

# Ethical allocation of future COVID-19 vaccines

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## ABSTRACT

The COVID-19 pandemic will likely recede only through development and distribution of an effective vaccine. Although there are many unknowns surrounding COVID-19 vaccine development, vaccine demand will likely outstrip early supply, making prospective planning for vaccine allocation critical for ensuring the ethical distribution of COVID-19 vaccines. Here, we propose three central goals for COVID-19 vaccination campaigns: to reduce morbidity and mortality, to minimise additional economic and societal burdens related to the pandemic and to narrow unjust health inequalities. We evaluate five prioritisation approaches, assess their likely impact on advancing the three goals of vaccine allocation and identify open scientific questions that may alter their outcomes. We argue that no single prioritisation approach will advance all three goals. Instead, we propose a multipronged approach that considers the risk of serious COVID-19 illness, instrumental value and the risk of transmission, and is guided by future research on COVID-19-specific clinical and vaccine characteristics. While we focus this assessment on the USA, our analysis can inform allocation in other contexts.

## INTRODUCTION

The COVID-19 pandemic has critically strained nearly every aspect of society within the USA and across the globe. Healthcare organisations are scrambling to stretch limited resources, and the rapid growth in cases of the disease has precipitated the need for tremendous planning. COVID-19 has also impacted national economies, causing rates of unemployment and business closures not seen since the Great Depression.<sup>1</sup> While promising therapies are being researched, many experts speculate that widespread vaccination ultimately will be required to enable significant recovery from the pandemic.<sup>2</sup>

With the elucidation of the genetic sequence of SARS-CoV-2, the virus responsible for COVID-19, major strides have been made in vaccine development.<sup>3</sup> As of November 2020, there are over 300 COVID-19 vaccine candidates worldwide.<sup>4</sup> Among these vaccines, the methodologies employed to create an immunological response are highly variable and include the use of nucleic acids, viral-like particles, peptides, viral vectors, recombinant proteins and inactivated virus.<sup>5</sup> Several vaccine candidates have moved forward into clinical testing, and in the USA, vaccines from Pfizer/BioNTech and Moderna are scheduled to be evaluated for emergency use authorisation by the US Food and Drug Administration (FDA).<sup>6</sup> Despite promising advancements in vaccine development, the timeline for public availability remains uncertain, pending adequate safety testing and rigorous proof of effectiveness.<sup>7</sup> This is further complicated by the fact that a number COVID-19 clinical characteristics

relevant to vaccine efforts are still unclear, and vaccine manufacturing and distribution issues such as adequate storage/transportation may further delay dissemination.<sup>8</sup>

Although there are many unknowns surrounding COVID-19 vaccine development, proactive planning is critical to ensure equitable and prudent distribution. Healthcare leaders have a moral duty to plan for the challenges presented by this pandemic. Even with unprecedented speed in vaccine development and testing, epidemiologists anticipate there will be a major shortage of COVID-19 vaccines, both within the USA and worldwide.<sup>9</sup> Discussion surrounding vaccine allocation both nationally and globally has already begun, and the Centers for Disease Control and Prevention (CDC)'s Advisory Committee on Immunisation Practices is actively deliberating allocation.<sup>10 11</sup> By prospectively evaluating the factors that will impact vaccine allocation, we will be better equipped to ensure distribution best addresses the substantial health, economic and social impacts of COVID-19.

To this end, we identify the ethical goals that vaccine distribution should aim to promote, assess the likely impact of different prioritisation strategies on achieving these goals and identify key empirical questions that will shape the likely outcomes associated with different national vaccine prioritisation strategies. While we place our discussion of these topics primarily in the context of the USA, COVID-19 vaccine allocation will take place internationally. Consequently, it is important to examine context-dependent factors within each country when considering the strategies and recommendations presented.

