

WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination

14 September 2020



Executive Summary

This Values Framework offers guidance globally on the allocation of COVID-19 vaccines between countries, and to offer guidance nationally on the prioritization of groups for vaccination within countries while supply is limited. The Framework is intended to be helpful to policy makers and expert advisors at the global, regional and national level as they make allocation and prioritization decisions about COVID-19 vaccines. This document has been endorsed by the [Strategic Advisory Group of Experts on Immunization](#) (SAGE).

The Framework articulates the overall goal of COVID-19 vaccine deployment, provides six core principles that should guide distribution and twelve objectives that further specify the six principles (Table 1). To provide recommendations for allocating vaccines between countries and prioritizing groups for vaccination within each country, the Values Framework needs to be complemented with information about specific characteristics of available vaccine or vaccines, the benefit-risk assessment for different population groups, the amount and pace of vaccine supply, and the current state of the

epidemiology, clinical management, and economic and social impact of the pandemic. Hence, the final vaccination strategy will be defined by the characteristics of vaccine products as they become available.

SAGE is currently engaged in the process of applying the Values Framework to emerging evidence on specific vaccines, and the evolving epidemiology and economic impact of the pandemic. The first stage of this process was the identification of populations and sub-populations which would be appropriate target groups for prioritization under the various values-based objectives in the Framework (Table 2), before data on Phase 3 vaccine performance are not yet available. Specific priority group recommendations for specific vaccines will be made as vaccine products become authorized for use; initial vaccine specific policy recommendations are expected in the final quarter of 2020 or early 2021, depending on timing of and findings from phase 3 vaccine trials.

The Framework also complements the principles on equitable access and fair allocation of COVID-19 health products developed for the ACT Accelerator COVAX facility.

Framework Goals and Principles at a Glance

Overarching Goal

COVID-19 vaccines must be a global public good. The overarching goal is for COVID-19 vaccines to contribute significantly to the equitable protection and promotion of human well-being among all people of the world.

Principles

Human Well-Being

Protect and promote human well-being including health, social and economic security, human rights and civil liberties, and child development.

Equal Respect

Recognize and treat all human beings as having equal moral status and their interests as deserving of equal moral consideration.

Global Equity

Ensure equity in vaccine access and benefit globally among people living in all countries, particularly those living in low-and middle-income countries.

National Equity

Ensure equity in vaccine access and benefit within countries for groups experiencing greater burdens from the COVID-19 pandemic.

Reciprocity

Honor obligations of reciprocity to those individuals and groups within countries who bear significant additional risks and burdens of COVID-19 response for the benefit of society.

Legitimacy

Make global decisions about vaccine allocation and national decisions about vaccine prioritization through transparent processes that are based on shared values, best available scientific evidence, and appropriate representation and input by affected parties.

Introduction

While there has been unprecedented progress in developing a vaccine against COVID-19, supplies of the first vaccine (or vaccines) to be authorized will be limited in the short to medium term. This Values Framework is intended to offer guidance globally on the allocation of COVID-19 vaccines between countries, and to offer guidance nationally on the prioritization of groups for vaccination within countries; particularly while supply is limited. It also complements the principles on equitable access and fair allocation of COVID-19 health products developed for the ACT Accelerator COVAX facility.

The Framework has been developed to provide a values foundation for SAGE recommendations on priority target groups for specific COVID-19 vaccines at different stages of supply availability. The intention is for the Framework to be a helpful tool to policy makers and expert advisors at the global, regional and national level as they make allocation and prioritization decisions about COVID-19 vaccines. In addition, the Framework is intended to be useful to all stakeholders, including community and advocacy groups, the general public, health professionals and other civil society organizations as they contribute to decisions about how limited supplies of COVID-19 vaccines should be deployed for optimal impact. The Framework is designed to address only ethical issues relating to the allocation and prioritization of COVID-19 vaccines. Other ethical issues related to COVID-19 vaccines, for example, vaccine trial design and the regulatory process, are outside of its scope.

The Framework articulates the overall goal of COVID-19 vaccine deployment, provides six core principles that should guide distribution and twelve objectives that further specify the six principles (Table 1). To provide recommendations for allocating vaccines between countries and prioritizing various groups

within each country, the Values Framework needs to be complemented with information about specific characteristics of available vaccine or vaccines, the benefit-risk assessment for different population sub-groups, the amount and pace of vaccine supply, and the current state of the epidemiology, clinical management, public health response, and economic and social impact of the pandemic.

