FRAMEWORK FOR EQUITABLE ALLOCATION OF COVID-19 VACCINE

Helene Gayle, William Foege, Lisa Brown, and Benjamin Kahn, *Editors*

Committee on Equitable Allocation of Vaccine for the Novel Coronavirus

Board on Health Sciences Policy

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Acronyms and Abbreviations

AAP	American Academy of Pediatrics
ACA	Patient Protection and Affordable Care Act
ACIP	Advisory Committee on Immunization Practices
ACT-A	Access to COVID Tools (ACT) Accelerator
ADI	Area Deprivation Index
AI/AN	American Indian/Alaska Native
AMC	advanced market commitment
BeSD	behavioral and social drivers of vaccination
BMI	body mass index
CARES	Coronavirus Aid, Relief, and Economic Security
CCVI	COVID-19 Community Vulnerability Index
CDC	Centers for Disease Control and Prevention
CEPI	Coalition for Epidemic Preparedness Innovations
CMS	Centers for Medicare & Medicaid Services
COVID-19	coronavirus disease 2019
COVID-NET	COVID-19 Associated Hospitalization Surveillance Network
CSC	crisis standards of care
DHS	U.S. Department of Homeland Security
DoD	U.S. Department of Defense
EMS	emergency medical services
EU	European Union

EUA	Emergency Use Authorization
FDA	U.S. Food and Drug Administration
GPMB	Global Preparedness Monitoring Board
HHS	U.S. Department of Health and Human Services
HMD	Health and Medicine Division
ICU	intensive care unit
IHR	International Health Regulations
IHS	Indian Health Service
IOM	Institute of Medicine
LGBTQ+	lesbian, gay, bisexual, transgender, queer, and others
MCM	medical countermeasure
mRNA	messenger RNA
NAM	National Academy of Medicine
n.d.	no date
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
OSHA	Occupational Safety and Health Administration
OWS	Operation Warp Speed
PHEP	public health emergency preparedness
PPE	personal protective equipment
PREP	Public Readiness and Emergency Preparedness
SAGE	Strategic Advisory Group of Experts
SARS	severe acute respiratory syndrome
SARS-CoV-2	SARS coronavirus 2
STLT	state, tribal, local, and territorial
SVI	Social Vulnerability Index
VTrckS	Vaccine Tracking System
WHO	World Health Organization

Preface

"Certainty," Richard Feynman said, "is the Achilles heel of science." We approach this task with humbleness and great uncertainty. At the time of this writing, we do not know when a vaccine for coronavirus disease 2019 (COVID-19) will pass Phase III studies or will be licensed by the U.S. Food and Drug Administration. Even then, we will not know the effectiveness of the vaccine in protecting the very old or the very young. If protective, we do not know the duration of protection. We do not know what will constitute primary immunization or the need for boosters, and we do not know if rare but potentially serious adverse events will occur, and, if so, in which groups.

We do not understand the nuances of virus spread. What increases the risk of acquisition and transmission? How long does immunity last? How rare or frequent is reinfection? Are there preventive measures beyond masks, hand washing, social distancing, minimizing size of groups, and improving indoor air quality, not yet defined?

How will a vaccine change the equation given the hesitancy expressed by many? How can risk categories be established that account for both personal and social vulnerabilities? What is the chance of a virus mutation that puts all of the investments in vaccine production at risk?

In addition to these scientific uncertainties, we approached this task in the face of gaps and conflicts in legal authority and unprecedented economic and political uncertainty. The Centers for Disease Control and Prevention and the National Institutes of Health understood such uncertainties but also understood the urgency of having guidance ready when a safe and effective vaccine becomes available. As such, these two agencies asked

the National Academies of Sciences, Engineering, and Medicine to make recommendations on the equitable allocation of a COVID-19 vaccine by assembling the best recommendations from scientists, ethicists, psychologists, epidemiologists, and others using the latest information available. Despite an intense effort, this framework should still be regarded as an evolving document—meant to be adapted and refined by its implementers in the face of continuing improvement in our understanding of the dynamics of the pandemic.

In embarking on our task, the committee started with equity. Inequity has been a hallmark of this pandemic, both locally and globally. Inequities in health have always existed, but at this moment there is an awakening to the power of racism, poverty, and bias in amplifying the health and economic pain and hardship imposed by this pandemic. Thus, we saw our work as one way to address these wrongs and do our part to work toward a new commitment to promoting health equity that is informed by but lives beyond this moment.

The committee then approached what the science reveals about transmission, susceptibility, and risks of severe disease or death. The committee decided that a single objective, even one as important as mortality, obscures the impact of this virus on the triad of suffering, death, and societal dysfunction. Therefore, a target of reducing all three seemed appropriate.

Nobel Laureate Albert Schweitzer reminded us that suffering can often be a greater burden than death itself. The increase in poverty, the cost of isolation, and the inability to work or to be forced to work in unsafe environments have led to mental as well as physical suffering of major proportions.

The proposal of phases versus the usual nomenclature of tiers may appear to be insignificant or artificial. But, it seemed more dynamic, indicates movement, and eliminates the suggestion of any group having greater importance. It asserts that all life has equal value but also allows for the importance of making timing decisions about a potentially scarce resource.

In the end, the real work will be done in states, localities, and tribal lands. It should use every lesson we have learned in getting vaccine to both children and adults. It should use the experience of a system that eliminated polio from this country and stopped measles transmission for long periods of time. It should use the commercial delivery systems that worked so well during the H1N1 outbreak. It should use every health worker and volunteer needed to make this a successful community and national effort.

A report by a National Academies committee is not the same as effectively getting a message to the public.[1] It does not vaccinate a single

[1] Bloom, B. R., G. J. Nowak, and W. Orenstein. 2020. "When will *we* have a vaccine?"—understanding questions and answers about COVID-19 vaccination. *The New England Journal of Medicine.* September 8, 2020. doi: 10.1056/NEJMp2025331.

person. But, it can provide guidelines and be the impetus for one of the most consequential peacetime efforts this country has ever seen as well as a springboard to resuming our place as a leader in global health.

"First, do no harm," is repeated endlessly in medical education. We do far more harm, and kill far more people, by our errors of omission, rather than by our errors of commission. It is the science not shared, the vaccine not provided, the assistance not given, that results in suffering in other countries. We have a chance to protect ourselves and to be a leader in protecting the rest of the world. It is a challenge worthy of this country.

Lastly, we want to say what a privilege, honor, and joy it has been to work with this committee and staff. The dedication to purpose and the esprit de corps that developed was impressive and heartening. It is exactly this kind of effort and selflessness that is needed to address a pandemic effectively, and this group definitely rose to the occasion. Thank you to Victor Dzau for his leadership and support throughout this activity. Thanks to Rose Marie Martinez and Andrew Pope for providing daily guidance in preparing a useful report. Special recognition goes to the staff; in particular, we note that Lisa Brown and Benjamin Kahn gave their all to support the committee process and writing of the report. They were tireless, thoughtful, and always pleasant despite the fact that "there are no weekends in a pandemic." Elizabeth Finkelman, Aurelia Attal-Juncqua, Emma Fine, and Rebecca Chevat rounded out the staff support and provided extensive assistance in the research and development of the report. What a joy it has been to work with such talented staff and committee members.

Helene D. Gayle, *Co-Chair*
William H. Foege, *Co-Chair*
Committee on Equitable Allocation of Vaccine
for the Novel Coronavirus

Summary[1]

In response to the coronavirus disease 2019 (COVID-19) pandemic and the societal disruption it has brought, national governments and the international community have invested billions of dollars and immense amounts of human resources to develop a safe and effective vaccine in an unprecedented time frame. Vaccination against this novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), offers the possibility of significantly reducing severe morbidity and mortality and transmission when deployed alongside other public health strategies (e.g., non-pharmaceutical interventions and better diagnostic tests) and improved therapies. According to the World Health Organization (WHO), 149 COVID-19 vaccines are currently in pre-clinical development and 38 candidate vaccines are undergoing evaluation in clinical trials in the United States, Europe, and China. Domestically, the U.S. government has homed in on six COVID-19 vaccine candidates, with four currently in Phase 3 trials: the Johnson & Johnson JNJ-78436735, the Moderna/NIAID mRNA 1273, the University of Oxford/AstraZeneca AZD1222, and the Pfizer and BioNTech BNT162.

However, even if one or more safe and effective COVID-19 vaccines under development are authorized for use, they are very unlikely to be immediately available in amounts sufficient to vaccinate a large portion of the U.S. population, despite plans to begin large-scale production of promising vaccines even before trials are completed. Planning is urgently needed to

[1] This Summary does not include references. Citations for the discussion presented in the Summary appear in the subsequent report chapters.

ensure equitable access to COVID-19 vaccine. To prepare for the inability to meet the anticipated high demand for COVID-19 vaccine in the early stages of availability, the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) asked the National Academies of Sciences, Engineering, and Medicine (the National Academies), in partnership with the National Academy of Medicine, to convene an ad hoc committee to develop an overarching framework for vaccine allocation to assist policy makers in the domestic and global health community. The full charge to the committee is presented in Chapter 1.

This report offers a framework for equitable allocation of COVID-19 vaccine. It is built on widely accepted foundational principles and recognizes the distinctive characteristics of COVID-19 disease, including its rates of infection, its modes of transmission, the groups and individuals most susceptible to infection, and varying rates of severe illness and death among those groups. This report's recommendations address the institutional and administrative commitments needed to implement equitable allocation policies.

COVID-19 AND HEALTH EQUITY

Race and ethnicity and health equity are intertwined with the impact of COVID-19 and there are certain populations that are at increased risk of severe illness or death from COVID-19. In the United States and worldwide, the COVID-19 pandemic has shed light on the pervasive impacts of social and structural inequities in society. COVID-19 is having a disproportionate impact on people who are already disadvantaged by virtue of their race and ethnicity, age, health status, residence, occupation, socioeconomic condition, and/or other contributing factors. At a moment when racial inequality and discrimination are at the center of national conversations in the United States, and a well-established source of poor health outcomes as well as the legacy of medical experimentation, these considerations must be a critical component of COVID-19 vaccine allocation. The committee weighed these realities not only because of their moral and ethical implications, but also because, in our highly interconnected world, the challenges experienced by particular subpopulations have an effect on us all. If we have learned anything from this pandemic, it is that we are inevitably all in this together.

Current evidence has shown how COVID-19 disproportionately affects particular racial and ethnic minority groups, including Black, Hispanic or Latinx, American Indian and Alaska Native, and Native Hawaiian and Pacific Islander communities. Many of these groups disproportionately face social and structural factors and comorbid conditions that put them at higher risk of severe morbidity and mortality from COVID-19. Furthermore, historically, non-Hispanic Whites have had higher coverage for routine

immunizations compared to racial and ethnic minority groups. CDC has compiled data by race and ethnicity on the rates of COVID-19 cases, age-adjusted hospitalizations, and death. Compared to non-Hispanic Whites, American Indian and Alaska Native persons had a case rate that was 2.8 times higher, a hospitalization rate that was 4.6 times higher, and a death rate that was 1.4 times higher. Hispanic or Latinx persons had a case rate that was 2.8 times higher, a hospitalization rate that was 4.7 times higher, and a death rate that was 1.1 times higher. Black and African American persons had a case rate that was 2.6 times higher, a hospitalization rate that was 4.7 times higher, and a death rate that was 2.1 times higher.

COVID-19 has also disproportionately affected members of other groups (see Table S-1). In particular, older adults are extremely vulnerable to severe outcomes and death due to COVID-19; people aged 65 and older represent 8 out of every 10 reported deaths due to COVID-19 in the United States.

TABLE S-1 Key Data on the Impact of COVID-19 on Certain Populations

Population	Key Impact Data
Black	• Compared to non-Hispanic White populations, this group has a case rate that is 2.6 times higher, a hospitalization rate that is 4.7 times higher, and a death rate that is 2.1 times higher (United States).
Hispanic/Latinx	• Compared to non-Hispanic White populations, this group has a case rate that is 2.8 times higher, a hospitalization rate that is 4.7 times higher, and a death rate that is 1.1 times higher (United States).
American Indian and Alaska Native	• Compared to non-Hispanic White populations, this group has a case rate that is 2.8 times higher, a hospitalization rate that is 4.6 times higher, and a death rate that is 1.4 times higher (United States).
Native Hawaiian and Pacific Islander	• Group has experienced mortality from COVID-19 at a rate up to five times its proportion of the population compared to the general population (United States).
Older adults (≥65 years)	• Group accounts for approximately 80 percent of reported deaths related to COVID-19 (United States). • Population-level COVID-19 mortality risk is estimated to be 16- to 52-fold higher (United States) and 30- to 100-fold higher (worldwide) for this group than for younger people.
Older adults (>80 years)	• Group is experiencing a mortality rate 5-fold greater than average (United States). • Group is experiencing an "overwhelming percentage" of severe outcomes due to COVID-19 (worldwide).

continued

TABLE S-1 Continued

Population	Key Impact Data
People with underlying or comorbid conditions	• Group is 6-fold more likely to be hospitalized and 12-fold more likely to die from COVID-19 as people without underlying conditions (United States). • Group is at a greater risk of SARS-CoV-2 infection.
People who live and/or work in congregate settings	• Older adults living in senior living facilities are at high risk of severe COVID-19. • Long-term care facility residents accounted for half of >10,000 COVID-19 deaths reported by April 2020 (United States).
Sex	• Men with COVID-19 are more at risk for worse outcomes and death than women, independent of age (China).
Children	• Children and adolescents account for 10 percent of COVID-19 cases and less than 0.3 percent of deaths (United States). • Among children with COVID-19, 1.8 percent of cases resulted in hospitalization (United States). • 78 percent of deaths among adolescents (under 21) reported to the Centers for Disease Control and Prevention between mid-February and the end of July 2020 were people from Black, Hispanic and Latinx, or American Indian and Native Alaskan communities.
People who are pregnant or breastfeeding	• Group may be at an increased risk of developing severe COVID-19 disease that requires intensive care unit admission and mechanical ventilation. • Black and Hispanic women who are pregnant appear to be disproportionately at risk of severe disease and hospitalization (United States). • Babies born to women infected with SARS-CoV-2 during pregnancy appear to be more likely to be born preterm or require neonatal intensive care.

NOTES: This table is included in Chapter 1 with references. The following groups are omitted from the table due to a lack of COVID-specific epidemiological data: people who are undocumented, people with mental and physical disabilities, and people experiencing homelessness.

LESSONS LEARNED FROM OTHER ALLOCATION EFFORTS

This is not the first time the nation, or the world, has faced the issue of allocating what is likely to be an early scarcity of resources in the midst of a public health emergency. Plans drawing on those experiences are beginning to emerge for ensuring equitable allocation of vaccines and therapeutics for COVID-19. The committee began its work by reviewing lessons learned from previous mass vaccination efforts in the United States and globally, including from the 2009 H1N1 influenza vaccination campaign and the 2013–2016 vaccination efforts during the Ebola outbreak in West Africa. These lessons are described in Box S-1.

BOX S-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.
- Use consistent, respectful, accurate communication to earn, secure, and maintain trust.

The committee also reviewed and synthesized relevant elements of principles, goals, and prioritization strategies proposed in other frameworks recently developed for allocating scarce resources during the COVID-19 pandemic. Some of these frameworks are vaccine specific (including an interim framework developed by a group at Johns Hopkins University, forthcoming efforts from CDC, and a values framework developed by WHO), some focused on inpatient treatments (like remdesivir), and others address the overall allocation of scarce medical resources. These frameworks are discussed in detail in Chapter 2.

A FRAMEWORK FOR EQUITABLE ALLOCATION OF COVID-19 VACCINE

Foundational Principles, Goal, and Allocation Criteria

The committee based its framework for equitable allocation of COVID-19 vaccine on current evidence, recognizing its uncertainties and the need for flexibility as evidence emerges and medical realities change. The framework's foundational principles guide its goal, allocation criteria, and allocation phases (see Figure S-1).

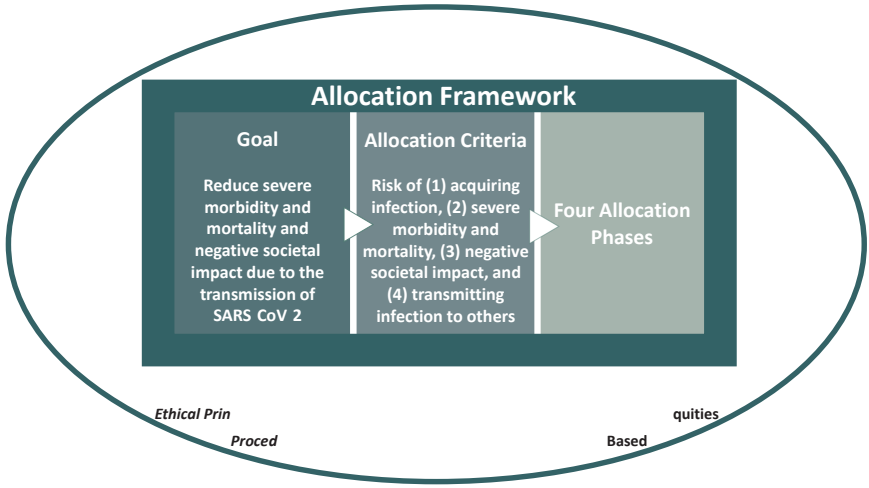

FIGURE S-1 Major elements of the framework for equitable allocation of COVID-19 vaccine.

To ensure that the allocation framework is equitable and can be seen as equitable, the committee designed its framework so that it (1) can be easily and equally understood by diverse audiences, (2) reflects widely accepted social and ethical principles, (3) can be reliably translated into operational terms, (4) distinguishes scientific and ethical judgments in its application, and (5) does not perpetuate discrimination and inequities. The foundational principles consist of ethical and procedural principles that reflect this line of thinking:

- **Ethical Principles**
  - **Maximum benefit** encompasses the obligation to protect and promote the public's health and its socioeconomic well-being in the short and long term.
  - **Equal concern** requires that every person be considered and treated as having equal dignity, worth, and value.
  - **Mitigation of health inequities** includes the obligation to explicitly address the higher burden of COVID-19 experienced by the populations affected most heavily, given their exposure and compounding health inequities.
- **Procedural Principles**
  - **Fairness** requires engagement with the public, particularly those most affected by the pandemic, and impartial decision making about and even-handed application of allocation criteria and priority categories.

- **Transparency** includes the obligation to communicate with the public openly, clearly, accurately, and straightforwardly about the allocation framework as it is being developed, deployed, and modified.
- **Evidence-based** expresses the requirement to base the allocation framework, including its goal, criteria, and phases, on the best available and constantly updated scientific information and data.

Guided by these foundational principles, the goal of the committee's framework for equitable allocation of COVID-19 vaccine is to:

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

The framework pursues that goal while mitigating health inequities, showing equal concern for all, being fair and transparent, and building on the best available evidence. Given the current state of the pandemic, the early phases of the committee's proposed framework emphasize prevention of severe morbidity and mortality, particularly with regard to maintaining essential health and emergency services. The focus shifts toward reducing transmission in later phases. There are multiple reasons for this approach:

- Death is an irreversible outcome. There are legitimate claims for many groups (e.g., schoolchildren, "non-essential" workers) to be in earlier phases as negative societal impact could occur if these groups are not prioritized. For example, there might be a substantial impact on the economy if a primarily transmission-focused strategy is not employed from the outset. However, the non-trivial effects of an economic downturn or an online semester can at least be partially reversed.
- Preventing severe morbidity and mortality protects the health care system from being overwhelmed, contributing to the prevention of excess morbidity and mortality from other causes as well, with ripple effects on society and the economy.
- For vaccination to materially reduce transmission requires vaccinating a critical mass of individuals, much greater than will be possible in the early phases of vaccine deployment.
- The ongoing COVID-19 vaccine trials are not designed to estimate the impact of the vaccine candidates on transmission and evidence of the vaccines' actual impact on transmission might not be available for some time after U.S. Food and Drug Administration approval.
- While data on all aspects of COVID-19 are emerging, data on transmission risk groups (e.g., age, profession) are particularly limited.

To operationalize its foundational principles, the committee developed four risk-based criteria that were then used to set general priorities among population groups.

- **Risk of acquiring infection:** Individuals have higher priority to the extent that they have a greater probability of being in settings where SARS-CoV-2 is circulating and of being exposed 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 infection to others:** Individuals have higher priority to the extent that there is a higher probability of their transmitting the infection to others.

The committee recognizes that decisions about COVID-19 vaccine allocation must be made under conditions of uncertainty. These unknowns include the safety and efficacy of the vaccines in specific populations (such as children, pregnant women, older adults, and individuals previously infected with COVID-19), the effectiveness of vaccines in tandem with existing preventive measures, public confidence in the vaccine, the possibility of ultra-cold storage requirements for the vaccine, the pharmacovigilance evidence, and many other unknowns. Chapter 4 describes how the allocation process can adapt to plausible scenarios involving these factors.

Allocation Phases

In light of the foundational principles, goal, and allocation criteria, the committee recommends a four-phased approach to equitable COVID-19 vaccine allocation (see Figure S-2 and described in detail in Chapter 3). The committee uses the term "phases," suggesting successive deployments, rather than the hierarchical term "tiers." **Within each phase, all groups have equal priority.** This approach applies the best available current evidence to implementing the framework's foundational principles. It cannot be emphasized enough that the dynamic nature of the COVID-19 pandemic means that features of the pandemic will change over time, as will collective understanding of its effects.

For each population group, the committee recommends prioritizing for areas identified as vulnerable through CDC's Social Vulnerability Index

(SVI) or another more specific index such as the COVID-19 Community Vulnerability Index (CCVI). The evidence clearly shows that people of color—specifically Black, Hispanic or Latinx, American Indian and Alaska Native, and Native Hawaiian and Pacific Islander—have been disproportionately impacted by COVID-19, with higher rates of severe morbidity, mortality, and transmission. This disproportionate burden largely reflects the impacts of systemic racism and socioeconomic factors that are associated with increased likelihood of acquiring the infection (e.g., frontline jobs that do not allow social distancing, crowded living conditions, lack of access to personal protective equipment, inability to work from home) and of having more severe disease when infected (as a result of a higher prevalence of comorbid conditions or other factors). Use of a vulnerability index, like SVI or CCVI, represents an attempt to incorporate the variables that the committee believes are most linked to the disproportionate impact of COVID-19 on people of color. A vulnerability index allows the efficient focus of resources on these needs instead of on discrete racial and ethnic categories. The committee does not propose an approach in which, within each phase, all vaccine is first given to people in high-SVI areas. Rather the committee proposes that state, tribal, local, and territorial (STLT) authorities ensure that special efforts are made to deliver vaccine to residents of high-vulnerability areas (defined as 25 percent highest in the state).

Summary of the Population Groups Within Each Allocation Phase

As summarized here and described more fully in Chapter 3, the committee based its specific proposals on broad estimates of the number of individuals covered across each phase of the allocation framework, a practice also used by WHO. **Importantly, the committee acknowledges that the population groups included in each allocation phase overlap to a certain extent, and there are assuredly individuals who fit into multiple categorizations.** When individuals within a group fall into multiple phases, the higher phase should take precedent. It also recognizes the heterogeneity within each group, with some members facing less risk and having greater ability to protect themselves and others. The framework provides guidance to the STLT authorities administering the program in adapting its risk-based criteria to these realities in ways consistent with its foundational principles.

Phase 1

Phase 1 of the allocation framework has two subsections: a "Jumpstart" Phase 1a that covers approximately 5 percent of the U.S. population, and a Phase 1b covering an additional 10 percent.

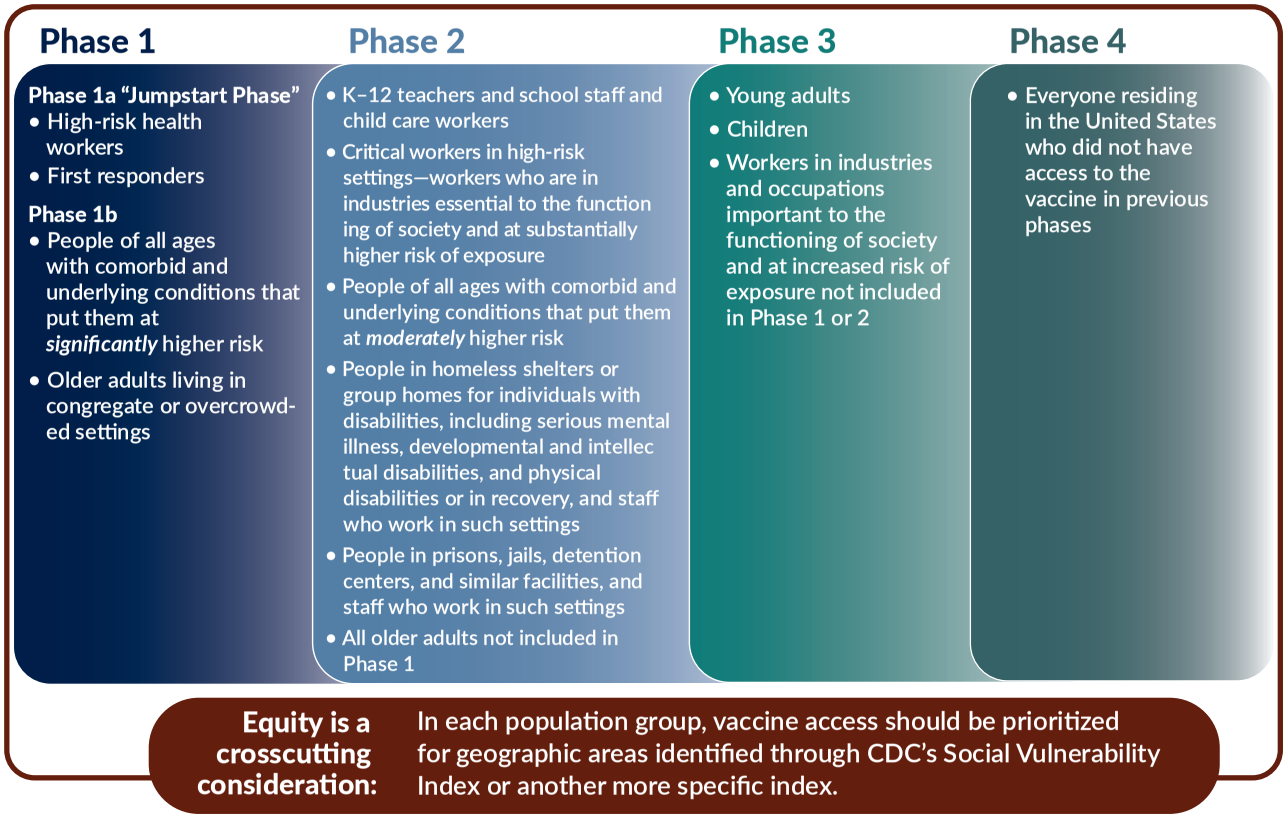

FIGURE S-2 A phased approach to vaccine allocation for COVID-19.

Phase 1a includes high-risk health workers (e.g., in hospitals or nursing homes, or providing home care). These health professionals are involved in direct patient care. Also included are workers who provide transportation, environmental services, and other health care facility services and who risk exposure to bodily fluids or aerosols. This group is included in Phase 1a for multiple reasons: their critical role in maintaining health care system functionality, their high risk of exposure to patients exhibiting symptoms of COVID-19, and their risk of then transmitting the virus to others, including family members. This is of particular concern for those workers who are members of communities that have been disproportionately impacted by COVID-19. First responders whose jobs put them at high risk of exposure to COVID-19 are also included in Phase 1a (although depending on the jurisdiction and outbreak context, this may not include all first responders). Like frontline health workers, first responders play vital roles in both the response to COVID-19 and society's overall functioning.

Phase 1b focuses attention on two groups that are particularly vulnerable to severe morbidity and mortality due to COVID-19: (1) people of all ages with comorbid and underlying conditions that put them at significantly higher risk and (2) older adults living in congregate or overcrowded settings. CDC currently lists the following comorbid conditions as associated with increased risk of severe COVID-19 disease: cancer, chronic kidney disease, chronic obstructive pulmonary disease, immunocompromised state from solid organ transplant, obesity (body mass index ≥30), serious heart conditions (e.g., heart failure, coronary artery disease, cardiomyopathies), sickle cell disease, and type 2 diabetes mellitus. Recognizing the limited initial vaccine supply, Phase 1b proposes setting a priority on individuals with two or more of these conditions, recognizing that these priorities can be refined as better evidence emerges. Based on data from the COVID-19 Associated Hospitalization Surveillance Network (COVID-NET), adults with two or more comorbid conditions make up the large majority of those hospitalized for COVID-19 in the United States.

Phase 1b also includes older adults living in congregate or overcrowded settings—including nursing homes, long-term care facilities, homeless shelters, group homes, prisons, or jails. As a group, they face the joint risk factors of severe disease and reduced resilience associated with advanced age and of acquisition and transmission due to their living settings. A significant proportion of COVID-19 deaths in the United States have occurred among individuals living in nursing homes and long-term care facilities, highlighting the critical need to protect individuals in this group.

Phase 2

Moving to Phase 2 and beyond, it is important to note the overlap issue discussed earlier. Individuals who fall within population groups in this

phase may also be high-risk health workers or first responders, have comorbid and underlying conditions that put them at significantly higher risk, or be older and living in congregate or overcrowded settings, and therefore should be vaccinated in Phase 1.

Phase 2 of the allocation framework would cover approximately 30–35 percent of the U.S. population, bringing the total coverage across Phases 1 and 2 to an estimated 45–50 percent of the total population. K–12 teachers, school staff, and child care workers are included in Phase 2. This category includes administrators, environmental services staff, maintenance workers, and school bus drivers, all of whom are essential to education and face disease exposure. Vaccinating these individuals supports their vital societal role in providing children's education and development, while reducing their role in transmission between schools and the community and protecting their own health risks from exposure in these settings. Phase 2 also includes critical workers in high-risk settings—a group of individuals whose occupations are in essential industries and who cannot avoid a high risk of exposure to COVID-19. They include workers in the food supply system, public transit, and other vital services. It would be useful for public health agencies, including CDC, the Occupational Safety and Health Administration, the Mine Safety and Health Administration, and state and local public health agencies, to provide additional guidance in the designation of jobs or tasks involved as well as occupational codes or job titles in this group.

Phase 2 includes people of all ages with comorbid and underlying conditions that put them at moderately higher risk, which the committee defined as having one of the previously mentioned conditions and potentially some rare diseases as well.

Phase 2 also includes people in homeless shelters or group homes, and staff who work in those settings. Group home populations include people with disabilities—such as serious mental illness, developmental and intellectual disabilities, and physical disabilities—as well as those in recovery. Many of these individuals have chronic health care needs and challenging living settings that increase potential exposure. Phase 2 includes people in prisons, jails, detention centers, and similar facilities, and staff who work in those settings, with the expectation that they have limited opportunity to follow public health measures such as maintaining physical distance, putting them at significant risk of acquiring and transmitting COVID-19.

All older adults not included in Phase 1b are included in Phase 2, because advanced age is in itself a risk factor for severe disease and death due to COVID-19.

Phase 3

Phase 3, which assumes wider availability of COVID-19 vaccine, focuses on preventing transmission of COVID-19 and restoring social and

economic activity. This phase would cover an estimated 40–45 percent of the U.S. population, bringing the total to 85–95 percent vaccination coverage across Phases 1–3. Phase 3 includes young adults, children, and workers in industries that are both important to the functioning of society and pose moderately high risk of exposure. Young adults between the ages of 18 and 30 typically have broader social networks than older adults, increasing their risks of infection and transmission, but are less likely to become severely ill or die due to COVID-19, making them targets for transmission prevention. Children, too, are much less likely than adults to experience severe outcomes due to COVID-19, but can play a role in transmission. However, it is important to note that clinical trials of COVID-19 vaccine have not started in children in the United States. Workers in this category are important to the functioning of society and are at moderately high risk of exposure. Representative industries may include universities, entertainment, and goods-producing industries, whose occupational risk of transmission is lower than those in Phase 2 because they work in settings where protective measures are likely to be implemented without great difficulty.

Phase 4

Finally, Phase 4 includes everyone residing in the United States who did not have access to the vaccine in prior phases.

While the committee's phased allocation approach is limited by imperfect data, information unknowns, and potential unintended consequences, it is intended to be adapted by STLT partners based on their needs, and should rely on mid-course corrections and real-time updates based on the science about effectiveness of different vaccines in different populations.

RECOMMENDATION 1. Adopt the committee's framework for equitable allocation of COVID-19 vaccine.

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

- This framework can also inform the decisions of other groups, such as the Advisory Committee on Immunization Practices and those in the global health community.
- STLT authorities will have to make final decisions on refining and applying the framework and should plan for situations when pri-

oritization has to be adapted midway through the process. In doing so, they should refer to the principles and allocation criteria that guided the formulation of the phases.

IMPLEMENTATION CONSIDERATIONS

In Chapters 5 and 6, the report also discusses the administration, monitoring, data collection, communication, community engagement, health promotion, and evaluation activities needed to implement an effective, equitable national COVID-19 vaccination program, including the roles of federal and STLT authorities and their partners. CDC traditionally holds a leadership role in vaccination program coordination, working with federal partners such as the Office of the Assistant Secretary for Preparedness and Response, the U.S. Food and Drug Administration, NIH, the Health Resources and Services Administration, and the Centers for Medicare & Medicaid Services. Secure vaccine storage, transport, and safe, efficient, and equitable vaccine distribution are critical to a successful national COVID-19 vaccination program, especially given the potential vaccine ultra-cold chain requirements and a multi-dose vaccine regimen. Successfully establishing a coordinated approach to COVID-19 vaccination will require leveraging existing systems, along with strong and real-time rapid monitoring and evaluation procedures, including assessment of the program's penetrance among key populations.

RECOMMENDATION 2. Leverage and expand the use of existing systems, structures, and partnerships across all levels of government and provide the necessary resources to ensure equitable allocation, distribution, and administration of COVID-19 vaccine.

The U.S. Department of Health and Human Services should commit to leveraging and expanding the use of existing systems, structures, and partnerships across all levels of government and provide the resources necessary to ensure equitable allocation, distribution, and administration of COVID-19 vaccine. Equitable allocation must be supported by equitable distribution and administration. Specific action steps to implement this recommendation are as follows:

- Provide resources (including resources for staff) to state, tribal, local, and territorial authorities and their implementation partners and adequately fund indirect assets (e.g., needles, syringes, personal protective equipment for vaccinators, resources for ultra-cold chain management, and so forth) necessary for effective vaccine allocation, distribution, and administration.
- To ensure identification and delivery of COVID-19 vaccine to priority population groups, develop the capacity and systems to collect

and integrate the necessary data (digital and other) from public health and private providers of care to facilitate the identification and monitoring of people with pre-existing conditions and other high-risk characteristics.
- Establish a robust and comprehensive surveillance system to monitor, detect, and respond to identified problems, gaps, inequities, and barriers. Monitoring should encompass equitable vaccine allocation and distribution, vaccine delivery, adverse events following immunization, promotion and communication, and uptake and coverage.
- Ensure that a rigorous COVID-19 vaccine safety monitoring program, built on existing systems, is in place, with an emphasis on rapid reporting and timely and transparent assessment of adverse events to determine whether events are associated with receipt of vaccine or occurring by chance.

Several COVID-19 vaccines under development have received considerable taxpayer support. Therefore, it is essential that COVID-19 vaccines be delivered through a central mechanism that ensures availability of vaccines to all individuals, regardless of their social and economic resources or their employment, immigration, or insurance status. This can best be achieved if this federal mechanism makes vaccines available at no cost to the public health and health care sectors. To ensure equity and to decrease vaccine hesitancy, there should be no out-of-pocket costs for those being vaccinated and this includes covering fees for administration of the vaccine.

RECOMMENDATION 3. Provide and administer COVID-19 vaccine with no out-of-pocket costs for those being vaccinated.

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

- Apply Patient Protection and Affordable Care Act regulations regarding no cost sharing for preventive services for COVID-19 vaccinations for insured individuals, while addressing instances where these regulations fail to protect the beneficiary from out-of-pocket costs. Require health insurance providers and self-insured employ-

ers to waive co-pays and deductibles for vaccine administration based on a reasonable nationally determined administrative rate set by the Centers for Medicare & Medicaid Services for all providers, irrespective of site of care or network participation status.

- To reach uninsured individuals, provide federal support and funding for mass vaccination clinics and for reimbursement for providers serving uninsured individuals directly. In all cases, a billing code of some kind will be needed to monitor uptake, for pharmacovigilance, and to monitor disparities.
- Keep barriers to provider participation in administration of the vaccine as low as possible, especially for those providers who are in communities that are disproportionately impacted by COVID-19 by ensuring vaccines are available at no cost and that administration of the vaccine is adequately reimbursed even if there is no cost sharing for the patient.

Engaging with communities will be a critical task for STLT authorities to ensure equity and develop effective, localized COVID-19 vaccination plans (further discussed in Chapters 5 and 6). Community-based organizations and other partner organizations—including hospitals, pharmacies, faith-based organizations, community centers, and schools and universities—can support community outreach and foster accountability. Employers and unions could support improved access by providing work-site clinics and by covering costs for employees.

As part of community engagement, the ethical principles, implementation processes, expected outcomes, and how well the program has achieved equitable allocation of safe and effective COVID-19 vaccine actual performance must be transparently communicated. Communication must be accessible and available for a diverse audience, and should pay attention to disease processes that can be misunderstood unless properly explained, equity in the vaccination program's procedures and performance, empirical testing, and appropriate tailoring. Effective communication requires cultural competence, establishment of a trusted authority, special consideration for unfamiliar material, and approaches to address different users' needs, including engagement with a variety of partners. The communication workforce must reflect the diversity of the communities being vaccinated, and must rely on the scientific foundations of risk communication and community engagement, as well as collect the evidence needed to serve the public effectively.

RECOMMENDATION 4. Create and appropriately fund a COVID-19 vaccine risk communication and community engagement program.

The U.S. Department of Health and Human Services should create and appropriately fund a COVID-19 vaccination risk communi-

cation and community engagement program to support state, tribal, local, and territorial (STLT) authorities as an integral part of an effective and equitable national COVID-19 vaccination program. The program should:

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

Achieving Acceptance of COVID-19 Vaccine

Recent polling data suggest that approximately one-third of U.S. residents would not accept a COVID-19 vaccine if offered today, with skepticism even higher among certain populations, including Black and Hispanic communities. Histories of medical research exploitation, such as during the Tuskegee syphilis study, fuel skepticism in minority communities. Beyond this understandable distrust, vaccine hesitancy is increasingly common in the United States, and influential anti-vaccine groups have been particularly effective in spreading their views online. Concerns about the development and approval of COVID-19 vaccines, including the unprecedented speed of testing for safety and efficacy in clinical trials, and significant concerns of political considerations affecting evaluation of the data from those trials, create a more challenging environment for vaccine hesitancy and reduced acceptance.

WHO's Measuring Behavioral and Social Drivers of Vaccination (BeSD) Increasing Vaccination Model offers one tool for investigating people's motivations toward becoming vaccinated. It considers people's thoughts and feelings, as well as the social processes that affect their motivation. Multiple reviews of the evidence have found that there is not a "one-size-fits-all" so-

lution to vaccine hesitancy. Rather, addressing this issue requires a combination of interventions, including the engagement of community leaders, mass media campaigns, and health care professional training. People-centered and dialogue-based solutions, including those based on social marketing tactics, will be key to promoting acceptance of COVID-19 vaccine. Those guiding and implementing these programs must represent the communities they are trying to reach. In Chapter 7, the committee reviews the complex and dynamic landscape of vaccine hesitancy and discusses its specific application and relevance to COVID-19 vaccination.

RECOMMENDATION 5. Develop and launch a COVID-19 vaccine promotion campaign.

The Centers for Disease Control and Prevention should rapidly develop and launch a national, branded, multi-dimensional COVID-19 vaccine promotion campaign, using rigorous, evidence-informed risk and health communication, social marketing, and behavioral science techniques. The COVID-19 vaccine promotion campaign should:

- Be consistent in its messaging but also flexible and modular to allow state, tribal, local, and territorial authorities to tailor it to specific communities and audiences, similar to the truth campaign against tobacco use.
- Partner with diverse stakeholders (e.g., health care providers, Historically Black Colleges and Universities research centers, Hispanic Association of Colleges and Universities, Tribal Colleges and Universities research centers, social marketing firms and other groups with specific expertise reaching underserved communities) and prioritize promoting the vaccine to Black, Hispanic or Latinx, American Indian and Alaska Native, Hawaiian Native and Pacific Islander, and other communities in which vaccine hesitancy and skepticism have been documented.
- Engage thought and opinion leaders, such as celebrities, to help promote COVID-19 vaccination acceptance and uptake.
- Incorporate messaging (in a variety of languages) and graphical elements that increase motivation, counter misinformation, and overcome perceived or actual practical barriers to vaccination.
- Include print, radio, television, and social media formats; incorporate toolkits, educational materials, and guidebooks to support community discussion about the COVID-19 vaccine; and make materials available in multiple languages.
- Be incorporated into broader messaging that provides consistent information on COVID-19 public health strategies that include nonpharmaceutical interventions, such as mask usage, physical distancing, hand washing, and so forth; expanded and accessible diagnostic

testing linked to contact tracing, isolation, and quarantine strategies aimed at containing transmission, suppressing outbreaks, and interrupting super-spreading events; and the deployment of therapeutic measures that mitigate morbidity and mortality.

RECOMMENDATION 6. Build an evidence base for effective strategies for COVID-19 vaccine promotion and acceptance.

The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health should invest in rapidly building an evidence base for effective strategies for COVID-19 vaccine promotion and acceptance, acknowledging the unique circumstances around COVID-19 vaccination and the knowledge gaps related to understanding community needs and perceptions and effective promotion and delivery strategies. Specific action steps to implement this recommendation include:

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

ENSURING EQUITY IN COVID-19 VACCINE ALLOCATION GLOBALLY

Entities outside of the United States are also working to ensure COVID-19 vaccine access and equitable allocation worldwide. The Access to COVID-19 Tools Accelerator was established by a diverse range of development partners and its vaccine pillar—referred to as COVAX—is convened by the Coalition for Epidemic Preparedness Innovations and Gavi, the Vaccine Alliance. Gavi, the Vaccine Alliance's financing approach for COVAX is designed to provide all countries with the opportunity to

participate in securing an initial supply of vaccine for 20 percent of their population. The COVAX Facility provides a pooling mechanism for procurement. A total of 156 economies, representing more than two-thirds of the global population, are now either committed to or eligible for the COVAX Facility—with more to expected to follow. Although the United States is not currently among those countries, the report discusses the reasons favoring its participation, including COVAX serving as an insurance policy to OWS, should the vaccine that it is supporting prove less effective or less available than hoped; the recognition that infectious disease threats do not respect international boundaries; the need for domestic preparedness and national security; and the moral duty to support it.

RECOMMENDATION 7. Support equitable allocation of COVID-19 vaccine globally.

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

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

CONCLUDING REMARKS

SARS-CoV-2 will continue to spread around the world until a vaccine is developed and widely distributed and administered. Ultimately, in these uncertain and challenging times, the integrity of the COVID-19 vaccine development, allocation, and distribution processes will be critical to ensuring widespread access to vaccines that are safe and effective, and convincingly so for the public. The committee hopes that the evidence-based deliberations and policy recommendations set forth in this report and summarized in Box S-2 contribute to society's ability to respond to and recover from the COVID-19 pandemic.

BOX S-2
Summary of Recommendations

The following points collectively summarize the necessary actions recommended by the committee to achieve equitable allocation of COVID-19 vaccine:

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

1

Introduction

In response to the coronavirus disease 2019 (COVID-19) pandemic and the societal disruption it has brought, national governments and the international community have invested vast sums of money in the development of a safe and effective vaccine. Although subject to myriad uncertainties, mass vaccination against this novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), offers the possibility of significantly reducing transmission and severe morbidity and mortality beyond what might be accomplished solely 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 from those under development are tested and quickly approved for use, they are unlikely to be available immediately in amounts sufficient to vaccinate the entire 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, a COVID-19 vaccine will almost certainly be available only in limited supplies. In this context, scarce vaccines will need to be allocated in ways that reduce morbidity and mortality and reduce SARS-CoV-2 transmission in order to protect the public's health and its socioeconomic well-being.

This chapter presents the study charge and approach and lays out the report's organization. The chapter also examines the ways in which race and ethnicity and health equity are intertwined with the impact of COVID-19, the populations that are at increased risk of severe illness or

death from COVID-19, and the current landscape of COVID-19 vaccines at the time of this writing—all of which have significant implications when planning for the equitable allocation of COVID-19 vaccine. This chapter concludes with a description of a national COVID-19 vaccine program that builds on the solid and tested national vaccine program that has existed in this country for more than half a century.

STUDY CHARGE

To meet the anticipated high demand for a COVID-19 vaccine in the early stages of availability, guidance is urgently needed to plan for equitably distributing a limited vaccine supply. To address this urgent need, the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) asked the National Academies of Sciences, Engineering, and Medicine (the National Academies), in partnership with the National Academy of Medicine, to convene an ad hoc committee to develop an overarching framework for COVID-19 vaccine allocation in order to assist policy makers in the domestic and global health communities. This framework could later inform the work of national health authorities and additional advisory bodies, including CDC's Advisory Committee on Immunization Practices (ACIP), during the development of national and local guidelines.

The full charge to the committee is in Box 1-1. The committee was comprised of 18 members with academic backgrounds and professional expertise in fields including public health, epidemiology, medicine, bioethics, law, public policy, economics, occupational health, health insurance, geriatrics, and global health. Biographies of the committee members are provided in Appendix B.

ABOUT THIS REPORT

Study Approach and Scope

In developing this report, the framework, and recommendations herein, the committee deliberated for approximately 2.5 months (mid-July 2020 through September 2020), and held eight virtual meetings. Three of these meetings included sessions open to the public (all public meeting agendas can be found in Appendix A).

Soliciting Public Comments on the Discussion Draft of the Preliminary Framework for the Equitable Allocation of COVID-19 Vaccine

Importantly, as part of its study process, the committee made available a discussion draft of its framework, *Discussion Draft of the Preliminary*

BOX 1-1
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, 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?

As part of the overall study, the committee will produce a discussion draft of the framework for public comment, and hold a public workshop to solicit feedback from external stakeholders.

Framework for Equitable Allocation of COVID-19 Vaccine,[1] to obtain input from members of the public, especially groups disproportionately affected by COVID-19, to inform the committee's final report (see Appendix

[1] See https://www.nap.edu/catalog/25914 (accessed September 15, 2020).

A for additional details on the process). Between September 1 and 4, 2020, the committee conducted its public comment period which consisted of written and oral comment opportunities. The public comment period served to convey the inclusiveness of the committee's process to foster trust and engagement around the final report and to ensure that the framework reflects the realities and concerns of those dealing with COVID-19 on the ground. Beyond the formal public comment period, members of the public were able to submit comments through a link on the study webpage[2] or through a designated email address for the duration of the study.

The committee hosted a public listening session where more than 2,000 members of the public attended and more than 50 individuals were able to formally address the committee. During this public listening session, the committee heard from stakeholders from minority communities, state and local government representatives, health and medical professional organizations, those representing older adults, those representing occupations at risk, and stakeholders from special populations, such as those representing incarcerated individuals, as well as individuals experiencing homelessness.

The committee also accepted written comments through an online form. The written comment opportunity elicited more than 1,400 written comments. A summary of comments and how the committee responded to these suggestions is described in Appendix A. All materials and comments received through the online form were placed in the committee's Public Access File, and are available by request through the National Academies' Public Access Records Office.

Study Scope

As specified in the committee's Statement of Task (see Box 1-1), the committee was charged with assisting policy makers in planning for the equitable allocation of vaccines against COVID-19. This report focuses primarily on the allocation of one or more COVID-19 vaccines and the best way to do so equitably without further exacerbating—and to the extent possible, mitigating—existing health inequities. The report also addresses implementation issues necessary to ensure equitable allocation. 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.

[2] See https://www.nationalacademies.org/our-work/a-framework-for-equitable-allocation-of-vaccine-for-the-novel-coronavirus (accessed September 15, 2020).

- **Legal, regulatory, and public health changes:** The committee recognizes that the allocation of COVID-19 vaccine could be changed by regulatory or public health requirements (e.g., mask mandates, greater spacing of workers in food processing facilities). Should these 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. It is crucial that these other protective measures not be prematurely abandoned. A full discussion of other legal and regulatory issues that could impact allocation is generally beyond the scope of this study. They include, but are not limited to, the process of vaccine approval, distribution, and reimbursement at the federal level; the potential intersection of allocation criteria with federal and state anti-discrimination laws; variability in state vaccination mandates aimed at schoolchildren and employees in certain sectors, such as patient care; professional licensing and scope of practice rules; recognition of out-of-state provider licenses when additional professionals are needed; payment and reimbursement provisions and processes for the varying public and private insurers within states; provider and manufacturer exposure to liability; and state-based surveillance and privacy protections.
- **Advances in medical treatment and therapeutic agents:** The committee recognizes the vast, creative efforts made to improve medical treatment and develop therapeutic agents for COVID-19. As they succeed, they should reduce the risk of disease severity and death and may reduce the risk of transmission of infection. Here, too, the adaptability of the allocation procedure can accommodate changes in risk.

The guidance offered through the committee's allocation framework is intended to inform the work of the federal government, ACIP, and that of state, tribal, local, and territorial (STLT) authorities in their COVID-19 vaccine allocation planning. Throughout the report, there are key terms that are routinely used in the public health field that may contain nuance or depend on the particular context and user. Box 1-2 shows the committee's definitions for these key terms.

Report Audiences and Uses

In developing this report, the committee recognized the need for clear, transparent, and unified messaging at the federal level. While the National Academies cannot implement these phases or recommendations, the intention is for this report to guide those who can. Key audiences who can ben-

BOX 1-2
Key Terms Used Throughout the Report

Administration: For a program, the management or execution of it. For a vaccine, the route by which a vaccine enters the body (e.g., intramuscularly).

Allocation: How a resource is assigned; the theoretical concept of planning how to divide a vaccine among various groups.

Critical workers in high-risk settings: Workers in industries essential to the functioning of society and at substantially high risk of exposure.

Distribution: The process of physically disseminating and transporting vaccine from manufacturing sites to downstream partners and administration sites (including hospitals, pharmacies, providers, etc.).

Equitable/equity: Being fair and impartial. According to the World Health Organization, health equity "implies that ideally everyone should have a fair opportunity to attain their full health potential and that no one should be disadvantaged from achieving this potential."

SOURCES: CDC, 2020g; WHO, 2020b.

efit from and be informed by this report include the federal government and STLT authorities, as well as groups such as ACIP as they create and implement national and/or local guidelines for COVID-19 vaccine allocation.

Organization of the Report

The organization of this report closely follows the Statement of Task (see Box 1-1). Chapter 2 provides lessons learned from previous situations in which scarce resources were allocated and it describes other COVID-19 vaccine allocation efforts currently under way at the national and international levels.

Chapter 3 describes the committee's framework for the equitable allocation of COVID-19 vaccine and lays out the foundational principles that inform the vaccine allocation framework, the goal of the framework, the risk-based allocation criteria used to apply the principles, and the resulting allocation phases. Chapter 3 also contains the rationale behind the inclusion of the groups listed in each phase. Chapter 4 explores the application of the framework in different scenarios, such as those in which the number and timing of vaccine doses is variable, when vaccine uptake may be lower than expected, or under changing social, economic, and legal contexts.

The remaining chapters highlight key implementation considerations. Chapter 5 examines issues of program administration and monitoring and evaluation to ensure effectiveness and equity, and challenges related to vaccination costs. Chapter 6 focuses on risk communication and community engagement. Chapter 7 addresses vaccine acceptance, including the landscape of vaccine hesitancy and mistrust and strategies for vaccine promotion. Chapter 8 discusses the role of U.S. participation in global vaccine allocation. Finally, Appendix A describes in detail the methods of the study process, and Appendix B presents biographical sketches of the committee members and staff.