## ETHICAL GOALS FOR DISTRIBUTING COVID-19 VACCINES

The first step in assessing the ethics of vaccine allocation for COVID-19 is to consider the intended goals of this endeavour.<sup>12</sup> We propose that there are three central goals for future COVID-19 vaccination campaigns, none of which is lexically prior to another. The first is the reduction of morbidity and mortality. This is consistent with position of the CDC, which asserts that the primary purpose of vaccine campaigns is ultimately to reduce the impact of disease on health.<sup>13</sup> The second is to minimise the pandemic's effects on societal infrastructure and the economy. This goal is particularly salient for COVID-19, given the magnitude of the economic toll wrought by the pandemic and the importance of maintaining societal infrastructure.<sup>12 13</sup> The third is to narrow unjust health inequalities, consistent with the view that the moral foundation of public health is social justice and, therefore, the reduction of inequalities faced



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by systematically disadvantaged groups.<sup>14</sup> This goal also finds particular resonance in the COVID-19 context, given the disproportionate health and economic burdens of the pandemic borne by racial and ethnic minorities as well as those of low socioeconomic status.<sup>15</sup>

Identifying these goals provides criteria to assess the ethical implications of different vaccine allocation strategies. However, even with these defined objectives in place, numerous complexities remain with respect to how these goals can be best achieved and how potential trade-offs should be weighed against one another. Below, we outline, in no order of priority, five proposed prioritisation approaches to guide vaccine allocation decisions and evaluate the likelihood of each to advance the aforementioned goals for future COVID-19 vaccination programmes.

### PRIORITISATION APPROACHES TO GUIDE COVID-19 VACCINE ALLOCATION

The first proposed strategy is to prioritise those most vulnerable to morbidity and mortality from COVID-19. This approach has been applied across multiple previous pandemics and is a central feature of CDC recommendations for potential influenza pandemics.<sup>13</sup> This prioritisation strategy also features prominently in contemporary guidance on allocating scarce medical resources during the COVID-19 pandemic.<sup>16 17</sup> Based on the current epidemiological data available for COVID-19, prioritising those most vulnerable to morbidity and mortality would largely entail vaccinating those above 65 years of age, who represent as much as 73.6% of COVID-19-related deaths,<sup>18</sup> and those with comorbidities such as hypertension, diabetes, cancer, cardiovascular disease and cerebrovascular disease.<sup>19</sup> This approach most directly aligns with the goal to reduce COVID-19's health impacts. This strategy may also align with the goal of narrowing unjust health inequalities, given communities of colour have higher COVID-19 infection, hospitalisation and mortality rates, reflecting numerous background systemic injustices, ranging from economic marginalisation to racial discrimination in healthcare systems, which put these populations at greater 'risk of risks'.<sup>15 20</sup> Furthermore, as the current economic toll of the pandemic is at least partially a reflection of societal measures to protect the elderly, such as population-wide stay-at-home orders to minimise viral to those vulnerable, this prioritisation strategy may move towards economic revival. However, it may not be the optimal approach to reducing the pandemic's economic burden, as non-fatal cases will likely continue to propagate, thereby perpetuating the pandemic's spread and the corresponding strain on healthcare systems.

The second strategy is prioritising by life-cycle, so as to ensure the greatest number of individuals have the opportunity to pass through all stages of life (childhood through old age).<sup>17 21</sup> This approach would entail vaccinating those younger than 65 years of age to ensure these individuals do not have a life-cycle cut short by COVID-19. Emerging evidence associating multi-system inflammatory syndrome with COVID-19 in children may provide some support for this approach, given accumulating evidence that children can die from a sequelae of COVID-19.<sup>22</sup> However, this approach is likely in tension with the goal of minimising overall mortality and morbidity, as current data suggest that children and adults under 65 years of age who do not have comorbidities are at lower risk of mortality from COVID-19.<sup>23</sup> Similarly, prioritising by life-cycle does not address social inequalities exacerbated by COVID-19. However, this strategy may be consistent with the goal to revive the economy, as those younger than 65 years are more likely to be employed. Vaccination

could therefore enable these individuals to return to participating in the exchange of goods and services, although this may have limited success given the strategy would still leave the elderly and vulnerable at risk and require continued societal measures to protect these populations (ie, stay-at-home orders). Yet, prioritising younger individuals may have the notable benefit of supporting return to in-person education, securing both extensive health and social benefits for students themselves as well as economic benefits for families, given the disruptions to work presented by the challenges of virtual learning.

