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Recommended Citation

Govind Persad, Monica E. Peek & Seema K. Shah, Fair Allocation of Scarce Therapies for Coronavirus Disease 2019 (COVID-19), *75 Clinical Infectious Diseases* e529 (2022).



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Fair Allocation of Scarce Therapies for Coronavirus Disease 2019 (COVID-19)

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The US Food and Drug Administration (FDA) has issued emergency use authorizations (EUAs) for monoclonal antibodies (mAbs) for nonhospitalized patients with mild or moderate coronavirus disease 2019 (COVID-19) disease and for individuals exposed to COVID-19 as postexposure prophylaxis. EUAs for oral antiviral drugs have also been issued. Due to increased demand because of the Delta variant, the federal government resumed control over the supply and asked states to ration doses. As future variants (eg, the Omicron variant) emerge, further rationing may be required. We identify relevant ethical principles (ie, benefiting people and preventing harm, equal concern, and mitigating health inequities) and priority groups for access to therapies based on an integrated approach to population health and medical factors (eg, urgently scarce healthcare workers, persons in disadvantaged communities hard hit by COVID-19). Using priority categories to allocate scarce therapies effectively operationalizes important ethical values. This strategy is preferable to the current approach of categorical exclusion or inclusion rules based on vaccination, immunocompromise status, or older age, or the ad hoc consideration of clinical risk factors.

Keywords. monoclonal antibodies; antivirals; paxlovid; molnupiravir; therapies; rationing; allocation; scarcity; COVID-19; bioethics.

The US Food and Drug Administration (FDA) has issued emergency use authorizations (EUAs) for monoclonal antibodies (mAbs)—interventions that can imitate or enhance individual immune responses—for non-hospitalized patients with mild or moderate COVID-19 disease and for individuals who have been exposed to COVID-19 as post-exposure prophylaxis [1]. Early in the pandemic, reports of wealthy, well-connected figures receiving mAbs without explanation of the selection process raised questions about ethical distribution of mAbs [2]. More recently, due to increased demand from low-vaccination states that have been hit hard by the Delta variant, the federal government has resumed control over the supply and asked states to ration doses [3]. Additionally, new oral antivirals have been developed (molnupiravir and paxlovid), with both recently receiving emergency use authorization [4]. Scarcity for these medications is likely as well. This scarcity will necessitate fair, principled, and transparent allocation. Building on prior work on fair vaccine allocation, we identify relevant ethical principles and priority groups for access to therapies, primarily focusing

on mAbs because current federal guidelines exist for allocation of this class of COVID treatment.

APPLYING ETHICAL PRINCIPLES TO PRIORITIZATION AMONG ELIGIBLE PATIENTS

Three mAb treatments have received emergency use authorization to date: bamlanivimab/etesevimab, casirivimab/imdevimab, and sotrovimab [5]. Their primary authorization is to treat infected patients who are more likely to progress to serious illness, including all adults ≥ 65 and adults with a body mass index (BMI) ≥ 25 , pregnancy, chronic kidney disease, diabetes, immunosuppression, cardiovascular disease, lung disease, sickle cell disease, neurodevelopmental or medically complex illness, or technological dependence such as an ostomy. Most recently, casirivimab and imdevimab have also been authorized for post-exposure prophylaxis in adults and children at high risk for severe disease, and for administration subcutaneously as well as via infusion. As described above, new orally administered antivirals have also been submitted, and recommended, for emergency use authorization.

CURRENT RULES AND ETHICAL PROBLEMS

Currently, the National Institutes of Health (NIH) proposes three different priority rules for mAb allocation under scarcity. First, they propose prioritizing treatment over post-exposure prophylaxis (PEP). Second, they propose giving higher priority to 2 other groups, who are not ranked against one another: “[u]nvaccinated or incompletely vaccinated individuals,” and

Received 18 October 2021; editorial decision 13 December 2021; published online 18 December 2021.

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Clinical Infectious Diseases® 2022;75(1):e529–33

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“[v]accinated individuals who are not expected to mount an adequate immune response (eg, immunocompromised individuals or individuals aged ≥ 65 years)” [6]. Third, they suggest that within these two priority groups, “clinicians consider prioritizing their use for patients at highest risk of clinical progression,” including the following conditions listed alphabetically: “age (risk increases with each decade after age 50), cancer, cardiovascular disease, chronic kidney disease, chronic lung disease, diabetes, immunocompromising conditions or receipt of immunosuppressive medications, obesity (BMI ≥ 30), pregnancy, and sickle cell disease.” As of December 2021, the NIH has not yet proposed prioritization rules for antiviral drugs, although similar principles would seem to apply to these therapies, which are also likely to have greatest benefit if provided rapidly post-infection to those at high risk of hospitalization.

