

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

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Executive Summary

The novel coronavirus disease 2019 (COVID-19) pandemic will continue for the foreseeable future, but widespread vaccination could hasten its end. At least 165 candidate vaccines for the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus are in development around the world and there is hope that 1 or more of these candidates will soon be shown to be sufficiently safe and effective to achieve emergency use authorization in the United States. When a vaccine is authorized for use, it will initially be in limited supply. A plan is needed for how to allocate and distribute the limited supply during this period of scarcity—which groups should be prioritized to receive the vaccine first and which groups can wait until later. This difficult and potentially contentious topic is being actively discussed in the United States by the US Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) and the National Academy of Medicine, as well as globally by the World Health Organization and other organizations and governments. The purpose of this report is to offer an ethics framework that can be used to make decisions about the allocation of a SARS-CoV-2 vaccine during the initial period of scarcity in the United States and make related suggestions about vaccine distribution. Our approach considers factors such as medical risk, public health, ethics, equity, economic impact, and logistics. We note where our approach aligns with or differs from the 2018 CDC guidance for vaccine allocation in a severe influenza pandemic, which is the most recent pandemic vaccine guidance from the US government.

This report is the product of deliberations of a multidisciplinary team of public health experts at Johns Hopkins University, including members from the Johns Hopkins Bloomberg School of Public Health Center for Health Security, Center for Vaccine Research, and International Vaccine Access Center; the Johns Hopkins School of Medicine Armstrong Institute for Patient Safety and Quality; and the Johns Hopkins Berman Institute of Bioethics. The deliberations were informed by a review of available literature and open source government documents. We were not privy to proprietary or unpublished information that may be available to other groups considering these issues that could alter judgments about prioritization. We also acknowledge the evolving state of the evidence about pathogenesis and vaccine response. Therefore, our suggested priority groups should be viewed only as plausible examples of candidates for top tier prioritization when applying the framework, and not as definitive recommendations.

The intended audience for this report includes policymakers and technical experts in the US federal government currently working on vaccine allocation plans, those at the state and local levels who will be implementing allocation plans, and community leaders, activists, and the general public interested in influencing vaccine allocation decisions. The principal product of this report is an ethical framework to guide discussion and inform decisions about vaccine allocation.

The framework places emphasis on promoting the common good by promoting public health and by enabling social and economic activity. It also emphasizes the importance of treating individuals fairly and promoting social equity by, for example, addressing racial and ethnic disparities in COVID-19 mortality, and by recognizing the contributions of essential workers who have been overlooked in previous allocation schemes. The framework includes a third ethical value not often well-articulated in ethics discussions of vaccine allocation and whose importance we wish to elevate—the promotion of legitimacy, trust, and a sense of community ownership over vaccine policy—while respecting the diversity of values and beliefs in our pluralist society. We consider the ethical principles that should guide COVID-19 vaccine allocation and identify specific policy goals and objectives that should be based on these ethical principles.

In this report, we compare the implications of our framework to the prior CDC guidance for prioritization of pandemic influenza vaccine allocation and suggest candidate groups who should be given serious consideration for inclusion in the top allocation tier when vaccine availability is limited and in a second tier (those also prioritized before the general public) if/when more vaccine supply becomes available. We also discuss how COVID-19 vaccines should be distributed so as to reach these 2 tiers.

It is important to emphasize that we are not providing a set of definitive recommendations about who should be prioritized for vaccination. Rather, based on our ethics framework, we have identified candidate groups that should be given serious consideration as priority groups. Our team's use of our ethics framework to identify these groups is just an example of how ethical principles and objectives could be integrated to produce an ethically defensible list of candidate priority groups. Others who use our ethics framework to deliberate about vaccine allocation might emphasize certain ethical objectives over others, reaching different conclusions about which population groups should be offered vaccines first. It is important to highlight that the candidate priority groups that emerged through our use of the framework were based on currently available public information. At the time of this writing, many important uncertainties remain about key issues that need to be taken into account in priority setting. These include how well contained the pandemic virus is when a vaccine becomes available, whether there are effective therapeutics that substantially lessen the severity of the disease, how many doses of the vaccine are expected, and what the characteristics of the vaccine are, including available evidence on safety; effectiveness, with respect to both prevention of severe disease, death, and interruption of transmission; and performance in different population groups.

We hope that our framework will serve as a conceptual resource to inform public dialogue and deliberation about vaccine allocation. Promoting legitimacy, trust, and a sense of ownership over vaccine allocation—a core ethical value we discuss—requires facilitating input from the public and stakeholders and developing vaccine allocation and distribution strategies that address their cultures and concerns. For the purpose of this initial analysis, we have not engaged a broader set of constituents, but instead relied

upon the multidisciplinary team’s judgment. We encourage a timely national dialogue through multiple forms of community engagement appropriate to a physical distancing environment and hope that actual vaccine allocation decisions are based on the most comprehensive and inclusive process as possible and adhere to the highest possible standards.

Our suggestions for ethically defensible candidate groups are based on information available on August 1, 2020. Using our ethics framework and the information available to us, we suggest that at this point in time it would be ethically defensible to include the following groups as candidates for high priority access to scarce SARS-CoV-2 vaccine.

Tier 1:

- Those most essential in sustaining the ongoing COVID-19 response
- Those at greatest risk of severe illness and death, and their caregivers
- Those most essential to maintaining core societal functions

Tier 2:

- Those involved in broader health provision
- Those who face greater barriers to access care if they become seriously ill
- Those contributing to maintenance of core societal functions
- Those whose living or working conditions give them elevated risk of infection, even if they have lesser or unknown risk of severe illness and death

As new information becomes available, we will continue to consider whether the groups we currently suggest as candidates for Tier 1 and Tier 2 should be further specified or retain their priority status or whether new groups should be added. Among the new information we will monitor is evidence about the values, views, and concerns of social groups and wider public.

We also recognize that initial supply and subsequent pace of supply will likely be insufficient to be able to offer vaccine to everyone in our suggested Tier 1 and Tier 2 groups. Prioritization decisions will likely have to be made within tiers. Depending on the characteristics of the vaccine products and available evidence, these within-tier decisions may be made largely on public health grounds based on the available scientific evidence. For example, the available vaccine may not be sufficiently effective in older adults or evidence from trial data or modeling might not yet support a transmission interruption strategy. However, it is likely that within-tier prioritization decisions will also engage value trade-offs of the sort our ethics framework addresses. Using this framework can help decision makers assess which population groups have the strongest claims to limited doses of vaccine on the basis of greatest need, greatest overall benefit, or presence of multiple strong claims related to individual and public health.

Introduction

The novel coronavirus disease 2019 (COVID-19) pandemic will continue for the foreseeable future but widespread vaccination could hasten its end. Characteristics of the virus, the disease it causes, and the immunological response to infection all have consequences for the progress of the pandemic and the development and roll out of vaccines. Like all RNA viruses, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, is measurably mutating, albeit at a slower rate than many other viruses, and scientists are monitoring changes in sequence to see whether they correlate with changes to important characteristics such as infectivity, transmission efficacy, or antigenicity.¹ The nature of the immune response to SARS-CoV-2 infection is not completely understood. While many survivors make protective antibodies, the levels of antibodies greatly range, as not all survivors make antibodies, and the duration of the immune response is uncertain.² Other important factors also contribute to the body's immune response.² Some of these questions will be answered during clinical trials and testing of vaccine candidates.

Many candidate vaccines for the SARS-CoV-2 virus are in development, and there is hope that 1 or more of these candidates will soon be shown to be sufficiently safe and effective to achieve licensure or, more likely, emergency use authorization from the US Food and Drug Administration. When a vaccine is authorized for use, its supply is usually limited due to finite manufacturing capacity, the slower speed of some technologies, and the logistical challenges of distribution and administration of the vaccine. During the time between when the vaccine is authorized and it is widely available, a plan should be developed and broadly communicated to address which groups should be prioritized to receive the vaccine first and which groups can wait until more vaccine is available. The duration of this period will likely vary around the world. In wealthy countries like the United States, it may be a matter of months, but in low- and middle-income countries, this period could last much longer despite aggressive global efforts to have 2 billion doses available by the end of 2021.³

The purpose of this report is to recommend an approach for making allocation and distribution decisions about a SARS-CoV-2 vaccine during this initial period of scarcity in the United States based on considerations of medical risk, public health, ethics, equity, societal and economic impact, and logistics. We offer an ethics framework that can be used to identify priority groups for SARS-CoV-2 vaccine allocation, and use our framework to suggest groups, based on publicly available information, that would be ethically defensible to include as candidates for high-priority access to scarce SARS-CoV-2 vaccine. We note where our approach aligns with or differs from the 2018 Centers for Diseases Control and Prevention (CDC) guidance for vaccine allocation in a severe influenza pandemic,⁴ the most recently published US pandemic vaccine guidance. It is our hope that this report will inform the ongoing deliberations by the CDC Advisory Committee on Immunization Practices (ACIP) and the National Academy of Medicine, within the federal and state governments, and globally by the World Health Organization and other organizations and governments.

It is important to acknowledge that a critical difference between the current pandemic and the context envisioned in the 2018 guidance for pandemic influenza vaccine allocation is not only the epidemiological differences between COVID-19 and influenza, such as the higher rates of asymptomatic transmission and fatality risk, but also that we are currently in the midst of a national reckoning on racial injustice, prompted by cases of police brutality and murder. The structural racism that is the root cause of police brutality is also the root cause of the disproportionate impact of the current pandemic on people of color and people living in poverty. Although structural racism was as present in the 2018 and previous influenza epidemics as it is today, the general public acknowledgment of racial injustice was not. Longstanding societal and economic inequities and structural racism in health systems have been barriers to disadvantaged populations gaining access to healthcare, contributing to their lack of trust in governments and public health authorities to meet their needs. Furthermore, communities of color, particularly Black populations, may be more wary of officials responsible for vaccine-related decisions due to past medical injustices committed by authorities on Black communities.

