that encourage them to be vaccinated.

Echoing what was stated in Phase 1, it is important to note that while community transmission of SARS-CoV-2 continues, vaccination is not a substitute for providing other interventions to mitigate exposure risk, such as engineering and administrative controls and providing adequate personal protective equipment (OSHA, 2020).

Estimated Group Size

Workers from numerous essential industries are included in this group, such as workers in food and beverage production (1,700,000), cashiers/food store workers (865,000), pharmacists and pharmacy staff (621,000), and public transit workers (179,000). There are more than 15 million health care workers in the United States, though a large percentage of them are already covered in Phase 1a above (BLS, 2019c, 2020b,c; USDA, 2020). Ideally, workers included in this group would cover the initial 20 percent of those from industries deemed to be essential.

Population: Teachers and School Staff

This group includes school staff, including teachers, child-care workers, administrators, environmental services staff, and maintenance workers, and school bus drivers.

Rationale

Across the nation, states and localities are placing a high priority on re-opening schools and expanding childcare programs to promote children's educational and social development and facilitate parents' employment. Exposure is very difficult to control in these institutions, especially those providing care or education to young children. All workers in these facilities are among those who need to be protected from the virus during Phase 2. Due to the nature of their work, teachers and school staff who return to work in schools are at higher risk of COVID-19 infection and serve an important societal role in ensuring that students' educational needs are met. One could also argue that vaccinating teachers and school staff could help to reduce viral transmission, with these teachers and staff serving as connections between schools and broader society.

Furthermore, the importance of re-opening schools, especially for elementary-aged children, cannot be understated. Reestablishing a sense of normalcy for students and their families through in-person education will help to achieve long-term health benefits for children and facilitate important social development for them as well.

As some states and localities choose to begin reopening schools, it is also important to consider the direct impact of COVID-19 disease on teachers and staff. A recent study found that 39.8 percent of teachers had "definite" and 50.6 percent had "definite or possible" risk factors for severe COVID-19 disease (with similar results for other school staff), emphasizing the vaccine's potential importance in protecting teachers and promoting in-person education safely (Gaffney et al., 2020). Therefore, it is likely that teachers at highest risk would be vaccinated in Phase 1b.

Estimated Group Size

Across the United States, there are 8,605,000 teachers and staff at elementary and secondary schools; there are also approximately 463,000 people who provide child care services (BLS, 2019).

Population: People of All Ages with Comorbid and Underlying Conditions That Put Them at Moderately Higher Risk

Drawing on CDC's list of comorbid conditions discussed in Phase 1b, this population group would include anyone with *one* of the previously mentioned conditions (Phase 1b includes individuals with multiple comorbid conditions from among those listed).

Other comorbid conditions may be considered for this phase as evidence emerges. In addition to CDC's list of comorbid conditions that put individuals at increased risk, CDC has also compiled a list of comorbid conditions that *might* put individuals at increased risk. This list includes asthma (moderate-to-severe); cerebrovascular disease; cystic fibrosis; hypertension; immunocompromised state from blood or bone marrow transplant, immune deficiencies, HIV/AIDS, use of corticosteroids, or use of other immunosuppressive medicines; neurologic conditions; liver disease; pregnancy; pulmonary fibrosis; smoking; thalassemia; and type 1 diabetes mellitus (CDC, 2020c).

Rationale

Similar to the discussion in Phase 1b, the rationale for prioritizing persons with such conditions is that the vaccine may have a greater impact among those with increased likelihood of severe illness (hospitalizations, intensive care unit admissions, and deaths) than in persons without these conditions, resulting in a decreased burden on the health care system and more lives being saved from all conditions. Based on the aforementioned COVID-NET data,

approximately 12 percent of adults hospitalized for COVID-19 in the United States. between March 1 and August 15, 2020 had one select comorbid or underlying condition.[26]

Estimated Group Size

Without accounting for those with multiple comorbid conditions in Phase 1b, the committee is not currently in a position to accurately estimate the number of individuals in this population group. Furthermore, it remains possible that additional comorbid conditions are included in this category as evidence emerges, but this population group would likely include tens of millions of people.

Population: All Other Older Adults

Beyond the older adult group already discussed in Phase 1b (those older adults living in congregate or overcrowded settings), this group includes all older adults residing in the United States. As discussed earlier, the committee defers to ACIP to determine specific age guidelines as health and vaccine efficacy data become more available.

Rationale

As discussed in the rational for a subset of older adults in Phase 1b, the case fatality proportion for COVID-19 is substantially higher among older adults in the United States, and the rate of hospitalization for COVID-19 increases with age. Ultimately, one could argue that age is itself an underlying condition for COVID-19 given the high risk of severe disease and death due to COVID-19 among older adults.

Estimated Group Size

There are estimated to be more than 49.2 million older adults (people 65 and older) living in the United States (Survey, 2018). Accounting for some overlap with the groups above, it is estimated that there are 13.2 million older adults in the United States without comorbid or underlying conditions.

[26] The list of comorbid conditions assessed in COVID-NET differs slightly from CDC's current list of conditions that put individuals at "increased risk" of severe illness from COVID-19 disease. The COVID-NET list includes hypertension, obesity, diabetes, cardiovascular disease, neurologic disease, chronic lung disease, renal disease, asthma, immune suppression, gastrointestinal/liver disease, and autoimmune disease.

Population: People in Homeless Shelters or Group Homes

This group includes people who live in homeless shelters or group homes for individuals with physical or mental disabilities or in recovery, as well as staff of these facilities.

Rationale

Many of these people are at risk because of their underlying diseases and because of their living setting (Landes et al., 2020). Individuals living in congregate settings face increased risk of exposure to COVID-19 if they have limited or shared bathroom facilities and limited ability to practice social distancing. In addition, staff at these facilities are at increased risk of exposure and are more likely to transmit COVID-19 if infected.

Among people who experience homelessness, many are at high risk of acquiring and transmitting infection given their frequent time spent in public places or in congregate settings such as shelters. In addition, many people who experience homelessness may suffer from one or more underlying health conditions that may put them at higher risk. Among group home residents, they may also have comorbid conditions that increase their risk of severe COVID-19 outcomes, and their autonomy is reduced by living in a group home setting, putting them at risk of COVID-19 acquisition and transmission.

Estimated Group Size

469,000 people live in group homes, and 575,000 people experience homelessness across the United States (Culhane, 2020; Williams, 2013).

Population: People in Prisons, Jails, Detention Centers, and Similar Facilities, and Staff Who Work in Such Settings

Another group to be included in Phase 2 are staff members and persons in prisons, jails, and detention centers, including immigration detention facilities. A prisoner is defined as anyone who is deprived of personal liberty against his or her will following conviction of a crime. Although not afforded all the rights of a free person, a prisoner is assured certain rights by the U.S. Constitution and the moral standards of the community. Detainees are individuals who are kept in jail or some other holding facility even though they have not been convicted of a crime. A majority of detainees in jails are individuals who cannot obtain sufficient funds to post bail and are not released from jail pending a trial on the criminal charges.

Rationale

Data show that persons in state and federal prisons are at a 5.5-fold greater risk of COVID-19 compared to the general U.S. population (Saloner et al., 2020). These people, as well as those in jails, have reduced autonomy and cannot physically distance from others in their congregate living setting and thus need additional protection (Page et al., 2020). As such, their risk of both acquiring and transmitting COVID-19 infection to others is high.

Others may be in detention centers after entering the country without documentation and are now awaiting resolution of their asylum or other claims in immigration detention facilities. Vaccination for this population in Phase 2 is important because other controls, such as maintaining 6-foot distancing, are difficult or impossible to achieve. Most of these people are housed in one of the more than 250 public and private facilities under contract with the federal government, but with varying levels of care as they are not always subject to federal standards. Outbreaks of seasonal influenza demonstrate the porous nature of the medical system in these facilities (Page et al., 2020). Furthermore, as has been described in literature on seasonal influenza vaccine, vaccinating individuals held in immigration detention facilities can help to prevent outbreaks of infectious disease both within these facilities and between facilities and the rest of society (Omer, 2019; Sunderji et al., 2020). This is an especially important consideration for staff in these facilities, as they serve as the conduit between the two.

Estimated Group Size

There are currently an estimated 2.3 million incarcerated or detained individuals in the United States, in addition to 423,000 correctional officers, jailers, and support staff, totaling more than 2.7 million people in this group (BLS, 2019).

Phase 3

Phase 3 includes the following groups:

- Young adults;
- Children; and
- Workers in industries essential to the functioning of society and at increased risk of exposure not included in Phases 1 or 2.

Phase 3 would cover approximately 40–45 percent of the U.S. population. Cumulatively, Phases 1–3 would then cover 85–95 percent of the U.S. population.

Population: Young Adults

This group includes all young adults aged 18–30 residing in the United States.

Rationale

In Phase 3, vaccine supply will become more widely available and allow for broader immunization of the U.S. population, which is essential to stem transmission and restore full social and economic activity. While both the case fatality rate and hospitalization rate for COVID-19 are substantially lower in young adults aged 18–30, there is increasing evidence that this group may be disproportionately fueling asymptomatic and/or pre-symptomatic transmission (CIDRAP, 2020; Moghadas et al., 2020). Studies have shown that adults under the age of 30 report significantly higher levels of social contacts, and broader social networks, than adults in any other age group (Bruine de Bruin et al., 2020), thus potentially putting them at heightened risk of both COVID-19 exposure and transmission.

In addition, this group includes college-aged individuals who are more likely to be living in congregate settings—such as college dormitories, house shares and other communal living facilities—and thus face increased risk of contracting SARS-CoV-2 infections. Numerous outbreaks of COVID-19 are already occurring in such settings in the United States (NYT, 2020b). Furthermore, SARS-CoV-2 infections in college-aged adults can threaten the health of professors and other university staff, many of whom are older or have underlying illnesses that put them at risk of severe COVID-19. Similarly, 2019 U.S. Census data show that approximately one in two young adults currently live in parental homes, thus are at higher risk of transmitting the infection to their family members, who may also be at increased risk of severe disease and death due to age or other comorbidity (U.S. Census, 2019).

