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### The Shared Ethical Framework to Allocate Scarce Medical Resources: A Lesson from COVID-19

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# The Shared Ethical Framework to Allocate Scarce Medical Resources: A Lesson from COVID-19

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### **Health Policy**



### (M) The shared ethical framework to allocate scarce medical resources: a lesson from COVID-19

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The COVID-19 pandemic has helped to clarify the fair and equitable allocation of scarce medical resources, both within and among countries. The ethical allocation of such resources entails a three-step process: (1) elucidating the fundamental ethical values for allocation, (2) using these values to delineate priority tiers for scarce resources, and (3) implementing the prioritisation to faithfully realise the funfdamental values. Myriad reports and assessments have elucidated five core substantive values for ethical allocation: maximising benefits and minimising harms, mitigating unfair disadvantage, equal moral concern, reciprocity, and instrumental value. These values are universal, None of the values are sufficient alone, and their relative weight and application will vary by context. In addition, there are procedural principles such as transparency, engagement, and evidence-responsiveness. Prioritising instrumental value and minimising harms during the COVID-19 pandemic led to widespread agreement on priority tiers to include health-care workers, first responders, people living in congregate housing, and people with an increased risk of death, such as older adults and individuals with medical conditions. However, the pandemic also revealed problems with the implementation of these values and priority tiers, such as allocation on the basis of population rather than COVID-19 burden, and passive allocation that exacerbated disparities by requiring recipients to spend time booking and travelling to appointments. This ethical framework should be the starting point for the allocation of scarce medical resources in future pandemics and other public health conditions. For instance, allocation of the new malaria vaccine among sub-Saharan African countries should be based not on reciprocity to countries that participated in research, but on maximally reducing serious illness and deaths, especially among infants and children.

### Introduction

In the past 100 years, no other event or novel technology-not the advent of penicillin, dialysis, organ transplantation, or new genetic therapeutics-has necessitated the allocation of scarce health resources for more people worldwide than the COVID-19 pandemic. The allocation of scarce resources has occurred both within countries and among countries. Many politicians, policy makers, and commentators called for a fair and equitable allocation of COVID-19 therapeutics, vaccines, and other medical interventions.1-3 But these key ethical concepts were frequently left inchoate-except for the need to send an unspecified, increased amount of resources to vulnerable communities within countries, and particularly to low-income countries worldwide.

The ethical allocation of scarce medical resources entails a three-step process: (1) elucidating the fundamental ethical values for allocation, (2) using the values to delineate priority tiers for scarce resources, and (3) actually implementing the prioritisation to faithfully realise the fundamental values. The COVID-19 pandemic engendered many assessments and reports on the ethical allocation of vaccines, therapeutics, and other medical interventions that have elucidated the definitive ethical framework for distributing scarce resources. The pandemic also provided major tests for implementing ethical allocation frameworks, revealing important lessons on the challenges of moving from theory to practice, and refinements that would enhance realisation of the ethical framework.

The COVID-19 pandemic is not the last time public health allocation decisions will need to be made. Because it is impossible to instantaneously produce and distribute

sufficient quantities of any medical intervention, scarcity will occur again and fair allocation will be necessary. Examples include the mpox (formerly known as monkeypox) vaccine, JYNNEOS (Bavarian Nordic, Hellerup, Denmark);4 the new malaria vaccine, Mosquirix (GlaxoSmithKline Biologicals, Rixensart, Belgium); and vaccines for cholera.5 Production shortages will mean that these vaccines will need to be rationed both among and within countries. How should the allocation of these vaccines be done ethically?

Distilling the knowledge gained from the COVID-19 pandemic about ethical frameworks for resource allocation-which were proposed in multiple countries and by scholars-and their practical implementation both within and among countries can enable rapid and ethical decision making in future health emergencies and in other health-care domains.

### Reports on allocating scarce medical resources

COVID-19 prompted many reports on allocating scarce medical resources, including from the US National Academies6 and the US Advisory Committee on Immunization Practices (ACIP),<sup>7</sup> many other countries,<sup>8-11</sup> international organisations such as the Nuffield Council<sup>12</sup> and WHO's Strategic Advisory Group of Experts on Immunization,13 individual states and health-care institutions, and independent scholars (table 1). Most of these reports identified similar substantive values and procedural principles, and proposed similar-but not necessarily identical-priority groups for allocating resources.