Ongoing social discord that continues to divide the country along political fault lines has also played a role in perceived fairness and transparency related to vaccine allocation and potential differences in vaccine acceptance and uptake across populations. Lastly, as COVID-19 vaccines will arrive after a sustained period of social and economic disruption, many of the associated burdens will fall disproportionately on already disadvantaged communities.⁵ Past thinking and strategies regarding allocation of scarce vaccines and resources have not sufficiently addressed these longstanding inequities or their consequences for vaccine acceptance and uptake among the populations who most need the vaccine. New approaches are needed, and this crisis has created an opportunity for positive change.

The intended audience for this report includes policymakers and technical experts in the US federal government currently working on vaccine allocation plans, those at the state and local levels who will be implementing allocation plans, and community leaders, activists, and the general public interested in influencing vaccine allocation decisions. We apply our framework and identify candidate priority groups using currently available information, but there are many important uncertainties that could alter which groups should be seriously considered as priority groups, including how well contained the pandemic virus is when vaccine become available, whether there are effective therapeutics that substantially lessen the severity of the disease, how many doses of the vaccine are expected and by when, and what the characteristics of the vaccine are, including available evidence on its safety and effectiveness in different populations or age groups. As new information becomes available, judgments about priority may reasonably change; therefore, our suggestions for which groups should be considered in the top 2 tiers of the initial allocation are limited by time and evidence. As we learn more, we may recommend considering other groups for prioritization. This report is intended to be the first in a series of publications from this team that will address changing issues related to COVID-19 vaccine allocation as the pandemic evolves and we learn more.

In this report, we discuss vaccine allocation, distribution, and administration. By allocation, we mean the process of prioritizing some groups over others to receive vaccines first when availability is limited. When we talk about distribution, we mean the process of getting the vaccine to those identified priority groups. By administration, we refer to the act of injecting the vaccine into individuals.

Methods

This report is the product of deliberations of a multidisciplinary team of public health experts at Johns Hopkins University, including members from the Johns Hopkins Bloomberg School of Public Health Center for Health Security, Center for Vaccine Research, and International Vaccine Access Center; the Johns Hopkins School of Medicine Armstrong Institute for Patient Safety and Quality; and the Johns Hopkins Berman Institute of Bioethics. The deliberations were informed by a review of available literature and open source government documents.

The team based our deliberations on the following organizing principles:

- Any allocation plan should be transparent, well-reasoned, and use a process that would be deemed by most of the public to be fair.
- All approaches to allocation that are legally and ethically valid in the expert judgment of the project team should be considered, even if not all are eventually included.
- Vaccine distribution and logistical challenges and allocation prioritization should be considered. Distribution and logistics issues also have implications for other vaccines that may contribute to improved health status. Therefore, the entire vaccine distribution system should be considered.
- Issues of equity, including access to healthcare, should be considered in decisions about allocation and distribution.⁶
- Any allocation plan needs to be politically acceptable and feasible to implement.
- The shortage of vaccine will be temporary, therefore, the question is how best to use the vaccine in the window between when the vaccine is approved (or authorized) and when it is available to all who desire it.
- To the extent possible, we should consider research, analysis, and lessons learned from prior epidemics.
- It is important to articulate goals and reasoning behind our recommendation, as differences between various COVID-19 vaccines could influence allocation decisions.
- Communications, community outreach, and community engagement are essential elements of a successful vaccine campaign. Facilitating input from the public and stakeholders, developing vaccine allocation and distribution strategies that address their cultures and concerns, and clearly explaining concepts such as allocation have far-reaching implications. These factors not only affect COVID-19 vaccine uptake but also influence trust in government, public health, and healthcare systems, which, in turn, can influence uptake of other vaccines.⁷

- Vaccine allocations decisions can not only directly impact disease burden, they can also indirectly impact society and the economy.

We factored the following assumptions into our deliberations:

- More than 1 vaccine may be available at the same time. These vaccines may have different safety and efficacy profiles across different population groups and may have different logistical requirements.
- No vaccine is 100% effective. At this point, the effectiveness of whatever vaccine might be approved/authorized is uncertain, and we are not likely to know this for some time. The effectiveness of a vaccine can be defined by its ability to prevent infection, serious disease, and/or transmission. Some vaccines may be very effective at preventing disease but not as effective at blocking infection or further transmission. We assume that a vaccine that is approved or authorized will be at least 50% effective in preventing symptomatic infection.⁸ It is common for vaccines to be less effective in older adults—often a higher dose is required. Lack of a strong immune response in older adults could affect the allocation approach; for example, the emphasis may be on vaccinating caretakers rather than those being cared for.
- For certain high-risk groups, such as individuals with rare diseases or multiple comorbidities, limited evidence may be available from trials specific to the safety and efficacy of the vaccine in these groups. Depending on the risk-benefit assessment of a vaccine, it may be necessary to protect these at-risk individuals through indirect approaches such as vaccination of household members. Additionally, every effort must be made to ensure that they are up-to-date on any other recommended vaccines.
- There is a lag from the time of vaccine administration to the production of a robust immune response, and some vaccines may require more than 1 dose to provide sufficient immune protection. For some vaccines, some minimal immunity may begin approximately 2 weeks after the first dose, but maximal immunity may not be achieved for 2 to 4 weeks after the second dose. Depending on the dosing regimen and schedule, it may take as long as 6 to 8 weeks for immunized individuals to realize the full benefits of a given vaccine following the first injection. Therefore, even with a highly effective vaccine, breakthrough infections of the virus may occur among immunized or partially immunized individuals in the first 2 months after they have been vaccinated. It is also possible that immunity induced by a vaccine may be short lived, lasting only several months to a few years. If this is the case, frequently repeated vaccination may be needed.
- There are over 165 vaccine candidates being developed around the world, and US Operation Warp Speed is focusing on a limited number of these. Each candidate will have a different safety and efficacy profile.⁹

- The ultimate safety of an approved vaccine is not completely knowable until it has been administered to millions of people. During clinical trials, tens of thousands of individuals will receive the vaccine but that may fail to show safety concerns that occur with less frequency, such as 1 in a million. This can be a concern for particularly severe adverse effects. It is also possible that certain adverse effects may occur more frequently in certain population subgroups, which may not be apparent until millions are vaccinated. The Vaccine Adverse Event Reporting System and other pharmacovigilance systems will provide critical information in the roll out that may inform adjustments to the optimal allocation.
- Vaccination will not eradicate SARS-CoV-2 from the planet, and COVID-19 is likely to become an endemic disease, even after widespread vaccination, with the occurrence of sporadic cases and occasional outbreaks.
- Both vaccine supply and distribution capacity will be limited initially, but availability will increase gradually over time. It may take many months before most US residents have access to vaccination; bottlenecks at various stages of the vaccine manufacturing process (eg, supply of vials or syringes, fill and finish process) could cause further delays in vaccine availability.
- Distribution capacity needs to be strengthened to handle the eventual scale of a COVID-19 vaccination campaign and reach all priority groups once vaccine supply increases. Current vaccine distribution systems are insufficient to provide access to some of the highest-risk populations, and outreach efforts may be needed.⁷
- Community mitigation efforts will continue to provide some degree of protection to high-risk groups who are able to follow them (eg, social distancing, staying at home, wearing masks), but not all people at high risk can stay home or maintain social distance. Furthermore, these measures are not without consequences; for example, staying at home may limit one's ability to work or access healthcare and may have an impact on people's psychological wellbeing.
- Serological studies (antibody tests) can provide evidence of prior infection but not necessarily proof of effective immunity. At this point, it is not possible to know whether a positive serologic result should change an individual's priority for vaccination.
- The prevalence of the disease will be in the range of what has been experienced to date such that, with some exceptions (eg, meat processors, emergency medical services), high levels of workplace absenteeism due to illness will be temporary in most industries. In some occupations where there are a small number of highly specialized, irreplaceable, essential personnel, concern over absenteeism may be valid. Examples include nuclear power operators or some medical personnel.
- Although more personal protective equipment will likely be available by the time a vaccine is available, the supply may not be sufficient for a large surge in cases and should not be counted on to adequately protect unvaccinated healthcare workers and other high-risk essential workers.

- The fatality risk will remain unchanged or decrease until a vaccine is readily available and will not disproportionately reduce the size of any of the potential priority groups. Various therapeutic countermeasures now in testing or development may reduce the fatality risk but, for now, are not assumed to substantially change the relative size of priority groups.
- Although there may be no out-of-pocket cost for the vaccine itself for most people (this has not yet been established), related costs—such as travel to a vaccination location or the need to take off from work—could create a financial hurdle for some.
- The vaccine will be distributed via multiple pathways such as medical offices, clinics, pharmacies, and open and closed points of dispensing. While these pathways can reach much of the population, they will not reach everyone. More investment and innovation are needed to offer vaccinations at nontraditional sites that are convenient, familiar, and feel safe to many vulnerable and underrepresented populations.⁷
- We assume that elected leaders and mission-critical military and national security personnel will be vaccinated from their own supply, separate from this allocation approach.
- A portion of the US population may hesitate to receive a COVID-19 vaccine. In addition to data indicating hesitancy to all vaccines, reports describe that many people are concerned that the COVID-19 vaccines are being rushed and may not be thoroughly tested.⁷
- Rapid social, behavioral, and communication science will be needed to deliver timely data and empirically based advice to support vaccine delivery strategies.⁷

Historical Approaches to Pandemic Vaccine Allocation

Since the 1970s, planning to respond to infectious disease pandemics—primarily and almost exclusively those caused by the influenza virus—has been a continuous activity in the United States.¹⁰ However, those efforts took on an increased urgency following the dual emergence of SARS coronavirus and influenza A/H5N1 virus in 2003.¹¹ The allocation and subsequent distribution of pandemic vaccines is a key aspect of the public health response and, as such, has been emphasized in national public health plans and guidance.

