Vaccine ethics: an ethical framework for global distribution of COVID-19 vaccines

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ABSTRACT

This paper addresses the just distribution of vaccines against the SARS-CoV-2 virus and sets forth an ethical framework that prioritises frontline and essential workers, people at high risk of severe disease or death, and people at high risk of infection. Section I makes the case that vaccine distribution should occur at a global level in order to accelerate development and fair, efficient vaccine allocation. Section II puts forth ethical values to guide vaccine distribution including helping people with the greatest need, reducing health disparity, saving the most lives and promoting narrow social utility. It also responds to objections which claim that earlier years have more value than later years. Section III puts forth a practical ethical framework to aid decision-makers and compares it with alternatives.

With the introduction of seemingly safe and effective vaccines against the novel coronavirus, ethical debate has shifted to the question of what is a fair and equitable way to distribute a limited supply of vaccines. Should each nation distribute doses only to its own population? Or should some form of global distribution occur? If global distribution takes place, what values and criteria ought to govern? This paper addresses these questions by setting forth an ethical framework for the just distribution of vaccines against the SARS-CoV-2 virus. Section I makes the case that vaccine distribution should occur at the global level in order to accelerate developing, producing and disseminating a vaccine on the scale needed in a fair, efficient manner. Section II presents ethical values that ought to guide the selection of distributive criteria. Section III puts forth a practical ethical framework for global vaccine distribution and compares it with alternatives.

I. VACCINE DISTRIBUTION SHOULD BE GLOBAL

Bioethical debates over allocating scarce healthcare resources often take for granted that distribution will occur at a local level, for example, within a local, regional or national context. In a critical review of the published bioethics literature addressing priority setting during an influenza pandemic, Williams and Dawson found that a 'major omission' was attention to global distributive justice[1] (p 6). However, during the COVID-19 pandemic, only a limited number of countries possess capacity to manufacture vaccines on their own against the virus. Absent global efforts to equitably distribute vaccines, country of residence will likely become the single most important factor determining vaccine distribution. Yet should it be? To clarify this question, consider a MOBS LAB analysis (which uses mathematical models and computational tools to describe and predict complex systems) of two counterfactual scenarios for vaccine distribution. In the first scenario, a vaccine against the SARS-CoV-2 virus that is 80% effective becomes available in mid-March 2020 and is distributed to high-income nations first, with the result that 33% of deaths are averted; in the second, it is distributed to all countries proportional to their populations, resulting in 61% of deaths averted.[2] If wealthier nations do not join forces to help their global neighbours, our future world may resemble the first scenario. Is this an outcome we can support on moral grounds?

A purely pragmatic reason for framing the distribution of vaccines against the SARS-CoV-2 virus at the global level is that governments from around the world, in partnership with philanthropic groups and consortiums, will be needed to bring a vaccine to market. Over the past decade, private companies have gradually retreated from investing in vaccines designed to combat emerging infectious diseases due to poor return on investment, a barrage of lawsuits and government control over pricing.[3] Moreover, the sheer number of doses required to contain the novel coronavirus exceeds the capability of any single manufacturer or nation. Practically speaking, to reach the more than 8 billion people around the globe, we will need to enlist not only national governments, but scaled-up global governance bodies in order to ensure the necessary organisation, institutions and tools to make and distribute a future vaccine effectively and efficiently to everyone who needs it.

In addition to pragmatic considerations, we should distribute vaccines globally because during global health emergencies, national governments have cross-border responsibilities. Cross-border responsibilities can be defended even on narrowly nationalistic grounds, since infectious diseases do not respect borders. Failing to contain the spread of disease anywhere potentially puts people everywhere at risk. For example, if it takes years before low- and middle-income countries (LMICs) gain access to vaccines, the SARS-CoV-2 virus could develop strains that render some vaccines ineffective, prolonging the pandemic. At a minimum, this suggests that prudent governments have self-interested reasons to release vaccines to other countries after vaccinating those within their borders.

However, an opponent might claim that wealthy nations can reasonably construe their nationalistic interests differently. For example, on 21 September 2020, 64% of the world's population in more than 156 countries (including 64 high-income nations) had joined COVAX, the international partnership that aims to distribute vaccines against the SARS-CoV-2 virus.[4] Yet the Trump administration refused to join. According to a senior United States (US) government official, the US government believed it could opt out of global vaccine alliances, such as COVAX, because the US had enough coronavirus vaccine candidates in advanced clinical trials to succeed on its own.[5]

Nor is vaccine nationalism limited to the US. Across the globe, wealthy nations have secured more than 2 billion doses of potential future vaccines against the novel coronavirus using advance purchase agreements, which are legally binding contracts in which a government obtains priority access to potential future vaccines by committing to purchase a certain number or percentage of doses from a vaccine manufacturer at a negotiated price if it is developed, licensed and manufactured.[6] The European Union (EU) has put forth an allocation framework explicitly focused on securing the production of vaccines for EU member states through advance purchase agreements.[7] According to a 17 September 2020 analysis by OXFAM, wealthy nations representing just 13% of the world's population have already cornered more than half (51%) of the promised doses of leading COVID-19 candidates.[8]

In response to vaccine nationalists, it is helpful to point out that competing moral visions underpin debates about national versus global vaccine distribution. Vaccine nationalists tend to assume *moral nationalism,* the ethical view that people have a special duty to their compatriots which stems from the ways they are related to one another.[9] By contrast, those who urge global vaccine allocation are inclined toward *moral cosmopolitanism*, an ethical position that denies special duties to compatriots and holds that we should impartially consider each person's claims irrespective of their place of origin.[10] Both views permit the possibility of duties to people inside and outside national borders that rely on other grounds. For example, although moral cosmopolitans reject special relationships as a basis for duties to compatriots, they may say that it is permissible to concentrate charitable efforts locally because doing so is more efficient and produces the greatest good.