COVID-19 AND HEALTH EQUITY CONSIDERATIONS

In the United States and worldwide, the COVID-19 pandemic has magnified the intersectional and pervasive impacts of social and structural inequities in society. COVID-19 is having a disproportionate impact on people who are already disadvantaged by virtue of their race and ethnicity, age, health status, residence, occupation, socioeconomic conditions, and/or other contributing factors (Williams and Cooper, 2020). In public health crises, certain populations are often falsely accused of being the cause of an outbreak, further worsening stigma and discrimination. The current moment of ethical reckoning playing out around race in the United States reveals the disproportionate impact of the COVID-19 pandemic on racial and ethnic minorities and other vulnerable and marginalized groups through cultural and political discourse across the country (Yancy, 2020). Given the legacies of inequality, injustice, and discrimination that have undermined the health and well-being of certain populations in the United States for centuries, considerations of equity should factor into plans for allocating and distributing COVID-19 treatments and vaccines to the population at large (Essien et al., 2020).

Racial and Ethnic Equity

An increasing body of evidence indicates that in the United States, certain racial and ethnic groups including Black, Hispanic or Latinx, American Indian and Alaska Native, and Native Hawaiian and Pacific Islander communities have been disproportionately affected by COVID-19 (Cohen, 2020b; Johnson and Buford, 2020). This is evident in the overrepresentation of these groups in the daily number of reported cases[3] and in their

[3] According to CDC data, among cases where race and ethnicity are reported, 33 percent are Hispanic, 22 percent are Black, and 1.3 percent American Indian and Alaska Native (AI/AN). This impact is disproportionate because Hispanics make up 18 percent of the U.S. population, Blacks make up 13 percent, and AI/AN make up 0.7 percent (CDC, 2020a).

increased risk of severe clinical outcomes, hospitalization, and death (Gold et al., 2020; Killerby et al., 2020; Millett et al., 2020; Price-Haywood et al., 2020; Stokes et al., 2020). In Chicago, for example, both the number of COVID-19 cases per 100,000 persons and the mortality rates are higher among Hispanic and Black populations than among White populations. Similarly, age-adjusted COVID-19 (cause-specific) mortality rates are higher among Hispanic and Black populations (Webb Hooper et al., 2020).

American Indian and Alaska Native individuals had a cumulative incidence of laboratory-confirmed COVID-19 cases that was 3.5 times greater than that among non-Hispanic White individuals, according to data from 23 states as of July 2020 (Hatcher et al., 2020). Pacific Islander communities have experienced mortality from COVID-19 at a rate up to five times their proportion of the population compared to the general population (Wong, 2020). Due to COVID-19, Native Hawaiians have experienced mortality rates that are three times higher than the proportion of the population in Hawaii (Wong, 2020).

CDC has compiled data by race and ethnicity on the rates of COVID-19 cases, age-adjusted hospitalizations, and death (CDC, 2020b,d). Compared to non-Hispanic Whites, American Indian and Alaska Native persons had a case rate that was 2.8 times higher, a hospitalization rate that was 4.6 times higher, and a death rate that was 1.4 times higher (CDC, 2020b,d). Hispanic or Latinx persons had a case rate that was 2.8 times higher, a hospitalization rate that was 4.7 times higher, and a death rate that was 1.1 times higher (CDC, 2020b,d). Black and African American persons had a case rate that was 2.6 times higher, a hospitalization rate that was 4.7 times higher, and a death rate that was 2.1 times higher (CDC, 2020b,d).

Intertwined inequities and disparities in the social determinants of health—which CDC defines as "conditions in the places where people live, learn, work, and play that affect a wide range of health and quality-of-life risks and outcomes" (CDC, 2020j)—tend to impact racial and ethnic minority groups disproportionately (CDC, 2020c; Cohen, 2020b). Chronic conditions that are associated with worse COVID-19 outcomes—for example, diabetes mellitus, asthma, hypertension, kidney disease, and obesity—are more common in Black and Hispanic or Latinx populations than in White populations (Arasteh, 2020; Hatcher et al., 2020; Kirby, 2020). In the United States, the Native Hawaiian and Pacific Islander community is one of the highest-risk populations for cardiometabolic diseases, including diabetes mellitus, obesity, and hypertension (Mau et al., 2009). American Indians and Alaska Natives also tend to have higher rates of diabetes mellitus, obesity, hypertension, and other chronic conditions compared to the White population in the United States (Adakai et al., 2018; Poudel et al., 2018).

In addition to experiencing higher incidence and prevalence rates of chronic medical conditions, racial and ethnic minority populations tend to have limited access to health care, are less likely to be insured, and are more likely to live and work in conditions that worsen health outcomes (Tai et al., 2020). Minority groups also comprise a greater percentage of essential workers—only 20 percent of African Americans are able to work from home, for example—and many rely on public transportation to travel to work, which increases their likelihood of exposure to SARS-CoV-2 (Kirby, 2020; Tai et al., 2020). In New York City, 75 percent of frontline workers are people of color and 40 percent of transit workers are African American. Native Hawaiian and Pacific Islander populations are also disproportionately represented in essential workers groups in areas such as the hospitality industries, family businesses, and low-paying health care occupations; they are also more likely to live in congregate living settings (Wong, 2020), increasing their risk for SARS-CoV-2 infection. CDC has identified several categories of risk factors that are associated with COVID-19 illness, hospitalization, and death in racial and ethnic minority communities (CDC, 2020c) (see Box 1-3), all of which tie back to the historical impact of systemic racism and the social determinants of health. An increasing body of evidence demonstrates that racism and discrimination, through the biological impacts of stress, poverty, and other negative outcomes, play a direct role in the health of communities of color (RWJF, 2020; Williams, 2020).

These points are important, and the committee has taken great pains to emphasize them not only because of the moral and ethical implications of this disproportionate experience with COVID-19 by these individuals, but also because in our highly interconnected world, for the reasons previously noted, the challenges experienced by particular subpopulations have an effect on us all. If we have learned anything from this pandemic, it is that we are inevitably all in this together.

Historical Gap in Immunization Coverage

Historical precedent for the current disparities in COVID-19 morbidity and mortality is reflected in the gaps in routine and 2009 H1N1 influenza immunization coverage between non-Hispanic White and racial and ethnic minority populations. Non-Hispanic Whites have had higher coverage for routine immunizations compared to racial and ethnic minority groups (Walker et al., 2014). A nationally representative survey indicated that 2009 H1N1 influenza vaccine uptake was greater for White and Hispanic respondents than for Black respondents; the same trend was present for seasonal influenza vaccine (42.6 percent versus 32.2 percent) (Uscher-Pines et al., 2011). Another study found that Black and Hispanic populations were significantly less likely than White populations to receive influenza vaccine

BOX 1-3
COVID-19 Risk Factors for Infection and for Severe Disease Associated with Social Determinants of Health

The Centers for Disease Control and Prevention (CDC) defines social determinants of health as the "conditions in the places where people live, learn, work, and play that affect a wide range of health risks and outcomes." CDC approaches social determinants of health across five key areas:

- Economic Stability
- Education
- Health and Health Care
- Neighborhood and Built Environment
- Social and Community Context

Many of these social determinants of health disproportionately and negatively impact racial and ethnic minority groups. Discrimination in health care, housing, education, criminal justice, or finance can lead to chronic stress and may put some racial and ethnic minority groups at an increased risk for COVID-19. People from racial and ethnic minority groups face risks associated with health care access and utilization, as they are less likely to be insured than non-Hispanic Whites. Furthermore, health care access and utilization can be limited by lack of transportation, lack of child care, the inability to take time off work, communication barriers, cultural differences between patients and providers, or discrimination. Some of the occupations designated as "essential work" during the COVID-19 pandemic, including health care professions, farming, grocery workers, and public transportation, have disproportionate representation of certain racial and ethnic minority groups.

Thus, members of those racial and ethnic minority groups will likely experience disproportionate contact with the public and are less likely to be able to work from home. Furthermore, members of these groups are less likely to be able to take paid sick leave. For certain racial and ethnic minority groups, inequities in access to high-quality education can lead to lower high school completion rates and barriers to college completion, which may result in limited job prospects. Members of such groups may be less likely to have the job flexibility that might protect them from exposure to SARS-CoV-2 or the economic impacts of the COVID-19 pandemic. Some members of racial and ethnic minority groups live in crowded housing conditions, which can limit the ability of individuals to practice COVID-19 prevention strategies. Many members of racial and ethnic groups live in intergenerational homes, and disproportionate unemployment rates among these groups may lead to less stable housing, more crowded housing conditions, greater eviction risk, or homelessness.

SOURCES: CDC, 2020c,k.

regularly (Crouse Quinn et al., 2011). The 2009 H1N1 influenza vaccine coverage generally was higher among non-Hispanic Whites than among non-Hispanic Blacks. Vaccination coverage among Black health care workers was also lower, indicating that access to care was not the only barrier to vaccination (CDC, 2010). Black and Hispanic survey respondents also tend to be less likely than White respondents to agree that vaccines are "safe in general" (Uscher-Pines et al., 2011). Data from a program of dispensing free H1N1 influenza vaccinations at public clinics in Los Angeles County in 2009 showed that African Americans had the lowest rates of vaccination uptake compared to other racial and ethnic groups. A major challenge encountered during this immunization drive was community messaging and discourse that was at odds with the government messaging in the area. In response, county public health officials pursued audience-specific advertising, contracted local organizations to support accurate messaging, and engaged in outreach to community leaders and partners (Plough et al., 2011), demonstrating the need for targeted messages delivered by trusted messengers, particularly for groups marginalized within our medical systems.

Additional Health Equity Considerations

The full extent of COVID-19 on people's health and well-being will likely not be fully understood for years, but long-term effects are anticipated to span multiple dimensions, including behavioral, developmental, social, emotional, mental health, educational, and economic impacts. These impacts are felt around the globe, spanning all populations and regions; however, certain groups are at an increased risk of suffering from the multifaceted impacts of COVID-19. Table 1-1 provides an overview of key data available thus far on the impact of COVID-19 on these populations.

TABLE 1-1 Key Data on the Impact of COVID-19 on Certain Populations

Population	Key Impact Data
Black	• Compared to non-Hispanic White populations, this group has a case rate that is 2.6 times higher, a hospitalization rate that is 4.7 times higher, and a death rate that is 2.1 times higher (United States) (CDC, 2020b,d).
Hispanic/Latinx	• Compared to non-Hispanic White populations, this group has a case rate that is 2.8 times higher, a hospitalization rate that is 4.7 times higher, and a death rate that is 1.1 times higher (United States) (CDC, 2020b,d).
American Indian and Alaska Native	• Compared to non-Hispanic White populations, this group has a case rate that is 2.8 times higher, a hospitalization rate that is 4.6 times higher, and a death rate that is 1.4 times higher (United States) (CDC, 2020b,d).

continued

TABLE 1-1 Continued

Population	Key Impact Data
Native Hawaiian and Pacific Islander	• Group has experienced mortality from COVID-19 at a rate up to five times its proportion of the population compared to the general population (United States) (Wong, 2020).
Older adults (≥65 years)	• Group accounts for approximately 80 percent of reported deaths related to COVID-19 (United States) (CDC, 2020f). • Population-level COVID-19 mortality risk is estimated to be 16- to 52-fold higher (United States) and 30- to 100-fold higher (worldwide) for this group than for younger people (Ioannidis et al., 2020).
Older adults (>80 years)	• Group is experiencing a mortality rate 5-fold greater than average (United States) (Nikolich-Zugic et al., 2020; UN, 2020b). • Group is experiencing an "overwhelming percentage" of severe outcomes due to COVID-19 (worldwide).
People with underlying or comorbid conditions	• Group is 6-fold more likely to be hospitalized and 12-fold more likely to die from COVID-19 as people without underlying conditions (United States) (CDC, 2020a). • Group is at a greater risk of SARS-CoV-2 infection (Sanyaolu et al., 2020).
People who live and/or work in congregate settings	• Older adults living in senior living facilities are at high risk of severe COVID-19 (Nikolich-Zugic et al., 2020). • Long-term care facility residents accounted for half of >10,000 COVID-19 deaths reported by April 2020 (United States) (Chidambaram, 2020).
Sex	• Men with COVID-19 are more at risk for worse outcomes and death than women, independent of age (China) (Jin et al., 2020).
Children	• Children and adolescents account for 10 percent of COVID-19 cases and less than 0.3 percent of deaths (United States) (AAP and CHA, 2020). • Among children with COVID-19, 1.8 percent of cases resulted in hospitalization (United States) (AAP and CHA, 2020). • 78 percent of deaths among adolescents (under 21) reported to the Centers for Disease Control and Prevention between mid-February and the end of July 2020 were people from Black, Hispanic and Latinx, or American Indian and Native Alaskan communities (Bixler et al., 2020).
People who are pregnant or breastfeeding	• Group may be at an increased risk of developing severe COVID-19 disease that requires intensive care unit admission and mechanical ventilation (Cohen, 2020b). • Black and Hispanic women who are pregnant appear to be disproportionately at risk of severe disease and hospitalization (United States) (Ellington et al., 2020). • Babies born to women infected with SARS-CoV-2 during pregnancy appear to be more likely to be born preterm or require neonatal intensive care (Allotey et al., 2020).

NOTE: The following groups are omitted from the table due to a lack of COVID-specific epidemiological data: people who are undocumented, people with mental and physical disabilities, and people experiencing homelessness.

Special Populations at an Increased Risk from COVID-19

Differential health impacts are also experienced by certain populations who tend to experience worse outcomes if they contract COVID-19. Like racial and ethnic minority groups, many of these populations face underlying social and structural disparities that intersect to exacerbate health inequities.

Older Adults Older people who contract COVID-19 are at a greater risk of developing severe disease and dying (UN, 2020b). This risk is likely exacerbated by the fact that many elderly people have underlying health conditions or live in congregate settings, such as long-term care facilities, where transmission of SARS-CoV-2 can occur readily (Cohen, 2020b). In the United States, adults aged 65 years and older account for approximately 8 out of 10 reported deaths related to COVID-19 (CDC, 2020f). Among those 65 years of age and older, the risk of severe COVID-19 disease and mortality increases sharply with age (see Figure 1-1, which shows cumulative hospitalization rates per 100,000 persons stratified by age groups). In the United States, people aged 85 and older are experiencing an "overwhelming percentage" of severe outcomes due to COVID-19 (Nikolich-Zugic et al., 2020). Worldwide, estimates suggest that people aged >80 years are experiencing a mortality rate from COVID-19 that is about five times the average mortality rate (UN, 2020b). A global modeling study suggests that around two-thirds of people aged ≥70 years have at least one underlying health condition, which compounds their risks of COVID-19 infection, severe disease, and death (Sanyaolu et al., 2020). Compared to people below the age of 65, the population-level COVID-19 mortality risk for people aged 65 years and older is estimated to be 16-fold to 52-fold higher in the United States (based on data from 13 U.S. states) and 30-fold to 100-fold higher in Europe and Canada (based on data from 10 European countries) (Ioannidis et al., 2020). Because of the significantly greater likelihood that older people with COVID-19 will die—particularly those with underlying conditions that enhance their risk—protecting this vulnerable group should be a key consideration in managing the pandemic (Ioannidis et al., 2020). This group also presents a growing challenge over time, as the United Nations estimates that by 2050 there will more than twice as many people over age 65 as there will be children under 5, and the cohort of adults older than 65 will exceed the cohort of individuals who are 15–25 years old (Koff and Williams, 2020).

People with Underlying Conditions or Comorbid Conditions The risk of severe disease and death due to COVID-19 is greater among people with underlying conditions or comorbid conditions. These conditions include cancer, chronic kidney disease, chronic obstructive pulmonary disease, an immunocompromised state or weakened immune system from solid organ

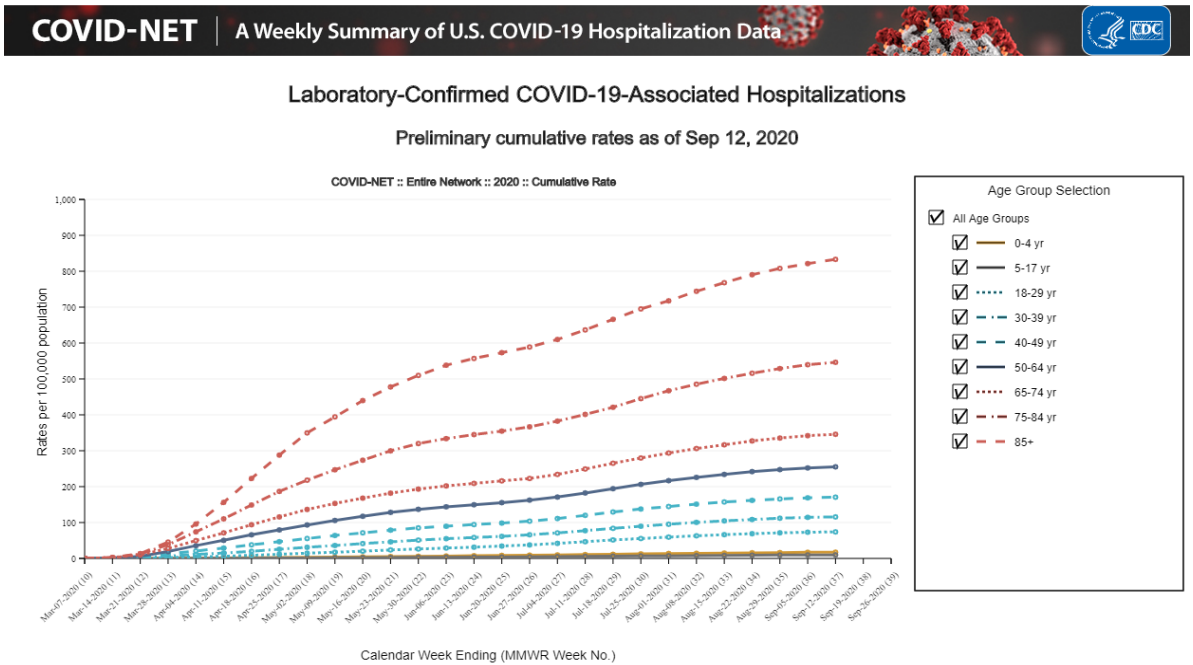

FIGURE 1-1 COVID-19 hospitalizations per every 100,000 persons, stratified by age group.
NOTES: The Coronavirus Disease 2019 (COVID-19)-Associated Hospitalization Surveillance Network (COVID-NET) conducts population-based surveillance for laboratory-confirmed COVID-19-associated hospitalizations in children and adults. The current network covers nearly 100 counties in the 10 Emerging Infections Program states, and 4 additional states through the Influenza Hospitalization Surveillance Project (14 states in total). The network represents approximately 10 percent of the U.S. population.
SOURCES: CDC, 2020f,i.

transplant, obesity, serious heart conditions, sickle cell disease, and type 2 diabetes mellitus (CDC, 2020g). Modeling estimates suggest that roughly 20 percent of people worldwide may be at an increased risk of severe COVID-19 disease due to their underlying health conditions. This risk also increases substantially with age, because both older adults and people with underlying health conditions tend to experience severe health outcomes if they contract COVID-19 (CDC, 2020a; UN, 2020b). 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 six times as likely to be hospitalized and 12 times as likely to die from the disease as those without underlying health conditions (CDC, 2020a; Sanyaolu et al., 2020). Although older people are more likely to have one or more comorbid conditions, people of any age with underlying health conditions are at greater risk of severe COVID-19 (Sanyaolu et al., 2020). CDC's data suggest that about one-third of patients aged 18–49 who are diagnosed with COVID-19 have underlying chronic lung disease, such as asthma (Sanyaolu et al., 2020). CDC has developed a list of medical conditions that increase the risk of severe COVID-19 illness, which is updated on an ongoing basis (see Box 1-4).

People Who Live and/or Work in Congregate Settings People who live or work (or both) in congregate settings, such as nursing homes or group residential homes, are at higher risk of acquiring COVID-19 and developing severe disease. Approximately 1,347,000 people in the United States live in nursing homes, 811,000 reside in assisted living facilities, and approximately 75,000 live in intermediate-care facilities—in addition to more than 3 million people who work in nursing or residential care facilities (CDC, 2020e,j; Chidambaram, 2020; True et al., 2020). Older adults residing in senior living facilities are at a high risk of severe COVID-19 due to the burden of chronic illness and their exposure to the virus while to living in congregate housing (Nikolich-Zugic et al., 2020). In a sample of 23 states with publicly reported death data as of April 23, 2020, more than 10,000 deaths—or 27 percent of all deaths due to COVID-19 in the sample—occurred among people living in long-term care facilities. Across Colorado, Delaware, Massachusetts, Oregon, Pennsylvania, and Utah, more than half of all COVID-19 deaths occurred among residents of long-term care facilities (Chidambaram, 2020).

Older people living in congregate settings tend to have one or more underlying health conditions. However, many people without such underlying conditions are at increased risk of SARS-CoV-2 infection due to living or working in congregate settings: for example, prisoners, meat packers, soldiers, and grocery store workers (Cohen, 2020b). People who are in-

BOX 1-4
Centers for Disease Control and Prevention's List of Medical Conditions That Increase the Risk of Severe COVID-19 Illness

People of any age with the following conditions are at an increased risk of severe illness from COVID-19:

- Cancer
- Chronic kidney disease
- Chronic obstructive pulmonary disease
- Immunocompromised state from solid organ transplant
- Obesity (body mass index ≥30)
- Serious heart conditions (e.g., heart failure, coronary artery disease, cardiomyopathies)
- Sickle cell disease
- Type 2 diabetes mellitus

People with the following conditions might be at an increased risk for severe illness from COVID-19:

- Asthma (moderate-to-severe)
- Cerebrovascular disease
- Cystic fibrosis
- Hypertension
- Immunocompromised state from blood or bone marrow transplant, immune deficiencies, HIV, use of corticosteroids, or use of other immune-weakening medicines
- Liver disease
- Neurologic conditions, such as dementia
- Pregnancy
- Pulmonary fibrosis
- Smoking
- Thalassemia
- Type 1 diabetes mellitus

SOURCE: CDC, 2020g.

carcerated tend to have multiple risk factors that can increase their risk of contracting SARS-CoV-2 infection and experiencing worse outcomes upon developing COVID-19. The United States incarcerates more individuals than any other country, with nearly 2.2 million people living in prisons and jails at the end of 2016 (Akiyama et al., 2020). The nature of incarceration makes it difficult or impossible to maintain adequate social distance, thus increasing transmission of SARS-CoV-2 (Hawks et al., 2020). For instance, at Rikers Island prison in New York, more than 200 additional infections were diagnosed within just 2 weeks after the first case was detected in the

facility (Hawks et al., 2020). At San Quentin prison in California, more than 1,600 infections have been diagnosed (Maxmen, 2020). Age and comorbid conditions can also exacerbate the risk of COVID-19 among people who are incarcerated. Due to longer sentences, the average age of the prison population in the United States has increased. Between 1993 and 2013, the number of people aged >55 years in prisons increased by nearly 400 percent (Hawks et al., 2020), and the U.S. Department of Justice reports that 81,600 persons who are incarcerated are aged >60 years (Akiyama et al., 2020). Half of the people who are incarcerated in state prisons have at least one chronic condition—for example, heart disease (10 percent) and asthma (15 percent)—at prevalence rates that are higher than those in the general population, even when age is taken into account (Hawks et al., 2020). Furthermore, some population groups are more likely to be disproportionately incarcerated, including racial ethnic minorities, people with unstable housing, and people with substance use disorders or mental illness (Akiyama et al., 2020). Despite their heightened risk of acquisition and transmission of infection, people who are incarcerated may also face barriers in accessing health care. For instance, the 2009 H1N1 vaccine roll-out exposed the failure to incorporate prisons into planning efforts (Akiyama et al., 2020). On the other hand, long-term carceral settings may facilitate easier deployment of a multi-dose vaccine.

People Experiencing Homelessness The United States has a large number of people experiencing homelessness, who also may experience greater risks related to COVID-19. Between 2007 and 2019, the United States had approximately 500,000 individuals experiencing homelessness on any given night (Tsai and Wilson, 2020). People aged <65 years experiencing homelessness have an all-cause mortality rate that was already 5–10 times higher than that in the general population before the arrival of COVID-19; this disparity in mortality could be further widened by the pandemic (Tsai and Wilson, 2020). Homelessness can exacerbate conditions that drive SARS-CoV-2 transmission, including crowded shelters/housing and limited access to basic hygiene, such as hand-washing facilities (Tsai and Wilson, 2020). Homeless individuals often have less access to health care, which can limit their access to COVID-19 testing, quarantine, and treatment (Tsai and Wilson, 2020). Additionally, the transient and geographically mobile nature of populations experiencing homelessness could undermine efforts to track infection and prevent transmission (Tsai and Wilson, 2020).

People with Mental and Physical Disabilities Having a disability, in and of itself, does not put individuals at a higher risk for SARS-CoV-2 infection or severe COVID-19 illness—according to CDC, the key factor lies in the likelihood of having serious underlying comorbid conditions (CDC,

2020h). However, adults with disabilities are three times more likely to have conditions such as heart disease, stroke, diabetes mellitus, or cancer when compared to adults without disabilities (CDC, 2020h), which puts them at a higher risk of severe illness from COVID-19. In addition, some groups experience an increased risk due to the living conditions necessitated by their disability. For example, some individuals with limited mobility will frequently come into unavoidable close contact with others, such as caregivers (CDC, 2020h). Additionally, millions of people with developmental disabilities live in group homes as a direct result of court mandates requiring depopulating institutions. Some people with disabilities who may have trouble understanding information or engaging in safe behavior—such as social distancing or hand washing—are also at increased risk (CDC, 2020h), and those who may not be able to communicate or convey the symptoms they experience from COVID-19 can lead to an increased risk of infecting others or having unrecognized illness (CDC, 2020h).

Differential Impact Across Sex and Gender Current evidence suggests that men and women have similar rates of COVID-19 disease. However, men who contract COVID-19 are at greater risk for severe outcomes and death, regardless of age. In one public data set, the proportion of men who died from COVID-19 was 2.4 times that of women (Jin et al., 2020). However, the broader social and economic impacts of COVID-19 are intensified for women and girls because of their gender (UNWomen, 2020). These impacts are being amplified in many contexts where social cohesion has been undermined and institutional capacity and services have been limited. The impacts of women's and girls' generally lower economic status have been compounded by COVID-19, and the disruption of services for children and older persons has created an additional burden of unpaid care work on women and girls. Deepening economic and social stress, restricted movement, and social isolation measures have led to exponential increases in gender-based violence (Kofman and Garfin, 2020), as many women have been forced to "lockdown" with their abusers while support services for survivors of abuse have become inaccessible (Usher et al., 2020).

Differential Impact Across Geographic Regions Across geographic regions within the United States, different trends have emerged. As of September 14, 2020, 31 out of 50 states are classified as COVID-19 hot spots (KFF, 2020). Hot spots are defined as states where (1) cases have increased by more than 5 percent over the last 2 weeks; (2) the 7-day rolling average positivity rate exceeds 10 percent or has increased by more than 1 percent over the last 2 weeks; and (3) per 1 million persons, new daily cases are more than 100 (KFF, 2020). Differences also exist across states based on policies such as social distancing requirements (e.g., non-essential business

closures, stay-at-home orders, large gathering bans), removal of barriers to testing and treatment (e.g., paid sick leave), and whether the states are reporting data regarding illness and mortality in long-term care facilities (KFF, 2020), a key factor contributing to the differential burden of COVID-19 across jurisdictions.

People Who Are Undocumented People who are undocumented or otherwise living without clear legal status may also experience higher risks due to COVID-19. Although the populations of Hispanic immigrant communities tend to be relatively young and healthy, the prevalence of diabetes mellitus—a risk factor for more severe COVID-19 disease—is 22 percent among people who are Hispanic, which is the highest prevalence in any racial ethnic group in the United States (Page et al., 2020). Additionally, many undocumented immigrants work in service industries and are unable to isolate at home (Page et al., 2020). Health care system and access problems also compound the inequities faced by this population. The Patient Protection and Affordable Care Act does not provide health insurance coverage eligibility to undocumented individuals; as a result, an estimated 7.1 million undocumented immigrants lack health insurance and are prevented from accessing health care (Page et al., 2020). Under the Public Health Service Act, the United States can provide free COVID-19 care, but it is unclear how this has applied in the current pandemic situation. Out-of-pocket fees will likely limit COVID-19 testing and provision of appropriate care; even those who can and do access health care, whether in person or via telehealth, may struggle with limited English and may rely on outdated or incorrect health information available online (Page et al., 2020).

Children More research is needed to understand the impact of SARS-CoV-2 infection on children. According to data compiled by the American Academy of Pediatrics (AAP) as of September 10, 2020, children and adolescents account for 10 percent of COVID-19 cases and less than 0.3 percent of deaths (AAP and CHA, 2020). Most children diagnosed with COVID-19 experience mild symptoms, most commonly fever and cough (NASEM, 2020). Although children tend to experience mild infections, a study of 582 children aged <18 years in 21 countries found that 62 percent of those with COVID-19 were admitted to the hospital, 8 percent required intensive care unit (ICU) admission, and 4 percent required mechanical ventilation (Gotzinger et al., 2020). Research on multisystem inflammatory syndrome in children, a rare but severe pediatric disease that is temporally associated with COVID-19, is ongoing (Ahmed et al., 2020), and consistent with observations previously described, children who are Black, Hispanic or Latinx, American Indian and Alaska Native, or who have certain underlying conditions (e.g., obesity, lung disease) are at increased risk of hospitalization or

death due to COVID-19 (Bixler et al., 2020; Kim et al., 2020). One study found that, among adolescent (under the age of 21) COVID-19-related deaths reported to CDC from mid-February through the end of July 2020, 78 percent were Black, Hispanic or Latinx, or American Indian and Alaska Native individuals (Bixler et al., 2020). Overall, AAP has reported that as of September 10, 2020, 1.8 percent of all child COVID-19 cases resulted in hospitalization (AAP and CHA, 2020). The COVID-19 pandemic will likely shape the worldview, hygiene habits, and consumer behavior of children, and it remains to be seen how profoundly the pandemic interferes with children's development, education, and long-term relationships. Some children may face permanent life alterations or developmental impairments, such as through the effects of acute malnutrition, exposure to toxic stress, family breakdown, child labor, or teenage pregnancy (UN, 2020a). Increasing joblessness associated with the COVID-19 pandemic will likely have long-term consequences for child poverty. Furthermore, the longer schools remain closed, the less likely children will be able to catch up in terms of both education and life skills (UN, 2020a). Current COVID-19 vaccine trials do not include children, a gap that must be filled to ensure safety and efficacy of COVID-19 vaccine in pediatric populations (Branswell, 2020).

People Who Are Pregnant or Breastfeeding Emerging evidence suggests that pregnant women may be at an increased risk of developing severe COVID-19 disease that requires ICU admission and mechanical ventilation (Cohen, 2020b; Ellington et al., 2020). Moreover, Black and Hispanic women who are pregnant appear to be disproportionately affected by SARS-CoV-2 infection during pregnancy (Ellington et al., 2020), and factors such as increased maternal age, high body mass index, chronic hypertension, and pre-existing diabetes have been associated with severe COVID-19 during pregnancy (Allotey et al., 2020). In addition, infants born to women who are infected with SARS-CoV-2 during pregnancy appear to be at an increased risk for adverse outcomes, including preterm birth and admission to a neonatal intensive care unit (Allotey et al., 2020). People breastfeeding infants while infected with SARS-CoV-2 does not appear to put the infants at risk (Chambers et al., 2020). Pregnant women are not generally prioritized to receive new vaccines, given the potential for fetal harm (Cohen, 2020b). Pregnant women have been excluded from COVID-19 vaccine clinical trials, leaving deployment of any COVID-19 vaccine in this group without evidence as to their safety and efficacy (LaCourse et al., 2020).

COVID-19 VACCINE LANDSCAPE

The development and widespread allocation and distribution of a safe and effective COVID-19 vaccine is the cornerstone of establishing

community-level protection and suppressing the COVID-19 pandemic (O'Callaghan et al., 2020). The global scope of the COVID-19 pandemic and the urgent need for widespread vaccination—perhaps of up to 60 percent of the worldwide population—has created an unparalleled scenario in which the timeline for vaccine development is being compressed from what has typically been 1–2 decades to just 1–2 years or less (Graham, 2020; Lurie et al., 2020; O'Callaghan et al., 2020; Steenhuysen and Kelland, 2020). Developing an effective vaccine against a newly discovered viral pathogen in such a short time frame is unprecedented, but efforts around the world have now generated multiple promising candidates that are entering various stages of clinical trials. However, the successful development of a vaccine will give rise to another host of unprecedented logistical challenges related to manufacturing, purchasing, distribution, allocation, and uptake. These challenges are compounded and intensified by the need to rapidly manufacture and equitably distribute billions of doses of vaccine concurrently across the globe.

Vaccine Development

A COVID-19 vaccine could be effective in two ways: either by preventing people from getting infected or by reducing the severity of disease if a person does become infected (Chen, 2020). Candidate vaccines are tested in three phases (see Table 1-2 for more detail) of clinical trials focusing on (1) safety, a primary concern through every phase of testing; (2) the

TABLE 1-2 Explanation of Phases of Vaccine Trials

Phase	Name	Explanation
Phase I	Safety Trials	The vaccine is given to a small number of people. Dosage, safety, and stimulation of the immune system are tested. This is the first trial in humans.
Phase II	Expanded Trials	The vaccine is given to hundreds of people across different population groups to see how and if the vaccine behaves differently in them. These test further the safety and stimulation of the immune system.
Phase III	Efficacy Trials	The vaccine is given to thousands of people to monitor how many become infected or develop the disease in comparison to a placebo control group. This helps establish whether or not the vaccine can protect against the virus, and additional safety monitoring is conducted as well. (A COVID-19 vaccine will have to protect at least 50 percent of those who received the vaccination in order to be deemed effective by the U.S. Food and Drug Administration.)

SOURCES: Corum et al., 2020; FDA, 2018; Lurie et al., 2020.

induction of an immune response; and (3) efficacy in an ideal setting, prior to assessing real-world effectiveness in post-marketing Phase IV trials (Chen, 2020). A key indicator of vaccine efficacy is a robust and durable immunogenic response (O'Callaghan et al., 2020). Fortunately, the genetic sequence of SARS-CoV-2 appears to be relatively stable thus far, which is promising for a vaccine's ability to provide durable protection and to match currently circulating variants of the virus (Chen, 2020; Dearlove et al., 2020). In order to be authorized for use, the U.S. Food and Drug Administration (FDA) guidance indicates that a COVID-19 vaccine will need to be at least 50 percent efficacious in placebo-controlled trials (Craven, 2020; FDA, 2020).

Major Ongoing Development Efforts

According to the World Health Organization (WHO), 149 COVID-19 vaccines are currently in pre-clinical development and 38 candidate vaccines are undergoing evaluation in clinical trials in the United States, Europe, and China (Lee et al., 2020; WHO, 2020a). As of early September 2020, the Regulatory Affairs Professionals Society (Craven, 2020) vaccine tracker is currently tracking 45 vaccine candidates, many of which are in Phase I–III trials and some of which are promising candidates in the preclinical stages of research and development (Craven, 2020). Globally to date, only one vaccine has been approved, from the Gamaleya Research Institute of Epidemiology and Microbiology in Moscow, Russia; however, it has not yet undergone Phase III clinical trials so its efficacy is unknown, and it has only been approved in Russia (Craven, 2020). Domestically, the U.S. government has homed in on six COVID-19 vaccine candidates, with four currently in Phase III trials: the Johnson & Johnson JNJ-78436735, the Moderna/NIAID mRNA 1273, the University of Oxford/AstraZeneca AZD1222, and the Pfizer and BioNTech BNT162 (Craven, 2020). More details follow about all six vaccine candidates currently funded through Operation Warp Speed (OWS). Other major candidates (several of which are also being funded by the Coalition for Epidemic Preparedness Innovations) include vaccines being developed by Clover Biopharmaceuticals, the University of Queensland, Sinovac, the Wuhan Institute of Biological Products/Sinopharm, CanSino Biologics, and the University of Melbourne and Murdoch Children's Research Institute (Craven, 2020).

Operation Warp Speed

In May 2020, the U.S. Department of Health and Human Services (HHS) launched OWS as a public–private partnership with the objective of delivering 300 million doses of a safe and effective COVID-19 vaccine by

January 2021 (HHS, 2020a). OWS is a collaboration that involves multiple federal entities (HHS and its agencies and the U.S. Department of Defense—with additional involvement by the U.S. Departments of Agriculture, Energy, and Veterans Affairs) and NIH's partnerships with 18 biopharmaceutical companies working to develop a COVID-19 vaccine (HHS, 2020a).

As of early September 2020, OWS has publicly announced six contracts supporting vaccine development, each including a clause that guarantees a supply of COVID-19 vaccine to the U.S. government should a vaccine receive approval and licensure from FDA (HHS, 2020a). The vaccine candidates included span four platform technologies: mRNA, replication-defective vector, subunit protein adjuvanted, and live-attenuated vector (Slaoui, 2020). It is anticipated that OWS may pursue one additional agreement to complete its portfolio, potentially under the live-attenuated vector platform. The six vaccine candidates currently supported under OWS include those being developed by:

- **AstraZeneca and the University of Oxford (replication-defective vector)**—OWS is providing up to $1.2 billion in support, and at least 300 million doses of vaccine are guaranteed to the U.S. government (HHS, 2020a).
- **GlaxoSmithKline and Sanofi (protein adjuvanted)**—OWS is providing up to $2 billion in support, and at least 100 million doses of vaccine are guaranteed to the U.S. government (HHS, 2020a).
- **Johnson & Johnson (Janssen) (replication-defective vector)**—OWS is providing up to $1 billion in support, and at least 100 million doses of vaccine are guaranteed to the U.S. government (HHS, 2020a).
- **Moderna (mRNA)**—OWS is providing up to $1.5 billion in support, and at least 100 million doses of vaccine are guaranteed to the U.S. government (HHS, 2020a).
- **Novavax (protein adjuvanted)**—OWS is providing up to $1.6 billion in support, and at least 100 million doses of vaccine are guaranteed to the U.S. government (HHS, 2020a).
- **Pfizer and BioNTech (mRNA)**—OWS is providing up to $1.95 billion in support, and at least 100 million doses of vaccine are guaranteed to the U.S. government (HHS, 2020a).

From among these six candidates, four vaccine candidates are furthest along in development, all of which aim to induce antibodies against the receptor-binding domain of the surface spike protein of SARS-CoV-2 (O'Callaghan et al., 2020). The four candidates span two categories:

1. Messenger RNA (mRNA) vaccines: Moderna (mRNA-1273) and Pfizer/BioNTech (BNT 162)

2. Adenovirus replication-defective vectored vaccines: AstraZeneca and the University of Oxford (AZD1222) and Johnson & Johnson (JNJ-78436735)

Categories of the OWS Candidate COVID-19 Vaccines Currently in Phase III Trials

An mRNA vaccine uses a novel method for inducing the production of a robust immune response that does not require introducing SARS-CoV-2 itself. It delivers mRNA coding for the SARS-CoV-2 antigen into human cells, where antigen can be produced (O'Callaghan et al., 2020). This type of vaccine would be easier to produce in mass quantities than would other categories of COVID-19 vaccine, but an mRNA vaccine has never before been approved for commercial use to prevent infections. Both Moderna's and Pfizer and BioNTech's versions of this type of vaccine are currently being tested in Phase III studies and will require two doses (28 days between doses for Moderna's vaccine and 21 days between doses for Pfizer and BioNTech's vaccine) to provide adequate immune response and clinical protection (Jackson et al., 2020; Pfizer, 2020).

Adenovirus replication-defective vectored vaccine candidates use different vectors to deliver recombinant SARS-CoV-2 spike protein genes—derived from the surface of the virus—to human cells and induce an immune response (O'Callaghan et al., 2020). AstraZeneca and the University of Oxford developed a replication-defective simian adenovirus vector-based COVID-19 vaccine candidate that recently resumed Phase III trials outside the United States after they were paused to allow for a safety review following a suspected adverse event (trials remain paused in the United States); the candidate is being tested for use with either one or two doses (AstraZeneca, 2020). Johnson & Johnson's adenovirus vector-based COVID-19 vaccine candidate leverages the company's AdVac technology, which was also used for its Ebola vaccine that has been approved for use by the European Commission; the candidate being tested in Phase III trials uses a one-dose regimen (Johnson & Johnson, 2020). Johnson and Johnson's candidate is anticipated to remain stable at –20 degrees Celsius, with similar requirements for the AstraZeneca and University of Oxford vaccine candidate. For the two COVID-19 vaccine candidates using mRNA technology, cold chain requirements are among the highest concerns for manufacturing, with ultra-cold storage (–80 degrees Celsius) potentially required (Slaoui, 2020; Taylor, 2020).

Expediting Vaccine Development

Given the urgency of the pandemic, multiple strategies are being employed or considered to help expedite the COVID-19 vaccine development

process. Some vaccine developers are conducting vaccine immunogenicity and efficacy trials in parallel, instead of sequentially, and liaising with multiple regulatory bodies to expedite the path to approval and licensure (Steenhuysen and Kelland, 2020). Human challenge trials offer the possibility of expediting this process by approving a vaccine based on its expected benefit, if the antibody levels in trial participants are similar to those observed in people infected in the real world (Chen, 2020). Human challenge trials have also been suggested to expedite vaccine development, but in addition to serious ethical concerns related to infecting healthy participants to test a vaccine, such trials necessarily involve very small sample sizes that are insufficient to assess safety (Chen, 2020; Cohen, 2020a). To facilitate large-scale clinical trial testing of COVID-19 vaccine candidates (and monoclonal antibodies), NIH's National Institute of Allergy and Infectious Diseases (NIAID) established the COVID-19 Prevention Trials Network in July 2020 (Cohen, 2020a) by merging four existing NIAID-funded clinical trial networks: the HIV Vaccine Trials Network, the HIV Prevention Trials Network, the Infectious Diseases Clinical Research Consortium, and the AIDS Clinical Trials Group.

In the United States, regulatory requirements have been adjusted to expedite authorization and clinical trials, and FDA is encouraging studies on the use of COVID-19 vaccines among pregnant women as well as the enrollment of racial and ethnic minorities disproportionately affected by the disease (Chen, 2020). Trials including children are anticipated to occur eventually and will be necessary to establish safety and efficacy in pediatric populations (Branswell, 2020). Other countries have existing emergency use provisions that allow for the use of a candidate vaccine among people at high risk of disease while Phase III trials are ongoing (Edmond, 2020). From the perspective of regulatory bodies, however, accelerating vaccine development increases the risk that adverse events will not be detected prior to widespread distribution, given smaller Phase III trial enrollment and shorter follow-up time with participants (GAO, 2020). Rapid development and testing may also give rise to concerns about vaccine safety and exacerbate vaccine hesitancy among the general public, which could impact vaccine uptake when distribution of a vaccine begins (Schaffer DeRoo et al., 2020).

Vaccine Manufacturing

When a successful COVID-19 vaccine has been approved, fulfilling the global demand will require the rapid production of an unprecedented number of doses. The required number of vaccine doses and the necessary manufacturing infrastructure and facilities will depend on the type of vaccine candidate(s) that is (are) successful (Khamsi, 2020). Inevitably,

this demand will create major manufacturing-related challenges, including insufficient capacity, material shortages, and bottlenecks. The current global supply chain for vaccines is characterized by a small number of large companies with the capacity to manufacture large quantities of vaccine doses, but those companies are already operating at or near capacity producing other critical vaccines for seasonal influenza and other infectious diseases (e.g., measles), which they must continue to produce (Edmond, 2020; Furlong, 2020; Khamsi, 2020). Some pharmaceutical companies are planning to manufacture different components of a COVID-19 vaccine at different sites worldwide (Furlong, 2020). However, travel restrictions are making it difficult for companies to deploy experts to oversee production sites and technology transfers in other countries (Chen, 2020).

A major limiting factor in vaccine manufacturing could be shortages in automated filling and finishing capacity—this involves the vaccine being placed into vials or syringes, sealed, and packed for shipping (Chen, 2020). Further manufacturing bottlenecks could be caused by shortages of raw materials and adjuvants for subunit vaccines, plus, vials, stoppers, and supplies for labels and package inserts (Chen, 2020; Khamsi, 2020). Vaccine manufacturing also requires a skilled workforce, which can prevent smaller manufacturers or those in low-resource settings from entering the market. This inequity has the potential to impede access to effective vaccines outside of wealthier nations (Anderson, 2020; Furlong, 2020).

Various strategies could help address these manufacturing challenges. For example, the adoption of platform technologies for manufacturing different types of vaccines using the same production process in a single facility could help solve problems of scale-up and speed (Furlong, 2020). However, platform technologies have not yet been used to produce mRNA-based vaccines (Furlong, 2020) and they do not enable single-dose vials to be filled at the same rapid speed at which doses are produced. Process intensification—which involves densification of equipment and chaining to ensure continuous or semi-continuous processing—could increase production volume, reduce costs, and enable smaller facilities in lower-resource settings with less access to skilled workers to enter the supply chain (Anderson, 2020).

Financing and Purchasing

From a financing perspective, developing and manufacturing vaccines is inherently risky and hugely costly, even in normal circumstances. Only about 6 percent of vaccine candidates ultimately make it to market (Steenhuysen and Kelland, 2020), and setting up a production facility in the United States can cost US$50–$500 million for a monovalent vaccine and up to US$700 million for a polyvalent vaccine (Anderson, 2020). Produc-

tion of a COVID-19 vaccine is projected to cost in the billions of dollars, which far exceeds current public and private financing commitments (Khamsi, 2020).[4] The current pandemic situation has required concurrent investment in developing candidate vaccines of unknown benefit and in scaling up vaccine-specific manufacturing capacity and supply chains—capacity that might never be used if that candidate proves unsafe or ineffective (Furlong, 2020; Khamsi, 2020). Some of this enormous financial risk is being mitigated by advance-purchase agreements with countries for promising vaccine candidates (Furlong, 2020). However, a major concern is the emergence of vaccine nationalism, whereby governments hoard supplies, buy up large amounts of future doses, and seek to manufacture vaccines domestically to maintain control (Furlong, 2020). Manufacturing "at risk" can expedite the distribution process through upfront investment to begin mass production of a vaccine while it is still undergoing clinical trials (Chen, 2020; Steenhuysen and Kelland, 2020). If clinical trials demonstrate that a vaccine is safe and effective, then huge numbers of doses will already be available for distribution to populations at greatest risk. The inherent risk is the loss of that investment if the candidate vaccine is unsuccessful.

Vaccine Distribution

If and when a sufficient number of doses of COVID-19 vaccine are manufactured, they must reach the people who need them. Distribution of the vaccine will present its own set of complex challenges related to cost, access, logistics, and allocation/prioritization of the limited number of doses that will be available in the early stages if a vaccine is successful, as well as mitigating concerns about vaccine safety. Some vaccines may require two doses to produce immunity, creating further complexity in distribution, although administering multiple doses might be easier in institutional settings (Chen, 2020). The global supply chain is untested in operating at this scale, and any breakdown could have serious consequences for effective vaccine deployment (Chen, 2020; Steenhuysen and Kelland, 2020). Lack of capacity for cold storage and insufficient cold supply chains could pose major barriers to global vaccine distribution. Some vaccines (e.g., mRNA vaccines) may require storage and shipping at an ultra-cold temperature (–80 degrees Celsius), which can cause glass vials to shatter (Chen, 2020), but companies developing mRNA vaccines are exploring ways to make the vaccines stable at higher temperatures (Chen, 2020). Broken cold chains are a major cause of vaccine wastage and could limit access to vaccines in

[4] Some large funders are investing in large companies with an established track record in vaccine development, regulatory approval, and production at scale, while others are investing in smaller entities with promising candidates but less experience in approval and production (Steenhuysen and Kelland, 2020).

regions of the world where breakdowns in the cold supply chain are already frequent.[5] Massive numbers of new vials, syringes, and needles will also be needed to deliver billions of vaccine doses to the people who need them (Chen, 2020). Potential solutions include innovations such as prefilled plastic syringes,[6] plastic vials with glass linings,[7] and multi-dose bags or vials that contain larger numbers of doses, which can be filled more quickly and are easier to store (Furlong, 2020). However, it is important to note that such novel solutions will require testing to ensure no interaction between the vaccine and storage materials, such as plastic.

Moving beyond supply concerns and onto demand side considerations, broad vaccine acceptance will be key to successful vaccine uptake as well. Already, surveys indicate that more work is needed to promote a potential COVID-19 vaccine and ensure public trust in a vaccine and the processes involved in its delivery. Chapter 7 of this report, focused on vaccine acceptance, discusses these issues at length.

Last, vaccine distribution, although essential, is but one part of a pandemic response and one tool for responding to the COVID-19 pandemic. Other efforts to mitigate the transmission of COVID-19, such as social distancing, testing, diagnostic testing, contact tracing, and wearing masks all continue to be of vital importance especially during the early phases of vaccinations. Continued guidance on these practices remains an important reality, including discussions of optimal strategies for leveraging these interventions in combination. The introduction of a COVID-19 vaccine would be a valuable addition to the pandemic response, but must be a part of a multi-pronged public health response to COVID-19.

CONTEXTUALIZING COVID-19 VACCINATION EFFORTS IN THE CURRENT SYSTEM

In conducting its work, the committee assumed that the national COVID-19 vaccine program will build on the solid and tested national vaccine program that has existed for 65 years and has evolved and improved over the years. The program started in 1955 with the development of an effective poliomyelitis inactivated vaccine. Over the years, it expanded to include a score of vaccines leading to major public health improvements. Polio was eliminated from the United States and measles transmission was

[5] Furthermore, cold chains are also very energy intensive and require refrigerants that contribute to global warming (Furlong, 2020).

[6] HHS and the U.S. Department of Defense are supporting efforts to increase capacity for manufacturing up to half a billion pre-filled plastic syringes by 2021, but this could be delayed by the need for FDA approval for the technology (Chen, 2020).

[7] However, larger vials that contain 5–20 doses can lead to potential waste if all of the doses are not used within 24 hours after the vial is opened (Chen, 2020).

interrupted, appearing now only as the result of importations of the virus. Mumps, rubella, *Haemophilus influenzae* B meningitis, and other diseases have become a memory and are likely to be unknown by new parents.

The United States national vaccine program is a coalition of seamless components, and OWS recently released a figure demonstrating anticipated plans for distribution of a COVID-19 vaccine that reflects the relationship between various partners (see Figure 1-2). FDA determines the safety and efficacy of new vaccines, and has the regulatory authority to license them for use in the United States. ACIP provides consultation to CDC on how to use the vaccines. CDC in turn develops guidelines on age groups, the routine immunization schedule, and the need for boosters, and it monitors the provision of the vaccines based on state needs. Within the framework of federal guidelines, STLT authorities have had the flexibility to adapt the system to their own needs. Over the years, some STLT authorities have developed strong programs using health care providers (e.g., pediatricians, family practitioners, registered nurses) to administer a vaccine—while other states have used public health clinics. For many years, varied systems for tracking vaccinated children could not communicate, but over time, even this difficulty has been addressed.

However, the vaccination program goes beyond this. States can request a CDC field assignee from the Program Operations Branch in the Immu-

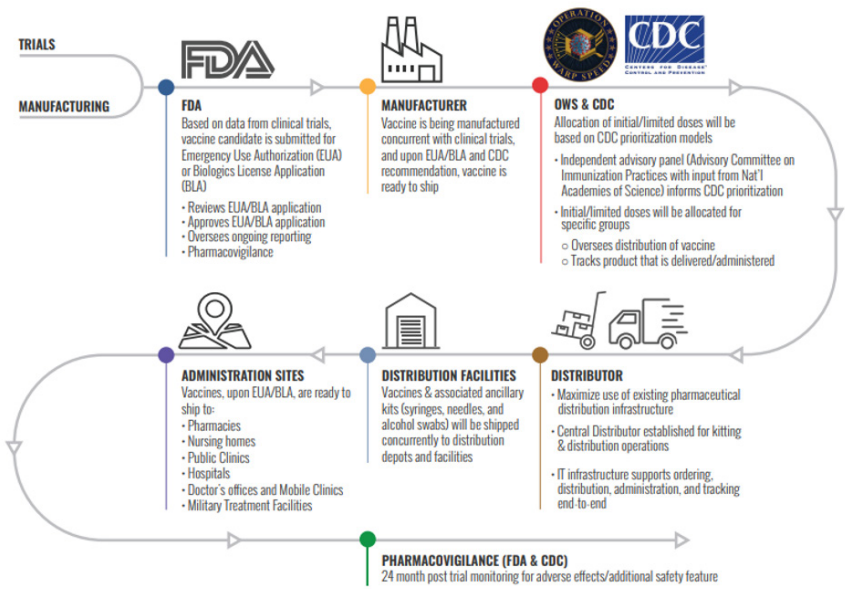

FIGURE 1-2 Operation Warp Speed vaccine distribution process.
SOURCE: HHS, 2020b.

nization Services Division of the National Center for Immunization and Respiratory Diseases to help in the delivery of vaccines (there are currently approximately 70 assignees managed under this program) (CDC, 2015). Over the decades, the vast majority of states have made use of that provision, providing a strong bond between the federal government and the states. Surveillance and assessment guidelines are developed by CDC with state input. Unusual problems such as adverse reactions, unexplained deaths in those vaccinated, failure to protect, and a host of other problems result in immediate assistance from CDC due to this unusual federal–state relationship. Assignees are supervised in their daily activities by the state rather than by CDC. The state health officer then coordinates with every county and city in the state to oversee the provision of vaccines, surveillance, and assessment. The coalition of federal, state, county, and city health workers focused on immunization activities has been historically very strong.