During past pandemics, the CDC has opted to allocate available vaccine supplies to states in proportion to their population, as was witnessed during the 1957 and 2009 influenza pandemics.^{12,13} However, more recent guidance has also included recommendations regarding the prioritization of specific subpopulations for immunization by healthcare providers and other health professionals. In this section, we will briefly review the recent history of national vaccine allocation plans, their contents and intended use, and the degree to which they informed pandemic response in a US context.

2008 Guidance

In 2008, the federal government issued *Guidance on Allocating and Targeting Pandemic Influenza Vaccine*.¹⁴ Development of this guidance was largely prompted by concerns over an impending pandemic caused by the H5N1 avian influenza strain then widely circulating in birds in Asia, Africa, and Europe. The guidance was developed by an interagency panel of experts and was the result of a process that included the solicitation of written and in-person stakeholder input to identify subpopulations that should be highly prioritized. The final document identified 5 tiers into which different high-risk populations and essential employees would be assigned. It also included a Pandemic Severity Index that helped the panel take into account underlying disease dynamics during the allocation process.

Under this framework, 24 million people, including pregnant women, infants and toddlers aged 6 to 35 months, deployed forces, critical healthcare providers, first responders (police, fire, EMS), and manufacturers of pandemic vaccines and therapeutics would have been prioritized to receive the vaccine first. Other essential employees and at-risk groups including other national security personnel and healthcare providers (Tier 2 and Tier 3), children (Tier 3), high-risk adults and the elderly (Tier 4), and others would follow, depending on pandemic severity and epidemiology. The remainder of the US population aged 19 to 64 years old comprised Tier 5, a population of over 123 million people. Pregnant people and young children were prioritized because of the high risk of severe illness and deaths in these groups from influenza.

2009 H1N1 Influenza Pandemic

In April 2009, a novel strain of influenza was diagnosed in 2 pediatric patients in southern California.¹⁵ That strain—named (H1N1)pdm09—caused the first influenza pandemic in over 3 decades. In total, the CDC estimated that over 60 million cases, 270,000 hospitalizations, and 12,000 deaths were caused by the (H1N1)pdm09 virus in the United States.¹⁶ During the response to the 2009 pandemic, a monovalent pandemic influenza vaccine was developed and distributed to states where it was administered to the public by healthcare providers, pharmacists, and public health professionals. That mass vaccination campaign provides us with the most recent real-world experience with allocating and distributing a pandemic vaccine.¹⁷

The CDC ACIP reviews information pertaining to vaccine safety and efficacy and makes recommendations regarding which vaccines should be used on a routine or emergency basis. In the run-up to the 2009 H1N1 mass vaccination campaign, the ACIP recommended 5 priority groups: pregnant women, people who live with or care for children younger than 6 months of age, healthcare and EMS personnel, children and young people aged 6 months to 24 years, and people aged 25 to 64 years at high risk due to chronic illness or compromised immune systems. These 5 subpopulations totaled approximately 159 million people.

However, in the event that available supplies of vaccine proved limited—which proved to be the case at the outset of the campaign—ACIP recommended using a more narrow

prioritization plan that included pregnant women, people who live with or care for children younger than 6 months old, healthcare and EMS providers with direct patient contact, children aged 6 months to 4 years, and children aged 5 to 18 years with chronic illness. This subset contained approximately 42 million people.¹⁸

Notably, the 2008 guidance was not fully implemented during the 2009 campaign, in part due to the relatively mild nature of the pandemic. The disease envisioned by the drafters of the 2008 guidance had been more severe, with more dire consequences for critical infrastructure. However, 2 groups identified as essential in the 2008 guidance were captured in the ACIP's 2009 priority groups: healthcare workers and EMS personnel.¹⁹

In total, the CDC has estimated that 80.8 million people in the United States were vaccinated against (H1N1)pdm09. Of those who had been in the initial priority groups, an estimated 53.7 million people were vaccinated.²⁰

2018 Revised Guidance

In 2018, the CDC issued an updated guidance document, *Allocating and Targeting Pandemic Influenza Vaccine During an Influenza Pandemic*.²¹ This document, which superseded the 2008 guidance, incorporated lessons learned during the response to the 2009 pandemic. Major changes included the inclusion of pharmacists and pharmacy technicians in Tier 1, a planning consideration for 2-dose vaccines that may be coadministered with an adjuvant, and updated pandemic severity measures. However, the need to provide vaccines to both vulnerable populations and critical infrastructure personnel remained consistent.

Like the 2009 influenza pandemic, many focused research and development programs have been initiated in different countries to develop a vaccine against SARS-CoV-2. According to the World Health Organization, 138 vaccine candidates are in preclinical evaluation and 29 are currently in clinical trials.²² Unlike 2009, however, the technical degree of difficulty is far higher and the timeline for vaccine availability is uncertain at this stage. However, when a vaccine does become available, similar allocation decisions will need to be made. In a fact sheet posted on June 16, Operation Warp Speed—the US government program to develop a vaccine for the COVID-19 pandemic—stated their intention to use a modified version of the 2018 pandemic influenza guidance as the foundation for SARS-CoV-2 vaccine guidance over the coming weeks and months.²³

Ethics Framework for Allocation of Scarce COVID-19 Vaccine

Ethics literature and existing plans for allocating vaccines during a pandemic provide 2 broad ethical orientations that should be used for vaccine allocation: a utilitarian orientation focused on maximizing overall benefits (usually health benefits, but sometimes broader social and economic benefits are also included) and a fairness/equity orientation focused on treating individuals fairly and advancing social equity.²⁴⁻²⁶ In our

analysis, we draw on a previous ethics framework developed for the COVID-19 response by some of the authors of this report. That framework assesses policies in light of 4 broad ethical values: wellbeing, liberty, justice, and legitimacy.²⁷ However, we do not consider liberty issues in this report because liberty issues relate primarily to whether vaccination should be mandatory, in some respect or for some groups of people. We do not address that issue in this report. For each of the other 3 broad ethical values, we identify more specific ethical principles that fall under them—for example, “promote economic and social wellbeing” is an ethical principle that falls under the broad ethical value “promote the common good.”

Wellbeing and Promoting the Common Good

Some vaccine allocation plans assume, implicitly or explicitly, that the overriding goal of vaccination is to maximize health benefits. While minimizing COVID-19 illness and deaths is a primary goal of vaccination, this is not the only dimension of wellbeing or the common good that should be considered. Health, economic stability, and social connection are all central to wellbeing, for both individuals and communities. Thus, promoting wellbeing and the common good involves not only promoting public health but also promoting economic and social wellbeing. This is reflected in a statement in the 2018 pandemic influenza vaccine allocation document: “The overarching objectives guiding vaccine allocation and use during a pandemic are to reduce the impact of the pandemic on health and minimize disruption to society and the economy.”²¹

Public health interventions in response to the pandemic have also had negative effects on some dimensions of wellbeing, even while they protect public health by reducing the spread of SARS-CoV-2. The closures of businesses and slowdown in economic activity have caused severe economic harms, with unemployment spiking and food and housing insecurity rising. Last spring’s school closures and the prospect that many children will begin a new school year in part or in whole at a distance this fall, may seriously threaten children’s wellbeing, not only with regard to lost learning but also in terms of socioemotional development and health. School disruptions during the pandemic have also made it harder for parents and guardians to work and generate income. People have lost the opportunity to gather in person for religious services and to celebrate life events. Thus, promoting wellbeing during the pandemic involves not only reducing the spread of SARS-CoV-2 and protecting essential services but also enabling children to return to school and enabling economic and social activity more broadly to resume. Enabling economic activity and a return to school will require getting a handle on mortality and transmission rates overall, but can also be furthered by, for example, prioritizing vaccination for workers who cannot work from home.

The public health effects of the pandemic extend beyond COVID-related illness and death. The implementation of movement restrictions, social distancing, and closure of organizations has dramatically slowed the spread of the virus but has also resulted in family isolation and attendant problems. For example, many victims of family violence may be facing a “worst case” scenario—finding themselves trapped at home

with a violent perpetrator during a time of severely limited contact with the outside world.²⁸ Reports of increasing gun and ammunition sales in the United States during the crisis are particularly concerning given the clear link between firearm access and fatal domestic violence incidents.^{29,30} The untold mental health burden of COVID-19 on the population has also yet to be fully revealed.³¹ In addition, there likely has been and will continue to be an excess in non-COVID-19 deaths, in part as a result of people not seeking medical care out of fear of COVID-19 infection.³² Thus protecting public health during the COVID-19 pandemic requires not only minimizing COVID-19 infection and illness but also minimizing other sources of injury, illness, and death. Attention to mitigating indirect health effects of COVID-19 may support allocating doses of vaccine to health workers providing services beyond COVID-19 care as well as to certain patient groups that require frequent interaction with the health system. Such an allocation could reduce disruptions to care seeking or health worker absenteeism, while also promoting longer-term health system resilience.

Justice, Fairness, and Equity

A second broad moral value to consider is justice, and the related concepts of fairness and equity. In the context of vaccine allocation, treating individuals fairly has sometimes been defined as treating everyone the same or *equally*, for example, by distributing vaccines on a first-come, first-served basis or by giving everyone an equal chance at getting vaccine via a lottery. Because the impact of the vaccine is different for different people (ie, some people are at greater risk of death), the straightforward ways of treating people equally are often rejected as unfair or as an inefficient use of vaccine.^{25,33}

There are other ways in which justice requires treating people equally that are important for vaccine allocation. Justice entails treating equally the interests of everyone affected by a vaccine policy and ensuring that people with relevantly similar interests are treated similarly. In the context of a COVID-19 vaccine, this broad understanding of justice requires a careful examination of whose interests are affected, to make sure that no individuals or groups whose interests should be considered—such as people living in the United States who are not citizens or legal residents or people who are in criminal or other involuntary detention facilities—are left out as allocation policies are being set. Allocation policies, and their implementation plans, should ensure that everyone who qualifies for vaccine under an allocation criterion is offered the opportunity to receive it. For example, if being at significantly elevated risk of severe COVID-19 disease or death is a criterion for inclusion in a high-priority tier, then all groups that experience roughly the same level of elevated risk should be so included.