A moral nationalist might charge that cosmopolitanism is just an attempt by poorer nations to promote their own national interests by beckoning wealthier nations to help them. Yet, moral cosmopolitanism gains ground from diverse justice principles.[11] For example, sufficitarian justice principles hold that people everywhere are entitled to have enough opportunity and capability to lead a minimally decent life.[12] Prioritarian justice combines general distributive principles that appeal to promoting human welfare (or capabilities or resources) with a prescription to place more weight on improving the situation of those who are worse off.[13] For example, a welfarist interpretation gives priority to getting benefits to those whose well-being is very low. Lastly, luck egalitarian justice principles identify a duty to correct disadvantages that result from unchosen disadvantages.[14] These diverse justice principles converge on the idea that people in wealthy nations have significant duties to people in poorer nations. Each leans cosmopolitan and rejects the most extreme forms of nationalism. Each places considerable weight on people's duty to help those who fare poorly irrespective of citizenship, suggesting a respect for human dignity as such.

Yet even if some degree of cosmopolitanism is warranted, this does not yet settle the question of how strong cosmopolitan duties are. For our purposes, it is sufficient to establish that nations have *some* duty to distribute vaccines to people everywhere in order to raise the question of what values ought to guide global distribution. We propose a moderate interpretation of cosmopolitanism, best expressed by Scheffler, who holds that 'in addition to one's relationships and affiliations with particular individuals and groups, one also stands in an ethically significant relation to other human beings in general'[15] (p 115). According to this proposal, a nation might be ethically justified in giving limited priority to its own citizens, a view we call *moderate nationalism*; beyond this, nations have a duty to distribute vaccines to people in other nations, a view we call *moderate cosmopolitanism*.

If this analysis is correct, it suggests that vaccines are best understood as goods that all people need to protect health and life; we are currently developing some of the tools needed to distribute them on a global basis; and nations have some duty to contribute to global efforts based both on moral nationalism and moral cosmopolitanism.

II. VALUES GOVERNING GLOBAL VACCINE DISTRIBUTION

We turn next to address the general ethical values that should guide global vaccine distribution, including helping those with the greatest need, reducing health disparities, saving the most lives and promoting narrow social utility. In the next section (section III) we will show how these broad values lend support to a practical framework that can guide decision-making and policy.

Helping people with the greatest need

The first and most obvious value at stake in the global distribution of vaccines against the SARS-CoV-2 virus is helping those with the greatest healthcare needs. We define a *healthcare need* as the capacity to benefit from healthcare services, such as disease prevention, diagnosis, treatment, rehabilitation and terminal care.[16] More formally, a healthcare need is 'the requirement for a specific clinical intervention in order to avoid or minimise sustained and serious disability.'[17] So understood, *healthcare* needs are distinct from *health* needs, for example, the need for social and environmental supports for health, such as housing, food security, education and employment. Healthcare needs are also distinct from *disease severity*, because they assume an effective intervention exists that can benefit the patient. The underlying basis for helping people with the *greatest* healthcare need is the general principle of equal access for equal needs.[18]

During the COVID-19 pandemic, older adults are the age group with by far the greatest healthcare needs, defined by both their far higher rate of severe disease or death from SARS-CoV-2 infections and by their ability to benefit from disease prevention, such as masking and physical distancing, and lifesaving interventions, such as ventilators. In the USA, 80% of COVID-19-related deaths have occurred among people aged 65 years and over; among people aged 65 years and over, rates of severe disease appear to increase with age, with those age 85 years and over experiencing 814.6 hospitalisations per 100 000 people.[19] Worldwide, emerging evidence shows a strong age gradient in morbidity and mortality,[20] with some variation between high-income countries versus LMICs.[21]

Why are older adults facing such disproportionate risk? One explanation is age-related decline in immune response, which renders older individuals less able to mount an effective defence against the virus.[22] Another explanation is that older people experience generally higher rates of underlying chronic diseases, such as hypertension, coronary heart disease and diabetes, which are associated with COVID-19-related morbidity and mortality. There are undeniably social determinants at play as well. Congregate populations in general fare worse, whether in prisons, homeless shelters or long-term care facilities serving older clientele, because physical distancing to contain disease spread cannot occur. Shortcomings at elder care facilities in many parts of the world exacerbate risk. For example, during the pandemic deficiencies at elder care facilities were reported across Europe, including inadequate testing, infection prevention and control, and monitoring programmes.[23 24] In the US, deficiencies at nursing homes and long-term care facilities serving mostly older adults were apparent both before and during the pandemic.[25 26]

To the extent that social conditions make matters worse for older adults, this heightens the responsibility of societies to come to their aid. Rather than simply saying to older adults that they are responsible for their plight, society must instead acknowledge the ways in which it contributes to poor outcomes for this age group. However, it could be argued that rather than prioritising older adults for access to vaccines while they are scarce, we should instead initiate social interventions to correct unsafe environments, such as long-term care facilities. In reply, we agree that such efforts are urgently needed. However, given the varied sources of older people's higher risk, remedying one source is at best a partial fix.

Reducing health disparities

Yet even if older adults have higher risk of severe disease and death, they are hardly the only group at heightened risk. Historically, pandemics rarely affect people in uniform ways, preying on the poorest populations. It is helpful to distinguish two ways in which people can be at elevated risk:

High infection risk: more likely to become infected.

