

Multivalued ethical framework for fair global allocation of a COVID-19 vaccine

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ABSTRACT

The urgent drive for vaccine development in the midst of the current COVID-19 pandemic has prompted public and private organisations to invest heavily in research and development of a COVID-19 vaccine. Organisations globally have affirmed the commitment of fair global access, but the means by which a successful vaccine can be mass produced and equitably distributed remains notably unanswered. Barriers for low-income countries include the inability to afford vaccines as well as inadequate resources to vaccinate, barriers that are exacerbated during a pandemic. Fair distribution of a pandemic vaccine is unlikely without a solid ethical framework for allocation. This piece analyses four allocation paradigms: ability to develop or purchase; reciprocity; ability to implement; and distributive justice, and synthesises their ethical considerations to develop an allocation model to fit the COVID-19 pandemic.

INTRODUCTION

Never in modern history has there been such an urgent drive for vaccine development as in the midst of the current COVID-19 pandemic. Recognising the tremendous health and economic benefits of a vaccine, public and private organisations have invested heavily in research and development, with remarkable fast tracking of clinical trials.^{1,2} However, the means by which a successful vaccine can be mass produced and equitably distributed remains notably unanswered.

On 24 April 2020, the WHO, in partnership with humanitarian and private sector organisations, affirmed a commitment towards fair global access to 'safe, quality, effective, and affordable COVID-19 diagnostics, therapeutics and vaccines'.³ Their Access to COVID-19 Tools (ACT) Accelerator has also promised 'equitable deployment'.⁴ While the President of the USA has refused further support of the WHO and the USA is conspicuously absent in the countries subsidising ACT, the rest of the world is expected to pledge resources. However, history has shown that such well-intentioned pledging is likely to be insufficient and ensuring equitable distribution of vaccines globally will be challenging.

Since 2000, the international company GAVI has leveraged donations from public and private sectors to subsidise vaccinations for low-income countries.⁵ Although GAVI has significantly increased vaccination rates in these nations, the current pandemic raises specific ethical and practical concerns. During usual times, the largest barriers to vaccination for low-income countries include the inability to afford vaccines and supplies as well as inadequate health-care systems and resources to vaccinate.⁶ However, during a pandemic, these barriers are exacerbated

by a global scarcity of vaccines, increasing vaccine price and worsening inequity and disparity. Therefore, it is unlikely that donations from high-income countries or through organisations like GAVI will ensure fair distribution of a pandemic vaccine without a solid ethical framework for allocation. This piece analyses four allocation paradigms and synthesises their ethical considerations to develop a model to fit the COVID-19 pandemic.

Principle 1: Ability to develop or to purchase

Vaccine distribution is currently determined by two primary considerations: (1) ability to develop and test and (2) ability to purchase. Five multinational companies produce most of the world's vaccines and negotiate with the private and public sector for purchasing.⁷ Perhaps not surprisingly, the US government has already attempted to purchase exclusive access to one COVID-19 vaccine candidate, and surely others will do the same.⁸ This kind of nationalistic approach results in unethical and inequitable allocation based on citizenship and a country's ability to pay.⁹

The H1N1 pandemic illustrates several problems with the pay-to-play method of vaccine distribution. In 2009, high-income countries placed advanced orders for the H1N1 vaccine and purchased virtually the entire global supply. Meanwhile, certain countries attempted to protect their own supply by awarding contracts domestically. For example, Australia prohibited its main manufacturer from exporting the vaccine. Although the USA had initially pledged to donate 10% of their vaccine purchases, due to shortages, the Secretary of Health and Human Services indefinitely postponed donations to meet national need and no vaccines were redistributed.¹⁰ These events highlight the inadequacy of a donation-based system and why the WHO course is likely to fail.

Principle 2: Reciprocity

In 2006, the WHO acknowledged that Australian companies had used samples provided by Indonesia to create and patent a H5N1 vaccine without Indonesian consent. As a result, Indonesia stopped sharing viral samples with the WHO for risk assessment and management, creating a significant barrier to virus global surveillance. Indonesia's actions bring attention to another global inequity, in which developing countries help to produce vaccines but do not subsequently benefit from them.¹¹ These historical events establish the need for a system of reciprocity, which improves equitable vaccine distribution to countries involved in drug development. Reciprocity is well established in research ethics and some clinical trial participants may have post-trial



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access to medications.¹² Recently, a similar recommendation has been proposed to prioritise those who participate in COVID-19 vaccine and treatment research in recognition of the risk they assume and to encourage research participation.⁹ Therefore, countries that share viral samples or have participants in clinical trials should receive priority for vaccine supplies.

Principle 3: Ability to implement

Although no single ethical principle can guide vaccine allocation, some consideration must be made for utilitarian considerations, which prioritise saving the most lives or life years.^{9 13 14} Vaccine deployment is inherently a resource-intensive endeavour that requires specialised transportation, trained personnel for administration and an intact public health infrastructure for identifying need and surveillance.¹⁵ Thus, to maximise vaccine benefits and reduce waste due to improper utilisation, allocation frameworks should consider a country’s ability to vaccinate.