Given the emerging evidence of the role of pre-symptomatic and asymptomatic transmission in intrafamilial situations and/or congregate settings, the committee deemed it critical to include this group in Phase 3.

Estimated Group Size

According the 2019 U.S. Census Bureau data, there are approximately 58 million young adults between the ages of 18 and 30 (U.S. Census, 2019). Accounting for the potential overlap with other groups across other phases, the committee estimates that approximately 46.5 million young adults would be included in this phase.

Population: Children

This group includes all children—including schoolchildren who attend preschool, elementary school, middle school, and high school.

Rationale

While the proportion of children who become infected with SARS-CoV-2 who become severely ill is much smaller than that in adults, severe cases of COVID-19 do occur in children, and the long-term effects of such illnesses are not yet understood. Children also can play a role in COVID-19 disease transmission (Gaffney et al., 2020). Furthermore, when SARS-CoV-2 infections are documented in children, they can cause major disruptions of educational activities (e.g., school closings, quarantine and isolation) for children, staff, and families. They can threaten the health of teachers and staff, many of whom are older or have underlying illnesses that put them at risk of severe COVID-19, as well as members of their extended families. These disruptions can also reduce their parents' or guardians' ability to work. Vaccination, any needed booster, and resultant transient or immunity to SARS-CoV-2 infection among children will allow schools of all types and sizes to safely re-open and remain open, which will, in turn, allow parents and guardians to return to the workforce. At the same time, the other important benefits to children being back in school (e.g., provision of nutritious meals, emotional well-being, detection of and response to possible child abuse or neglect, etc.) can be realized. It will also be critical to conduct additional trials to gain better understanding of safety and efficacy of COVID-19 vaccine among children before they receive the vaccine.

Estimated Group Size

There are well over 80 million children (infant – 19 years of age) in the United States.

Population: Workers in Both Industries Essential to the Functioning of Society and at Moderately High Risk of Exposure

Examples of such occupational groups include workers in restaurants, hotels, and the entertainment industry; in banks and libraries; and in hair and nail salons, barber shops, and exercise facilities, or in factories or other goods producing facilities. Many of these workers are among the DHS designated categories of "Essential Critical Infrastructure Workers" and include workers whose job is of economic importance, and who have continued to work from outside their homes since the beginning of the pandemic. However, their risk of exposure or severe illness is lower than that of members of Phase 2. The jobs of some of these workers are primarily in settings where distancing and other protective measures can be implemented without great difficulty, but who may still be at increased risk. There are others in this population group, like those employed in entertainment, who cannot easily social distance or use PPE, but whose industry was not considered as essential to societal functioning and was therefore suspended at the beginning of the pandemic.

Rationale

These workers play important roles in society; are central to the return of commerce; and are often exposed to large numbers of individuals in the performance of their jobs. Their safe return to work is important as society re-opens and, comparing this cohort of workers to those discussed in Phase 2, their inclusion in Phase 3 focuses more on prevention of transmission of COVID-19. In comparison to workers called out in Phase 2, workers in Phase 3 are likely to have lower exposure risk to COVID-19 through their occupation, hold a role that is considered less central to economic and social recovery, or both. Nonetheless, including this group in Phase 3 will support social and economic recovery and restoration as access to the vaccine becomes more widespread.

Estimated Group Size

The workers included here cover a wide variety of industries that are important to societal function and reopening. Among those listed included restaurant wait staff (nearly 2.6 million), hotel cleaning and management staff (nearly 1.2 million), bank tellers (442,000), librarians (136,000), barbers, hair stylists and cosmetologists (406,000), and exercise instructors (326,000)

(BLS, 2019a). Ideally, these workers included in this group would cover 80 percent of those from industries deemed to be essential.

Phase 4

Phase 4 includes everyone residing in the United States. who did not receive the vaccine in previous phases (and for whom the vaccine is not medically contraindicated, though none are known at this time). In a pandemic caused by a new pathogen, most—if not all—individuals are at risk of being infected by the pathogen. Estimates in the percent of the population with immunity vary for COVID-19 and the efficacy of COVID-19 vaccines is yet to be determined (Britton et al., 2020). Therefore, precise estimates of target vaccination coverage are not available. Nevertheless, resumption of social functions will require high vaccination coverage in the general population. Moreover, individuals have the right to protect themselves against SARS-CoV-2 and thus the right to have equitable access to vaccines against this virus in a timely manner. Therefore, the Unites States should ensure that all U.S.-based individuals who did not receive the vaccine in previous phases (and for whom the vaccine is not medically contraindicated) receive the vaccine within the first 12-18 months after the commencement of the vaccine roll out.

Ensuring Equity

As discussed earlier in this chapter, the principles and allocation criteria underlying these phases explicitly avoid perpetuating health inequities, while implicitly valuing the essential social roles played by individuals in groups that have faced discrimination, as well as their greater risk due to health conditions reflecting inequities (Karaca-Mandic et al., 2020). In defining each priority group, the committee has considered their equity implications. For example, it has included all health care staff at the risk of infection exposure, and not those who are better paid (e.g., physicians, nurses). Each phase gives equal priority to all individuals in a group, facing similar exposure and with similar vulnerability. Nonetheless, when applying these criteria, vaccine distribution systems must actively ensure equity.

Social Vulnerability Index

The data clearly demonstrate that people of color—specifically Black, Hispanic or Latinx, and American Indian and Alaska Native—have been disproportionately impacted by

COVID-19 with higher rates of morbidity, mortality, and transmission. As previously mentioned, there is currently no evidence that this is biologically mediated, but rather reflects the impact of systemic racism leading to higher rates of comorbidities that increase the severity of COVID-19 infection and the socioeconomic factors that increase likelihood of acquiring the infection.

The committee's allocation framework focuses on these underlying causes through the application of CDC's Social Vulnerability Index within its framework instead of focusing on discrete racial and ethnic categories. Vaccine should be allocated in adequate quantities to areas of high social vulnerability and delivered, in a timely manner, at locations accessible to the populations living in those areas. CDC's Social Vulnerability Index, developed for local preparedness for public health emergencies such as natural disasters and disease outbreaks, identifies geographic areas of vulnerability based on 15 census variables (ATSDR, 2018). These variables capture many recognized social determinants of health (e.g., income or race/ethnicity), indicators of access (e.g., transportation), infection transmission (e.g., crowding), increased risk of adverse COVID-19 outcomes (e.g., proportion 65 or older). This index can be calculated at the census tract level—enabling immunization programs to better identify areas of vulnerability. Using CDC's Social Vulnerability Index in the committee's framework represents an attempt to incorporate the variables that the committee believes are most linked to the disproportionate impact of people of color. While other equity considerations such as disability status and age are partially addressed in the criteria underlying the phases, there are additional concerns that need to be addressed. For example, the ability of frail or disabled individuals to access vaccination location must be taken into account while operationalizing vaccine access and delivery.

Costs Associated with Vaccination

Several vaccines under development have received considerable taxpayer support. Therefore, it is essential that COVID-19 vaccines are delivered through a central mechanism that ensures vaccines to all individuals whatever their social and economic resources, employment, immigration or insurance status. This is especially a concern when vaccine courses are administered through private health providers, who may otherwise demand fees for the service. In the national interest, Medicare and Medicaid should require free vaccine administration; providers should not charge private plans or consumers; and private insurers and employers should not charge co-pays or deductibles for vaccine administration.

The 2020 Coronavirus Aid, Relief, and Economic Security (CARES) Act requires health insurance plans (group and individual) to offer vaccination without patient cost sharing (Section 3203) (KFF, 2020). The Patient Protection and Affordable Care Act (ACA) required all private insurance coverage to cover—without cost-sharing—immunizations that have a favorable ACIP rating, but the CARES Act requires the coverage to begin within 15 days of the ACIP recommendation, rather than the ordinarily much longer lag time.

For those on Medicare, Part B will cover co-pay or administrative charges (Section 3713). Those on Medicare Advantage plans are similarly covered. The U.S. Department of Veterans Affairs covers immunizations but service members and their families may have to pay for the cost of an office visit.

For Medicaid, coverage depends on the several factors. Most state Medicaid agencies cover at least some adult immunizations but not all offer vaccines at the ACIP standards. Generally, Medicaid covers ACIP-recommended vaccines for all beneficiaries up to age 21 under the program's Early and Periodic Screening, Diagnostics, and Treatment (EPSDT) program. For children under 19, the Vaccines for Children Program guarantees free vaccination to uninsured, underinsured, and American Indian and Native Alaskan children. Adults in a Medicaid expansion plan or an Alternative Benefit Plan also receive ACIP-recommended vaccines with no cost sharing. But for other adults, who are not in states with Medicaid expansion and who are on traditional Medicaid coverage, it is up to each state to determine whether to cover vaccines. There is an incentive to do so, as states that cover ACIP-recommended vaccines and all the services recommended by the U.S. Preventive Services Task Force may be eligible for increased federal payments. However, a survey of states prior to the pandemic showed that only 22 were offering the full list of ACIP-recommended adult vaccinations under their program (Granade et al., 2020; Shen and Orenstein, 2020).

Additional resources are available to cover eventual COVID-19 vaccines for the uninsured, including funds made available in the CARES Act through the Public Health and Social Service Emergency Fund. The federal government has also used authorities under Section 317 of the Public Health Service Act to make vaccines available to uninsured adults. As of October 1, 2012, Section 317-funded vaccines can be used to vaccinate uninsured or underinsured adults, and for fully insured individuals seeking vaccines during public health

response activities including outbreak response, mass vaccination campaigns or exercises for public health preparedness and individuals in correctional facilities and jails.

Legal Status

All individuals in the United States and its territories should receive the vaccine in the appropriate phase irrespective of their legal status, and individuals whose legal status is uncertain should be reassured that their coming forward to receive the vaccine will not lead to deportation or be used against them in immigration proceedings. In addition to considerations of equity and fairness, including all individuals in the immunization program is appropriate from a disease control perspective. If there are pockets of susceptibility among those who do not receive the vaccine, the risk of outbreaks is likely to increase for everyone—including those who are legally present in the United States—as no vaccine is 100 percent effective.