High risk of severe disease or death: more likely to experience high morbidity or mortality if infected.

Older adults have a high risk of serious disease or death if infected; however, they do not necessarily have a high infection risk. For example, consider the case of two men, aged 70 and 19 years.

Case 1: The case of two men

A 70-year-old man with type 2 diabetes is at high risk of severe disease or death if infected with the SARS-CoV-2 virus. Yet, he is at very low risk of contracting the disease because he is affluent, lives at home and can safely socially isolate. Contrast his situation with that of a 19-year-old man who lives in a crowded apartment in an urban environment and works full-time at a hardware store where he earns minimum wage. Like his coworkers, he would be hard pressed financially to stay home if he develops symptoms because he does not have paid sick leave. The younger man has a high infection risk, but a relatively low risk of serious disease or death, because if he became infected, his chance of doing well would be much higher than that of the 70-year-old man with type 2 diabetes.

How ought we weigh these different types of risk? When we turn to address practical allocation criteria (in section III), we will argue that the best approach is to count both risk factors and sort each into appropriate priority groups. For now, the critical point to notice is that during the COVID-19 pandemic, people at high risk of severe disease or death and those at high risk of infection tend to cluster disproportionately among the most disadvantaged subgroups within a population. One reason is the social determinants of health; others include the adverse effects of systemic racism and historic injustices, such as colonialism. For example, in the UK, systemic racism against black, Asian and minority ethnic (BAME) communities has been apparent during the pandemic, with BAME communities not only demonstrating higher rates of infection, but more severe COVID-19 complications and deaths when infected compared with the general population.[27–29] In the US, black and Latinx people are disproportionately affected by the SARS-CoV-2 virus: they have triple the chance of becoming infected compared with white people.[30] These same US groups have high risk of severe disease or death if infected compared with the general population: among those who contract the virus, the mortality rate is six times higher among people living in predominantly black counties compared with white counties.[31]

In addition to their greater healthcare need, mounting evidence in public health shows that an important reason for disparate health burdens among disadvantaged people relates to the background social conditions in which people are born, live and work.[32] A principle of health equity expresses the underlying idea that equitable sharing of burdens and benefits implies duties of non-discrimination in the treatment of others.[33] Systemic injustices both within and between nations violate non-discrimination. Rather than opting for a 'colour blind' approach, we seek to mitigate the adverse effects of racism.[34 35] A principle of health equity gains support from luck egalitarianism (discussed above). According to luck egalitarianism, society should compensate people who suffer unchosen disadvantages.

To define more precisely the population that a principle of health equity should be designed to help, we draw on the National Institute on Minority Health and Health Disparities (NIMHD) definition of a 'health disparity population' as a population displaying 'a pattern of poorer health outcomes, indicated by the overall rate of disease incidence, prevalence, morbidity, mortality or survival compared with the general population'[36] (p S16). This definition encompasses both high risk of severe disease or death and high risk of infection. While the general NIMHD definition has not been applied in a disease-specific way, it is helpful to further specify it by distinguishing a COVID-19 health disparity population, defined as follows.

COVID-19 health disparity population: (a) high risk of severe disease or death if infected or (b) high risk of infection.

A critic might argue that considering health disparities in vaccine distribution is a quagmire if applied at a global level. For example, does our distributive scheme prioritise all people in Bangladesh or another country with limited healthcare infrastructure? Liu *et al* seem to allow this when they claim that we ought to prioritise people in low-income countries because they generally lack the capacity to access treatment if they become critically ill, making vaccines the only potential intervention for patients in low-income countries.[37] Yet, how do we account for the fact that all 165 000 000 people living in Bangladesh merit priority? In reply, additional sorting after the initial sorting will be needed, which could appeal to different values. We might, for example, apply a lottery if a high number of people qualify for a priority group after first-pass sorting. Alternatively, the government of Bangladesh might receive vaccines and determine allocation based on its own selection criteria after the first sort occurs; according to this scenario, the role of global distribution might shift to assisting as needed with implementation according to each nation's criteria for distributing the vaccines it was allotted.

Saving the most lives

A third ethical value guiding global vaccine distribution is the utilitarian value of saving the most lives. It is important to notice that when the good being allocated is a lifesaving resource, such as ventilators, saving the most lives requires prioritising those most likely to survive with the resource. For example, during the COVID-19 pandemic, *ventilators save more lives if distributed to younger, healthy people*. However, when the good being distributed is preventive, such as vaccines, the logic of saving the most lives is turned on its head. In the case of vaccines, saving the most lives requires selecting those most likely to die without the resource. During the COVID-19 pandemic, *vaccines save more lives if distributed to older people and others at high risk of dying if infected*. The utilitarian value of saving the most lives underlies the logic of standard triage implemented in hospital emergency departments during short-term disasters, such as a mass shooting or earthquake; it aims to save the most people by prioritising those likely to die without a resource and likely to survive with it.[38] Saving the most lives also represents the dominant approach in bioethics literature addressing resource distribution during global pandemic emergencies. In their review of the bioethics literature on setting priorities during pandemic influenza, Williams and Dawson reported that most bioethics articles 'took a line that was broadly either explicitly or implicitly consequentialist in nature, with a tendency to focus on outcomes'[1] (p 4). Consistent with this finding, during the COVID-19 pandemic, Emanuel *et al* argue that 'the value of maximising saving lives justifies giving older persons priority for vaccines immediately after healthcare workers and first responders'[39] (p 5). They go on to argue that prioritising younger people would be justified 'only if epidemiological modelling shows that this would be the best way to reduce viral spread and the risk to others'[39] (p 5).