Allocating scarce COVID-19 resources among countries, particularly the short supply of vaccines, was a

	Substantive principles					Procedural principles	Top allocation tiers
	Maximising benefit and reducing harm	Mitigating disadvantage (equity)	Equal moral concern	Reciprocity	Instrumental value		
Federal							
National Academies (2020) <sup>6</sup>	Maximise benefit		Equal concern		*	Fairness; transparency; evidence-based	Phase 1a: high-risk health workers and first responders; phase 1b: people of all ages with comorbid conditions that put them at substantially higher risk, and older adults living in congregate or overcrowded settings
Advisory Committee on Immunization Practices (2020); <sup>14</sup> (2021) <sup>15</sup>	Maximise benefit and minimise harm	Mitigate health inequities	Promote justice		*	Promote transparency	Phase 1a: health-care workers and long- term facility residents; phase 1b: front-line essential workers and people aged 75 years and older; phase 1c: people aged 65-74 years, people aged 16-64 years with high-risk medical conditions, and other essential workers
US state							
California (2020) <sup>16</sup>	Benefiting people and limiting harm	Prioritising equity	Ensuring equal concern		*	Promoting transparency; prioritising based on evidence	Phase 1a: health-care personnel and long- term care personnel at risk of exposure, residents of skilled nursing or assisted living facilities and similar settings; additional subfactors of prioritisation include the type of facility or role, location of facility, and the attributes of individuals
Massachusetts (2020) <sup>17</sup>	Limit severe morbidity and mortality	Promote equity			Preserve the health-care system		Phase 1: clinical and non-clinical health-care workers doing direct and COVID-19-facing care,† long-term care facilities, rest homes and assisted living facilities, first responders, congregate care settings, home-based health-care workers, and health-care workers doing non-COVID-19- facing care
Washington state (2021) <sup>18</sup>	Maximise benefits	Mitigation of health inequities	Equal concern		*	Fairness; transparency; evidence-based	Phase 1a: high-risk workers in health-care settings, high-risk first responders, residents and staff of nursing homes and assisted living facilities, and residents and staff of other community-based, congregate living settings where most individuals older than 65 years are receiving care, supervision, or assistance; phase 1b: all people older than 65 years, people aged 50 years and older in multigenerational households, workers in child-care settings, and staff working in early childhood education, primary education, and secondary education
International							
WHO (2020) <sup>13</sup>	Human well-being	Global equity and national equity	Equal respect	Reciprocity	*	Legitimacy	Priority groups unranked
Nuffield Council (2021) <sup>19</sup>	Maximising benefit and minimising harm	Equity	Equal respect	Reciprocity		Transparency	NA
UK (2020); <sup>20</sup> (2021) <sup>20</sup>	Maximising benefit and minimising harm	Reduce health inequities			*	Transparency; relevancy; provisions in place for revision	Ranked in order: residents in a care home for older adults and their carers; people aged 80 years and older, and frontline health and social-care workers; people aged 75 years and older; people aged 70 years and older, and clinically extremely vulnerable individuals; people aged 65 years and older, all individuals aged 16–64 years with underlying health conditions that put them at higher risk of serious disease and mortality; people aged 60 years and older; people aged 55 years and older; people aged 50 years and older
							(Table 1 continues on next page)

	Substantive principles					Procedural principles	Top allocation tiers
	Maximising benefit and reducing harm	Mitigating disadvantage (equity)	Equal moral concern	Reciprocity	Instrumental value		
(Continued from previou	us page)						
Ontario, Canada (2020) <sup>11,21</sup>	Minimise harms and maximise benefits	Equity	Fairness		*	Public trust; transparency; legitimacy	Phase 1: congregate living for older people; health-care workers; adults in First Nations, Métis and Inuit populations; adults receiving ongoing home care; adults aged 80 years and older
Norway (2020) <sup>9</sup>	Welfare	Equity	Equal respect		*	Trust; legitimacy	Phase 1: people with risk factors for severe illness and death;* phase 2: health-care workers; phase 3: workers with essential societal function
Australia (2020); <sup>8</sup> (2021) <sup>22</sup>	People at an increased risk of exposure; people who have an increased risk, relative to others, of developing severe disease or outcomes				People working in services essential to societal functioning		Phase 1a: quarantine and border workers, front-line health-care worker subgroups for prioritisation, aged care and disability care staff, and aged care and disability care residents
New Zealand (2021) <sup>23</sup>	Maximising resources, health protection, minimising harm, and active protection‡	Achieving equity	All people are equally deserving of care	-	Mentioned but not delineated as separate principle	Inclusiveness; whanaungatanga; openness; reasonableness; responsibleness; tino rangatiratanga\$; partnership¶; options	No prioritisation tiers specified; however, priority groups to be considered were suggested but not ranked; groups include: front-line health-care workers at high risk of exposure to patients with COVID-19, people with less capacity to socially isolate, and vulnerable patient groups such as immunocompromised individuals and people with comorbidities