Considerations for Pregnant Women

While data on the risk of adverse outcomes associated with COVID-19 in pregnancy are uncertain, current evidence suggests that pregnant women are more likely to be hospitalized with COVID-19 than non-pregnant women (CDC, 2020h). Therefore, it is concerning that most, if not all, of the current Phase II/III trials exclude pregnant women; thus, putting them at a disadvantage for protecting themselves against SARS-CoV-2. OWS, NIH, and CDC should include assessment of vaccine efficacy, effectiveness, and safety among pregnant women in their clinical development and post-marketing surveillance plans. These data, and characteristics of the approved vaccine(s), will enable ACIP to develop recommendations for vaccinating pregnant women against SAS-CoV-2.

Vaccine Allocation for the Military

The U.S. military, which is tasked with protecting the United States from foreign threats, currently comprises approximately 1.2 million active duty troops, 781,000 reservists, and 728,000 civilian employees working for the U.S. Department of Defense (DoD, 2020). The U.S. military has its own health care system, which serves active duty troops and their dependents; they live in diverse settings inside and outside the United States, ranging from onboard ships to military bases to civilian communities. Among active duty troops and their dependents are individuals at varying levels of risk of infection and life-threatening complications of COVID-

19, including frontline health care providers; those living in congregate settings or in tightly confined spaces (e.g., outbreaks have occurred on U.S. naval ships): and those with underlying comorbid conditions associated with an increased risk of severe COVID-19, among others. While the U.S. military has separate advisory groups (e.g. the Armed Forces Epidemiology Board) and decision-making processes with regard to health care, disease prevention, and public health, in the absence of a separate allotment of COVID-19 vaccine to the U.S. military, the committee recommends that priority setting for the use of COVID-19 vaccine among active duty troops and their dependents, as well as reservists, follow the principles and criteria set forth for use in the civilian population. Civilian employees working for DoD should be considered for COVID-19 vaccination, as appropriate, through programs established to provide vaccine to other civilian populations.

Vaccine Allocation for Volunteer Participants in Vaccine Trials

There is a long tradition in biomedical research of offering research volunteers priority access to interventions following trials (Cook, 2015; Emanuel et al., 2020; Resnik, 2018). . Given this precedent, the committee assumes that volunteer participants in vaccine trials will be vaccinated early *regardless* of the committee's phased prioritization scheme because doing so is a typical standard of vaccine trial protocol.

The ethical principle underlying this allocation priority is the principle of fairness, which includes what is often called reciprocity. This prioritization acknowledges the service that volunteers have provided and the additional risk they have assumed in participating in the trial, irrespective of any financial compensation for research subjects. A further justification for including COVID-19 Phase III vaccine trial volunteers as an early priority group is the possible effect on motivation to volunteer for trials, which may in turn increase the pace of recruitment into trials and decrease the time needed to complete the target enrollment.

The anticipated total in this group is approximately 150,000 individuals. OWS expects to support up to seven Phase III trials of promising vaccine candidates, of which two are underway in the United States as of mid-August 2020. Each Phase III trial plans to enroll approximately 30,000 participants. The total calculated here assumes that

- Four of the trials will fail, and *all* subjects in those trials are offered access to an approved vaccine (4 × 30,000 = 120,000)
- Three of the trials will succeed, and, under a 1:1 ratio between members of the treatment group compared to the placebo group, 15,000 participants from each of those trials who were assigned to the placebo condition are offered an approved vaccine (3 x 15,000 = 45,000) (HHS, 2020; NIH, 2020a,b).

Limitations and Additional Considerations on the Framework

The committee notes the following limitations and considerations as SLTT authorities adapt it to their local conditions. First, the phases identify population groups of similar priority. Within phases, authorities have the flexibility to adapt to their conditions. For example, some counties have no tertiary hospitals and are served by neighboring counties, and others may have chicken and pork production facilities. Some areas may have no evidence of virus spread and be given a lower geographic priority as compared to other areas of a state. SLTT authorities will have to make final decisions on refining and applying the suggested priorities listed here. In so doing they can refer to the principles and allocation criteria that guided the formulation of the phases.

Second, the committee acknowledges the risk of potential unintended consequences of the allocation framework and the need to assess prioritization based on operational and supply realities. For example, immunizing older adults early on, and the resulting perception of their security, could "neutralize" one of the key reasons used to encourage younger people to follow guidance on preventive measures currently being encouraged to prevent the spread of COVID-19. This argument could apply to everyone who receives the vaccine and chooses not to be careful in regards to following key preventive measures. As such, the committee acknowledges that SLTT authorities and other decision makers need to remain vigilant of these realities and other public health interventions being implemented in tandem with the vaccine allocation and distribution.

Third, the committee recognizes that properly classifying individuals in specific categories described above may be difficult to do in practice given the need to sort people based on individual level information, some of which may be difficult to collect or ascertain. Furthermore, as noted earlier, the dynamic nature of the COVID-19 pandemic means that

features of the pandemic will change over time and collective understanding of its effects will, too (e.g., the list of comorbid conditions that put individuals at higher risk of severe disease or death due to COVID-19 infection).

Last, it is critical to acknowledge the limitations around the use of demographic data across phases in this chapter. The task of accurately describing the total number of individuals included in each priority group and phase was challenging because of the near-certain—and as of yet uncaptured—overlap between individuals counted across phases. For example, there is likely significant overlap between those counted above in the nursing home population and the population of older adults living in overcrowded settings, and significant overlap between members of multigenerational families and other categories listed in earlier phases, such as occupational groups. As such, the committee acknowledges that the population estimates provided serve as a guidepost for the general size of key priority groups discussed, but do not reflect a wholly accurate and nuanced analysis of phase population size in relation to one another.

CONCLUDING REMARKS

This iterative vaccination allocation framework will be dynamic and hopefully ever-improving. While current population data values are large, values for each group will be improved as the program is underway. Populations in each phase, especially in Phases 1a and 1b, may well exceed the vaccine available. In such a case, SLTT authorities should make best efforts to complete each phase before proceeding to the next phase. Additional adjustments in response to new evidence and data will be made as necessary. For example, the committee will consider new information on important vaccine characteristics emerging from vaccine trials and other sources such as the number of vaccine courses to be made available, considerations for special populations (e.g., pregnant women or individuals previously infected with COVID-19), anticipated vaccine efficacy, and anticipated vaccine safety and pharmacovigilance planning as it becomes available. Making mid-course corrections will be the rule rather than the exception and will be dependent on real-time surveillance of all aspects of the program.

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Applying the Framework for Equitable Allocation of COVID-19 Vaccine in Various Scenarios

At the time of writing, no COVID-19 vaccine has been approved for use in the U.S. population, although a number of clinical trials are underway. There are many uncertainties regarding if and when vaccines against COVID-19 will become available, under what regulatory framework they will be approved for first use, what their ultimate product profiles will be (e.g., in terms of efficacy among different age groups, dosage schedule(s), and safety/adverse reactions), as well as the schedule and timelines for expanding vaccine supply availability (e.g., when doses will become available and how quickly supply will expand). Chapter 2 of this report outlined the foundational principles and allocation framework to be used in guiding the fair and equitable use of scarce COVID-19 vaccine supply. This section envisions potential scenarios that federal, state, local, tribal, and territorial (SLTT) authorities may face in the use of new COVID-19 vaccines. Consequently, this section starts with describing the best scenario. Subsequently, the section identifies the possible and, in some cases, probable, deviations from this ideal scenario.

AN ADAPTABLE AND DYNAMIC FRAMEWORK

It is important to emphasize that, whenever they become available, COVID-19 vaccines will be added to an already complex (and evolving) mix of public health strategies that include: nonpharmaceutical interventions (NPIs) (such as mask usage, physical distancing, hand washing, etc.); expanded diagnostic testing linked to contact tracing, isolation, and quarantine (TTIQ) strategies aimed at containing transmission, suppressing outbreaks, and interrupting super-spreading events; and the deployment of therapeutic measures that mitigate morbidity and mortality and, ultimately, curtail transmission from those who do become infected (CDC, 2020; IOM, 2004; CDC, 2017). The principle that public policy should be evidence-based is essential to guiding the allocation of scarce countermeasures.

Box 6 outlines some of the key uncertainties regarding COVID-19 vaccines. Given these uncertainties, SLTT authorities will need to be ready for varied and sometimes unexpected scenarios in determining how best to use their federal allocation.

BOX 6

Uncertain Factors Affecting Vaccine Allocation

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

An ideal COVID-19 vaccine would be a one-dose vaccine that produces high levels of neutralizing antibodies in all age groups, prevents moderate-to-severe disease as well as infection, prevents transmission from infected individuals to other susceptible persons,[27] has very

[27] Current clinical trials are focused on clinical endpoints related to infection or mild-moderate symptomatic COVID syndrome and do not explicitly address the issue of transmission blocking.

mild adverse reactions, has no severe adverse effects, and provides long-term protection. This is the "best" scenario because such a product profile would be most compatible with widespread use of the vaccine, both for personal protection and outbreak interruption. It would also be the scenario that produces the greatest demand for the vaccine. Few vaccines will have such an ideal product profile, with each shortcoming reducing demand (e.g., lack of efficacy in some age groups, complex administration, adverse reactions), as will vaccine hesitancy.

While major efforts are being made by the federal government through Operation Warp Speed (OWS) to have a significant supply of vaccine as soon as possible, the committee has been tasked with considering the tough choices that will need to be made with the tightly constrained initial supplies (e.g., 10–15 million doses, enough to vaccinate 3–5 percent of the U.S. population). In the initial period when demand exceeds supply, the committee, in Chapter 2, recommended a phased approach, guided by evidence to maximize societal benefit by reducing morbidity and mortality caused by the transmission of novel coronavirus. As highlighted above, a range of uncertain factors related to the available vaccine(s) may affect the implementation of the framework. Table 3 at the end of this chapter summarizes how the framework could be affected in various scenarios.

Number and Timing of Available Vaccine Doses

OWS estimates that it will begin delivery of COVID-19 vaccines by January 2021. However, given the uncertainty regarding how many doses will actually be available by January 2021, available vaccines should initially be allocated to individuals according to the phases described in Chapter 2.