Objections to saving the most lives

We turn next to examine important counterarguments to the value of saving the most lives. Each makes a pitch for valuing the lives of younger people more, rather than maximising the total number of all lives saved.

The first counterargument expresses concern that during the COVID-19 pandemic, the value of saving the most lives conflicts with the weightier value of promoting global health equity. The argument holds that saving the most lives entails prioritising older people for vaccine distribution, yet this advantages high-income nations, which generally have more older residents and higher average life expectancies, while disadvantaging LMICs, which generally have fewer older residents and shorter average life expectancies.[40] Yet, in reply, saving the most lives makes a broader appeal. Rather than focusing narrowly on chronological age, this value speaks to the greater need that arises from having a high risk of severe disease or death if infected with the SARS-CoV-2 virus. While this category includes older people, it includes other groups too, such as people of any age with obesity or other chronic diseases that place them at greater risk of severe disease or death. Furthermore, while our appeal to people at high risk of becoming infected includes, for example, older people living in congregate populations, such as nursing homes, it also includes people of any age living or working in crowded conditions, such as people living in prisons and people working low-wage jobs in warehouses or meat-packing plants. Finally, rather than appealing only to these immediate high risks, our reasoning takes stock of upstream social determinants that yield health disparities. Thus, we assign priority to people who belong to disadvantaged groups when those groups are associated with a higher risk of infection and/or higher risk of serious disease or death from the virus.

A second counterargument raises the practical point that saving the most lives implies lower, not higher, priority to older adults, because they are less responsive to vaccine prevention.[22] In this sense, prioritising them produces less 'return on investment' measured in terms of lives saved. Reasoning along these lines, Arras sounds the alarm that 'the debilitated elderly in nursing homes' may be 'extremely inefficient hosts' for vaccines; he cautions that vaccinating them might put 'healthier people whose bodies could put the vaccine to better use' at risk[41] (p 292). Yet, a variety of factors other than immune senescence reduce immune response, such as having certain underlying chronic conditions; being of the male sex; obesity and genetic polymorphisms.[42] Should we give people in these groups less priority too? Perhaps a utilitarian would claim that we should, arguing that vaccinating groups with lower immunogenicity would yield worse outcomes. Yet, at this point, we part company with the utilitarian viewpoint. We pair a commitment to saving lives with commitments to help those in need and to reduce health disparities.

A third objection to saving the most lives proposes that a better approach is dividing lives into life years and then maximising standard expected years of life lost (SEYLL).[40] The idea is to maximise life years that occur prior to a person's standard expected number of life years, which is specified by reference to model life tables that assume the lifespan of developed nations as a norm toward which most populations aspire.[43] Emanuel *et al* defend this approach on the ground that it is 'both prudent and ethical' to abide by SEYLL, which, 'regards all deaths as important but earlier deaths as particularly important'[40] (p 1310–1311).

In response, although younger people generally have more years to live before they reach the standard number, dramatically higher death rates from the SARS-CoV-2 virus for people aged 65 years and over will generally lead to favouring *older*, not younger, people. Mallapaty summarises age-based differences in fatality rates during the COVID-19 pandemic this way:

> for every 1,000 people infected with the coronavirus who are under the age of 50, almost none will die. For people in their fifties and early sixties, about five will die…The risk then climbs steeply as the years accrue. For every 1,000 people in their mid-seventies or older who are infected, around 116 will die[44] (p 16).

To illustrate, consider a simple example in which a 90% effective vaccine becomes available and we have 100 doses to distribute among a population of 1000 people. When setting priorities, the objective is maximising life years saved before the standard expected number for a model population, which we set at 80 years. The population we are distributing the vaccine among has the following characteristics (shown in table 1): it is divided between people aged 20 years, who comprise 85% of the population and people aged 73 years, who comprise the remaining 15% of the population.

Table 2 shows age-related fatalities resembling the COVID-19 pandemic, in which death rates are higher (11.6%) among the

Table 1 Characteristics of hypothetical population

Characteristics	Value
Total population	1000
% age 20	85
% age 73	15
Standard expected years of life	80

Table 2 Fatality rates resembling the 2019 coronavirus pandemic

Group	Age (years)	Infection fatality rate (%)	Vaccine efficacy (%)	Standard expected life years saved
Young	20	0.1	90	45.9
Old	73	11.6	90	109.6

Table 3 Fatality rates resembling the 1918 influenza pandemic

Group	Age (years)	Infection fatality rate (%)	Vaccine efficacy (%)	Standard expected life years saved
Young	20	11.6	90	5323.4
Old	73	0.1	90	0.9

older group and lower (0.1%) among the younger group. In this scenario, prioritising older over younger people saves 63.7 more life years (109.6 minus 45.9).

In table 2, the key driver of life years saved is the infection fatality rate, not chronological age.

This point is brought into sharp relief if we compare the age-based fatality rates in table 2 with those in table 3, where death rates are flipped, so that the younger group has higher fatality rates than the older group.

When the fatality rates are flipped, we save 5322.5 life years (5323.4 minus 0.9) by prioritising the younger group. While the age-based fatalities shown in table 2 roughly resemble those occurring during the COVID-19 pandemic, in which the highest fatality rates are among older people; those shown in table 3 look more like the 1918 influenza pandemic, in which fatality rates were highest among younger people.[45] During both pandemics, large differences in age-based fatality rates make age a reliable predictor for how to save the most life years when distributing a limited vaccine: during the COVID-19 pandemic, we should prioritise older age groups and during the 1918 pandemic, we should prioritise younger age groups. Our analysis does not establish that SEYLL should be rejected; instead, it establishes that the results of applying SEYLL during the COVID-19 pandemic match the results of applying the standard of saving the most lives.