and respond to public health measures to prevent and manage the spread and transmission of disease among their people. SMaon communities are key decision makers in the design, delivery, prioritisation, and monitoring of health-care and disability services and the response to pandemics or public health emergencies. The health-care and disability system works alongside Māori leaders to enable a coordinated and united response to a pandemic or public health emergency, whereby the Māori population has the resources to govern, design, deliver, manage, and monitor the response and effect of a pandemic or emergency on Māori communities. []The health-care and disability system is agile in adapting and responding to the pandemic resource needs of kaupapa Māori health-care and disability services to serve Māori communities.

Table 1: COVID-19-inspired reports on allocating scarce medical resources

further challenge that extended to the distribution of oral antiviral treatments for COVID-19.

The COVAX facility established by WHO, the GAVI vaccine alliance, the Coalition for Epidemic Preparedness Innovations, and several other organisations proposed a population-based model for allocating scarce medical resources among countries.<sup>24</sup> However, the US Government adopted an alternative approach for its distribution of vaccines,<sup>25</sup> and, as part of a group of independent scholars, we proposed a framework based on COVID-19 disease burden.<sup>26</sup>

A consensus exists on what ethical values are relevant to addressing the challenges of allocating scarce medical resources within and among countries. National governments can specify and enforce allocation domestically. By contrast, distinctive implementation challenges for global allocation stem from the lack of an authoritative body to enforce allocation among countries.<sup>27</sup> The development of coordinating bodies for international allocation is a process of ongoing negotiation. Crucially, the relevant ethical values are not inherently different.

## Fundamental substantive values for allocating scarce medical resources

Across COVID-19 guidance documents, five fundamental ethical values inform allocating scarce medical resources (table 2). Appeals to medical need are uninformative in allocating medical resources, because all candidates have medical need. Instead, the allocation decision should focus on the differential effects of allocating medical resources to some candidates in need rather than others.

The first value, improving benefits and preventing harm, is sometimes described as utilitarian but is integral to all plausible ethical theories. Harms that allocation policies aim to prevent include death, loss of future life, morbidity and hospital admissions, loss of family, loss of work, poverty, and disruption to education and social life. These undesirable outcomes need to be assessed over a lifetime,<sup>28</sup> as we not only care about near-term hospitalisations and deaths, but also the possibility of long-term impairment or disadvantage, such as post-COVID-19 condition (also known as long COVID). Some harms are direct, caused by the disease or by intensive interventions needed to treat

the disease, such as mechanical ventilation.<sup>26</sup> Others are indirect, such as worse overall health outcomes or excess deaths because hospitals are overwhelmed and are forced to adopt contingency or crisis standards of care, or worse socioeconomic outcomes because of closed schools and workplaces. In emergencies, efforts to improve benefits and prevent harm can often be pursued even with uncertainty about important facts, such as what areas are most vulnerable to pandemic spread, or which individuals are most vulnerable to long-term complications. Research into these questions can help policy makers to better design allocation policies.<sup>29,30</sup>

A second value is mitigating unfair disadvantage, which can be characterised as promoting equity. This value emphasises the idea that allocating scarce medical resources should avoid exacerbating past inequities, and that there is special urgency in preventing harm to individuals who are subject to unfair disadvantage.<sup>31,32</sup> There are many dimensions of disadvantage, such as ill health, poverty, and exclusion from opportunity. Unfair disadvantage can result from various background injustices, including discrimination on the basis of race, religion, sex, or other categories.<sup>31-36</sup>

Because disadvantaged patients tend to face a greater risk of medical and other harms, mitigating inequities can often ensure that allocation also benefits people and prevents harm. Nevertheless, the two ethical objectives are distinct. Not every characteristic associated with harm is necessarily an unjust disadvantage. For instance, being male or having lived longer is associated with an increased risk of death following COVID-19 infection, but neither are unfair disadvantages.<sup>6,37-39</sup> Mitigating inequities provides additional justification for prioritisation arrangements that prevent harm to people experiencing unjust disadvantage.