Unlike guidance for vaccine prioritization, the NIH guidelines are not explicitly grounded in ethical principles, such as benefiting people and preventing harm, equal concern, and mitigating health inequities, proposed by the National Academies of Sciences, Engineering and Medicine (NASEM), Advisory Committee for Immunization Practices (ACIP), and others for vaccine distribution, or in other ethical principles such as reciprocity for past contributions. Notably, the NIH panel, unlike the National Academies or ACIP, did not include ethics expertise. We first consider how therapy prioritization guidelines may conflict with ethical principles.

First, even if vaccination is assumed to increase probability of recovery without therapy administration, prioritizing all unvaccinated people over any vaccinated person without immunocompromise and under age 65 years may not best prevent harm to recipients. Some unvaccinated people may be at lower risk of severe outcomes, including adolescents and young adults, or individuals with prior infection. Meanwhile, some vaccinated people without diagnosed immunocompromise or below age 65 years may also be at high risk of severe outcomes. This includes people with undiagnosed immunocompromise or other high-risk medical conditions, people under 65 years who may nevertheless be at higher personal risk than others over 65 years, and people with lesser immunity due to a longer period since their initial vaccination series or a less efficacious initial vaccine.

Second, the use of age 65 years as a one-size-fits-all cutoff for vaccinated people without immunocompromise to access scarce therapies both conflicts with the goal of mitigating health inequities and may not optimize the goal of benefiting people and preventing harm. Studies conducted before vaccine availability have demonstrated that age-based COVID-19 risk was not uniform across the US population: Blacks, Hispanic persons, and Native Americans tended to face higher risk at earlier ages, likely reflecting the impact of structural inequalities [7–9]. The lack of comprehensive data on breakthrough infections prevents a rigorous assessment of whether this

differential in risk persists post-vaccination, but the continuation of differential risk is plausible. A more recent study on vaccine allocation demonstrated that adjusting age cutoffs according to social vulnerability, to respond to differential age-based risk, would have both saved more lives and reduced health inequities compared to a one-size-fits-all age cutoff [10]. The same may be true for allocation of scarce therapies. In addition, people with lower incomes and members of many racial minority groups are underrepresented among the population at the oldest ages [11, 12].

Similarly, categorically prioritizing treatment over post-exposure prophylaxis may not best prevent harm. For instance, if an immunocompromised person with other risk factors is exposed via sustained close-quarters contact (eg, while assisting an infected family member), scarce therapies may avert more expected harm than if used in response to infection in a young, healthy unvaccinated person without immunocompromise. The NIH guidelines are not clear regarding how to compare the benefit of prevention in high-risk populations against the benefit of treatment in lower-risk individuals who test positive.

Additionally, priority for nonvaccinated people may jeopardize harm prevention on a population level by encouraging those uncertain about vaccination to wait in order to improve their access to therapies, and discouraging people who are considering vaccination. Although no comprehensive study has examined this hypothesis empirically, reporting suggests that some people who refuse vaccination are counting on access to therapies instead [13].

Prioritizing access for non-vaccinated people may also be inconsistent with equal concern and mitigation of health inequities. Although vaccination rates are lower in some disadvantaged communities, they are higher among others, particularly among older adults who are more likely to be at high risk of progressing to severe complications if infected. For instance, New York’s data indicate that the rate of receiving one or more vaccine doses is equal or higher among Black people over 65 years, compared with White people over 65 years, in the Bronx and Brooklyn; higher among Hispanic people over 65 years than White people over 65 years in all boroughs except Manhattan; and higher among Asian-American/Native Hawaiian or Pacific Islander (NHPI) people over 65 years than White people over 65 years in all boroughs [14]. Other data sources show similar trends in Southern states, such as Alabama, Louisiana, and Mississippi [15], and more recent polling data suggest that “similar shares of Black adults (73%), White adults (72%) and Hispanic adults (70%)” report receiving at least 1 COVID-19 vaccine dose. In addition to the reasons provided above, it could also be argued that prioritizing unvaccinated people fails to show appropriate reciprocity toward people who have protected themselves and others by becoming vaccinated, or to differentiate those who cannot gain protection against COVID-19 for medical reasons from those who cannot do so by choice.