A last objection to saving the most lives appeals to common morality and a 'popular agreement' that deaths that prevent people from realising goals earlier in life are worse than deaths later in life[40] (p 1310). Consistent with this claim, during the COVID-19 pandemic, a PEW Research Center survey found that 45% of US citizens were willing to give less priority for critical care resources to people who were older and sicker.[46] While these findings may not extend to vaccines, they might reflect an underlying view that the lives of the young are more valuable than the lives of the old, with implications for vaccine distribution. However, people around the world hold diverse views about the value of life at different ages. According to the WHO, residents of LMICs more often than those in high-income countries report that their society respects older adults.[47] In sub-Saharan African ethics, many people accord higher moral status to individuals the older they become.[48] Diverse views from people around the world deserve a fair hearing when formulating distributive criteria to be applied at a global level. Yet, even if it were in fact true that people around the world respected older people less than younger people, this would hardly show that older people *deserve* less respect. It might instead reveal moral 'blindspots', which are implicit biases we hold due to factors like upbringing and the way our brains process information.[49]

Narrow social utility

A final value guiding global vaccine distribution is narrow social utility. In contrast to *broad social utility*, which indicates a person's overall value to society, *narrow social utility* indicates a person's short-term value to society during a public health crisis or other emergency.[50] An example of narrow social utility is the reported practice during World War II of distributing the scarce resource of penicillin first to soldiers who had contracted syphilis and could return to battle, over soldiers who had sustained wartime injuries and could not return to battle. Beecher describes the ethical predicament this way.

> When the wonders of penicillin were new, but recognized, and the supply heartbreakingly meager, a small shipment finally arrived in north Africa during World War II. The hospital beds were overflowing with wounded men. Many had been wounded in battles; many also had been wounded in brothels. Which group would get the penicillin? By all that is just, it would go to the heroes who had risked their lives, who were still in jeopardy, and some of whom were dying. They did not receive it, nor should they have; it was given to those infected in brothels[51] (p 209).

Beecher goes on to explain the justification for narrow social utility as threefold:

> First, there were desperate shortages of manpower at the front. Second those with broken bodies and broken bones would not be swiftly restored to the battle line, even with penicillin, whereas those with venereal disease, on being treated with penicillin, would in a matter of days free the beds they were occupying and return to the front. Third, no one will catch osteomyelitis from his neighbor; the man with venereal disease remains, if he is cured, a reservoir of infection and constant threat[51] (pp 209–210).

He concludes that although, 'In terms of customary morality, a great injustice was done; in view of the circumstances… the course chosen was the proper one.'[51] (p 210). Properly understood, narrow social utility is a reluctant, highly circumscribed form of social utility. As this passage shows, values shift during catastrophes to survival of individuals and the societies in which they live.

In contrast to Beecher's constrained form of social utility, advocates for broad social utility endorse the unqualified maximisation of utility. For example, in Seattle during the 1960s, members of an anonymous committee charged with distributing access to the artificial kidney favoured 'men with the highest potential to society', and those with 'the finest educational backgrounds', not because these men were needed to win a war, but simply because it was thought that they would benefit society most[52] (p 115).

During the COVID-19 pandemic, ending the pandemic and safeguarding lives represent urgent public goods, realised by prioritising people who can perform the tasks of fighting disease and saving lives. Safeguarding society's essential functioning requires prioritising people who can perform essential tasks. The implication is not that the favoured groups are ultimately more valuable, but instead that in the moment, they are best able to help people and society carry on.

III. AN ETHICAL FRAMEWORK FOR GLOBAL VACCINE DISTRIBUTION

Stepping back from the discussion of ethical values and principles, we turn next to place these values within a practical ethical framework and to set forth criteria to help with allocation decisions. A 'framework' is literally, 'a structure made of parts joined to form a frame; especially one designed to enclose or support.'[53] The meaning evokes the act of enclosing something within a frame to better appreciate its content. As we use the term here, the parts that comprise our framework are allocation criteria, the specific content they enclose is global vaccine distribution, and what the framework accentuates is the underlying