This document has been prepared by the SAGE Working Group on COVID-19 vaccination, and reviewed and endorsed by SAGE at an extra-ordinary plenary meeting of 26 August 2020.

SAGE is currently engaged in the process of applying the Values Framework to emerging evidence on specific vaccines, and the evolving epidemiology and economic impact of the pandemic. These assessments will be continuously updated as data become available. The first stage of the process in utilizing the Framework, now completed, was the identification of candidate priority groups for vaccination that, in an abstract scenario for a vaccine and based on current knowledge, are appropriate candidates for prioritization under the different values-based objectives in the Framework, shown in the “Values to Priority Groups” section below (Table 2). One benefit of this step is that it allows policy makers to identify the evidence and modeling questions that need to be answered while data are being collected about specific vaccine candidates. Another is that the values-based justification for different candidate priority groups is now explicitly displayed to guide decision-making.

SAGE will make specific priority group recommendations for specific vaccines as they become authorized for use; initial recommendations are expected in the final quarter of 2020 or early 2021.

Table 1. Values Framework

Goal Statement	COVID-19 vaccines must be a global public good. The overarching goal is for COVID-19 vaccines to contribute significantly to the equitable protection and promotion of human well-being among all people of the world.
Principles	Objectives
Human Well-Being	Reduce deaths and disease burden from the COVID-19 pandemic;
	Reduce societal and economic disruption by containing transmission, reducing severe disease and death, or a combination of these strategies;
	Protect the continuing functioning of essential services, including health services.
Equal Respect	Treat the interests of all individuals and groups with equal consideration as allocation and priority-setting decisions are being taken and implemented;
	Offer a meaningful opportunity to be vaccinated to all individuals and groups who qualify under prioritization criteria.
Global Equity	Ensure that vaccine allocation takes into account the special epidemic risks and needs of all countries; particularly low- and middle-income countries;
	Ensure that all countries commit to meeting the needs of people living in countries that cannot secure vaccine for their populations on their own, particularly low- and middle-income countries.
National Equity	Ensure that vaccine prioritization within countries takes into account the vulnerabilities, risks and needs of groups who, because of underlying societal, geographic or biomedical factors, are at risk of experiencing greater burdens from the COVID-19 pandemic;
	Develop the immunization delivery systems and infrastructure required to ensure COVID-19 vaccines access to priority populations and take proactive action to ensure equal access to everyone who qualifies under a priority group, particularly socially disadvantaged populations.
Reciprocity	Protect those who bear significant additional risks and burdens of COVID-19 to safeguard the welfare of others, including health and other essential workers.
Legitimacy	Engage all countries in a transparent consultation process for determining what scientific, public health, and values criteria should be used to make decisions about vaccine allocation between countries;
	Employ best available scientific evidence, expertise, and significant engagement with relevant stakeholders for vaccine prioritization between various groups within each country, using transparent, accountable, unbiased processes, to engender deserved trust in prioritization decisions.

Why a Values Framework?

Decisions about how to allocate and prioritize limited supplies of COVID-19 vaccines must be guided by the best available science about the epidemiology of the pandemic and the measures available to control it, the clinical course of COVID-19, the transmissibility of the virus, the efficacy and safety of available vaccines, and their delivery characteristics. However, decisions about how to deploy limited COVID-19 vaccines should not be based on only public health considerations. Nor should they be driven by economics considerations alone, even though the impact of this pandemic on the economies of nations and the financial security of families has for many been devastating.

There are two reasons why allocation and prioritization decisions cannot be made on the basis of public health science or economics alone. The first is that the two are inextricably linked; economies cannot recover so long as the public health crisis continues. The second, and perhaps more foundational, reason is that the COVID-19 pandemic is having a devastating impact on many important aspects of social and individual life, and not just public health and the economy. Determining how best to deploy vaccines requires taking into account the various ways in which vaccines can make a difference, and the many different groups whose lives could be improved as a consequence.¹

Starting with a Values Framework allows decision makers to think through these competing demands with an explicit recognition of the values and principles that are at stake. Employing a Values Framework also decreases the likelihood that decision-makers will overlook morally important uses or claims to vaccination. In addition, basing allocation and prioritization decisions on the *integration of explicit values with evolving scientific and economic evidence* will help keep decision-makers accountable, in at least three ways. First, it will assist decision makers to be as clear as possible about the reasons for the decisions they take, reasons that they can then share in ways that can be readily understood, if not always readily accepted, by the people affected by these decisions. Second, being clear and explicit about the full range of reasons behind allocation and prioritizing decisions will permit groups who think they qualify under the reasoning to press their case for inclusion. And third, being explicit about the values as well as the data that were used to make decisions will allow for more precise and therefore potentially more useful feedback and criticism.