It is possible that the vaccine will require two doses instead of one to ensure adequate protection (IOM, 2013). In this case, two doses will be allocated to each person so that, in effect, half as many people could be vaccinated. Vaccination would still follow the proposed allocation framework, but some individuals would receive vaccination later. If the vaccine requires two doses, strategies and systems (e.g., use of established providers or use of federally qualified health centers) are necessary to help ensure continuity of care between the first and second dose. This is important because if efficacy with only one dose is low, individuals who receive only one dose are effectively unvaccinated and that vaccine dose was in essence wasted.

A related issue is durability of protection. It may be that duration of protection is short enough that people vaccinated in an early phase must receive a booster dose before some individuals in later phases receive vaccination. Again, vaccination would still follow the proposed allocation framework, but some individuals in subsequent phases would receive vaccination later.

Vaccine Efficacy

Trials of a number of candidate vaccines are currently underway, but at this time the likely efficacy of each COVID-19 vaccine in preventing infection or in preventing severe disease is unknown. The level of efficacy in preventing infection will affect transmission of the infection in the population, and the level of efficacy in preventing severe disease will affect demand for acute and intensive hospital care—key factors relating to future management of COVID-19. Vaccine efficacy may also differ in different population groups (e.g., it might be less efficacious in older adults). Moderate to low efficacy may lead people to reject the vaccine, believing their risk of side effects or the "unknown" outweigh the benefit of vaccination (Smith, 2017).[28] Epidemic modeling—once a vaccine becomes available—could be useful to determine whether individuals in the priority groups identified in the committee's framework should still be offered vaccination if the vaccine is determined to be less efficacious for their group. Once widespread vaccination commences, presumed efficacy may be influenced by how adherent people are to other basic protective measures such as masks and social distancing (CDC, 2020). Additional public messaging about maintaining such behaviors may be called for, particularly if people who are vaccinated erroneously believe they are no longer at risk of infection or transmission.

Vaccine Safety

Significant numbers of individuals must be vaccinated before vaccine safety is fully understood. When a vaccine becomes available, the knowledge concerning vaccine safety will be based on existing clinical trials which, of necessity, are limited. If it is found that certain population groups (e.g., children or older adults) experience significant side effects from the

[28] To ensure that a widely deployed COVID-19 vaccine is effective, FDA stated the primary efficacy endpoint point estimate for a placebo-controlled efficacy trial should be at least 50 percent, and the statistical success criterion should be that the lower bound of the appropriately alpha-adjusted confidence interval around the primary efficacy endpoint point estimate is >30 percent. https://www.fda.gov/media/139638/download (accessed August 18, 2020).

vaccine, it may be advisable to allocate the vaccine with caution to such population groups or to reallocate it to a different group that is less vulnerable to those particular side effects. As the vaccine starts to be allocated broadly in the U.S., monitoring of side effects and possible adjustment of the allocation framework are essential to minimize possible side effects in the population, while maximizing benefit by preventing deaths and severe disease. Effective collection and communication of evidence regarding population effects, both efficacy and adverse effects, are also essential to securing and maintaining public trust. Additionally, vaccinated individuals should be assured of compensation (especially for health care costs) for vaccine-related injuries. If the Department of Health and Human Services issues a Public Readiness and Emergency Preparedness (PREP) Act declaration, preempting state tort remedies, the government must then fully fund and make accessible PREP Act compensation. Failing to do so will lead to distrust and anger if and when adverse events arise.

Vaccine Uptake

Vaccine hesitancy has been well documented among numerous population groups in the United States. The COVID-19 vaccine is no exception: Many individuals will be hesitant to receive a new COVID-19 vaccine, particularly if there are perceived safety concerns or if vaccine efficacy is thought to be relatively low. Vaccine hesitancy will also be greater if there is any suspicion that political or economic considerations have influenced the vaccine safety assessments made by government regulatory or advisory bodies, such as the Food and Drug Administration and the Advisory Committee on Immunization Practices (ACIP). It may be that some people are "COVID-vaccine hesitant" and do not want to be vaccinated when it is offered to them—despite their individual risk—but would be willing to be vaccinated later when more evidence about vaccine safety has accrued. Thus, although an individual may be prioritized in our allocation framework, that person may refuse to be vaccinated when vaccination is offered to them, in which case the vaccine should be offered to another individual within that priority group. Of course, if enough individuals refuse to accept the vaccine, the resulting population protection (reduction in deaths and COVID-19 transmission) due to the vaccine may not be high.

Messages about vaccine safety and efficacy are essential for all people and at all phases. Direct-to-consumer advertising may influence public perceptions and preferences. It is critical that the communication campaign accompanying the vaccine outline the risks and benefits of the

vaccine in a way that members of the population can understand (Malik et al., 2020). Health care providers can also play an important role in communicating vaccine risks and benefits to their patients. Additionally, if vaccine uptake is low, the idea of adhering to an allocation framework could lead some providers to shift to lower priority groups or be left with excess vaccine stock. Programs should do everything possible to reach all individuals in one priority group, before proceeding to the next one. That will include making special efforts to address issues related to health inequities that may reduce trust in some groups or make health care less accessible to them.

Number and Timing of Available Vaccine Types

It is possible that multiple vaccine types, and not just a single vaccine, will be made available in early 2021. If this happens, the available vaccines might be rated on a spectrum by ACIP with recommendations about which groups should receive which vaccines. The available vaccines may have major differences in important features (e.g., safety and efficacy, overall and in different populations; duration of protection; robustness of immune response; etc.) and it is important to determine which vaccine is best for different groups, based on all the information available when a vaccine is released. Vaccines would still be allocated to the different phases, with the rate of allocation to different groups determined by availability of the vaccine(s) for that group. For example, if Vaccine A is determined to be best for individuals in Phases 1 and 4, and Vaccine B is determined to be best for individuals in Phases 2 and 3, then vaccination with Vaccine A would proceed for individuals in Phase 1 followed by Phase 4, while vaccination with Vaccine B would proceed for individuals in Phase 2 followed by Phase 3. It is also possible that, after an initial vaccine is made available, a safer or more effective vaccine may be released. In this case, vaccine allocation must take into account the benefits and harms of the vaccine for each particular population group. To the extent possible, vaccines would continue to be made available in the same phases as outlined in the framework. However, if a particular vaccine is inappropriate for use by a particular group, that group would need to wait for a new form of a vaccine, and the existing vaccine might be provided to those who otherwise are slated for a later phase. With multiple available vaccines, it is particularly important to monitor safety and efficacy as immunization efforts progress so as to ensure that different population groups receive an appropriate vaccine.

Epidemic Conditions and Immune Status

At the time of writing, COVID-19 is spreading widely in the U.S., across many states and jurisdictions, with 50,000–70,000 newly identified cases each day and 1,000–2,000 deaths daily. Increasing numbers of cases are occurring among younger people, who are also thought to be key agents in transmitting the disease. It is currently not known how long immunity from COVID-19 infection lasts, nor the extent to which transmission may be reduced in different populations due to more people acquiring immunity from having been infected. If sufficient numbers of individuals in a population group are immune due to previous infection, then it may be that scarce vaccine doses should be allocated to individuals in other prioritized population groups. Conversely, if the infection is found to be spreading particularly rapidly in a particular geographic region or population group, it may be reasonable to prioritize allocating vaccines to that region or group. This could be done by holding back a certain fraction of vaccine doses (e.g., 10 percent) for use in vaccinating individuals in COVID-19 "hot spots" who are at high risk of infection and who cannot protect themselves.

Personal protective behavior—such as sheltering in place, social distancing, and wearing face masks—also affects the spread of COVID-19 (CDC, 2020). It is essential that vaccinated individuals be encouraged to engage in personal protective behavior to the extent that they are able to.

Vaccine Distribution and Administration

Specific details of how the COVID-19 vaccine will be distributed and administered have not been fully determined at this time. The vaccine is being developed through the federal OWS initiative, and presumably the federal government will issue guidelines for allocation, distribution, and administration of the vaccine. The extent to which states will be obligated to follow such guidelines is not known. Such state-level decisions will affect the implementation of the vaccine allocation framework. As an example, a state may make a commitment to set aside a certain fraction of vaccine doses for tribal governments in that state (this would be a supplement to what would be allocated by the federal government through the Indian Health Service).

Social, Economic, and Legal Contexts

The social, economic, and legal contexts will affect vaccine distribution and uptake. For example, if some health insurers, care providers, or employers fail to cover the full vaccine administration cost, the allocation framework is unchanged, but the federal government or states should make efforts to provide funds to cover the cost of vaccine administration (and other vaccination costs) for low-income individuals.

Once vaccine availability has increased sufficiently and vaccine safety in younger groups has been assessed, children will be offered a COVID-19 vaccine (Mello et al., 2020). Historically, the most effective way to ensure broad uptake of vaccine in children is through mandates that condition school attendance on evidence of vaccination or an accepted reason for exemption, such as a medical contraindication. There will certainly be wide variation among states and even within states regarding such mandates, particularly with respect to whether non-medical exemptions will be allowed. To ensure an orderly return to schools, states may benefit from having their mandates clarified by attorneys general issuing interpretations of existing authorities and their departments and agencies issue interpretative guidance, or by considering ways to tighten existing law regarding exemptions. Despite the allocation framework, it is possible that some school districts may be tempted to mandate vaccination of schoolchildren immediately, as a means of moving more quickly toward re-opening schools. At a state level, this would allocate the vaccine in a manner different from the committee's proposed allocation framework (i.e., by prioritizing schoolchildren).