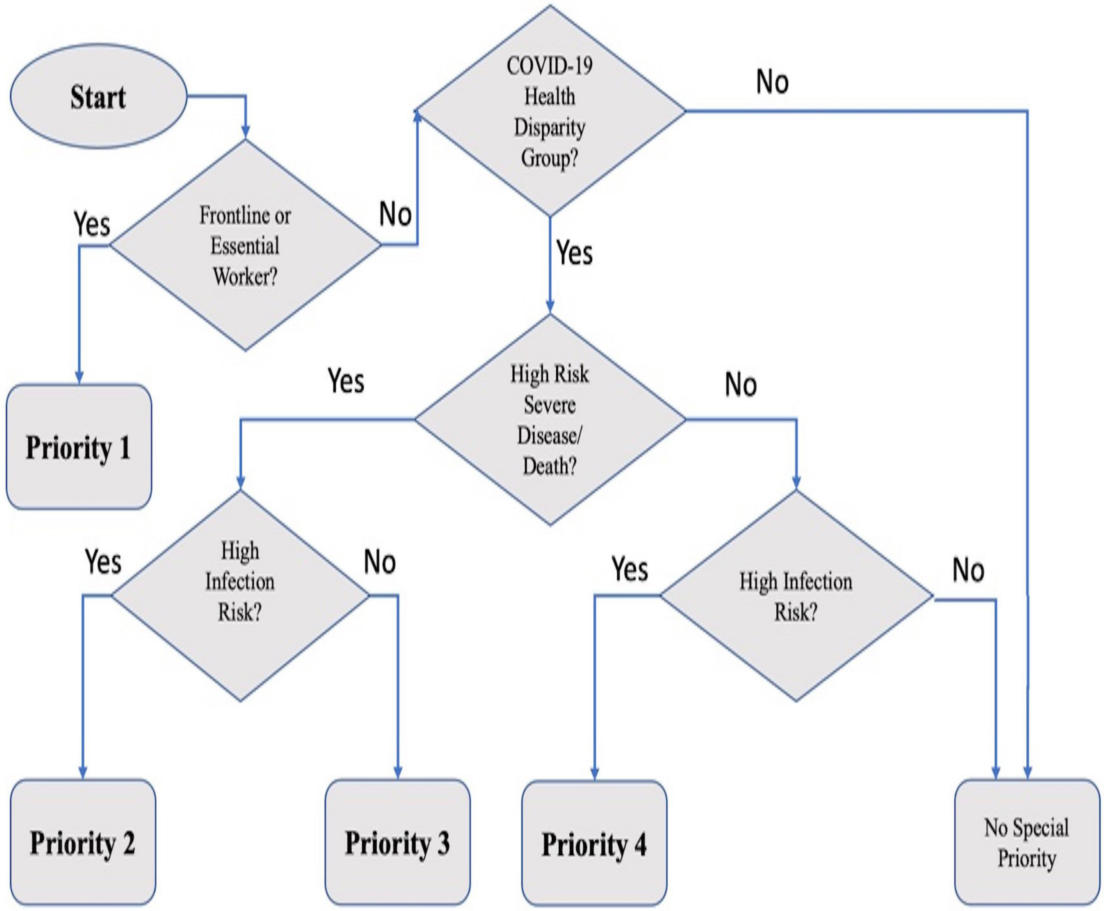

Figure 1 Priority groups for the SARS-CoV-2 virus.

values that ought to guide global vaccine distribution. More precisely, a framework is simply 'a practical document that helps with deliberation about what we should do'[54] (p 2). Because it is designed specifically to aid decision-making, it differs from a list of general values or principles, of the sort discussed in section II, which specifies values or principles without indicating *how* they are to be used and applied to cases or in decision-making. Figure 1 shows the criteria that comprise our framework as a set of ordered questions; this clarifies how the criteria work. The order of questions displays the priority of different criteria, which we discuss in detail below.

Frontline and essential workers

Prior to releasing a vaccine to groups in the general population, we give priority to frontline and essential workers. *Frontline workers* may vary from one nation to the next but might include, for example, people who enter the room of patients with COVID-19 to provide care, such as pulmonologists and respiratory therapists, as well as non-medical personnel, such as custodians who clean and sanitise rooms, security workers who keep patients and staff safe, and personal aides in long-term care facilities who help older adults with activities of daily living. *Essential workers* will also vary from one nation to the next, but might include, for example, deployed military personnel (in nations that have a standing military); pharmacists; first responders; communication services (eg, utilities) and general healthcare workers. Our defence of this position appeals to the value of narrow social utility introduced in section II and discussed at length in the literature.[55]

COVID-19 health disparity populations

Drawing on the definition of a COVID-19 health disparity population, also set forth in section II, we assign the next highest priority to members of this population, which includes both (a) people at high risk of severe disease or death if infected and (b) people at high risk of infection. Within the COVID-19 health disparity population, we assign the highest priority to those who are *both* at high risk of severe disease or death and at high risk of infection; we assign next priority to those at high risk of severe disease or death without high risk of infection; we assign last priority within the COVID-19 health disparity population to those at high risk of infection, but no higher risk of severe disease or death if infected. For example, our approach prioritises the following groups immediately after frontline and essential workers (who are priority 1):

Priority 2: people aged 65 years and over who live in nursing homes; people belonging to racial/ethnic groups associated with both higher risk of infection and higher risk of severe disease or death; people with underlying chronic conditions linked to high risk of severe disease or death who live in crowded environments, such as prisons.

Priority 3: people with underlying chronic conditions linked to higher risk of severe disease or death who can safely socially distance; people with high body mass index (BMI) who attend school remotely; people aged 65 years or over who can work remotely and shelter at home.

Table 4 Priorities within the COVID-19 health disparity population

	High risk if infected?	High risk of infection?
Priority 2	Yes	Yes
Priority 3	Yes	No
Priority 4	No	Yes
None	No	No

Priority 4: healthy young adults working in crowded environments, such as childcare facilities; healthy young adults aged 18–22 years living in college dormitories; healthy people under age 65 years residing in prisons; healthy adults under age 65 years working in high-exposure environments.

Expressed differently, we sort the COVID-19 health disparity population into three priority groups, shown in table 4.

To illustrate, consider again the case of two men (discussed in section II), modified slightly.

Case 2: The case of two men modified slightly

Suppose the 19-year-old man (from Case 1) who works in a hardware store and lives in a crowded apartment has a BMI of 30 or more. The young man then qualifies for the highest priority immediately after frontline and essential workers, because he would have both a high risk of serious disease or death and a high risk of becoming infected. By contrast, the 70-year-old man with type 2 diabetes has relatively lower priority for accessing a vaccine, because despite his elevated risk of serious disease or death if infected, he is unlikely to become infected because he can safely shelter at home.

Finally, consider the situation of a third man who is young and healthy.

Case 3: The case of a third man

A third man is a 20-year-old coworker of the 19-year-old in Case 2 and has roughly the same risk of becoming infected on the job as his coworker does, but he is not at high risk for serious disease or death if he falls ill. The third man falls into the lowest priority group within the COVID-19 health disparity population because although he has a high risk of infection, he has no known risk factors for serious disease or death if infected.