However, the existing national vaccine program will require significant modifications to address the challenges posed by the delivery of new COVID-19 vaccines. Early COVID-19 vaccines may require ultra-cold storage not needed for other vaccines. States will have to arrange for these vaccines to be given in settings with special capabilities, such as medical facilities.

The need for real-time information on people vaccinated by age, sex, occupation, etc., as well as the need for rapid information on adverse events following immunization (equivalent to a Phase IV study) will require augmentation of the current surveillance/assessment system, probably involving training programs and new assignees to the vaccination program. Flexibility and agility will be important, and opportunities to embed the national COVID-19 vaccine program within current vaccination program activities must be sought. The basic approach of federal guidelines and close federal/state administration of programs will continue to be crucial.

REFERENCES

AAP (American Academy of Pediatrics) and CHA (Children's Hospital Association). 2020. *Children and COVID-19: State data report*. American Academy of Pediatrics and Children's Hospital Association. https://downloads.aap.org/AAP/PDF/AAP%20and%20CHA%20-%20Children%20and%20COVID-19%20State%20Data%20Report%208.6.20%20FINAL.pdf (accessed September 17, 2020).

Adakai, M., M. Sandoval-Rosario, F. Xu, T. Aseret-Manygoats, M. Allison, K. J. Greenlund, and K. E. Barbour. 2018. Health disparities among American Indians/Alaska Natives—Arizona, 2017. *Morbidity and Mortality Weekly Report* 67(47):1314.

Ahmed, M., S. Advani, A. Moreira, S. Zoretic, J. Martinez, K. Chorath, S. Acosta, R. Naqvi, F. Burmeister-Morton, F. Burmeister, A. Tarriela, M. Petershack, M. Evans, A. Hoang, K. Rajasekaran, S. Ahuja, and A. Moreira. 2020. Multisystem inflammatory syndrome in children: A systematic review. *EClinicalMedicine*. doi: 10.1016/j.eclinm.2020.100527.

Akiyama, M. J., A. C. Spaulding, and J. D. Rich. 2020. Flattening the curve for incarcerated populations—COVID-19 in jails and prisons. *The New England Journal of Medicine* 382:2075–2077. doi: 10.1056/NEJMp2005687.

Allotey, J., E. Stallings, M. Bonet, M. Yap, S. Chatterjee, T. Kew, L. Debenham, A. C. Llavall, A. Dixit, D. Zhou, R. Balaji, S. I. Lee, X. Qiu, M. Yuan, D. Coomar, M. van Wely, E. van Leeuwen, E. Kostova, H. Kunst, A. Khalil, S. Tiberi, V. Brizuela, N. Broutet, E. Kara, C. R. Kim, A. Thorson, O. T. Oladapo, L. Mofenson, J. Zamora, and S. Thangaratinam. 2020. Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: Living systematic review and meta-analysis. *BMJ* 370:m3320. doi: 10.1136/bmj.m3320.

Anderson, T. 2020. Intensifying vaccine production. *Bulletin of the World Health Organization* 98:302–303. doi: 10.2471/BLT.20.020520.

Arasteh, K. 2020. Prevalence of comorbidities and risks associated with COVID-19 among Black and Hispanic populations in New York City: An examination of the 2018 New York City community health survey. *Journal of Racial and Ethnic Health Disparities*. doi: 10.1007/s40615-020-00844-1.

AstraZeneca. 2020. *COVID-19 vaccine AZD1222 showed robust immune responses in all participants in Phase I/II trial*. https://www.astrazeneca.com/media-centre/press-releases/2020/covid-19-vaccine-azd1222-showed-robust-immune-responses-in-all-participants-in-phase-i-ii-trial.html (accessed September 17, 2020).

Bixler, D., A. D. Miller, C. P. Mattison, et al. 2020. SARS-CoV-2–associated deaths among persons aged <21 years—United States, February 12–July 31, 2020. *Morbidity and Mortality Weekly Report*. https://www.cdc.gov/mmwr/volumes/69/wr/mm6937e4.htm (accessed September 17, 2020).

Branswell, H. 2020. Will COVID-19 vaccines be safe for children and pregnant women? The data, so far, are lacking. *STAT*. https://www.statnews.com/2020/08/19/will-covid-19-vaccines-be-safe-for-children-and-pregnant-women-the-data-so-far-are-lacking/#:~:text=Outside%20of%20the%20U.S.%2C%20two,12%20to%2065%20to%20enroll (accessed September 15, 2020).

CDC (Centers for Disease Control and Prevention). 2010. Interim results: Influenza A (H1N1) 2009 monovalent vaccination coverage—United States, October–December 2009. *Morbidity and Mortality Weekly Report* 59(02):44–48. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5902a4.htm (accessed September 17, 2020).

CDC. 2015. *Immunization Services Division (ISD)*. Atlanta, GA: CDC. https://www.cdc.gov/ncird/isd.html (accessed September 21, 2020).

CDC. 2020a. Coronavirus disease 2019 case surveillance—United States, January 22–May 30, 2020. 69(2). *Morbidity and Mortality Weekly Report* 69(24):759–765. https://www.cdc.gov/mmwr/volumes/69/wr/mm6924e2.htm (accessed September 17, 2020).

CDC. 2020b. *COVIDview Weekly Summary*. Atlanta, GA: CDC. https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html (accessed September 15, 2020).

CDC. 2020c. *COVID-19: Health equity considerations and racial and ethnic minority groups*. Atlanta, GA: CDC. https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html (accessed September 17, 2020).

CDC. 2020d. *COVID-19: Hospitalization and death by race/ethnicity.* Atlanta, GA: CDC. https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html (accessed September 17, 2020).

CDC. 2020e. *COVID-19: Nursing home care*. Atlanta, GA: CDC National Center for Health Statistics. https://www.cdc.gov/nchs/fastats/nursing-home-care.htm (accessed September 17, 2020).

CDC. 2020f. *COVID-19: Older adults*. Atlanta, GA: CDC. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/older-adults.html (accessed September 17, 2020).

CDC. 2020g. *COVID-19: People with certain medical conditions*. Atlanta, GA: CDC. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html (accessed September 17, 2020).

CDC. 2020h. *COVID-19: People with disabilities*. Atlanta, GA: CDC. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-disabilities.html (accessed September 17, 2020).

CDC. 2020i. COVID-NET: A weekly summary of U.S. COVID-19 hospitalization data. Atlanta, GA: CDC. https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html (accessed September 15, 2020).

CDC. 2020j. *Residential care communities*. Atlanta, GA: CDC National Center for Health Statistics. https://www.cdc.gov/nchs/fastats/residential-care-communities.htm (accessed September 17, 2020).

CDC. 2020k. *About social determinants of health (SDOH)*. Atlanta, GA; CDC. https://www.cdc.gov/socialdeterminants/about.html (accessed September 21, 2020).

Chambers, C., P. Krogstad, K. Bertrand, D. Contreras, N. H. Tobin, L. Bode, and G. Aldrovandi. 2020. Evaluation for SARS-CoV-2 in breast milk from 18 infected women. *JAMA*. Published online August 19, 2020. doi: 10.1001/jama.2020.15580.

Chen, C. 2020. How—and when—can the coronavirus vaccine become a reality? *ProPublica*. https://www.propublica.org/article/how-and-when-can-the-coronavirus-vaccine-become-a-reality (accessed September 17, 2020).

Chidambaram, P. 2020. *State reporting of cases and deaths due to COVID-19 in long-term care facilities*. Kaiser Family Foundation. https://www.kff.org/coronavirus-covid-19/issue-brief/state-reporting-of-cases-and-deaths-due-to-covid-19-in-long-term-care-facilities (accessed September 17, 2020).

Cohen, J. 2020a. Controversial "human challenge" trials for COVID-19 vaccines gain support. *Science*. July 20, 2020. doi: 10.1126/science.abd9203.

Cohen, J. 2020b. The line is forming for a COVID-19 vaccine. Who should be at the front? *Science*. June 29, 2020. doi: 10.1126/science.abd5770.

Corum, J., S.-L. Wee, and C. Zimmer. 2020. Coronavirus vaccine tracker. *The New York Times*. https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html (accessed September 17, 2020).

Craven, J. 2020. *COVID-19 vaccine tracker*. Rockville, MD: Regulatory Affairs Professionals Society. https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker (accessed September 17, 2020).

Crouse Quinn, S., S. Kumar, V. S. Freimuth, D. Musa, N. Casteneda-Angarita, and K. Kidwell. 2011. Racial disparities in exposure, susceptibility, and access to health care in the US H1N1 influenza pandemic. *American Journal of Public Health* 101(2):285–293. doi: 10.2105/AJPH.2009.188029.

Dearlove, B., E. Lewitus, H. Bai, Y. Li, D. B. Reeves, M. G. Joyce, P. T. Scott, M. F. Amare, S. Vasan, N. L. Michael, K. Modjarrad, and M. Rolland. 2020. A SARS-CoV-2 vaccine candidate would likely match all currently circulating variants. *Proceedings of the National Academy of Sciences* 117(38):23652–23662. doi: 10.1073/pnas.2008281117.

Edmond, C. 2020. 3 challenges in creating a coronavirus vaccine—and how they are being overcome. *The World Economic Forum COVID Action Platform*. 14 May 2020. https://www.weforum.org/agenda/2020/05/coronavirus-covid-19-vaccine-industry (accessed September 17, 2020).

Ellington, S., P. Strid, V. Tong, K. Woodworth, R. Galang, L. Zambrano, J. Nahabedian, K. Anderson, and S. Gilboa. 2020. Characteristics of women of reproductive age with laboratory-confirmed SARS-CoV-2 infection by pregnancy status—United States, January 22–June 7, 2020. *Morbidity and Mortality Weekly Report* 69(25):769–775.

Essien, U. R., N. D. Eneanya, and D. C. Crews. 2020. Prioritizing equity in a time of scarcity: The COVID-19 pandemic. *Journal of General Internal Medicine* 35:2760–2762. doi: 10.1007/s11606-020-05976-y.

FDA (U.S. Food and Drug Administration). 2018. *What are the different types of clinical research?* Silver Springs, MD: FDA. https://www.fda.gov/patients/clinical-trials-what-patients-need-know/what-are-different-types-clinical-research (accessed September 15, 2020).

FDA. 2020. *Development and licensure of vaccines to prevent COVID-19: Guidance for industry.* Silver Springs, MD: FDA. https://www.fda.gov/media/139638/download (accessed September 17, 2020).

Furlong, A. 2020. Europe's challenge of a lifetime: Manufacturing enough coronavirus vaccines. *Politico*.

GAO (U.S. Government Accountability Office). May 26, 2020. Science & tech spotlight: COVID-19 vaccine development. *GAO Science, Technology Assessment, and Analytics*. Washington, DC: GAO. https://www.gao.gov/products/GAO-20-583SP (accessed September 17, 2020).

Gold, J., K. Wong, C. Szablewski, P. Patel, J. Rossow, J. Da Silva, P. Natarajan, S. Bamrah Morris, R. Neblett Fanfair, J. Rogers-Brown, B. Bruce, S. Browning, A. Hernandez-Romieu, N. Furukawa, M. Kang, M. Evans, N. Oosmanally, M. Tobin-D'Angelo, C. Drenzek, D. Murphy, J. Hollberg, J. Blum, R. Jansen, D. Wright, W. Sewell III, J. Owens, B. Lefkove, F. Brown, D. Burton, T. Uyeki, S. Bialek, and B. Jackson. 2020. Characteristics and clinical outcomes of adult patients hospitalized with COVID-19—Georgia, March 2020. *Morbidity and Mortality Weekly Report* 69(18):545–550. doi: 10.15585/mmwr.mm6918e1.

Gotzinger, F., B. Santiago-Garcia, A. Noguera-Julian, M. Lanaspa, L. Lancella, F. Calo Carducci, N. Gabrovska, S. Velizarova, P. Prunk, V. Osterman, U. Krivec, A. Lo Vecchio, D. Shingadia, A. Soriano-Arandes, S. Melendo, M. Lanari, L. Pierantoni, N. Wagner, A. L'Huillier, U. Heininger, N. Ritz, S. Bandi, N. Krajcar, S. Roglic, M. Santos, C. Christiaens, M. Creuven, D. Buonsenso, S. Welch, M. Bogyi, F. Brinkmann, and M. Tebruegge. 2020. COVID-19 in children and adolescents in Europe: A multinational, multicentre cohort study. *The Lancet Child & Adolescent Health* 4(9):P653–P661. doi: 10.1016/S2352-4642(20)30177-2.

Graham, B. 2020. Rapid COVID-19 vaccine development. *Science* 368(6494):945–946. doi: 10.1126/science.abb8923.

Hatcher, S. M., C. Agnew-Brune, M. Anderson, L. D. Zambrano, C. E. Rose, M. A. Jim, A. Baugher, G. S. Liu, S. V. Patel, and M. E. Evans. 2020. COVID-19 among American Indian and Alaska Native persons—23 states, January 31–July 3, 2020. *Morbidity and Mortality Weekly Report* 69(34):1166–1169. doi: 10.15585/mmwr.mm6934e1.

Hawks, L., S. Woolhandler, and D. McCormick. 2020. COVID-19 in prisons and jails in the United States. *JAMA Internal Medicine* 180(8):1041–1042. doi: 10.1001/jamainternmed.2020.1856.

HHS (U.S. Department of Health and Human Services). 2020a. *Fact sheet: Explaining Operation Warp Speed*. Washington, DC: HHS. https://www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html (accessed September 17, 2020).

HHS. 2020b. *Trump administration releases COVID-19 vaccine distribution strategy*. Washington, DC: HHS. https://www.hhs.gov/about/news/2020/09/16/trump-administration-releases-covid-19-vaccine-distribution-strategy.html (accessed September 22, 2020).

Ioannidis, J., C. Axfors, and D. G. Contopoulos-Ioannidis. 2020. Population-level COVID-19 mortality risk for non-elderly individuals overall and for non-elderly individuals without underlying diseases in pandemic epicenters. *Environmental Research* 188(September 2020):10980. doi: 10.1016/j.envres.2020.109890.

Jackson, L., E. Anderson, N. Rouphael, P. Roberts, M. Makhene, R. Coler, M. McCullough, J. Chappell, M. Denison, L. Stevens, A. Pruijssers, A. McDermott, B. Flach, N. Doria-Rose, K. Corbett, K. Morabito, S. O'Dell, S. Schmidt, P. Swanson, M. Padilla, J. Mascola, K. Neuzil, H. Bennett, W. Sun, E. Peters, M. Makowski, J. Albert, K. Cross, W. Buchanan, R. Pikaart-Tautges, J. Ledgerwood, B. Graham, and J. Beigel. 2020. An MRNA vaccine against SARS-CoV-2—preliminary report. *The New England Journal of Medicine*. doi: 10.1056/NEJMoa2022483.

Jin, J.-M., P. Bai, W. He, F. Wu, X.-F. Liu, D.-M. Han, S. Liu, and J.-K. Yang. 2020. Gender differences in patients with COVID-19: Focus on severity and mortality. *Frontiers in Public Health* 8(29 April 2020). doi: 10.3389/fpubh.2020.00152.

Johnson, A., and T. Buford. 2020. Early data shows African Americans have contracted and died of coronavirus at an alarming rate. *ProPublica*. http://wallstreetwindow.com/2020/04/early-data-shows-african-americans-have-contracted-and-died-of-coronavirus-at-an-alarming-rate-akilah-johnson-and-talia-buford-propublica-04-06-2020 (accessed September 17, 2020).

Johnson & Johnson. 2020. *Johnson & Johnson initiates pivotal global phase 3 clinical trial of Janssen's COVID-19 vaccine candidate*. https://www.jnj.com/johnson-johnson-initiates-pivotal-global-phase-3-clinical-trial-of-janssens-covid-19-vaccine-candidate (accessed September 25, 2020).

KFF (Kaiser Family Foundation). 2020. *State data and policy actions to address coronavirus*. https://www.kff.org/coronavirus-covid-19/issue-brief/state-data-and-policy-actions-to-address-coronavirus (accessed September 17, 2020).

Khamsi, R. 2020. If a coronavirus vaccine arrives, can the world make enough? *Nature* 580. https://www.nature.com/articles/d41586-020-01063-8 (accessed September 17, 2020).

Killerby, M., R. Link-Gelles, S. Haight, C. Schrodt, L. England, D. Gomes, M. Shamout, K. Pettrone, K. O'Laughlin, A. Kimball, E. Blau, E. Burnett, C. Ladva, C. Szablewski, M. Tobin-D'Angelo, N. Oosmanally, C. Drenzek, D. Murphy, J. Blum, J. Hollberg, B. Lefkove, F. Brown, T. Shimabukuro, C. Midgley, J. Tate, and CDC COVID-19 Response Clinical Team. 2020. Characteristics associated with hospitalization among patients with COVID-19—Metropolitan Atlanta, Georgia, March–April 2020. *Morbidity and Mortality Weekly Report* 69(25):790–794. doi: 10.15585/mmwr.mm6925e1.

Kim, L., M. Whitaker, A. O'Halloran, et al. 2020. Hospitalization rates and characteristics of children aged <18 years hospitalized with laboratory-confirmed COVID-19—COVID-NET, 14 states, March 1–July 25, 2020. *Morbidity and Mortality Weekly Report* 69(32):1081–1088. doi: 10.15585/mmwr.mm6932e3.

Kirby, T. 2020. Evidence mounts on the disproportionate effect of COVID-19 on ethnic minorities. *The Lancet Respiratory Medicine* 8(6):547–548. doi: 10.1016/S2213-2600(20)30228-9.

Koff, W., and M. Williams. 2020. COVID-19 and immunity in aging populations—a new research agenda. *The New England Journal of Medicine* 383:804–805. doi: 10.1056/NEJMp2006761.

Kofman, Y. B., and D. R. Garfin. 2020. Home is not always a haven: The domestic violence crisis amid the COVID-19 pandemic. *Psychological Trauma: Theory, Research, Practice, and Policy* 12(S1):S199–S201. doi: 10.1037/tra0000866.

LaCourse, S., G. John-Stewart, and K. Adams Waldorf. 2020. Importance of inclusion of pregnant and breastfeeding women in COVID-19 therapeutic trials. *Clinical Infectious Diseases* 71(15):879–881. doi: 10.1093/cid/ciaa444.

Lee, G. M., B. P. Bell, and J. R. Romero. 2020. The Advisory Committee on Immunization Practices and its role in the pandemic vaccine response. *JAMA* 324(6):546–547. doi: 10.1001/jama.2020.13167.

Lurie, N., M. Saville, R. Hatchett, and J. Halton. 2020. Developing COVID-19 vaccines at pandemic speed. *The New England Journal of Medicine* 382(21):1969–1973. doi: 10.1056/NEJMp2005630.

Mau, M. K., K. Sinclair, E. P. Saito, K. N. Baumhofer, and J. K. Kaholokula. 2009. Cardiometabolic health disparities in native Hawaiians and other Pacific Islanders. *Epidemiologic Reviews* 31(1):113–129. doi: 10.1093/ajerev/mxp004.

Maxmen, A. 2020. California's San Quentin Prison declined free coronavirus tests and urgent advice—now it has a massive outbreak. *Nature* 583:339–340. doi: 10.1038/d41586-020-02042-9.

Millett, G., A. Jones, D. Benkeser, S. Baral, L. Mercer, C. Beyrer, B. Honermann, E. Lankiewicz, L. Mena, J. Crowley, J. Sherwood, and P. Sullivan. 2020. Assessing differential impacts of COVID-19 on black communities. *Annals of Epidemiology* 47:37–44. doi: 10.1016/j.annepidem.2020.05.003.

NASEM (National Academies of Sciences, Engineering, and Medicine). 2020. *Reopening K–12 schools during the COVID-19 pandemic: Prioritizing health, equity, and communities*. Washington, DC: The National Academies Press.

Nikolich-Zugic, J., K. Knox, C. Tafich Rios, B. Natt, D. Bhattacharya, and M. Fain. 2020. SARS-CoV-2 and COVID-19 in older adults: What we may expect regarding pathogenesis, immune responses, and outcomes. *GeroScience* 42:505–514. doi: 10.1007/s11357-020-00193-1.

O'Callaghan, K. P., A. M. Blatz, and P. A. Offit. 2020. Developing a SARS-CoV-2 vaccine at warp speed. *JAMA* (324(5):437–438. doi: 10.1001/jama.2020.12190.

Page, K. R., M. Venkataramani, C. Beyrer, and S. Polk. 2020. Undocumented U.S. immigrants and COVID-19. *The New England Journal of Medicine* 382(21):e62. doi: 10.1056/NEJMp2005953.

Pfizer. 2020. Pfizer and Biontech announce early positive data from an ongoing phase 1/2 study of MRNA-based vaccine candidate against SARS-CoV-2. *Pfizer News*. https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-early-positive-data-ongoing-0 (accessed September 17, 2020).

Plough, A., B. Bristow, J. Fielding, S. Caldwell, and S. Khan. 2011. Pandemics and health equity: Lessons learned from the H1N1 response in Los Angeles County. *Journal of Public Health Management and Practice* 17(1):20–27. doi: 10.1097/PHH.0b013e3181ff2ad7.

Poudel, A., J. Y. Zhou, D. Story, and L. Li. 2018. Diabetes and associated cardiovascular complications in American Indians/Alaskan Natives: A review of risks and prevention strategies. *Journal of Diabetes Research* 2018:2742565. doi: 10.1155/2018/2742565.

Price-Haywood, E., J. Burton, D. Fort, and L. Seoane. 2020. Hospitalization and mortality among black patients and white patients with COVID-19. *The New England Journal of Medicine* 382:2534–2543. doi: 10.1056/NEJMsa2011686.

RWJF (Robert Wood Johnson Foundation). 2020. Race, racism, and health. Princeton, NJ: RWJF. https://www.rwjf.org/en/library/collections/racism-and-health.html (accessed September 21, 2020).

Sanyaolu, A., C. Okorie, A. Marinkovic, R. Patidar, K. Younis, P. Desai, Z. Hosein, I. Padda, J. Mangat, and M. Altaf. 2020. Comorbidity and its impact on patients with COVID-19. *SN Comprehensive Clinical Medicine* 2:1069–1076. doi: 10.1007/s42399-020-00363-4.

Schaffer DeRoo, S., N. J. Pudalov, and L. Y. Fu. 2020. Planning for a COVID-19 vaccination program. *JAMA* 323(24):2458–2459. doi: 10.1001/jama.2020.8711.

Slaoui, M. 2020. *Operation Warp Speed*. Presentation at Committee on Equitable Allocation of Vaccine for the Novel Coronavirus Public Workshop.

Steenhuysen, J., and K. Kelland. 2020. Vaccine makers face biggest medical manufacturing challenge in history. *Yahoo! News*. https://news.yahoo.com/vaccine-makers-face-biggest-medical-110231019.html (accessed September 17, 2020).

Stokes, E. K., L. D. Zambrano, K. N. Anderson, E. P. Marder, K. M. Raz, S. El Burai Felix, Y. Tie, and K. E. Fullerton. 2020. Coronavirus disease 2019 case surveillance—United States, January 22–May 30, 2020. *Morbidity and Mortality Weekly Report* 69(24):759–765. doi: 10.15585/mmwr.mm6924e2.

Tai, D. B. G., A. Shah, C. A. Doubeni, I. G. Sia, and M. L. Wieland. 2020. The disproportionate impact of COVID-19 on racial and ethnic minorities in the United States. *Clinical Infectious Diseases* ciaa815. doi: 10.1093/cid/ciaa815.

Taylor, N. P. 2020. *J&J starts COVID-19 vaccine phase 3, eyes early 2021 approval*. Fierce Biotech. September 23, 2020. https://www.fiercebiotech.com/biotech/j-j-starts-covid-19-vaccine-phase-3-eyes-early-2021-approval (accessed September 22, 2020).

True, S., J. Cubanski, R. Garfield, M. Rae, G. Claxton, P. Chidambaram, and K. Orgera. 2020. *COVID-19 and workers at risk: Examining the long-term care workforce*. Kaiser Family Foundation. https://www.kff.org/medicaid/issue-brief/covid-19-and-workers-at-risk-examining-the-long-term-care-workforce (accessed September 17, 2020).

Tsai, J., and M. Wilson. 2020. COVID-19: A potential public health problem for homeless populations. *The Lancet Public Health* 5(4). doi: 10.1016/S2468-2667(20)30053-0.

UN (United Nations). 2020a. *UN Secretary-General's policy brief: The impact of COVID-19 on children*. New York: UN. https://unsdg.un.org/resources/policy-brief-impact-covid-19-children (accessed September 17, 2020).

UN. 2020b. *UN Secretary-General's policy brief: The impact of COVID-19 on older persons*. New York: UN. https://www.un.org/development/desa/ageing/news/2020/05/covid-19-older-persons (accessed September 17, 2020).

UNWomen. 2020. *UN Secretary-General's policy brief: The impact of COVID-19 on women*. New York: UNWomen. https://www.unwomen.org/en/digital-library/publications/2020/04/policy-brief-the-impact-of-covid-19-on-women (accessed September 17, 2020).

Uscher-Pines, L., J. Maurer, and K. M. Harris. 2011. Racial and ethnic disparities in uptake and location of vaccination for 2009-H1N1 and seasonal influenza. *American Journal of Public Health* 101(7):1252–1255. doi: 10.2105/AJPH.2011.300133.

Usher, K., N. Bhullar, J. Durkin, N. Gyamfi, and D. Jackson. 2020. Family violence and COVID 19: Increased vulnerability and reduced options for support. *International Journal of Mental Health Nursing* 29(4). doi: 10.1111/inm.12735.

Walker, A. T., P. J. Smith, and M. Kolasa. 2014. Reduction of racial/ethnic disparities in vaccination coverage, 1995–2011. *MMWR Supplements* 63(1):7–12.

Webb Hooper, M., A. M. Nápoles, and E. J. Pérez-Stable. 2020. COVID-19 and racial/ethnic disparities. *JAMA* 323(24):2466–2467. doi: 10.1001/jama.2020.8598.

WHO (World Health Organization). 2020a. *Draft landscape of COVID-19 candidate vaccines*. Geneva, Switzerland: WHO. https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines (accessed September 22, 2020).

WHO. 2020b. *Health equity*. Geneva, Switzerland: WHO. https://www.who.int/topics/health_equity/en (accessed September 15, 2020).

Williams, D. R. 2020. Stress was already killing black Americans. COVID-19 is making it worse. *The Washington Post*. https://www.washingtonpost.com/opinions/2020/05/13/stress-was-already-killing-black-americans-covid-19-is-making-it-worse (accessed September 21, 2020).

Williams, D. R., and L. A. Cooper. 2020. COVID-19 and health equity—a new kind of "herd immunity." *JAMA* 323(24):2478–2480. doi: 10.1001/jama.2020.8051.

Wong, W. 2020. Presented at Equitable Allocation of COVID-19 Vaccine: Public Listening Session. Washington, DC: National Academies of Sciences, Engineering, and Medicine. https://www.nationalacademies.org/event/09-02-2020/public-listening-session-discussion-draft-of-the-preliminary-framework-for-equitable-allocation-of-covid-19-vaccine (accessed October 28, 2020).

Yancy, C. W. 2020. COVID-19 and African Americans. *JAMA* 323(19):1891–1892. doi: 10.1001/jama.2020.6548.

2

Lessons Learned from Other Allocation Efforts

This is not the first time the United States, or the world, has faced the issue of allocating scarce resources in the midst of a public health emergency. In developing a framework for equitable allocation of coronavirus disease 2019 (COVID-19) vaccine, the committee's deliberations were informed by practical lessons from previous efforts to allocate vaccines for 2009 H1N1 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 vaccine.

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, monitoring, and other considerations. Each infectious disease outbreak differs in terms of its clinical characteristics, epidemiology, 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 alloca-

tion, it is instructive to look back at some of the broader successes and challenges of previous mass vaccination campaigns from both operational and ethical perspectives. The committee identified several key lessons learned from prior mass vaccination campaigns that relate to or have an impact on vaccine allocation; these are outlined in Box 2-1.

H1N1 Influenza Vaccination Campaign (2009)

The development of the U.S. plan for vaccine allocation 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 H1N1 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

BOX 2-1
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.
- Use consistent, respectful, accurate communication to earn, secure, and maintain trust.

with chronic health conditions or compromised immune systems. At that time, the number of vaccine doses that would be required was unknown.

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). 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 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 the 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.

Potential Impact of Allocation Decisions on Vaccine Uptake and Risk Communications

During the 2009 H1N1 vaccine campaign, decisions about how to prioritize groups for allocation impacted the rates of vaccine uptake and posed specific challenges to risk communication (IOM, 2010). ACIP's priority groups for this campaign were different than the priority groups established during prior pandemic preparedness efforts. For instance, the priority groups included pregnant women and younger people aged >6 months to 24 years, but did not include adults aged >65 years, first responders, or critical infrastructure personnel. At the local level, it was challenging to communicate the rationale for establishing these target groups; this was compounded by the availability of multiple vaccine formulations that had varying contraindications for use among those priority groups. Older adults were excluded because the 2009 H1N1 influenza virus was found to predominantly affect younger people. However, older adults are a group targeted for receipt of the seasonal influenza vaccines and some felt alienated by their exclusion from the priority groups for H1N1 vaccination (IOM, 2010). In certain tribal areas, the exclusion of tribal elders—who are well-respected community leaders—is believed to have contributed to reducing the overall H1N1 vaccination rates among American Indians who were included in ACIP's priority groups (IOM, 2010). This highlights the need to consider the impact of excluding older adults when making

[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).

allocation decisions and developing communications strategies. Although pregnant women were a priority group due to their high risk of complications, severe disease, and mortality related to 2009 H1N1, vaccine uptake among this group was relatively low nationwide (IOM, 2010). Many pregnant women and their health care providers reported having concerns about the safety of receiving the vaccine during pregnancy, further underscoring the need for clear risk communication with priority groups and health care providers.

Potential Impact of Distribution Strategies on Allocation

Although distribution is not the focus of the committee's framework, prior vaccination 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. For example, to facilitate centralized distribution of the forthcoming H1N1 vaccine in 2009, 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 the number of people who fell into ACIP's priority categories. 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 from the use of a central distribution mechanism. Although it provided state and local jurisdictions with flexibility and autonomy in developing their own distribution methods (e.g., health care providers, local health departments, pharmacies), this led to confusion and communication challenges. Health authorities struggled with dilemmas, such as deciding whether to turn away patients who were not part of the initial priority groups, determining when to allow broader immunization to occur, and coordinating across jurisdictions about their decisions. Some jurisdictions allotted the vaccine on a first-come, first-served basis while others attempted to adhere to CDC guidance, resulting in shortages of vaccine in some locales. Furthermore, the 100-dose minimum vaccine order required for shipment was a barrier for localities that did not need that many doses (GAO, 2011). 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.

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 try to reach 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).

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 efforts to target and allocate pandemic influenza vaccine in scenarios in which vaccine demand exceeds supply (CDC, 2018). 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 includes 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 includes groups critical to national security (e.g., the 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 includes other critical infrastructure groups (e.g., those who maintain transportation, financial infrastructure), other health care and critical government personnel, and children aged 3–18 years without a high-risk condition;
- Tier 4 includes adults aged 19–64 years with high-risk conditions and adults aged >65 years; and
- Tier 5 includes healthy adults aged 19–64 years not included in the other groups (CDC, 2018).

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

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

WHO developed an operational plan for the allocation 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 Guinea, Liberia, and Sierra Leone (Costa, n.d.). Phases II and III trial results were available to inform the strategy, including data on vaccine efficacy, impacts of vaccination, feasibility of vaccination, and vaccination policies for various age groups and sexes. 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 implementation 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.

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

Consequences of Vaccine Allocation Decisions for Pregnant and Breastfeeding Women

The Ebola vaccine campaign also illustrates the stark consequences of allocation decisions to exclude certain groups—in this case, pregnant and breastfeeding women—from potentially life-saving vaccination. It highlights the critical importance of considering in advance how to represent fairness principles in the absence of group-specific data on safety and efficacy. During the Ebola vaccine campaign, the proposed criteria for deployment according to vaccine availability considered including pregnant women (Costa, n.d.), but 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 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). The magnitude of these repercussions on pregnant and lactating women underscores the need to ensure that allocation decisions are fair, even if they are ethically complex or otherwise challenging due to the absence of group-specific data, for example.

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, as outbreaks differ in terms of specific clinical and epidemiology characteristics and the differential burden of disease across populations (Williams and Dawson, 2020). However, a re-

[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.

view of pandemic vaccination prioritization strategies in 31 countries[5] found some commonalities. For instance, more than 80 percent had at least one vaccination priority group (Straetemans et al., 2007). All of those countries prioritized health care workers and almost all prioritized essential service providers and other 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 vaccination during an influenza pandemic based on literature published between 2005 and 2015,[6] much of which was informed implicitly or explicitly by interest in the ethics of vaccination 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., those in utility, transportation, food, and law enforcement jobs). 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 the 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 giving priority to vulnerable groups, whereas appeals to reciprocity were used to justify priority given to health care workers.

LESSONS FROM PAST CRISIS STANDARDS OF CARE GUIDANCE

During the 2009 influenza pandemic, HHS asked the Institute of Medicine (IOM) to convene a committee of experts to develop guidance for health officials toward establishing and implementing a system of standards of care during disasters, or crisis standards of care (CSC). The committee defined

[5] The 27 European Union (EU) member states and the 4 non-EU countries of the Global Health Security Action Group.

[6] One of the 40 articles was published in 2017.

CSC as "a substantial change in usual health care operations and the level of care it is possible to deliver, which is made necessary by a pervasive (e.g., pandemic influenza) or catastrophic (e.g., earthquake, hurricane) disaster" (IOM, 2009, p. 3). The committee identified five key elements to uphold in order to equitably allocate scarce resources under disaster conditions:

- **A strong ethical grounding.** In order to be recognized as fair by all those affected by them, CSC must uphold a set of core ethical principles, including fairness; duty to care; duty to steward scarce resources; transparency in design and decision making; consistency in application across all populations; proportionality in the public and individual requirements in a way that is commensurate with the scale of the emergency and degree of scarce resources; and accountability of individuals and governments deciding and implementing CSC (IOM, 2009).
- **Integrated and ongoing community and provider engagement, education, and communication.** CSC planning must proactively involve both providers and the public, including vulnerable populations and those with special medical needs, in order to ensure transparency, accountability, inclusivity and the legitimacy of the process, and to warrant the public's trust (IOM, 2009).
- **Assurances regarding legal authority and environment.** Under disaster and emergency circumstances, health care workers may have to make difficult decisions while implementing CSC, and thus must have adequate guidance and legal protections to do so. It is therefore crucial to have a legal environment that, under certain conditions, empowers necessary and appropriate actions and interventions through statutory or regulatory provisions that can be altered as needed in real time. Clarity is crucial regarding the division of legal authority between the federal government and the states and among executive, judicial, and legislative branches (in both federal and state governments), and regarding the relative authority in each state among its statewide, countywide, and municipal governments (IOM, 2009).
- **Clear indicators, triggers, and lines of responsibility.** Key indicators need to be pre-defined and shared among all institutions. When observed, those indicators must trigger detailed plans to shift to CSC levels of care, with clearly defined lines of authority and accountability (IOM, 2009).
- **Evidence-based clinical processes and operations.** Under CSC, decisions made at the bedside should follow clear and evidence-based predictive scoring systems for patient outcomes. Updated evidence-based care guidelines may evolve over the course of the crisis, as the further data are gathered (IOM, 2009).

More recently, at the beginning of the COVID-19 pandemic, the National Academies Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats drafted a rapid expert consultation to provide a rationale for the implementation of CSC in response to the outbreak. The expert committee reiterated key elements of CSC planning and implementation outlined in the 2009 and 2012 IOM reports. Although the committee did not outline details of actual choices and preferences, it provided the rationales and ethical principles upon which such decisions could be made. Importantly, the committee reemphasized that any health care decision made under crisis conditions must be transparent, inclusive, and communicated to the public, and must justify the legalities of such decisions. Failure to do so would "diminish public trust in health care providers and systems, as well as in government leadership" (NASEM, 2020, p. 6).

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

In addition to lessons learned from prior mass vaccination campaigns, the committee's deliberations were informed by the principles, goals, and prioritization strategies set forth in guidance and frameworks recently developed for allocating scarce resources during the COVID-19 pandemic. This section provides an overview of the frameworks that address the overall allocation of scarce medical resources and specifically inpatient treatments. The last section of this chapter focuses on those frameworks that are vaccine specific. At the end of this section, Box 2-2 summarizes key guiding principles gleaned by the committee from these efforts, and Table 2-1 provides an overview of the ethical values, principles for allocation, and prioritization strategies set forth by the frameworks presented in this section.

Ethical Frameworks for Broadly Allocating Scarce Medical Resources

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

In May 2020, an article 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

[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).

BOX 2-2
Guiding Principles from Frameworks for Allocating Scarce Medical Resources During 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.

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 the benefits of scarce resources, which could aim to save 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 others' 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

TABLE 2-1 Overview of Principles and Prioritization Strategies Used in Frameworks for Allocating Scarce Medical Resources During the COVID-19 Pandemic

Framework	Ethical Values and Principles for Allocation	Prioritization Strategies
Fair Allocation of Scarce Medical Resources in the Time of COVID-19 (Emanuel et al., 2020)	• Maximize benefit of limited resources. • Treat people equally. • Promote and reward instrumental value. • Give priority to the worst off.	• Balance the aims of saving the greatest number of lives and maximizing improvements in people's length of life after treatment. • Prioritize health care workers and others who maintain critical infrastructure. • Use random allocation to prioritize patients with similar prognoses. • Assign some priority to research participants, but only as a tiebreaker. • Use the same criteria for allocation to people with and without COVID-19.
Ethics of Creating a Resource Allocation Strategy During the COVID-19 Pandemic (Laventhal et al., 2020)	• Allocate resources to those most likely to survive to optimize the likelihood of benefit. • Allocate resources to those with the greatest urgent or acute need for people with similar likelihood of benefit. • Consider the absolute number of people who can be helped by available resources and maximize opportunities to help more people. • Use randomization to prioritize allocation when all other factors are equal.	• Use short-term survival (i.e., survival to discharge) as a criterion for prioritization. • Prioritize people who perform vital functions (e.g., health care workers, first responders) as a tiebreaker in decisions between people with similar likelihood of survival.
Ethics and COVID-19: Resource Allocation and Priority Setting (WHO Working Group on Ethics and COVID-19, 2020)	• Use the principle of equality to allocate scarce resources to individuals or populations expected to derive the same benefit (e.g., lottery system). • Use the principle of best outcomes (i.e., utility) to guide the allocation of scarce resources according to potential to maximize good or minimize harm. • Balance the aim of maximizing utility with the principle of prioritizing the worst off.	• Prioritize people at greatest risk of becoming infected and seriously ill. • Prioritize people who would prevent the greatest spread of the virus if vaccinated. • Prioritize people who have volunteered to participate in research to develop the vaccine.

Fair and Equitable Access to COVID-19 Treatments and Vaccines (Nuffield Council on Bioethics, 2020)	• Ensure equal respect, dignity, and human rights. • Help to reduce suffering of those who are sick or otherwise in need. • Maintain fairness both through non-discriminatory treatment of others and through equitable distribution of benefits and burdens.	
Minnesota's Ethical Framework for Distributing Remdesivir (Lim et al., 2020)	• Reduce risk while providing benefit. • Save the most lives possible while respecting rights and fairness. • Promote the common good through transparency, accountability, and trustworthiness. • Use best available evidence to address uncertainty.	• Allocate remdesivir to patients based both on need and on likelihood of survival to hospital discharge.
Pennsylvania's Weighted Lottery System for Allocating Scarce Medications for COVID-19[a]	• Steward scarce resources in the interest of public health. • Mitigate the impact of social inequities on COVID-19 outcomes in disadvantaged communities.	• Use a weighted lottery system if the supply of a medication for treating COVID-19 is limited. • Give heightened priority to people living in disadvantaged areas and to essential workers. • Do not exclude but give lower priority to people expected to die within 1 year from an end-stage condition.
Ethical Framework for Allocating Therapies to Hospitalized Patients with COVID-19 (DeJong et al., 2020)	• Maximize benefit to patients. • Mitigate disparities. • Adhere to ethical principles. • Revise allocation policies as more evidence becomes available. • Reduce mortality to provide benefit to the community as a whole. • Assess benefit using the best available evidence.	• Use random allocation (e.g., lottery) to prioritize allocation among eligible patients. • Assign some priority to workers in essential jobs.

[a] 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).

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 in *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:

- Allocation frameworks should optimize the likelihood of benefit by allocating resources to those most likely to survive.
- For people with similar likelihood of benefit, resources should be allocated to those with the greatest urgent or acute need.
- Consider the absolute number of people who can be helped by available resources and maximize opportunities to help more people.
- 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.

- 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 in a 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-served 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 WHO's guidance on the allocation of a 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" (WHO Working Group on Ethics and COVID-19, 2020, p. 3) 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" (WHO Working Group on Ethics and COVID-19, 2020, p. 3), 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 are 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 nondiscriminatory treatment of others and equitable distribution of benefits and burdens.

Ethical Frameworks for Specifically Allocating Scarce Inpatient 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 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

[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).

[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).

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, agriculture, and custodial work). Individuals who are expected to die within 1 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 to 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-served" system is not random and puts people who face barriers to care at a disadvantage. An additional advantage of a 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 and 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 randomized controlled trials and develop a stronger evidence base for effective therapies.

SPECIFIC FRAMEWORKS FOR COVID-19 VACCINE ALLOCATION WITHIN AND AMONG COUNTRIES

This section outlines ethical frameworks developed specifically for COVID-19 vaccine allocation within and among countries, including an interim framework developed by a group at Johns Hopkins University, forthcoming efforts from CDC, and a values framework developed by WHO. It is important to note that these frameworks were and are being developed in the context of rapidly changing goals for vaccination (e.g., as schools began to re-open in August 2020) and evolving data about SARS-CoV-2 and vaccine candidates. Table 2-2 at the end of this chapter summarizes the goals, ethical principles, and prioritization approaches of these COVID-19 vaccine-specific allocation frameworks.

Johns Hopkins 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 (Toner et al., 2020) 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 a 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 the protection of essential services, supporting economic activity, and enabling children to return to school and child care. 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 a scarce vaccine, including provisional examples of the groups in each tier.

Tier 1 priority groups include the following:

- 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 the following:

- 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 the 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 an elevated risk of infection, even if they have a lesser or unknown risk of severe illness and death (e.g., people who are unable to maintain safe physical distances in their home or work environments, including people living in shelters, people who are incarcerated, and people who work in prisons).

CDC's Ongoing 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 U.S. civilian population and provides guidance to CDC and the Secretary of HHS on the optimal use of vaccines, but ACIP does not traditionally play a role in implementation (Lee 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. The focus of ACIP is on vaccine recommendations, rather than implementation; the latter will depend on partnerships with state and local public health entities. During ACIP's 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). At its September 22, 2020, meeting, ACIP presented its proposed ethics/equity framework for COVID-19 vaccine (Oliver, 2020) with the goals of minimizing death and serious disease; preserving functioning of society; reducing disproportionate burden on those with existing disparities; and increasing equity of opportunity to enjoy health and well-being. The proposed ethical principles are:

- Maximize benefits and minimize harms: minimize death and serious disease; address the obligation to promote public health and promote the common good, balanced with the obligation to respect and care for persons; and is based on best available science.
- Equity: vaccine allocation reduces rather than increases health disparities and ensures that everyone has a fair and just opportunity to be as healthy as possible.

- Justice: commitment to remove unfair, unjust, and avoidable barriers to good health and well-being that disproportionately affect the most disadvantaged populations; interventions must intentionally ensure that groups, populations, and communities affected by a policy are being treated fairly.
- Fairness: commitment to fair stewardship in the distribution of a scarce resource.
- Transparency: supporting principles and process for allocation decisions are clear, understandable, and open for review; to the degree possible, given the urgency of the response, public participation in the creation and review of processes should be recognized and honored; essential to build and maintain public trust during planning and implementation; and all recommendations are evidence based, with information used to make recommendations made publicly available.

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

WHO has several related global planning efforts under way for global COVID-19 vaccine allocation. WHO leads the efforts pertaining to global vaccine allocation guidance, which informs the COVAX Facility's (the vaccines pillar of the Access to COVID Tools Accelerator) procurement schemes.[10] These global efforts are discussed further in Chapter 8. WHO has been working with its member states and the Strategic Advisory Group of Experts (SAGE)—which is the vaccine advisory body within WHO—to finalize the allocation framework of vaccines from the COVAX Facility among countries. Within-country allocation decisions remain under the authority of each individual Member State.

The WHO SAGE *Values Framework for the Allocation and Prioritization of COVID-19 Vaccination*, published in September 2020, provides guidance both on allocating COVID-19 vaccines among countries and on prioritizing groups for vaccination within countries while the supply is limited (WHO, 2020). The overarching goal of the framework is to ensure that

[10] Access to COVID Tools Accelerator is 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. More information about the Access to COVID Tools Accelerator is available at https://www.who.int/publications/m/item/access-to-covid-19-tools-(act)-accelerator (accessed August 25, 2020). The COVAX pillar's primary goal is to accelerate the development and manufacture of vaccines and ensure equitable access worldwide. More information about COVAX is available at https://www.who.int/initiatives/act-accelerator/covax (accessed August 25, 2020).

COVID-19 vaccines are a global public good that contributes significantly to equitably protecting and promoting human well-being for all people worldwide. The framework is guided by six ethical values:

- **Human well-being:** Protect and promote human well-being including health, social and economic security, human rights and civil liberties, and child development.
- **Equal respect:** Recognize and treat all human beings as having equal moral status and their interests as deserving of equal moral consideration.
- **Global equity:** Ensure equity in vaccine access and benefit globally among people living in all countries, particularly those living in low- and middle-income countries.
- **National equity:** Ensure equity in vaccine access and benefit within countries for groups experiencing greater burdens from the COVID-19 pandemic.
- **Reciprocity:** Honor obligations of reciprocity to those individuals and groups within countries who bear significant additional risks and burdens of COVID-19 response for the benefit of society.
- **Legitimacy:** Make global decisions about vaccine allocation and national decisions about vaccine prioritization through transparent processes that are based on shared values, best available scientific evidence, and appropriate representation and input by affected parties.

This framework also describes how those ethical values can be operationalized into specific objectives and unranked priority groups for vaccination. For the principle of human well-being, the objective of reducing COVID-19-related deaths and disease burden could translate to prioritizing populations with significantly elevated risks of severe disease or death (e.g., older adults, people with certain comorbid conditions or health states, sociodemographic groups at disproportionately higher risks) and populations with significantly elevated risks of infection (e.g., health workers, employment categories and social groups of people who are unable to physically distance, people living in dense neighborhoods and multigenerational households).

The objective of reducing societal and economic disruption could warrant prioritizing groups such as those at high risk of transmitting SARS-CoV-2, school-aged children, and workers in non-essential but economically critical sectors. To protect the continuity of essential services, priority could be assigned to health workers, non-health-sector essential workers, and other essential personnel (e.g., government leaders and those involved in producing vaccines, therapeutics, and diagnostics). The principle of equal

respect requires that no one who is eligible for inclusion in a priority group is excluded for unjustifiable reasons.

The principle of global equity holds that (1) the priority groups identified by the WHO SAGE values framework should inform global-level allocation decisions and (2) countries with greater financial resources should not undermine vaccine access for low- and middle-income countries. According to the principle of national equity, within-country vaccine prioritization should take into account the risks and needs of vulnerable groups at risk of disproportionate burdens from the COVID-19 pandemic, including people living in poverty, people experiencing homelessness, migrants, refugees, other hard-to-reach groups, and groups that are disadvantaged or persecuted based on ethnicity, race, gender, religion, sexual orientation, or disability status. The principle of reciprocity calls for protecting people who "bear significant additional risks and burdens of COVID-19 to safeguard the welfare of others" (WHO, 2020, p. 2), including health workers, other essential workers, and COVID-19 vaccine clinical trial participants who did not receive an effective vaccine. The objectives of the legitimacy principle are to ensure transparency, trust, and lack of bias in the process of making evidence-based allocation decisions.

Table 2-2 starts on next page.

TABLE 2-2 Overview of Ongoing COVID-19 Vaccine Allocation Efforts

Effort	Leaders	Goals
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.
ACIP COVID-19 Vaccine Workgroup	ACIP	• Develop a plan for allocation of vaccine in the United States.
WHO SAGE *Values Framework for the Allocation and Prioritization of COVID-19 Vaccination*	WHO SAGE	• Ensure that COVID-19 vaccines are a global public good that contributes significantly to equitably protecting and promoting human well-being for all people worldwide.

Guiding Principles	Prioritized Groups

• Promote the common good
  ◦ Promote public health
  ◦ Promote economic and social well-being
• Treat people fairly and equally
  ◦ Address background and emerging inequities between groups
  ◦ Give priority to worst-off individuals
  ◦ Reciprocity
• Promote legitimacy, trust, and a sense of ownership in a pluralistic society
  ◦ Respect the diversity of views in a pluralistic society
  ◦ Engage community members to improve vaccine program design and effectiveness
	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 an elevated risk of infection, even if they have lesser or unknown risk of severe illness and death

• Maximize benefits and minimize harms • Equity • Justice • Fairness • Transparency	• In progress at the time of this writing
• Human well-being • Equal respect • Global equity • National equity • Reciprocity • Legitimacy	• Those with elevated risks of severe disease or death • Those with significantly elevated risks of being infected • Groups at high risk of transmitting SARS-CoV-2 • Vulnerable, disadvantaged, and persecuted groups at risk of disproportionate burdens • Those who bear significant additional risks and burdens of COVID-19 to safeguard the welfare of others (e.g., health workers and other essential workers)

REFERENCES

Bebell, L. M., T. Oduyebo, and L. E. Riley. 2017. Ebola virus disease and pregnancy: A review of the current knowledge of ebola virus pathogenesis, maternal, and neonatal outcomes. *Birth Defects Research* 109(5):353–362. doi: 10.1002/bdra.23558

Black, B. O., S. Caluwaerts, and J. Achar. 2015. Ebola viral disease and pregnancy. *Obstetric Medicine* 8(3):108–113. doi: 10.1177/1753495X15597354.

CDC (Centers for Disease Control and Prevention). 2018. *Roadmap for vaccination of critical workforce personnel during an influenza pandemic*. https://www.cdc.gov/flu/pandemic-resources/pdf/roadmap_panflu.pdf (accessed September 22, 2020).

Costa, A. n.d. *Development of an operational plan for distribution of ebola vaccines*.

Dada, S., G. McKay, A. Mateus, and S. Lees. 2019. Lessons learned from engaging communities for Ebola vaccine trials in Sierra Leone: Reciprocity, relatability, relationships and respect (the four R's). *BMC Public Health* 19(1):1665. doi: 10.1186/s12889-019-7978-4.

DeJong, C., A. H. Chen, and B. Lo. 2020. An ethical framework for allocating scarce inpatient medications for COVID-19 in the US. *JAMA* 323(23):2367–2368. doi: 10.1001/jama.2020.8914.

Emanuel, E. J., G. Persad, R. Upshur, B. Thome, M. Parker, A. Glickman, C. Zhang, C. Boyle, M. Smith, and J. P. Phillips. 2020. Fair allocation of scarce medical resources in the time of COVID-19. *The New England Journal of Medicine* 382:2049–2055. doi: 10.1056/NEJMsb2005114.