Another possibility is that some employers would require employees to be vaccinated or to have some evidence of prior infection (on the employer's assumption that this confers immunity) (Phelan, 2020). If a state is not allocating vaccine supplies in accordance with the recommended phases, this would divert vaccine supplies toward many who are not in the higher risk categories described in Phases 1 and 2. If large employers acquire doses of the vaccine, as has happened in the past with 2009 H1N1 vaccines, this could limit supplies available to state and local health departments. Although there is precedent for employers requiring vaccination, subject to some limitations based on union agreements or religious exemptions, (e.g., many hospitals and nursing homes require employees to be vaccinated against the flu) a number of concerns arise when vaccine supply is limited, as it will be with COVID-19 vaccine(s). If employers require vaccination, the allocation framework would be unchanged, but pressure

would certainly be brought to bear on health care providers by people needing to maintain their employment, regardless of whether they are at high risk of infection. Such a requirement could change rates of vaccine uptake, and would pose a dilemma for those individuals for whom the vaccine is medically contraindicated—either take the vaccine or lose employment—and would be a possible violation of the Americans with Disabilities Act (Yang et al., 2020). Mandated vaccination could also violate Title VII of the Civil Rights Act of 1964 if there is a religious exemption or could violate collective bargaining rights (in unionized workplaces). Additionally, it is important to note that the equitable allocation scheme will fail if a separate private vaccine market emerges for those who can pay the most. SLTT authorities should not waiver from their adherence to the proposed equitable allocation scheme to satisfy the demands of private employers or institutions that are seeking or requiring vaccination of all workers.

As a final example, if states do not provide free vaccine access to people without documentation of legal status, then the allocation framework is unchanged, but other sources of financial support (e.g., philanthropy, health systems, pharmaceutical companies) will be needed to assure access to vaccination for those individuals.

2428 **DRAFT TABLE 3** Summary Table of the Application of the Committee's Framework in Various Scenarios

Scenario	Change in Allocation Framework
Number and Timing of Vaccine Doses	
Fewer vaccine courses available than expected by Operation Warp Speed	Allocation framework is unchanged. Some individuals receive vaccination later than they would otherwise.
Vaccine requires two doses, rather than one	Allocation framework is unchanged, but some individuals receive vaccination later. Vaccination should use strategies and systems (e.g., use of established providers or use of federally qualified health centers) to ensure continuity of care between the first and second dose.
Number of Vaccine Types	
More than one vaccine type available	Allocation framework is unchanged, but which vaccines are allocated to which population groups must take into account the benefits and harms of the vaccine for each population group.
Vaccine Efficacy	
Low vaccine efficacy among older adults or other population subgroup	Only allocate to this population subgroup if vaccine benefits outweigh the risks.
Vaccine Safety	
Unanticipated vaccine side effects	Continuously monitor vaccine safety as the vaccine is rolled out. Only allocate to individuals for whom vaccine benefits outweigh the risks
Significant vaccine side effects among older adults or other population subgroup	Continuously monitor vaccine safety as the vaccine is rolled out. Only allocate to this population subgroup if vaccine benefits outweigh the risks.
Vaccine Uptake	
Vaccine uptake is lower than expected	Allocation framework is unchanged. The communication campaign accompanying the vaccine must outline the risks and benefits of the vaccine in a factual way that members of the population can understand.
Epidemic Conditions and Immune Status	
Epidemic spread is continuing across much of the U.S. when the vaccine becomes available	Allocation framework is unchanged. Public health messages must continue to stress the need for personal protective measures (e.g., masks, social distancing).
Epidemic is spreading most rapidly in particular hot spots when the vaccine becomes available	A certain fraction of vaccine courses (e.g., ten percent) is reserved for vaccinating individuals in hot spots. Public health messages must continue to stress the need for personal protective measures (e.g., masks, social distancing).
Vaccine Distribution and Administration	

States are required to follow federal guidelines for vaccine allocation	Allocation framework is unchanged.
States have some leeway in the extent to which they follow federal guidelines for vaccine allocation	States adapt the allocation framework to their needs (e.g., they may set aside a certain number of doses for particularly vulnerable populations in their state).
Social, Economic, and Legal Contexts	
Some health insurers do not cover full vaccine administration cost	Allocation framework is unchanged, but the federal government or states should make efforts to provide funds to cover the cost of vaccine administration (and other vaccination costs) for low-income individuals.
Some employers require proof of vaccination	Allocation framework is unchanged, but such requirements could change rates of vaccine uptake, and would pose hazards for those individuals for whom the vaccine is medically contraindicated and could raise issues around discrimination against those unable to obtain the vaccine and therefore unable to work
Some states mandate vaccination of schoolchildren	Allocation framework is unchanged, but states mandating vaccination of schoolchildren might allocate the vaccine in a manner different from the Committee's proposed allocation framework (i.e., prioritize schoolchildren)
Some states do not provide free vaccine access to people without documentation of legal status	Allocation framework is unchanged. Other sources of financial support (e.g., philanthropy, health systems, pharmaceutical companies) should be sought to provide vaccination for those individuals.

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This discussion draft was reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise. The purpose of this independent review is to provide candid and critical comments that will assist the National Academies of Sciences, Engineering, and Medicine in making each published report as sound as possible and to ensure that it meets the institutional standards for quality, objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process.

We thank the following individuals for their review of this discussion draft:

G. CALEB ALEXANDER, Johns Hopkins Bloomberg School of Public Health
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CONSUELO WILKINS, Meharry-Vanderbilt Alliance

Although the reviewers listed above provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations of this discussion draft nor did they see the final draft before its release. The review of this discussion draft was overseen by **Bruce N. Calonge,** The Colorado Trust, **Ellen W. Clayton,** Vanderbilt University, and **Susan J. Curry,** University of Iowa**.** They were responsible for making certain that an independent examination of this discussion draft was carried out in accordance with the standards of the National Academies and that all review comments were carefully considered. Responsibility for the final content rests entirely with the authoring committee and the National Academies.

Appendix A

Committee Biosketches

William H. Foege, M.D., M.P.H. ***(Co-Chair)*****,** is Emeritus Presidential Distinguished Professor of International Health, Rollins School of Public Health, Emory University, and a Gates Fellow. Dr. Foege, an epidemiologist, worked in the successful campaign to eradicate smallpox in the 1970s. Dr. Foege became Chief of the U.S. Centers for Disease Control and Prevention's (CDC's) Smallpox Eradication Program, and was appointed director of the CDC in 1977. In 1984, Dr. Foege co-founded the Task Force for Child Survival, a working group for the World Health Organization, UNICEF, The World Bank, United Nations Development Programme, and the Rockefeller Foundation. Dr. Foege served The Carter Center between 1986–1992 as its Executive Director, Fellow for Health Policy and Executive Director of Global 2000. Between 1992–1999, he contributed to the Center's work as a Fellow and as Executive Director of the Task Force for Child Survival and Development. Between 1999–2001, Dr. Foege served as Senior Medical Advisor for the Bill and Melinda Gates Foundation.

Helene D. Gayle, M.D., M.P.H. ***(Co-Chair)*****,** has been president and chief executive officer (CEO) of The Chicago Community Trust, one of the nation's oldest and largest community foundations, since October 2017. Under her leadership, the Trust has adopted a new strategic focus on closing the racial and ethnic wealth gap in the Chicago region. For almost a decade, she was president and CEO of CARE, a leading international humanitarian organization. An expert on global development, humanitarian and health issues, Dr. Gayle spent 20 years with the Centers for Disease Control and Prevention, working primarily on HIV/AIDS. She worked at the Bill & Melinda Gates Foundation, directing programs on HIV/AIDS and other global health issues. She also launched the McKinsey Social Initiative (now McKinsey.org), a nonprofit that builds partnerships for social impact. Dr. Gayle serves on public company and nonprofit boards, including The Coca-Cola Company, Colgate-Palmolive Company, Brookings Institution, the Center for Strategic and International Studies, New America, the ONE Campaign, the Federal Reserve Bank of Chicago and the Economic Club of Chicago. She is a member of the Council on Foreign Relations, the American Public Health Association, the National Academy of Medicine, the National Medical Association and the American Academy of Pediatrics. Named one of Forbes' "100 Most Powerful Women" and one of NonProfit Times' "Power and Influence Top 50," she has authored numerous articles on global and domestic public health issues, poverty alleviation, gender equality and social justice. Dr. Gayle was born and raised in Buffalo, NY. She earned a B.A. in psychology at Barnard College, an M.D. at the University of Pennsylvania and an M.P.H. at Johns Hopkins University. She has received 18 honorary degrees and holds faculty appointments at the University of Washington and Emory University.

Margaret L. Brandeau, Ph.D., M.S., is the Coleman F. Fung Professor of Engineering and Professor of Medicine (by Courtesy) at Stanford University. Her research focuses on the development of applied mathematical and economic models to support health policy decisions. Her recent work has examined HIV and drug abuse prevention and treatment programs, programs to control the opioid epidemic, and preparedness plans for public health emergencies. She is a Fellow of The Institute for Operations Research and Management Science (INFORMS) and a member of the Omega Rho Honor Society for Operations Research and Management Science. From INFORMS, she has received the Philip McCord Morse Lectureship Award, the President's Award (for contributions to the welfare of society), the Pierskalla Prize (for research excellence in healthcare management science), and the Award for the Advancement of Women in Operations Research and the Management Sciences. She has also received the Award for Excellence in Application of Pharmacoeconomics and Health Outcomes Research from the International Society for Pharmacoeconomics and Outcomes Research and a Presidential Young Investigator Award from the National Science Foundation, among other awards. She is a member of the National Institutes of Health Office of AIDS Research Advisory Council and a member of the Stanford-Lancet Commission on the North American Opioid Crisis. She previously served as a member of the Board of Scientific Counselors, a Federal Advisory Committee to the Office of Public Health Preparedness and Response of the Centers for Disease Control and Prevention, and served on several Institute of Medicine committees. Professor Brandeau earned a BS in Mathematics and an MS in Operations Research from Massachusetts Institute of Technology, and a Ph.D. in Engineering-Economic Systems from Stanford University.

Alison M. Buttenheim, Ph.D., M.B.A., is an Associate Professor of Nursing and Health Policy at the University of Pennsylvania. Dr. Buttenheim is a leading expert in the application of behavioral economics to infectious disease prevention. Her research agenda has focused on vaccine acceptance and vaccine exemption policy in the United States, zoonotic disease prevention in Peru, and HIV prevention in South Africa. She is Associate Director of Penn's Center for Health Incentives and Behavioral Economics, as well as Associate Director of Penn's National Clinician Scholar Program, and Director of Engagement at the Leonard Davis Institute of Health Economics at the University of Pennsylvania. She was recently appointed Commissioner to the Lancet Commission on Vaccine Refusal, Acceptance, and Demand in the United States. Dr. Buttenheim holds a Ph.D. in Public Health from the University of California, Los Angeles, and an M.B.A. from the Stanford University Graduate School of Business.

