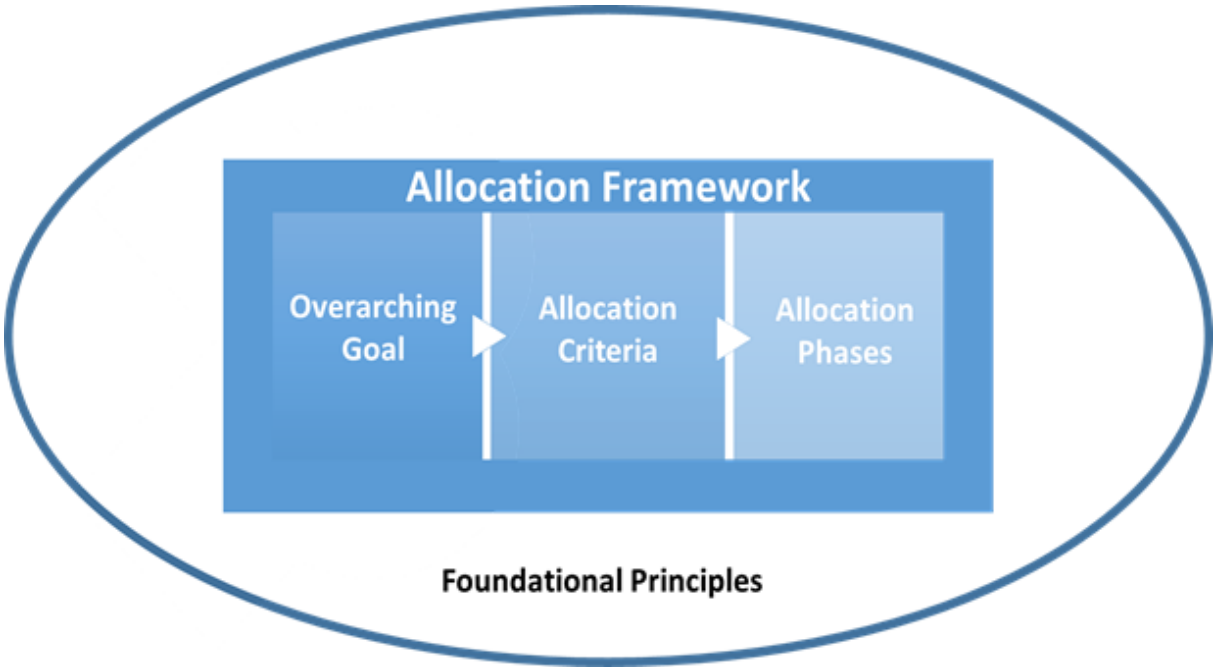
A Framework for Equitable Allocation of COVID-19 Vaccine

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



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

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

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

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

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

FOUNDATIONAL PRINCIPLES OF THE FRAMEWORK

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

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

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

Foundational Principles

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

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

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

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

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

BOX 3

Foundational Principles for Equitable Allocation

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

Maximization of Benefits

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

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

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

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

Equal Regard

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

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

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

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

Mitigation of Health Inequities

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

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

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

BOX 4

Health Inequities

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

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

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

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

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

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

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

Fairness

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

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

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

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

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others. Given the currently available evidence about the pandemic's behavior, priority for older adults in certain phases, if warranted, would probably be based mainly on risk of severe outcomes of infection, whereas priority for young adults, if warranted, would probably be based mainly on risk of transmission to others.. The conflict is not so direct between these two populations in the current pandemic because children who are infected with the novel coronavirus and can transmit it tend not to have such severe outcomes as older adults. If such a direct conflict existed because of widespread severe outcomes among children, there would be strong arguments for prioritizing children over older adults on the basis of severe outcomes. Children would be "worse off" because of the years of life they would lose, older adults have had their "fair innings," and so forth (Daniels, 2008; Emanuel and Wertheimer, 2006; Emanuel et al., 2020; Kamm, 1993; Williams, 1997). In the current context, the more difficult conflict to resolve is between reducing transmission among children in order to make it more likely that they can attend school in person and to reduce transmission to others in the community, on the one hand, and reducing severe illness and death among older adults, on the other hand.

A related debate about age concerns the loss of life years versus the loss of life. Older adults in their eighties, for instance, generally lose fewer life years if they die than children or young adults who die. However, given the large numbers of older adults who die from COVID-19, those numbers multiplied by fewer life years can still end up being quite substantial. Resolving these conflicts depends on evidence about the relative effectiveness of different vaccine strategies at particular stages in the pandemic give available supplies of vaccine, as will be examined later in this chapter.