The third strategy is prioritising individuals who provide 'instrumental value'. This would entail vaccinating essential healthcare workers, individuals who provide life-saving services (ie, fire department workers, emergency medical services, police and so on) and workers who provide services that are necessary for society to function as normally as possible (ie, food industry employees, essential airport personnel and so on).<sup>24</sup> Prioritising these populations is consistent with the principle of reciprocity, recognising the additional risks assumed by essential workers to maintain critical services for society during the pandemic. This approach conflicts with allocating vaccines according to other considerations discussed here (such as vaccinating those with the greatest risk of mortality). Nevertheless, it may be consistent with the goal of minimising the mortality and morbidity of COVID-19—both by ensuring that those who play a key role in the ongoing COVID-19 response are able to continue to serve in this capacity and by reducing the risk of spread, as essential workers generally have far more social contacts than others.<sup>25</sup> This prioritisation approach is also consistent with the goal of maintaining the economy and minimising societal impacts of the pandemic, given workers are needed to continue operating essential services. Furthermore, protecting these individuals would most directly preserve the healthcare system as a whole, an important consideration given the persistent impact of COVID-19. Finally, 70% of essential workers do not have college degrees, and 45% are of ethnic minorities, suggesting prioritising essential workers may also support a commitment to addressing social inequalities.<sup>26</sup>

The fourth prioritisation strategy is that of ensuring equal access. This approach may involve giving equal priority to all individuals for vaccination, respecting each person's inherent moral equality. On the surface, this may seem achievable by implementing a first-come, first-served policy to vaccine administration or by employing a lottery system to select individuals to receive vaccination. However, such policies fail to acknowledge the background structural inequalities that impact certain groups' abilities to even access the queue, as illustrated by disparities in access to COVID-19 testing resources.<sup>27</sup> Thus, this approach is unlikely to achieve the goal of narrowing health disparities and may even exacerbate them, given that equal access is not equivalent to equitable access. Furthermore, by not targeting those groups most likely to secure the greatest health or economic benefits, an 'equal access' policy is unlikely to achieve any of the three outlined goals.

Fifth is prioritising the reduction of spread of COVID-19 infections. One approach to this strategy is to reduce infection spread within confined communities, which would entail vaccinating groups of individuals who are in very close contact with one another, such as nursing homes and prisons. Another approach is to reduce spread through the community as a whole, which would entail vaccinating those most likely to infect large numbers of individuals (such as those regularly attending large community events). This may also include those whose jobs require in-person contact with many others. Application

of this approach may be consistent with efforts to reduce the total number of cases and accelerate the reopening of the nation (and therefore, revival of the economy). However, it may not align with the overall goal of reducing morbidity and mortality, given the heterogeneity of risk factors for severe COVID-related illnesses across the various communities with elevated risk of spread. While prioritising certain groups at elevated risk for spreading COVID-19 may narrow some health disparities, the particular impact will largely depend on the specific subpopulations targeted for vaccination.

### MAJOR UNKNOWNNS THAT MAY ALTER THE OUTCOMES OF DIFFERENT PRIORITISATION STRATEGIES

The aforementioned prioritisation strategies can provide guidance in decision-making regarding the ethical allocation of COVID-19 vaccines. However, the specific application of these strategies and their implications for achieving the goals of COVID-19 vaccination inevitably rest on several empirical features, many of which are as yet unknown. It is vital to consider how this information, once elucidated, may influence the ethical dimensions of allocation decisions. The major variables that may impact vaccine distribution can be organised into three categories: COVID-19 clinical characteristics, vaccine clinical characteristics and miscellaneous factors.

While many clinical characteristics of COVID-19 have been discovered, several relevant to vaccine allocation remain unknown. Namely, the risk of children spreading the disease to others is still uncertain, and this may impact the prioritisation of children for vaccination. This is especially relevant given many children are returning to in-person schools in the USA. Preliminary data show that children may have significantly higher viral loads compared with hospitalised adults with COVID-19 but may not spread the virus as readily as adults.<sup>28 29</sup> Furthermore, it is likely that children will require separate, pediatric-specific vaccine clinical trials prior to widespread distribution. Additionally, discovering the degree to which individuals are immune to COVID-19 following recovery from infection may change allocation procedures and decisions. For example, if those previously infected are conferred long-term immunity following recovery, testing individuals for immunity prior to vaccination may be warranted, and those with immunity may not require immediate vaccination.