R. Alta Charo, J.D., is the Warren P. Knowles Professor of Law and Bioethics at the University of Wisconsin, where she teaches public health law, biotechnology policy, and bioethics. In government, she has worked at the former congressional Office of Technology Assessment, the U.S. Agency for International Development, and the U.S. Food and Drug Administration. From 1996–2001, she served on President Clinton's National Bioethics Advisory Commission. A member of the National Academy of Medicine, Ms. Charo co-chaired the National Academies' committees that wrote guidelines for embryonic stem cell research and recommendations for U.S. policy and global principles regarding human genome editing. She was a member of the Institute of Medicine's committee on the safety of the pediatric vaccine schedule and the committee to review of the smallpox vaccine program. At present she is a member of the World Health Organization's committee on global governance of genome editing, and serves on several

National Academies of Sciences, Engineering, and Medicine activities, including committees on emerging infectious diseases and on emerging science and technology issues. She received her B.A. in biology from Harvard University in 1979 and her J.D. from Columbia Law School in 1982.

James F. Childress, Ph.D., M.A., is emeritus professor, previously University Professor, the John Allen Hollingsworth Professor of Ethics, Professor of Religious Studies, and Professor of Research in Medical Education at the University of Virginia. Dr. Childress also served as the Joseph P. Kennedy, Sr., Professor of Christian Ethics at the Kennedy Institute of Ethics at Georgetown University and a Visiting Professor at the University of Chicago Divinity School and Princeton University. In 1990, he was named Professor of the Year in the Commonwealth of Virginia by the Council for the Advancement and Support of Education, and in 2002 he received the University of Virginia's highest honor—the Thomas Jefferson Award. In spring 2010 he held the Maguire Chair in American History and Ethics at the Library of Congress. Dr. Childress is the author of numerous articles and several books in various areas of ethics, including (with Tom Beauchamp) *Principles of Biomedical Ethics,* now in its 8th edition and translated into several languages. Dr. Childress was vice chair of the national Task Force on Organ Transplantation, and he also served on the Board of Directors of the United Network for Organ Sharing (UNOS), the UNOS Ethics Committee, the Recombinant DNA Advisory Committee, the Human Gene Therapy Subcommittee, the Biomedical Ethics Advisory Committee, and several Data and Safety Monitoring Boards for National Institutes of Health clinical trials. He was a member of the presidentially appointed National Bioethics Advisory Commission (1996–2001). Dr. Childress is a member of the National Academy of Medicine and he has participated in and chaired several studies at the National Academies of Sciences, Engineering, and Medicine. His current research focuses on public bioethics, public health ethics, and just-war theory and practice. Dr. Childress received his B.A. from Guilford College, his B.D. from Yale Divinity School, and his M.A. and Ph.D. from Yale University.

Ana V. Diez Roux, M.D., Ph.D., M.P.H., is Dean and Distinguished University Professor of Epidemiology in the Dornsife School of Public Health at Drexel University. Dr. Diez Roux is internationally known for her research on the social determinants of population health, the study of how neighborhoods affect health, and urban health. Her work on neighborhood health effects has been highly influential in the policy debate on population health and its determinants. She has led large National Institutes of Health and foundation funded research and training programs in the United States and in collaboration with various institutions in Latin America and is currently Principal Investigator of the Wellcome Trust funded SALURBAL (Salud Urbana en América Latina) study. Dr. Diez Roux has served on numerous editorial boards, review panels and advisory committees including the Clean Air Scientific Advisory Committee of the Environmental Protection Agency (as Chair), the Board of Scientific Counselors of the National Center for Health Statistics, the Committee on Health and Wellbeing in the Changing Urban Environment of the International Council for Science, and the Center for Disease Control and Prevention's Community Preventive Services Taskforce. She has received the Wade Hampton Frost Award for her contributions to public health from the American Public Health Association and the Award for Outstanding Contributions to Epidemiology from the American College of Epidemiology. She is an elected member of the American Epidemiological Society and the

Academy of Behavioral Medicine Research. She was elected to the National Academy of Medicine of the National Academy of Sciences, Engineering, and Medicine in 2009.

Abigail Echo-Hawk, M.A., is an enrolled citizen of the Pawnee Nation of Oklahoma. She is currently the Chief Research Office at Seattle Indian Health Board and the Director of Urban Indian Health Institute, a national tribal epidemiology center serving urban-dwelling American Indians and Alaska Natives. Currently, Abigail is part of multiple committees, boards, and workgroups that are focused on ending health disparities through health equity approaches including the Best Starts for Kids Board, the March of Dimes Health Equity Workgroup, the Tribal Collaboration Working Group with the National Institutes of Health (NIH) All of Us Research Program, the Advisory Committee for Health Equity Research at the Robert Wood Johnson Foundation, the National Institute on Drug Abuse American Indian and Alaska Native Collaborative Research Engagement Workgroup, and Data for Indigenous Justice Board. In the past, Ms. Echo-Hawk spent eight years as the Tribal Liaison with Partnerships for Native Health at the School of Public Health at The University of Washington. In 2016, she became the Co-director of Partnerships of Native Health at the Washington State University Institute for Research and Education to Advance Community Health. Ms. Echo-Hawk was also the Tribal Relationship Facilitator at the Institute of Translational Health Sciences at the University of Washington from 2010 to 2015. In 2015, she became a Board Member for the Center for Indigenous Law and Justice. She has a B.A. in Interdisciplinary Studies and an M.A. in Policy Studies, both from the University of Washington who honored her with the Distinguished Alumna of the Year Award in 2011. She is an expert in American Indian and Alaska Native health, including strengths and resiliencies as well as disparities and was recently awarded the Washington State Public Health Association Secretary of Health Award and 2020 Indian Woman of the Year by a national organization of Indigenous women. Ms. Echo-Hawk began working in health equity in 2000 as a community advocate to address the high rates of infant mortality among American Indians and Alaska Natives (AI/AN). After recognizing the lack of evidence-based practices that were informed and shaped by AI/AN communities, she began working in research on health disparities and achieving health equity in 2010. Since then, she has been the tribal liaison for 26 multi-year, NIH-funded studies of Native health. Her role in each study was to ensure that relationships between academia and Native communities are bi-directional and grounded in health equity principles. In her current role as the Director of Urban Indian Health Institute (UIHI), she directs the only national tribal epidemiology center, and they are conducting COVID-19 epidemiologic surveillance with urban Indian health programs. In addition, UIHI is focused on health equity approaches ensuring AI/AN access to prevention and treatment of COVID-19 through Indigenous public health and epidemiology practices. An essential component of Ms. Echo-Hawk's work in facilitating protocols and ground rules for research partnerships has included negotiating equity through tribal data-sharing, control, and ownership. Many communities have experienced untrustworthy practices where agencies and individuals have exploited and used data with little to no meaningful impact, while people of color continue to bear the burden of health disparities. Data is increasingly valued as a resource that represents opportunities for improving community well-being and health outcomes if it is used in an equitable manner. Ms. Echo-Hawk works nationally with collaborative partnerships to ensure equitable health outcomes for people of color and other marginalized communities. Much of her work involves community-based participatory research, with a strong emphasis on cultural humility, respect for tribal sovereignty, and achieving health equity to undo health disparities. In

addition to many health equity-focused publications, she is a co-author of several manuscripts in development.

Christopher Elias, M.D., M.P.H., is the president of the Global Development Division at the Bill and Melinda Gates Foundation, where he leads the foundation's efforts in a diverse range of program areas aimed at finding creative new ways to ensure solutions and products get into the hands of people in poor countries who need them most. Focusing on areas with the potential for high-impact, sustainable solutions that can reach hundreds of millions of people, Dr. Elias oversees Global Development's portfolio in Emergency Response; Family Planning; Maternal, Newborn & Child Health; Nutrition; Polio Eradication; and Vaccine Delivery. A common theme of these programs is innovative and integrated delivery, including an emphasis on strengthening of primary health care systems. Dr. Elias' professional background is in public health and medicine. Prior to joining the Gates Foundation in February 2012, he worked in various positions and countries for international nonprofit organizations, most recently serving as the president and chief executive officer of PATH, an international, nonprofit organization dedicated to improving the health of people around the world by advancing technologies, strengthening systems, and encouraging healthy behaviors. Chris holds an M.D. from Creighton University, having completed postgraduate training in internal medicine at the University of California San Francisco, and an M.P.H. from the University of Washington, where he was a fellow in the Robert Wood Johnson Clinical Scholars Program. He is a member of the National Academy of Medicine.

Baruch Fischhoff, Ph.D., is Howard Heinz University Professor, Department of Engineering and Public Policy and Institute for Politics and Strategy, Carnegie Mellon University (CMU). A graduate of the Detroit Public Schools, he holds a B.S. (mathematics, psychology) from Wayne State University and a Ph.D. (psychology) from the Hebrew University of Jerusalem. He is a member of the National Academy of Sciences and of the National Academy of Medicine. He is past President of the Society for Judgment and Decision Making and of the Society for Risk Analysis. He has chaired the Food and Drug Administration Risk Communication Advisory Committee and been a member of the Eugene (Oregon) Commission on the Rights of Women, the Department of Homeland Security Science and Technology Advisory Committee and the Environmental Protection Agency Scientific Advisory Board, where he chaired the Homeland Security Advisory Committee. He has received the American Psychological Association (APA) Award for Distinguished Contribution to Psychology, CMU's Ryan Award for Teaching, an honorary Doctorate of Humanities from Lund University, and an Andrew Carnegie Fellowship. He is a Fellow of APA, the Association for Psychological Science, Society of Experimental Psychologists, and Society for Risk Analysis. His books include *Acceptable Risk*, *Risk: A Very Short Introduction*, *Judgment and Decision Making*, *A Two-State Solution in the Middle East*, *Counting Civilian Casualties*, and *Communicating Risks and Benefits.* He has co-chaired three National Academy Colloquia on the Science of Science Communication, as well as its committees on applying decision science to intelligence analysis and its committee on foundational science for cybersecurity.