One key question is whether or how the US vaccine allocation plan should consider the interests of those who would qualify for vaccine under top tier criteria if they were US residents but live in countries with insufficient resources to offer the vaccine to them. Although this key issue is beyond the scope of the current report, we do note here that there are compelling arguments grounded both in national self-interest and global

justice for the United States and other wealthy nations to commit to equitable global access of COVID-19 vaccine.³⁴⁻³⁷

Some argue that fairness and justice require placing a high priority in resource-constrained contexts on those who are disadvantaged, especially if they are disadvantaged in ways that can be ameliorated by the resource. This would mean that people who are at high or highest risk of death or serious COVID-19 disease would have a claim to disadvantaged status, especially given the focus in vaccine trials on these endpoints. In the United States and many other countries, older adults are at highest risk of serious disease and death, but other groups, some of which are much younger, also face high risk of serious COVID-19 outcomes. One argument is that the “worst off” are the younger populations who have the most life left to live. About 12% of COVID-19 deaths in the United States have been individuals under the age of 65.³⁸ Thus, in conditions of significant scarcity, as much as possible, we should consider prioritizing for vaccination those at higher risk of illness and death, who are also younger than age 65. The “worst off” also includes those individuals and groups who face both severe health and severe economic risks, specifically essential workers at higher risk of severe illness—or whose household members are at higher risk—who will suffer severe economic harm if they stop working. In addition, there are higher rates of severe COVID-19 illness and death among some systematically disadvantaged populations (eg, Black and Latinx communities), who are also suffering higher rates of economic harm during the pandemic.

Another consideration that falls under the broad heading of fairness is reciprocity. Reciprocity is often given as a reason for prioritizing healthcare workers, based on the argument that “if healthcare workers were considered to have a special obligation to attend work in times of increased personal risk then they (and perhaps their families) ought to be recompensed in the form of priority access to vaccine.”²⁶ In the United States, there has been broad recognition of and appreciation for the sacrifice made by healthcare workers and other essential workers, such as grocery and public transportation workers, who have continued working even in the face of risk to their health. Prioritizing essential workers who are at heightened risk of severe illness, or who have household members at heightened risk of severe illness, is a way to reduce the burdens on them and to recognize and reward them for their sacrifice. It is important to recognize both healthcare workers and this broader class of essential workers have made these sacrifices; most of the earlier allocation schemes only recognized the contributions of healthcare workers.

An additional, distinct justice/equity/fairness concern is to advance equity and justice within society as a whole by addressing inequities between social groups, especially those rooted in entrenched, unfair patterns of power and advantage.³⁹

In the context of vaccine allocation, promoting equity and social justice requires addressing higher rates of COVID-19-related severe illness and mortality among systematically disadvantaged or marginalized groups. For example, non-Hispanic

Black, non-Hispanic Native American, or Alaskan Native persons currently have a hospitalization rate 5 times greater than non-Hispanic white persons.⁴⁰ Communities of color, particularly Black communities, have been at significantly higher risk of contracting COVID-19 due to disproportionately high representation in the essential workforce; underlying health disparities, such as higher rates of chronic conditions; and challenges accessing care. Undocumented immigrant communities of color could particularly experience challenges in or hesitancy accessing care due to fears of potential interaction with law enforcement agencies. In addition, incarcerated populations are highly vulnerable to COVID-19 infection and have unique challenges regarding access to care and resources.⁴¹ Other populations to consider addressing in this framework include differently abled and mentally challenged populations, who can experience difficulties in accessing healthcare and could be in higher-risk living settings, such as assisted living facilities.

As a matter of justice, these disparities in COVID-19 risk and adverse outcomes across racial and ethnic groups should be addressed in our overall COVID-19 response.⁴² The key questions here are whether these disparities should be addressed through a vaccine allocation plan, and, if so, how is that best achieved? For example, a question to consider is whether racial and ethnic groups should be prioritized directly. While this approach could potentially enable the greatest impact on reducing COVID-19 burden in these populations, awareness of historical or ongoing injustice in the medical system has led some Black individuals to lack confidence in the safety or efficacy of vaccines.⁴³ Directly prioritizing Black populations could further threaten the fragile trust that some have in the medical and public health system, particularly if there is the perception that there has been a lack of testing to assess vaccine safety and that they are the “guinea pigs.”^{7,43} The implementation of directly prioritizing communities of color could also be challenging and divisive, as determining how to access specific populations and how to determine eligibility based on race or ethnicity includes many sensitive challenges.

Another consideration is whether prioritizing other cohorts of the population, such as essential workers or those with underlying health conditions associated with poorer COVID-19 outcomes, could also indirectly help address the disproportionate burden of this pandemic on communities of color. While this approach might avoid some of the challenges outlined above, it would also need to be implemented in a way that ensures vaccines are equitably distributed across subcategories of these categories. For example, the types of occupations that fall under the “essential workers” category are large and diverse, and racial disparities exist within that categorization.⁴⁴

Along with calls to address disparities between racial and ethnic groups, in recent years there have been increasing calls to include and, in some cases prioritize, other groups that have been overlooked in past vaccination development and delivery efforts, for example, pregnant people.⁴⁵ More generally, there have been calls to adopt a life-course approach to immunization and ensure that people receive vaccines appropriately at all stages of life.^{46,47}

Legitimacy, Trust, and Sense of Ownership in a Pluralist Society

So far, the discussion has focused on moral values that should inform *whom* we should prioritize when allocating the vaccine. Other moral values concern *how* we should go about *deciding* whom to prioritize. These moral values have to do with the *legitimacy* of decision making about resource allocation in a pluralistic society where material life circumstances and cultural values may vary greatly. These moral values are relevant for a number of reasons. First, different individuals and communities will disagree about which ethical values should guide vaccine allocation and about who is entitled to a vaccine. Second, different individuals and communities will have various attitudes about vaccines themselves, which raise specific challenges for implementing allocation decisions. Third, communities themselves may hold cultural values and beliefs that differ from dominant frameworks under consideration, which, if not ascertained respectfully, could curtail policymakers' ability to convey decisions in meaningful terms to diverse populations. Lastly, affected groups may have unique moral and material vantage points with which to assess allocation options and how they can be implemented successfully. Rather than a one-sided, top-down process, allocation decision making should consist of discussion, deliberation, and joint problem solving, which should result in allocation policies that have greater social legitimacy, cultural competence, and practical feasibility and foster the broader public's ownership of the vaccination enterprise itself. There are a number of considerations relevant to the legitimacy of the decision-making process.

Respect and Disagreement

First, different individuals and communities will disagree about who is entitled to a vaccine. This disagreement will arise because people have different opinions about the implications of the values discussed, such as what best promotes the common good. Another source of disagreement relates to the perceived importance of the different values. For example, some people may think that when considerations of fairness conflict with promoting the common good, priority should be given to fairness, whereas others may think the common good should be maximized. Moreover, as with other decisions about how to allocate scarce medical resources, whatever is decided will have significant impact on people's lives. There will inevitably be "winners" and "losers"; some people who would like to receive a vaccine will have to wait until the supply significantly increases, while others will have more immediate access. Ordinarily, when reasonable people disagree about difficult, high-stakes moral questions like these, additional important considerations come into play. In particular, some argue that to respect each person involved, the decision reached about allocation must be *acceptable* to different affected parties, even when the parties disagree that the decision is the right one.^{48,49} Furthermore, in the face of reasonable moral disagreements about questions like these, affected parties should get a say, so trying to provide opportunities for voice and engagement is important.⁵⁰ Accordingly, policymakers should try to provide opportunities for citizen input into decisions about allocation.

Vaccine Confidence and Trust

The second consideration relevant to legitimacy involves different attitudes toward vaccines, attitudes that are often informed by one's views of government or public health authorities, among other factors. As measles outbreaks in recent years suggest, low confidence in vaccines in various communities predates this pandemic. This low confidence is relevant when thinking about implementation.⁵¹ A plan for allocating vaccines that is insensitive to this challenge runs the risk of failure. It would be tragic if allocation decisions were made, but vaccine was wasted due to the low confidence of the intended recipients. The impact of low COVID-19 vaccine confidence on other vaccines should also be considered. If COVID-19 vaccines are not trusted, that could lead to a decline in existing vaccinations; if the health system only provides access to COVID-19 vaccines—to the exclusion of other vaccines—we risk declines in a health system designed to protect against a variety of diseases. To avoid this outcome, various efforts need to be made, including engaging a diverse array of stakeholders from different communities to give input. This should occur during the vaccine development and allocation decision-making processes, so that stakeholders are assured that the vaccines are safe and know that decision makers are responsive to their concerns. After a vaccine is available there should be ongoing, transparent, active monitoring for vaccine safety so that people can base their level of confidence on actual data. The CDC should strengthen the Vaccines Adverse Event Reporting System, which now is a passive reporting system that “relies on individuals to send in reports of their experiences to CDC and FDA [US Food and Drug Administration],”⁵² and make it an active safety surveillance system directed by the CDC that monitors all vaccine recipients—perhaps by short message service or other electronic mechanisms—with criteria based on the World Health Organization Global Vaccine Safety Initiative.⁵³ Finally, where feasible, public health officials should work with health care providers to effectively respond to concerns that members of the prioritized groups might have. Appropriate expectations also must be communicated so that people know what to expect with regards to safety.⁵⁴

The presence of moral disagreement about vaccine allocation and different attitudes toward vaccines makes transparency in decision making morally important. First, if we are to respectfully resolve moral disagreements, it is important that the ethical reasoning involved is transparent to those affected. Given the stakes, people are entitled to know how and why allocation decisions were made. Second, transparency at each stage in the decision-making process will ideally prevent or mitigate distrust of government. At the very least, such transparency can prevent sowing additional distrust.