Faden, R., R. Karron, and C. Krubiner. 2018. An "indefensible" decision: Not vaccinating pregnant and lactating women in an Ebola outbreak. *STAT*. https://www.statnews.com/2018/08/27/ebola-vaccine-pregnant-lactating-women (accessed September 22, 2020).

GAO (U.S. Government Accountability Office). 2011. *Influenza pandemic: Lessons from the H1N1 pandemic should be incorporated into future planning. Report to Congressional Requesters*. Washington, DC: GAO. https://www.gao.gov/new.items/d11632.pdf (accessed September 22, 2020).

Gomes, M. F., V. de la Fuente-Núñez, A. Saxena, and A. C. Kuesel. 2017. Protected to death: Systematic exclusion of pregnant women from Ebola virus disease trials. *Reproductive Health* 14(Suppl 3):172. doi: 10.1186/s12978-017-0430-2.

Gostin, L. O. 2014. Ethical allocation of drugs and vaccines in the West African Ebola epidemic. *The Milbank Quarterly* 92(4):662–666. doi: 10.1111/1468-0009.12089.

IOM (Institute of Medicine). 2009. *Guidance for establishing crisis standards of care for use in disaster situations: A Letter Report*. Washington, DC: The National Academies Press.

IOM. 2010. *The 2009 H1N1 influenza vaccination campaign: Summary of a workshop series*. Washington, DC: The National Academies Press.

Laventhal, N., R. Basak, M. L. Dell, D. Diekema, N. Elster, G. Geis, M. Mercurio, D. Opel, D. Shalowitz, M. Statter, and R. Macauley. 2020. The ethics of creating a resource allocation strategy during the COVID-19 pandemic. *Pediatrics* 146(1):e20201243. doi: 10.1542/peds.2020-1243.

Lee, G. M., B. P. Bell, and J. R. Romero. 2020. The Advisory Committee on Immunization Practices and its role in the pandemic vaccine response. *JAMA* 324(6):546–547. doi: 10.1001/jama.2020.13167.

Lim, S., D. A. DeBruin, J. P. Leider, N. S. Sederstrom, R. Lynfield, J. V. Baker, S. Kline, S. Kesler, S. Rizza, J. Wu, R. R. Sharp, and S. M. Wolf. 2020. Developing an ethics framework for allocating remdesivir in the COVID-19 pandemic. *Mayo Clinic Proceedings*. doi: 10.1016/j.mayocp.2020.06.016.

NASEM (National Academies of Sciences, Engineering, and Medicine). 2020. *Rapid expert consultation on crisis standards of care for the COVID-19 pandemic (March 28, 2020)*. Washington, DC: The National Academies Press.

Nuffield Council on Bioethics. 2020. Fair and equitable access to COVID-19 treatments and vaccines. https://www.nuffieldbioethics.org/assets/pdfs/Fair-and-equitable-access-to-COVID-19-treatments-and-vaccines.pdf (accessed September 22, 2020).

Oliver, S. 2020. *Overview of vaccine equity and prioritization frameworks*. Paper read at ACIP September 2020 Meeting. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-09/COVID-06-Oliver.pdf (accessed September 22, 2020).

Persad, G., A. Wertheimer, and E. J. Emanuel. 2009. Principles for allocation of scarce medical interventions. *The Lancet* 373(9661):423–431. doi: 10.1016/S0140-6736(09)60137-9.

Rambhia, K. J., M. Watson, T. K. Sell, R. Waldhorn, and E. Toner. 2010. Mass vaccination for the 2009 H1N1 pandemic: Approaches, challenges, and recommendations. *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 8(4):321–330. doi: 10.1089/bsp.2010.0043.

Schmidt, H. 2020. The way we ration ventilators is biased. *The New York Times*, April 15, 2020. https://www.nytimes.com/2020/04/15/opinion/covid-ventilator-rationing-blacks.html (accessed September 22, 2020).

Soucheray, S. 2019. Ebola vaccine to be given to pregnant, lactating women. Minneapolis, MN: CIDRAP. https://www.cidrap.umn.edu/news-perspective/2019/02/ebola-vaccine-be-given-pregnant-lactating-women (accessed September 22, 2020).

Splete, H. 2020. ACIP plans priority groups in advance of COVID-19 vaccine. Parsippany, NJ: MDedge. https://www.mdedge.com/hematology-oncology/article/224632/coronavirus-updates/acip-plans-priority-groups-advance-covid-19 (accessed September 22, 2020).

Straetemans, M., U. Buchholz, S. Reiter, W. Haas, and G. Krause. 2007. Prioritization strategies for pandemic influenza vaccine in 27 countries of the European Union and the Global Health Security Action Group: A review. *BMC Public Health* 7:236–236. doi: 10.1186/1471-2458-7-236.

Toner, E., A. Barnill, C. Krubiner, J. Bernstein, L. Privor-Dumm, M. Watson, E. Martin, C. Potter, D. Hosangadi, N. Connell, C. Watson, M. Schoch-Spana, T. Goodwin Veenema, D. Meyer, E. L. Daugherty Biddison, A. Regenberg, T. Inglesby, and A. Cicero. 2020. *Interim framework for COVID-19 vaccine allocation and distribution in the United States*. Baltimore, MD: Johns Hopkins Center for Health Security. https://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2020/200819-vaccine-allocation.pdf (accessed September 22, 2020).

Truog, R. D., C. Mitchell, and G. Q. Daley. 2020. The toughest triage—allocating ventilators in a pandemic. *The New England Journal of Medicine* 382:1973–1975. doi: 10.1056/NEJMp2005689.

UN News. 2019. Pregnant, nursing women can now be given Ebola vaccine, UN health agency announces. New York: UN. https://news.un.org/en/story/2019/02/1033281 (accessed September 22, 2020).

White, D. B., and D. C. Angus. 2020. A proposed lottery system to allocate scarce COVID-19 medications: Promoting fairness and generating knowledge. *JAMA* 324(4):329–330. doi: 10.1001/jama.2020.11464.

WHO (World Health Organization). 2020. Values Framework for the Allocation and Prioritization of COVID-19 Vaccination. Geneva, Switzerland: WHO. https://apps.who.int/iris/bitstream/handle/10665/334299/WHO-2019-nCoV-SAGE_Framework-Allocation_and_prioritization-2020.1-eng.pdf?sequence=1&isAllowed=y#:~:text=The%20Framework%20proposes%20six%20values,and%20legitimacy%20(Table%201) (accessed September 15, 2020).

WHO Working Group on Ethics and COVID-19. 2020. *Ethics and COVID-19: Resource allocation and priority-setting*. Geneva, Switzerland: WHO. https://www.who.int/ethics/publications/ethics-covid-19-resource-allocation.pdf?ua=1 (accessed August 25, 2020).

Williams, J. H., and A. Dawson. 2020. Prioritising access to pandemic influenza vaccine: A review of the ethics literature. *BMC Medical Ethics* 21(1):40. doi: 10.1186/s12910-020-00477-3.

3

A Framework for Equitable Allocation of COVID-19 Vaccine

Drawing from the lessons learned from other allocation frameworks, outlined in Chapter 2, the committee has derived foundational principles that inform its recommended coronavirus disease 2019 (COVID-19) vaccine allocation framework. Here, the committee describes the goal of its framework, the risk-based allocation criteria used to apply the principles, and the resulting allocation phases (see Figure 3-1). The chapter concludes with an in-depth description and discussion of the phases, including the rationale behind the inclusion of population groups listed in each phase.

The committee recognizes that decisions about COVID-19 vaccine allocation must be made under conditions of uncertainty. These unknowns include the safety and efficacy of the vaccines in specific populations (such as children, pregnant women, older adults, and individuals previously infected with COVID-19); the effectiveness of vaccines in tandem with existing preventive measures; public confidence in the vaccine; the possibility of ultra-cold storage requirements for the vaccine; the pharmacovigilance evidence; and many other unknowns.

Such unknowns 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 COVID-19 vaccination program, the state of the pandemic, the

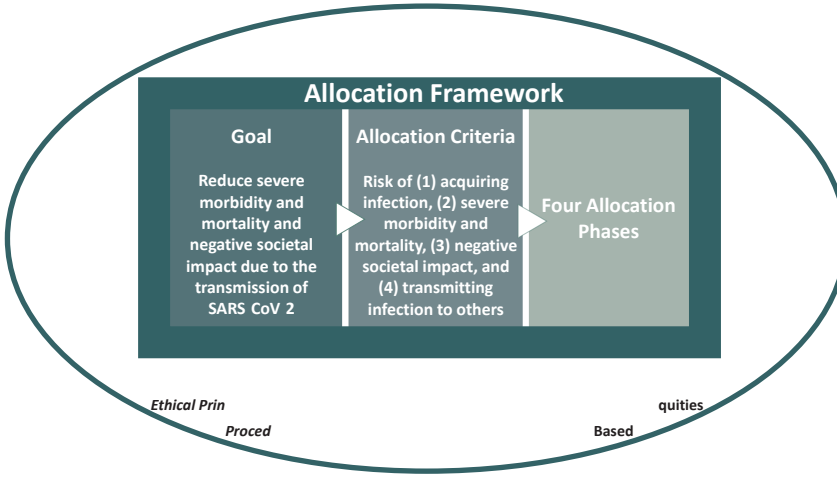

FIGURE 3-1 Major elements of the framework for equitable allocation of COVID-19 vaccine.

state of the science, and the extent to which people are engaging in social distancing and other preventive measures. Chapter 4 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, it must be possible to accurately and quickly identify individuals or groups who have been prioritized to receive the vaccine.

One-third or more of the U.S. population may decline a free U.S. Food and Drug Administration (FDA)-approved vaccine for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Mullen O'Keefe, 2020). Concerns about inclusion and diversity in COVID-19 vaccine trials (Jaklevic, 2020) and unknowns like those previously noted compound the already significant doubts that some members of the public have about the vaccine. A mass vaccination program for public health will fail if there is widespread public mistrust. However, the committee believes its equitable allocation framework, if properly implemented and communicated, can secure public trust in the processes and outcomes of allocation by being based on foundational principles that are simple, clear, coherent, and consistent in their application. The hope is that this framework will gain public trust by fairly providing benefits to individuals and communities, thereby mitigating the damage that has been 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 people in phases over time. In presenting the sponsors' charge at the committee's first meeting on July 24, 2020, the director of the National Institutes of Health (NIH), Francis Collins, stressed that the overarching framework should include "foundational principles." Such principles, which are summarized and explicated in the next section, 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 presentation and communication of the framework 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 framework 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 procedural principles embedded in U.S. social institutions and culture (see Box 3-1). The committee recognized that the principles required for its deliberations had to be solid and broad enough to urgently address a pandemic of a magnitude not seen in a century with disastrous effects not only for persons with COVID-19 and their communities but also for the economy, education, and other central aspects of society.

The committee identified the principles in Box 3-1 as both necessary and sufficient for formulating vaccine allocation criteria and their implementation in phases of vaccine allocation. These principles do not reflect any specific ethical theory, but are both consonant with many ethical theories and grounded in U.S. social values and cultural discourse. The three substantive ethical principles have direct implications for allocation criteria and prioritization in different phases of allocation; the three procedural

BOX 3-1
Foundational Principles for Equitable Allocation of COVID-19 Vaccine

Ethical Principles
- Maximum benefit
- Equal concern
- Mitigation of health inequities

Procedural Principles
- Fairness
- Transparency
- Evidence-based

principles are important for the development and implementation of allocation criteria and prioritizations that can be deemed equitable and legitimate and can thus be accepted by the public.

In its deliberations about allocation criteria, the committee quickly invoked a principle of *maximum benefit* that emphasizes maximizing societal benefit through the reduction of severe morbidity and mortality caused by the transmission of SARS-CoV-2. While spreading throughout the society, the virus has significantly harmed some populations more than others, particularly causing higher rates of infection, serious illness, hospitalization, and death among older adults in congregate settings and among people of color, the combination of which has been particularly lethal. This reality led the committee to formulate a principle of *mitigation of health inequities* to address the higher risks faced by such persons in work environments and living arrangements that pose higher risk of transmitting and acquiring infection and with a higher prevalence of health problems that make it more likely that they will suffer severe outcomes and even die from COVID-19. In difficult choices about vaccine allocation, the principle of *equal concern* directs attention to the equal worth and value of every person, protecting each person from discrimination. The procedural principle of *fairness* requires the engagement and participation of affected populations in setting allocation criteria and determining priority groups. Furthermore, the procedural principle of *transparency* ensures the disclosure of the principles, criteria, and priority groups that will determine people's chances of getting a vaccine sooner rather than later. Finally, the framework cannot accomplish its goals unless all decisions are *evidence-based*.

Not unexpectedly, these principles overlap significantly with those in other frameworks for the allocation of scarce medical and public health resources, including vaccines for pandemic influenza (Williams and Dawson,

2020). Virtually every such framework has a principle like the committee's with regard to maximum benefit. Most frameworks also include principles like the committee's relating to equal concern and to equity and fairness (Emanuel et al., 2020; Nuffield Council on Bioethics, 2020; Persad et al., 2009; Toner et al., 2020; Williams and Dawson, 2020). These frameworks vary in how clusters of ethical considerations are combined into primary principles and in the weight assigned to those principles. The overlaps are evident in comparisons with the several COVID-19 vaccine allocation frameworks discussed in Chapter 2 (see Table 3-1). These frameworks are comparable to the committee's framework in that they were also prepared by diverse multidisciplinary groups who aimed to produce practical frameworks that could be adopted and implemented.

TABLE 3-1 Comparison of Principles Across Different Frameworks for COVID-19 Vaccine Allocation

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

[a] Several frameworks for vaccine allocation include a principle of reciprocity, defined as rewarding people for their past contributions. It is important to recognize and honor people's important and often risky contributions to help others, in part to encourage such actions in the future. However, there are ways of doing so without assigning priority for scarce resources such as vaccines. In the committee's judgment, reciprocity should not be a criterion for priority in the allocation of a vaccine for COVID-19 in this pandemic. In this context, reciprocity is too broad and vague to clearly and impartially identify those particular individuals and or groups to whom it applies. However, in recruiting participants, sponsors of COVID-19 vaccine trials can promise or offer post-trial access to a safe and effective vaccine to those who receive a placebo or an ineffective vaccine.

Maximum Benefit

This principle encompasses the obligation to protect and promote the public's health and its socioeconomic well-being in the short term and long term. Societal benefit is broadly understood in this context as the public's health and socioeconomic well-being. While societal benefit includes the health and well-being of individuals, the committee recognizes that conflicts may emerge between societal and individual needs and risks that will 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 SARS-CoV-2 for those (a) most at risk of infection and serious outcomes, for example, those in congregate living arrangements with comorbid conditions; (b) in roles considered to be essential for societal functioning; and (c) most at risk of transmitting SARS-CoV-2 to others. Individuals in the roles considered to be essential for societal functioning include 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.).

Equal Concern

The government's obligation to express equal concern or regard for its 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 every person be considered and treated as having equal dignity, worth, and value. It presupposes basic equality: no one person is intrinsically more valuable or worthy of consideration than another. It entails the treatment of all as equals rather than, automatically, the provision of equal share (several versions of an egalitarian principle appear in Dworkin, 2011, which features a principle of equal concern and respect; Emanuel et al., 2020; Nuffield Council on Bioethics, 2020; Persad et al., 2009, 2020; Waldron, 2017).

The principle of equal concern 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 solely on characteristics such as religion, race, ethnicity, national origin, disabilities, and others. The moral right to equal concern requires allocation of vaccine to proceed impartially according to fair criteria.

The principle of equal concern does not preclude consideration of people's social roles in vaccine 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 (e.g., clinicians, emergency responders, food processors) may legitimately gain priority in those circumstances.

If the supply of vaccine is too limited to provide it to everyone in a particular priority group at the same time, and there are no further identifiable risk-based differences within that group, the principle of equal concern can support random selection (e.g., lottery) within that population group. It can also support a weighted lottery[1] 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. SARS-CoV-2 infections and COVID-19 illnesses and deaths are strongly associated with race, ethnicity, occupation, and socioeconomic status. A significantly higher burden is experienced by Black, Hispanic or Latinx, American Indian and Alaska Native, and Native Hawaiian and Pacific Islander populations. This disproportionate burden largely reflects the impacts of systemic racism and socioeconomic factors that are associated with increased likelihood of acquiring the infection (e.g., frontline jobs that do not allow social distancing, crowded living conditions, lack of access to personal protective equipment [PPE], inability to work from home) and of having more severe disease when infected (as a result of a higher prevalence of comorbid conditions or other factors). The social groups at higher risk of COVID-19 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 3-2). Fundamental health inequities in COVID-19 and in other health conditions are rooted in structural inequalities, racism, and residential segregation. Any vaccine allocation framework 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 health inequities is, therefore, a moral imperative of an equitable vaccine allocation framework. 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.

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

BOX 3-2
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 group 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, p. 100).
- **Social determinants of health**, or the *"*conditions in the places where people live, learn, work, and play that affect a wide range of health risks and outcomes*"* (CDC, 2020a).

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 inequities in COVID-19 resulting from the factors just described. The committee's allocation criteria do so in part by taking into account the "vulnerability" of

- People at increased risk of infection because of social conditions, such as crowded workplaces and multigenerational homes;[2] and
- People at increased risk of severe outcomes because of comorbid conditions associated with social factors, 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 illness or death. Such criteria are sometimes 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 a metric of social disadvantage, such as the Centers for Disease Control and Prevention's (CDC's) Social Vulner-

[2] Multi-generational homes consist of more than two generations living under the same roof.

ability Index (SVI),[3] the Area Deprivation Index (ADI),[4] or the COVID-19 Community Vulnerability Index (CCVI),[5] into the prioritization of vaccine recipients by making it an additional consideration (Schmidt, 2020).

The mitigation of health inequities also includes development and deployment of distribution systems that ensure that people who are allocated a vaccine actually receive it (e.g., by bringing it to them, if they cannot reach central distribution centers). Trusted community-based organizations, particularly those serving racial and ethnic populations most affected by COVID-19, should be involved in the implementation of the framework to ensure cultural and language proficiency and mitigate ongoing health inequities. This is discussed further in Chapter 6.

Fairness

Procedural fairness or justice is vitally important for the legitimacy and public acceptance of the allocation criteria and prioritizations based on these ethical principles (Daniels, 1996, 2007). The three substantive ethical principles must be interpreted in practical terms when applied in the vaccination program. These decisions about allocation, distribution, and access to vaccine should incorporate input from affected groups, especially those disproportionately affected by the pandemic. In developing its allocation phases, the committee benefited greatly from a public listening session and written public comments (described further in Appendix A). Chapters 5, 6, and 7 discuss the importance of further public engagement throughout this entire process.

Once informed by public input, 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

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

[4] The ADI is based on a measure created by the Health Resources and Services Administration to allow for rankings of neighborhoods by socioeconomic status disadvantage in a region of interest and includes factors for the domains of income, education, employment, and housing quality. It is primarily for county-level use but adapted and validated to the U.S. Census block group/neighborhood (University of Wisconsin School of Medicine and Public Health, 2020).

[5] Developed by the Surgo Foundation, the CCVI combines indicators specific to COVID-19 with CDC's SVI. These indicators are grouped into six themes: socioeconomic status, household composition and disability, minority status and language, housing type and transportation, epidemiologic factors, and health care system factors. An overall score is generated at the U.S. Census tract, and at the county and state levels (Surgo Foundation, 2020).

able to appeal decisions. The committee believes that the transparency of its principles will help adjudicate those deliberations.

Fairness should guide not only the formulation of allocation criteria, but also their application, which should be impartial and evenhanded, avoiding arbitrary exceptions and opportunities for gaming the system. Implementation should be as uniform as possible across the country, consistent with allowing discretion to state, tribal, local, and territorial (STLT) authorities to address specific patterns of SARS-CoV-2 transmission, extent of spread, and severity of outcomes. Unless clearly communicated and justified, extreme variation in applying the criteria can evoke charges of unfairness.

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 vaccination 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 framework performs and how it responds to the unanticipated consequences inevitable with such a complex human enterprise. It also extends to any alterations of or departures from the allocation criteria and priority categories in practice along with the justification for doing so.

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 allocation principles and processes 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 the allocation procedures and guiding principles easily, following their normal search patterns? Can they interpret them in ways that inform their evaluations regarding the allocation procedures' legitimacy and their own vaccination choices? Chapter 6 discusses the science of risk communication, as applied to fulfilling this ethical principle.

Evidence-Based

Vaccination phases, specifying who receives the vaccine when, should be based on the best available scientific evidence, regarding risk of disease, transmission, and societal impact. 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 vaccines prove more useful for particular populations than others. If the criteria used to identify categories of individuals or groups for each phase evolve accordingly, those changes will need to be stated and applied clearly and in keeping with the framework's foundational principles.

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, and so forth. Chapter 1 describes the current pandemic's "personality" in detail. 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. The ethical 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.

For example, applying the ethical principle of *maximum benefit* for vaccine allocation requires determining how best to protect and promote the public's health and socioeconomic well-being, both immediate and long term, before the vaccine is available to everyone. That determination requires the best available scientific evidence, following the procedural principle of *evidence based*. Similar points apply to the ethical principles of *mitigation of health inequities* and *equal concern*, as well as to the procedural principles of *fairness* and *transparency*. The application of each allocation criterion and procedure must comply with each of these principles.

When conflicts arise, their resolution will require judicious balancing by trusted parties. 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

Goal of the Framework

Previous proposals for allocation of scarce resources in pandemics and other settings articulate various overarching goals and also focus on reducing severe 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 (CDC, 2018).

Given the current state of the pandemic, the early phases of the committee's proposed framework emphasize prevention of severe morbidity and mortality, particularly with regard to maintaining essential health and emergency services. The focus shifts toward reducing transmission[6] in later phases. There are multiple reasons for this approach:

- Death is an irreversible outcome. There are legitimate claims for many groups (e.g., schoolchildren, "non-essential" workers) to be in earlier phases as negative societal impact could occur if these groups are not prioritized. For example, there might be a substantial impact on the economy if a primarily transmission-focused strategy is not employed from the outset. However, the non-trivial effects of an economic downturn or an online semester can at least be partially reversed.
- Preventing severe morbidity and mortality protects the health care system from being overwhelmed, contributing to the prevention of excess morbidity and mortality from other causes as well, with ripple effects on society and the economy.
- For vaccination to materially reduce transmission requires vaccinating a critical mass of individuals, much greater than will be possible in the early phases of vaccine deployment.

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

- The ongoing COVID-19 vaccine trials are not designed to estimate the impact of the vaccine candidates on transmission and evidence of the vaccines' actual impact on transmission might not be available for some time after FDA approval.
- While data on all aspects of COVID-19 are emerging, data on transmission risk groups (e.g., age, profession) are particularly limited.

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

The committee considered years of life lost (YLL) averted, instead of number of deaths avoided, as an alternative metric for maximizing benefit. The committee favored the number of deaths avoided for the following reasons. First, the relative risk of COVID-19-related mortality is so high in older age groups (e.g., the mortality risk is 90 times higher among 65–74-year-olds compared to 18–29-year-olds) (CDC, 2020a) that from a pragmatic perspective, the YLL averted approach does not provide substantial additional advantage. This is not to say the YLL averted approach would be futile in all situations. For example, in a pandemic with a mortality pattern similar to seasonal influenza—in which the very young as well as older adults have disproportionately high mortality or that of the 1918 pandemic—young adults were also included in the high-mortality risk groups (in addition to older adults and the very young) (Dauer and Serfling, 1961). Second, YLL averted has not been widely used in policies for preventive interventions in pandemics and large outbreaks (with the exception of a few well-argued academic exercises) and there is little evidence of a social consensus around this approach in these situations, whereas reduction of number of deaths is a widely understood and accepted goal. Third, a YLL-focused approach is inconsistent with the committee's principles of equal concern and mitigating health inequities and could be viewed as discriminating on the basis of age and not addressing the disproportionate impact on older adults.

The goal of the committee's framework for equitable allocation of COVID-19 vaccine is to:

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

The framework pursues that goal while mitigating health inequities, showing equal concern for all, being fair and transparent, and building on the best available evidence. 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 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 goal (see Box 3-3). After presenting these criteria briefly, this section discusses their compatibility with the foundational principles, practical aspects of implementation, and likely implications for allocation as vaccine 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 regarding vaccine safety, efficacy, and distribution. Achieving this goal requires comprehensive, consistent, real-time data collection that includes variables needed to assess the program's success in mitigating health inequities, such as participants' race and ethnicity, age, sex, and social status. The section provides operational definitions of these criteria, as suited to current and emerging evidence regarding the disease, the vaccine, and their impacts on society.

BOX 3-3
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 SARS-CoV-2 is circulating and of being exposed 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 infection to others:** Individuals have higher priority to the extent that there is a higher probability of their transmitting the infection to others.

Risk of Acquiring Infection

Individuals have higher priority to the extent that they have a greater probability of being in settings where SARS-CoV-2 is circulating and of being exposed 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. While no person is intrinsically more valuable than any other, some jobs are more valuable to society at this moment and under these extraordinary circumstances.

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 are limited data on differential transmissibility.

Compatibility of Allocation Criteria with Foundational Principles

Maximum Benefit

Each of these four types of risk reflects a threat to the public's health, social, and economic well-being. Reducing each risk would bring both short- and long-term benefits. These risk-based criteria express the foundational principles in terms that are further specified in the allocation phases that follow.

Equal Concern

These criteria treat all people equally. They make no reference to who people are—only 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, they do so indirectly. The first criterion addresses health inequities insofar as individuals subject to them are more likely to live and work in dense settings, where exposure to the virus is more likely. The second 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 third criterion addresses them indirectly insofar as workers who have been subject to health inequities play essential roles in jobs with greater societal impact (e.g., health and elder care).

Fairness

In applying the three substantive ethical principles to the development of allocation criteria, procedural fairness requires that we incorporate input from affected groups, especially those disproportionately affected by the pandemic. The committee's deliberations benefited from its public listening session and written input. Its risk-based 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 they more frequently live in high-density settings, work in jobs that cannot be done without having personal contact with others, and have multiple comorbid conditions due to their circumstances and their relative lack of access to health care) and Black, Hispanic or Latinx, American Indian and Alaska Native, and Native Hawaiian and Pacific Islander communities, given the ways in which these risks disproportionately affect people in these groups.

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).

Evidence-Based

These four risk-based criteria apply well-understood analytical procedures to the best available scientific evidence (NRC, 2009). The criteria should 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 individu-

als and communities and the health inequities that must be mitigated in that process (NRC, 2009).

Allocation Phases

The committee has been tasked with considering the difficult choices that will need to be made for allocating a 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 will be incrementally phased in so that some people or groups receive it earlier than others. The committee here uses the term "phases," suggesting successive deployments of a scare resource that is expected to be more broadly available over time. This approach applies the best available current evidence to implementing the framework's foundational principles.

It should be noted that the guidance offered through the committee's allocation framework is intended to inform the work of the federal government, the Advisory Committee on Immunization Practices (ACIP), STLT authorities, and potentially other countries in their COVID-19 vaccine allocation planning. Certain communities (such as the U.S. military) may handle vaccine allocation separately 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, that allocation could be based on these jurisdictions' population size.[7] While there is obviously variation among STLT communities in disease burden and demographic features, these differences are not large enough to justify the delay and deliberation that would be required to decide on customized allocations to locations. 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 to the allocation of vaccine 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 (identified through a vulnerability index, such as the SVI or the CCVI) or epidemiological "hot spots."[8] Transparency of deployment will be important. If by the time a COVID-19 vaccine becomes available, the United States has achieved the success seen in other countries in stopping widespread community transmission with non-

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

[8] 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.).

pharmaceutical (behavioral) interventions, including test, trace, isolate, and quarantine approaches, a more focused outbreak response may be feasible.

It is important to acknowledge that the federal government will allocate vaccine to Indian Health Service (IHS), tribal, and urban Indian facilities directly through existing IHS system mechanisms. Federal trust responsibility for delivery of health care to citizens of federally recognized tribes 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 the IHS, tribal, and urban Indian allocation with a portion of their own supply of vaccine, in order to protect the public's health. However, even in this scenario, in order to ensure tribal sovereignty, states would not oversee how tribal governments allocate vaccine.

Operationalizing the Criteria to Determine Allocation Phases

Data will not be available to characterize each individual in terms of the framework's risk-based criteria. Even were such data available, an allocation scheme based on individual priority scores would be technically impractical for expeditiously delivering millions of courses of vaccine to geographically distributed individuals. To determine the population groups that comprise each allocation phase, the committee operationalized the 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 3-2). In applying the risk-based criteria and determining priorities, the committee also considered the roles of mitigating factors such as access to PPE and the ability to social distance and isolate or telework. The committee recognizes that each of the four risks depends on what mitigation strategies are possible and employed. Its analyses reflect typical current mitigation actions for each group. Thus, it does not consider whether the individuals involved, their employers, regulators, and others could do more to mitigate the risks.

Table 3-2 summarizes the committee's assessments. It shows risk levels, relative to the general population, for typical members of specific major population groups, for each of the four risk-based criteria (see Box 3-3). Where risks depend on the behavior of institutions (e.g., providing PPE) or individuals (e.g., hand washing), the risk rating assumes current practices when this report was written. Actual risk levels will depend on actual practices, with the right-hand column noting some critical mitigating factors. Those practices are one source of the heterogeneity in the risks faced by members of each group. STLT authorities will need local knowledge to understand which members of each group, in their community, face higher and lower risk of each type.

There is no simple way to aggregate the four risk-based criteria, which interact in different ways in different settings. Criteria 1 (risk of acquiring infection) and 2 (risk of severe morbidity and mortality) combine to determine individuals' health risk (the probability that they will get the disease and become very ill, or die, if they do). Those two criteria combine with Criterion 3 (risk of negative societal impact) to determine the risk to vital social functions. Criteria 1 (risk of acquiring infection) and 4 (risk of transmitting infection to others) combine to determine how fast the infection spreads (what is the chance of someone getting the infection and giving it to others). Those two risks are often, but not always, related. For example, some people with high risk of acquiring infection may circulate little after being exposed. Because of these interactions among the criteria, the committee deliberately proposes no weighting scheme. Rather, the committee has set priorities by the groups' risk profiles, treating those within each phase equally and relying on the dedication and good judgment of STLT authorities to work out the details in keeping with the framework's guiding principles and the best available evidence.

Discussion of the Allocation Phases

The committee recommends a four-phased approach to COVID-19 vaccine allocation. For each population group, the committee recommends prioritizing for areas identified as vulnerable through CDC's SVI or by another more specific index such as the CCVI. This issue is discussed further later in this chapter. **Within each phase, all groups have equal priority.**

The first phase includes a "jumpstart" phase: Phase 1a. Included in Phase 1a would be "frontline" health workers—health professionals who are involved in direct patient care, as well as those working in transport, environmental services, 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 an 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 with SARS-CoV-2 (despite the use of PPE, which can be limited in some settings); the fact that they work in an essential industry, but may be precluded from performing their professional duties if they are exposed or infected; and the reality that many such workers are potentially important nodes in onward transmission networks, given that many who are in low-wage jobs may also contribute to further transmission due to living in crowded, often multi-generational living situations where social distancing is unrealistic. The latter is especially true for many individuals who work in nursing homes, assisted living facilities, group homes, and as home health aides. In addition to frontline health care workers, first responders are included

TABLE 3-2 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 health workers	H	M	H	H	Adequate access to personal protective equipment. Workplace management of exposure.
1a	First responders	H	M	H	H	Adequate access to personal protective equipment. Workplace management of exposure.
1b	People with significant comorbid conditions (defined as having two or more)	M	H	M	M	Ability to maintain social distance and isolate.
1b	Older adults in congregate or overcrowded settings	H	H	L	M	Effective institutional management of exposure.
2	K–12 teachers and school staff and child care workers	H	M	H	H	Online schooling, especially for lower grades, recognizing educational and social impacts.
2	Critical workers in high-risk settings	H	M	H	M	Adequate access to personal protective equipment. Workplace management of exposure.
2	People with moderate comorbid conditions	M	M	M	M	Ability to maintain social distance and isolate.

2	People in homeless shelters or group homes and staff	H	H	L	H	Adequate access to personal protective equipment. Effective institutional/workplace management of exposure.
2	Incarcerated/detained people and staff	H	M	L	H	Adequate access to personal protective equipment. Effective institutional/workplace management of exposure.
2	All older adults	M	H	L	L	Ability to maintain social distance and isolate.
3	Young adults	H	L	M	H	Ability to maintain social distance and isolate. Closure of congregate settings (e.g., bars).
3	Children	M	L	M	H	Ability to participate in online schooling.
3	Workers in industries important to the functioning of society	M	M	M	M	Adequate access to personal protective equipment. Effective institutional/workplace management of exposure.

NOTES: Cell entries are for a typical member of each group. H = high risk; L = low risk; M = medium risk. All groups are heterogeneous, and ratings indicate the median 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 unknowns at the time of the report's writing. There is no weighting of these different criteria and no aggregation. Within each phase, the population groups are of similar priority, and authorities have the flexibility to adapt the priority population groups to their specific conditions. Lastly, the committee has elected not to use the designation "essential worker." Instead, the committee refer to these workers as critical workers in high-risk settings 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 in additional detail later in this chapter.

as well. The "jumpstart" phase is followed by Phase 1b, which includes 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. Knowledge of the relative risks stemming from specific underlying risk factors is evolving quickly and will be better known by the time vaccines become available. This would allow decision makers to target for vaccination, more effectively than is possible today, those individuals at greatest risk of severe morbidity and mortality.

Recognizing the importance of education and child development, K–12 teachers and school staff are included in Phase 2. It is important to include this group relatively early to restart in-person education. The first cohort of critical workers who are in industries essential to the functioning of society and at higher risk of exposure are included in Phase 2. The 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. 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 difficulty of preventing spread in such settings should COVID-19 be introduced. Last, all older adults not included in Phase 1 would be included.

In Phase 3, vaccine supply will become even more widely available and allow the broader immunization of workers important 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. The broad immunization of children and young adults is included in this phase, 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 COVID-19 vaccines have been adequately tested for safety and efficacy in these age groups—similar issues also apply to pregnant women. Most initial trials are testing vaccines among older age groups, who are known to suffer more severe morbidity and mortality.

Finally, once vaccine supply becomes more broadly available (Phase 4), vaccines would be made available to individuals who are 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 unknowns about the COVID-19 vaccine and the nature of the pandemic itself persist, but the committee ap-

proached its framework under the best available evidence today. Under the context described, the committee's allocation approach is shown in Figure 3-2 and is further described in greater detail—first as a description of the various phases, followed by discussion of ensuring equity across all phases. The proposed approach assumes a poorly controlled outbreak in which the relative distribution of severe morbidity and mortality burden is similar to what exists today. Given the epidemiological features of COVID-19 so far, it is reasonable to assume these conditions will hold around the anticipated start of the U.S. COVID-19 vaccination program. However, it is possible that the United States will be able to substantially control the outbreak, as in countries such as New Zealand. In that case, a prioritization approach that initially emphasizes reducing transmission over direct protection from severe morbidity and mortality could be considered.

Overlap and Size of the Allocation Phases

The committee acknowledges that the population groups included in each phase overlap to a certain extent. A population may fit into multiple phases; for example, a group of critical workers in high-risk settings may also belong to a population with significant comorbid conditions, and an older adult may live in a congregate multi-generational setting. When individuals within a group fall into multiple phases, the higher phase should take precedent. STLT authorities must consider the cumulative effect of populations belonging to multiple groups and adhere to the stated foundational principles and apply the risk-based criteria to ensure that the implementation of the allocation phases meets the goal to reduce severe morbidity, mortality, and negative societal impact due to the transmission of the SARS-CoV-2.

The committee's estimates of group size do not consider either the heterogeneity of the groups nor their overlap. The effective size of each group will be smaller to the extent that some of its members have lower risks or are in an earlier phase. The committee has not attempted to estimate that heterogeneity and overlap. As a result, the group sizes presented here are upper bounds that are very unlikely to be reached. For example, some health care facilities will be in regions with very low disease prevalence or will have the resources and management needed for stringent mitigation strategies, thereby reducing the number of high-risk workers in Phase 1a. Some K–12 teachers and staff will have more than one significant comorbid condition, putting them in Phase 1b, reducing the group size in Phase 2. Some members of each group may refuse the vaccine when their group's time comes, reducing its initial size, perhaps delaying demand until field experience satisfies those individuals' need for demonstrations of safety and effectiveness.

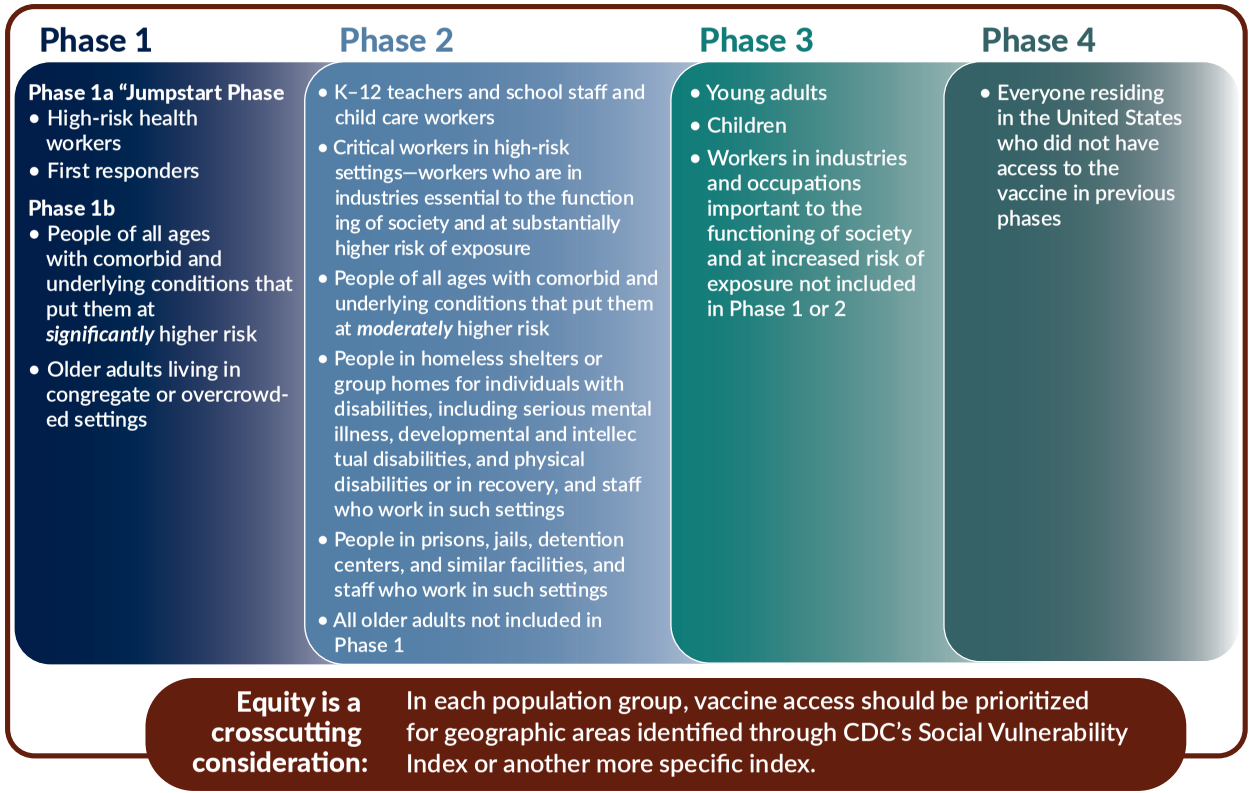

FIGURE 3-2 A phased approach to vaccine allocation for COVID-19.

Phase 1

Phase 1 includes the following groups:

- High-risk health workers;
- 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.

In a 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 STLT authorities prepare distribution procedures for the next phases.

Phase 1a

Population: High-Risk Health Workers

This group includes frontline health care workers (who are in hospitals, nursing homes, or providing home care) who either (1) work in situations where the risk of SARS-CoV-2 transmission is higher, or (2) are at an elevated risk of transmitting the infection to patients at higher 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 facility staff, long-term care facility staff, group home staff, and home caregivers). The health care settings employing these workers who are at increased risk of exposure to the virus may also include ambulatory and urgent care clinics; dialysis centers; blood, organ, and tissue donation facilities; and other non-hospital health care facilities. Finally, there are community and family settings where care for infected patients occurs. Not all the workers in these settings are paid for their labor, but, while they are caring for infected people, they all need to be protected from the virus.

Situations associated with higher risk of transmission include caring for COVID-19 patients, cleaning areas where COVID-19 patients are admitted, treated, and housed, and performing procedures with higher 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. In addition, there are other frontline health care workers who, if they have uncontrolled exposure to the patients or the public in the course of their work, should be in this initial phase. This group includes those individuals distributing or administering the vaccine—especially in areas of higher community transmission—such as pharmacists, plasma and blood donation workers, public health nurses, and other public health and emergency preparedness workers. The committee also includes morticians, funeral home workers, and other death care professionals involved in handling bodies as part of this high-risk group.

Rationale

Frontline health 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 the 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, and when they return to their own homes and communities.

Frontline health workers are at significantly higher risk of becoming infected with SARS-CoV-2 compared to members of the general public. A recent 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). This risk is exacerbated by the ongoing shortage of PPE especially in nursing homes and, in a study of health care personnel at 13 academic medical centers, workers who reported inadequate access to PPE had a higher rate of detectable SARS-CoV-2 antibodies than did those who did not report a PPE shortage (McGarry et al., 2020; Self et al., 2020). Protecting health care 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.

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 had 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; McGarry et al., 2020). Individuals who provide home care or work in hospitals, nursing homes, and assisted living (or similar) facilities—who are also at higher risk for severe illness and death because of comorbid conditions and age—should be among the first to receive the vaccine.

Vaccination is not a substitute for non-medical preventive policies and equipment. All exposed workers should, for example, be provided an adequate supply of appropriate PPE. It is vitally important that the prospect of vaccination not supplant efforts to either ensure adequate supplies of PPE or continue mitigation strategies after vaccination.

In considering those health care workers who are at an elevated risk of transmitting the infection to patients at higher risk of mortality and severe morbidity, it is also important to note that nursing home residents and staff have been at the center of the pandemic since the first reported cases. Nearly 80 percent of all COVID-19 deaths in the United States have occurred in people over the age of 65 (CDC, 2020g). As of September 8, 2020, there were 331,864 confirmed or suspected COVID-19 cases and 51,700 deaths among nursing home residents, according to the Centers for Medicare & Medicaid Services (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 spreading infection within and between institutions (CMS, 2020b). Asymptomatic spread by nursing home workers is well established (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 of exposing others. In addition to their occupational and community exposures, these workers are statistically at a higher risk of contracting COVID-19 and experiencing severe health effects because they come from populations with higher rates of comorbid conditions (Silver et al., 2020). A notable proportion of nursing home workers are Black (27.8 percent), as are home care workers (Black: 29.7 percent and Latinx: 17.5

percent) (McCormack et al., 2020). A sizable proportion of such workers are over 65 as well (Black: 9.1 percent and Latinx: 11.3 percent).

Estimated Group Size[9]

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, 2019d). There are approximately 291,000 public health workers in the United States (Beck et al., 2014), including 41,000 public health nurses in state and local health departments and 59,000 community health workers (Beck et al., 2014; BLS, 2019c). There are also 621,000 pharmacists and pharmacy staff (BLS, 2019e), as well as 200,000 dentists in the United States (ADA, 2020). The number of morticians, undertakers, and funeral directors in the United States is estimated to be approximately 25,000 (*Statista*, 2020).

Population: First Responders

This group includes emergency medical services (EMS) personnel, police, and firefighters (including volunteer firefighters). Like health workers, many first responders have been working in situations in which exposure to infected individuals is sometimes unavoidable. However, first responders in some jobs and in some communities may not be at an increased risk of exposure, and inclusion in this category should reflect occupational risk. First responders who are not at higher risk of exposure need not be prioritized. Given their public serving role, first responders who become ill can transmit infection to their families and to the broader community. Although data on exposure risk for first responders are limited, initial estimates indicate higher infection rates among first responders in higher COVID-19 transmission settings.

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

[9] 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.

firefighters 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 firefighting services, is impaired. First responders who are at higher risk of exposure and who are also at higher risk for severe illness and death because of comorbid conditions and age should be among the first receiving the vaccine in this group.

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 the assumption of additional risk by these groups, and—in some cases—higher risk of acquiring infection and, potentially, transmitting the virus. Similarly, until substantial and sustained suppression of SARS-CoV-2 transmission is achieved, first responders are likely to need PPE for performing their responsibilities.

Estimated Group Size

An estimated 2.1 million first responders are included in 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) (BJS, 2019; BLS, 2019f, 2020c; Evarts and Stein, 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, 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 these comorbid conditions in Phase 1b is not possible, because 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 should

evolve. The committee acknowledges that there are uncertainties about the feasibility of identifying and administering vaccine to this group, but expect that a spectrum of approaches may be employed to identify these high-risk individuals in the initial phase. 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 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).[10]

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 six 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 City 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 at particularly higher risk (Petrilli et al., 2020). Ultimately, given the higher 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 severe morbidity and mortality at the individual level.

Estimated Group Size

There are currently no clear data from which to accurately estimate the size of the population group with multiple select comorbid conditions,

[10] 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.

which the committee acknowledges as a key limitation and something that could benefit from future research. A recent modeling study by Clark et al. (2020) may provide a general range of the size of this population group. In the study, the authors highlighted a "high-risk" group 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 preceding CDC list).

Population: Older Adults Living in Congregate or Overcrowded Settings

This group includes older individuals living in congregate and overcrowded situations (e.g., long-term care facilities, homeless shelters or group homes, prisons, and jails) 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, ACIP should 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 previously mentioned, approximately 80 percent of all deaths have occurred in adults 65 and older (CDC, 2020g). Similarly, the risk of hospitalization from COVID-19 increases with age, with rates per 100,000 persons being significantly higher for adults aged 65 and older (~199 per 100,000 for 65–74-year-old individuals, ~329 per 100,000 for 75–84-year-old individuals, and ~513 per 100,000 for individuals 85 and older) (CDC, 2020c). 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, suggest that the percentage of COVID-19 deaths occurring in residents of long-term care facilities may be higher than indicated by CDC's database (CIHI, 2020; *NYT*, 2020).

Whatever the precise numbers, it is clear that directly protecting older adults—particularly those living in congregate or overcrowded settings—

will have a 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 aged 60 or older compared to people younger than 60 (Lipsitch, 2020). In addition, adjuvanted vaccines, such as the recombinant zoster vaccine (Shingrix), have been demonstrated to provide efficacy to older adults across the age spectrum (Bastidas et al., 2019; Dagnew et al., 2020).

The committee suspects that many older adults living in overcrowded settings may live in multigenerational households. Historically, in virtually every society, people have 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 opportunities for practicing social distancing. Because many individuals living in multi-generational households in the United States also work in jobs that put them at an elevated risk of exposure to COVID-19 it is important to vaccinate the older adults in those households, to protect them from acquiring COVID-19.

The combination of the risk of severe disease due to advanced age and the higher risk of acquiring infection and transmission among older adults included in this population group makes 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, 2020b,f,h; Cubanski et al., 2018). In addition, according to 2016 estimates, 21 percent of adults aged 65 and older in the United States lived in multi-generational households (out of approximately 49.2 million total), with a disproportionate number from communities of color (Cohn and Passel, 2018; Rieger, 2017; Roberts et al., 2018).

Phase 2

Phase 2 includes the following groups:

- K–12 teachers and school staff and child care workers;

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

It is important to note the changing vaccine supply levels at various points during the allocation process, and as vaccine supply increases, efforts should be expanded to the additional populations listed in Phase 2. 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. Moving to Phase 2, it is important to note the overlap issue discussed earlier in this chapter. Individuals who fall within population groups in this phase may also be high-risk health workers or first responders, may have comorbid and underlying conditions that put them at significantly higher risk, or may be older and living in congregate or overcrowded settings and therefore should be vaccinated in Phase 1.

Population: K–12 Teachers and School Staff and Child Care Workers

This group includes K–12 school staff and child care workers (such as nursery school staff), including teachers, administrators, environmental services staff, maintenance workers, and school bus drivers.

Rationale

Across the nation, states and localities are placing a high priority on reopening schools and expanding child care 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 SARS-CoV-2 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 SARS-CoV-2 transmission, with these teachers and staff serving as connections between schools and the community.

Furthermore, the importance of re-opening schools, especially for elementary-aged children, cannot be overstated. 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 will facilitate important social development for them as well.

As some states and localities choose to begin re-opening schools, it is also important to consider the direct impact of COVID-19 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 many 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, 2019f, 2020e).

Population: Critical Workers in High-Risk Settings—Workers Who Are in Industries Essential to the Functioning of Society and at Substantially Higher Risk of Exposure

Another group included in Phase 2 is comprised of people whose work is vital to the functioning of society and the economy, and whose work causes them to have a higher 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[11] 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, p. 3).

The list of categories of workers designated by DHS includes many groups of workers who are at higher risk of exposure. Others designated by DHS, however, are either able to telework or are otherwise isolated and not at higher 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,

[11] See https://www.cisa.gov/publication/guidance-essential-critical-infrastructure-workforce (accessed September 15, 2020).

while performing "essential work," these employees 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 workers in high-risk settings because 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 workers are employed are essential to keeping 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 that markets have food; drug stores have pharmaceutical products; public safety and order are maintained; mail and packages are delivered; and buses, trains, and planes are operating. This group also includes other health workers who are not already accounted for in Phase 1a. Importantly, only those whose jobs or occupations in these essential industries where the workers cannot avoid a high risk of exposure qualify as critical workers in this group.

There is no single complete list of all workers who should be in the Phase 2 prioritization. The designation of critical worker in a high-risk setting should be a function of the likelihood of uncontrolled exposure and will undoubtedly vary by state and situation. It may be, for example, that coal miners, many of whom already have occupational lung disease, are not provided adequate protection. If this is the case, they would be included in this category. Similarly, there are likely to be government workers who have uncontrolled exposure; for example, workplace inspectors or meat and poultry inspectors employed by the U.S. Department of Agriculture are likely to fit into this category.

It would be useful if public health agencies, including CDC, the Occupational Safety and Health Administration, the Mine Safety and Health Administration, and state and local public health agencies, provided additional guidance in the designation of jobs or tasks involved as well as occupational code or job title 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; Michaels and Wagner, 2020). Those members of these sectors who are at higher risk for exposure and infection should be given priority. These workers are more likely to be Black or Latinx than workers who are able to work safely from home (Hawkins, 2020; McCormack et al., 2020). Many of them work without adequate protection while in close proximity with coworkers and members of the public. Groups of critical risk workers who are at higher risk

of exposure (Waltenburg et al., 2020) include workers in the U.S. food supply system who plant, harvest, and package crops; slaughter and process meat; and deliver food to stores and stock shelves and staff checkout lines. In many food system workplaces, adequate protections have not been provided. There are many reasons why food system 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 workforce (i.e., migrant workers), shared transportation to and from the workplace, lack of paid sick leave, and congregate housing situations (including living in employer-furnished housing and shared living quarters, and living in crowded and multi-generational homes) (Oliver, 2020). For economic and legal reasons, these low-paid workers may be less likely to attempt to use the health care system for care. 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. Included in this population group are postal workers and workers in warehouses and fulfillment centers. In addition, there are many other workers whose jobs are vital to society's functioning and who therefore are required to work when other workers are home. Members of these groups whose work entails being in close proximity to other potentially infected people, and who are not able to be adequately protected from exposure, are in this phase as well. Not all critical risk workers 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, paid sick leave for potentially infectious workers, and providing adequate PPE (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 and food store workers (865,000), workers in the utilities sector (e.g., electric, water, telecommunications; 539,000), postal service workers (497,000), delivery workers (e.g., truck drivers; 1,506,000), passenger vehicle drivers (1,077,000), construction workers (7,214,000), 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 (BLS, 2019d,f, 2020a,b,d,f; USDA, 2020; USPS, 2020; Walten-

burg et al., 2020). Ideally, 20 percent of workers from those in industries deemed to be essential would be covered in this initial group.

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 two or more comorbid conditions from among those listed.

Other comorbid conditions and potentially rare diseases should be considered for inclusion in 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, 2020d).