The third value, equal moral concern, emphasises not treating people differently for any reason other than realising morally important values. Equal moral concern does not require identical treatment of people who are differently situated. In this sense, context matters. For instance, treating people facing a COVID-19 surge the same as people in geographies with very low case rates does not show appropriate concern for people at greater risk, and does not minimise harm. Typically, equal concern will require differential treatment that recognises that not everyone faces equal jeopardy from a given threat to health.

Reciprocity, the fourth value, is the preferential allocation of medical resources towards people who previously took on burdens to address the current health problem. During the COVID-19 pandemic, countries invoked reciprocity as one reason to prioritise health-care staff and other essential workers,<sup>33,40</sup> and to justify prioritising participants in COVID-19 vaccine trials.<sup>41</sup> At the global level, reciprocity has been referenced as a reason to prioritise countries that contributed to the pandemic response.<sup>42</sup> Thus, reciprocity could also

	Definition
Maximising benefits and preventing harm	Preferential allocation of medical resources towards individuals who can gain most benefit and protection against harm; harms can be broad to include both health (eg, death) and non-health (eg, poverty); harms can occur directly from the disease and indirectly when health-care system functioning is compromised
Mitigating disadvantage	Preferential allocation of medical resources towards people who are disadvantaged by income, race, ethnicity, religion, or other characteristics
Equal moral concern	Treating similar people similarly, and not discriminating on the basis of morally irrelevant characteristics such as race, ethnicity, or religion; typically requires noi treating people the same, but treating people in different circumstances (eg, in communities with a higher or lower burden of COVID-19) differently
Reciprocity	Preferential allocation of medical resources towards people, communities, or countries who in the past took on burdens to address the current health problem
Instrumental value	Preferential allocation of medical resources towards people who will be able to mitigate harms and disadvantage of others; not an independent value but facilitates realising the other values particularly benefiting people

incentivise helping to address or forestall health threats. Outside of pandemic contexts, reciprocity has played a role in organ transplantation, with past or pledged donors receiving priority.<sup>43</sup> Crucially, reciprocity has generally been used to differentiate among similar recipients rather than override other values. As WHO notes, "reciprocity is a principle of narrower scope and more limited importance" than others.<sup>44</sup> The importance of reciprocity in future health emergencies will depend on whether some individuals or countries are being asked to accept outsized burdens to help others. For instance, in a pandemic where health-care workers were placed at much higher absolute risk, reciprocity might be more important.

Finally, instrumental value prioritises allocations that indirectly realise other values in the future, such as maximising benefits. For instance, front-line health personnel might be prioritised even if they will not directly gain the most protection against illness and are not individually the most disadvantaged.7 Why? Because protecting front-line professionals would probably minimise harm and enhance benefits for others by forestalling the need for crisis standards of care due to staff shortages. Instrumental value is not an independent value, but it depends on the importance of helping to realise other worthy values. Guidance documents often do not specify instrumental value as relevant even when it is invoked to justify allocations aimed at preventing health system collapse-instead, it is implicitly assumed. But it should be distinguished as a key value.

Thus, the values for ethical allocation of scarce medical resources are settled (table 2). These values are universal. However, their application and relative weight could vary in different countries and across contexts. The authority charged with implementing allocation decisions could also change, ranging from transnational bodies to decentralised local councils. But the fundamental importance of these five values has been recognised by global decision makers and aligns with the Universal Declaration of Human Rights. In a future pandemic or other situation requiring the allocation of scarce medical resources, these values should be the starting place. There is no need to develop all-new underlying values. The challenge is to implement them faithfully in different contexts.

Importantly, none of the values are sufficient alone.<sup>45</sup> A multivalue framework is necessary for ethical allocation, but this framework requires weighting and balancing the five values. In an emergency situation, the consensus is that benefiting people and preventing harm, and mitigating disadvantage, should be weighted most heavily. How much weight the other values receive will vary by context, and requires procedural principles that should not be conflated with the substantive principles.

### Procedural principles for allocating scarce medical resources

The main procedural principles include transparency, engagement, and evidence-responsiveness. Transparency requires that allocation not be done in a hidden manner; instead, the weighting should be publicly available and justified with the evidence supporting it.46 Engagement requires that the affected public-not just specific-interest groups or experts-have an opportunity to assess and comment on the proposed resource allocation. Potential approaches to engagement include surveys, deliberation, notice-and-comment processes.<sup>47–49</sup> and Evidenceresponsiveness requires that the operationalisation of allocation guidance be regularly reviewed and revised in light of evolving data concerning which populations might benefit or are unfairly disadvantaged.