David Michaels, Ph.D., M.P.H., is an epidemiologist and Professor of Environmental and Occupational Health at the Milken Institute School of Public Health of George Washington University. He served as Assistant Secretary of Labor for the Occupational Safety and Health

Administration from 2009 to 2017, the longest serving in the agency's history. From 1998 to 2001, Dr. Michaels was Assistant Secretary of Energy for Environment, Safety and Health, charged with protecting the workers, community residents, and environment in and around the nation's nuclear weapons facilities. In that position, he was the chief architect of the historic initiative to compensate nuclear weapons workers who were sickened by radiation, beryllium, and other toxic exposures. Much of Dr. Michaels' work has focused on protecting the integrity of the science underpinning public health, safety, and environmental protections. On this topic, he is the author of *Doubt is Their Product: How Industry's Assault on Science Threatens Your Health* (Oxford University Press, 2008) and *The Triumph of Doubt: Dark Money and the Science of Deception* (Oxford University Press, 2020). He is a recipient of the American Association for the Advancement of Science's Scientific Freedom and Responsibility Award, and the American Public Health Association's David P. Rall Award for Advocacy in Public Health. Dr. Michaels is a member of the Board of Scientific Counselors of the National Toxicology Program, the Administrative Conference of the United States, and the Lucian Leape Institute of the Institute for HealthCare Improvement. He currently provides consulting advice on protecting workers from COVID-19 exposure to the Actors' Equity Association and the National Football League Players Association.

Jewel Mullen, M.D., M.P.H., M.P.A., FACP, is Associate Dean for Health Equity and Associate Professor of Population Health and Internal Medicine at the University of Texas at Austin Dell Medical School, as well as Director of Health Equity at Ascension Seton. An internist and psychosocial epidemiologist, Dr. Mullen is the former Principal Deputy Assistant Secretary for Health at the U.S. Department of Health and Human Services where she also served as the acting Assistant Secretary for Health and acting Director of the National Vaccine Program Office. Formerly the commissioner of the Connecticut Department of Public Health, she led the agency's successful implementation of an expanded childhood vaccine program. She also completed bioethics training and served on the Ethics Consultation Service at the University Of Virginia School Of Medicine. A former President of the Association of State and Territorial Health Officials, Dr. Mullen is a current member of the Center for Disease Control and Prevention's Morbidity and Mortality Weekly Report Editorial Board. She also serves on the COVID-19 Expert Advisory Panel for the City of Austin, Texas.

Saad B. Omer, Ph.D., M.P.H., M.B.B.S., FIDSA, is the Director of the Yale Institute for Global Health, a Professor of Medicine and Epidemiology at Yale University, Schools of Medicine and Public Health and an Adjunct Professor at Yale School of Nursing. He has conducted studies in the United States, Guatemala, Kenya, Uganda, Ethiopia, India, Pakistan, Bangladesh, Australia and South Africa. Dr Omer's research portfolio includes epidemiology of respiratory viruses such as influenza, RSV, and—more recently—SARS-Cov-2 (COVID-19); clinical trials to estimate efficacy of maternal and/or infant influenza, pertussis, polio, measles and pneumococcal vaccines; and trials to evaluate drug regimens to reduce mother-to-child transmission of HIV. Moreover, he has conducted several studies on interventions to increase immunization coverage and acceptance. His work has also included public health preparedness strategies to effectively respond to large emerging and re-emerging infectious disease outbreaks. Dr Omer's work has been cited in global and country-specific policy recommendations and has informed clinical practice and health legislation in several countries. Dr. Omer is the Co-Chair of the Lancet Commission on Vaccine Hesitancy in the US, serves on the National Vaccine Advisory Committee Working Group for

Vaccine Hesitancy and is on the Board of Trustees for the Sabin Vaccine Institute. He is also a member of the World Health Organization (WHO) Global Advisory Committee on Vaccine Safety, the WHO Strategic Advisory Group of Experts (SAGE) Working Group on COVID-19 Vaccines, and the WHO SAGE Working Group on Measles and Rubella Vaccines. Dr. Omer is also currently an academic affiliate for the U.S. Government Accountability Office's Office of Evaluation Sciences. He has previously served on several advisory panels including the U.S. National Vaccine Advisory Committee, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria - Vaccine Innovation Working Group, WHO Expert Advisory Group for Healthcare Worker Vaccination, and the Public Health Committee of the Infectious Diseases Society of America. Dr. Mullen serves as a public health advisor to the Carnival Corporation and advises the Director of the Center for Disease Control and Prevention's Foundation on development of internal organizational equity goals.

Daniel Polsky, Ph.D., M.P.P., is the 40th Bloomberg Distinguished Professor of Health Economics at Johns Hopkins University. He holds primary appointments in both the Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health and the Carey Business School. From 1996–2016 he was on the faculty at the University of Pennsylvania, where he was the Robert D. Eilers Professor at the Wharton School and the Perelman School of Medicine. From 2012–2019 he served as executive director of the Leonard Davis Institute for Health Economics. Dr. Polsky a national leader in the field of health policy and economics, has dedicated his career to exploring how health care is organized, managed, financed, and delivered, especially for low-income populations. His own research has advanced our understanding of the cost and quality tradeoff of interventions whether they are changes to large federal programs or local programs. He is a member of the National Academy of Medicine. He serves on the Health and Medicine Division Committee for the National Academies of Sciences, Engineering, and Medicine. He serves on the Congressional Budget Office's Panel of Health Advisers and was the senior economist on health issues at the President's Council of Economic Advisers. He received a M.P.P. degree from the University of Michigan in 1989 and a Ph.D. in economics from the University of Pennsylvania in 1996.

Sonja Rasmussen, M.D., M.S., is Professor in the Departments of Pediatrics, Epidemiology, and Obstetrics and Gynecology at the University of Florida (UF) College of Medicine and College of Public Health and Health Professions where she serves as director of UF's Precision Health Program, which focuses on integration of genomics into clinical care. Dr. Rasmussen joined UF in 2018 after 20 years at the Centers for Disease Control and Prevention (CDC) in Atlanta, where she held several scientific leadership roles. In her recent roles as a public health leader, she served as Deputy Director of the Influenza Coordination Unit, responsible for CDC's pandemic influenza preparedness and response activities, and led CDC's Office of Public Health Preparedness and Response, an office with a $1.3 billion annual budget and >900 staff members, as Acting Director during the 2014 Ebola response. She served as Editor-in-Chief of CDC's Morbidity and Mortality Weekly Report (MMWR) Series, the #1 journal in the field of epidemiology according to number of citations, and as the Director of the Division of Public Health Information Dissemination. Dr. Rasmussen was lead author of the paper confirming Zika virus as a cause of birth defects, published in the New England Journal of Medicine in 2016. She served in leadership roles during several CDC responses to public health emergencies, including 2009 H1N1 influenza, H7N9 influenza, Middle East Respiratory Syndrome (MERS), and Zika virus. Dr. Rasmussen received

her B.S. in Biology and Mathematics with magna cum laude honors from the University of Minnesota-Duluth, her M.S. degree in Medical Genetics from the University of Wisconsin, and her M.D. degree with honors from University of Florida. She completed her pediatrics residency at Massachusetts General Hospital and her fellowship in clinical genetics at Johns Hopkins and University of Florida. Dr. Rasmussen is currently serving in a leadership role at the University of Florida in its response to COVID-19, including consulting with university leadership about containment and mitigation measures. She has published seven papers focused on what is known about this new virus in children and pregnant women. She is an author on >240 peer-reviewed publications and is the lead editor of The CDC Field Epidemiology Manual, released by Oxford University Press in 2019.

Arthur L. Reingold, M.D., is Professor and Head of the Division of Epidemiology at the School of Public Health at the University of California, Berkeley, having joined the faculty there in 1987. His research interests encompass the prevention and control of infectious diseases in the United States and internationally, particularly infections spread via the respiratory route and vaccine preventable diseases. He has previously served on the Advisory Committee on Immunization Practices of the U.S. Department of Health and Human Services and on the Strategic Advisory Group of Experts on immunizations of the World Health Organization. He was elected to membership in the National Academy of Medicine in 2003 and has previously served on multiple committees of the National Academies of Sciences, Engineering, and Medicine.

Reed V. Tuckson, M.D., FACP, is Managing Director of Tuckson Health Connections, LLC, a health and medical care consulting business that brings people and ideas together to promote optimal health outcomes and value through innovation and integration across the fields of prevention; public health; consumer activation; quality care delivery; the translation of science and technology into value producing interventions; and optimization of big data and analytics. Previously, he enjoyed a long tenure as Executive Vice President and Chief of Medical Affairs for UnitedHealth Group; Senior Vice President for Professional Standards of the American Medical Association; Senior Vice President of the March of Dimes Birth Defects Foundation; President of the Charles R. Drew University of Medicine and Science; and Commissioner of Public Health for the District of Columbia. Currently, Dr. Tuckson is President of the American Telemedicine Association and he serves on the Board of Directors of LifePoint Health, a leading hospital company dedicated to providing high-value care and services to growing regions, rural communities and vibrant small towns across the nation; Cell Therapeutics, Inc., a public corporation concerned with the development of cancer pharmaceuticals; and he is a special advisor to the CEO of ViTel Net, LLC, a leading innovator in telehealth solutions. Additionally, he serves on the National Advisory Council for Complementary and Integrative Health of the National Institutes of Health; he is an elected member of the National Academy of Medicine, serving in a leadership position on the use of data and analytics in healthcare; he is a board member of The Arnold P. Gold Foundation, which is concerned with advancing humanism in medical care; an advisory board member of the Johns Hopkins Berman Institute of Bioethics; and a trustee of the Board of Howard University. Previously, Dr. Tuckson was a member of the Advisory Committee to the Director of the National Institutes of Health; served as Chairman of the Secretary of Health's Advisory Committee on Genetics, Health and Society; and he has served on several U.S. Government cabinet level health advisory committees concerned with health reform, infant mortality, children's health, violence, and radiation testing. He is a graduate of

Howard University, Georgetown University School of Medicine, and the Hospital of the University of Pennsylvania's General Internal Medicine Residency and Fellowship Programs, where he was also a Robert Wood Johnson Foundation Clinical Scholar studying at the Wharton School of Business.