Rationale

As per to the discussion of 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 (hospitalization and intensive care unit admission) and death 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 of the listed comorbid or underlying conditions.[12]

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

[12] 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.

remains possible that additional comorbid conditions will be included in this category as evidence emerges, but this population group would likely include tens of millions of people.

Population: People in Homeless Shelters or Group Homes for Individuals with Disabilities, Including Serious Mental Illness, Developmental and Intellectual Disabilities, and Physical Disabilities or Who Are in Recovery, and Staff Who Work in Such Settings

This group includes people who live in homeless shelters or group homes for people with disabilities that include serious mental illness, developmental and intellectual disabilities, and physical disabilities or who live in recovery in group homes, as well as the staff in these facilities.

Rationale

Many of these people are at risk because of their underlying diseases, chronic health care needs, limited access to health care, and because of their living setting (Landes et al., 2020).

Among people who experience homelessness, many are at higher risk of acquiring and transmitting infection, given the frequency of time spent in public places or in congregate settings such as shelters and due to other challenges (e.g., not receiving proper communication about the pandemic). Individuals living in congregate settings face increased risk of exposure to COVID-19 if they have limited or shared bathroom facilities, share utensils and other personal items, and have limited ability to practice social distancing or hygiene, including frequent hand washing. In addition, staff at these facilities are at increased risk of exposure and are more likely to transmit SARS-CoV-2 if infected. Many people who experience homelessness may suffer from one or more underlying health conditions that may put them at higher risk and therefore they are included in vaccination in the first phase.

People with disabilities, including serious mental illness, developmental and intellectual disabilities, and physical disabilities or who are in recovery in group homes may also have 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 acquiring infection and transmission. Additionally, group homes may differ from more institutionalized settings in that residents often have the right and ability to access their local communities, work outside the residence, and have visitors from outside the home, which increases the risk of exposure and transmission (NCD, 2020).

Estimated Group Size

It is estimated that 469,000 people live in group homes and 575,000 people experience homelessness across the United States (Culhane et al., 2020; Williams et al., 2013); staff at such facilities should be included here as well.

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 people 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 who are not released from jail pending a trial on the criminal charges. 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.

Rationale

Data show that persons in state and federal prisons have a 5.5-fold greater risk of contracting COVID-19 compared to the general U.S. population (Saloner et al., 2020). These people, as well as those in jails and detention centers, have reduced autonomy and cannot physically distance themselves from others in their congregate living setting and thus need additional protection (Page et al., 2020). As a result, the risk of their both acquiring and transmitting SARS-CoV-2 infection to others is higher.

Vaccination in Phase 2 of those in detention centers after entering the country without documentation 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 because they are not always subject to federal standards.

Outbreaks of seasonal influenza demonstrate the inadequate nature of the medical system in these facilities (Page et al., 2020). Furthermore, as has been described in studies of 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, bringing the total to more than 2.7 million people in this group (Akiyama et al., 2020; BLS, 2019f).

Population: All Other Older Adults Not Included in Phase 1

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 higher risk of severe disease and death due to COVID-19 among older adults.

Estimated Group Size

It is estimated there are more than 49.2 million older adults (people 65 and older) living in the United States (Roberts et al., 2018). Accounting for some overlap with the previous groups, it is estimated that there are 13.2 million older adults in the United States without comorbid or underlying conditions.

Phase 3

Phase 3 includes the following groups:

- Young adults;
- Children; and
- Workers in industries and occupations important 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 proportion and the 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 presymptomatic transmission (Moghadas et al., 2020; Souchery, 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 acquiring infection 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. Furthermore, SARS-CoV-2 infections in college-aged adults can threaten the health of faculty and other university staff, many of whom are older or have underlying illnesses that put them at risk of severe COVID-19. Similarly, the 2019 U.S. Census data show that approximately one in two young adults currently live in parental homes, and 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 comorbidity (U.S. Census, 2019b).

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, 2019a). 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 and 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 parents' and guardians' ability to work. Vaccination and the resultant 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, and so on) can be realized.

It is important to note that clinical trials of COVID-19 vaccine have not started in children in the United States. It will be critical to conduct trials to gain a better understanding of the safety and efficacy of COVID-19 vaccine among children before they receive the vaccine.

Estimated Group Size

There are approximately 74 million children (infant to 17 years of age) in the United States (Federal Interagency Forum on Child and Family Statistics, 2020).

Population: Workers in Industries and Occupations Important to the Functioning of Society and at Increased Risk of Exposure Not Included in Phases 1 or 2

The inclusion of workers in this category represents a social choice: beyond the workers designated in Phases 1 and 2, which jobs and industries

are important or desirable to maintaining the normal functioning of society? Examples of such occupational groups include university professors and staff, workers in restaurants, hotels, and the entertainment industry; those in banks and libraries; and those 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 jobs are 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 individuals in 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 theater, sports, and other aspects of entertainment, who cannot easily socially distance or use PPE, but whose industry was not considered to be 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 normalcy; 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 the virus. In comparison to workers included in Phase 2, workers in Phase 3 are likely to have lower exposure risk to SARS-CoV-2 through their occupation, or hold a role that is considered less central to economic and social recovery, or both. 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 re-opening. Among the occupations that could potentially be included here are college and university faculty and staff (~3,089,000); factory workers in production and non-supervisory roles (~8,400,000); 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,b,f). Ideally, Phase 3 would vaccinate the remaining 80 percent of workers from industries deemed to be essential.

Phase 4

Shifting to a more routine vaccination strategy, Phase 4 includes every person residing in the United States who did not have access to the vaccine in previous phases (and for whom the vaccine is not medically contraindicated, although no contraindications 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 of 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, the resumption of social functions will require high vaccination coverage in the general population. The United States should ensure that all U.S.-based individuals who did not have access to the vaccine in previous phases (and for whom the vaccine is not medically contraindicated) have access to the vaccine.

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 risks 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 staff at risk of exposure, not just those who are paid or 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 evidence clearly shows that people of color—specifically Black, Hispanic or Latinx, American Indian and Alaska Native, and Native Hawaiian and Pacific Islander—have been disproportionately impacted by COVID-19, with higher rates of morbidity, mortality, and transmission. As previously mentioned, this largely reflects the impacts of systemic racism and socioeconomic adversity that are associated with higher exposures to the virus and greater severity of disease among those infected, due to comorbid conditions, lack of access to health care or other public health services, and other factors such as inadequate housing and lack of access to clean water and nutrition.

The committee's allocation framework focuses on these underlying causes by recommending the application of a vulnerability index, and spe-

cifically CDC's SVI or another more specific index such as the CCVI, within its framework instead of focusing on discrete racial and ethnic categories. The committee considered multiple options for addressing inequities before deciding on a vulnerability index-based approach. For example, a purely race/ethnicity-based prioritization approach is likely to increase mistrust in communities of color, because they may suspect a lack of ethical and safety oversight for a new vaccine given a long history of mistreatment by the medical community in the name of research. Second, a purely race/ethnicity-based allocation may omit other important social determinants of health. Third, such an allocation could be legally challenged.

Among vulnerability-based indices, the committee also considered the ADI for identifying vulnerable areas. While the ADI captures several important sociodemographic factors, several variables relevant to COVID-19, such as crowding and the proportion of the population over age 65, are not a part of the ADI.

Use of CDC's SVI in the committee's framework represents an attempt to incorporate the variables that the committee believes are most linked to the disproportionate impact of COVID-19 on people of color and other vulnerable populations. CDC's SVI was developed for local preparedness for public health emergencies such as natural disasters and disease outbreaks, and it identifies geographic areas of vulnerability based on 15 U.S. Census variables (ATSDR, 2018). These variables capture many recognized social determinants of health (e.g., income or race and ethnicity), indicators of access (e.g., transportation), infection transmission factors (e.g., crowding), and increased risk of adverse COVID-19 outcomes (e.g., proportion aged 65 or older). This index can be calculated at the U.S. Census tract level—enabling immunization programs to better identify areas of vulnerability. Where relevant data are available, vaccine programs could also consider SVI-derived indices such as the CCVI—an index that includes SVI variables as well as COVID-19-specific ones: (1) indicators of known COVID-19 comorbidities, and (2) health system factors, which account for access to health care resources in a community that are relevant to this pandemic (e.g., intensive care unit beds).

Operationalizing the Social Vulnerability Index

The committee does not propose an approach in which, within each phase, all vaccine is first given to people in high-SVI areas. Rather the committee proposes that the SVI be used in two ways. First as previously noted, a reserved 10 percent portion of the total federal allocation of COVID-19 vaccine may be reserved to target areas with a high-SVI (defined as the top 25 percent of the SVI distribution within the state). Second, the committee proposes that STLT authorities ensure that special efforts are made to

deliver vaccine to residents of high-vulnerability areas (defined as the 25 percent highest in the state).

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 locations must be taken into account while operationalizing vaccine access.

Costs Associated with Vaccination

Several COVID-19 vaccines under development have received considerable taxpayer support. Therefore, it is essential that COVID-19 vaccines be delivered through a central mechanism that ensures the availability of vaccines to all individuals, whatever their social and economic resources, employment, immigration, or insurance status. This can best be achieved if this federal mechanism makes vaccines available at no cost to public health and health care sectors. To ensure equity and to decrease vaccine hesitancy, there should be no out-of-pocket costs for those being vaccinated and this includes covering fees for the administration of vaccine. Chapter 6 and Recommendation 3 discuss further the issue of costs associated with vaccination.

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 by federal and state authorities that their coming forward to receive the vaccine will not lead to deportation or be used against them in immigration proceedings, or be considered use of a public benefit under the "Public Charge" rule and therefore be potentially detrimental to attaining citizenship (Page et al., 2020). 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—because no vaccine is 100 percent effective.

Considerations for Pregnant Women

Although data are uncertain regarding the risk of adverse outcomes associated with COVID-19 in pregnancy, current evidence suggests that pregnant women are more likely to be hospitalized with COVID-19 than are non-pregnant women, and infants born to women infected with SARS-CoV-2 during pregnancy appear to have increased risk for preterm birth and admission to

a neonatal intensive care unit (Allotey et al., 2020; CDC, 2020e). Therefore, it is concerning that most, if not all, of the current Phase 2 and 3 vaccine trials are excluding pregnant women, thus putting them at a disadvantage for protecting themselves against SARS-CoV-2. Operation Warp Speed, NIH, and CDC should prioritize an assessment of vaccine efficacy, effectiveness, and safety among pregnant and lactating women in their pre-clinical and clinical development and post-marketing surveillance plans. These data and the characteristics of the approved vaccines will enable ACIP to develop recommendations for vaccinating pregnant women against SAS-CoV-2.

Vaccine Allocation for the Military[13]

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, who 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 with varying levels of risk for infection and life-threatening complications of COVID-19. These include 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.

Additional Considerations of the Framework

The committee notes the following considerations as STLT authorities adapt the allocation framework to their local conditions.

[13] This specific discussion is focused on active duty troops and their dependents. Veterans would be considered in the phases previously described.

STLT Flexibility with Transitioning Between and Within Phases

It is important to reiterate that the COVID-19 vaccination phases identify population groups of similar priority. Within phases, STLT authorities have the flexibility to adapt the priority population groups to their specific conditions. For example, some counties have no tertiary hospitals and are served by neighboring counties, and others may have chicken and pork production facilities or universities. Some areas may have no evidence of virus spread and be given a lower geographic priority as compared to other areas of a state. Furthermore, populations in each phase, especially in Phases 1a and 1b, may well exceed the amount of vaccine available, or Phases 1 and 2 may even become merged or overlapping. Currently, some individual-level data to properly classify individuals in specific categories may be difficult to collect or ascertain. It is important that the allocation process *does not* obstruct or slow down vaccination—the ability to move quickly to vaccinate priority groups does matter. Also, as previously mentioned many unknowns remain regarding the safety and efficacy of the vaccines in certain populations (such as children, pregnant women, older adults, and individuals previously infected with COVID-19). STLT authorities will have to make final decisions on refining and applying the suggested priorities previously listed, and should plan for situations when prioritization has to be adapted mid-process. In doing so, they should refer to the principles and allocation criteria that guided the formulation of the phases.

Unintended Consequences

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 affect 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 following key preventive measures. As a result, the committee acknowledges that STLT 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.

Demographic Data Limitations

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 in the nursing home population and the population of older adults living in overcrowded settings, and significant overlap between members of multi-generational families and other categories listed for vaccination during earlier phases, such as occupational groups. As a result, 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. Population values for each group will be improved as the program is under way.

CONCLUDING REMARKS

This equitable COVID-19 vaccination allocation framework will be dynamic and, it is hoped, ever-improving. Features of the COVID-19 pandemic will change over time, as will collective understanding of its effects (e.g., the list of comorbid conditions that put individuals at higher risk of severe disease or death due to COVID-19 infection). The committee recognizes the current uncertainty regarding COVID-19, its spread, the availability of treatments, and the possibility that new evidence may change the risks and, with them, the priorities. Additional adjustments in response to new evidence and data should be made as necessary. For example, it is important to consider new information on key 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.

RECOMMENDATION 1. Adopt the committee's framework for equitable allocation of COVID-19 vaccine.

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

- This framework can also inform the decisions of other groups, such as the Advisory Committee on Immunization Practices and those in the global health community.

- STLT authorities will have to make final decisions on refining and applying the framework and should plan for situations when prioritization has to be adapted mid-process. In doing so, they should refer to the principles and allocation criteria that guided the formulation of the phases.

REFERENCES

ADA (American Dental Association). 2020. *Workforce*. https://www.ada.org/en/science-research/health-policy-institute/dental-statistics/workforce (accessed September 22, 2020).

Akiyama, M. J., A. C. Spaulding, and J. D. Rich. 2020. Flattening the curve for incarcerated populations—COVID-19 in jails and prisons. *The New England Journal of Medicine* 382:2075–2077. doi: 10.1056/NEJMp2005687.

Allotey, J., E. Stallings, M. Bonet, M. Yap, S. Chatterjee, T. Kew, L. Debenham, A. C. Llavall, A. Dixit, D. Zhou, R. Balaji, S. I. Lee, X. Qiu, M. Yuan, D. Coomar, M. van Wely, E. van Leeuwen, E. Kostova, H. Kunst, A. Khalil, S. Tiberi, V. Brizuela, N. Broutet, E. Kara, C. R. Kim, A. Thorson, O. T. Oladapo, L. Mofenson, J. Zamora, and S. Thangaratinam. 2020. Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: Living systematic review and meta-analysis. *BMJ* 370:m3320. doi: 10.1136/bmj.m3320.

ATSDR (Agency for Toxic Substances and Disease Registry). 2018. *CDC's Social Vulnerability Index*. https://www.atsdr.cdc.gov/placeandhealth/svi/index.html (accessed September 22, 2020).

Baker, M. G., T. K. Peckham, and N. S. Seixas. 2020. Estimating the burden of United States workers exposed to infection or disease: A key factor in containing risk of COVID-19 infection. *PLOS ONE* 15(4):e0232452. doi: 10.1371/journal.pone.0232452.

Bastidas, A., G. Catteau, S. Volpe, T. Mrkvan, A. Enemuo, J. Smetana, T. Schwarz, L. Rombo, K. Pauksens, E. Berengier, C. Hervé, L. Oostvogels, and A. Schuind. 2019. Long-term immunological persistence of the adjuvanted recombinant zoster vaccine: Clinical data and mathematical modeling. *Open Forum Infectious Diseases* 6(Suppl 2):S84–S85. doi: 10.1093/ofid/ofz359.183.

Beck, A. J., M. L. Boulton, and F. Coronado. 2014. Enumeration of the governmental public health workforce, 2014. *American Journal of Preventive Medicine* 47(5 Suppl 3):S306–S313. doi: 10.1016/j.amepre.2014.07.018.

BJS (U.S. Bureau of Justice Statistics). 2019. *Local police departments, 2016: Personnel summary*. Washington, DC: U.S. Department of Justice. https://www.bjs.gov/content/pub/pdf/lpd16p_sum.pdf (accessed August 28, 2020).

BLS (U.S. Bureau of Labor Statistics). 2019a. *Manufacturing: NAICS 31-33*. https://www.bls.gov/iag/tgs/iag31-33.htm (accessed September 15, 2020).

BLS. 2019b. *May 2019 national industry-specific occupational employment and wage estimates: NAICS 611300—colleges, universities, and professional schools*. https://www.bls.gov/oes/current/naics4_611300.htm (accessed September 15, 2020).

BLS. 2019c. *Occupational employment and wages, May 2019: 21-1094 community health workers*. https://www.bls.gov/oes/current/oes211094.htm (accessed September 15, 2020).

BLS. 2019d. *Occupational employment and wages, May 2019: 29-0000 healthcare practitioners and technical occupations (major group)*. https://www.bls.gov/oes/current/oes290000.htm#nat (accessed September 22, 2020).

BLS. 2019e. *Occupational employment statistics: May 2018 national industry-specific occupational employment and wage estimates: NAICS 446110-pharmacies and drug stores*. https://www.bls.gov/oes/2018/may/oessrci.htm (accessed September 22, 2020).

BLS. 2019f. *Occupational employment statistics: May 2019 occupational profiles*. https://www.bls.gov/oes/current/oes_stru.htm (accessed August 28, 2020).
BLS. 2020a. *Construction: NAICS 23*. https://www.bls.gov/iag/tgs/iag23.htm (accessed September 15, 2020).
BLS. 2020b. *Delivery truck drivers and driver/sales workers*. https://www.bls.gov/ooh/transportation-and-material-moving/delivery-truck-drivers-and-driver-sales-workers.htm (accessed September 15, 2020).
BLS. 2020c. *EMTs and paramedics*. https://www.bls.gov/ooh/healthcare/emts-and-paramedics.htm (accessed August 28, 2020).
BLS. 2020d. *Industries at a glance: Utilities: NAICS 22*. https://www.bls.gov/iag/tgs/iag22.htm (accessed September 15, 2020).
BLS. 2020e. *Occupational employment statistics: May 2019 national industry-specific occupational employment and wage estimates-NAICS 611100-elementary and secondary schools*. https://www.bls.gov/oes/current/oessrci.htm (accessed September 22, 2020).
BLS. 2020f. *Occupational employment statistics-occupational employment and wages, May 2019-53-3052-bus drivers, transit and intercity*. https://www.bls.gov/oes/current/oes533052.htm (accessed September 22, 2020).
Braveman, P. 2006. Health disparities and health equity: Concepts and measurement. *Annual Review of Public Health* 27:167–194. doi: https://doi.org/10.1146/annurev.publhealth.27.021405.102103.
Britton, T., F. Ball, and P. Trapman. 2020. A mathematical model reveals the influence of population heterogeneity on herd immunity to SARS-CoV-2. *Science* 369(6505):846–849. doi: 10.1126/science.abc6810.
Bruine de Bruin, W., A. M. Parker, and J. Strough. 2020. Age differences in reported social networks and well-being. *Psychology and Aging* 35(2):159–168. doi: 10.1037/pag0000415.
CDC (Centers for Disease Control and Prevention). 2018. *Interim updated planning guidance on allocating and targeting pandemic influenza vaccine during an influenza pandemic*. Atlanta, GA: CDC. https://www.cdc.gov/flu/pandemic-resources/pdf/2018-Influenza-Guidance.pdf (accessed September 22, 2020).
CDC. 2020a. *About social determinants of health (SDOH)*. Atlanta, GA: CDC. https://www.cdc.gov/socialdeterminants/about.html (accessed September 21, 2020).
CDC. 2020b. *COVID-19 hospitalization and death by age*. https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-age.html (accessed September 22, 2020).
CDC. 2020c. *COVID-19: Older adults*. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/older-adults.html (accessed September 22, 2020).
CDC. 2020d. *COVID-19: People with certain medical conditions*. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fneed-extra-precautions%2Fgroups-at-higher-risk.html (accessed August 28, 2020).
CDC. 2020e. *COVID-19: Pregnancy Data*. https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/special-populations/pregnancy-data-on-covid-19.html (accessed September 22, 2020).
CDC. 2020f. *Nursing home care*. https://www.cdc.gov/nchs/fastats/nursing-home-care.htm (accessed August 28, 2020).
CDC. 2020g. *Provisional COVID-19 death counts by sex, age, and state*. https://data.cdc.gov/NCHS/Provisional-COVID-19-Death-Counts-by-Sex-Age-and-S/9bhg-hcku (accessed September 22, 2020).
CDC. 2020h. *Residential care communities*. https://www.cdc.gov/nchs/fastats/residential-care-communities.htm (accessed August 28, 2020).

CIHI (Canadian Institute for Health Information). 2020. *Pandemic experience in the long-term care sector: How does Canada compare with other countries?* Ottowa, ON: CIHI. https://www.cihi.ca/sites/default/files/document/covid-19-rapid-response-long-term-care-snapshot-en.pdf (accessed September 22, 2020).

Clark, A., M. Jit, C. Warren-Gash, B. Guthrie, H. H. X. Wang, S. W. Mercer, C. Sanderson, M. McKee, C. Troeger, K. L. Ong, F. Checchi, P. Perel, S. Joseph, H. P. Gibbs, A. Banerjee, R. M. Eggo, E. S. Nightingale, K. O'Reilly, T. Jombart, W. J. Edmunds, A. Rosello, F. Y. Sun, K. E. Atkins, N. I. Bosse, S. Clifford, T. W. Russell, A. K. Deol, Y. Liu, S. R. Procter, Q. J. Leclerc, G. Medley, G. Knight, J. D. Munday, A. J. Kucharski, C. A. B. Pearson, P. Klepac, K. Prem, R. M. G. J. Houben, A. Endo, S. Flasche, N. G. Davies, C. Diamond, K. van Zandvoort, S. Funk, M. Auzenbergs, E. M. Rees, D. C. Tully, J. C. Emery, B. J. Quilty, S. Abbott, C. J. Villabona-Arenas, S. Hué, J. Hellewell, A. Gimma, and C. I. Jarvis. 2020. Global, regional, and national estimates of the population at increased risk of severe COVID-19 due to underlying health conditions in 2020: A modelling study. *The Lancet Global Health* 8(8):e1003–e1017. https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(20)30264-3/fulltext (accessed September 22, 2020).

Clark, C. A. 2020. *AHCA/NCAL:* "COVID-19 testing positivity rates and PPE supply shortage for nursing homes across nation." *Los Alamos Daily Post*, August 7, 2020. https://ladailypost.com/ahca-ncal-covid-19-testing-positivity-rates-ppe-supply-shortages-for-nursing-homes (accessed September 22, 2020).

CMS (Centers for Medicare & Medicaid Services). 2020a. *COVID-19 nursing home data*. https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg (accessed September 22, 2020).

CMS. 2020b. *COVID-19 nursing home dataset-archived data-week ending 7/12/20*. https://data.cms.gov/Special-Programs-Initiatives-COVID-19-Nursing-Home/COVID-19-Nursing-Home-Dataset-Archived-Data-Week-E/e9t9-t34c (accessed September 22, 2020).

Cohn, D., and J. S. Passel. 2018. A record 64 million Americans live in multigenerenational households. *Pew Research Center FactTank: News in the Numbers*, April 5, 2018. https://www.pewresearch.org/fact-tank/2018/04/05/a-record-64-million-americans-live-in-multigenerational-households (accessed September 22, 2020).

Cubanski, J., W. Koma, A. Damico, and T. Neuman. 2018. *How many seniors live in poverty?* Kaiser Family Foundation. https://www.kff.org/medicare/issue-brief/how-many-seniors-live-in-poverty (accessed September 22, 2020).

Culhane, D., D. Treglia, K. Steif, R. Kuhn, and T. Byrne. 2020. *White Paper: Estimated emergency and observational/quarantine capacity need for the US homeless population related to COVID-19 exposure by county; projected hospitalizations, intensive care units and mortality*. http://www.bu.edu/ssw/files/2020/03/COVID-paper_0325_1127am.pdf (accessed September 22, 2020).

Dagnew, A. F., N. P. Klein, C. Hervé, G. Kalema, E. Di Paolo, J. Peterson, B. Salaun, and A. Schuind. 2020. The adjuvanted recombinant zoster vaccine in adults aged ≥65 years previously vaccinated with a live-attenuated herpes zoster vaccine. *The Journal of Infectious Diseases* jiaa083. doi: org/10.1093/infdis/jiaa083.

Daniels, N. 1996. *Justice and justification: Reflective equilibrium in theory and practice*. New York: Cambridge University Press.

Daniels, N. 2007. *Just health: Meeting health needs fairly*. New York: Cambridge University Press.

Dauer, C. C., and R. E. Serfling. 1961. Mortality from influenza. *American Review of Respiratory Disease* 83(2P2):15–28. https://www.atsjournals.org/doi/abs/10.1164/arrd.1961.83.2P2.15 (accessed September 22, 2020).

Dingel, J., and B. Neiman. 2020. *White Paper: How many jobs can be done at home?* Chicago, IL: Becker Friedman Institute for Economics at the University of Chicago.

DoD (U.S. Department of Defense). 2020. *DoD Personnel, Workforce Reports & Publications*. https://www.dmdc.osd.mil/appj/dwp/dwp_reports.jsp (accessed August 28, 2020).

Dworkin, R. 2011. *Justice for hedgehogs*. Cambridge, MA: Belknap Press.

Emanuel, E. J., G. Persad, R. Upshur, B. Thome, M. Parker, A. Glickman, C. Zhang, C. Boyle, M. Smith, and J. P. Phillips. 2020. Fair allocation of scarce medical resources in the time of COVID-19. *The New England Journal of Medicine* 382(21):2049–2055. doi: 10.1056/NEJMsb2005114.

Evarts, B., and G. P. Stein. 2020. *U.S. fire department profile 2018*. NFPA Research. https://www.nfpa.org/-/media/Files/News-and-Research/Fire-statistics-and-reports/Emergency-responders/osfdprofile.pdf (accessed September 22, 2020).

Federal Interagency Forum on Child and Family Statistics. 2020. *America's children in brief: Key national indicators of well-being, 2020*. Washington, DC: U.S. Government Printing Office. https://www.childstats.gov/americaschildren/index.asp (accessed October 29, 2020).

Gaffney, A. W., D. Himmelstein, and S. Woolhandler. 2020. Risk for severe COVID-19 illness among teachers and adults living with school-aged children. *Annals of Internal Medicine*. doi: 10.7326/M20-5413.

Hawkins, D. 2020. Differential occupational risk for COVID-19 and other infection exposure according to race and ethnicity. *American Journal of Industrial Medicine* 63(9):817–820. doi: 10.1002/ajim.23145.

Jaklevic, M. C. 2020. Researchers strive to recruit hard-hit minorities into COVID-19 vaccine trials. *JAMA* 324(9):826–828. doi: 10.1001/jama.2020.11244.

Karaca-Mandic, P., A. Georgiou, and S. Sen. 2020. Assessment of COVID-19 hospitalizations by race/ethnicity in 12 states. *JAMA Internal Medicine*. Published online August 17, 2020. doi: 10.1001/jamainternmed.2020.3857.

Krebs, C. C. 2020. *Advisory memorandum on identifications of essential critical infrastructure workers during COVID-19 response*. Washington, DC: U.S. Department of Homeland Security. https://www.cisa.gov/sites/default/files/publications/Version_3.1_CISA_Guidance_on_Essential_Critical_Infrastructure_Workers_0.pdf (accessed August 28, 2020).

The Lancet. 2020. Editorial: The plight of essential workers during the COVID-19 pandemic. *The Lancet* 395(10237):1587. doi: 10.1016/S0140-6736(20)31200-9.

Landes, S. D., M. A. Turk, M. K. Formica, K. E. McDonald, and J. D. Stevens. 2020. COVID-19 outcomes among people with intellectual and developmental disability living in residential group homes in New York State. *Disability and Health Journal* 100969. doi: 10.1016/j.dhjo.2020.100969.

Lee, S., P. Meyler, M. Mozel, T. Tauh, and R. Merchant. 2020. Asymptomatic carriage and transmission of SARS-CoV-2: What do we know? *Canadian Journal of Anaesthesia* 67:1424–1430. doi: 10.1007/s12630-020-01729-x.

Lighter, J., M. Phillips, S. Hochman, S. Sterling, D. Johnson, F. Francois, and A. Stachel. 2020. Obesity in patients younger than 60 years is a risk factor for COVID-19 hospital admission. *Clinical Infectious Diseases* 71(15):896–897. doi: 10.1093/cid/ciaa415.

Lipsitch, M. 2020. *Using models of SARS-CoV-2 dynamics to inform vaccine prioritization*. Paper read at Committee on Equitable Allocation of Vaccine for the Novel Coronavirus Public Workshop.

McClung, N. 2020. *Epidemiology of individuals at increased risk of COVID-19 disease*. Presented at the August 26, 2020, Meeting of the Advisory Committee on Immunization Practices.

McCormack, G., C. Avery, A. K.-L. Spitzer, and A. Chandra. 2020. Economic vulnerability of households with essential workers. *JAMA* 324(4):388–390. doi: 10.1001/jama.2020.11366.

McGarry, B. E., D. C. Grabowski, and M. L. Barnett. 2020. Severe staffing and personal protective equipment shortages faced by nursing homes during the COVID-19 pandemic. *Health Affairs*. doi: 10.1377/hlthaff.2020.01269.

Michaels, D., and G. R. Wagner. 2020. Occupational Safety and Health Administration (OSHA) and worker safety during the COVID-19 pandemic. *JAMA*. doi: 10.1001/jama.2020.16343.

Miller, R. B., and C. A. Nebeker-Adams. 2017. Multigenerational households. In *Encyclopedia of couple and family therapy*, edited by J. Lebow, A. Chambers, and D. C. Breunlin. Cham, Switzerland: Springer International Publishing. Pp. 1–3.

Moghadas, S. M., M. C. Fitzpatrick, P. Sah, A. Pandey, A. Shoukat, B. H. Singer, and A. P. Galvani. 2020. The implications of silent transmission for the control of COVID-19 outbreaks. *Proceedings of the National Academy of Sciences* 117(30):17513–17515. doi: 10.1073/pnas.2008373117.

Mullen O'Keefe, S. 2020. One in three Americans would not get COVID-19 vaccine. *Gallup News*. https://news.gallup.com/poll/317018/one-three-americans-not-covid-vaccine.aspx (accessed September 22, 2020).

NASEM (National Academies of Sciences, Engineering, and Medicine). 2017. *Communities in action: Pathways to health equity*. Washington, DC: The National Academies Press.

NCD (National Council on Disability). 2020. *NCD comments to National Academies on preliminary COVID-19 vaccine allocation framework*. https://ncd.gov/publications/2020/ncd-comments-national-academies-preliminary-covid-19-vaccine-allocation-framework (accessed September 9, 2020).

Nguyen, L. H., D. A. Drew, M. S. Graham, A. D. Joshi, C.-G. Guo, W. Ma, R. S. Mehta, E. T. Warner, D. R. Sikavi, C.-H. Lo, S. Kwon, M. Song, L. A. Mucci, M. J. Stampfer, W. C. Willett, A. H. Eliassen, J. E. Hart, J. E. Chavarro, J. W. Rich-Edwards, R. Davies, J. Capdevila, K. A. Lee, M. N. Lochlainn, T. Varsavsky, C. H. Sudre, M. J. Cardoso, J. Wolf, T. D. Spector, S. Ourselin, C. J. Steves, A. T. Chan, on behalf of the Coronavirus Pandemic Epidemiology Consortium. 2020. Risk of COVID-19 among front-line healthcare workers and the general community: A prospective cohort study. *The Lancet Public Health* 5(9):E475–E483. doi: 10.1016/S2468-2667(20)30164-X.

NRC (National Research Council). 1996. *Understanding risk: Informing decisions in a democratic society*. Washington, DC: National Academy Press.

NRC. 2009. *Science and decisions: Advancing risk assessment*. Washington, DC: The National Academies Press.

Nuffield Council on Bioethics. 2020. *Rapid Policy Briefing: Fair and equitable access to COVID-19 treatments and vaccines*. https://www.nuffieldbioethics.org/assets/pdfs/Fair-and-equitable-access-to-COVID-19-treatments-and-vaccines.pdf (accessed September 22, 2020).

NYT (*The New York Times*). 2020. *More than 40% of U.S. coronavirus deaths are linked to nursing homes*. https://www.nytimes.com/interactive/2020/us/coronavirus-nursing-homes.html#:~:text=More%20Than%2040%25%20of%20U.S.%20Coronavirus%20Deaths%20Are%20Linked%20to%20Nursing%20Homes,-By%20The%20New&text=At%20least%2068%2C000%20residents%20and,a%20New%20York%20Times%20database (accessed August 28, 2020).

Oliver, S. 2020. *Epidemiology of COVID-19 in essential workers, including healthcare personnel*. Paper read at ACIP July 2020 Meeting.

Omer, S. 2019. Withholding flu vaccine from migrants isn't just cruel. It's dangerous. *The Washington Post*, August 26, 2019. https://www.washingtonpost.com/outlook/2019/08/26/withholding-flu-shots-detained-migrants-isnt-just-cruel-its-dangerous (accessed September 22, 2020).

OSHA (Occupational Safety and Health Administration). 2020. *Guidance on preparing workplaces for COVID-19*. Washington, DC: OSHA. https://www.osha.gov/Publications/OSHA3990.pdf (accessed August 28, 2020).

Ouslander, J. G., and D. C. Grabowski. 2020. COVID-19 in nursing homes: Calming the perfect storm. *Journal of the American Geriatrics Society*. doi: 10.1111/jgs.16784.

Page, K. R., M. Venkataramani, C. Beyrer, and S. Polk. 2020. Undocumented U.S. immigrants and COVID-19. *The New England Journal of Medicine* 382(21):e62. doi: 10.1056/NEJMp2005953.

Persad, G., A. Wertheimer, and E. J. Emanuel. 2009. Principles for allocation of scarce medical interventions. *The Lancet* 373(9661):423–431. doi: 10.1016/S0140-6736(09)60137-9.

Persad, G., M. E. Peek, and E. J. Emanuel. 2020. Fairly prioritizing groups for access to COVID-19 vaccines. *JAMA*. Published online September 10, 2020. doi: 10.1001/jama.2020.18513.

Petrilli, C. M., S. A. Jones, J. Yang, H. Rajagopalan, L. O'Donnell, Y. Chernyak, K. A. Tobin, R. J. Cerfolio, F. Francois, and L. I. Horwitz. 2020. Factors associated with hospital admission and critical illness among 5279 people with coronavirus disease 2019 in New York City: Prospective cohort study. *BMJ* 369:m1966. doi: 10.1136/bmj.m1966.

Rieger, S. 2017. *The continued growth of multigenerational living*. Joint Center for Housing Studies of Harvard University. March 9, 2017. https://www.jchs.harvard.edu/blog/the-continued-growth-of-multigenerational-living (accessed September 15, 2020).

Roberts, A. W., S. U. Ogunwole, L. Blakeslee, and M. A. Rabe. 2018. The population 65 years and older in the United States: 2016—American Community Survey Reports. ACS-38 Issued October 2018. https://www.census.gov/content/dam/Census/library/publications/2018/acs/ACS-38.pdf (accessed September 22, 2020).

Saloner, B., K. Parish, J. A. Ward, G. DiLaura, and S. Dolovich. 2020. COVID-19 cases and deaths in federal and state prisons. *JAMA* 324(6):602–603. doi: 10.1001/jama.2020.12528.

Schmidt, H. 2020. Vaccine rationing and the urgency of social justice in the COVID-19 response. *Hastings Center Report 50*(3):46–49. doi: 10.1002/hast.1113.

Self, W. H., M. W. Tenforde, and W. B. Stubblefield. 2020. Seroprevalence of SARS-CoV-2 among frontline health care personnel in a multistate hospital network—13 academic medical centers, April–June 2020. *Morbidity Mortality Weekly Report* 69:1221–1226. doi: 10.15585/mmwr.mm6935e2.

Silver, S. R., J. Li, W. L. Boal, T. L. Shockey, and M. R. Groenewold. 2020. Prevalence of underlying medical conditions among selected essential critical infrastructure workers—behavioral risk factor surveillance system, 31 states, 2017–2018. *Morbidity and Mortality Weekly Report* 69:1244–1249. doi: 10.15585/mmwr.mm6936a3.

Snowden, F. M. 2019. *Epidemics and society: From the black death to the present*. New Haven, CT: Yale University Press.

Souchery, S. 2020. COVID-19 cases among US young adults spike. *CIDRAP News*, June 26, 2020. https://www.cidrap.umn.edu/news-perspective/2020/06/covid-19-cases-among-us-young-adults-spike (accessed September 22, 2020).

Statista. 2020. *Number of morticians, undertakers, and funeral directors in the United States from 2012 to 2019*. Statista. https://www.statista.com/statistics/752908/number-of-morticians-undertakers-and-funeral-directors-us (accessed September 22, 2020).

Sunderji, A., K. N. Mena, J. Winickoff, J. Melinek, and J. Sharfstein. 2020. Influenza vaccination and migration at the US southern border. *American Journal of Public Health* 110(4):466–467. doi: 10.2105/AJPH.2019.305547.

Surgo Foundation. 2020. *The COVID-19 community vulnerability index* (*CCVI*). https://precisionforcovid.org/ccvi (accessed September 15, 2020).

Toner, E., A. Barnill, C. Krubiner, J. Bernstein, L. Privor-Dumm, M. Watson, E. Martin, C. Potter, D. Hosangadi, N. Connell, C. Watson, M. Schoch-Spana, T. Goodwin Veenema, D. Meyer, E. L. Daugherty Biddison, Al Regenberg, T. Inglesby, and A. Cicero. 2020. *Interim framework for COVID-19 vaccine allocation and distribution in the United States*. Baltimore, MD: Johns Hopkins Center for Health Security. https://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2020/200819-vaccine-allocation.pdf (accessed September 22, 2020).

University of Wisconsin School of Medicine and Public Health. 2020. *Neighborhood atlas: Area deprivation index*. https://www.neighborhoodatlas.medicine.wisc.edu (accessed September 15, 2020).

U.S. Census. 2019a. *National population by characteristics: 2010–2019*. https://www.census.gov/data/datasets/time-series/demo/popest/2010s-national-detail.html (accessed September 22, 2020).

U.S. Census. 2019b. *Historical living arrangements of adults*. https://www.census.gov/data/tables/time-series/demo/families/adults.html (accessed September 22, 2020).

USDA (U.S. Department of Agriculture). 2020. *Ag and food sectors and the economy*. https://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/ag-and-food-sectors-and-the-economy/#:~:text=In%202018%2C%20the%20U.S.%20food,of%20all%20U.S.%20nonfarm%20employment (accessed August 28, 2020).

USPS (U.S. Postal Service). 2020. Number of postal employees since 1926. https://about.usps.com/who-we-are/postal-history/employees-since-1926.pdf (accessed September 15, 2020).

Waldron, J. 2017. *One another's equals: The basis of human equality*. Cambridge, MA: The Belknap Press of Harvard University Press.

Waltenburg, M. A., T. Victoroff, C. E. Rose, et al. 2020. Update: COVID-19 among workers in meat and poultry processing facilities—United States, April–May 2020. *Morbidity and Mortality Weekly Report* 69:887–892. doi: 10.15585/mmwr.mm6927e2.

White, D. B., M. Schmidhofer, E. McCreary, R. Bariola, G. M. Snyder, R. Sackrowitz, N. N. Jonassaint, J. Daley, D. M. Yealy, T. Sonmez, M. U. Unver, P. Pathak, G. Persad, and R. Truog. 2020. *A model hospital policy for fair allocation of scarce medications to treat COVID-19*. University of Pittsburgh Department of Critical Care Medicine. https://www.ccm.pitt.edu/?q=content/model-hospital-policy-allocating-scarce-critical-care-resources-available-online-now (accessed September 22, 2020).

WHO (World Health Organization). 2017. *10 facts on health inequities and their causes*. https://www.who.int/features/factfiles/health_inequities/en (accessed August 28, 2020).

Williams, J. H., and A. Dawson. 2020. Prioritising access to pandemic influenza vaccine: A review of the ethics literature. *BMC Medical Ethics* 21(1):40. doi: 10.1186/s12910-020-00477-3.

Williams, J., D. De Vos, and D. Russell 2013. *2010 Census Group quarters enumeration assessment report*. Washington, DC: U.S. Census Bureau. https://www.census.gov/content/dam/Census/library/publications/2013/dec/2010_cpex_243.pdf (accessed September 22, 2020).

4

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

There are many unknowns regarding if and when vaccines against coronavirus disease 2019 (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., 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 3 of this report outlined the foundational principles and allocation framework to be used in guiding the fair and equitable use of a scarce COVID-19 vaccine supply. This chapter envisions potential scenarios that federal and state, tribal, local, and territorial (STLT) authorities may face in the use of new COVID-19 vaccines. This chapter starts with describing the best scenario. Subsequently, the chapter identifies 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 (1) non-pharmaceutical interventions such as mask usage, physical distancing, hand washing, and others; (2) expanded diagnostic testing linked to contact tracing, isolation, and quarantine strategies aimed at containing transmission, suppressing outbreaks, and interrupting super-spreading events; and (3) the deployment of therapeutic measures that mitigate morbidity and mortality and, ultimately, curtail transmission from those who do become infected (CDC,

2017, 2020a,b). The principle that public policy should be evidence based is essential to guiding the allocation of scarce countermeasures.

Box 4-1 outlines some of the key unknowns regarding COVID-19 vaccines. Given these unknowns, STLT authorities will need to be ready for varied and sometimes unexpected scenarios in determining how best to use their federal allocation.

An ideal COVID-19 vaccine would be a one-dose vaccine that can be easily handled and stored, 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,[1] has very 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 (e.g., lack of efficacy in some age groups, complex administration, adverse reactions) reducing demand, 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). For an initial period when demand exceeds supply, the committee, in Chapter 3, recommended a phased approach, guided by evidence to maximize societal benefit by reducing morbidity and mortality caused

BOX 4-1
Unknowns Affecting Vaccine Allocation

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

[1] Current COVID-19 vaccine clinical trials are focused on clinical endpoints related to infection or mild-moderate symptomatic disease and do not explicitly address the issue of transmission blocking.

by the transmission of the novel coronavirus. As previously highlighted, a range of uncertain factors related to the available vaccine(s) may affect the implementation of the framework. Table 4-1 at the end of this chapter summarizes how the framework could be affected in various scenarios.

Number and Timing of Available Vaccine Doses

To ensure adequate protection, it is likely that the vaccine will require two doses instead of one. 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) will be 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 would be, in essence, wasted.

A related issue is durability of protection. It may be that duration of protection will be short enough so 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 under way, 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 the future management of COVID-19. Vaccine efficacy may also differ in different population groups (e.g., a vaccine might be less efficacious in older adults). Moderate-to-low efficacy may lead people to reject the vaccine, believing their risk of adverse effects or the unknown outweigh the benefit of vaccination (Smith, 2017).[2] Epidemic modeling—once a vaccine becomes

[2] "To ensure that a widely deployed COVID-19 vaccine is effective, the U.S. Food and Drug Administration stated that the primary efficacy endpoint 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." See https://www.fda.gov/media/139638/download (accessed August 18, 2020).

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, apparent efficacy may be influenced by how adherent people are to other basic protective measures such as masks and social distancing (CDC, 2017, 2020a,b). 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 adverse events from the 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 adverse events. As the vaccine starts to be allocated broadly in the United States, monitoring of safety through passive and active surveillance and possible adjustment of the allocation framework will be essential in order to minimize possible adverse effects in the population, while maximizing benefit by preventing deaths and severe disease. Effective and timely collection and communication of evidence regarding population effects, both efficacy and adverse events, will also be essential in order to secure and maintain the public's trust. Additionally, vaccinated individuals should be assured of compensation (especially for health care costs) for vaccine-related injuries. The U.S. Department of Health and Human Services (HHS) has issued a Public Readiness and Emergency Preparedness (PREP) Act declaration, preempting state tort remedies (HHS, 2020). Therefore, 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

The committee discusses vaccine hesitancy concerns, including the anti-vaccination movement, in greater detail in Chapter 7. Vaccine hesitancy has been well documented among numerous population groups in the United States. 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

because there is suspicion that political or economic considerations have influenced the vaccine safety assessments made by government regulatory or advisory bodies, such as the U.S. Food and Drug Administration and the Advisory Committee on Immunization Practices (ACIP). It may be that some people are hesitant to receive COVID-19 vaccine 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 severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2] transmission) due to the vaccine may not be high.

Messages about vaccine safety and efficacy are essential for all people and at all phases. Risk communication considerations are discussed further in Chapter 6. Direct-to-consumer advertising may influence public perceptions and preferences. It is critical that the communication campaign accompanying the vaccine outlines 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 among some groups or that make health care less accessible to them. This is why it is essential that before COVID-19 vaccine candidates are approved and disseminated, enrollment of minority patients in the clinical trials for COVID-19 vaccine should be large enough to draw reasonable conclusions regarding the safety and efficacy of the vaccine candidate in these populations, thereby enabling experts and community advocates to accurately solicit vaccine acceptance. Without this critical step being achieved, vaccines cannot be responsibly marketed to communities of color, thereby exacerbating disparities in health.

Number and Timing of Available Vaccine Types

It is possible that multiple vaccine types, and not just a single vaccine, will be made available. 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., platform, construct, and adjuvant; safety and efficacy, overall and in different populations; duration of protection; robustness of immune response; among others) and it will be 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 the 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 effectiveness 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 United States, across many states and jurisdictions. Increasing numbers of cases are occurring among younger people, who are also thought to be key agents in transmitting the infection. It is currently not known how long immunity from SARS-CoV-2 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 have a 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, 2017, 2020a,b). It is essential that vaccinated individuals be encouraged to engage in personal protective behavior to the extent that they are able to do so.

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 supplement what would be allocated by the federal government through the Indian Health Service). State-based distribution should be monitored and supported through data. Current efforts to have regional responses should be encouraged and should allow for states to flexibly respond to changes in the allocation methodology, population needs, or supply.

Social, Economic, and Legal Contexts

The committee recognizes that social, economic, and legal contexts will affect the equitable allocation of vaccine in our efforts to combat COVID-19. These legal issues include, but are not limited to, the process of vaccine approval, distribution, and reimbursement at the federal level; the potential intersection of allocation criteria with federal and state antidiscrimination laws; variability in state vaccination mandates aimed at schoolchildren and employees in certain sectors, such as patient care; professional licensing and scope of practice rules; recognition of out-of-state provider licenses when additional professionals are needed; payment and reimbursement provisions and processes for the varying public and private insurers within states; provider and manufacturer exposure to liability; and state-based surveillance and privacy protections. More generally, the need for vaccination will be affected by states' legal efforts to increase mask usage and social distancing and to decrease exposure.

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 and day care attendance on evidence of vaccination or an accepted reason for exemption, such as a medical contraindication. There will cer-

tainly 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 legal interpretations of existing authorities, or by considering ways to tighten existing law regarding exemptions. Despite the allocation framework, some school districts may mandate vaccination of schoolchildren immediately, as a means of moving more quickly toward re-opening schools for in-person learning. 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).

Some employers will require employees to be vaccinated or to have some evidence of prior infection (based 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 as a condition of employment, subject to some limitations based on union agreements or religious exemptions (e.g., many hospitals and nursing homes require employees to be vaccinated against influenza and a host of other diseases such as tuberculosis and measles), a number of concerns arise when vaccine supply is

TABLE 4-1 Summary Table of the Application of the Committee's Framework in Various Scenarios

Scenario
Number and Timing of Vaccine Doses
Fewer vaccine courses available than expected by Operation Warp Speed
Vaccine requires two doses, rather than one
Vaccine Efficacy
Low vaccine efficacy among older adults or other population subgroup
Vaccine Safety
Unanticipated vaccine side effects
Significant vaccine side effects among older adults or other population subgroups

limited, as it will be with the COVID-19 vaccine. 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 have a 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 (they would either take the vaccine or lose employment) and would be a possible violation of the Americans with Disabilities Act or corresponding state-based disability protection (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. STLT authorities should not waver from their adherence to the proposed equitable allocation framework 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 ensure access to vaccination for those individuals.

Change in Allocation Framework
Allocation framework is unchanged. Some individuals receive vaccination later than they would otherwise.
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. Both doses would need to be the same type of vaccine, so this would complicate the second dose if several types are available.
Only allocate to this population subgroup if vaccine benefits outweigh the risks.
Continuously monitor vaccine safety as the vaccine is rolled out. Only allocate to individuals for whom vaccine benefits outweigh the risks.
Continuously monitor vaccine safety as the vaccine is rolled out. Only allocate to this population subgroup if vaccine benefits outweigh the risks.

continued

TABLE 4-1 Continued

Scenario
Vaccine Uptake
Vaccine uptake is lower than expected
Number of Vaccine Types
More than one vaccine type available
Epidemic Conditions and Immune Status
Epidemic spread is continuing across much of the United States when the vaccine becomes available
Epidemic is spreading most rapidly in particular hot spots when the vaccine becomes available
Vaccine Distribution and Administration
States are required to follow federal guidelines for vaccine allocation
States have some leeway in the extent to which they follow federal guidelines for vaccine allocation
Social, Economic, and Legal Contexts
Some states mandate vaccination of schoolchildren
Some employers require proof of vaccination
Some states do not provide free vaccine access to people without documentation of legal status

REFERENCES

CDC (Centers for Disease Control and Prevention). 2017. Community mitigation guidelines to prevent pandemic influenza—United States, 2017. *Morbidity and Mortality Weekly Report* 66:1–34. https://www.cdc.gov/mmwr/volumes/66/rr/rr6601a1.htm (accessed September 21, 2020).

CDC. 2020a. *Nonpharmaceutical interventions (NPIs)*. Atlanta, GA: CDC. https://www.cdc.gov/nonpharmaceutical-interventions/index.html (accessed August 19, 2020).

CDC. 2020b. *COVID-19: Social distancing: Keep a safe distance to slow the spread*. Atlanta, GA: CDC. https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/social-distancing.html (accessed August 19, 2020).

Change in Allocation Framework
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.
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.
Allocation framework is unchanged. Public health messages must continue to stress the need for personal protective measures (e.g., masks, social distancing). A certain fraction of vaccine courses (e.g., 10 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).
Allocation framework is unchanged. 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).
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). 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. 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.

HHS (U.S. Department of Health and Human Services). 2020. Declaration under the public readiness and emergency preparedness act for medical countermeasures against COVID-19. *Federal Register* 85(52). https://www.govinfo.gov/content/pkg/FR-2020-03-17/pdf/2020-05484.pdf (accessed August 19, 2020).

Malik, A. A., S. M. McFadden, J. Elharake, and S. B. Omer. 2020. Determinants of COVID-19 vaccine acceptance in the U.S. *EClinicalMedicine*. doi: 10.1016/j.eclinm.2020.100495.

Mello, M. M., R. D. Silverman, and S. B. Omer. 2020. Ensuring uptake of vaccines against SARS-CoV-2. *The New England Journal of Medicine*. doi: 10.1056/NEJMp2020926.

Phelan, A. L. 2020. COVID-19 immunity passports and vaccination certificates: Scientific, equitable, and legal challenges. *The Lancet* 395(10237):1595–1598. doi: 10.1016/S0140-6736(20)31034-5.

Smith, T. C. 2017. Vaccine rejection and hesitancy: A review and call to action. *Open Forum Infectious Diseases* 4(3):ofx146. doi: 10.1093/ofid/ofx146.

Yang, Y. T., E. Pendo, and D. R. Reiss. 2020. The Americans with Disabilities Act and healthcare employer-mandated vaccinations. *Vaccine* 38(16):3184–3186. doi: 10.1016/j.vaccine.2020.03.012.

5

Administering and Implementing an Effective and Equitable National COVID-19 Vaccination Program

The administration, implementation, and evaluation of effective and equitable coronavirus disease 2019 (COVID-19) vaccination efforts is an inherently complex enterprise, given the range of constraints under which state, tribal, local, and territorial (STLT) health departments and their partners are operating. As plans for program implementation are developed in different jurisdictions, the foundational principles and criteria for determining an equitable allocation framework laid out earlier in this report need to be taken into account. Different jurisdictions may need to make adjustments to the recommended approach to accommodate the needs of their populations and resources available; however, continuing to be guided by the goal of reducing severe morbidity and mortality and negative societal impact due to the transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is essential. The ideal national program would be designed with sufficient operational simplicity to ease the burden on STLT public health entities. This requires robust coordination and clear, consistent communication within and across partner entities involved in the program. This chapter describes key coordination, cost, communication, and community engagement considerations to ensure an effective and equitable national COVID-19 vaccination program. Chapter 6 discusses risk communication and community engagement in further depth, and Chapter 7 highlights key considerations related to vaccine acceptance.