Culturally Competent Policy

A third consideration for the process by which a vaccine allocation strategy is developed is the coexistence of different cultural beliefs in a pluralistic form.⁵⁵⁻⁵⁷ Diverse moral frames of reference can have cascading implications for vaccine allocation decisions. When their input is elicited in connection with limited vaccine doses, communities that come from different cultural traditions can offer unanticipated insights that expand, or possibly contract, the ethical terms that govern vaccine allocation. In essence,

diverse cultural and moral beliefs give us the opportunity for innovation in vaccine allocation. Moreover, by facilitating feedback from communities on allocation strategies, vaccination planners can learn what communities ultimately value, and when they share the rationale for an allocation policy, they can communicate why vaccines were allocated the way they were with genuine empathy, and in terms that are clear to and relevant for those communities. Also, by learning any cultural or social beliefs that are prevalent in a community, decision makers can also communicate in culturally meaningful ways about why an allocation framework is necessary and important in the first place. For instance, in US jurisdictions where large numbers of Latino communities reside, public health authorities can exercise sensitivity to the strong cultural value placed upon the family when developing, implementing, and communicating vaccine allocation.⁵⁵ Through displays of cultural competence, vaccination planners are able to provide concrete evidence of mutual understanding, respect, and inclusion.

Vaccination Co-Ownership

Broad availability of a future SARS-CoV-2 vaccine is a collective good, calling for immense societal investments, across the life cycle of development, deployment, and population uptake. To date, Operation Warp Speed, the US enterprise to develop SARS-CoV-2 vaccines, has entailed a \$10 billion dollar outlay, immense political will, and multiagency operational effort. The ultimate success of the vaccination program, however, hinges on the public's ability and willingness to get vaccinated, including those groups most at risk of COVID-19 impacts. Opening up allocation decision-making processes, and vaccination program planning more broadly, to public and stakeholder input is an opportunity to promote a sense of public ownership over the vaccine supply, to strengthen individuals' desire for vaccination, and to foster collective responsibility for public health.⁷ Moreover, for a COVID-19 vaccination program to be effective, it will be important to anticipate any social and material conditions that would inhibit public access to this life-preserving good. On the receiving end of vaccination efforts, the broader community can help innovate the vaccination program and identify circumstances that would prevent them from accessing vaccines as members of specific target groups.

Combining and Balancing Ethical Values and Principles in an Allocation Plan

Once the relevant ethical values and principles are identified, an allocation plan should combine and balance them in some way. Should certain ethical values and principles be given overriding importance? Are some ethical values relatively less important? For example, some might argue that the goal of promoting public health has overriding importance during a pandemic and, more specifically, that we should adopt whatever allocation approach will prevent the most deaths from COVID-19. Others might argue that while saving lives is of great importance, so, too, is addressing inequities, and, therefore, we should allocate vaccines with the goal of reducing higher rates of COVID-19 deaths among systematically disadvantaged social groups and marginalized populations, even if we are not confident that this will save the most lives.

In some cases, different ethical values and principles will align and highlight the importance of prioritizing the same groups of people. For example, prioritizing frontline healthcare workers helps protect the COVID-19 response, protects the healthcare system, targets a group at high risk of infection, and expresses reciprocity. Similarly, prioritizing other essential workers at higher risk of infection accomplishes multiple objectives at once: it protects essential services, enables economic activity more broadly, targets a group at high risk of infection, expresses reciprocity, and helps to reduce higher rates of severe COVID-19 illness experienced by Black and Latino people, who have high rates of employment in essential jobs.

In other cases, there may be trade-offs between ethical values and principles, and hard choices will have to be made. For example, one could imagine a trade-off of allocating the vaccine to enable children to return to school quickly (by including school workers in the highest priority group), which would help stimulate the economy versus allocating the vaccine to save the most lives (by allocating the vaccine first to those at highest risk of severe COVID illness, before school workers).

Adapting to Changing Conditions and Evolving Evidence

Changing pandemic conditions may change the appropriate balance of ethical values and principles. As Williams and Dawson wrote,

*“Changing conditions, therefore, could lead to changing priorities. For example, an aim of preventing the most illness could be justified initially and for a mild pandemic. In the event of a severe pandemic, however, maintaining social order was considered increasingly important. In that case, priority populations for vaccine access would change as the aims for the vaccination program changed, and those aims would change mostly in response to the perceived severity of the outbreak.”*²⁶

Thus, decisions about which ethical principles to endorse, and decisions about how to balance ethical principles when they are in tension, should be sensitive to the specific features of SARS-CoV-2 and the COVID-19 pandemic as it plays out in the United States.

Changing conditions and evolving evidence should also be taken into account when determining which groups should be prioritized. For example, if the elderly are first identified as a priority group because of their higher risk of severe illness, but evidence emerges that the elderly do not mount a strong immune response to the vaccines that are available for us, it may be appropriate to remove them as a priority group for vaccine and find other ways of providing them with protection. Two preventative options might be stepping up efforts to reduce obstacles to and harms and burdens of sheltering for the elderly and vaccinating younger family members to enable them to provide assistance to and social connection for older relatives. Ideally, a vaccine allocation plan would be developed and assessed as part of an overall pandemic response plan. Which groups should be prioritizing for vaccination will depend upon conditions on the ground and

other policies in place. Whether a group should be prioritized for vaccination should depend in part on whether there are other means of protecting them. For example, can some groups of essential workers be adequately protected from workplace transmission by modifications to the workplace and provision of effective personal protective equipment, and can policies incentivize providing these protections?

Any good allocation scheme should incorporate, as a core feature, the ability to manage the high level of uncertainty about the vaccines that will be developed and about public willingness to get vaccinated. A good allocation plan should be adaptable to changing conditions and evolving evidence and engineered to quickly adapt to lessons learned as we gain knowledge and experience. In conjunction, we need a robust and nimble communications effort for letting the public know about the plan and how allocation decisions were made. The success of the plan may be dependent upon society's acceptance of the allocation scheme and, given the current political and cultural polarization across the United States, it is important to include portals for communicating the plan and providing updates as circumstances change.

Linking Ethical Values and Principles with Policy Goals and Objectives

[Table 1](#) summarizes the ethical values and principles discussed, as well as the policy goals that follow these principles. There are 3 broad ethical values: promote the common good; treat people fairly and promote equity; promote legitimacy, trust, and sense of ownership in a pluralistic society. Under these 3 broad ethical values are a series of 7 ethical principles. More specific goals follow these ethical principles.

Table 1. Ethical Values, Ethical Principles, and Related Policy Goals to Guide Vaccine Allocation in the United States During the COVID-19 Pandemic

1. Promote the common good
 - Promote public health
 - Prevent COVID-19-related illness and death
 - Prevent injury, illness, and death from other causes
 - Protect the health system
 - Promote economic and social wellbeing
 - Protect (other) essential services
 - Enable economic activity more broadly
 - Enable children to return to school and childcare settings
2. Treat people fairly and promote equity
 - Address background and emerging inequities between groups
 - Reduce higher rates of severe COVID-19 illness and mortality being experienced by systematically disadvantaged social groups and marginalized populations
 - Address disproportionate economic and social impacts on some population groups, especially those that are marginalized or systematically disadvantaged
 - Give priority to worst-off individuals
 - Protect those at highest risk of severe illness and death, especially those with the most years of life left to live
 - Reduce burdens on those individuals who are multiply burdened
 - Reciprocity
 - Protect those who face increased risk of COVID-19 disease in order to provide essential services for the benefit of others or advance the development of COVID-19 vaccines and therapeutics
3. Promote legitimacy, trust, and sense of ownership in a pluralistic society
 - Respect the diversity of views in a pluralistic society
 - Create allocation schemes with the input of a diverse set of experts and constituencies
 - Establish mechanisms for public engagement and input
 - Engage community members to improve vaccine program design and effectiveness
 - Develop and implement allocation schemes in a culturally competent way, including for improved communication and crisis leadership
 - Enable community ownership of decision making to strengthen desire to vaccinate and steward shared resources responsibly

Building on [Table 1](#), [Table 2](#) provides additional detail, linking ethical principles and goals to more specific objectives for vaccine allocation. For example, the goal “Enable children to return to school and childcare settings” supports the objective “Provide vaccination to enable safer and more rapid return to in-building school and childcare.”

[Table 2](#) also links these objectives with example groups whose prioritization for vaccination could potentially advance those objectives. For example, prioritizing “Teachers and other school workers” would advance the objective of “Provide vaccination to enable safer and more rapid return to in-building school and childcare.” It is important to emphasize that these examples of priority groups are not meant to be exhaustive, are provisional, and may be somewhat speculative.

[Tables 1](#) and [2](#) list unranked ethical principles, goals, and objectives. These tables provide, in essence, a menu of options that policymakers, stakeholders, and the public can reference and choose from when they are deliberating about vaccine allocation. Based on these tables, our team identified candidate priority groups for vaccine allocation. Our candidate priority groups are just 1 example of how these ethical principles and vaccine objectives could be balanced and just 1 example of priority groups that would be ethically defensible. Other teams who deliberate about vaccine allocation might well reach different ethically defensible conclusions, emphasizing certain ethical objectives over others and concluding that different population groups should be offered vaccines first. [Tables 1](#) and [2](#) are intended to be as a conceptual resource to inform a timely national dialogue about vaccine allocation.

This national dialogue would, ideally, be guided by and advance the third broad ethical value we identify, namely “Promote legitimacy, trust, and sense of ownership in a pluralistic society.” [Table 3](#) identifies specific concrete activities that could advance this ethical value and advance the more specific objectives that follow from it, namely “Respect the diversity of views in a pluralistic society” and “Engage community members to improve vaccine program design and effectiveness.”