In response to the proposed ranking, it could be argued that in the case of the SARS-CoV-2 virus, emerging evidence suggests that severity of disease might be proportionate to viral dose inoculum, that is, the initial dose of virus that a patient takes in.[56] If this turns out to be the case, then people at high risk of infection would overlap significantly with people at higher risk of severe disease and death; this in turn, would potentially erode the proposed distinction between these groups. To illustrate, consider the case of unprotected churchgoers.

Case 4: The case of unprotected churchgoers

A group of people gather together inside a church and sing. They are at high risk of infection and are likely to receive a high viral dose inoculum, which potentially places them at higher risk of severe disease or death, even absent other known risk factors.

In this case, those at high risk of infection and those at high risk of severe disease and death are identical.

In reply, we maintain that placing individuals who are at high risk of infection (eg, the unprotected churchgoers), in a queue behind individuals at high risk of severe disease and death is ethically justified, because there is more evidence and certainty about the latter group's risk of severe disease and death than the former group's. However, we acknowledge that a shift in criteria might be supportable in the future, if more information became available which showed that people who are at high risk of infection are also at high risk of severe disease and death just by virtue of the conditions that put them at higher risk of infection.

Risk of transmission

It could be argued that risk of transmission is also an ethically significant factor, distinct from the others we have discussed. Yet, at first glance, people at high risk of transmitting the novel coronavirus roughly coincide with people at high risk of infection. The defining feature for both groups is high exposure to the virus. For example, in the case of unprotected churchgoers, those at high risk of infection and those at high risk of transmission were the very same individuals. Still, one can imagine exceptions. For example, if one of the unprotected churchgoers in the example donned a mask, they would still seem to be at high risk of infection, but they would no longer represent a high risk of transmission. However, it is unclear if this kind of distinction holds up under closer inspection or holds up at a sufficient level to justify separate treatment for the group at high risk of transmission. This is because of still emerging evidence showing that masks protect users by reducing infection and/or severe disease and death, due to reducing viral dose inoculum.[57]

A further reply to the proposal to add risk of transmission is that absent evidence showing that a particular vaccine in fact curbs transmission, the criterion would not apply. For example, phase III trials for Pfizer and Moderna tell us only whether vaccines against the SARS-CoV-2 virus prevent illness and hospitalisation, not whether they prevent asymptomatic infection and transmission.[57] That leaves open the chance that some vaccinated people were infected without showing symptoms. Some immunologists maintain that the SARS-CoV-2 virus might replicate in the nasal mucosa faster than the immune system of vaccinated people could attack it; if this were the case and if vaccinated people stop wearing masks, they could infect others.[58] Yet if we learn that either vaccine reduces infection and curbs transmission, or if a future vaccine does this, it might be thought that risk of transmission would become ethically salient in ways it is currently not.

Yet, even if vaccines that reduce infection are in the offing, we reject the proposal to use risk of transmission as a criterion for distributing limited vaccines. The reason is that there is a readily available and effective alternative. To illustrate, consider a revised version of the case of the unprotected churchgoers (Case 4 above).

Case 5: The case of protected churchgoers

The same group as in Case 4 gathers inside the same church but they wear masks, avoid shaking hands, leave every other seat unoccupied and refrain from singing. They are still at high risk of infection by virtue of being together with a group of people inside a church, but each caveat lowers their viral dose inoculum and potentially places them at lower risk of severe disease or death.

While we could have vaccinated each and every one of the churchgoers, this would not be ethically permissible if vaccines were in short supply and masks were readily available absent some independent reason to vaccinate them. For example, in both versions of the churchgoer case, the churchgoers might

Table 5 Ethical framework for global distribution of COVID-19 vaccines

Priority	Group	Ethical values	Examples
1	1. Frontline workers or 2. Essential workers	Narrow social utility	1. Healthcare workers caring for patients with the SARS-CoV-2 virus 2. EMS, utility workers
2	People at high risk of (a) severe disease or death or (b) infection	Help the needy, reduce health disparities, save the most lives	1. Older adults, people with certain chronic diseases 2. Congregate populations, racial and ethnic minorities
3	Lottery/weighted lottery	Show equal respect, build trust /Reduce health disparities	N/A

EMS, emergency medical services; N/A, not applicable.

not be members of health disparity populations. If they were, they would already receive priority for vaccines on that basis.

Lottery

After prioritising frontline and essential workers, people at high risk of serious disease or death, and people at high risk of infection, vaccines should be made available to the general public by means of a lottery. The ethical reasons for using a lottery are that it minimises arbitrary and unfair manipulation of vaccine distribution, can build trust in the integrity of the distribution process and shows equal respect for persons. As a tool to reduce global health disparity, weighted lotteries might also be considered that assign priority to nations with greater disadvantage, for example, based on income. Table 5 summarises our three-stage proposal setting forth an ethical framework for global distribution of vaccines against the SARS-CoV-2 virus.

Comparison with alternatives

Table 6 shows how our framework compares with six alternatives: the WHO[59]; WHO/Strategic Advisory Group of Experts (SAGE)[60]; Emanuel *et al*[36]; Johns Hopkins University[61]; National Academies of Sciences, Engineering and Medicine (NASEM)[62] and the Advisory Committee on Immunization Practices (ACIP).[63]

Although not all proposals are designed for global vaccine distribution, all indicate views consistent with the ethical arguments we present in section I. Several proposals emphasise procedural requirements, such as transparency and publicity, which we do not address but which we see as crucial for maintaining public trust in any allocation scheme.