COORDINATION OF A NATIONAL COVID-19 VACCINATION PROGRAM

Implementing a coordinated national COVID-19 vaccination program on the ground at STLT levels will be challenging on multiple fronts, but there are lessons to be gleaned from past efforts. An analysis of key policy barriers encountered during the 2009 H1N1 pandemic response was conducted by the Centers for Disease Control and Prevention (CDC), the Association of State and Territorial Health Officials, and the National Association of County & City Health Officials (Logan Circle Policy Group, 2010). Multiple barriers to coordination were identified, including (1) inadequate coordination of state and local policies related to emergency management, public health, and education; (2) deficient communication and coordination with city- and county-level public information officers; and (3) conflicts between state- and local-level response efforts and federal-level communication and coordination practices (Logan Circle Policy Group, 2010). The latter barrier hindered the ability of STLT response efforts to provide timely information and caused STLT authorities and nonprofit partners to receive conflicting messages from the federal partners. The H1N1 vaccine campaign also illustrates challenges related to allocating vaccines in states that have more complex and diverse population needs.

Without question, coordination and administration depend on a host of laws and regulations that govern everything from transportation of vaccines, payments to institutional, business, and individual providers, licensure and scope of practice rules within and across state lines, liability exposures and insurance coverage, and treaty or other provisions specific to federally recognized tribes, among other things. The conflicts between federal and STLT authorities, and the wide variation among triggering mechanisms and powers for public health emergencies among states, makes it complex to administer vaccines according to any framework. These, and many other aspects of public health law at the national and state levels, are already being subjected to close evaluation (Burris et al., 2020). In addition, if any COVID-19 vaccine is approved through an Emergency Use Authorization (EUA), it may come with special provisions limiting off-label use (e.g., pediatric use if not labeled for such use based on the clinical trials) or with requirements for post-market studies. Such studies would need to be coordinated with existing mechanisms for reporting adverse events and the vaccine compensation entities at the federal level. Furthermore, such an approval would need to be revisited once the declared public health emergency has ended. The committee acknowledges these issues, but they are not addressed within this report.

Implementing an effective and equitable national COVID-19 vaccination program will require robust coordination across federal agencies

and with STLT partners. Traditionally, CDC leads coordination. However, CDC is not the sole entity responsible for vaccination program administration, delivery, surveillance, and evaluation. Within the U.S. Department of Health and Human Services (HHS), regional teams from the Office of the Assistant Secretary for Preparedness and Response, and other agencies such as the U.S. Food and Drug Administration (FDA), the National Institutes of Health, the Health Resources and Services Administration, and the Centers for Medicare & Medicaid Services support STLT partners. In addition, coordination with the U.S. Department of Defense will be important. To maximize efficient operations and minimize complexity, and to advance equity, guidance and communication from HHS divisions must be timely, internally consistent, and aligned with the allocation framework.

CDC's Coordinating Role

CDC will play a key role in the national COVID-19 vaccination program by distributing COVID-19 vaccine and working with STLT authorities to assist with vaccine program implementation. This role is established in HHS's *Pandemic Influenza Plan*[1] and consistent with CDC's role in the 2009 H1N1 pandemic (Rambhia et al., 2010). CDC will likely provide guidance to STLT partners on planning for different components of the COVID-19 vaccination program, including (1) defining priority groups, (2) assisting with tracking vaccine supply and administration, (3) monitoring for adverse events following immunization (in collaboration with FDA), and (4) assessing vaccine coverage and effectiveness. CDC may also develop communications and educational materials for use by stakeholders to address vaccine confidence concerns and increase vaccine demand, including strategies to reach underserved and hard-to-reach populations.

COVID-19 Vaccine Distribution

In Chapter 3, the committee suggested that, in the interest of speed and workability, federal allocation of COVID-19 vaccine to states could be made based on these jurisdictions' population size—after which the committee's allocation framework would be applicable. One exception to a straightforward population-based approach to allocation of vaccine would be to withhold a percentage (e.g., 10 percent) of the available vaccine supply at the federal level as a reserve for deployment by CDC for use in areas of special need (identified through a vulnerability index) or to epidemiological "hot spots."

[1] HHS's *Pandemic Influenza Plan* is available from https://www.cdc.gov/flu/pandemic-resources/planning-preparedness/national-strategy-planning.html (accessed September 7, 2020).

Secure vaccine storage and transport, and safe, efficient, and equitable vaccine distribution are critical to a successful national COVID-19 vaccination program. Based on pre-pandemic plans, CDC has scaled up existing vaccine distribution programs to support the response.[2] To facilitate vaccine distribution during COVID-19, CDC has expanded its existing partnership with the McKesson Corporation so that they can be the distributor of COVID-19 vaccines and ancillary supplies (HHS, 2020; McKesson, 2020). CDC had an existing contract with McKesson to support the distribution of CDC's Vaccines for Children Program, which included an option for pandemic vaccine distribution. During the 2009 H1N1 vaccination campaign, this system was expanded to include providers of vaccinations to adults and was shown to be effective at large-scale distribution of vaccine (IOM, 2010). For the national COVID-19 vaccination program, according to CDC plans, McKesson will fill orders, with vaccines and supplies being delivered to point-of-care sites across the United States, including health departments, large health care organizations and affiliated clinics, hospitals, doctors' offices, and pharmacies (NCIRD, 2020). The jurisdiction will be responsible for the management and approval of vaccine orders from enrolled providers within their jurisdiction, based on populations prioritized for vaccination depending on the phase of the immunization program (CDC, 2020). Other possible sites for vaccination depending on the phase of the program will include school clinics, workplaces, and mobile vaccination clinics. This possible system ensures maintenance of the cold chain, which is essential to vaccine effectiveness.

Depending on the COVID-19 vaccine product, maintenance of cold chain storage and handling could be a particular challenge because some products could require frozen (–20 degrees Celsius) or ultra-cold (–60 to –80 degrees Celsius) temperatures to retain stability. To ensure inequities are not exacerbated or created, assistance from CDC with plans for cold chain management might be required for some jurisdictions with limited resources. Another challenge to COVID-19 vaccine distribution is that a two-dose regimen separated by at least 21 or 28 days will be required for immunity for most of the vaccines currently under study. Methods to ensure that patients receive the same type of vaccine for both doses and to remind patients that their second dose is due will be needed for two-dose vaccine regimens. In addition, it is expected that some COVID-19 vaccine products might require reconstitution with diluent or adjuvant at the time of their administration (*NYT*, 2020). According to current plans from CDC shared with STLT partners, distribution of vaccines by jurisdictions will be allowed while maintaining the cold chain; however, CDC indicated that

[2] More information about distribution, tracking, and monitoring within CDC's Pandemic Vaccine Program is available from https://www.cdc.gov/flu/pdf/pandemic-resources/pandemic-influenza-vaccine-distribution-9p-508.pdf (accessed September 7, 2020).

jurisdictions be judicious in their redistribution and that redistribution be limited to refrigerated vaccines (*NYT*, 2020).

Jurisdictions must maintain an emphasis on equity in their vaccine distribution strategies, and in doing so, they should refer to the principles and allocation criteria that guided the committee's allocation framework. Providers' orders for vaccines will be placed via the Vaccine Tracking System (VTrckS). VTrckS is a secure web-based information technology system that integrates the vaccine supply chain, from purchasing and ordering through distribution to health departments and health care providers.[3] Existing Immunization Information Systems will be used to record vaccine doses administered.

Dedicated efforts should focus on ensuring equitable distribution across tribal nations and territories. For instance, administration of the COVID-19 vaccine must include consultation and coordination with Indian country in order to fulfill the federal trust responsibility of providing health care services to American Indians and Alaska Natives.[4] The Indian Health Service (IHS) is the federal program that provides health services to members of federally recognized tribes based on a special government-to-government relationship between the federal government and tribes established in 1787 based on Article I, Section 8 of the U.S. Constitution. Responsibility for these health services is spread across direct-service IHS programs, tribal programs, and urban Indian programs known as the I/T/U system of care. The I/T/U is an essential partner and holds the responsibility for the coordination and administration of vaccines for this patient population in partnership with federal agencies like CDC. For tribes that exercise their right of self-determination and self-governance through a compact with IHS to provide services for their population, vaccine administration could be coordinated through the IHS Office of Tribal Self-Governance.[5] This would respect the government-to-government relationship between the U.S. and federally recognized tribes.

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[3] More information about distribution, tracking, and monitoring within CDC's Pandemic Vaccine Program is available from https://www.cdc.gov/flu/pdf/pandemic-resources/pandemic-influenza-vaccine-distribution-9p-508.pdf (accessed September 7, 2020).

[4] "Indian country" is a legal term with a specific definition that applies only to federally recognized tribes. U.S. Code § 1151 defines Indian country as: "Except as otherwise provided in sections 1154 and 1156 of this title, the term 'Indian country,' means (a) all land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and, including rights-of-way running through the reservation, (b) all dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a state, and (c) all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same" (June 25, 1948, ch. 645, 62 Stat. 757; May 24, 1949, ch. 139, § 25, 63 Stat. 94).

[5] More information about the Office of Tribal Self-Governance is available from https://www.ihs.gov/SelfGovernance (accessed September 7, 2020).

Leveraging Existing Systems to Support Coordination

To establish a coordinated approach for the national COVID-19 vaccination program, existing systems should be leveraged and augmented as needed. For example, public health emergency preparedness (PHEP) experts could be leveraged along with immunization program managers to help facilitate storage and cold chain management, distribution, and additional logistical needs. To conduct this work, coordinators and immunization managers will need to forge strong local partnerships with PHEP teams and other community-level partners. To facilitate vaccination programs at the local level, CDC's National Center for Immunization and Respiratory Diseases has funded immunization program managers in 64 state, territorial, and local sites. This Center could be the coordinating point for gathering federal government input and assisting local programs. These immunization program managers will play a critical role in the implementation of a local COVID-19 vaccination program in their jurisdictions. The Association of Immunization Managers has developed guidance to support managers in preparing for a local COVID-19 vaccination program.[6]

It is important that, at the local level, attention is directed to using existing data aggregation and integration infrastructures for the vaccine administration effort. Many states already have immunization registries that facilitate tracking and monitoring of immunization status between public health agencies and private practitioners. Immunization registries also represent valuable systems to be leveraged. However, registries vary state by state, with some states having more well-established, highly functioning immunization registries than others. Those states who need additional support for their immunization strategies should be identified and bolstered through collaborative approaches. Given the need to identify at-risk individuals with multiple risk factors and the need to track dosing for those vaccines requiring more than one dose, this becomes especially important. The Office of the National Coordinator for Health Information Technology could work with CDC and professional medical and hospital societies to advance this work.

Monitoring and Evaluation

Within the national COVID-19 vaccination program, real-time, rapid monitoring and evaluation will be critical components that must also be robustly coordinated. Monitoring and evaluation systems are also critical for enabling the successful delivery of vaccines through appropriate ramp-

[6] The guidance for immunization managers is available from https://cdn.ymaws.com/www.immunizationmanagers.org/resource/resmgr/covid-19_preparation_tips_fo.pdf (accessed September 7, 2020).

up of supplies related to administration, including both direct supplies (e.g., vaccines, needles, syringes) and indirect supplies, such as personal protective equipment for vaccinators.

A rigorous vaccine safety monitoring program will need to be in place, with an emphasis on rapid and transparent review of information on adverse events following immunization, defined as health problems or conditions that occur after vaccination that could be caused by the vaccine or purely occurring by chance, unrelated to vaccination. The system should build on existing systems, including lessons learned from the H1N1 vaccination campaign and CDC's plans for monitoring vaccine safety in emergencies (Iskander and Broder, 2008). CDC has several systems in place to monitor the safety of vaccines in the United States, including the Vaccine Adverse Event Reporting System (co-administered by CDC and FDA), the Vaccine Safety Datalink (a collaboration among CDC's Immunization Safety Office and nine organizations), and the Clinical Immunization Safety Assessment Project, a network of vaccine safety experts from across the country (CDC, 2020). Resources need to be made available so reporting systems can be implemented across all populations and capture race, ethnicity, and language information about different populations to ensure there is no bias in interpreting and reporting signs and symptoms being registered. The evaluation of adverse events to determine whether or not they are related to COVID-19 vaccine needs to be timely and updates on these evaluations should be shared regularly with STLT authorities, partner organizations involved in vaccination efforts, and the public. In addition to these vaccine safety reporting systems, FDA recommends that at the time of a biologics license application submission the applicants submit a Pharmacovigilance Plan. It is possible that a COVID-19 vaccine could be released under an EUA. FDA guidance states that this might be appropriate after studies have demonstrated vaccine efficacy and safety, but before the vaccine has received full approval. Under EUA requirements, monitoring and reporting of adverse events is required "to the extent practicable." In the case of injuries related to COVID-19 vaccines, the Public Readiness and Emergency Preparedness Act "authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration of covered countermeasures, including vaccines" (HRSA, 2020).

Assessing COVID-19 Vaccine Coverage and Effectiveness

To promote equity, the monitoring and evaluation systems should assess the COVID-19 vaccination program's penetrance—that is, its ability to reach key populations identified in the committee's phases—by building

a real-time assessment program that includes community engagement and expertise. This would align with CDC's COVID-19 Response Health Equity Strategy,[7] which aims to reduce COVID-19's disproportionate burden among populations with increased risks for infection, severe illness, and death, and to broadly address COVID-19-related health disparities and inequities through a holistic approach. The plan's guiding principles are to (1) reduce health disparities, (2) use data-driven approaches, (3) foster meaningful engagement with community institutions and diverse leaders, (4) lead culturally responsive outreach, and (5) reduce stigma, including race- and ethnicity-associated stigma.

ADDRESSING COST AND FINANCING BARRIERS

In this section, the committee calls attention to the key gaps in the cost and financing of COVID-19 vaccine administration. These gaps must be addressed to ensure equitable allocation. In particular, costs may be a barrier to vaccination to the extent that individuals deciding to get vaccinated are asked to share in the cost of the vaccine or its administration. Any required fee would present a greater barrier to those without sufficient financial means to pay. Given the framework's priority on mitigating health inequities, particularly as tied to COVID-19 severe illness and deaths, addressing costs becomes a key priority given the correlation between high cost barriers and the populations experiencing health inequities. Moreover, justification for mitigating the costs borne by those choosing to be vaccinated come from their positive spillovers. The positive spillover, or externality, of a vaccine derives from the extent to which the vaccine protects others by reducing the rate of transmission of the virus. There is a history of providing services with positive spillovers for free as this can help address the provision of vaccines that can help reduce virus transmission. The goal would be to make vaccination available to all and reduce any vaccine hesitancy tied to cost thereby increasing the individual and societal benefits of having a highly vaccinated population.

Cost Implications of the Coronavirus Aid, Relief, and Economic Security Act

The 2020 Coronavirus Aid, Relief, and Economic Security (CARES) Act requires health insurance plans (group and individual) to add coverage of any CDC Advisory Committee on Immunization Practices (ACIP)-recommended COVID-19 vaccine within 15 days and offer COVID-19 vaccination without

[7] More information about CDC's COVID-19 Response Health Equity Strategy is available from https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html (accessed September 7, 2020).

patient cost sharing (Section 3203) (*Federal Register*, 2015; KFF, 2020). This requirement adjusts the Patient Protection and Affordable Care Act (ACA) regulation that people with health insurance—with few exceptions—have no cost sharing for vaccines recommended by ACIP. The CARES Act ensures that COVID-19 vaccines will fall under this regulation quickly.

However, this requirement is not sufficient to support the vaccine allocation recommended by this report, for multiple reasons. For instance, it is possible that, under an EUA, the administrative fees that are covered under the ACA regulation may not apply at all, leaving patients potentially entirely at risk of cost sharing for the administration of the vaccine. The CARES Act requires coverage for the vaccine, but has not specified whether this requirement extends to the administration of the vaccine. Furthermore, this regulation does not apply to individuals without insurance. In 2018, 27.9 million non-elderly individuals were uninsured (Berchick et al., 2019). Urban Institute models project that the loss of jobs during the COVID-19 pandemic may add another 3–4 million uninsured individuals, after accounting for the millions of people who lose their jobs but who may obtain coverage through Medicaid, the ACA marketplace, or other sources (Banthin et al., 2020). Furthermore, the ACA requirements do not apply to many health insurance products, including recently promoted short-term plans, health care sharing ministry plans, grandfathered health plans, and Farm Bureau plans. Critically, for the plans where ACA requirements do apply, situations may arise in which patients receive bills where they are responsible for a share of the cost of administration. When the vaccine is administered by an out-of-network provider, the zero cost-sharing requirement is not applicable, and if a vaccine is delivered during an office visit that is not exclusively for preventive care (e.g., a patient's medical problem is discussed), then the visit might be billed as a diagnostic visit and cost sharing would be applied to the visit.

Finally, the U.S. Supreme Court is expected to hear arguments and rule on the ACA during the period in which the vaccine is being distributed. It is possible that the ruling could affect the ACA or ACA provisions and have consequences for insured people and increase the number of uninsured people (Boumil and Curfman, 2020). This could result in severe difficulties with regard to reimbursement for and access to the vaccine for significant numbers of Americans.

Medicare and Medicaid

For those on Medicare, Part B will cover co-pay or administrative charges (Section 3713). Those on Medicare Advantage plans are similarly covered. For Medicaid, coverage depends on several factors. Most state Medicaid agencies cover at least some adult immunizations but not all offer

vaccines recommended by ACIP. Generally, Medicaid covers ACIP-recommended vaccines for all beneficiaries up to age 21 under the program's Early and Periodic Screening, Diagnostic and Treatment program. For children under 19, the Vaccines for Children Program guarantees free vaccination to uninsured, underinsured, and Native American and Alaska Native 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, because 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 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, individuals in correctional facilities and jails, and fully insured individuals seeking vaccines during public health response activities, including outbreak response, mass vaccination campaigns, or exercises for public health preparedness.

Additional Cost Barriers Related to Vaccination

Removing cost sharing for the vaccine and its administration does not eliminate all costs for people who might consider vaccination. For instance, the costs to individuals in terms of time, child care, and transportation cannot be ignored. Therefore, making the vaccine easy to access by offering vaccination clinics at schools, workplaces, and other locations in the community that people frequent can be as important as zero cost sharing in driving down cost barriers and mitigating inequities.

Even if cost sharing is zero, providers still incur costs of vaccination. The reimbursement from insurers to those delivering the vaccine may not be sufficient to cover the outlays needed to safely administer the vaccine efficiently to large numbers of recipients. Moreover, the cost of supplies and equipment needed to store and administer the vaccine may quickly exceed the revenue from insurers for all but the very largest providers. This could limit provider participation in vaccine administration and thus lead to an undersupply of critical points of access. Yet, many of these access challenges are being

addressed by HHS clarifications that a wide array of health care workers, notably pharmacists, can administer the vaccine when available, thus increasing the potential number of willing providers. Furthermore, unique cost barriers exist for Native Americans and Alaska Natives who are eligible to receive vaccinations free of charge via the IHS I/T/U system of care. The IHS I/T/U system of care is chronically underfunded and understaffed; a 2018 U.S. Government Accountability Office report found that on average, there is a 25 percent shortage of doctors, nurses, and other care providers across the I/T/U (GAO, 2018). The additional administrative and provider costs associated with COVID-19 vaccination may increase the stress on an already-struggling system unless offset with additional federal funding. Attention will need to be paid to the costs of administration for the providers.

Additional Federal Funding Needed to Eliminate Financial Barriers

To fully address these cost challenges, it is critically important for the government to pay for the vaccine to be delivered and administered, especially in the context of the well-funded vaccine development enterprise for COVID-19. As a first step, the Congressional Budget Office and other budget entities could model the net budget impact of a bill that would provide federal funds to guarantee zero out-of-pocket costs for everyone receiving a COVID-19 vaccine, particularly during the first year of vaccine administration. Additional federal funds need to be allocated both to cover the costs of vaccination for people who do not fall under the ACA regulations and to set up non-traditional modes and locations of administration to stand-up vaccination clinics at schools, workplaces, and other places that people frequent. Eliminating financial barriers to vaccine uptake will help promote equitable vaccine allocation which, in turn, could more rapidly ease social distancing and thus increase gross domestic product and tax revenue. The allocation framework proposed by the committee prioritizes reducing morbidity, mortality, and negative societal impacts due to the transmission of SARS-CoV-2. Therefore, federal funding to execute on these priorities would allow for a more rapid easing of social distancing than would be possible if the allocation of vaccines were restricted exclusively to states and individuals with the funds for vaccine administration.

ENGAGING COMMUNITIES IN LOCAL COVID-19 VACCINATION PLANS

STLT Implementation Requires Community Engagement

To ensure equity, STLT authorities will need to collaborate closely and foster community partnerships to create and develop local COVID-19

vaccination plans. Communities, especially those disproportionately impacted by COVID-19, must be effectively, authentically, and meaningfully engaged in local vaccination plans. To that end, strong partnerships need to be developed urgently with community-based organizations and other community partners in order to build effective vaccine delivery systems that are convenient for the people they are intended to reach.

Role of Community-Based Organizations in Vaccine Administration

Community-based organizations, the so-called "boots on the ground," often have deeper insights about the people and families they serve than do many public health program managers serving in primarily administrative roles. Those insights help characterize the social inequities and community assets that make equitable allocation an imperative for program administrators. Shared authority can foster transparency and mutual accountability. It also allows deployment of limited resources to be informed by first-hand knowledge of current community needs, thereby increasing the likelihood of program effectiveness. Furthermore, partnerships with community-based organizations can improve the ability of local agencies to negotiate opportunities when they seek program flexibility so as to maximize the benefit of their service to their communities. Such partnerships can build on agencies' experience implementing strategies to mitigate inequities through the design of programs that are available, affordable, and accessible (including strategies involving mobile services). Through collaborations, community organizations and immunization administrators can ensure that vaccination initiatives are based on the best-available evidence and that initiatives are culturally and linguistically appropriate for the people and communities who need them.

Role of Other Community Partners in Vaccine Administration

Although some jurisdictions may develop new methods to engage communities in planning for COVID-19 vaccination efforts, an extensive array of partnerships already exists in many locations. All community partners must embed ethics, equity, and cultural competence into their activities. Providers in the community can play a valuable role in reaching community members, but their own potential fragility in the context of the pandemic needs to be taken into account. Some are considered "traditional" public health partners, such as federally qualified health centers, hospitals, and pharmacies (including community pharmacies). Other entities that can serve as community partners in the vaccination campaign include community centers, schools, universities, Historically Black Colleges and Universities, Hispanic Association of Colleges and Universities, Tribal Colleges

and Universities, faith-based organizations, public safety organizations, philanthropic organizations, and employers.

Role of Workplaces, Employers, and Unions

Employers and unions must also be engaged in planning for COVID-19 vaccination efforts. The role of employers and other potentially responsible parties is likely to be particularly important in the early phases of vaccine roll-out. STLT authorities might collaborate with employers to deliver vaccination clinics. Workplace clinics may be especially critical for achieving high vaccination rates among many workers whose jobs place them in the framework's earliest phases, such as workers in correctional and long-term care facilities, and others who perform essential roles. In addition to offering convenient access, employers may commit to covering the costs for their employees. For instance, employers could play a key role in covering immunization for those who are not insured, those who are undocumented, those who are part-time employees, and others.

Trade unions and worker centers can play an important role in encouraging and enabling workers to get vaccinated, as well as in reaching workers who are undocumented or otherwise hesitant to engage with employer or government programs. Union and worker center involvement can be especially useful in efforts to gain the trust and cooperation of their members, especially in cases in which the employer is providing the vaccines. In workplaces where the workers have union representation, employers could develop vaccination plans and programs in collaboration with the unions representing their employees. Furthermore, many workers, especially in the building trades, have health insurance coverage through joint union–management insurance plans, and some workers get their health care through clinics run by unions or joint union–management plans.

IMPORTANCE OF COMMUNICATION

Public communication from the federal to the local level about the national COVID-19 vaccination program must be timely, consistent, and accurate in order to foster public trust, encourage participation, and manage expectations. Given the complexity of the national vaccine administration ecosystem, state and local strategies for community engagement need to entail identifying and training partners who are the best messengers for specific audiences. The chapters that follow will address national-level considerations for risk communication. Administration done well "behind the scenes," but communicated in ways that belie public trust, may undermine public confidence that COVID-19 vaccine will be allocated equitably at the state and local levels. Governors could contribute to the quality of public

messaging by committing to the adoption of consistent communication, perhaps through the National Governors Association or through regional coalitions. Leaders may even choose to be vaccinated as a model for their community.

Vaccination programs that are culturally and linguistically appropriate can improve communication about COVID-19 vaccine and its benefits among people and their families. Improved communication may build trust in care providers and public health authorities; it also supports informed decision making and may help temper vaccine hesitancy. Because racial or ethnic concordance may increase a person's trust in care providers, it would be beneficial for vaccine program administrators to prioritize involving diverse partners to engage communities. To help increase vaccine uptake among minority groups, vaccination planning efforts could provide resources for vaccination program implementation to members of organizations such as the National Medical Association, the National Hispanic Medical Association, the Association of American Indian Physicians, and the National Council of Asian Pacific Islander Physicians. Additionally, community health workers may help achieve successful administration by acting as health educators, navigators, and cultural brokers.

Through those roles, community health workers may also be key collaborators for surveillance, safety monitoring, and program evaluation. Those actions may be especially critical in communities that lack technology and other systems for managing data in real time, monitoring adverse events, and tracking community concerns. In addition to helping report information back to federal and STLT authorities, community health workers can maintain an ongoing dialogue with people, families, and neighborhoods in the community. Both communication and community engagement strategies should be monitored to ensure that the national COVID-19 vaccination program is responsive and adaptable to community needs. These issues are discussed further in Chapters 6 and 7.

CONCLUDING REMARKS

An effective and equitable national COVID-19 vaccination program must be framed by an overarching commitment to the principles on which the committee's allocation framework is founded: maximum benefit, equal concern, mitigation of health inequities, fairness, transparency, and evidence-based. However, the mere establishment of foundational principles does not guarantee equitable allocation: **equitable allocation must be supported by equitable distribution and administration.** The principles of equity should guide each program component—from its design through its administration and evaluation—and be the central tenets that guide partners responsible for implementation and monitoring.

RECOMMENDATION 2. Leverage and expand the use of existing systems, structures, and partnerships across all levels of government and provide the necessary resources to ensure equitable allocation, distribution, and administration of COVID-19 vaccine.

The U.S. Department of Health and Human Services should commit to leveraging and expanding the use of existing systems, structures, and partnerships across all levels of government and provide the resources necessary to ensure equitable allocation, distribution, and administration of COVID-19 vaccine. Equitable allocation must be supported by equitable distribution and administration. Specific action steps to implement this recommendation are as follows:

- Provide resources (including resources for staff) to state, tribal, local, and territorial authorities and their implementation partners and adequately fund indirect assets (e.g., needles, syringes, personal protective equipment for vaccinators, resources for ultra-cold chain management, and so forth) necessary for effective vaccine allocation, distribution, and administration.
- To ensure identification and delivery of COVID-19 vaccine to priority population groups, develop the capacity and systems to collect and integrate the necessary data (digital and other) from public health and private providers of care to facilitate the identification and monitoring of people with pre-existing conditions and other high-risk characteristics.
- Establish a robust and comprehensive surveillance system to monitor, detect, and respond to identified problems, gaps, inequities, and barriers. Monitoring should encompass equitable vaccine allocation and distribution, vaccine delivery, adverse events following immunization, promotion and communication, and uptake and coverage.
- Ensure that a rigorous COVID-19 vaccine safety monitoring program, built on existing systems, is in place, with an emphasis on rapid reporting and timely and transparent assessment of adverse events to determine whether events are associated with receipt of vaccine or occurring by chance.

RECOMMENDATION 3. Provide and administer COVID-19 vaccine with no out-of-pocket costs for those being vaccinated.

The U.S. Department of Health and Human Services should coordinate across agencies so that (1) COVID-19 vaccine is available at no cost to the public health and health care sectors and thus free to the individual; (2) providers are assured that they have the ability to submit for reimbursement of allowable and reasonable administration fees to a third party but with no costs shared by the individual being vaccinated; and (3) public health mass vaccination clinics are federally

supported and funded to provide vaccinations at no cost to individuals being vaccinated, which is particularly important for reaching populations that do not have insurance. Specific action steps to implement this recommendation are as follows:

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

REFERENCES

Banthin, J., L. J. Blumberg, M. Simpson, M. Buettgens, and R. Wang. 2020. *Changes in health insurance coverage due to the COVID-19 recession: Preliminary estimates using microsimulation*. July 13, 2020. Washington, DC: Urban Institute. https://www.urban.org/research/publication/changes-health-insurance-coverage-due-covid-19-recession (accessed September 21, 2020).

Berchick, E. R., J. C. Barnett, and R. D. Upton. 2019. *Health insurance coverage in the United States: 2018*. Washington, DC: U.S. Census Bureau. https://www.census.gov/library/publications/2019/demo/p60-267.html (accessed September 21, 2020).

Boumil, M. M., and G. Curfman. 2020. The Affordable Care Act returns to the Supreme Court: *Maine Community Health Options v United States*. *JAMA Internal Medicine*. Published online September 14, 2020. doi: 10.1001/jamainternmed.2020.3549.

Burris, S. C., S. de Guia, L. Gable, D. Levin, W. E. Parmet, and N. P. Terry. 2020. Assessing legal responses to COVID-19. *Boston: Public Health Law Watch*, Temple University Legal Studies Research Paper No. 2020-22. https://ssrn.com/abstract=3675884 (accessed September 21, 2020).

CDC (Centers for Disease Control and Prevention). 2020. *COVID-19 vaccination program interim playbook for jurisdiction operations*. Atlanta, GA: CDC. https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf (accessed September 21, 2020).

Federal Register. 2015. Coverage of certain preventive services under the Affordable Care Act. Final rules. *Federal Register* 80(134):41318–41347.

GAO (U.S. Government Accountability Office). 2018. *Indian Health Service: Agency faces ongoing challenges filling provider vacancies*. GAO-18-580. August 15, 2018. Washington, DC: GAO. https://www.gao.gov/products/gao-18-580 (accessed September 21, 2020).

Granade, C. J., R. F. McCord, A. A. Bhatti, and M. C. Lindley. 2020. State policies on access to vaccination services for low-income adults. *JAMA Network Open* 3(4):e203316. doi: 10.1001/jamanetworkopen.2020.3316.

HHS (U.S. Department of Health and Human Services). 2020. *Trump administration collaborates with McKesson for COVID-19 vaccine distribution*. Washington, DC: HHS. https://www.hhs.gov/about/news/2020/08/14/trump-administration-collaborates-mckesson-covid-19-vaccine-distribution.html (accessed September 21, 2020).

HRSA (Health Resources and Services Administration). 2020. Frequently asked questions. Washington, DC: HRSA. https://www.hrsa.gov/cicp/faq#covid (accessed September 21, 2020).

IOM (Institute of Medicine). 2010. *The 2009 H1N1 influenza vaccination campaign: Summary of a workshop series*. Washington, DC: The National Academies Press.

Iskander, J., and K. Broder. 2008. Monitoring the safety of annual and pandemic influenza vaccines: Lessons from the US experience. *Expert Review of Vaccines* 7(1):75–82. doi: 10.1586/14760584.7.1.75.

KFF (Kaiser Family Foundation). 2020. *The Coronavirus Aid, Relief, and Economic Security Act: Summary of key health provisions*. https://www.kff.org/coronavirus-covid-19/issue-brief/the-coronavirus-aid-relief-and-economic-security-act-summary-of-key-health-provisions (accessed August 28, 2020).

Logan Circle Policy Group. 2010. *ASTHO H1N1 policy barriers project—state meetings: Summary and analysis*. Washington, DC: Logan Circle Policy Group LLC.

McKesson. 2020. *McKesson to distribute future COVID-19 vaccines in support of Operation Warp Speed*. https://www.mckesson.com/About-McKesson/Newsroom/Press-Releases/2020/McKesson-Distribute-Future-COVID-19-Vaccines-Operation-Warp-Speed (accessed September 21, 2020).

NCIRD (National Center for Immunization and Respiratory Diseases). 2020. Pandemic vaccine program distribution, tracking, and monitoring. *Interim Pandemic Distribution Plan*. Atlanta, GA: CDC. https://www.cdc.gov/flu/pdf/pandemic-resources/pandemic-influenza-vaccine-distribution-9p-508.pdf (accessed September 21, 2020).

NYT (*The New York Times*). 2020. COVID-19 vaccination program planning assumptions for jurisdictions. https://int.nyt.com/data/documenttools/covid-19-vax-planning-assumptions-8-27-2020-final/6fc8a9ec0c3e5817/full.pdf (accessed September 21, 2020).

Rambhia, K. J., M. Watson, T. K. Sell, R. Waldhorn, and E. Toner. 2010. Mass vaccination for the 2009 H1N1 pandemic: Approaches, challenges, and recommendations. *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 8(4):321–330. doi: 10.1089/bsp.2010.0043.

Shen, A. K., and W. Orenstein. 2020. Continued challenges with Medicaid coverage of adult vaccines and vaccination services. *JAMA Network Open* 3(4):e203887. doi:10.1001/jamanetworkopen.2020.3887.

6

Risk Communication and Community Engagement

To ensure an effective and equitable national coronavirus disease 2019 (COVID-19) vaccination program, the ethical principles, implementation processes, and expected outcomes must be transparently communicated. Those communications also must be easily accessible, given people's normal sources of information.

In the words of the committee's Statement of Task the federal government and the state, tribal, local, and territorial (STLT) authorities responsible for COVID-19 vaccine allocation, distribution, and administration must "communicate to the American public [so as] to minimize perceptions of lack of equity." As noted in Chapter 3, the "[COVID-19 vaccine allocation] 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."

To achieve these ends, STLT authorities must engage the diverse communities that they serve, forming partnerships with organizations that can provide the two-way communication channels needed to hear public concerns and deliver messages from trusted sources, and in accessible ways (e.g., with needed ombudspersons, translations, and translators). Such communication addresses the foundational principles of transparency and procedural fairness, supporting and respecting the public in both what is said and how it is said. Without such transparency, vaccination efforts will struggle to deserve, generate, and sustain trust. Chapters 5 and 7 describe some of the potential partners for this mission.

Such communication and engagement must begin immediately. Although it may be natural to wait until allocation and distribution details

have been set, today's dynamic news and social media environment does not allow any delay. Given the intense public interest in COVID-19 vaccines, if responsible parties are silent, the vacuum will be filled by other less credible sources, some well meaning and some not. As a result, the public will face confusing, inconsistent, and sometimes misleading information. Moreover, STLT authorities and their partners will cede the opportunity to establish themselves as the authoritative sources of reliable information, then have to wrest that status from competitors. As described more fully in Chapter 7, problems can already be seen in the difficulties experienced with clinical trial recruitment, in surveys where many Americans report unwillingness to get vaccinated, and in anecdotal reports of health care professionals who are reluctant as well—absent trustworthy assurances of vaccine safety and efficacy (Callaghan et al., 2020; Fisher et al., 2020; Kamisar and Holzberg, 2020; Resnick, 2020). Equitable allocation and distribution of COVID-19 vaccine is impossible unless members of high-priority groups trust the vaccine and the people delivering it (Chastain et al., 2020; Feuerstein et al., 2020).

Thus, coordinated, evidence-based risk communication and community engagement are essential to the COVID-19 vaccination strategies. Those communications must be (1) consistent with the evidence, (2) consistent with one another, (3) responsive to public needs, (4) tested for comprehension by members of target audiences, and (5) delivered by trusted sources through effective channels. Those channels may include national and social media campaigns, news media interviews, health care personnel, and community leaders. Achieving these goals require listening to public concerns, conveying them to STLT authorities, and reporting back the responses. The listening channels may include surveys, social media monitoring, consultation with community partners, and reports from frontline personnel. Thus, risk communication and community engagement provide the "ear to the ground," informing STLT authorities about success in fulfilling the foundational principles of this framework.

All these efforts depend on having scientifically sound, independently reviewed, candidly reported information about the vaccines and about the allocation, distribution, and administration process. Risk communicators and their community partners must know how safe and effective vaccines were in clinical trials and subsequent use, as captured by rigorous, transparent surveillance programs. They must also know how vaccines have been distributed and how well that reality corresponds to the equitable allocation framework described in this report. The collection and analysis of that information must be an integral part of vaccination planning. It must include scientists independent of government and firms with commercial interests. Those scientists must represent the diverse communities that are asked to put their faith in the process, including scientists from minority-serving academic institutions.

SCIENTIFIC FOUNDATIONS

These efforts should be grounded in scientific knowledge of risk communication and community engagement. Summaries of that research, as applied to related topics, can be found in many prior National Academies reports, including *Improving Risk Communication* (NRC, 1989), *Understanding Risk* (NRC, 1996), *Toward Environmental Justice* (IOM, 1999), *Characterizing and Communicating Uncertainty in the Assessment of Benefits and Risks of Pharmaceutical Products* (IOM, 2014), *Potential Risks and Benefits of Gain-of-Function Research* (IOM and NRC, 2015), *Building Communication Capacity to Counter Infectious Disease Threats* (NASEM, 2017), and special issues of the *Proceedings of the National Academy of Sciences* on the science of science communication (Bruine de Bruin and Bostrom, 2013; Fischhoff, 2013, 2019; Fischhoff and Davis, 2014). The 2008 National Academies report *Public Participation in Environmental Assessment and Decision Making* summarizes research on community engagement, with applications to the related domain of environment. The 1999 Institute of Medicine report *Toward Environmental Justice* devotes two of its three key principles to community engagement with affected populations and risk communication of findings to all stakeholders.

RISK COMMUNICATION

The discipline of risk communication involves an iterative process with four steps (Fischhoff, 2013, 2019; Fischhoff and Davis, 2014):

1. Summarize the evidence relevant to the decisions that members of the intended audiences face;
2. Describe their current beliefs;
3. Create communications designed to close critical gaps in understanding; and
4. Test to ensure that they can make informed choices, and repeat as necessary.

Research following this discipline has addressed many specific topics. These include communicating potentially difficult kinds of information (e.g., very low probabilities, uncertainty, exponential transmission processes) and reaching audiences with varied backgrounds (Bruine de Bruin and Bostrom, 2013; Peters, 2020; Schwartz and Woloshin, 2013).

A guiding principle in the research is that communications must be tested before they are disseminated. This principle reflects a common research finding: People overestimate how well they understand other people's perspectives and how well they themselves are understood (Nickerson, 1999). As a result, unless messages are tested, audiences can be frustrated

by the failure to tell them what they need to know and misled by saying things that are not interpreted as intended. A simple, fast, inexpensive testing procedure is the *think-aloud protocol* (Ericsson and Simon, 1980): Ask people drawn from the intended audience to think aloud as they read a draft message, sharing how they interpret it and what impression it creates regarding the people behind it.

To promote equity, communications regarding allocation, distribution, and administration of COVID-19 vaccine must meet both content and process goals.

RISK COMMUNICATION CONTENT GOALS

STLT authorities must communicate their guiding principles clearly enough that members of the public can judge their acceptability. They must also communicate the performance of the process clearly enough so that members of the public can judge how well they have achieved equitable allocation and distribution of safe and effective vaccine. For that to happen, STLT authorities must gather and communicate the relevant information about adverse events. Chapter 5 addresses organizational capabilities relevant to monitoring and evaluation.

STLT authorities must communicate about the vaccines' safety and effectiveness and about the allocation, distribution, and administration process well enough so that people can decide whether they want them for themselves and their families. These communications include the effects of vaccination on disease transmission, disease severity, health risks, and economic activity—for individuals, groups, communities, and the country as a whole. The goal of these communications is informed judgment, not persuasion, and the intent and success of the vaccination efforts should speak for themselves, when clearly communicated.

When describing the expected outcomes of their vaccination efforts, STLT authorities should indicate how uncertain the estimates are, what is being done to reduce that uncertainty, and when better evidence is likely. For example, initial estimates of risks and benefits will reflect the relatively limited samples and observation periods of the clinical trials. Risk communications must explain those limits and plans for updating them, so that people will not feel deceived when later, better evidence reveals rare side effects or ones that took more time to emerge. The STLT authorities must communicate in ways suited to audiences with different backgrounds and knowledge, enhancing their ability to understand the pandemic as it unfolds and their sense of partnership. In order to achieve these goals, implementers must reflect the diversity of the groups that it serves and engage an array of community partners, so as to secure their communities' trust, hear their concerns, and address them in culturally appropriate, effective ways. Those partners should

include research and educational institutions dedicated to those communities, including the Historically Black Colleges and Universities, Hispanic Serving Institutions, Tribal Colleges and Universities, and other local organizations with strong community roots. Health care professionals will be a vital link in both communication and engagement and deserve special attention.

Communications about COVID-19 vaccination should be placed in the context of other measures for managing the pandemic, including wearing masks and adhering to the social distancing measures needed to protect those who have not been vaccinated (and perhaps cannot be safely vaccinated) and those for whom the vaccine was not effective.

RISK COMMUNICATION CONTENT

COVID-19 vaccination risk communication efforts will be most efficient by creating and testing message prototypes that can be adapted to specific situations. These messages should be suited both for national distribution and for adaptation to the needs of community partners. These efforts should draw on the results and methods of existing research, paying special attention to the following issues, with particular relevance to COVID-19.

Disease Processes That Can Be Misunderstood Unless Properly Explained

Disease processes that will require clear explanation include how quickly diseases spread, how diseases can be transmitted to distant individuals, how to interpret noisy diagnostic test results, and how even imperfect precautions (e.g., face masks, social distancing, hand washing, vaccines) can combine to provide overall protection.

Equity in Vaccination Efforts Procedures and Performance

STLT authorities will be scrutinized for how they equitably treat people in their COVID-19 vaccination efforts. STLT authorities will need to explain the efforts' procedures and performance authoritatively—perhaps facing criticism based on incomplete information or political goals, as well as criticism from parties who reject the foundational principles or disagree with the interpretation of the evidence of the vaccination efforts.

Empirical Testing

Communications must be tested for comprehensibility, appropriateness, usefulness, and accessibility. Instructions for simple user testing procedures should be provided to all partners, so that vaccination efforts are not un-

dermined by needless misunderstanding—and so that partners receive the feedback that such testing provides.

Appropriate Tailoring

Messages should be tailored to the needs of diverse populations (e.g., considering native languages, reading levels, potential hesitancy, health beliefs, and historic harms and distrust) and delivered through accessible channels (e.g., for people with limited vision or hearing). Here, too, community partnerships and buy-in will be critical to success.

COMMUNITY ENGAGEMENT

STLT authorities must demonstrate respect for diverse audiences. Providing clear, relevant, accessible information is part of that demonstration. However, people will judge the communication process as well as its content (as captured in this report's foundational principle of transparency). The widely accepted best practice is continuing two-way communication between the public and experts. That process begins with a project's initiation, so that it can best address community concerns and establish trusting relations. It continues through execution and monitoring of a project's performance. Figure 6-1 has one depiction of such a process. Creating the two-way communication channels requires community partners with the knowledge and relationships needed to engage those whose trust and insights are vital to success.

Communication during the early, formative stages increases the chance of meeting the public's needs. Such communication may also improve success in recruiting members of hesitant populations for vaccine clinical trials. Early community engagement demonstrates that the public is central to conception and has knowledge of key needs and values. Continued engagement during implementation reduces the risk of drifting from the original design in ways that undermine its acceptability. In dynamic environments, such as a pandemic, changes are inevitable as new research, treatments, and problems emerge. As a result, continuous public engagement is needed.

STLT authorities will need a process for coordinating its communications, so that the public is not confused by conflicting messages or deluged by repetitive ones. That coordination must recognize community leaders' key role in achieving the two-way communication essential to success. Those leaders have a unique ability to translate vaccination efforts into terms meaningful to their communities. They are also uniquely positioned to hear and convey the needs of their communities to STLT authorities. As noted in Chapters 5 and 7, these community leaders and stakeholders include members of professional societies representing minority populations,

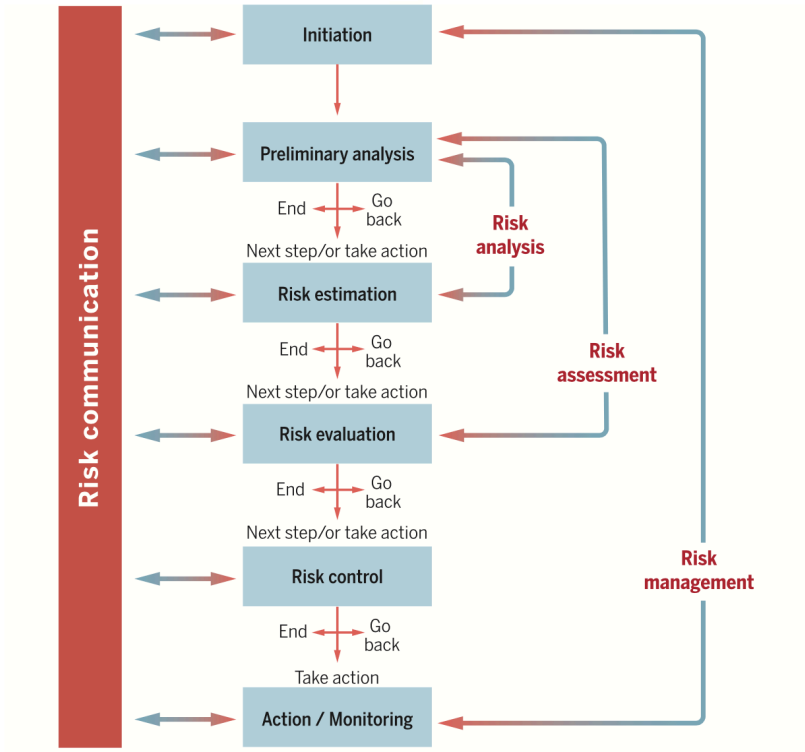

FIGURE 6-1 An analytical-deliberative process in which analysts and decision makers collaborate in managing risks.
SOURCE: Fischhoff, 2015.

community health workers, and leaders from other community-based organizations and non-traditional public health partner organizations.

In summary, public engagement, procedural fairness, and transparency are crucial to the success of a national COVID-19 vaccination program. This committee worked to uphold these principles in its own work, through open public sessions, a public listening session, and a written public comment period (see Appendix A for additional details). Effective risk communication and community engagement will help ensure that the national COVID-19 vaccination program supports STLT authorities, their partners, stakeholders, and the public in respectful, effective ways.

COMMUNITY ENGAGEMENT PROCESS

Community engagement for COVID-19 vaccination efforts should draw on the extensive science and practice cited throughout this report.

It should pay particular attention to continuous community engagement, engagement across multiple channels, timeliness, and trustworthiness.

Continuous Community Engagement

Community engagement must establish two-way communication channels early enough to provide input for the allocation, distribution, and administration of vaccine and to demonstrate commitment to partnership. It is important to have a strategy for hearing multiple voices.

Engagement Across Multiple Channels

Community engagement must use channels suited to key audiences, including people who cannot attend public meetings (e.g., because they work, live remotely, are incarcerated, or undocumented), who have limited broadband service, who speak languages other than English, or who cannot use written text.

Timeliness

Community engagement must monitor and anticipate the community's needs. It must provide STLT authorities with information about vaccination efforts, as seen by the people it serves. Contracts with organizations experienced in reaching minority communities can enlist their expert assistance, with needed material support.

Trustworthiness

Community engagement must seek to position STLT authorities as trustworthy sources of information about COVID-19 vaccination. The verbal and nonverbal behavior of the vaccination efforts should be monitored self-critically, in order to avoid violations of trust. It should be ready with counsel when a problem is encountered. Success is, of course, contingent on the actual performance and transparency.

RISK COMMUNICATION AND HEALTH PROMOTION

By fulfilling the duty to inform, the broad risk communication and community engagement efforts described here complement the specific health promotion and demand generation efforts described in the following chapter.

Risk communication and health promotion support one another best when clearly distinguished. Information is trusted less when it appears to

have been presented with persuasive intent. Persuasive communication is more effective when recipients have already absorbed the information needed to understand the science underlying public health recommendations and when trust has already been won. Some people will follow recommendations without background information. Some will want that information in order to feel better about their decision and explain it to themselves and others. Some will need that information in order to accept the legitimacy of the COVID-19 vaccination efforts, particularly given the fractured social environment described in other sections of this report.

Although these efforts are different, their work must be coordinated, drawing on the same facts regarding the disease and vaccination efforts. There may also be cost savings in sharing research resources (e.g., monitoring surveys, communication materials).

CONCLUDING REMARKS

Several concerns will be key to the risk communication and community engagement needed to connect vaccination efforts with the public that they must serve. First, they will require great cultural competency in order to reach groups with diverse backgrounds, concerns, and histories with health care systems and research (Taylor and Lurie, 2004). Second, they must provide consistent, authoritative communications from trusted sources, lest the public be justifiably confused by inconsistent, unclear messages from sources whose validity cannot be independently assessed. Third, some features of the COVID-19 vaccination efforts will be unfamiliar and will need special efforts to communicate effectively; those include how it handles heterogeneity within priority groups, how it accommodates uncertainty in transmission patterns, how it addresses legal and treaty rights, and how it responds to changing scientific evidence regarding effectiveness and side effects. Fourth, information about COVID-19 vaccination efforts will have to serve members of the public with different needs, including informing individual patients, engaging community partners, recruiting candidates for research participation (including potentially additional clinical trials), facilitating program administration, coordinating with surveillance programs, supporting health care professionals in their client contacts, and countering misinformation and disinformation. Fifth, some community partners will need material and financial support, provided in ways that do not compromise the independence that affords them the moral authority needed to secure trust. Sixth, these efforts must begin immediately, as perceptions of COVID-19 vaccine are already forming, in ways that might limit successful vaccination.

The entity responsible for the recommended COVID-19 vaccination risk communication and community engagement program must have the

following properties: *agility*, to respond rapidly to changing circumstances and feedback; *competence*, to apply relevant risk communication research; *diversity*, to involve needed perspectives; and *independence*, to secure trust and provide candid feedback. The U.S. Department of Health and Human Services could build on the institutional capabilities of its agencies to implement such a program. Risk communication and community engagement will naturally liaise with partners like those described elsewhere (especially Chapters 5, 7, and 8). Given the difficulty and urgency of the mission, the work should start immediately at a proper scale.

RECOMMENDATION 4. Create and appropriately fund a COVID-19 vaccine risk communication and community engagement program.

The U.S. Department of Health and Human Services should create and appropriately fund a COVID-19 vaccination risk communication and community engagement program to support state, tribal, local, and territorial (STLT) authorities as an integral part of an effective and equitable national COVID-19 vaccination program. The program should:

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

REFERENCES

Bruine de Bruin, W., and A. Bostrom. 2013. Assessing what to address in science communication. *Proceedings of the National Academy of Sciences* 110(Suppl 3):14062–14068. doi: 10.1073/pnas.1212729110.

Callaghan, T., A. Moghtaderi, J. Lueck, P. Hotez, U. Strych, A. Dor, E. Fowler, and M. Motta. 2020. Correlates and disparities of COVID-19 vaccine hesitancy. *SSRN Electronic Journal*. https://ssrn.com/abstract=3667971 (accessed September 21, 2020).

Chastain, D. B., S. P. Osae, A. F. Henao-Martínez, C. Franco-Paredes, J. S. Chastain, and H. N. Young. 2020. Racial disproportionality in COVID clinical trials. *The New England Journal of Medicine* 383(9):e59. doi: 10.1056/NEJMp2021971.

Ericsson, K. A., and H. A. Simon. 1980. Verbal reports as data. *Psychological Review* 87(3):215–251. doi: 10.1037/0033-295X.87.3.215.

Feuerstein, A., D. Garde, and R. Robbins. 2020. *COVID-19 clinical trials are failing to enroll diverse populations, despite awareness efforts*. *STAT*. https://www.statnews.com/2020/08/14/covid-19-clinical-trials-are-are-failing-to-enroll-diverse-populations-despite-awareness-efforts (accessed September 21, 2020).