Michael R. Wasserman, M.D., C.M.D., is a geriatrician and President of the California Association of Long Term Care Medicine. He has been an advocate for vulnerable older adults during the COVID-19 pandemic, as the lead author of "Diagnostic Testing for SARS-Coronavirus-2 in the Nursing Facility: Recommendations of a Delphi Panel of Long-Term Care Clinicians*,"* and *"*An Aspirational Approach to Nursing Home Operations During the COVID-19 Pandemic." He is Editor-in-Chief of Springer's upcoming textbook, *Geriatric Medicine: A Person Centered Evidence Based Approach*. He previously served as chief executive officer for Rockport Healthcare Services, overseeing the largest nursing home chain in California. Prior to that, he was the Executive Director, Care Continuum, for Health Services Advisory Group, the Quality Innovation Network–Quality Improvement Organization for California. In 2001 he co-founded Senior Care of Colorado, which became the largest privately-owned primary care geriatrics practice in the country, before selling it in 2010. In the 1990's he was President and chief medical officer for GeriMed of America, where he helped to develop GeriMed's Clinical Glidepaths. In 1989, in the Journal of the American Geriatrics Society, Doctor Wasserman published "Fever, White Blood Cells and Differential Count in Diagnosing Bacterial Infection in the Elderly," the findings of which are now part of the McGeer Criteria, used widely in nursing homes to evaluate residents for infections. Dr. Wasserman is a graduate of the University of Texas, Medical Branch. He completed an Internal Medicine residency at Cedars-Sinai Medical Center and a Geriatric Medicine Fellowship at University of California at Los Angeles. He was formerly a Public Commissioner for the Continuing Care Accreditation Commission. He was the lead delegate from the State of Colorado to the 2005 White House Conference on Aging, and co-chaired the Colorado Alzheimer's Coordinating Council. Dr. Wasserman serves on the Boards' of the Wish of a Lifetime Foundation and the American Geriatrics Society's Foundation for Health in Aging.

Appendix B

Staff Biosketches

Lisa Brown, M.P.H., serves as the study director for the Committee on Equitable Allocation of Vaccine for the Novel Coronavirus and is a senior program officer on the Board on Health Sciences Policy at the National Academies of Sciences, Engineering, and Medicine. Her primary interests are in health security, and she currently directs several activities on emerging infectious diseases and 21st century health threats, evidence-based practices for public health emergency preparedness and response, and resiliency of the medical supply chain. Previously, she directed consensus studies on data needs to monitor the evolution of SARS-CoV-2 and the resiliency of the academic biomedical research community. Prior to joining the National Academies, Ms. Brown served as Senior Program Analyst for Public Health Preparedness and Environment Health at the National Association of County and City Health Officials (NACCHO). In this capacity, she served as project lead for medical countermeasures and the Strategic National Stockpile, researched radiation preparedness issues, and was involved in high-level CDC initiatives for the development of clinical guidance for anthrax and botulism countermeasures in a mass casualty event. In 2015, Ms. Brown was selected as a fellow in the Emerging Leaders in Biosecurity Initiative at the Center for Health Security, a highly competitive program to prepare the next generation of leaders in the field of biosecurity. Prior to her work at NACCHO, Ms. Brown worked as an Environmental Public Health Scientist at Public Health England (PHE) in London, England. While at PHE, she focused on climate change, the recovery process following disasters, as well as the impact of droughts and floods on emerging infectious diseases. She received her M.P.H. from King's College London in 2012 and her B.S. in biology from The University of Findlay in 2010.

Aurelia Attal-Juncqua, M.Sc., is an associate program officer at the Board on Health Science and policy, with the Forum on Medical and Public Health Preparedness for Disasters and Emergencies. Prior to joining the National Academies, Aurelia worked for three years as a Senior Research Associate at the Center for Global Health Science and Security at Georgetown University. Previously, Ms. Attal-Juncqua also briefly worked as a business analyst in the healthcare and pharmaceutical industry in London, as well as a researcher for the World Health Organization (WHO) in Geneva. In addition to her role at the National Academies, Ms. Attal-Juncqua is a part-time doctoral student in Health Security at the Johns Hopkins Bloomberg School of Public Health. She previously received a B.Sc. (Hons) in Biology and Microbiology from Imperial College in London, and an M.Sc. in Control of Infectious Diseases from the London School of Hygiene and Tropical Medicine. Her main professional interests include

biosecurity, capacity building for prevention and control of infectious diseases, as well as public health emergency preparedness and response.

Rebecca F. Chevat is a senior program assistant in the Health and Medicine Division of the National Academies. She was a recipient of a Health and Medicine Division Spot Award in 2019. Ms. Chevat graduated from American University in 2018. She received her B.A. in public health with concentrations in psychology and political science. During her undergraduate career, she worked in the Office of the Secretary and in the Office of Health Affairs at the Department of Homeland Security where she examined public–private partnerships and their role on points of dispensing models during emergencies. Ms. Chevat also has experience working on Capitol Hill and on political campaigns. Additionally, she is a National Registered Emergency Medical Technician. She plans to pursue her M.P.H. in global health.

Emma Fine is an associate program officer on the Board on Health Sciences Policy and has worked at the National Academies of Sciences, Engineering, and Medicine for four years. Previously, she staffed a project on the Board on Global Health assessing morbidity and mortality from HIV/AIDS in Rwanda. She also worked on the Board on Behavioral, Cognitive, and Sensory Sciences where she helped bridge the gap between academic experts and intelligence analysts for the Office of the Director of National Intelligence. Prior to joining the National Academies, Ms. Fine interned for the U.S. Department of Health and Human Services in the Office of the Assistant Secretary for Preparedness and Response where she contributed research to the National Health Security Strategy Implementation Plan as well as the intersection between terrorism and public health preparedness. In 2016, Ms. Fine graduated from the University of California, Berkeley where she earned her Bachelor of Arts in public health and public policy. She is particularly interested in the nexus between public health, intelligence, and national security and plans to pursue a degree in national security or enter the Foreign Service.

Elizabeth Finkelman, M.P.P., is a senior program officer in the Office of the President at the National Academy of Medicine (NAM). In her role, she directs NAM special projects and initiatives, including the Action Collaborative on Countering the U.S. Opioid Epidemic, the Healthy Longevity Global Competition, and previously, the Vital Directions for Health and Health Care initiative. Prior to joining the NAM in 2015, Ms. Finkelman spent several years working in program administration and research within the Division on Earth and Life Studies at the National Academies. She completed her undergraduate degree at McGill University, double majoring in cell and molecular biology and political science. She has a M.P.P. from the George Washington University with a concentration in health policy.

Ben Kahn, M.P.H., is an associate program officer on the Board on Health Sciences Policy (HSP), and he currently staffs the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats and the Committee on Equitable Allocation of Vaccine for the Novel Coronavirus. Ben completed his M.P.H. in May 2020 at the Johns Hopkins Bloomberg School of Public Health, where he also earned a certificate in Vaccine Science and Policy. His M.P.H. capstone project, conducted in collaboration with Bloomberg's International Vaccine Access Center, focused on characterizing and understanding vaccine hesitancy in South Asia. While completing his M.P.H., Ben also interned at the Coalition for Epidemic Preparedness Innovations, supporting the organization's work around vaccine development for COVID-19. Prior to his time

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Rose Marie Martinez, Sc.D., is Senior Board Director of the National Academies of Sciences, Engineering, and Medicine's Board on Population Health and Public Health Practice (1999 – Present). The board has a vibrant portfolio of studies that address high profile and pressing issues that affect population health. The board addresses the science base for population health and public health interventions and examines the capacity of the health system, particularly the public health infrastructure, to support disease prevention and health promotion activities, including the education and supply of health professionals necessary for carrying them out. The board has examined such topics as the safety of childhood vaccines and other drugs; systems for evaluating and ensuring drug safety post-marketing; pandemic influenza planning; the health effects of cannabis and cannabinoids; the health effect of environmental exposures; the integration of medical care and public health; women's health services; health disparities; health literacy; tobacco control strategies; chronic disease prevention; and other topics. Prior to joining the National Academies, Dr. Martinez was a Senior Health Researcher at Mathematica Policy Research (1995–1999) where she conducted research on the impact of health system change on the public health infrastructure, access to care for low-income populations, managed care, and the healthcare workforce. Dr. Martinez is a former Assistant Director for Health Financing and Policy with the U.S. General Accounting Office where she directed evaluations and policy analysis in the area of national and public health issues (1988–1995). Her experience also includes six years directing research studies for the Regional Health Ministry of Madrid, Spain (1982–1988). Dr. Martinez is a member of the Council on Education for Public Health, the accreditation body for schools of public health and public health programs. Dr. Martinez received the degree of Doctor of Science from the Johns Hopkins School of Hygiene and Public Health.

Andrew Pope, Ph.D., is Director of the Board on Health Sciences Policy of the National Academies of Sciences, Engineering, and Medicine. He has a Ph.D. in physiology and biochemistry from the University of Maryland and has been a member of the National Academies staff since 1982 and of the Health and Medicine Division staff since 1989. His primary interests are science policy, biomedical ethics, and environmental and occupational influences on human health. During his tenure at the National Academies, Dr. Pope has directed numerous studies on topics that range from injury control, disability prevention, and biologic markers to the protection of human subjects of research, National Institutes of Health priority-setting processes, organ procurement and transplantation policy, and the role of science and technology in countering terrorism. Since 1998, Dr. Pope has served as Director of the Board on Health Sciences Policy which oversees and guides a program of activities that is intended to encourage and sustain the continuous vigor of the basic biomedical and clinical research enterprises needed to ensure and improve the health and resilience of the public. Ongoing activities include Forums on Neuroscience, Genomics, Drug Discovery and Development, and Medical and Public Health Preparedness for Disasters and Emergencies. Dr. Pope is the recipient of the Health and Medicine Division's Cecil Award and the National Academy of Sciences President's Special Achievement Award.