Relying on these values would have facilitated more rapid development of priority groups and avoided mistakes made in some reports. During the pandemic, some reports needlessly proliferated principles or misidentified procedural values as substantive ones. For instance, ACIP includes promoting justice and mitigating health inequities as fundamental principles, but defines them in similar ways: "does the allocation plan result in fair and equitable access of vaccine to all groups?" and "does the plan identify and address barriers to vaccination among any groups who are disproportionately affected by COVID-19 or who face health inequities resulting from social determinants of health, such as income and health-care access?"7 The first principle-fair and equitable access of vaccine to all groups—seems akin to equal moral concern, but ACIP does not specify whether fair and equitable access encompasses more than mitigating health inequities. In addition, ACIP confuses substantive and procedural principles by making transparency its fourth principle. Similarly, WHO includes legitimacy as a fundamental principle when it is actually a procedural one.44 Whatever their source, clearly distinguishing between substantive and procedural principles means these confusions need never occur again.

### From ethical values to priority tiers

During the COVID-19 pandemic, these substantive values led to relatively convergent recommendations for priority tiers for vaccines and antiviral treatments within countries. The reports implicitly invoked instrumental value and prioritising health-care workers and first responders because they could reduce harms, especially to people who are disadvantaged. By invoking the substantive value of benefiting people and preventing harm, allocation guidelines also prioritised people at highest risk of death if infected, such as older adults and people with risk-increasing medical conditions.

Conversely, other characteristics associated with higher risk, such as multigenerational and congregate housing, occupation,<sup>50</sup> geography, race,<sup>51</sup> and sex,<sup>52</sup> were inconsistently used in prioritisation. For instance, the ACIP guidelines included age and medical comorbidities but not other risk factors.7 People in long-term care facilities were prioritised, but not similarly aged and vulnerable adults living in crowded community housing or adults held in crowded prisons. Many US states did not prioritise front-line workers. The National Academies' report notes that men and individuals from minority and ethnic communities were at an increased risk of poor COVID-19 outcomes, but did not propose using these factors in prioritisation.<sup>6</sup> Legal, political, public acceptability, or logistical constraints could limit the use of factors other than age and medical conditions in operationalising ethical values. However, transparency requires clearly acknowledging these constraints when creating priority groups, not silently ignoring them.

### Lessons in going from theory to practice

The best ethical framework and priority tiers for allocating scarce medical resources are only as good as their implementation. Many obstacles can impede the faithful progression from ethical values to prioritisation frameworks, and to actual distribution of resources. Politicians could be ignorant of or ignore established ethics.<sup>53</sup> Some individuals will try to secure scarce medical resources by identifying loopholes or intentionally circumventing the prioritisation schemes.<sup>54,55</sup> A balance between different goals is required: overly restrictive eligibility and rigid interpretation of priority tiers can lead to scarce resources sitting idle for want of interested, eligible candidates, whereas overbroad eligibility criteria without further prioritisation leads to unfair and inefficient queuing.

The distribution of COVID-19 vaccines and therapeutics revealed at least six major challenges in going from theory to practice (table 3). First, the allocation of vaccines and therapeutics from central pools to the organisations distributing them, both within and between countries, was typically on the basis of population, ignoring differences in community-level risk or disadvantage. Under the Trump administration, the US Federal Government's initial allocation of vaccines to states was