Meanwhile, prioritization based primarily on diagnosed immunocompromise presents the problem that undiagnosed immunocompromise (eg, due to human immunodeficiency virus [HIV] infection) is more common in poorer and racial minority communities [16, 17].

In addition to potential conflicts with relevant ethical principles, the NIH's recommendations fail to provide guidance in many cases: for instance, if the number of unvaccinated and/or immunocompromised people exceeds available supply. This lack of guidance is particularly concerning given that unvaccinated people, immunocompromised people, and people over 65 are all given the same priority. This lack of guidance could lead to ad hoc decisions that fail to prevent harm, show equal concern, or remediate health inequities.

The recommendations do attempt to provide further prioritization guidance by focusing on the risk of progression to severe COVID-19 based on clinical factors, but this guidance has many problems. The same conditions that correlate with progression to severe COVID-19 may also reduce the extent to which patients can benefit from therapies. Ideally, antibodies and antiviral drugs should go to those who are vulnerable enough that they are less likely to recover without them, but not so vulnerable (eg, with late-stage metastatic cancer) that they are unlikely to recover even with them. The guidance does not recognize this potential trade-off, which is relevant to whether scarce therapies best benefit people and prevent harm. Additionally, the clinical criteria for severe disease progression are based on research done before the availability of vaccines and before the Delta variant became dominant [18]. Even if this research is assumed to remain applicable to therapy allocation—not the purpose for which it was developed—the listed conditions do not raise risk equally, nor is the evidence equally strong for each. Similarly, although the strong correlation between age and progression to severe disease should be recognized, a fair allocation policy must also consider whether age worsens prognosis after therapy receipt, and whether (as discussed above) one-size-fits-all age cutoffs inaccurately measure risk in ways that predictably worsen health disparities.

The substantial clinical uncertainty around evidence is likely to lead to ad hoc bedside decision making in the face of scarcity—precisely the sort of scenario where biased and inaccurate decisions are more likely to occur. While a pandemic presents the need to act without ideal data, a framework that does not simply rely on clinical intuition is preferable when scarce resource prioritization—rather than ordinary clinical care—is at issue. Even though the NIH guidelines suggest that “[p]roviders should use their clinical judgment when prioritizing the use of anti-SARS-CoV-2 mAbs for treatment or PEP in a specific situation,” other guidance has recognized that the allocation of scarce resources among patients is a poor context for the exercise of clinical discretion [19]. Asking clinicians to shoulder the burden of allocation decisions without binding institutional

guidance also generates moral distress and may expose them to more frustration from patients and families who are not prioritized for access [20, 21].

IMPROVING ALLOCATION

NIH's guidance could be revised to address some of these concerns by explicitly prioritizing immunocompromised people, as well as those few individuals who are medically ineligible for vaccination, as the highest priority group, over people who are eligible but unvaccinated. While severe “breakthrough” (post-vaccination) cases remain uncommon, with vaccine effectiveness against hospitalization over 80%, the CDC reports that 40–44% of hospitalized breakthrough cases have occurred in immunocompromised people [22].

This would differentiate vulnerability based on medical condition (immunocompromise or vaccine ineligibility) from that based on a medical decision (to refuse vaccination). Using reciprocity-based factors, such as whether someone has become vaccinated once eligible, as a tiebreaker to select between people at similar medical risk would be similar to NASEM and other organizations' proposal to prioritize vaccine trial participants for later vaccine access, based on reciprocity for their contributions, within priority groups that are otherwise defined by risk [23].

More generally, provision of scarce therapies such as monoclonal antibody or antiviral treatment is part of the public health response. Therefore, prioritizing purely on the basis of individual medical differences such as immune compromise or vaccination status, or attempting to identify other medical differences based on minimal evidence (as the NIH currently recommends), may be misguided. Rather, a preferable approach would incorporate both population-level factors as well as relevant medical factors.

Most notably, eligible health workers whose absence jeopardizes delivery of urgently needed treatment should be prioritized: for instance, eligible ICU nurses and respiratory therapists, particularly those working in under-resourced hospitals where absence due to illness would jeopardize patient care. Prioritizing urgently scarce workers limits harm directly by reducing illness and death among providers and indirectly by enabling needed treatment. It also mitigates health inequities indirectly because disadvantaged populations face more health threats and more often need treatments provided by scarce health workers.