Fischhoff, B. 2013. The sciences of science communication. *Proceedings of the National Academy of Sciences* 110(Suppl 3):14033–14039. doi: 10.1073/pnas.1213273110.

Fischhoff, B. 2015. The realities of risk-cost-benefit analysis. *Science* 350(6260):aaa6516. doi: 10.1126/science.aaa6516.

Fischhoff, B. 2019. Evaluating science communication. *Proceedings of the National Academy of Sciences* 116(16):7670–7675. doi: 10.1073/pnas.1805863115.

Fischhoff, B., and A. L. Davis. 2014. Communicating scientific uncertainty. *Proceedings of the National Academy of Sciences* 111(Suppl 4):13664–13671. doi: 10.1073/pnas.1317504111.

Fisher, K. A., S. J. Bloomstone, J. Walder, S. Crawford, H. Fouayzi, and K. M. Mazor. 2020. Attitudes toward a potential SARS-CoV-2 vaccine: A survey of U.S. adults. *Annals of Internal Medicine*. doi: 10.7326/M20-3569.

IOM (Institute of Medicine). 1999. *Toward environmental justice: Research, education, and health policy needs*. Washington, DC: The National Academies Press.

IOM. 2014. *Characterizing and communicating uncertainty in the assessment of benefits and risks of pharmaceutical products: Workshop summary*. Washington, DC: The National Academies Press.

IOM and NRC (National Research Council). 2015. *Potential risks and benefits of gain-of-function research: Summary of a workshop*. Washington, DC: The National Academies Press.

Kamisar, B., and M. Holzberg. 2020. Poll: Less than half of Americans say they'll get a coronavirus vaccine. *NBC News*. August 18, 2020. https://www.nbcnews.com/politics/2020-election/poll-less-half-americans-say-they-ll-get-coronavirus-vaccine-n1236971 (accessed September 21, 2020).

NASEM (National Academies of Sciences, Engineering, and Medicine). 2017. *Building communication capacity to counter infectious disease threats: Proceedings of a workshop*. Washington, DC: The National Academies Press.

Nickerson, R. S. 1999. How we know—and sometimes misjudge—what others know: Imputing one's own knowledge to others. *Psychological Bulletin* 125:737–759. doi: 10.1037/0033-2909.125.6.737.

NRC (National Research Council). 1989. *Improving risk communication*. Washington, DC: National Academy Press.

NRC. 1996. *Understanding risk: Informing decisions in a democratic society*. Washington, DC: National Academy Press.

Peters, E. 2020. *Innumeracy in the wild: Misunderstanding and misusing numbers*. New York: Oxford University Press.

Resnick, B. 2020. A third of Americans might refuse a COVID-19 vaccine. How screwed are we? *Vox*. Updated September 10, 2020. https://www.vox.com/science-and-health/21364099/covid-19-vaccine-hesitancy-research-herd-immunity (accessed September 21, 2020).

Schwartz, L. M., and S. Woloshin. 2013. The drug facts box: Improving the communication of prescription drug information. *Proceedings of the National Academy of Sciences* 110(Suppl 3):14069–14074. doi: 10.1073%2Fpnas.1214646110.

Taylor, S. L., and N. Lurie. 2004. The role of culturally competent communication in reducing ethnic and racial healthcare disparities. *American Journal of Managed Care* 10(Spec No:Sp1–4).

7

Achieving Acceptance of COVID-19 Vaccine

Approval, allocation, and distribution of one or more safe and effective coronavirus disease 2019 (COVID-19) vaccines will be a remarkable achievement. However, as has been pointed out repeatedly since the earliest days of the COVID-19 pandemic, readying a vaccine is just the starting point of what will be a challenging journey to achieving widespread public acceptance of COVID-19 vaccines. Strong demand for and acceptance of COVID-19 vaccines will be critical for protecting vulnerable populations and for regaining our pre-pandemic social and economic lives, but ensuring demand and promoting acceptance will be challenging.

Recent survey data from several sources suggest that willingness to be vaccinated with a novel COVID-19 vaccine is hovering at around 60–70 percent of the general population (Fisher et al., 2020; Kamisar and Holzberg, 2020; Mullen O'Keefe, 2020; Resnick, 2020; Thigpen and Funk, 2020). It is lower—in some cases, much lower—in specific sociodemographic groups: Black or Hispanic communities; those with lower educational attainment; and those who live in rural areas, among other groups (Callaghan et al., 2020; Fisher et al., 2020; Kamisar and Holzberg, 2020; Reich, 2020; Resnick, 2020). The reasons given for COVID-19 vaccine hesitancy are many. Some people have concerns about the safety of the vaccine, particularly given the unprecedented speed with which COVID-19 vaccines have moved through the development pipeline (Silverman, 2020). Distrust in the government, in the medical research community, and in pharmaceutical companies is also common (Fisher et al., 2020). Some people may feel they do not need the vaccine, either because they have already had (or believe they have had) COVID-19, they do not believe COVID-19

is a serious threat to their health, or they simply do not believe in vaccination (Fisher et al., 2020).

In surveys that capture a "not sure" or "maybe" response to questions about accepting a COVID-19 vaccine, this hesitant group is often larger than the "no" or plan to decline group (Fisher et al., 2020; Kamisar and Holzberg, 2020). Hesitant or unsure respondents may be waiting for more information about vaccine trial outcomes (safety and efficacy) or the vaccine approval process; they may also want to wait and see how those in their social networks behave. If the "wait and see" group sits out the early months of widespread vaccine rollout, achieving high population coverage will be delayed. Among the majority of U.S. residents reporting that they do plan to take the vaccine, ensuring that they actually receive the vaccine is also challenging. As has been observed frequently with seasonal influenza vaccination, even individuals with strong intentions to receive an influenza vaccine will often procrastinate, forget, or balk at seemingly small logistic or financial barriers (Harris et al., 2009, 2011; Schmid et al., 2017).

In this chapter, the committee reviews the complex and dynamic landscape of vaccine hesitancy, discusses its specific application and relevance to COVID-19 vaccination, and highlights the World Health Organization's (WHO's) Measuring Behavioral and Social Drivers of Vaccination (BeSD) Increasing Vaccination Model as an organizing framework for recommendations to address COVID-19 vaccine hesitancy and ensure robust demand for an approved vaccine.

THE LANDSCAPE OF VACCINE HESITANCY

Many intersecting social, cultural, legal, and historical factors shape the landscape into which a COVID-19 vaccine will be launched. The committee highlights several of the most relevant in the following sections.

Vaccine Hesitancy Is Common and on the Rise

Over the past 20 years, U.S. residents—and in particular, parents of young children—have reported increasing concerns about vaccine safety, the number of vaccines included in the routine childhood immunization schedule, and purported links (repeatedly proved incorrect) between vaccination and neurocognitive or biomedical conditions (Maglione et al., 2014). Potential consequences of vaccine hesitancy—which the committee views as an attitude, preference, or motivational state—are the behaviors of vaccine refusal or delay (Brewer et al., 2017). A cohort study by Glanz and colleagues (2013) found that in eight managed care organizations across the United States more than 10 percent of parents reported delaying or refusing vaccinations for their children. Another behavioral manifestation

of increased hesitancy is rising rates of personal belief and other nonmedical exemptions from school and day care entry vaccine mandates. From 2005–2006 through 2012–2013, the national rate of nonmedical exemptions almost doubled, and from 2011–2012 to 2017–2018, the median total nonmedical exemption rate increased by nearly 67 percent (Bednarczyk et al., 2019; Wang et al., 2014). Vaccine refusal and exemptions are high enough in some focused geographic regions to sustain outbreaks of vaccine-preventable diseases. According to one 2018 study, a select group of metropolitan "hot spots" in the United States are responsible for a large number of nonmedical exemptions, and overall, there is an inverse relationship between nonmedical exemption rates and measles, mumps, and rubella vaccine coverage in states with hot spots (Olive et al., 2018). Recent outbreaks of infectious diseases, including measles and mumps, may be attributed to current trends in childhood vaccine hesitancy and refusal among parents (Saint-Victor and Omer, 2013; Zipprich et al., 2015). Beyond routine childhood immunizations, many U.S. residents decline the seasonal influenza vaccine, and coverage rates for many teen and adult vaccines are well below what is needed to achieve adequate population health protection (Williams et al., 2017). Globally, vaccine hesitancy was listed among WHO's list of Ten Threats to Global Health in 2019 (WHO, 2019).

Organized, Well-Funded, and Influential Anti-Vaccine Groups

Anti-vaccine sentiment is as old as vaccination itself. Today, groups dedicated to anti-vaccination advocacy are active across the United States (Ball, 2020; Cohen and Vigue, 2020; Johnson et al., 2020; Reich, 2020), and have spurred disease outbreaks including measles outbreaks in the Somali community in Minneapolis, Minnesota (2017), and the Orthodox Jewish community in New York (2019). Recently, online social networks have become a leading source of deliberate misinformation on vaccines, driven by both anti-vaccination advocates and by bots and trolls hoping to amplify debates and drive skepticism. A 2018 study on vaccination activity on Twitter found that bots, trolls, and so-called "content polluters" covered the topic more extensively than did average users, with polluters in particular driving anti-vaccine content (Broniatowski et al., 2018). A 2020 analysis of nearly 100 million people expressing views regarding vaccination on Facebook showed significant growth in anti-vaccination clusters, compared to pro-vaccination clusters, with anti-vaccination clusters being more likely to engage with undecided individuals; the authors predicted that based on current trends, anti-vaccination views will dominate in the next 10 years (Johnson et al., 2020). They also noted that, unlike the singularly focused messaging of pro-vaccination advocates, anti-vaccination messages typically draw on a combination of issues, including safety concerns, con-

spiracy theories, and distrust of government and scientists. Examination of vaccine advertisements on Facebook showed that the median number of ads per buyer was higher for anti-vaccine ads than for pro-vaccine ads and were paid for by a small set of anti-vaccine advertisement buyers (Jamison et al., 2020).

Evidence suggests that members of the anti-vaccination movement are already mobilizing to discourage individuals from receiving a COVID-19 vaccine (Ball, 2020). Deliberately false information about COVID-19 vaccinations (e.g., they are a mechanism to implant microchips into people) is already being widely disseminated. Some members of the anti-vaccination movement have been opposed to other measures to deal with the COVID-19 pandemic, including stay-at-home orders, mask wearing, and contact tracing (Bogel-Burroughs, 2020). A better understanding of both the anti-vaccination movement and approaches that could be successful to counter their actions is needed.

Medical Exploitation and Distrust

Beyond a history of a system that has not always been trustworthy for many populations, a painful legacy of health care discrimination, medical research exploitation, and unconsented experimentation on Black, Latinx, American Indian, Alaska Native, and other marginalized communities has contributed to justified distrust of government-sponsored medical research (Frakt, 2020; Gamble, 1997). Examples include the infamous Tuskegee study—in which hundreds of Black men in Alabama were lied to about being treated for syphilis while the disease was allowed to run its course; the Edmonston-Zagreb vaccine trial, during which parents of immunized infants (mostly Black and Latinx) were not informed that the vaccine used was an unapproved experimental vaccine; and less well known but equally abhorrent instances of unconsented sterilization of Latinx and American Indian and Alaska Native women (Carpio, 2004; Gamble, 1997; University of Wisconsin, 2018). This legacy leaves many communities of color wary of participation in medical research, suspicious of initiatives to engage them in health promotion or surveillance efforts, and, in many cases, reluctant to become vaccinated (Hoffman, 2020). For example, in a study of influenza vaccine uptake among Medicare Fee-for-Service beneficiaries, vaccine receipt was higher among White (49.4 percent) and Asian (47.6 percent) beneficiaries compared to Black (32.6 percent) and Hispanic (29.1 percent) beneficiaries (Hall et al., 2020). Multiple surveys have shown Black and Latinx respondents to be less likely to report intentions to get vaccinated when a COVID-19 vaccine is available (Callaghan et al., 2020; Cohen and Vigue, 2020; Fisher et al., 2020; Kamisar and Holzberg, 2020; Resnick, 2020), and there is widespread concern about the ability of COVID-19

vaccine Phase III trials to enroll individuals from Black, Latinx, Indigenous, and other marginalized communities (Chastain et al., 2020; Feuerstein et al., 2020). Culturally tailored outreach and promotion campaigns that acknowledge this history and actively seek to rebuild trust among marginalized communities will be needed to ensure that the benefits of vaccination are available to all, and to help mitigate disparities that already exist.

Unique Challenges to COVID-19 Vaccine Acceptance

Even among persons typically supportive of vaccination, concerns have been raised about COVID-19 vaccines given the unique circumstances of its development and testing. In one study, 15 percent of persons who said they were at least somewhat supportive of vaccines said they would not get a COVID-19 vaccine (Murphy, 2020). The unprecedented speed with which COVID-19 vaccines have been developed is an important component of safety concerns. If a COVID-19 vaccine is approved or authorized (e.g., through Emergency Use Authorization) by the U.S. Food and Drug Administration (FDA) in the coming months, the vaccine development and approval process will have occurred far more quickly than for any previous vaccine.

Concerns have also been raised that the vaccine development process is being rushed for political ends and are reflected in recent polling as well (Silverman, 2020). To counter these concerns, FDA has developed recommendations for the performance of any approved COVID-19 vaccine (e.g., it will be at least 50 percent effective) and has committed to the use of an independent advisory committee to decide about licensure of candidate vaccines (Burton, 2020). Nine leading pharmaceutical companies involved in COVID-19 vaccine development have also signed a public pledge that no shortcuts will be taken during the approval process (Facher, 2020). Despite these reassurances, the recent emergency use authorization of convalescent plasma (a COVID-19 therapy) based on what many considered insufficient data to support efficacy has reinforced concerns about the politicization of the FDA process (Mahase, 2020; NIH, 2020). It is also important to note that potential mistrust in public health authorities and a COVID-19 vaccine are not emerging on a "blank canvas." More broadly, other systemic failures to contain or mitigate COVID-19, including personal protective equipment shortages, inconsistent and frequently changing guidelines regarding the use of masks and diagnostic testing, and inadequate testing and contact tracing programs, have further eroded the public's trust in government response. In light of these events and the other circumstances previously described, ensuring confidence in COVID-19 vaccines in tandem with other preventive measures will be an important challenge, and one that will likely require greater attention than for a typical new vaccine.

WHO BeSD INCREASING VACCINATION MODEL

In 2018, WHO convened an expert working group called BeSD to advance the development of tools to track and address under-vaccination; BeSD also published a theoretical Increasing Vaccination Model. This model, based on earlier work by Brewer and colleagues (2017), provides a useful organizing framework for important demand-side considerations related to addressing vaccine hesitancy and successfully promoting the novel coronavirus vaccine (WHO, 2020) (see Figure 7-1).

Motivation

At the heart of WHO's BeSD Increasing Vaccination Model is motivation to be vaccinated. Motivation can be captured by concepts like readiness, willingness, hesitancy, or intention. Motivation is what is measured in survey questions such as, "How likely is it that you will get a COVID-19 vaccine when it is available?" In the Increasing Vaccination Model, motivation is shaped both by what people think and feel about vaccination, and also by social processes that play out in their environment. What people believe about the severity of COVID-19 and the effectiveness and safety of a vaccine, their trust in public health or medical authorities, their tolerance for risk, and how they feel about needles are all examples of "think and feel" elements that precede motivation.

At the same time, it is well known that humans are very socially motivated (Reid et al., 2011). It is generally important to people that they fit in and garner social approval; and people commonly take their behavioral cues from those around them. This means that a strong recommendation from a health care provider or a clergy member can increase motivation to vaccinate, whereas hearing from friends, family members, or social net-

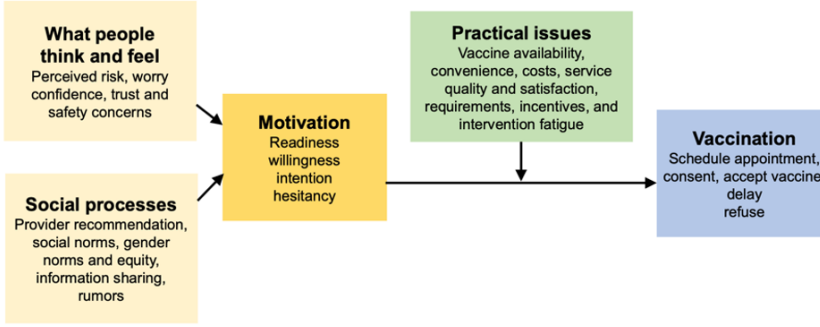

FIGURE 7-1 WHO BeSD Increasing Vaccination Model.
SOURCE: WHO, 2020.

work contacts who choose not to become vaccinated can decrease motivation. The importance of both thoughts and feelings and social processes in shaping motivation makes it very evident how influential, disruptive, and "sticky" misinformation can be. Myths about vaccine risks, misinterpretations of data about the severity of the disease being prevented, or intentional distortions or misreporting of scientific evidence can all shape what people think and feel; the impact of misinformation on motivation increases as it is propagated and amplified through social networks.

Practical Issues

The motivation to be vaccinated results in actual vaccination only if practicalities of availability, accessibility, cost, convenience, service quality, and incentives are all addressed. As previously noted, researchers know from seasonal influenza vaccination (and other screening and prevention behaviors, such as colonoscopies and the proper use of sunscreen) that the motivation–behavior gap can be large. While many of these practical issues were addressed in Chapter 5, it is worth highlighting the aspects of vaccination that can impact demand through behavioral mechanisms. These include:

- **Vaccine availability:** Is the vaccine available in my neighborhood? Do I have to go to a doctor's office, or can I get vaccinated at my pharmacy, my job, or my gym?
- **Cost:** Do I have to pay for the vaccine? Is there an administration fee? What's my co-pay? Even small fees and cost sharing can introduce friction and reduce demand.
- **Convenience:** Can I get the vaccine after hours? Do they have a drive-through? Is there a long wait? How easy is it to make an appointment and sign-in?
- **Service quality:** Do I feel welcome at the vaccine location? Am I treated well? Is there an opportunity to ask questions or follow up with concerns?

STRATEGIES FOR VACCINE PROMOTION AND ADDRESSING VACCINE HESITANCY

A 2015 systematic review of strategies to address vaccine hesitancy stated that "given the complexity of vaccine hesitancy and the limited evidence available on how it can be addressed, identified strategies should be carefully tailored according to the target population, their reasons for hesitancy, and the specific context" (Jarrett et al., 2015). This lesson will be critically important for addressing hesitancy around COVID-19 vaccination

in the United States and elsewhere, especially as unique concerns around the development and safety of COVID-19 vaccines continue to evolve. There is no "one-size-fit-all" solution to vaccine hesitancy, and nuanced approaches are key to ensuring that existing health inequities are addressed and to ensuring that those who are hesitant do not turn to outright vaccine refusal. By addressing vaccine hesitancy in order to gain and build public trust, it is critical to consider the needs and input of specific populations, a position endorsed by WHO's tailoring immunization programmes guidance (WHO, 2020). Multiple literature reviews have noted that single-component interventions to address vaccine hesitancy and promote vaccine uptake are not as effective as those that include multiple components, though the ideal combination of intervention strategies requires further investigation (Brewer et al., 2017; Dubé et al., 2015; Jarrett et al., 2015). Furthermore, the strength of the relationship between stated intentions to vaccinate and actual vaccination behavior requires further investigation (Brewer et al., 2017). Interventions that target direct behavior change, as opposed to those that aim to modify thoughts and feelings about vaccination or the social norms around them, have also been found to be more effective (Brewer et al., 2017). Strategies categorized as behavior focused include incentives, sanctions, and requirements—including, for example, vaccination requirements for school entry. A shared theme among these strategies is that many attempt to shift the framing of vaccination such that it is viewed as a routine, expected behavior—such that vaccination is viewed as the accepted norm (Brewer et al., 2017). This approach is already popular for many routine childhood immunizations in the United States.

Among the strategies discussed by WHO to address vaccine hesitancy are the engagement of community leaders, social mobilization tactics, mass media campaigns, the use of reminder and follow-up systems, training and education of health care professionals, nonfinancial incentives, vaccine mandates, efforts to make vaccination more convenient, and efforts to increase general knowledge and awareness about vaccines and vaccination (Jarrett et al., 2015; WHO, 2020). Ultimately, using a combination of these elements and others, evidence suggests that efforts to counter vaccine hesitancy and promote the vaccine should emphasize putting "people at the center" of efforts, as stated by a 2020 report produced by the Johns Hopkins Center for Health Security focused on the role of the public in COVID-19 vaccination (a report that strongly emphasized the importance of community-informed social and behavioral research and interventions in preparing for mass COVID-19 vaccination) (Schoch-Spana et al., 2020). In particular, dialogue-based interventions—which include social mobilization, engagement with community leaders and trusted community representatives (as discussed in Chapters 5 and 6), and other communication across scales—have been highlighted as potentially effective, and they rein-

force the importance of community involvement in creating, adjusting, and implementing these solutions to ensure adequate buy-in and trust (Dubé et al., 2015; Jarrett et al., 2015). The immunization of thought leaders and celebrities could also play a role in compelling members of the public to vaccinate (Freed et al., 2011; Hoffman et al., 2017; Najera, 2019), and overall, vaccine promotion messengers should be trusted, credible, and consistent (Tumpey et al., 2018). Structurally, a COVID-19 vaccine promotion campaign with its expected large scale and impact could look to mimic the success of an example such as the "Truth campaign" against tobacco use in the United States (Farrelly et al., 2009), and could draw on the experience of existing government investment in this area through CDC (including the Vaccinate with Confidence approach) and the National Vaccine Program (CDC, 2019; NVPO and Emory University, 2017).

Approaches such as social marketing and human-centered design can also support vaccine promotion strategies that are community centered and nuanced, such that those most hesitant to be vaccinated or those most vulnerable to severe outcomes from COVID-19 are targeted appropriately (Nowak et al., 2015; Schoch-Spana et al., 2020). Social marketing, which has been used previously to improve coverage and understanding of human papillomavirus vaccination, among other examples, does this through "tactical segmentation" and consideration of both shared demographic and behavioral characteristics *and* the reasoning behind these characteristics (Nowak et al., 2015). Given that social marketing is end-user driven, the use of such tactics will be critical for reaching potentially skeptical populations, such as communities of color, workers in essential industries, and even health care professionals, who also have been shown to play a critical role in driving vaccination trust and coverage through their own recommendations and communications with patients (Brewer et al., 2017; Dubé et al., 2015; Jarrett et al., 2015; Schoch-Spana et al., 2020). Strategies derived from the fields of behavioral economics and choice architecture could play a role as well.

CONCLUDING REMARKS

Operation Warp Speed has been granted a nearly $10 billion budget to develop one or more safe and effective COVID-19 vaccines, and additional funds will be spent to distribute and deliver a vaccine (HHS, 2020). Ensuring public acceptance of a vaccine is a crucial "last mile" challenge; failing to address vaccine hesitancy or rebuild trust puts the entire investment at risk. Bridging this last mile will require additional resources and significant effort at the national and community levels to ensure that equitable allocation of a COVID-19 vaccine becomes a reality. Operation Warp Speed has been an unprecedented effort to rapidly bring to market a safe and effective

vaccine, and a similarly urgent initiative is needed to speed innovations in social, behavioral, and communication science in order to promote acceptance of that same vaccine.

RECOMMENDATION 5. Develop and launch a COVID-19 vaccine promotion campaign.

The Centers for Disease Control and Prevention should rapidly develop and launch a national, branded, multi-dimensional COVID-19 vaccine promotion campaign, using rigorous, evidence-informed risk and health communication, social marketing, and behavioral science techniques. The COVID-19 vaccine promotion campaign should:

- Be consistent in its messaging but also flexible and modular to allow state, tribal, local, and territorial authorities to tailor it to specific communities and audiences, similar to the truth campaign against tobacco use.
- Partner with diverse stakeholders (e.g., health care providers, Historically Black Colleges and Universities research centers, Hispanic Association of Colleges and Universities, Tribal Colleges and Universities research centers, social marketing firms and other groups with specific expertise reaching underserved communities) and prioritize promoting the vaccine to Black, Hispanic or Latinx, American Indian and Alaska Native, Hawaiian Native and Pacific Islander, and other communities in which vaccine hesitancy and skepticism have been documented.
- Engage thought and opinion leaders, such as celebrities, to help promote COVID-19 vaccination acceptance and uptake.
- Incorporate messaging (in a variety of languages) and graphical elements that increase motivation, counter misinformation, and overcome perceived or actual practical barriers to vaccination.
- Include print, radio, television, and social media formats; incorporate toolkits, educational materials, and guidebooks to support community discussion about the COVID-19 vaccine; and make materials available in multiple languages.
- Be incorporated into broader messaging that provides consistent information on COVID-19 public health strategies that include nonpharmaceutical interventions, such as mask usage, physical distancing, hand washing, and so forth; expanded and accessible diagnostic testing linked to contact tracing, isolation, and quarantine strategies aimed at containing transmission, suppressing outbreaks, and interrupting super-spreading events; and the deployment of therapeutic measures that mitigate morbidity and mortality.

RECOMMENDATION 6. Build an evidence base for effective strategies for COVID-19 vaccine promotion and acceptance.

The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health should invest in rapidly building an evidence base for effective strategies for COVID-19 vaccine promotion and acceptance, acknowledging the unique circumstances around COVID-19 vaccination and the knowledge gaps related to understanding community needs and perceptions and effective promotion and delivery strategies. Specific action steps to implement this recommendation include:

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

REFERENCES

Ball, P. 2020. *Anti-vaccine movement could undermine efforts to end coronavirus pandemic, researchers warn*. Nature. https://www.nature.com/articles/d41586-020-01423-4#ref-CR1 (accessed September 22, 2020).

Bednarczyk, R. A., A. R. King, A. Lahijani, and S. B. Omer. 2019. Current landscape of nonmedical vaccination exemptions in the United States: Impact of policy changes. *Expert Review of Vaccines* 18(2):175–190. doi: 10.1080/14760584.2019.1562344.

Bogel-Burroughs, N. 2020. Antivaccination activists are growing force at virus protests. *The New York Times*. https://www.nytimes.com/2020/05/02/us/anti-vaxxers-coronavirus-protests.html (accessed September 22, 2020).

Brewer, N. T., G. B. Chapman, A. J. Rothman, J. Leask, and A. Kempe. 2017. Increasing vaccination: Putting psychological science into action. *Psychological Science in the Public Interest* 18(3):149–207. doi: 10.1177/1529100618760521.

Broniatowski, D. A., A. M. Jamison, S. Qi, L. AlKulaib, T. Chen, A. Benton, S. C. Quinn, and M. Dredze. 2018. Weaponized health communication: Twitter bots and Russian trolls amplify the vaccine debate. *American Journal of Public Health* 108(10):1378–1384. doi: 10.2105/AJPH.2018.304567.

Burton, T. M. 2020. *FDA to require proof virus vaccine is effective before approving its use*. https://www.wsj.com/articles/fda-to-issue-guidance-on-covid-19-vaccine-approval-11593516090?mod=hp_lead_pos3 (accessed September 22, 2020).

Callaghan, T., A. Moghtaderi, J. Lueck, P. Hotez, U. Strych, A. Dor, E. Fowler, and M. Motta. 2020. Correlates and disparities of COVID-19 vaccine hesitancy. *SSRN Electronic Journal*. doi: 10.2139/ssrn.3667971.

Carpio, M. V. 2004. The lost generation: American Indian women and sterilization abuse. *Social Justice* 31(4)(98):40–53. http://www.jstor.org/stable/29768273 (accessed September 22, 2020).

CDC (Centers for Disease Control and Prevention). 2019. *Vaccinate with confidence*. https://www.cdc.gov/vaccines/partners/vaccinate-with-confidence.html (accessed September 15, 2020).

Chastain, D. B., S. P. Osae, A. F. Henao-Martínez, C. Franco-Paredes, J. S. Chastain, and H. N. Young. 2020. Racial disproportionality in covid clinical trials. *The New England Journal of Medicine* 383(9):e59. doi: 10.1056/NEJMp2021971.

Cohen, E., and D. Vigue. 2020. *US government slow to act as anti-vaxxers spread lies on social media about coronavirus vaccine*. CNN. https://www.cnn.com/2020/08/12/health/anti-vaxxers-covid-19/index.html (accessed September 22, 2020).

Dubé, E., D. Gagnon, and N. E. MacDonald. 2015. Strategies intended to address vaccine hesitancy: Review of published reviews. *Vaccine* 33(34):4191–4203. doi: 10.1016/j.vaccine.2015.04.041.

Facher, L. 2020. *Amid broad mistrust of FDA and Trump administration, drug companies seek to reassure public about COVID-19 vaccine safety*. STAT. https://www.statnews.com/2020/09/08/pharma-pledge-reassure-covid-19-safety (accessed September 22, 2020).

Farrelly, M. C., J. Nonnemaker, K. C. Davis, and A. Hussin. 2009. The influence of the national truth® campaign on smoking initiation. *American Journal of Preventive Medicine* 36(5):379–384. doi: 10.1016/j.amepre.2009.01.019.

Feuerstein, A., D. Garde, and R. Robbins. 2020. *COVID-19 clinical trials are failing to enroll diverse populations, despite awareness efforts*. STAT. https://www.statnews.com/2020/08/14/covid-19-clinical-trials-are-are-failing-to-enroll-diverse-populations-despite-awareness-efforts (accessed September 22, 2020).

Fisher, K. A., S. J. Bloomstone, J. Walder, S. Crawford, H. Fouayzi, and K. M. Mazor. 2020. Attitudes toward a potential SARS-CoV-2 vaccine: A survey of U.S. Adults. *Annals of Internal Medicine*. September 4, 2020, online ahead of print. doi: 10.7326/M20-3569.

Frakt, A. 2020. Bad medicine: The harm that comes from racism. *The New York Times*, July 8, 2020. https://www.nytimes.com/2020/01/13/upshot/bad-medicine-the-harm-that-comes-from-racism.html (accessed September 22, 2020).

Freed, G. L., S. J. Clark, A. T. Butchart, D. C. Singer, and M. M. Davis. 2011. Sources and perceived credibility of vaccine-safety information for parents. *Pediatrics* 127(Suppl 1):S107–S112. doi: 10.1542/peds.2010-1722P.

Gamble, V. N. 1997. Under the shadow of Tuskegee: African Americans and health care. *American Journal of Public Health* 87(11):1773–1778. doi: 10.2105/AJPH.87.11.1773.

Glanz, J. M., S. R. Newcomer, K. J. Narwaney, S. J. Hambidge, M. F. Daley, N. M. Wagner, D. L. McClure, S. Xu, A. Rowhani-Rahbar, G. M. Lee, J. C. Nelson, J. G. Donahue, A. L. Naleway, J. D. Nordin, M. M. Lugg, and E. S. Weintraub. 2013. A population-based cohort study of undervaccination in 8 managed care organizations across the United States. *JAMA Pediatrics* 167(3):274–281. doi: 10.1001/jamapediatrics.2013.502.

Hall, L. L., L. Xu, S. M. Mahmud, G. A. Puckrein, E. W. Thommes, and A. Chit. 2020. A map of racial and ethnic disparities in influenza vaccine uptake in the medicare fee-for-service program. *Advances in Therapy* 37(5):2224–2235. doi: 10.1007/s12325-020-01324-y.

Harris, K. M., J. Maurer, and N. Lurie. 2009. Do people who intend to get a flu shot actually get one? *Journal of General Internal Medicine* 24(12):1311–1313. doi: 10.1007/s11606-009-1126-2.

Harris, K. M., J. Maurer, L. Uscher-Pines, A. Kellermann, and N. Lurie. 2011. *Seasonal flu vaccination: Why don't more Americans get it?* RAND Corporation.

HHS (U.S. Department of Health and Human Services). 2020. *Fact sheet: Explaining Operation Warp Speed*. https://www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html (accessed September 22, 2020).

Hoffman, J. 2020. Mistrust of a coronavirus vaccine could imperil widespread immunity. *The New York Times*, July 18, 2020. https://www.nytimes.com/2020/07/18/health/coronavirus-anti-vaccine.html (accessed September 22, 2020).

Hoffman, S. J., Y. Mansoor, N. Natt, L. Sritharan, J. Belluz, T. Caulfield, Y. Freedhoff, J. N. Lavis, and A. M. Sharma. 2017. Celebrities' impact on health-related knowledge, attitudes, behaviors, and status outcomes: Protocol for a systematic review, meta-analysis, and meta-regression analysis. *Systematic Reviews* 6(1):13. doi: 10.1186/s13643-016-0395-1.

Jamison, A. M., D. A. Broniatowski, M. Dredze, Z. Wood-Doughty, D. Khan, and S. C. Quinn. 2020. Vaccine-related advertising in the Facebook ad archive. *Vaccine* 38(3):512–520. doi: 10.1016/j.vaccine.2019.10.066.

Jarrett, C., R. Wilson, M. O'Leary, E. Eckersberger, and H. J. Larson. 2015. Strategies for addressing vaccine hesitancy—a systematic review. *Vaccine* 33(34):4180–4190. doi: 10.1016/j.vaccine.2015.04.040.

Johnson, N. F., N. Velásquez, N. J. Restrepo, R. Leahy, N. Gabriel, S. El Oud, M. Zheng, P. Manrique, S. Wuchty, and Y. Lupu. 2020. The online competition between pro- and anti-vaccination views. *Nature* 582(7811):230–233. doi: 10.1038/s41586-020-2281-1.

Kamisar, B., and M. Holzberg. 2020. *Poll: Less than half of Americans say they'll get a coronavirus vaccine*. NBC News. https://www.nbcnews.com/politics/2020-election/poll-less-half-americans-say-they-ll-get-coronavirus-vaccine-n1236971 (accessed September 22, 2020).

Maglione, M. A., L. Das, L. Raaen, A. Smith, R. Chari, S. Newberry, R. Shanman, T. Perry, M. B. Goetz, and C. Gidengil. 2014. Safety of vaccines used for routine immunization of US children: A systematic review. *Pediatrics* 134(2):325–337. doi: 10.1542/peds.2014-1079.

Mahase, E. 2020. COVID-19: US FDA fires spokesperson over misleading claims about convalescent plasma. *BMJ* 370:m3400. doi: 10.1136/bmj.m3400.

Mullen O'Keefe, S. 2020. *One in three Americans would not get COVID-19 vaccine*. Gallup News. https://news.gallup.com/poll/317018/one-three-americans-not-covid-vaccine.aspx (accessed September 22, 2020).

Murphy, J. 2020. *What happens if some Americans refuse the COVID-19 vaccine?* MDLinx. https://www.mdlinx.com/article/what-happens-if-some-americans-refuse-the-covid-19-vaccine/5Yqy3Q84Wt27BQktRnhGnD (accessed September 22, 2020).

Najera, R. F. 2019. *Celebrities have influence on vaccination*. https://www.historyofvaccines.org/content/blog/vaccine-celebrities (accessed September 21, 2020).

NIH (National Institutes of Health). 2020. *The COVID-19 treatment guidelines panel's statement on the emergency use authorization of convalescent plasma for the treatment of COVID-19*. https://www.covid19treatmentguidelines.nih.gov/statement-on-convalescent-plasma-eua (accessed September 22, 2020).

Nowak, G. J., B. G. Gellin, N. E. MacDonald, and R. Butler. 2015. Addressing vaccine hesitancy: The potential value of commercial and social marketing principles and practices. *Vaccine* 33(34):4204–4211. doi: 10.1016/j.vaccine.2015.04.039.

NVPO (National Vaccine Program Office) and Emory University. 2017. *The vaccine confidence meeting: Collaborating to advance vaccine confidence. Meeting report August 15–16, 2017*. NVPO. https://www.hhs.gov/sites/default/files/2017-vaccine-confidence-meeting-report.pdf (accessed September 22, 2020).

Olive, J. K., P. J. Hotez, A. Damania, and M. S. Nolan. 2018. The state of the antivaccine movement in the United States: A focused examination of nonmedical exemptions in states and counties. *PLOS Medicine* 15(6):e1002578. doi: 10.1371/journal.pmed.1002578.

Reich, J. 2020. *How anti-vaxxers are thinking about a COVID-19 vaccine*. Vox. https://www.vox.com/first-person/2020/7/28/21337621/coronavirus-covid-19-vaccine-anti-vaxxer (accessed September 22, 2020).

Reid, A. E., R. B. Cialdini, and L. S. Aiken. 2011. Social norms and health behavior. In *Handbook of behavioral medicine: Methods and applications*. New York: Springer Science + Business Media. Pp. 263–274.

Resnick, B. 2020. *A third of Americans might refuse a COVID-19 vaccine. How screwed are we?* Vox. https://www.vox.com/science-and-health/21364099/covid-19-vaccine-hesitancy-research-herd-immunity (accessed September 22, 2020).

Saint-Victor, D. S., and S. B. Omer. 2013. Vaccine refusal and the endgame: Walking the last mile first. *Philosophical Transactions of the Royal Society of London. Series B, Biological Sciences* 368(1623):20120148.

Schmid, P., D. Rauber, C. Betsch, G. Lidolt, and M.-L. Denker. 2017. Barriers of influenza vaccination intention and behavior—a systematic review of influenza vaccine hesitancy, 2005–2016. *PLOS ONE* 12(1):e0170550. doi: 10.1371/journal.pone.0170550.

Schoch-Spana, M., E. Brunson, R. Long, S. Ravi, A. Ruth, and M. Trotochaud. 2020. *The public's role in COVID-19 vaccination: Planning recommendations informed by design thinking and the social, behavioral, and communication sciences*. Baltimore, MD: Johns Hopkins Bloomberg School of Public Health Center for Health Security.

Silverman, E. 2020. *Poll: Most Americans believe the COVID-19 vaccine approval process is driven by politics, not science*. STAT News. https://www.statnews.com/pharmalot/2020/08/31/most-americans-believe-the-covid-19-vaccine-approval-process-is-driven-by-politics-not-science (accessed September 22, 2020).

Thigpen, C. L., and C. Funk. 2020. *Most Americans expect a COVID-19 vaccine within a year; 72% say they would get vaccinated*. Pew Research Center Fact Tank. https://www.pewresearch.org/fact-tank/2020/05/21/most-americans-expect-a-covid-19-vaccine-within-a-year-72-say-they-would-get-vaccinated (accessed September 22, 2020).

Tumpey, A. J., D. Daigle, and G. Nowak. 2018. *Communicating during an outbreak or public health investigation*. Atlanta, GA: CDC.

University of Wisconsin. 2018. *Sterilization of Puerto Rican women: A selected, partially annotated bibliography (Louis de Malave, 1999)*. https://www.library.wisc.edu/gwslibrarian/bibliographies/sterilization (accessed September 22, 2020).

Wang, E., J. Clymer, C. Davis-Hayes, and A. Buttenheim. 2014. Nonmedical exemptions from school immunization requirements: A systematic review. *American Journal of Public Health* 104(11):e62–e84. doi: 10.2105/AJPH.2014.302190.

WHO (World Health Organization). 2019. *Ten threats to global health in 2019*. https://www.who.int/vietnam/news/feature-stories/detail/ten-threats-to-global-health-in-2019 (accessed September 22, 2020).

WHO. 2020. *Improving vaccination demand and addressing hesitancy*. https://www.who.int/immunization/programmes_systems/vaccine_hesitancy/en/#:~:text=In%20November%202018%2C%20a%20global,be%20finalized%20in%20late%202020 (accessed September 22, 2020).

Williams, W. W., P. J. Lu, A. O'Halloran, D. K. Kim, L. A. Grohskopf, T. Pilishvili, T. H. Skoff, N. P. Nelson, R. Harpaz, L. E. Markowitz, A. Rodriguez-Lainz, and A. P. Fiebelkorn. 2017. Surveillance of vaccination coverage among adult populations—United States, 2015. *Morbidity and Mortality Weekly Report Surveillance Summaries* 66(11):1–28. doi: 10.15585/mmwr.ss6611a1.

Zipprich, J., K. Winter, J. Hacker, D. Xia, J. Watt, and K. Harriman. 2015. Measles outbreak—California, December 2014–February 2015. *Morbidity and Mortality Weekly Report* 64(06):153–154.

8

Ensuring Equity in COVID-19 Vaccine Allocation Globally

Vaccine development, especially during public health emergencies, requires collaborative, multi-sectoral, and international efforts, with private pharmaceutical companies teaming up with governmental and nongovernmental agencies, philanthropies, and academic laboratories. For example, the recently approved Ebola vaccine is a result of a close collaboration between the pharmaceutical company Merck, Canadian and U.S. governmental agencies, and the World Health Organization (WHO) (Felter, 2020). When severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) emerged in late 2019 and began spreading across the world, the global community mobilized rapidly to start developing and mass-producing effective vaccines. As some high-income countries start securing vaccine allotments through bilateral agreements with pharmaceutical companies, it is clear that an inequitable distribution of vaccines at the global level will ultimately fail to eliminate the risk of new outbreaks in the future. As recently highlighted in a report from the Bill & Melinda Gates Foundation, "According to modeling from Northeastern University, if rich countries buy up the first 2 billion doses of vaccine instead of making sure they are distributed in proportion to the global population, then almost twice as many people could die from COVID-19" (Bill & Melinda Gates Foundation, 2020, p. 16; Chinazzi et al., 2020).

The United States has already made large investments through Operation Warp Speed (OWS) to accelerate the development, manufacturing, and domestic distribution of coronavirus disease 2019 (COVID-19) vaccines. While the United States has yet to actively engage with global vaccine devel-

opment and allocation efforts, it has officially acknowledged and welcomed them. Indeed, on May 4, 2020, the U.S. Department of State stated that the

> United States is bringing together the brightest minds in U.S. government agencies, the private sector, universities, and overseas partners to develop vaccines and therapeutic interventions to protect the world from COVID-19. The United States is using its G7 Presidency to catalyze the power and resilience of the world's leading democracies and free economies in this effort. The United States welcomes efforts by other countries to mobilize resources to mitigate and ultimately end the COVID-19 pandemic, efforts like the pledging conference in Europe which, among other things, will support investments in the Coalition for Epidemic Preparedness Innovations (CEPI) and the United Kingdom's June 4 pledging conference for the Global Alliance for Vaccines and Immunization (GAVI). (U.S. Department of State, 2020)

Unfortunately, the current tension between the United States and WHO over its initial response to the pandemic, including a halt to U.S. funding and formal notification of the United States' intent to withdraw from membership in the World Health Assembly, has further complicated these multilateral discussions. As highlighted in the above quote, the U.S. government is a long-term supporter of Gavi, the Vaccine Alliance and, indeed, one of the vaccine alliance's largest donors.[1]

This chapter will explore existing multilateral strategies to accelerate and equitably deploy future vaccines needed to address the COVID-19 pandemic internationally, as well as the United States' potential leadership role in supporting global vaccine access mechanisms.

GLOBAL PREPAREDNESS AND RESPONSE TO THE COVID-19 PANDEMIC

Global Preparedness Monitoring Board

The 2014–2016 Ebola outbreak in West Africa uncovered important gaps in the global community's capacities to effectively prepare, detect, respond to and recover from emerging and re-emerging infectious disease outbreaks. In the wake of this unprecedented crisis and in response to recommendations by the United Nations Secretary-General's Global Health Crises Task Force, the Global Preparedness Monitoring Board (GPMB) was created. In 2018, the GPMB was formally launched by the World Bank

[1] The United States is also the largest donor to The Global Fund to Fight AIDS, Tuberculosis and Malaria. While the Global Fund does not have a role in the ACT-A Vaccines Pillar, it has played a leading role in the Diagnostics and Therapeutics Pillars, as well as the Health Systems connector.

and WHO as an independent body tasked with monitoring and evaluating epidemic and pandemic preparedness around the world (GPMB, 2019).

In September 2019, the GPMB released its first comprehensive annual report, *A World at Risk* (GPMB, 2019). The report highlighted key actions for global leaders to take. The report warned, "Countries, donors and multilateral institutions must be prepared for the worst" (GPMB, 2019, p. 8). Specifically:

> A rapidly spreading pandemic due to a lethal respiratory pathogen (whether naturally emergent or accidentally or deliberately released) poses additional preparedness requirements. Donors and multilateral institutions must ensure adequate investment in developing innovative vaccines and therapeutics, surge manufacturing capacity, broad-spectrum antivirals and appropriate non-pharmaceutical interventions. All countries must develop a system for immediately sharing genome sequences of any new pathogen for public health purposes along with the means to share limited medical countermeasures across countries. (GPMB, 2019, p. 30)

While retrospectively prescient, the GPMB's recommendation was based on knowledge of the certainty of the periodic, but unpredictably sudden, emergence of new pandemic influenza strains. The board recognized that, while some progress had been made in recent years in preparedness for local emerging infection outbreaks, such as Ebola, the global preparedness for a rapidly moving respiratory pathogen had lagged.

Unfortunately, the world's leaders had less than 6 months to act on the recommendations of the GPMB before the emergence of SARS-CoV-2 and its rapid spread throughout the world. The GPMB's recommendation urged leaders to identify the "means to share limited countermeasures across countries" and cautioned that, "limited medical countermeasures are shared inequitably at times and are likely to be prioritized for domestic use during a pandemic" (GPMB, 2019).

COVID-19 Vaccine Nationalism

The GPMB's concern about the domestic prioritization of medical countermeasures has proved perceptive, as the world has seen a rush to what has been called "vaccine nationalism" in response to the COVID-19 pandemic (Weintraub et al., 2020). Many high-income countries, including the United States, the United Kingdom, and those in the European Commission, have sought to quickly secure reservations of scarce capacities for vaccine production for their domestic deployment, often in return for sizeable investments in research and development or at-risk scaling of vaccine manufacturing capacity (HHS, 2020a,b; Rockoff and Hopkins, 2020).

The current approach has several obvious inefficiencies. Few countries will have enough resources to invest in a full portfolio of vaccine constructs.

Consequently, most countries will place very specific bets on individual vaccine partnerships. Given the uncertainties regarding the immunology of the novel SARS-CoV-2 virus, the highly diverse range of potential vaccine constructs, and the low risk-adjusted probability of the technical and regulatory success of any specific vaccine, they simply may not pick the winner(s).

Additionally, both the time and costs of ultimately meeting the world's needs will likely increase with highly fragmented pursuits of countermeasures against the virus. Countries may make redundant investments; fail to efficiently harness global capacities for sourcing key supplies, vaccine production, and fill/finish facilities; and be slowed by the lack of regulatory harmonization, integrated post-marketing surveillance, and coordinated management of product liability.

Another obvious problem with the vaccine nationalism approach relates to the global nature of the pandemic. In a global economy, people, goods, and services move rapidly around the world. We have seen the devastating economic consequences of the slowdown of global trade and travel caused by the COVID-19 pandemic (CRS, 2020). There is a strong urge to get back to some semblance of normal economic and social activity, which will be difficult to attain if there remain areas of the world where the virus is circulating widely. Countermeasures to control and contain the COVID-19 outbreak are needed everywhere, not just in those countries that are able to finance and secure scarce supplies. Global solidarity in ensuring rapid access to and deployment of vaccines is not just the right approach, it is also the best strategic approach for interrupting the pandemic.

Finally, if successful vaccines are developed in high-income countries and not equitably shared with low- and middle-income countries, we will continue to see differential morbidity and mortality, as well as economic and social shocks that will further increase global inequities—and with them global instability, displacement, large-scale migration, and, ultimately, insecurity.

ACCESS TO COVID-19 TOOLS ACCELERATOR AND THE COVAX FACILITY

Access to COVID-19 Tools Accelerator

On April 24, 2020, the president of the European Commission, Ursula van der Leyen, and President Macron of France, together with the director general of WHO and a host of other development partners and heads of states issued a Call to Action for the Access to COVID-19 Tools (ACT) Accelerator (ACT-A) (WHO, 2020c). At subsequent pledging events on May 4, 2020, and June 27, 2020, a wide range of countries, industries, civil society, and development partners pledged significant resources to support

the ACT-A in a remarkable expression of global solidarity (European Commission, 2020a,b,c).

The ACT-A is a global initiative to:

> speed up an end to the pandemic by supporting the development and equitable distribution of the tests, treatments and vaccines the world needs to reduce mortality and severe disease, restoring full societal and economic activity globally in the near term, and facilitating high-level control of COVID-19 disease in the medium term. (WHO, 2020a)

The ACT-A initiative is primarily a coordinating mechanism to bring together governments, health organizations, scientists, businesses, civil society, and philanthropists for concerted action in order to efficiently pair resources with the organizations best placed to accelerate and deploy the key countermeasures needed to address the COVID-19 pandemic. The initiative has three "pillars" focused on vaccines, therapeutics, and diagnostics, as well as a health systems "connector" that focuses on identifying and solving the limitations of weak health systems that may delay or frustrate the effective delivery of these vital countermeasures. One of the early benefits of this initiative has been its ability to consolidate an "investment case," highlighting the resource needs required to accelerate the global availability of COVID-19 tools (WHO, 2020a,b,c). The vaccine pillar of the ACT-A estimates a need of $15.9 billion over the next 18 months to secure two billion doses of vaccines for global use by the end of 2021. The vaccine pillar of ACT-A, also referred to as COVAX, is convened by CEPI and Gavi, the Vaccine Alliance (2020c). CEPI is leading the development of a robust portfolio of vaccine development partnerships. They currently have 10 separate partnerships with a range of companies and, if fully financed, will have potentially the largest portfolio of COVID-19 vaccines under development, increasing the likelihood that one or more will achieve technical and regulatory success. Gavi, the Vaccine Alliance is leading the work on vaccine procurement and financing. Together, CEPI and Gavi, the Vaccine Alliance are working closely with WHO and its Strategic Advisory Group of Experts (the apical vaccine advisory body within WHO), which is leading the development of a framework for fair and equitable allocation and prioritization of COVID-19 vaccines together with the member states of the World Health Assembly.

Gavi, the Vaccine Alliance's Global Vaccine Procurement Strategy

Gavi, the Vaccine Alliance has developed a financing approach through the COVAX Facility for the global procurement of COVID-19 vaccines (Gavi, the Vaccine Alliance, 2020b). The facility is designed to provide all countries with an opportunity to participate in securing initial access to

vaccine supply sufficient to cover at least 20 percent of their population. Once an allocation of 20 percent for all countries participating in COVAX is met, additional allocations will be made to all participating countries using a weighted allocation framework that balances a country's threat of infection and the vulnerability of its population and health system. This more complex allocation schema is described in the working draft of the *Fair Allocation Mechanism for COVID-19 Vaccines Through the COVAX Facility* published by WHO (2020e). WHO estimates that vaccines for 20 percent of the population should be enough to immunize frontline health care workers, other essential workers, older adults, and those with significant comorbid conditions that increase the risk of serious COVID-19 illness in most countries. Vaccines for low- and lower-middle-income countries would be financed through an advanced market commitment (AMC) funded from traditional sources of overseas development assistance. Ninety-two lower- and lower-middle-income countries are eligible for vaccine financing through the AMC. High- and upper-middle-income countries would self-finance vaccines through the facility. Gavi, the Vaccine Alliance would use these combined financing streams to issue contingent volume guarantees to specific countries to scale vaccine production, as well as to provide a strong demand signal to the vaccine industry in general. These types of market-shaping interventions have proven successful as part of Gavi, the Vaccine Alliance's innovative financing for other vaccines needed by low- and middle-income countries over the past 20 years (e.g., the successful pneumococcal conjugate vaccine AMC [Gavi, the Vaccine Alliance, 2019]). The COVAX Facility provides all countries a mechanism to pool procurement, reduce prices, and minimize the risk of not having any effective vaccines. As of September 21, 2020, 64 higher-income nations have officially joined the COVAX Facility, including commitments from 35 countries, as well as the European Commission, representing the 27 European Union member states plus Norway and Iceland. These 64 self-financing economies are joined by 92 lower-income economies who are eligible for financial support through the AMC. A total of 156 economies, representing more than two-thirds of the global population, are now either committed to or eligible for the COVAX Facility—with more expected to follow (Gavi, the Vaccine Alliance, 2020a; WHO, 2020d). It should be noted that some of these countries also have separate bilateral partnerships with vaccine developers to acquire vaccines directly.

U.S. PARTICIPATION IN GLOBAL VACCINE ALLOCATION

The United States and the COVAX Facility

Despite a long history of leadership in global health, particularly with regard to issues of global health security, the United States has yet to engage

in any significant manner in the global discussions regarding the ACT-A. On September 2, 2020, the White House announced it would opt out of the COVAX Facility.