	Example	Ethical problem	Potential mitigating policies
Distributing vaccines to locales on the basis of population size rather than population risk or the benefit likely to be produced	US Federal Government distribution of COVID-19 vaccines to states based on population while ignoring case rates, COVID-19 deaths, or proportion of at-risk people; COVAX allocation of COVID-19 vaccines to countries based on population size for first 20% of population	Does not minimise harms; exacerbates inequities; emphasises equal treatment of unequal communities or individuals; violates equal moral concern	Distribute scarce resource based on how well it can mitigate harms in a community or mitigate disadvantages; prioritise vulnerable communities or people living in congregate housing
Overbroad and underinclusive priority tiers	Prioritising workers at health-care facilities even when the workers were not involved in patient care or addressing COVID-19 (eg, administrators or non- COVID-19 researchers)	Does not fulfil instrumental value; does not minimise harm	Carefully delineated priority tiers; simultaneously allocate resources by proportion to different priority tiers rather than sequentially to priority tiers
Using rigid age cutoffs for priority tiers	Using a cutoff age of 75 years for vaccine access when, because of life expectancy, Black and male patients are underrepresented among people older than 75 years, and are also at higher risk at a given age	Exacerbates prior inequities based on life expectancy between races and sexes	
Using passive allocation, through open websites or accessing facilities, rather than active identification of individuals who are eligible for vaccines with defined access opportunities	Allocating vaccines through internet sign- ups or pharmacy queuing, thereby preferencing privileged individuals with better education, broadband access, computer skills, and free time	Does not mitigate harms to high- risk communities; exacerbates prior inequities based on income and education	Proactively identify at-risk communities and patients from insurance enrolment and medical records; go door-to-door in vulnerable communities—eg, care homes, assisted living facilities, and high-risk communities
Accepting personal attestation of key eligibility criteria	Relying on individual self-attestation on age, comorbidities, occupation, and other eligibility criteria; incentivising the violation of rules and lying by individuals and, by adhering to social norms, encouraging such unethical behaviour	Does not mitigate harms to high- risk communities; exacerbates prior inequities based on income and education; normalises evasion of prioritisation tiers	Proactively identify at-risk communities and patients from insurance enrolment and medical records
Rigidly excluding people not in a priority tier		Does not mitigate harms by wasting scarce resources	Allocate resources by proportion to different priority tiers rather than sequentially to priority tiers, ensuring supply does not exceed demand

purely based on state population.<sup>56</sup> Many states also distributed vaccines to localities solely based on population. Consequently, vaccines went unused or were offered to low-priority groups in geographical areas with low case rates or low vaccine demand, yet vaccines were unavailable in high-demand and high-risk geographies.<sup>57,58</sup> In response, some people travelled long distances across state borders to vaccine sites,<sup>59</sup> exacerbating inequities and promoting viral spread.

Similarly, COVAX initially proposed to allocate COVID-19 vaccines to countries to cover 20% of their populations, before shifting to an allocation scheme on the basis of disease burden.<sup>24</sup> Such population-based allocation emphasises equal treatment but thereby violates equal moral concern, because countries had different numbers of at-risk people, COVID-19 cases, hospital admissions, and deaths. In addition, countries differed by their capacity and willingness to distribute interventions based on the substantive ethical values. Consequently, many vaccines sat idle in countries like Congo and South Sudan,<sup>60,61</sup> even as other low-income and middle-income countries such as Nepal and Peru faced shortages as demand outstripped supply.<sup>62</sup> Because few medical crises present identical risk to everyone, purely population-based distribution of scarce interventions is nearly always ethically wrong.

The second challenge occurred when many priority tiers were poorly characterised to be both overbroad and underinclusive. For instance, in Massachusetts, USA, the top priority group included all health-care workers,<sup>63</sup> even if their jobs did not entail COVID-19 exposure and were not instrumental to patient care. Thus, administrators, laboratory researchers, and graduate students not conducting COVID-19-related work or delivering medical care received the vaccine before residents of nursing homes or other high-risk people.<sup>64</sup>

Thirdly, the use of rigid minimum age cutoffs to establish priority tiers exacerbates inequalities that have life-shortening effects. In 2019, the life expectancies of Black Americans (74·8 years) were substantially shorter than White Americans (78·8 years).<sup>65</sup> Early in the pandemic, the average age of death from COVID-19 for a non-White American was 72 years, but for a White American it was 81 years.<sup>66</sup> By prioritising people aged 75 years and older, the ACIP<sup>7</sup> implicitly gave precedence to White people with reduced risks of severe outcomes, rather than to their Black peers. Similarly, American men have substantially shorter life expectancies than women—76.3 years versus 81.4 years.<sup>65</sup> Prioritising on the basis of age favoured women who, for unclear reasons, had reduced risks of severe outcomes and death from COVID-19.<sup>52</sup> Ignoring both race and sex in allocating vaccines heavily exacerbated the disadvantages of Black men.

Even within the priority tiers, the fourth challenge was that vaccines and therapeutics were often allocated to people passively rather than actively, thereby exacerbating established disadvantages. Typically, in apparently fair competitions the wealthy are better at securing resources. Their privileged position gives them more education, free time, computer and other skills, stable broadband connections, and access to social networks. When people were asked to schedule appointments online using first-come, first-served processes, the wealthy had more success in doing so.67 Similarly, having people travel to pharmacies to receive vaccines and antiviral oral therapeutics made access dependent on the location of pharmacies.68 But these locations are determined by economic profitability, and thus tend to be located in higher-income geographies, underserving lower-income, rural, and other vulnerable communities. This outcome reveals the inherent flaw embodied in first-come, first-served allocation that superficially appears open to all on a non-discriminatory basis, but surreptitiously privileges the wealthy and exacerbates disparities.