Fairness should guide not only the formulation of allocation criteria, but also their application, which should be impartial and evenhanded, and avoid arbitrary exceptions and gaming. Implementation should be as uniform as possible across the country, consistent with allowing discretion to state, local, tribal, and territorial (SLTT) authorities to address specific patterns of COVID-19 transmission, extent of spread, and severity of outcomes. Unless clearly communicated and justified, extreme variation in applying the criteria can evoke charges of unfairness.

Procedural fairness is also crucial. This means that decisions about allocation, distribution, and access to vaccine should incorporate input from affected groups, especially

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

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

Evidence-Based

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

Transparency

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

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

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

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

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

Using the Principles

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

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

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

COVID-19 VACCINE ALLOCATION FRAMEWORK

Primary Goal of the Framework

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

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

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964
965 **"Maximize societal benefit by reducing morbidity and mortality caused by**
966 **transmission of the novel coronavirus."**
967
968 The primary goal of the committee's allocation framework has a dual focus:
969 maximization of benefit through prevention of morbidity and mortality and through reduction in
970 transmission. Moreover, the framework attempts to mitigate health inequities and is informed by
971 the current evidence. In the early phases, prevention of morbidity and mortality, and maintenance
972 of health and emergency services to aid prevention of morbidity and mortality is emphasized
973 more than the reduction in transmission;[21] with an increased focus on transmission in later
974 phases.
975 There are multiple reasons for this approach.
976
977 • Morbidity and mortality are clearly identified and provide a logical and
978 understandable start to selecting the first vaccine recipients.
979 • Any substantive impact of vaccination on reducing transmission would require a
980 critical mass of individuals to be vaccinated. Even if this critical mass is lower than
981 the nominal herd immunity threshold, in the early phases of vaccine deployment,
982 there will not be sufficient courses of the vaccine available for an effective
983 transmission-focused strategy.
984 • The ongoing COVID-19 vaccine trials are not designed to estimate the impact of the
985 vaccine candidates on transmission and evidence of the vaccines' impact on
986 transmission might not be available for some time after approval or authorization.
987 • While data on all aspects of COVID-19 are emerging, data on transmission risk
988 groups (e.g., by age, profession etc.) is particularly limited.
989 • There are legitimate claims for many groups (such as school children, "non-essential"
990 workers important for the economy) to be in earlier phases as damage could occur if
991 these groups are not prioritized. For example, there might be a substantial impact on

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

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

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

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

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

Allocation Criteria

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

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

BOX 5
Risk-Based Criteria

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

Risk of Acquiring Infection

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

Risk of Severe Morbidity and Mortality

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

Risk of Negative Societal Impact

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

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

Risk of Transmitting Infection to Others

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

Compatibility of Allocation Criteria with Foundational Principles

Maximization of Benefits

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

Equal Regard

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

Mitigation of Health Inequities

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

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Fairness

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

Evidence-Based

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

Transparency

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

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

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

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

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

Allocation Phases

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

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

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

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

[22] There remains uncertainty as to whether private entities, such as healthcare systems or businesses, will be able to access allotments of COVID-19 vaccines outside of a federal-to-state allotment system.
[23] Planning for whether an epidemiological "hot spot" reserve would be valuable and make a difference also depends on the characteristics of the vaccine (e.g., how long it takes for immunity to develop, etc.).

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Operationalizing the Criteria to Determine Allocation Phases