Orientation to the Framework

The Framework proposes six values principles to guide COVID-19 vaccination programs, the promotion of: human well-being, equal respect, global equity, national equity, reciprocity and legitimacy (Table 1). Human well-being, equal respect, global equity, national equity and legitimacy are all of comparable importance and significance. While COVID-19 vaccination programs would be remiss if they did not take reciprocity into account, reciprocity is a principle of narrower scope and more limited importance than the other five.

The Framework identifies twelve objectives that further specify these six principles (Table 1). As with the principles, these twelve objectives are not presented in order of importance. Ideally, a COVID-19 vaccination program would secure all of these objectives simultaneously without needing to balance competing objectives. In the real world, however, constraints on timely supply and the specific characteristics of the vaccines that become available will narrow the options for vaccine allocation between countries and prioritization of groups for specific vaccines within countries.

In some cases or phases of vaccine supply, multiple objectives will provide justification for prioritizing some countries or groups. For example, prioritizing health care workers directly engaged in the COVID-19 response is supported by objectives linked to both the well-being and reciprocity principles. In other cases, hard choices may need to be made. For example, a decision may need to be taken about which objective to prioritize when several come into conflict, or about which groups to prioritize when there is insufficient supply to offer vaccine to all who would otherwise qualify under a particular objective. Sometimes these choices will be dictated by the characteristics of the initial vaccine products that become available for use. For example, early vaccines may show more promise in reducing deaths and disease than in containing transmission, or they may not work well in older adults. In some cases, candidate priority groups may encompass multiple values objectives. For example, some groups who are at increased risk for social reasons may also be disproportionately represented in some workforces that are important to the functioning of essential services.

Thus, priority groups cannot be simply read off from the list of objectives, not only because the objectives are not themselves rank ordered, but also because which objectives are most salient and most able to be met will depend on multiple contextual features, including the epidemiology of COVID-19, the characteristics of specific vaccine products, and the level of societal and economic disruption at the time vaccine is available. Nevertheless, identifying the groups that correspond to the values objectives is essential for planning.

Explication of the Principles

The Values Framework

The Framework articulates the overall goal of COVID-19 vaccine deployment, puts forward six core principles that should guide distribution, and twelve objectives that further define the six principles^{*,2,3,4,5,6,7,8,9,10,11,12}

Overarching Goal

COVID-19 vaccines must be a global public good.† The overarching goal is for COVID-19 vaccines to contribute significantly to the equitable protection and promotion of human well-being among all people of the world.^{13,14}

Traditional approaches to the allocation of limited public health resources, including vaccines, have implicitly or explicitly appealed to a utilitarian value in which the aim is to maximize the amount of societal good or benefit that can be secured from the resource available. Typically, the good to be maximized is health benefit, although occasionally broader social or economic benefits are also considered. Maximizing benefit is critical, especially when resources are limited and stakes are high. However, it is not the sole or necessarily most important value that should guide the deployment of limited public health resources. Equity is equally important, where the aim is to ensure that the interests and rights of all groups and individuals are treated fairly.

The Goal for Covid-19 vaccination incorporates *both* the value of producing benefit, broadly construed, through the promotion of human well-being, *and* the value of ensuring equitable access to these benefits, both globally and within countries.

Principles

Human Well-Being

Protect and promote human well-being including health, social and economic security, human rights and civil liberties, and child development.

As of 1 September 2020, globally, over eight hundred thousand people have died from COVID-19 disease, many more have suffered from significant clinical disease and over 25 million cases of SARS CoV-2 infection have been reported.¹⁵ The pandemic's negative impact on

health has not been limited to COVID-19 mortality and morbidity. Essential public health services have been disrupted in many countries, including routine immunization services (increasing the risk of vaccine-preventable disease like measles); prevention and treatment services for non-communicable diseases and their complications (including hypertension, diabetes, cancer, cardiovascular and chronic respiratory diseases); maternal and child health services; and mental health and rehabilitation services (a key to healthy recovery following severe illness from COVID-19).^{16,17,18,19,20,21,22,23}

Health is not, however, the only dimension of well-being that has been severely affected by the pandemic. The closures of businesses, interruptions to trade, transport, and value chains, reduced consumer and business demand, and concomitant slowdown in economic activity have caused severe economic harms, undoing many recent gains made in global poverty reduction, and destroying or threatening the livelihoods and access to food of millions.^{24,25,26,27,28} School closures have not only resulted in significant setbacks in learning for over 1.5 billion young people, worldwide, they have also undermined their socioemotional development, and in many cases their physical health and safety.²⁹ Lockdowns and travel restrictions have separated loved ones for long periods of time, isolating many. This pandemic thus continues to negatively impact numerous human rights, including the right to health, freedom of movement, food, an adequate standard of living and education.