Fifth, leaving the distribution of a scarce, potentially life-saving intervention to a self-reporting or honour system incentivises people to behave selfishly and violate rules. These actions create a sense that the system is unfair and that cheating is an acceptable social norm, further inducing unethical behaviour.69 People do not want to feel as if they are losing out to others' unethical practices and start to behave unethically themselves. Consequently, people lied about their comorbidities, place of residence, or age to obtain vaccines.54,70 This deception could have been normalised by the persistence of restrictive age cutoffs and eligibility requirements even after vaccines were no longer scarce in the USA. The policy of restricting booster doses to people older than 50 years or to individuals who are immunocompromised could have prompted dishonesty about age.71

Finally, categorically excluding everyone below a certain priority tier led to vaccines and therapies sitting idle and, sometimes, expiring. Medical providers in New York, USA, were forced to throw out vaccine doses because of difficulties in finding patients who matched the state's strict vaccination guidelines, combined with penalties for vaccinating people outside the guidelines.<sup>72</sup> Rigid tiers led to wastage of vaccines—the worst possible outcome involving a scarce, life-saving resource.

### Improving mechanisms to implement ethical prioritisation

As the COVID-19 pandemic elucidated, good design can mitigate—if not fully pre-empt—these challenges both by better defining the actual priority tiers and by using better implementation mechanisms appropriate to the particular context (table 3).

First, allocation among countries, states, or localities should be dependent on ethical values, not population. To minimise harm, the US Federal Government should have allocated vaccines on the basis of anticipated development of high case rates in states. Similarly, it should have directed a proportion of vaccines to disadvantaged communities. Notably, the USA took this approach with its initial allocation decisions of JYNNEOS vaccines for mpox.<sup>4</sup> When it distributed COVID-19 vaccines globally, the US Government adopted a hybrid approach, sending some vaccines to COVAX to be distributed on the basis of population and allocating about 25% of vaccine supply to countries with a high burden of COVID-19.<sup>25</sup>

Second, the use of instrumental value and reciprocity as an allocation mechanism means prioritising people who are actually engaged in patient care or combating the pandemic, not just anyone who happens to work for a health system or hospital. Third, eligibility for scarce resources should depend on multiple factors, including those factors that increase exposure such as living in crowded housing or facilities, and being at an increased risk of death or admission to the intensive care unit.

Fourth, distributing interventions to the priority tiers needs to be more active and less passive. Active distribution also minimises the challenge posed by self-attestation of eligibility characteristics. In the UK, people in high-risk groups received a text message inviting them to book their vaccinations, and a follow-up letter and call if they had not booked an appointment.73 In the USA, this approach would mean identifying people as eligible on the basis of age, geography, participation in programmes such as Medicaid, and comorbidities listed in enrolment information or medical records. Eligible people should be texted, called, emailed, and even contacted in person to schedule appointments. It could also entail administering vaccines door-to-door in vulnerable communities. This method would require improving the data collection and integrity of enrolment information, such as that for Medicare and Medicaid, to include race, address, and other relevant information.<sup>74</sup> This approach would also make it easier to sort by factors such as medical conditions or living situations, without having to rely entirely on a selfreporting system.

Finally, allocation might not be done strictly by ordered tiers; instead, portions of the scarce resource might be allocated to multiple tiers at once.<sup>75</sup> For instance, the initial allocation might have been for 50% of vaccine doses to go to the highest tier of front-line health workers, 25% to the next tier of older individuals in crowded living

conditions, and 25% to other front-line workers such as grocery store employees, food processors, teachers, and first responders. Distributing resources among multiple priority tiers simultaneously helps to ensure none of the scarce resources are wasted for want of demand.