Table 2. Linking Ethical Principles and Goals with Vaccine Objectives and Example Priority Groups

Ethical Principle	Policy Goal During COVID-19 Pandemic	Objective for COVID-19 Vaccine Allocation	Example Priority Groups for Vaccination
Promote public health	Prevent COVID-19-related illness and death	Protect those at greatest risk of poor outcome from infection	<ul style="list-style-type: none"> • Those older than 65 years of age • Those with comorbid conditions (eg, hypertension, diabetes, cardiovascular disease, chronic kidney disease, immunosuppression, obesity, chronic obstructive pulmonary disease, pregnancy) • Those in close contact with people at very high risk of poor outcomes (eg, nursing home and long-term care facility workers, home health aides, household contacts of those at very high risk of poor outcomes)
		Protect those at greatest risk of infection and further transmission	<ul style="list-style-type: none"> • Health system workers in contact with COVID-19 patients (eg, nursing home and long-term care facility residents and workers; healthcare workers assigned to care for COVID-19 patients; frontline healthcare workers doing direct patient care; emergency medical services personnel) • Workers in high public contact jobs (eg, grocery workers; transportation workers, including bus drivers, train conductors, flight attendants and Transportation Security Administration agents) • Workers in high density workplaces (eg, food-processing workers) • People residing or working in high-density housing (eg, incarcerated individuals and prison workers, homeless residing in shelters, migrant workers in congregate housing) • Others in contact with high numbers of other people
	Prevent injury, illness, and death from other causes (non-COVID-19)	Protect workers needed to maintain public safety	<ul style="list-style-type: none"> • Emergency medical services personnel • Public health personnel • Police and fire personnel

	Protect the health system	Protect health system workers	<ul style="list-style-type: none"> Healthcare workers (including healthcare support staff such as environmental, food, and maintenance services) Emergency medical services personnel Workers needed for the vaccination effort (eg, vaccinators, vaccine and supply chain workers)
Promote economic and social wellbeing	Protect essential services	Protect workers needed to maintain critical infrastructure and provide other important services	<ul style="list-style-type: none"> Transportation workers Food system workers Warehouse and delivery workers Police and fire personnel Workers involved in maintaining operation of electricity, water, information, financial, fuel infrastructure Transportation Security Administration and border security workers Childcare workers Teachers and other school workers
	Enable economic activity more broadly	Protect workers to enable economic activity to resume more quickly	<ul style="list-style-type: none"> Workers (essential or nonessential) who cannot work remotely and have higher infection risk in their workplace (eg, retail workers, even if nonessential) Workers (essential or nonessential) who cannot work remotely and have higher risk of poor outcomes (eg, workers with comorbid conditions)
	Enable children and adult staff to return to school and childcare settings	Provide vaccination so as to enable safer and more rapid return to in-building school and childcare	<ul style="list-style-type: none"> Teachers and other school workers Childcare workers Children with comorbid conditions Household contacts of children who have comorbid conditions Children living with high-risk adults School-age children

Address background and emerging inequities between social groups	Reduce higher rates of severe COVID-19 illness and mortality being experienced by systematically disadvantaged social groups and marginalized populations	Protect hard to reach groups and workers in occupations that include a disproportionate percentage of disadvantaged groups	<ul style="list-style-type: none"> • Essential workers • Worker groups with a high rate of Black and Latino workers (eg, food retail, food production, delivery) • Worker groups with a high rate of undocumented workers • Worker groups with a high rate of lower-income workers (eg, home health aides, long-term care facility workers, food retail workers, farmworkers) • Incarcerated people • Those who face greater barriers to access care if they become seriously ill (eg, those living in shelters due to homelessness, evacuation, etc.), those living in remote locations with substandard infrastructure and healthcare access (Native American reservations, isolated rural communities)
	Address disproportionate economic and social impacts on some population groups, especially those that are marginalized or systematically disadvantaged groups	Protect workers who face elevated economic harm from not working	<ul style="list-style-type: none"> • Worker groups with a high rate of lower-income workers (eg, home health aides, long-term care facility workers, food retail workers, farmworkers)
Give priority to the worst-off individuals	Protect those at highest risk of severe illness and death, especially those with the most years of life left to live	Protect young people with comorbid conditions	<ul style="list-style-type: none"> • Young workers who have comorbid conditions and cannot work remotely • Children and young adults who have comorbid conditions who wish to attend school in person
	Reduce burdens on those individuals who have both high health and economic risks	Protect workers at significant health risk who also risk significant economic harm from not working outside the home	<ul style="list-style-type: none"> • Worker groups with a high rate of lower-income workers (eg, home health aides, long-term care facility workers, food retail workers, farmworkers)
Reciprocity	Protect those who face increased risk of COVID-19 disease in order to provide essential services for the benefit of others or advance the development of COVID-19 vaccines and therapeutics	Protect essential workers and their household contacts who are at significant health risk	<ul style="list-style-type: none"> • Essential workers at higher risk of infection (eg, healthcare workers, food processing and retail workers, transportation workers) • Essential workers with comorbid conditions • Essential workers who have household contacts with comorbid conditions

Table 3. Potential Activities with Which to Operationalize the Ethical Principle of “Promoting Legitimacy, Trust, and Sense of Ownership in a Pluralistic Society”

Ethical Objective	Example Activities ⁷	
Respect the diversity of views in a pluralistic society	Elicit input indirectly (via public surveys/polls on concerns and values regarding vaccine allocation) to inform allocation decision making and to develop communication strategies for conveying final policy and rationale	Convene stakeholder and public engagement sessions to elicit feedback on vaccine allocation and targeting strategies and then report publicly on the proceedings and how they informed policy decision
Engage community members to improve vaccine program design and effectiveness	Develop partnerships among local/state health departments, grassroots organizations, businesses, and other stakeholders to engage community (especially underserved, marginalized groups) on vaccine risks, benefits, supply allocation, and availability	Establish state-level accountability mechanisms for the vaccination program that include public oversight, community involvement, rubrics for evaluating effectiveness and equity, and public reporting on allocation strategies and their implementation

Comparison to 2018 CDC Guidance for a High-Severity Influenza Pandemic

The 2018 CDC pandemic influenza guidance is a thoughtful approach for its intended purpose. However, COVID-19 is not influenza and although there are some similarities, there are also important differences, as described next. The candidate groups that we identify for serious consideration as priority groups align in some ways with the 2018 CDC guidance for a high-severity influenza pandemic but deviate from it in several important ways. Like the 2018 guidance, we include frontline healthcare workers, EMS providers, and vaccine workers as candidates for Tier 1 access to vaccines. We also include additional workers most essential to maintaining essential functions, for example frontline public transportation workers and some groups of food system workers. However, we have not included active military, police, and homeland security personnel as candidate Tier 1 groups, because of evidence that they are generally young and healthy and far less likely to have severe illness or be out of commission for a prolonged period or in great numbers at any one time.

We include as a candidate group for Tier 1 those with close contact with high-risk individuals (eg, caretakers of the elderly) because of their risk of exposure and as a way to protect those in their care who may not manifest a robust immune response to

vaccination. We also do not include children as a candidate group for Tier 1, because they rarely manifest severe illness. However, aligned with the 2008 guidance, we do include pregnant women as a candidate priority group because of evidence that they are at increased risk, but recognize that safety trials in this group will be needed before we can definitively recommend vaccination in this group. Things may change as the pandemic proceeds in ways that could affect our suggestions about candidate priority groups, and therefore any plan may need to be revised, perhaps repeatedly.

Recommendations

The US Federal Government Must Provide Guidance on Vaccine Allocation and Distribution

There must be overall national guidance on vaccine allocation and distribution supported and promoted by the federal government. Although every state has a different context, travel and commerce affect all states and people, and the virus easily crosses both state and international borders. Furthermore, with a limited supply, only a national strategy can ensure that the vaccine gets to the priority groups. We have learned a great deal over the first 6 months of this pandemic in terms of who is most at risk and who is not. In addition, over the recent months, issues of societal inequities and marginalized and disadvantaged populations have become ever more apparent. As we plan for how the vaccine is distributed and administered, we must have more of a focus on equity and access. Plans should address how to get the vaccine to underserved and marginalized populations that may not be easily reached through the traditional routes. For these reasons, prior federal guidance addressing pandemic influenza must be significantly modified in order to be applicable to COVID-19. Despite some overlaps, the priority scheme envisioned in 2018 for pandemic influenza does not comport with the realities of the COVID-19 pandemic and new guidance is needed.

One aspect of the 2018 guidance, and its predecessor document, that should feature in the development of national COVID-19 vaccine allocation and distribution guidance is stakeholder and public engagement, as conveyed in the ethical principle of “promoting legitimacy, trust, and sense of ownership in a pluralistic society.” While the analysis contained in this document did not involve the input of broad constituencies, relying instead on the team’s expert judgment, we believe that this initial framework could serve as the conceptual foundation upon which materials are rapidly developed to hold an inclusive, national dialogue—one that would necessarily have to rely on multiple forms of community engagement that are appropriate to a physical-distancing environment.

Governors, Mayors, and State Health Departments Must Plan How They Will Implement Federal Guidance

Although we expect federal guidance to include a prioritization plan and a distribution plan, much of the implementation of this guidance will be at the state and local level. Because every state is different, actions must be local but driven by national principles.

Therefore, states should be planning how they will reach targeted groups, especially those that may be hard to reach. This is the opportunity to engage the populace and bring in community voices.⁷

Candidate Groups Should Be Prioritized

We here suggest candidate priority groups for vaccine allocation, divided into 2 tiers. These are offered as candidate groups to whom those creating an allocation scheme should give serious consideration. The groups within each tier are not rank-ordered. It is important to emphasize again that these candidate priority groups are based upon our multidisciplinary team’s analysis at this point in time, with the information available to us, and without benefit of extensive engagement with stakeholders and community groups. Other groups who deliberate about vaccine allocation might well reach different conclusions as to the criteria for inclusion in the different tiers or the groups within each tier. However, any group that proposes priority groups for vaccine allocation must be able to defend their recommendations in terms of explicitly acknowledged values and principles of the sort we present in our framework.

If enough vaccine is available at the beginning, all of these candidate groups could be offered vaccine concurrently. However, this scenario is unlikely. It is more likely that only enough vaccine will be available for 2 of our Tier 1 groups—people over age 65 and those with comorbidities that increase their risk—who together comprise an estimated 93 million people in the United States.⁵⁶ If enough vaccine is not available, hard choices will need to be made about which groups are offered vaccine first.