Additional unknowns remain regarding vaccine clinical characteristics, including which COVID-19 vaccine(s) will be the first approved for distribution. Yet the vaccine type may impact dosing and 'booster' schedules for given individuals (ie, immunocompromised people may require higher strength or additional doses, as is the case for certain immunocompromised individuals receiving the current hepatitis B vaccine). Similarly, the need for separate vaccines based on patient age (such as for the influenza vaccine), the timeline of development of such vaccines and whether there will be differences in COVID-19 vaccine efficacy based on patient's age or demographics may impact decisions on who is initially vaccinated.<sup>30</sup> Furthermore, the number of doses required to achieve immunity in an individual is unknown, with the majority of candidate vaccines requiring either two or three doses spread across 2–8 weeks, including the front-running Pfizer/BioNTech and Moderna vaccines.<sup>5</sup> Similarly, the length of immunity that will be conferred to recipients following vaccination is unclear. Although immunity from infection is the intent of vaccination, it is also currently unknown whether COVID-19 vaccines will prevent infection and transmission among those vaccinated or simply prevent symptomatic disease. This is

an important consideration given some allocation strategies proposed rest on the former while others focus on reducing the latter.

Given that multiple initial doses will likely be needed, the impact of any prioritisation approach on the goal of minimising morbidity and mortality may also be influenced by the feasibility of follow-up. This can present a conflict between the goal of advancing overall health and that of narrowing health disparities, given that at least some groups that may present the greatest challenges for reliable follow-up are also those who face systematic patterns of disadvantage.<sup>31</sup> Differences in side-effect profile based on age and demographics may also impact the outcomes resulting from different prioritisation strategies.<sup>32</sup> For example, if vaccine side-effect risks are too high among the elderly, these individuals may receive lower priority for vaccination, and individuals who come into frequent close contact with the elderly may be prioritised instead. If multiple vaccines are approved near one another temporally, careful consideration of the characteristics of each vaccine (ie, dosing schedules, side-effect profiles) will be vital in order to determine whether one may be better suited for given populations over another. Furthermore, if multiple vaccines demonstrate differing efficacy overall (ie, one vaccine demonstrates 90% overall efficacy while another demonstrates 80%), this may introduce an ethical dilemma surrounding who will receive which particular vaccine. If this occurs, clearly describing the reasoning behind distribution will be paramount for promoting transparency and public buy-in for these allocation decisions.

Underlying all vaccine allocation plans is the broader context of national reopening. With fluid changes to quarantine requirements and shelter-in-place mandates, vaccination priorities may change depending on which groups of people can reliably self-quarantine and reduce their disease risk until a vaccine is available for them. This concept has important implications for health equity, as disparities exist in the ability to self-quarantine based on employment obligations, among other reasons. In addition, nations may prioritise reopening certain establishments, such as schools, prior to others (eg, bars, or other areas for socialisation), under the argument of differential utility to society. In this case, vaccination priorities may need to be adjusted to protect those frequenting establishments with high population densities. Vaccine allocation will also be impacted by the discovery of satisfactory treatments for COVID-19. Bamlanivimab, a neutralising monoclonal antibody, currently has emergency use authorisation from the FDA given its promise among non-hospitalised patients with COVID-19 at risk of disease progression.<sup>33</sup> As research into novel treatments continues, the focus of COVID-19 vaccine allocation may shift to reducing morbidity and mortality in individuals who, based on currently unknown clinical factors, are unlikely to respond to treatments. Finally, questions remain about vaccine refusals. Partisan differences in attitudes towards COVID-19 vaccination have been steadily growing, while intention to vaccinate has been declining, with as few as 50% of Americans indicating they would elect to be vaccinated against COVID-19.<sup>34</sup> This percentage is not high enough to achieve herd immunity, suggesting the critical need to develop evidence-based strategies that promote support for COVID-19 vaccines among vaccine-hesitant groups.