However, this approach will bias against countries that do not have the resources and infrastructure for successful vaccine deployment. Therefore, before allocating based on this principle, all reasonable efforts should be taken to redistribute human and supply chain resources to alleviate these inherent inequalities. Otherwise, disparities are perpetuated (and amplified) by a utilitarian approach to allocation, as low-income countries with poor health outcomes have less access to preventative treatment. After the acute pandemic response, interpandemic years should focus on building up resources in low-income countries.

Principle 4: Distributive justice for developing countries

Distributive justice is the fundamental consideration for equitable vaccine deployment. This principle requires fair allocation of scarce resources, which can be applied to communities both locally and globally. However, limited supply and mass demand during a catastrophic situation, such as the current pandemic, make equitable distribution suboptimal or even impossible.

Since a primary goal of vaccination is reducing infectious disease burden and spread by herd immunity, people with a higher risk of infection or poor outcomes should be prioritised in allocation. Such reasoning was employed in the 2009 influenza pandemic by the Commonwealth of Australia for determining influenza vaccine allocation.¹⁶ Proponents of health equity argue for the prioritisation of poor communities and countries because of their higher disease burden, denser living conditions and lack of healthcare access.^{17 18} These factors increase transmissibility

and result in treatment delays, further contributing to more severe disease burden. On a local level, prioritised groups should include immunocompromised patients, persons with comorbid illnesses, the elderly and lower socioeconomic groups. In a global sense, the populations of developing countries are most at risk due to lack of food and clean water, as well as sanitation hazards that lead to increased infectious disease transmission. Furthermore, without access to acute care in developing countries, prevention with a vaccine may be the only available intervention. Distributive justice requires prioritisation of developing countries when distributing vaccines, in particular at the expense of developed nations that will try to influence vaccine access by the ability to pay. Although this seems infeasible, it is not impossible.

A multivalued ethical framework for vaccine stewardship

Given the inevitable demand for the COVID-19 vaccine and the high burden of disease already placed on many countries, there is a need for an equitable global framework for vaccine distribution.² Without advanced planning and thoughtful execution, pre-existing health and socioeconomic disparities will only be exacerbated by this pandemic. It seems inevitable that high-income countries will obtain and use the bulk of vaccines, while lower income countries are in far greater need. Planning for distribution must begin as the vaccine is being developed so that a paradigm is ready when distribution begins. Otherwise, the framework loses efficacy as national interests for developed states favour perpetuation of existing international disparities as seen in the influenza pandemic.¹⁰ Although it is difficult to correct for already existing international disparities in healthcare resources, a vaccine for COVID-19 does not yet exist to fall into this trap. The following framework is proposed to align with ethical values for utilitarian resource stewardship and equitable access with prioritisation for those most at need.

Like prior frameworks used for equipment allocation (eg, ventilators) to patients,^{19 20} we propose stratifying countries into groups based on three guiding principles (table 1). Our multivalued ethical framework operationalises the principles previously addressed to promote fair vaccine allocation. For example, balancing successful implementation so that vaccines reach the patient, and socioeconomic needs so that limited access to care does not overwhelm healthcare infrastructure is important to maximally save lives.

Table 1 A multivalued ethical framework for the global allocation of a severe acute respiratory syndrome coronavirus 2 vaccine

Principle	Reasoning	Point system			
		0	1	2	3
Ability to provide care	Without the capacity to treat critically ill patients, a vaccine is the only potential intervention for patients in low-income countries; they should receive priority	–	High (well-developed ICU resources)	Medium (limited ICU care or respiratory resources)	Low (no ICU care)
Ability to implement	Vaccines should not be allocated if they cannot be used. Efforts should be made to support low-income countries for distribution and implementation	Would need significant external resources to implement.	Can acquire supplies and train personnel to implement, but not immediately ready	Has necessary supplies and personnel to implement	Has necessary supplies and personnel to implement, shares resources with other countries
Reciprocity	A country and its people should be rewarded for their participation in develop and testing vaccines.	Hindered global efforts or attempted to obtain exclusive access	Did not participate in vaccine development process	Indicated desire to participate but was unable due to resources or ability	Participated in clinical trials, aided in surveillance efforts, donated viral samples

ICU, intensive care unit.

This framework provides an algorithmic scoring system that can be used to balance utilitarian and egalitarian values in country-by-country vaccine allocation. Further considerations will be necessary on the national level regarding distribution within smaller geographical areas. Additionally, specific criteria for scoring are omitted because there are no standardised measurement systems for each variable. Although we provide guidelines on point allocation, we recognise that this omits specifics on the quantity of countries per grouping and point cut-offs per group. We leave the framework up for interpretation based on the status quo of the pandemic. Guidelines should respond to emerging scientific, supply chain and public health updates. A framework is paramount to prevent inevitable global inequity during this time of crisis and our allocation framework offers a starting point for discussion. Success is dependent on global collaboration, and if ever there was an opportunity for cooperation, that time is now.

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