Candidate Groups for Tier 1

We suggest the following as broad candidate groups that should be given serious consideration for Tier 1 vaccination:

- Those most essential in sustaining the ongoing COVID-19 response
- Those most essential to maintaining core societal functions
- Those at greatest risk of severe illness and death, and their caregivers

The primary reason for including these candidate groups within Tier 1 is that their prioritization would likely avert the greatest overall harm. More precisely, including these groups in Tier 1 advances the ethical value of “Promoting the common good,” and the more specific goals of preventing COVID-19-related illness and death, protecting the health system, and protecting essential services.

Inclusion of the first 2 groups is clear—they help address the pandemic and keep basic services available. Additionally, while there are limited doses of vaccine, direct protection against COVID-19 of those most vulnerable to severe disease, and those who have the highest contact with them as care providers, would likely to be the most efficient way to minimize overall morbidity and mortality from COVID-19.

While the primary reason for including these 3 groups in Tier 1 is that this is the best way to promote the common good, other ethical values also speak in favor of including them. Those at greatest risk of severe illness and death have strong claims to limited doses of vaccine on the prioritarian basis of protecting those who are “worse off.” The value of reciprocity and rewarding sacrifice gives us another reason to prioritize those fulfilling essential roles within the COVID-19 response, such as frontline health workers with direct patient contact, as well as those maintaining core societal functions that put them at increased risk, such as public transportation, food provision, and grocery work. In addition, Black and Latinx people are overrepresented in the essential workforce, thus prioritizing essential workers for vaccination may also help to address disproportionate illness and mortality among Black and Latinx people.

In [Table 4](#), we provide some examples of specific populations groups that may fall into these priority groups. Just as there are value judgments involved in picking broad priority groups, there are additional value judgments involved in identifying specific groups of people who fall into those priority groups (eg, which groups of workers are most essential to collective wellbeing?). Thus, the groups in [Table 4](#) are only examples, not an exhaustive list. Other groups who deliberate about vaccine allocation may reach somewhat different conclusions.

Those at greatest risk of severe illness and death if they become infected includes adults aged 65 years and older and individuals with high-risk health conditions, including pregnancy. Which population groups should be prioritized may depend upon facts about the vaccines developed. For example, if the first available vaccine does not mount a strong immune response in older people, it may not make sense to prioritize adults over age 65; they should be protected in other ways. Prioritization may also depend on advances in treating COVID-19 patients. Effective medical interventions are becoming available, including therapeutics (eg, remdesivir, dexamethasone, immune sera) and other clinical approaches (eg, proning, increase in critical care capacity). Very active research into novel antiviral compounds, along with the study of repurposed drugs, continues apace with promising developments.⁵⁷ These new therapies, if safe and effective, could change the risk profiles of certain groups more than others, requiring some reassessment of priority group and distribution strategies.

Judgments about which population groups to prioritize in a given geographic area would, ideally, be informed by local data about which groups are at greatest absolute risk of severe illness and death as a result of all factors (health status, workplace exposure, healthcare access, housing density, the presence of other measures to protect those groups, or other social, economic, or environmental factors). In this way, groups would be prioritized based on the most current and relevant data available in their area.

Judgments about which workers groups should be included in Tier 1 could be informed by how essential that job is to societal functioning and collective wellbeing, how challenging it would be to restaff a particular role or function, and whether the workers can be protected by other means besides vaccination. Some workers groups are likely

to be at the top of the list because they check multiple boxes. For example, frontline inpatient healthcare workers assigned to care for COVID-19 patients are at high risk of infection, essential to society, hard to replace, and they are due considerations of reciprocity. Frontline long-term care providers are at high risk of infection and high risk of transmitting the virus to those at elevated risk within their facilities. EMS workers are essential and cannot predict when they might encounter a COVID-19 patient. Frontline public transportation workers (eg, bus drivers, train conductors, flight attendants) are essential, not easily replaced, and at high risk of infection. School workers are essential to educating children and enabling many parents to return to work and may turn out to be at high risk of infection depending on their work conditions.

As of this writing, the following groups, while not exhaustive, are good examples of candidates for Tier 1 prioritization.

Table 4. Provisional Examples of Tier 1 Groups (each supported by multiple ethical principles/policy goals)

Priority Groups	Examples
Essential in sustaining the ongoing COVID-19 response	<ul style="list-style-type: none"> • Frontline health workers providing care for COVID-19 patients • Frontline emergency medical services personnel • Pandemic vaccine manufacturing and supply chain personnel • COVID-19 diagnostic and immunization teams • Public health workers carrying out critical, frontline interventions in the community
Greatest risk of severe illness and death, and their caregivers	<ul style="list-style-type: none"> • Adults aged 65 years and older and those living with them or otherwise providing care to them • Other individuals and groups at elevated risk of serious COVID-19 disease, including people with health conditions that put them at significant increased risk of serious COVID-19 disease, potentially including those who are pregnant (as evidence warrants) or are members of social groups experiencing disproportionately high fatality rates. • Frontline long-term care providers • Healthcare workers providing direct care to patients with high-risk conditions • Other groups yet to be identified who are shown to be at significant risk of severe illness and death
Most essential to maintaining core societal functions	<ul style="list-style-type: none"> • Frontline public transportation workers • Food supply workers • Teachers and school workers (pre-kindergarten through 12th grade)

Prioritizing Within Tier 1 Groups

There will likely not be enough vaccine supply for all members of Tier 1 candidate groups to be offered vaccines concurrently. In this case, how might we think about prioritizing within these groups? Decision makers prioritizing within Tier 1 groups should consider whether certain subgroups have greater needs, provide greater benefit, or have multiple strong claims to limited doses.

Prioritizing within the group of 93 million people at highest risk of bad health outcomes should consider which subgroups are at the greatest risk of bad outcomes. Some may be less equipped to protect themselves from potential exposures, compared to others who fall into the broader high-risk category; for example, people with comorbidities who work in high density workplaces or who live with people at high risk of infection are less able to protect themselves as compared to other people with comorbidities. Some may face higher biological risks as compared to others; for example, people in their late 80s are at significantly higher risk than people in their late 60s. A countervailing ethical consideration, however, speaks in favor of prioritizing younger people over older people. As discussed above, the ethical principle of prioritizing the worst off is sometimes understood as requiring us to prioritize those who will lose the most years of life, if they die. This would speak in favor of prioritizing younger rather than older people.

Prioritizing within the essential workers in Tier 1 could be informed by how essential a job is, how challenging it would be to restaff, and whether the workers can be protected by other means besides vaccination. For example, when these issues are taken into account, healthcare workers should be prioritized above meat processing workers, even if they face the same level of risk of infection and/or serious COVID-19 disease. High rates of infection among health workers resulting in absenteeism or death poses an immediate threat to both health worker and patient lives and an ongoing threat to the COVID-19 response and health system, whereas temporary shutdowns of meat processing plants in response to outbreaks are unlikely to threaten the food supply. Also, the comparatively faster turnaround time to restaff and train food processing workers may make them a more resilient workforce than the health workforce.

Prioritizing within the essential workers in Tier 1 could also be informed by equity considerations. For example, priority could be given to those worker groups with higher rates of Black and Latinx people, or higher rates of people from other social groups at higher risk of infection and death.

Candidate Groups for Tier 2

We suggest the following as broad candidate groups that should be given serious consideration for Tier 2 vaccination:

- Those involved in broader health provision beyond the COVID-19 response
- Those who face greater barriers to access care if they become seriously ill
- Those contributing to maintenance of other essential services not listed in Tier 1

- Those whose living or working conditions give them elevated risk of infection, even if they have lesser or unknown risk of severe illness and death

Following the same logic as Tier 1, Tier 2 expands upon the Tier 1 categories to address those who are required to sustain the health system beyond more direct COVID-19 care and those who provide the next level of essential services for a functioning society. Tier 2 also includes those who are at higher risk of bad outcomes because they face barriers to accessing care.

Tier 2 also includes, as a potential priority group, those whose living or working conditions give them elevated risk of infection, even if they have lesser or unknown risk of severe illness and death. Examples would be groups of farmworkers or people living in shelters. There are 2 distinct reasons for prioritizing this broad group over the general population: first, they are at higher personal risk of getting COVID-19, and offering them the protection of vaccination advances the goal of preventing COVID-19-related illness and death. Second, those at higher risk of infection may be more likely to transmit the virus to others and contribute to spread of the virus through their community. Therefore, prioritizing these groups might, in some circumstances, slow transmission of the virus through their communities and prevent the emergence of “hot spots.”

Whether it makes sense to prioritize groups at elevated risk of infection as a way of slowing transmission, and which groups it makes sense to prioritize, will depend on at least 4 factors.

First, will vaccination actually slow transmission of the virus? A vaccine will be approved based on data about its ability to generate a protective immune response in individuals and prevent illness and death. When a vaccine is licensed, we will not have direct data about its ability to slow transmission of the virus through the population; this data will not be available until later. However, it is possible that vaccinated individuals will have a decreased risk of transmitting the virus to others.

Second, how connected is a particular group of people to the larger community or to those at high risk of severe illness and death? Is this a group of people who are relatively isolated from the larger community, or a group of people who have significant contact with the larger community? For example, do many of these workers live in multigenerational households, where they are more likely to infect people aged over 65 years at elevated risk of bad outcomes?

Third, when considering whether a group should be prioritized as a way of slowing transmission in their communities, we should consider whether it is feasible to achieve high enough vaccine coverage in that group to achieve reduced virus transmission. Some groups at high risk of infection might also be groups that it are harder to reach, and, therefore, it may not be possible to vaccinate enough of a particular group to achieve reduced transmission.

Fourth, when considering whether a particular group should be prioritized as a way of slowing transmission through their communities, we should consider whether prioritizing that group would take resources (vaccines, but also other resources) that otherwise could be used to achieve higher vaccination rates in another group, with better results for public health.