### RECOMMENDATIONS FOR THE DISTRIBUTION OF COVID-19 VACCINES

As the above analysis indicates, a single prioritisation approach is unlikely to provide comprehensive guidance for COVID-19



vaccine distribution. However, by placing the strategies and current unknowns in the context of the proposed goals of a COVID-19 vaccination programme, we are able to reject approaches that do not reasonably achieve multiple programme goals. Prioritising equal access to vaccines, such as via a first-come first-served or lottery system, would likely not achieve any outlined programme goals. Prioritising life-cycles would likely accelerate reopening of the nation, as this approach would entail vaccinating those <65 years of age; however, this does not align with reducing morbidity and mortality nor does it address health inequities underscored by COVID-19.

To most closely achieve COVID-19 vaccination programme goals, a combination of the other prioritisation strategies likely will be needed. This is similar to what has been proposed previously for the allocation of ventilators and other scarce medical supplies during the pandemic.<sup>16 17</sup> For COVID-19 vaccines, the extent to which these strategies are followed may also depend on whether multiple vaccines are approved for distribution simultaneously, increasing supply. Prioritising a combination of individuals above age 65 years, those with comorbidities, individuals who provide 'instrumental value' and those at the highest risk of spreading disease would be the most prudent approach. This aligns with CDC guidance on vaccine prioritisation in preparation for possible influenza pandemics.<sup>13</sup> Individuals who belong to intersections of these groups should be vaccinated first so as to maximise the immediate benefit. Following this, the application to specific groups will likely vary based on future empirical data, as detailed by the unknowns discussed above.

Our recommendations align largely and should be taken together with the growing discourse surrounding COVID-19 vaccine distribution. In interim guidance provided for vaccine allocation in the USA, Toner *et al* discuss similar goals for a COVID-19 vaccination programme as presented here, advocating for prioritising essential workers as well as those at greatest risk of developing severe illness and death, while balancing distribution to those with elevated risk of infection and low healthcare access.<sup>11</sup> They also discuss that vaccination programmes should aim to promote legitimacy, incorporate the diverse views in a given society and work together with community members. While the many unknowns in vaccine development may shift the practical aspects of vaccine allocation, these goals are achievable in any of the strategies discussed here, as engaging the community is vital to medical decisions made that substantially impact society. This is particularly salient for COVID-19 vaccination programmes given that programme success may rest on public willingness to accept the chosen allocation strategy. These considerations underscore the importance of transparency in communicating decisions regarding vaccine allocation strategies as well as the reasons behind those decisions and how they reflect community values.

Of note, our analysis does not specifically consider questions regarding allocation to COVID-19 vaccine clinical trial participants, including whether specific priority should be given to those who received placebos in earlier trials. Such decisions require careful weighing of the rights of participants against potential societal benefits related to long-term scientific evaluations. While these issues are beyond the scope of this analysis, we welcome continued analysis on these important ethical considerations.

Finally, national prioritisation strategies must be implemented within a larger global allocation context. Liu *et al* outlined an ethical framework for the future global allocation of COVID-19 vaccines, based on utilitarian resource allotment and equitable access.<sup>10</sup> Their framework includes assessing a country's ability

to provide care, ability to implement a vaccination programme and level of reciprocity in worldwide vaccine development efforts. WHO has also developed the COVAX initiative, which is a global initiative focused on ensuring equitable access to COVID-19 vaccines through open discussion, prudent international distribution and financial planning.<sup>35</sup> Our recommendations and strategies similarly rely heavily on these factors, namely the ability to provide care and implement an organised vaccination programme.

## CONCLUSION

Ending the COVID-19 pandemic will likely require widespread vaccination. Proactive planning for the ethical distribution of vaccines against COVID-19 is critical to ensuring that any resulting allocation approach advances the intended public health goals for COVID-19 vaccination: namely, to minimise morbidity and mortality loss, prevent economic harms from the pandemic and to narrow unjust health inequalities. No single prioritisation approach can effectively advance all three goals. Instead, a multipronged approach that considers risk of serious COVID-19 illness, instrumental value and risk of transmission should be implemented, guided by ongoing empirical work regarding, among other factors, clinical and vaccine characteristics specific to COVID-19.

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