Unfortunately, the international impression is that the United States has decided to go its own way, with its large investments through OWS tied to reservations of manufacturing capacity for exclusively domestic use. While certainly not alone among high-income countries in this type of "vaccine nationalism" approach, the speed, size, and extent of the U.S. investments with specific vaccine manufacturers may have set the example that others have followed, resulting in the fragmented global response that ACT-A and COVAX are trying to resolve.

Reasons to Support and Engage with Current Global Allocation Efforts

There are several compelling reasons why the U.S. government could reconsider engaging in the discussions on global vaccine allocation and, in particular, the ACT-A and COVAX facilities, as a complement to the efforts currently pursued through OWS.

As an Insurance Policy

Participation in ACT-A and COVAX could ensure the highest likelihood of early access to a safe and effective vaccine to prevent and interrupt transmission of SARS-CoV-2 and reduce the morbidity and mortality of COVID-19 among those most susceptible to poor outcomes. Despite having the largest investments in the broadest portfolio of COVID-19 vaccines of any nation (six vaccine partnerships announced to date with more to come), the United States has not invested in every potential vaccine construct, including some of those that CEPI has within its portfolio and that are pioneered by non-U.S. companies. In the event that the first, or most effective, vaccine emerges from the ACT-A portfolio, the United States would be negotiating late and at a disadvantage for access. In the context of OWS, a modest investment in the COVAX Facility would be a reasonable hedge, a sort of insurance policy, to ensure access to *any* successful COVID-19 vaccine as soon as possible, at least for the highest-risk Americans.

A Disease Threat Anywhere Is a Threat Everywhere

Shaping the global allocation of COVID-19 vaccines should be of strong interest to the United States, given its global trade interests, foreign military deployments, and vital diplomatic alliances. The reality of the global pandemic is summed up in the truism that "no one is safe until everyone is safe." A rapid U.S. economic recovery will most certainly depend on economic

recovery elsewhere, and thus on containing the COVID-19 pandemic around the world as quickly as possible. The United States also has the scientific expertise to potentially help shape the deployment of vaccines and other countermeasures in the most effective and timely manner. Most recently, the United States has played an important role in supporting the global response to the Ebola outbreak in West Africa in 2014–2015, where hundreds of Centers for Disease Control and Prevention assignees and many American volunteers joined in a historic response to a global health crisis. Similarly, as effective medical countermeasures (MCMs) become available, a U.S. engagement would speed their effective deployment and protect Americans, at home and abroad, and their interests, in the timeliest manner.

Global Health Security Agenda

Participation in ACT-A and COVAX is an important way to help shape the future of the global health security agenda. SARS-CoV-2 will not be the last—or potentially even the most severe—global health threat to emerge. The COVID-19 pandemic, for example, does not change the likelihood of emergence of the next influenza pandemic. Three influenza pandemics occurred in the 20th century and only one has occurred thus far in the 21st century. In March 2020, the World Economic Forum stated that COVID-19 "isn't an outlier, it's part of our interconnected viral age," coinciding with globalization, urbanization, and climate change (Whiting, 2020). Following the large Ebola outbreak in West Africa in 2014–2015 there was a global effort to strengthen global health security. Numerous countries undertook Joint External Evaluations, budgets for preparedness were increased, and the International Health Regulations (IHR) were strengthened. But, as highlighted by the Johns Hopkins Global Security Index and the GPMB in its 2019 report, these steps were insufficient to stop the cycle of crisis and neglect (GPMB, 2019; Johns Hopkins Bloomberg School of Public Health and Nuclear Threat Initiative, 2019). There will undoubtedly be a deeper assessment in the wake of the COVID-19 pandemic, which is the worst global health security event in over a century. Those assessments will take many forms, including through the GPMB, The Independent Panel for Pandemic Preparedness & Response, which was called for at the most recent World Health Assembly and is to be chaired by Helen Clark, former Prime Minister of New Zealand, and Ellen Johnson Sirleaf, former President of Liberia (WHO, 2020f). The ACT-A and COVAX, however, provide a specific opportunity for focused lessons to be learned about how to most effectively and quickly harness science and technology in response to an emerging global health threat. Given the scientific strength of the United States, it has much to contribute to that discussion and the strengthening of future global health preparedness.

A Historic and Successful Partnership with Gavi, the Vaccine Alliance

COVAX could be an opportunity for the United States to further strengthen its partnership with Gavi, the Vaccine Alliance, one of the United States' highest-return development partnerships. For the past 20 years the U.S. government has been one of the largest donors supporting Gavi, the Vaccine Alliance across multiple administrations. The return on this investment has been more than 7 million lives saved from vaccine-preventable disease, and those results have garnered strong, consistent, bipartisan support. The COVAX Facility will expand Gavi, the Vaccine Alliance's innovative financing model to additional geographic regions (the Gavi, the Vaccine Alliance Board just approved the expanded eligibility for COVAX AMC financing to 92 countries), which provides an opportunity to expand the influence of one of the largest U.S. development partnerships.

An Investment in Future Domestic Pandemic Preparedness

Participating in the global allocation of COVID-19 vaccines, including the possibility of devoting some of the reserved capacity of the U.S. supply, could be a wise investment in future domestic preparedness. Per the 2018 U.S. National Biodefense Strategy, "an interconnected world increases the opportunity for pathogens to emerge and spread so that a disease threat anywhere is a disease threat everywhere" (The White House, 2018). Recent experiences with Ebola, SARS, Zika, Middle East respiratory syndrome, Nipah, and 2009 H1N1 have indeed proven repeatedly that new pandemic threats can emerge anywhere on the globe. Rapid sharing of information about emerging pathogens is essential for early containment and the expedient development of needed countermeasures (The White House, 2018). In 2009, the United States decided to proactively dedicate 10 percent of its domestic supply of H1N1 influenza vaccine for global deployment through WHO, both for global solidarity and to ensure the continued willingness of all countries to share viral samples and genetic sequences. The impressive scientific prowess of U.S. companies and academic institutions may become impotent if their researchers cannot obtain samples of novel pathogens as they emerge. Consequently, an investment in global solidarity is not only the right thing to do, but also a wise investment in national preparedness for future outbreaks. This will be especially true if the United States follows through with its intent to withdraw from WHO in 2021 and, presumably, the IHR, a treaty obligation of WHO member states and part of WHO's global mandate. The IHR currently provides a framework, albeit imperfect, for the sharing of information concerning emergent pathogens (WHO, 2005). Without its guarantees, the United States will be solely dependent on diplomatic goodwill. This alone is a good reason for the United States to reconsider its decision to withdraw from WHO.

An Investment in National Security

Participation in ACT-A and COVAX might be an important way to help the United States meet the ambitious national security goals laid out in its 2018 National Biodefense Strategy. More specifically, contributions to the ongoing global efforts could help the United States meet one of its goals, namely, to "ensure biodefense enterprise preparedness to reduce the impact of bioincidents" (The White House, 2018). One of the key objectives underpinning this goal is to "strengthen international preparedness to support international response and recovery capabilities" (The White House, 2018). In the context of this particular goal, the 2018 National Biodefense Strategy makes clear that it is in the United States' national security interest to

> promote increased global capacities for research, development, evaluation, manufacturing, acquisition, stockpiling, deployment, and distribution of MCMs, including through collaborative arrangements," and to "develop appropriate plans and agreements to facilitate the rapid international deployment and distribution of MCMs under the appropriate regulatory mechanisms, or for the rapid development, including clinical trials, of investigational MCMs during a crisis. (The White House, 2018, p. 21)

Even a comparatively modest investment in the ACT-A and COVAX Facility might allow the United States to quickly and most effectively meet key national security goals laid out in the 2018 National Biodefense strategy, while still pursuing separate bilateral partnerships with vaccine developers.

A Moral Duty

Re-engaging in discussions on global vaccine allocation, in particular with ACT-A and the COVAX Facility, would allow the United States to maintain its historical position as a leader in global health. The United States has earned this leadership position through long-standing successful humanitarian engagements across the globe, with strong bipartisan support in Congress across both Republican and Democratic administrations. The historic eradication of smallpox in the 1980s could not have happened without strong international partnerships and, importantly, U.S. leadership.

More recently, by providing logistical, technical, and financial support, including the purchase of vaccines, the U.S. government has been instrumental in the ongoing global efforts to eradicate polio (Bristol, 2012). Amid the catastrophic COVID-19 pandemic, the United States should consider it a moral duty, as a leading nation and member of the G7/G20, to embrace its humanitarian legacy by re-engaging and leading on the international stage in support of lower-resourced nations.

CONCLUDING REMARKS

While the U.S. government works tirelessly to develop and eventually distribute safe and effective vaccines within its own borders, it is important to note that an inequitable distribution of vaccines among countries will ultimately fail to eliminate the risk of new outbreaks in the future. The U.S. government has made multiple large investments in a broad portfolio of COVID-19 vaccine partnerships. It is possible that several vaccines may succeed in achieving technical and regulatory success, including some that may not be included in the COVAX portfolio. It should be a matter of global health and national security that the United States embrace its long-held leadership role on the international stage and support ongoing global vaccine access strategies, such as the ACT-A and the COVAX Facility.

RECOMMENDATION 7. Support equitable allocation of COVID-19 vaccine globally.

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

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

REFERENCES

Bill & Melinda Gates Foundation. 2020. *COVID-19: A Global Perscpective. 2020 Goalkeepers Report*. https://www.gatesfoundation.org/goalkeepers/report/2020-report/?download=false#GlobalPerspective (accessed September 15, 2020).

Bristol, N. 2012. *The U.S. role in global polio eradication*. Washington, DC: Center for Strategic and International Studies. https://csis-website-prod.s3.amazonaws.com/s3fs-public/legacy_files/files/publication/121217_Bristol_USRolePolio_Web.pdf (accessed September 7, 2020).

Chinazzi, M., J. T. Davis, N. E. Dean, K. Mu, A. Pastore y Piontti, X. Xiong, M. E. Halloran, I. M. Longini, Jr., and A. Vespignani. 2020. Estimating the effect of cooperative versus uncooperative strategies of COVID-19 vaccine allocation: A modeling study. *NetSI*. https://www.networkscienceinstitute.org/publications/estimating-the-effect-of-cooperative-versus-uncooperative-strategies-of-covid-19-vaccine-allocation-a-modeling-study (accessed September 22, 2020).

CRS (Congressional Research Service). 2020. *Global economic effects of COVID-19*. https://fas.org/sgp/crs/row/R46270.pdf (accessed September 6, 2020).

European Commission. 2020a. *Coronavirus global response: 7.4 billion raised for universal access to vaccines*. https://ec.europa.eu/commission/presscorner/detail/en/ip_20_797 (accessed September 6, 2020).

European Commission. 2020b. *Coronavirus global response: Breakdown of the pledges made today in the "global goal" summit*. https://ec.europa.eu/commission/presscorner/detail/en/qanda_20_1216 (accessed September 6, 2020).

European Commission. 2020c. *Coronavirus: Commission continues expanding future vaccines portfolio with new talks*. https://ec.europa.eu/commission/presscorner/detail/en/IP_20_1494 (accessed September 6, 2020).

Felter, C. 2020. *What is the world doing to create a COVID-19 vaccine?* Council on Foreign Relations. https://www.cfr.org/backgrounder/what-world-doing-create-covid-19-vaccine (accessed September 9, 2020).

Gavi, the Vaccine Alliance. 2019. *Advance market commitment for pneumococcal vaccines: Annual report 1 January–31 December 2019*. https://www.gavi.org/sites/default/files/document/2020/2019-Pneumococcal-AMC-Annual-Report.pdf (accessed September 6, 2020).

Gavi, the Vaccine Alliance. 2020a. *COVAX commitment agreements*. https://www.gavi.org/sites/default/files/covid/pr/COVAX_CA_COIP_List_COVAX_PR_V5.pdf (accessed September 22, 2020).

Gavi, the Vaccine Alliance. 2020b. *COVAX Facility explainer*. https://www.gavi.org/sites/default/files/covid/covax/COVAX_Facility_Explainer.pdf (accessed September 6, 2020).

Gavi, the Vaccine Alliance. 2020c. *COVAX, the ACT-Accelerator vaccines pillar: Insuring accelerated vaccine development and manufacture*. https://www.gavi.org/sites/default/files/covid/COVAX-Pillar-background.pdf (accessed September 6, 2020).

GPMB (Global Preparedness Monitoring Board). 2019. *A world at risk: Annual report on global preparedness for health emergencies*. https://apps.who.int/gpmb/assets/annual_report/GPMB_annualreport_2019.pdf (accessed September 6, 2020).

HHS (U.S. Department of Health and Human Services). 2020a. *Trump administration collaborates with Moderna to produce 100 million doses of COVID-19 investigational vaccine*. https://www.hhs.gov/about/news/2020/08/11/trump-administration-collaborates-with-moderna-produce-100-million-doses-covid-19-investigational-vaccine.html (accessed September 6, 2020).

HHS. 2020b. *U.S. government engages Pfizer to produce millions of doses of COVID-19 vaccine*. https://www.hhs.gov/about/news/2020/07/22/us-government-engages-pfizer-produce-millions-doses-covid-19-vaccine.html#:~:text=The%20U.S.%20Department%20of%20Health,vaccine's%20successful%20manufacture%20and%20approval (accessed September 6, 2020).

Johns Hopkins Bloomberg School of Public Health and Nuclear Threat Initiative. 2019. *Global health security index*. https://www.ghsindex.org/wp-content/uploads/2020/04/2019-Global-Health-Security-Index.pdf (accessed September 6, 2020).

Rockoff, J., and J. S. Hopkins. 2020. Novavax, J&J ink COVID-19 vaccine deals with U.K. for tens of millions of doses. *The Wall Street Journal*, August 14, 2020. https://www.wsj.com/articles/novavax-inks-covid-19-vaccine-deal-with-u-k-for-60-million-doses-11597381320 (accessed September 6, 2020).

U.S. Department of State. 2020. *The U.S. is leading the response to the COVID-19 pandemic and developing a vaccine*. https://www.state.gov/the-u-s-is-leading-the-response-to-the-covid-19-pandemic-and-developing-a-vaccine (accessed September 9, 2020).

Weintraub, R., A. Bitton, and M. L. Rosenberg. 2020. *The danger of vaccine nationalism*. Harvard Business Review. https://hbr.org/2020/05/the-danger-of-vaccine-nationalism (accessed September 6, 2020).

The White House. 2018. *National biodefense strategy*. https://www.whitehouse.gov/wp-content/uploads/2018/09/National-Biodefense-Strategy.pdf (accessed September 7, 2020).

Whiting, K. 2020. Coronavirus isn't an outlier, it's part of our interconnected viral age. *World Economic Forum*. https://www.weforum.org/agenda/2020/03/coronavirus-global-epidemics-health-pandemic-covid-19 (accessed September 6, 2020).

WHO (World Health Organization). 2005. *International Health Regulations (2005)*. Geneva, Switzerland: WHO. https://www.who.int/ihr/publications/9789241580496/en (accessed September 7, 2020).

WHO. 2020a. *The access to COVID-19 tools (ACT) Accelerator*. 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 September 6, 2020).

WHO. 2020b. *Access to COVID-19 tools (ACT) accelerator: A global collaboration to accelerate the development, production and equitable access to new COVID-19 diagnostics, therapeutics and vaccines*. https://www.who.int/publications/m/item/access-to-covid-19-tools-(act)-accelerator (accessed September 6, 2020).

WHO. 2020c. *ACT-Accelerator investment case: Invest now to change the course of the COVID-19 pandemic*. https://www.who.int/docs/default-source/coronaviruse/act-consolidated-investment-case-at-26-june-2020-(vf).pdf?sfvrsn=2f9386e4_2&download=true (accessed September 6, 2020).

WHO. 2020d. *Boost for global response to COVID-19 as economies worldwide formally sign up to COVAX Facility*. https://www.who.int/news-room/detail/21-09-2020-boost-for-global-response-to-covid-19-as-economies-worldwide-formally-sign-up-to-covax-facility (accessed September 22, 2020).

WHO. 2020e. *Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility*. https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility (accessed September 22, 2020).

WHO. 2020f. *Independent evaluation of global COVID-19 response announced*. https://www.who.int/news-room/detail/09-07-2020-independent-evaluation-of-global-covid-19-response-announced (accessed September 6, 2020).

Appendix A

Study Methods

At the request of the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health, the National Academies of Sciences, Engineering, and Medicine (the National Academies) convened the Committee on Equitable Allocation of Vaccine for the Novel Coronavirus. In addressing its charge and preparing its final report, the committee pursued several avenues for information collection and analysis. In addition to conducting a review of the relevant literature, the committee held eight virtual meetings, three of which included open public sessions that incorporated remarks from and discussion between invited stakeholders and experts. Midway through the study process, the committee released *Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine*, which was open for written public comment over the 4-day period September 1–4, 2020. As part of the public comment period, the committee also held a 5-hour public listening session on September 2, 2020, to hear oral comments from members of the public. This appendix describes the committee's study process in detail, including a summary of the written public comments received by the committee and copies of the three open session agendas.

MEETINGS AND INFORMATION-GATHERING ACTIVITIES

The committee held eight virtual meetings from mid-July 2020 through September 2020. The first and third meetings included portions open to the public. The committee also hosted a separate public listening session. The agendas for these open sessions are included at the end of this appendix. The remaining meetings were held entirely in closed session.

To inform its deliberations, the committee gathered information through a variety of mechanisms: (1) reviews of the literature on previous allocation efforts; (2) the first and third committee meetings, which included sessions open to the public; and (3) an open public comment period to solicit written and oral comments on the discussion draft of the committee's framework. All written information provided to the committee from external sources is available by request through the National Academies' Public Access Records Office.

Literature Review

The National Academies' staff conducted targeted searches of literature and fast-breaking research to ensure both adequate background knowledge of key issues as well as the latest developments in coronavirus disease 2019 (COVID-19)-related science. Other targeted literature reviews were conducted iteratively and as needed as novel issues arose throughout the committee's deliberations and authoring of the report, given the rapidly evolving nature of work around COVID-19. This research process ensured that the committee and staff were monitoring both ongoing developments regarding COVID-19 and progress regarding COVID-19 vaccines.

Open Sessions

The first meeting's open session provided an opportunity for the committee to hear the sponsors' perspectives on the charge and scope of the study. This session afforded the members the chance to engage in conversation regarding anticipated challenges, points of clarification, and to define the project's boundaries. The committee was also able to hear from a representative from the Advisory Committee on Immunization Practices (ACIP), a key stakeholder, implementer, and beneficiary of the report's recommendations.

The third meeting's open session served to provide updates relevant to the project's topical landscape and to hear from experts who could inform the committee's thinking and framing of key topics. The committee heard from stakeholders representing ongoing vaccine initiatives, local and state health department officials, those speaking about ensuring public trust and equity, and experts using statistical modeling to inform vaccine efforts in different scenarios given the innumerable unknowns and variables.

PUBLIC COMMENT PERIOD

The committee made available a discussion draft of its framework to obtain input from members of the public, especially groups disproportionately affected by COVID-19, to inform the committee's final report.

Between September 1 and September 4, 2020, the committee conducted its public comment period which consisted of written and oral comment opportunities.

The *Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine*[1] was posted on the National Academies Press (NAP) website at 12:00 p.m. ET on September 1, 2020. Written comments were accepted through an online form until 11:59 p.m. ET on September 4, 2020. In addition, the committee hosted a public listening session from 12:00 p.m. to 5:00 p.m. ET on September 2, 2020. Beyond the formal public comment period, members of the public were able to submit comments through a link on the study webpage[2] or through a designated e-mail address for the duration of the study.

Outreach Strategy

Two overarching goals informed outreach strategies during the public comment period: (1) obtain input from members of the public, especially groups disproportionately affected by COVID-19, to inform the committee's final report and (2) convey the inclusiveness of the committee's process to foster trust and engagement around the final report.

The formal public comment period was announced on August 27, 2020, 5 days in advance of posting the discussion draft. The announcement consisted of a comprehensive overview of written and oral comment opportunities[3] posted on the study webpage, as well as an e-mail[4] sent to listservs maintained by the National Academy of Medicine (NAM); the Health and Medicine Division (HMD) of the National Academies; and NAP.[5] In addition, the announcement was posted on NAM, HMD, and National Academies social media platforms (Twitter, Facebook, and LinkedIn), including a paid, "boosted" Facebook post using internal National Academies funds. Finally, the National Academies issued a media advisory,[6] which was also distributed among congressional and government contacts.

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[1] See https://www.nap.edu/catalog/25914 (accessed September 15, 2020).

[2] See https://www.nationalacademies.org/our-work/a-framework-for-equitable-allocation-of-vaccine-for-the-novel-coronavirus (accessed September 15, 2020).

[3] See https://www.nationalacademies.org/our-work/a-framework-for-equitable-allocation-of-vaccine-for-the-novel-coronavirus/announcement/public-comment-opportunities (accessed September 15, 2020).

[4] See https://mailchi.mp/nam.edu/vaccineframeworkpublicommentopportunities (accessed September 15, 2020).

[5] NAM, HMD, and NAP are entities within a single organization, the National Academies of Sciences, Engineering, and Medicine, whose legal name is the National Academy of Sciences.

[6] See https://www.nationalacademies.org/news/2020/08/national-academies-to-seek-public-comment-hold-listening-session-on-draft-framework-for-equitable-allocation-of-a-covid-19-vaccine-week-of-aug-31 (accessed September 15, 2020).

A list of more than 300 stakeholder organizations was developed across the following focus areas: racial/ethnic minority populations, urban and rural populations, health care providers and public health workers, essential workers across a variety of industries, individuals with disabilities, individuals with serious illness and other health conditions, older adults, immigrants, LGBTQ+ individuals, incarcerated and homeless individuals, veterans and active service members, faith groups, community groups, and others. Representatives from these organizations received a personal e-mail or phone call from NAM staff alerting them to the public comment opportunities between August 27 and September 1, 2020.

At 12:00 p.m. ET on September 1, 2020, the discussion draft was posted on an NAP webpage[7] as a free PDF for download or electronic file for in-browse reading. A prominent announcement on the page encouraged visitors to submit written comments using a simple online form available from the webpage. A second e-mail[8] was sent to NAM, HMD, and NAP listservs, and an alert was posted on NAM, HMD, and National Academies social media platforms (including a second "boosted" Facebook post). The National Academies issued a press release,[9] which was also distributed among congressional and government contacts. On September 4, 2020, at 9:00 a.m., a final e-mail[10] was sent to NAM, HMD, and NAP listservs notifying audiences that it was the final day of the formal public comment period. The written comment form was removed from the NAP website at 12:00 a.m. ET on September 5, 2020.

Public Listening Session

On September 2, 2020, from 12:00 p.m. to 5:00 p.m. ET, the committee hosted a public listening session via Zoom. NAM president Victor Dzau provided a welcome, and committee co-chairs William Foege and Helene Gayle presented an overview of the committee's process and discussion draft. Next, public commenters representing minority communities, state and local government and health care, health and medical professional organizations, older adults, occupational risk groups, special populations (such as children and homeless individuals), and groups representing additional considerations from groups such as pharmacists and other public

[7] See https://www.nap.edu/catalog/25914 (accessed September 15, 2020).

[8] See https://mailchi.mp/nam.edu/vaccineframeworkpublicommentopportunities-667026 (accessed September 15, 2020).

[9] See https://www.nationalacademies.org/news/2020/09/national-academies-release-draft-framework-for-equitable-allocation-of-a-covid-19-vaccine-seek-public-comment (accessed September 15, 2020).

[10] See https://mailchi.mp/nam.edu/vaccineframeworkpublicommentopportunities-667034 (accessed September 15, 2020).

health stakeholders delivered oral comments directly to the committee during 5-minute, pre-assigned time slots. At the end of the session, all members of the public were given an opportunity to speak if desired. This session afforded the committee the opportunity to hear feedback on various components of the discussion draft of the report to ensure multiple perspectives were taken into consideration and that any recommendations would be feasible and actionable on the ground. Slides and a recording of the session are available from the National Academies website.[11] A total of 55 people delivered oral comments at the public listening session, which was also attended by a total of 2,432 people.

Written Comments

Between September 1 and 4, 2020, the committee also accepted written comments on its discussion draft through an online form. During this period, a total of 1,403 comments were received via the online comment form, in addition to 12 comments received via e-mail or the comment link on the study webpage. Comments were submitted on behalf of an organization (410 submissions, 29 percent) or on behalf of an individual (993 submissions, 71 percent). Of those who indicated that they were submitting comments on behalf of an organization, the majority indicated that they were associated with a nonprofit organization, advocacy group, or health care organization. A majority of the comments addressed issues associated with the priority populations, foundational principles and criteria, vaccine safety and efficacy, and health disparities. All materials and comments received through the online form were placed in the committee's Public Access File and are available by request through the National Academies' Public Access Records Office.

Summary of Comments and Revisions Made in Response to the Comments

Summary of Comments on Lessons Learned from Other Allocation Efforts

- Suggest inclusion of a discussion on the 2009 Institute of Medicine (IOM) crisis standards of care (CSC) report *Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations: A Letter Report.*

[11] See https://www.nationalacademies.org/event/09-02-2020/public-listening-session-discussion-draft-of-the-preliminary-framework-for-equitable-allocation-of-covid-19-vaccine (accessed September 15, 2020).

- Consider including a lesson learned from the 2013–2016 Ebola epidemic about the issues with vaccinating pregnant women.
- Revise the description of World Health Organization (WHO) activities.

Committee Response

- The committee added a discussion on the 2009 IOM CSC report, revised the language on vaccine allocation decisions for pregnant and breastfeeding women in the 2013–2016 Ebola epidemic, and revised the description of WHO's activities.

Summary of Comments on Foundational Principles and Goal

- Clarify the issue of the principles being unranked, but the goal appearing to focus only on maximization of benefits.
- Be more explicit about the inclusion of people with mental and physical disabilities.
- The draft appropriately does not recommend that individuals be prioritized based on years of remaining life. The final report should expressly reject remaining life-years as an allocation principle.
- The draft does not address the issue of conflicting principles and how those conflicts were resolved and decisions justified.
- Be explicit that fairness turns on equal access—and right now, there is not equal access for many in communities of color.
- Consider how the committee can resolve problems of procedural justice in creating its proposal.

Committee Response

- The committee revised the goal statement to clarify that it is not ranking maximization of benefits higher than the other principles, made more mention of those with disabilities, explicitly mentioned that the committee does not invoke life-years in its allocation framework for this pandemic, and added several statements throughout to justify the decisions that were made. The issue of procedural justice is addressed explicitly in Chapter 6 on risk communications and community engagement.

Summary of Comments on the Risk-Based Allocation Criteria

- Consider clarifying that while all have equal worth, all individuals do not have equal risk, nor do they pose equal risk to others.

- Consider whether to include the risk of transmitting infection to others.
- Refine and revise Table 3-2: Applying the Allocation Criteria to Specific Population Groups. Comments for consideration:
  - Quantitative analysis is urgently needed to evaluate whether the framework outlined in this table actually is consistent with the principle that it will maximize benefit in terms of saving lives.
  - Markers of inequity could be explicitly added as allocation criteria. For example, a criterion for "risk of experiencing significant economic harm from infection" would capture those who are uninsured or underinsured, as well as those who are likely to be harmed the most by long-term infections, missed work, or lengthy hospital stays.
  - Older adults in congregate settings are coded in the draft table as having a low risk of transmitting the infection. This appears to be an error given the clusters of infection in long-term care.
  - The designation M used in the table is ambiguous meaning either "a heterogeneous group" or "one whose typical member bears medium risk." The M designation should be defined unambiguously.
  - The allocation criteria should be applied consistently so as to prevent the bias associated with certain population groups (such as incarcerated or unhoused persons) from undermining both the equity-promoting potential of the framework as well as the public's perception of the framework's equity.

Committee Response

- The committee added additional narrative before the table to clarify and describe how the committee applied and interpreted the ratings in the table. The committee clarified the M rating, revised several ratings for population groups, and clarified that within each phase, the population groups are of similar priority. The committee did not remove the risk criterion of transmitting infection to others.

Summary of Comments on the Allocation Phases

- In general, a majority of the comments were supportive of the phases and most of the comments asked for additional clarity in defining specific population groups within phases and also additional clarity on the intersectionality of the population groups.
- Specific population groups that required additional clarification included:

- High-risk workers in health care facilities
  - Consider inclusion of dentists/dental professionals, pharmacists, plasma and blood donation workers, public health workers and nurses, ombudsmen, death care professionals, and those individuals distributing or administering the vaccine especially in at-risk areas.
  - Consider an expansive definition of the health care workforce, one comprehensive as to type of worker and care setting—family caregivers or community-based workers who take care of high-risk populations.
- First responders
  - Adopt a formal definition for first responders.
- Comorbid conditions/rare diseases
  - There is a need for definitional clarity around the difference between significant morbidity versus moderate morbidity and what the impact of multiple comorbid conditions play.
  - Consider expanding "underlying condition" to include environmental, societal, and communal conditions.
  - Epidemiological studies show that adverse outcomes from COVID-19 are overwhelmingly related to age, with comorbidities having a modest effect in comparison.
  - Consider why type 1 and type 2 diabetes are placed in different phases.
  - Consider adding some language around rare diseases: spinal muscular atrophy; congenital heart defect; spleen disease; microscopic polyangiitis.
- Older adults living in congregate or overcrowded settings
  - Consider whether it is more equitable to include all individuals (or at least all older adults) in other congregate settings, such as temporary farmworker housing, jails, prisons, detention facilities, and shelters, in the same phase.
  - Specifically include those who live in federal or subsidized housing.
  - Clarify distinctions between those in independent living facilities, assisted living facilities, memory care, and others.
- Critical workers in high-risk settings
  - Need to carefully define who is an essential worker in Phase 2 and Phase 3. These designations should be aligned with h
  - For essential workers, consider including COVID-19 vaccine manufacturing workers, persons who are employed in all public utilities (gas, electricity, water, the power grid, sewage management, Internet function, telecommunica-

tions, gasoline distribution), public transit, postal service, delivery/shipping (trucking and air)/port workers, classified personnel, taxi/rideshare drivers, farm, fish, and food system workers, and construction and engineering.
    - Teachers and school staff
        - Use the broadest description of school staff, which includes classroom teachers, librarians, and administrators; paraeducators, custodial staff, and other education support professionals; nurses and other specialized instructional support personnel; and the faculty and other staff in institutions of higher education.
        - Consider the addition of university professors.
    - Homeless shelters or group homes and staff
        - Be more explicit about those with mental health conditions and disabilities in these settings and others.
        - Clarify whether older adults in these settings would be included in Phase 1b.
    - Incarcerated/detained people and staff
        - Clarify whether older adults in these settings would be included in Phase 1b.
- Consider more explicit inclusion of multi-generational homes of those at high-risk or their families for Phase 1 recipients.
- Clarify whether those previously infected with COVID-19 would be vaccinated.
- Clarify the state flexibility in applying the phases and the practical considerations in transitioning from phase to phase.

Committee Response

- The committee added language throughout the chapter on the intersectionality considerations. The committee also added additional language on the practicality considerations of transitioning between phases and the uncertainties on whether those previously infected with COVID-19 would be vaccinated.
- The committee also made its best effort, within reason, to clarify population groups and address the concerns raised in the comments.
- The committee did not include university professors within the teachers' category in Phase 2 because of the differences in remote learning for children versus young adults and other mitigating factors.
- The committee did not include a complete list of all critical workers in high-risk settings. But, it added language that it would be useful for public health agencies, including CDC, the Occupational

Safety and Health Administration, the Mine Safety and Health Administration, and state and local public health agencies, to provide additional guidance in the designation of jobs and occupations in this group. These designations should consider how states and local governments have defined them.

- Additionally, the concerns regarding lack of clarity around the comorbid conditions population groups are valid, but without additional information at this time, the committee suggests that ACIP and CDC should play a key role in assessing relevant evidence on this topic.

Summary of Comments on Equity

- In general, a majority of the comments were supportive of the use of a vulnerability index such as the Social Vulnerability Index (SVI). However, there were issues raised about how the committee proposed operationalizing the SVI and whether such a proposal was practical and feasible.
- Call out race and ethnicity more explicitly, if possible, and acknowledge the heterogeneity of certain population groups.
- Use the term cultural competency in the report.
- Explicitly include the Native Hawaiian and Pacific Islander population when discussing those populations disproportionately impacted by COVID-19.
- Consider whether population-based allocation appears to complicate allocating according to the report's principal framework. It could mean that states with larger populations that are disadvantaged on the SVI receive relatively fewer vaccines than those with smaller populations. Insofar as state-level quotas are addressed, it would therefore seem more consistent with the main approach to vary a state's quota not simply by populations sizes, but by its overall score on a measure of disadvantage.

Committee Response

- The committee added additional language on how it envisions entities operationalizing the SVI and also added language indicating that entities should use the SVI or another more specific vulnerability index.
- The committee proposed one exception to a straightforward population-based approach to the allocation of vaccine, which 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 (identified through a vulnerability index, such as the SVI or the COVID-19 Community Vulnerability Index) or epidemiological "hot spots."
- The committee added stronger language throughout the report regarding race and ethnicity, and particularly in Chapter 1.
- The committee added the term cultural competency in Chapter 6 on risk communication and community engagement and explicitly discussed the impact of COVID-19 on the Native Hawaiian and Pacific Islander population in Chapter 1 and throughout the report.

Summary of General Considerations

- Numerous comments highlighted key implementation considerations that were not part of the final draft including coordination, distribution, administration, funding/costs/compensation, monitoring and evaluation, data collection, informed consent, use of existing systems, outreach and patient education, technology, communication, and public engagement.

Committee Response

- The committee closely reviewed the many implementation-related suggestions as they developed their final report and recommendations.

PUBLIC AGENDAS

Committee on Equitable Allocation of Vaccine for the Novel Coronavirus

First Committee Meeting Public Agenda

Friday, July 24, 2020
4:30 p.m.–5:30 p.m. ET
Zoom Webinar

Meeting Objective

Hold an open session to hear from sponsoring agencies on their perspectives of the Statement of Task.

Friday, July 24, 2020

OPEN SESSION

SESSION **Sponsor Briefing: Discussion of the Committee's Charge**

4:30 p.m. **Welcome and Introductions**

Victor Dzau
President
National Academy of Medicine

William Foege, *Committee Co-Chair*
Presidential Distinguished Professor of International Health (*Emeritus*)
Rollins School of Public Health
Emory University

Helene Gayle, *Committee Co-Chair*
President and Chief Executive Officer
The Chicago Community Trust

4:45 p.m. **Sponsor Perspective on Charge to the Committee**

Francis Collins, *Sponsor*
Director
National Institutes of Health

Jay Butler, *Sponsor*
Deputy Director for Infectious Diseases
Centers for Disease Control and Prevention

5:00 p.m. **Presentation from the Advisory Committee on Immunization Practices**

José Romero
Chair
Advisory Committee on Immunization Practices

5:10 p.m. **Discussion with Committee**

5:30 p.m. **ADJOURN OPEN SESSION**

Third Committee Meeting Public Agenda

Friday, August 7, 2020
3:15 p.m.–6:15 p.m. ET
Zoom Webinar

Meeting Objective

Hold an open public session to hear from experts who can inform the committee's thinking and framing of key topics such as updates on relevant COVID-19 work, downstream allocation and distribution considerations, and modeling needs.

DAY 1—Friday, August 7, 2020

OPEN SESSION

3:15 p.m. **Welcome and Introductions**

WILLIAM FOEGE, *Committee Co-Chair*
Presidential Distinguished Professor of International Health (*Emeritus*)
Rollins School of Public Health
Emory University

HELENE GAYLE, *Committee Co-Chair*
President and Chief Executive Officer
The Chicago Community Trust

SESSION I Updates from Relevant Ongoing SARS-CoV-2 Vaccine Activities

3:20 p.m. **Operation Warp Speed Update: Understanding the SARS-CoV-2 Vaccine Development and Procurement Landscape in the United States**

MONCEF SLAOUI
Chief Advisor
Operation Warp Speed

3:30 p.m. **Discussion with Committee**

3:40 p.m. **Ethics and Process Considerations: A Perspective from the WHO SAGE Working Group on COVID-19 Vaccines**
Ruth Faden
Founder and Philip Franklin Wagley Professor of Biomedical Ethics
Berman Institute of Bioethics
Johns Hopkins University
Member, WHO SAGE Working Group on COVID-19 Vaccines

3:50 p.m. **Discussion with Committee**

SESSION II Downstream Allocation and Distribution Considerations

4:00 p.m. **Health Department Perspectives: Learning from Past Experience and Understanding Current Needs**
Cara Christ
Director
Arizona Department of Health Services

Ngozi Ezike
Director
Illinois Department of Public Health

4:20 p.m. **Discussion with Committee**

4:40 p.m. **Ensuring Public Trust and Equity in SARS-CoV-2 Vaccine Efforts**
Monica Schoch-Spana
Senior Scholar, Johns Hopkins Center for Health Security
Senior Scientist, Department of Environmental Health & Engineering
Johns Hopkins Bloomberg School of Public Health
Co-Lead and Author, *The Public's Role in COVID-19 Vaccination*

Steven Wakefield
Former External Relations Director (*Retired*)
HIV Vaccine Trials Network
Fred Hutchinson Cancer Research Center

Julie Morita
Executive Vice President
Robert Wood Johnson Foundation

5:00 p.m. **Discussion with Committee**

SESSION III Modeling for SARS-CoV-2 Vaccine Scenarios

5:20 p.m. **Using Infectious Disease Dynamics to Inform Prioritization Efforts**

Marc Lipsitch
Professor of Epidemiology
Department of Epidemiology
Department of Immunology and Infectious Diseases
Director, Center for Communicable Disease Dynamics
Harvard T.H. Chan School of Public Health

Ali Mokdad
Chief Strategy Officer, Population Health
Director, Middle Eastern Initiatives
Professor, Health Metrics Sciences
Institute for Health Metrics and Evaluation, School of Medicine
University of Washington

5:40 p.m. **Discussion with Committee**

SESSION IV Concluding the Workshop

6:00 p.m. **Open Discussion with Panelists**

6:10 p.m. **Workshop Synthesis and Conclusions**

William Foege, *Committee Co-Chair*
Presidential Distinguished Professor of International Health (*Emeritus*)
Rollins School of Public Health
Emory University

Helene Gayle, *Committee Co-Chair*
President and Chief Executive Officer
The Chicago Community Trust

6:15 p.m. **ADJOURN OPEN SESSION**

Public Listening Session on *Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine*

September 2, 2020
12:00 p.m.–5:00 p.m. ET
Zoom Webinar

Meeting Objectives

- Led by the committee co-chairs, review *Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine*.
- Hear from previously identified members of the public for feedback on various components of *Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine*.
- Hold an open public comment period between members of the public and members of the committee.

Wednesday, September 2, 2020

OPEN SESSION

12:00 p.m. **Welcome and Introductions**

Victor Dzau
President
National Academy of Medicine

William Foege, *Committee Co-Chair*
Presidential Distinguished Professor of International Health (*Emeritus*)
Rollins School of Public Health
Emory University

Helene Gayle, *Committee Co-Chair*
President and Chief Executive Officer
The Chicago Community Trust

SESSION I Overview of *Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine*

12:10 p.m. **Presentation by Committee Co-Chairs**
WILLIAM FOEGE, *Committee Co-Chair*
Presidential Distinguished Professor of International Health (*Emeritus*)
Rollins School of Public Health
Emory University

HELENE GAYLE, *Committee Co-Chair*
President and Chief Executive Officer
The Chicago Community Trust

SESSION II Public Comment Period with Confirmed Speakers

12:20 p.m. **Public Comment Period: Minority Communities**
Randall Morgan, W. Montague Cobb/NMA Health Institute
Elizabeth Ofili, Association of Black Cardiologists
Ellen Provost, Alaska Native Tribal Health Consortium EpiCenter
Elena Rios, National Hispanic Medical Association
Jim Roberts, Alaska Native Tribal Health Consortium
Winston Wong, National Council of Asian Pacific Islander Physicians

12:50 p.m. **Public Comment Period: State and Local Government and Health Care**
Oscar Alleyne, National Association of County & City Health Officials
David Gerstner, Dayton (OH) Metropolitan Medical Response System
Syra Madad, NYC Health + Hospitals (NY) (Individual)
Aaron Payment, Chairperson, Sault Ste. Marie Tribe of Chippewa Indians
Marcus Plescia, Association of State and Territorial Health Officials
Christian Ramers, Family Health Centers of San Diego (CA)
Umair Shah, Harris County (TX) Public Health

1:25 p.m. **BREAK**

1:40 p.m. **Public Comment Period: Health and Medical Professional Organizations**
Claire Hannan, Association of Immunization Managers
Michelle Hood, American Hospital Association
Anthony Hsu, American College of Emergency Physicians
Scott Knoer, American Pharmacists Association
Kathleen O'Laughlin, American Dental Association

2:05 p.m. **Public Comment Period: Older Adults**
Louise Aronson, University of California, San Francisco (Individual)
Timothy Farrell, American Geriatrics Society
Brendan Flinn, LeadingAge
Nicole Lynch, VOYCE
Mark Parkinson, American Health Care Association/ National Center for Assisted Living
David Schless, American Seniors Housing Association
Chad Worz, American Society of Consultant Pharmacists

2:40 p.m. **Public Comment Period: Occupational Risk**
Debbie Berkowitz, National Employment Law Project
Scott DiMauro, National Education Association/Ohio Education Association
Alexis Guild, Farmworker Justice
Gary Ludwig, International Association of Fire Chiefs
Peter Matz, Food Industry Association
Rebecca Reindel, AFL–CIO
Mily Trevino-Sauceda, Alianza Nacional de Campesinas
Randi Weingarten, American Federation of Teachers

3:20 p.m. **BREAK**

3:30 p.m. **Public Comment Period: Special Populations**
Alleanne Anderson, SchoolHouse Connection
Gabriella Barbosa, Children's Partnership
Chandra Crawford, National Alliance to End Homelessness
Charles Lee, American College of Correctional Physicians
Karen Mountain, Migrant Clinicians Network
Oluwaferanmi Okanlami, University of Michigan (Individual)
Amy Pisani, Vaccinate Your Family

4:05 p.m. **Public Comment Period: Additional Considerations**
Georges Benjamin, American Public Health Association
Paul Conway, American Association of Kidney Patients
Nicole Cruz, California State University, East Bay (Individual)
Anna Legreid Dopp, American Society of Health-System Pharmacists
Ann Kimball, Rotary (Individual)
Harald Schmidt, University of Pennsylvania (Individual)
Lynlee Swartz, Body Politic (Individual)

SESSION V Open Public Comment Period with the General Public

4:40 p.m. **Open Public Comment Period with the General Public**

5:00 p.m. **Closing Comments from Co-Chairs and Adjourn Meeting**

Appendix B

Committee and Staff Biosketches

COMMITTEE MEMBERS

William H. Foege, M.D., M.P.H. (*Co-Chair*), is the Presidential Distinguished Professor of International Health (emeritus), Rollins School of Public Health, Emory University. Dr. Foege, an epidemiologist, worked in the successful campaign to eradicate smallpox in the 1970s. Dr. Foege became chief of the Centers for Disease Control and Prevention's (CDC's) Smallpox Eradication Program, and was appointed the director of 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, the United Nations Development Programme, and The Rockefeller Foundation. Dr. Foege served The Carter Center between 1986 and 1992 as its executive director, fellow for health policy, and executive director of Global 2000. Between 1992 and 1999, he contributed to the Center's work as a fellow and as the executive director of the Task Force for Child Survival and Development. Between 1999 and 2009, Dr. Foege served as the senior medical advisor for the Bill & Melinda Gates Foundation.

Helene D. Gayle, M.D., M.P.H. (*Co-Chair*), has been the president and the 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 the president and the 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, the 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, New York. 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 a 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 health care 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 she

has served on several Institute of Medicine committees. Professor Brandeau earned a B.S. in mathematics and an M.S. in operations research from the 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 School of Nursing. 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 the associate director of Penn's Center for Health Incentives and Behavioral Economics, as well as the associate director of Penn's National Clinician Scholar Program, and the 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 Law School, 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 to 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 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 with several National Academies of Sciences, Engineering, and Medicine efforts, 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 a university professor (emeritus) and formerly the John Allen Hollingsworth Professor of Ethics, a professor of religious studies, and a professor of research in medical education at the University of Virginia. Dr. Childress also served as the Joseph P. Ken-

nedy, Sr., Professor of Christian Ethics at the Kennedy Institute of Ethics at Georgetown University and is 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 eighth edition and translated into several languages. Dr. Childress was the vice chair of the national Task Force on Organ Transplantation, and he has served on the boards 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 the dean and the 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 Centers for Disease Control and Prevention's Community Preventive Services Taskforce. She has received the Wade Hampton Frost Award for her contribu-

tions 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 in 2009.

Abigail Echo-Hawk, M.A., is an enrolled citizen of the Pawnee Nation of Oklahoma. She is currently the chief research officer at the Seattle Indian Health Board and the director of the 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. These include 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 the Data for Indigenous Justice board. In the past, Ms. Echo-Hawk spent 8 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, which 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, in 2010 she began working in research on health disparities and achieving health equity. 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 bidirectional and grounded in health equity principles. In her current role as the director of the Urban Indian

Health Institute (UIHI), she directs the only national tribal epidemiology center, and they are conducting COVID-19 epidemiological surveillance with urban Indian health programs. In addition, UIHI is focused on health equity approaches to ensure 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. If used in an equitable manner, data are increasingly valued as a resource that represents opportunities for improving community well-being and health outcomes. 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 coauthor of several manuscripts in development.

Christopher Elias, M.D., M.P.H., is the president of the Global Development Division at the Bill & 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 that 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 primary health care systems. Dr. Elias's 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. Dr. Elias 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 the National Academy of Medicine. He is the past president of the Society for Judgment and Decision Making and of the Society for Risk Analysis. He has chaired the U.S. Food and Drug Administration Risk Communication Advisory Committee and has been a member of the Eugene (Oregon) Commission on the Rights of Women, the U.S. 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, the Society of Experimental Psychologists, and the 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 served on many National Academies of Sciences, Engineering, and Medicine committees and chaired or co-chaired three National Academies colloquia on the Science of Science Communication and its committees on applying decision science to intelligence analysis, and on foundational science for cybersecurity.

David Michaels, Ph.D., M.P.H., is an epidemiologist and a professor of environmental and occupational health at the Milken Institute School of Public Health of The George Washington University. He served as the assistant secretary of labor for the Occupational Safety and Health Administration from 2009 to 2017, the longest-serving person in the agency's history. From 1998 to 2001, Dr. Michaels was the 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's 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; the American Public Health Association's David P. Rall Award for Advocacy in Public Health; and the John P. McGovern Science and Society Award given by Sigma Xi, the Scientific Research Society. 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 received his Ph.D. and M.P.H. from Columbia University and his B.A. from the City College of New York.

Jewel Mullen, M.D., M.P.H., M.P.A., FACP, is the associate dean for health equity and an associate professor of population health and internal medicine at The University of Texas at Austin Dell Medical School, as well as the 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 Centers for Disease Control and Prevention's *Morbidity and Mortality Weekly Report* editorial board, the Robert Wood Johnson Foundation's Policies for Action National Advisory Committee, and the ChangeLab Solutions Board of Directors. She is a member of the COVID-19 Expert Advisory Panel for the City of Austin, Texas, and provides COVID-19-related consultation to the Carnival Corporation. Board certified in internal medicine, Dr. Mullen received her bachelor's degree and M.P.H. from Yale University, where she also completed a postdoctoral fellowship in psychosocial epidemiology. She graduated from the Mount Sinai School of Medicine, and completed her residency at the Hospital of the University of Pennsylvania. She also holds an M.P.A. from the Harvard University John F. Kennedy School of Government.

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 the Yale University Schools of Medicine and Public Health, and an adjunct professor at the 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 the epidemiology of respiratory viruses such as influenza, RSV, and more recently, SARS-CoV-2; 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 reemerging 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 United States, 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, the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria—Vaccine Innovation Working Group, the WHO Expert Advisory Group for Healthcare Worker Vaccination, and the Public Health Committee of the Infectious Diseases Society of America.

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 the Department of Health Policy and Management, the Johns Hopkins Bloomberg School of Public Health, and the Carey Business School. From 1996 to 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 to 2019 he served as the 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 trade-offs 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

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Sonja A. Rasmussen, M.D., M.S., is a 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 the director of UF's Precision Health Program, which focuses on the 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 she led CDC's Office of Public Health Preparedness and Response, an office with a $1.3 billion annual budget and more than 900 staff members, as acting director during the 2014 Ebola response. She has served as editor-in-chief of CDC's *Morbidity and Mortality Weekly Report* Series, the #1 journal in the field of epidemiology according to a number of citations, and as the director of the Division of Public Health Information Dissemination. Dr. Rasmussen was the lead author of the paper confirming that Zika virus is 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, 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. in medical genetics from the University of Wisconsin, and her M.D. with honors from UF. She completed her pediatrics residency at Massachusetts General Hospital and her fellowship in clinical genetics at Johns Hopkins and UF. Dr. Rasmussen is currently serving in a leadership role at UF 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 more than 240 peer-reviewed publications and is the lead editor of *The CDC Field Epidemiology Manual*, released by the Oxford University Press in 2019.

Arthur L. Reingold, M.D., is a professor and the 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 the 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. Previously, Dr. Tuckson served as the president of the American Telemedicine Association; a board member of the Arnold P. Gold Foundation, which is concerned with advancing humanism in medical care; a member of the Advisory Committee to the director of the National Institutes of Health (NIH); as chairman of the Secretary of Health's Advisory Committee on Genetics, Health and Society; on several U.S. government cabinet-level health advisory committees concerned with health reform, infant mortality, children's health, violence, and radiation testing; on the National Advisory Council for Complementary and Integrative Health of NIH; and 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. He currently serves on the board of directors of Cell Therapeutics, Inc., a public corporation concerned with the development of cancer pharmaceuticals; and he is a special advisor to the chief executive officer of ViTel Net, LLC, a leading innovator in telehealth solutions. Additionally, he is an elected member of the National Academy of Medicine, serving in a leadership position on the use of data and analytics in health care; as an advisory board member of the Johns Hopkins Berman Institute of Bioethics; and as a trustee of the Board of Howard University. He is a graduate of Howard University, the 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 the 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 the editor-in-chief of Springer's upcoming textbook, *Geriatric Medicine: A Person Centered Evidence Based Approach*. He previously served as the 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 the 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 he sold it in 2010. In the 1990s he was the president and the 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*, Dr. 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, 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.

STAFF

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 a senior program analyst for public health preparedness and environment health at the National Association of County & 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 Centers for Disease Control and Prevention 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, and the impacts 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.

Benjamin Kahn, M.P.H., is an associate program officer on the Board on Health Sciences Policy (HSP) and 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. Mr. Kahn 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., Mr. Kahn also interned at the Coalition for Epidemic Preparedness Innovations, supporting the organization's work around vaccine development for COVID-19. Prior to his time at Johns Hopkins, Mr. Kahn spent 4 years working at the National Academies of Sciences, Engineering, and Medicine in research and project management, supporting a range of activities including several in HSP's health security and public health preparedness portfolios. Mr. Kahn received his B.A. in history and anthropology from the University of Michigan.

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

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Aurelia Attal-Juncqua, M.Sc., is an associate program officer on the Board on Health Sciences Policy with the Forum on Medical and Public Health Preparedness for Disasters and Emergencies. Prior to joining the National Academies of Sciences, Engineering, and Medicine, Ms. Attal-Juncqua worked for 3 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 health care and pharmaceutical industry in London, as well as a researcher for the World Health Organization 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 the Imperial College in London and an M.Sc. in control of infectious diseases from the London School of Hygiene & Tropical Medicine. Her main professional interests include biosecurity, capacity building for prevention and control of infectious diseases, and public health emergency preparedness and response.

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 4 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 B.A. in public health and public policy. She is particularly interested in the nexus between public health, intelligence, and national security and she plans to either pursue a degree in national security or enter the Foreign Service.

Rebecca Chevat is a senior program assistant in the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine.

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 U.S. Department of Homeland Security, where she examined public–private partnerships and their role on points of dispensing models during emergencies. Additionally, she is a national registered emergency medical technician. She plans to pursue her M.P.H. in global health.

Rose Marie Martinez, Sc.D., is the senior 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 effects 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 health care 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 6 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 M. Pope, Ph.D., is the senior 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 the 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.