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

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

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

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

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

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

Discussion of the Allocation Phases

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

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

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

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

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

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

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

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

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

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

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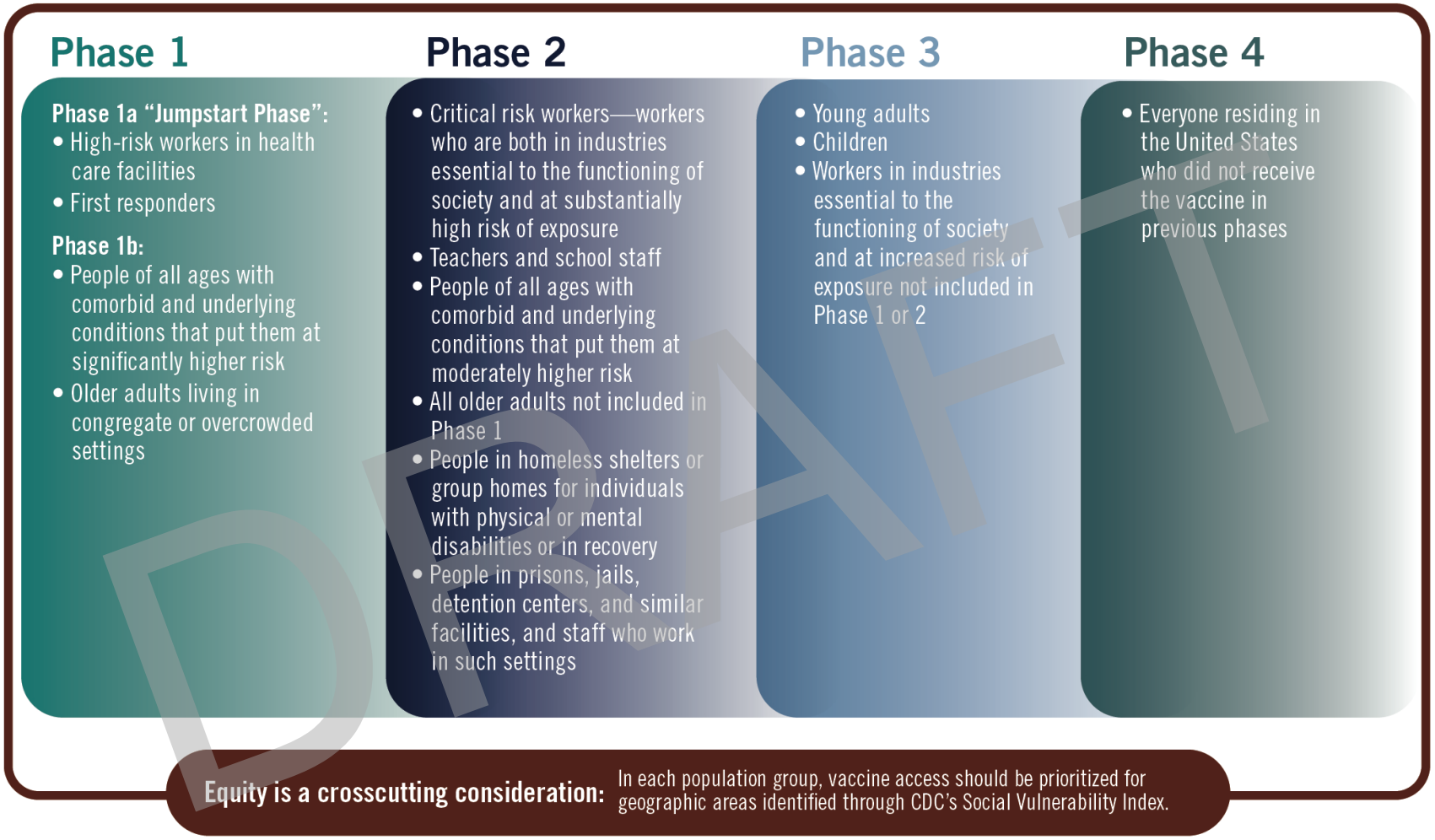

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1245 **DRAFT FIGURE 2** A phased approach to vaccine allocation for COVID-19

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A Phased Approach to Vaccine Allocation

Phase 1

Phase 1 includes the following groups:

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

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

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

Phase 1a

Population: High-Risk Workers in Health care Facilities

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

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

Rationale

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

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

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

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

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

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

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

Estimated Group Size[24]

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

Population: First Responders

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

Rationale

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

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

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

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

Estimated Group Size

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

Phase 1b

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

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

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

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

Rationale

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

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

Estimated Group Size

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

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

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

Population: Older Adults Living in Congregate or Overcrowded Settings

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

Rationale

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

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

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

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

Estimated Group Size

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

Phase 2

Phase 2 includes the following groups:

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

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

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

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

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

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

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

Rationale

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

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

Estimated Group Size

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

Population: Teachers and School Staff

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

Rationale

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

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

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

Estimated Group Size

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

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

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

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

Rationale

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

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

Estimated Group Size

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

Population: All Other Older Adults

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

Rationale

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

Estimated Group Size

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

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

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Population: People in Homeless Shelters or Group Homes

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

Rationale

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

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

Estimated Group Size

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

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

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

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Rationale

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

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

Estimated Group Size

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

Phase 3

Phase 3 includes the following groups:

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

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

Population: Young Adults

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

Rationale

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

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

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

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Estimated Group Size

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

Population: Children

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

Rationale

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

Estimated Group Size

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

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

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

Rationale

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

Estimated Group Size

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

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

Phase 4

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

Ensuring Equity

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

Social Vulnerability Index

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

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

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

Costs Associated with Vaccination

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

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

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

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

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

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

Legal Status

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

Considerations for Pregnant Women

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

Vaccine Allocation for the Military

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

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

Vaccine Allocation for Volunteer Participants in Vaccine Trials

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

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

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

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

Limitations and Additional Considerations on the Framework

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

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

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

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

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

CONCLUDING REMARKS

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

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