Three proposals present criteria designed specifically for global vaccine allocation. Yet each falls short in at least one respect we regard as crucial: prioritising people with the greatest need, reducing health disparities and saving the most lives. The WHO's 'Fair Allocation Mechanism for COVID-19 Vaccines Through the COVAX Facility' distributes vaccines proportional to the population of each country. This allows for the possibility, which our proposal does not, of distributing vaccine first to people who are at relatively low risk of infection and/or low risk of severe disease or death. In contrast to the WHO, we apply a principle of equality (represented by a lottery) only after first giving priority to frontline and essential workers, people at high risk of severe disease or death, and people at high risk of infection. We also allow weighted lotteries to address global health equity.

The WHO/SAGE's 'Values Framework for the Allocation and Prioritization of COVID-19 Vaccination' promotes the value of human well-being, understood as including a broad

Table 6 Comparison of ethical frameworks for distribution of COVID-19 vaccines

	Priority to frontline and essential workers?	Priority to high risk of severe disease/ death?	Priority to high risk of infection?	Priority to saving the most lives?	Other criteria?
Global allocation criteria					
Jecker, Wightman, Diekema	Yes	Yes	Yes	Yes	Narrow social utility, help the needy, reduce health disparities, show equal respect, build trust
WHO	Yes	No	No	No	Proportional to population
WHO/ SAGE	Yes	Qualified	Qualified	Qualified	Opening economies
Emanuel, *Persad, Kern, et al*	Yes	No	No	No	SEYLL, priority to the disadvantaged, reduce risk of transmission
Domestic allocation criteria					
NASEM	Yes	Yes	Yes	Yes	Reduce risk of transmission, equality
Johns Hopkins University	Yes	Yes	Qualified	Yes	Reduce risk of transmission, reciprocity, trust, opening economies
ACIP	Yes	Yes	No	Yes	Maximise benefits/minimise harms, equity

ACIP, Advisory Committee on Immunization Practices; NASEM, National Academies of Sciences, Engineering and Medicine; SAGE, Strategic Advisory Group of Experts; SEYLL, standard expected years of life lost.

swath of factors, such as 'the closures of businesses, interruptions to trade, transport and value chains, reduced consumer and business demand, and concomitant slowdown in economic activity' along with school closures and travel restrictions[60] (p 6). While these factors merit consideration, we distinguish among them by assigning higher priority to those that place people at high risk of severe disease or death, which is context dependent. For example, during lockdowns, the health and lives of residents in LMICs may be at risk because they live from one day to the next and cannot purchase food until they receive pay for a day's work.

Lastly, as noted, Emanuel *et al*'s 'Ethical Framework for Global Vaccine Allocation' does not save the most total lives, but instead prioritises preventing earlier deaths and life years prior to the standard expected number[40] (p 1310). They also promote priority to the disadvantaged but define this in terms of people who have lived less life, interpreting an early death as a 'proxy for being disadvantaged,' which we do not[40] (p 1310).

The next three proposals address domestic allocation, yet each identifies underlying values that could be extrapolated to global allocation. Johns Hopkins University's 'Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States' overlaps with our proposal in the priority it assigns frontline and essential workers and those at greatest risk of severe illness and death and their caregivers. Their proposal also overlaps with ours by giving priority to people at high risk of infection; yet, unlike us, they make this priority contingent on people's risk of transmission (eg, being connected to a larger community). While we share a commitment to reducing risk of transmission, we have argued that even if data demonstrate that a vaccine can reduce transmission risk, so long as vaccines are in short supply, alternatives, such as masking, which are readily available and effective, should be used instead.

The values underpinning NASEM's 'Framework for Equitable Allocation of COVID-19 Vaccine' align closely with ours in crucial respects. They stress, as we do: reducing morbidity and mortality from the SARS-CoV-2 virus and protecting frontline workers, including nursing home workers. In addition, NASEM shares our focus on saving the most lives, rather than the most life years. Yet we make the stronger case that during the COVID-19 pandemic, a strategy of giving priority to years of life lost before a standard number backfires, costing more life years overall. An additional area of overlap is attention to mitigating health inequities. In contrast to us, NASEM considers risk of transmission to others.

ACIP's 'Scientific and Ethical Principles Underlying Recommendations From the ACIP for COVID-19 Vaccine Implementation' sets forth the ethical principle of maximising benefits and minimising harms to justify prioritising healthcare personnel with potential exposure to patients with COVID-19 or infectious materials. By contrast, we appeal to narrow social utility to justify prioritising all frontline workers, not just healthcare personnel. We share ACIP's commitment to health equity, which they describe as removing unjust avoidable barriers that affect the most disadvantaged groups disproportionately. We go further, precisely defining a 'COVID-19 health disparity population' in order to operationalise this idea and hold societies accountable.

Whatever framework is selected for global vaccine distribution, there is a real risk that political influence or corruption could taint distribution at the national level. To minimise corruption, global policymakers should implement best practices for vaccine distribution, such as those recommended by the United Nations Development Programme's 2011 report on fighting corruption[64] and Transparency International's handbook for preventing misconduct in global distribution.[65]

CONCLUSION

We began by asking, what is a fair and equitable way to distribute a vaccine against the SARS-CoV-2 virus? Should each nation distribute doses to its own population or should distribution be global? If distribution is global, what values and criteria ought to govern? In response to these questions, we argued that vaccines should be distributed globally, with priority to frontline and essential workers worldwide. We proposed assigning vaccine priority both to people at higher risk of serious disease or death and to those at higher risk of infection. Our priorities for just distribution highlight values of helping the neediest, reducing health disparities, saving lives and keeping society functioning.

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