## Applying lessons to allocate non-COVID-19 scarce resources

Currently, about 77% of all malaria deaths are among children younger than 5 years.76 RTS, S/AS01E (Mosquirix) is a malaria vaccine recently approved for infants and voung children to reduce severe disease. Phase 1 trials began in the USA and Belgium before expanding to adults, adolescents, children, and infants in Mozambique.77 Between 2009 and 2014, a phase 3 study was conducted in seven African countries, and in 2019 a phase 4 pilot programme was initiated in Malawi, Ghana, and Kenya.<sup>78</sup> Four doses of the vaccine can reduce severe disease among infants and children by about 30%.79 In regions with a malaria prevalence of 10-65%, models predict that RTS,S/AS01 would avert a median of 116480 clinical cases and 484 deaths for the four-dose schedule, per 100000 fully vaccinated children.80 In October, 2021, WHO recommended using the vaccine to prevent severe Plasmodium falciparum disease among infants and children in about 30 sub-Saharan countries with moderate to high malaria transmission.5

Unfortunately, there is not enough vaccine to treat all children who can benefit. With a four-dose schedule and an estimated 25 million eligible children per year in 30 countries, about 100 million doses will be needed per year. But there is only enough to vaccinate 1 million children initially, and it will take 4–6 years until supply meets demand.<sup>81</sup> This shortage presents challenges of fair allocation, paralleling other allocation challenges that antimalaria efforts have already faced.<sup>82,83</sup> Who should be prioritised?

The ethical framework for allocating scarce resources and practical lessons delineated from the COVID-19 pandemic suggest five conclusions about allocating the RTS,S/AS01 vaccine. First, distributing it among the 30 sub-Saharan countries purely on the basis of the population of infants and children, or another populationbased metric, is wrong. This method violates the value of maximally reducing harm and relieving unfair disadvantage. Some countries could have fewer malaria cases per person due to geography, be better placed to reduce malaria cases by use of approaches other than vaccination, or have health systems that are better equipped to treat children with malaria. Second, reciprocity should not be a primary value for distributing the vaccine.<sup>84</sup> Therefore, Malawi, Ghana, and Kenya's role in the phase 3 and 4 trials should not automatically place them ahead of all other countries. Four other countries also participated in pivotal phase 3 trials, and Mozambique participated in earlier phase studies necessary for approval. Minimising harm and mitigating

previous disadvantage should take precedence over reciprocity.

Third, scarce, potentially life-saving vaccines should be allocated to countries that can effectively distribute and administer the vaccines. Wasting a scarce resource or letting it sit idle violates minimising harm and does nothing to mitigate disadvantage. Countries without distribution or administrative capacity should receive other forms of assistance to stem the burden of malaria, including building vaccination capacity, but until their capacities are improved they should not receive vaccines. Where countries vary in effective distribution capacity, harder tradeoffs between different values can exist, but sending vaccines where they predictably will not be used is of no ethical value.

Fourth, vaccines should be primarily distributed to countries where they can maximally reduce serious illness and death among infants and children. This distribution will require relying on data to carefully identify the children at highest risk within countries and target vaccines to them. For instance, this approach could require prioritising rural areas and enhancing distribution efforts in those geographies. In this sense, data and context greatly matter to realise ethical allocation. Finally, measures need to be taken to ensure infants and children of the wealthy or politically connected are not prioritised over children who are disadvantaged. These measures will require evaluating apparently open allocation processes, such as queuing or first-come, first served approaches, to ensure they do not surreptitiously benefit the privileged.

Pregnant women face a particularly high risk of malaria complications, often even higher than infants and children, but have been excluded from clinical trials.<sup>85</sup> Categorically excluding pregnant women from clinical trials is inappropriate.<sup>86</sup> Thus, minimising harm might include prioritising some doses for trials to identify the effectiveness of the vaccine in this population. Ethical allocation should not begin only after an intervention is proven effective, but should also shape the design of research trials and selection of eligible participants.

### Conclusion

The COVID-19 pandemic necessitated the allocation of multiple scarce medical resources, and forced clarification on the ethics of such allocation. The lessons learned clarify that the ethical framework to guide allocation entails five substantive values—minimising harms, mitigating disadvantage (ensuring equity), equal moral concern (not identical treatment), reciprocity, and instrumental value. The pandemic also helped to clarify the establishment of priority tiers that primarily emphasise instrumental value, minimising harm, and mitigating disadvantage. Finally, the pandemic showed that implementation requires careful attention to ensure disadvantaged groups are not further disadvantaged. This aim necessitates carefully delineating eligible groups, avoiding seemingly open access methods that prioritise the wealthy with capabilities and skills to access resources, and applying active—not passive—distribution methods, since passivity favours the privileged. Learning these lessons on the ethical allocation of scarce medical resources from COVID-19 should facilitate the rapid distribution of other scarce medical interventions in the next health emergency.

#### Contributors

EJE and GP jointly drafted the manuscript, revised it, and reviewed it for important intellectual content.

#### Declaration of interests

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