Thus, it is a complicated empirical question whether prioritizing a group at elevated risk of infection will reduce community-level transmission and, ultimately, prevent illness and save lives. We encourage decision makers to use modeling to better understand these issues and inform vaccine allocation.

It is important to note that it is not just living and working contexts that have the potential to be “superspreading” contexts. There is emerging evidence that many superspreading events are social, such as parties, worship services, funerals, and other gatherings.⁵⁸ However, it is not feasible to preemptively vaccinate against many of these superspreading events, given that vaccines may take weeks to be fully effective. In addition, using vaccine to enable social activity may not seem like an acceptable use of vaccine to many people. Therefore, a more practical way to leverage vaccine to prevent high transmission contexts is to consider whether there are contexts of high transmission due to living and working conditions that are foreseeable, and for which it is practical to achieve high enough vaccination rates to reduce transmission. For example, a state could consider whether there are groups of workers whose foreseeable return to work is likely to result in significant infection and transmission (eg, particular groups of farmworkers during harvesting season). Ideally, these decisions would be guided by modeling.

The groups in [Table 5](#) are examples of candidates for Tier 2 prioritization. The list is not exhaustive and subject to change based on evolving evidence and the state of the pandemic.

Table 5. Provisional Examples of Tier 2 Groups

Priority Groups	Examples
Essential to broader health provision	<ul style="list-style-type: none"> • Health workers and staff with direct patient contact (non-COVID-19 specific) • Pharmacy staff
Least access to health care	<ul style="list-style-type: none"> • Those living in remote locations with substandard infrastructure and healthcare access (Native American reservations, isolated rural communities).
Needed to maintain other essential services	<ul style="list-style-type: none"> • Frontline workers involved in maintaining operation of electricity, water, sanitation, information, financial, fuel infrastructure (who cannot work remotely) • Warehouse, delivery workers (including postal workers) • Deployed military (including National Guard) involved in operations • Police and fire personnel with frequent public contact • Transportation Security Administration and border security personnel with direct public contact
Elevated risk of infection	<ul style="list-style-type: none"> • Those unable to maintain safe physical distance within their living or work environments <ul style="list-style-type: none"> ◦ Those working in high-density or high-contact jobs where distancing may not be feasible ◦ Those living in shelters (eg, homeless, domestic violence) ◦ Incarcerated individuals and prison workers • Other groups yet to be identified who are shown to be at elevated risk of infection because of other working or living conditions

Effective Distribution Requires a National Strategy

An overarching national strategy will be needed to guide vaccine distribution. That strategy should be complementary to existing strategies for distribution of routine immunizations to help ensure that the system as a whole is strengthened. As they did in prior pandemic plans, the federal government could make vaccine available to the states and territories on a per capita basis. The states and territories would then distribute the vaccine to priority groups within their jurisdiction. However, this approach may disadvantage at-risk and marginalized individuals in states with large at-risk and marginalized populations that already experience significant disparities for influenza vaccines.⁵⁹ Other, more inclusive approaches, might include states being allocated the vaccine based on estimates of the targeted populations within each state, if reliable estimates are possible. Or, distribution approaches could involve targeting areas based on analysis of local epidemiological data. As vaccines become available but are in short supply, epidemiology should be a major factor in vaccine distribution decisions. Geographic spread of the virus should be considered when applying any vaccine allocation framework. As we are seeing now, epidemics of the virus will ebb and flow

according to the application or retraction of public health response measures like stay-at-home orders. Viral hot spots will likely continue to arise, and with them the threat of uncontrolled spread, overwhelmed healthcare systems, and greater numbers of severe illnesses and deaths. Even countries with very good control of SARS-CoV-2 transmission have experienced large spikes of disease.^{60,61} Because the incidence and prevalence of SARS-CoV-2 will not be uniform across the country, distribution decisions may need to account for geographic variability. For example, if vaccine becomes available, and there is a location or locations experiencing severe epidemics, consideration should be given as to whether the vaccine should be preferentially distributed to those locations in order to mitigate the impacts.

Mass vaccination is not the only approach to controlling epidemics, however. The smallpox eradication program shows us that it is possible to deploy vaccine strategically to break chains of transmission—vaccinating contacts of cases and contacts of contacts to place a ring of immunity around those who are sick or around hot spots with high transmission numbers, depending on the quantity of vaccine available.⁶² While ring vaccination is more useful in limited outbreaks, it is another possible approach to vaccine use and allocation. The epidemiology of the COVID-19 pandemic at the time distribution decisions are made should be a primary consideration and may result in modified distribution priorities. All of these distribution approaches require careful monitoring and evaluation to ensure the greatest impact. Additionally, where adult vaccination systems are weak, there may not be established mechanisms to track and call back adults who need to receive a second dose of vaccine. Additionally, these systems should offer other needed vaccines so they do not miss the opportunity to ensure that adults are protected from other vaccine preventable diseases that may increase the risk of poor outcomes.

All available means should be used to carry out vaccination as quickly as the supply and distribution logistics will allow. Medical offices, pharmacies, clinics, health departments, and businesses should all be encouraged to order vaccine and administer it according to the allocation scheme and guidance. The amount of vaccine that each site can receive should be centrally managed at the state level and in accordance with the adopted allocation plan.

Certain populations may require special efforts. There is a legal and moral duty to provide healthcare to incarcerated individuals and a moral duty to provide healthcare to other populations. Incarcerated individuals and the homeless are both at high risk of infection, transmission, and poor outcomes because of comorbidities and poor healthcare access. Furthermore, there is a high public cost of medical care if either become seriously ill. Native American populations that live on remote reservations will also require special effort to reach, as will migrant farm workers. Historically marginalized low-income populations in both urban and rural areas will also require special efforts.⁷

The distribution process should ensure that people's attitudes, beliefs, and the realities of their daily lives are considered to ensure vaccines are accessible in convenient locations run by people they trust. If it is too difficult to get needed vaccines, particularly when other work or home priorities make it difficult, the populations that need to be protected the most could be left out. Additionally, considerations may need to be made for other family members who come with the person who is to be vaccinated. Vaccinating only certain people may create a distrust of the system, and policies should be weighed in that context.

Many logistical issues must be considered in planning a vaccination campaign. Not only does enough vaccine have to be appropriately stored and handled, but enough peripheral supplies, such as syringes and vaccine safety boxes, must also be available. Some vaccines deteriorate quickly and require rapid distribution and administration while being kept frozen at very low temperatures.⁶³ States will have to determine how to identify and reach individuals in targeted groups, and mechanisms for accountability will need to be established. If more than 1 dose is needed, there will need to be a way to track who has had a first dose. This will be especially important if multiple vaccines are available, so that the second dose is the same vaccine as the first. The mass vaccination dispensing points and clinics will have to be set up in such a way as to maintain social distance. Additionally, if new points of vaccination are added to increase convenience, they will need to have adequate access to cold chain storage, waste disposal, syringes, and other needed equipment, and the staff will need to be trained on the storage and administration of vaccines and communication, to ensure trust in the program. In addition, vaccinators should be trained to encourage people coming in take other preventive measures for COVID-19 and their health more generally, including influenza immunization. While it is not clear yet whether influenza vaccines can be coadministered with COVID-19 vaccines, ensuring people are up-to-date on required immunizations can also save lives.⁶⁴

We anticipate that there may be considerable vaccine hesitancy, especially from those who perceive that the COVID-19 vaccine is being rushed.⁷ Evidence, or even perceptions, of problems with safety or efficacy can affect vaccine acceptance. Some priority groups may be especially distrustful of government or pharmaceutical companies. Some may believe the vaccine has not been sufficiently tested, and others may not feel safe going to a vaccination site. Poor public perception of the safety of a COVID-19 vaccine could feed into existing antivaccine narratives and adversely affect vaccine rates for other vaccines. If there is pervasive hesitancy, vaccine uptake in some of the priority groups may be slow. States will have to determine when to move on to lower tiers despite substantial underpenetration of the higher tiers. It will be very important to have a robust communications effort along with the vaccination campaign.

Conclusion

We have presented an ethics framework for how best to approach allocation and distribution decisions related to scarce SARS-CoV-2 vaccine. We have used that framework and information available as of August 1, 2020, to identify ethically defensive priority groups worthy of serious consideration. New information is emerging nearly every day that could affect our assessment of these priority groups; therefore, we will update and revise these candidates as appropriate.

Among the ethical principles we name in this report is “legitimacy, trust, and sense of ownership in a pluralist society”; to enact this principle requires facilitating input from the public and stakeholders and developing vaccine allocation and distribution strategies that address their cultures and concerns. For the purpose of this initial analysis, we have not engaged a broader set of constituents, but instead relied upon the multidisciplinary team’s judgment. We believe, however, that this initial framework could serve as a conceptual resource to inform the design and execution of a timely national dialogue—one achieved through multiple forms of community engagement appropriate to a physical distancing environment. This is a task the federal government should undertake or commission as soon as possible. The state of knowledge when vaccine product first becomes available cannot now be reliably predicted,⁶⁵ and the SARS-CoV-2 vaccination will be a long-term endeavor; the virus is likely to become endemic and require ongoing vaccinations and revaccinations into the foreseeable future.

Evidence, or even perceptions, of problems with safety or efficacy can affect vaccine acceptance. If there is pervasive hesitancy, vaccine uptake in some of the priority groups may be slow. States will have to be prepared to determine when to move on to lower tiers despite substantial underpenetration of the higher tiers.

What is done early in a vaccination campaign will have implications for every aspect of our personal and public life. We risk reducing confidence in government, as well as our public health and healthcare systems if the allocation, distribution, and administration of the vaccine is not handled appropriately and clearly communicated. If, on the other hand, an allocation strategy is ethical, nationally consistent, fair, and informed by key constituency groups, then vaccination campaign is more likely to go smoothly and be accepted by the public, which would result in many lives saved and faster economic recovery.

This report is intended to be the first in a series of publications from this team that will address changing issues related to COVID-19 vaccine allocation as the pandemic evolves and we continue to learn more.

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