Communities that are, or will be, hard hit by COVID-19, due to structural inequities, are another priority group. Distributing therapies using indices of disadvantage mitigates health inequities and likely prevents harm because chronic disease, including undiagnosed disease, is disproportionately prevalent in vulnerable communities. Although the NIH lists “race or ethnicity” as a factor that “may also place individual patients at high risk for progression to severe COVID-19,” [24] the association

Table 1. Principles and Implementation Strategies for Fair Allocation of Scarce Therapies

Ethical Principle	Relevant Considerations	Priority Factors/Groups	Implementation
Benefit people and prevent harm	Risk of severe disease without therapy	Immunocompromised condition Underlying co-morbidities Older age Social vulnerability Unvaccinated status	Prioritize portions of available treatments for certain groups (e.g. health workers, people in vulnerable areas), with the remaining portion open to all who are medically eligible. If needed, further priority for access within each priority group should be based on, in order: 1. Risk and responsiveness. 2. Capacity to benefit or protect others, 3. Exposure to societal disadvantage, and 4. Reciprocity.
	Expected response to and side effects of the therapy	Recent onset of infection Variant responsive to therapy Compatibility with existing medications Absence of benefit-limiting conditions (e.g. late stage cancer)	
	Extent to which treating a patient would benefit or protect others	Scarce health care workers Parents and other caregivers Pregnant individuals People with immunocompromised family members	
Mitigate health inequities	Exposure to societal disadvantage	Social vulnerability and poverty Risk-increasing health conditions (diagnosed and undiagnosed)	
Reciprocity	Individuals' past actions to mitigate scarcity and pandemic severity	Health workers Vaccinated patients COVID-19 clinical trial volunteers	

between race and progression to severe COVID-19 is mediated by structural racism, rather than “race” constituting a biological risk factor akin to heart or kidney disease. The use of indices therefore better picks out the pathway by which race may be associated with greater risk. Using disadvantage indices in combination with the NIH’s prioritization rules also may help recognize a difference between lower vaccination rates due to understandable distrust connected with historical injustice or due to continuing access barriers, and refusal of vaccination due to political commitments. As explained by Rubin and colleagues, indexes of disadvantage have already been used for mAb allocation in some health systems [25].

IMPLEMENTATION

At a hospital or health system level, implementation of these principles should employ a categorized priority system such as that used by Rubin and others, rather than a ranking that gives one category, such as unvaccinated people, priority over all others [26]. Similar to the approach used in Massachusetts, a categorized priority system would start by designating a specified portion (such as 50%) of a shipment of therapies for priority access for specific groups, such as scarce health personnel or hard-hit communities [19] (Table 1). Therapies could then be allocated within each priority group using medical criteria, such as immunocompromise, high-risk conditions, or—with the caveats noted above—older age.

Additionally, more data are needed on which patients benefit most from therapies and on comparative effectiveness between therapies (eg, between different mAbs or antivirals). Provision of therapies should require standardized reporting of recipients’ demographics, comorbidities, and clinical outcomes. Allocation should ensure availability for continued

research studies, discuss continuing uncertainties regarding benefit during informed consent, and avoid interference with study enrollment. As data accrue, allocation may shift based on new authorizations or evidence about benefit, such as evidence that some antibody therapies are less effective against certain variants. Although not dispositive, data on public preferences regarding the allocation of therapies are also relevant, just as it was for vaccine allocation [27, 28].

CONCLUSION

Using priority categories to allocate scarce therapies effectively operationalizes important ethical values. It is preferable to the current approach of categorical rules based on vaccination, immunocompromise status, or older age, or the ad hoc consideration of clinical risk factors. Clear public health messaging about the reasons for allocation of scarce therapies will be critically important to its successful implementation.

Notes

Financial support. The authors have no funding to report for this manuscript.

G. P. reports grants and personal fees from the Greenwall Foundation, World Health Organization, and ASCO Post. S. K. S. reports participation as a Member of the National Institute of Allergy and Infectious Diseases COVID-19 Preventive mAb Data and Safety Monitoring Board.

Potential conflicts of interest. The authors: No reported conflicts of interest. All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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