The human well-being principle requires that those making vaccine allocation and prioritization decisions determine what vaccine deployment strategies will best promote and protect all the implicated dimensions of well-being,³⁰ including strategies for containing transmission, reducing severe disease (including long term sequelae) and death, or a combination.

Equal Respect

Recognize and treat all human beings as having equal moral status and their interests as deserving of equal moral consideration

The principle that all people are and should be treated as moral equals, entitled to equal respect and equal consideration of their interests, is enshrined in the Universal Declaration of Human Rights³¹ and in the constitutional documents of many countries. Equal respect is also generally understood to be a foundational principle of ethics, and of justice or equity in particular.

previously released guidance on ethical considerations necessary for vaccination programs in acute humanitarian emergencies.¹²

† We use the term “public good” as it is used in global health to mean a good that should be available universally because of its critical importance to health, and not as the term is used in economics to mean a good that is both non-excludable and non-rivalrous.

* Other ethics frameworks for COVID-19 vaccines have been proposed, for both the national^{2,3} and the global^{4,5} context. See also WHO and Nuffield Council ethics briefs for COVID-19 treatments and vaccine,^{6,7} other ethics frameworks for the allocation of COVID-19 interventions,^{8,9} a general ethics framework for vaccines,¹⁰ and a WHO ethics framework for allocation of health resources.¹¹ Note that the World Health Organization's Strategic Advisory Group of Experts (SAGE) on Immunization has also

Global Equity

Ensure equity in vaccine access globally among all countries, particularly for low-and middle-income countries

Because the havoc wrought by the COVID-19 pandemic on human well-being and rights has been global, people living everywhere in the world are entitled to equal consideration for COVID-19 vaccine access and in allocation decisions. Countries and territories have primary responsibility for protecting and promoting the well-being and human rights of those living within their borders. It is thus reasonable and appropriate for countries to be concerned with securing sufficient COVID-19 vaccines to meet the needs of their own populations. However, this national concern does not absolve nation-states of obligations to people in other countries.³² Although there is little consensus about the meaning and reach of global justice^{33,34,35}, at a minimum, nation-states have an obligation in global equity not to undermine the ability of other countries to meet their obligations to their own populations to secure vaccines. **Error! Bookmark not defined.** The global community also has an obligation to address the human rights claims to vaccines of people living in countries who cannot, without assistance, meet their needs by, for example, reducing obstacles to obtaining vaccines that confront countries with fewer resources and geopolitical power.

The reasons why all nations should be concerned to ensure that people everywhere have access to COVID-19 vaccine are not limited to obligations of global equity.^{36,37} Infectious threats to health know no borders; as long as there is active SARS-CoV-2 transmission anywhere there will be a risk of transmission everywhere. Moreover, protecting the public health of one's residents is not the only national interest countries have in containing the pandemic globally. The recovery of national economies also depends on securing stable global supply chains and global markets and regularizing international travel, which will not be possible until the pandemic is contained globally. Hence the equitable allocation of vaccines globally is in all countries' enlightened self-interest.

National Equity

Ensure equity in vaccine access and benefit within countries for groups experiencing greater burdens from the COVID-19 pandemic

There are many ways to think about what equity or justice requires within a country when COVID-19 vaccine is in short supply.³⁸ It is clearly important to be efficient in the use of constrained resources, especially when the resource is as high-value as vaccines in a devastating pandemic. From the perspective of some utilitarian positions, maximizing the net good that can be secured is considered the most

just way to deploy limited resources. However, relying solely on maximizing utility to make decisions about limited vaccine supply can perpetuate and even exacerbate existing injustices affecting human well-being. In public health, the moral importance of looking beyond efficiency to address other pertinent justice concerns is often expressed as the obligation to pursue health equity. Health equity requires that public policies, including how to prioritize vaccines when supply is limited, reduce unjust disparities in health and other aspects of well-being. **Error! Bookmark not defined.**³⁹

Although everyone is affected by the COVID-19 pandemic, it is not the case that the burdens of the pandemic are being experienced equally by all people. Some groups are experiencing serious illness and death at higher rates. In some cases, these higher rates are specifically associated with biological factors. For example, those who are older or have comorbidities like chronic kidney disease and diabetes have claims for prioritization because of their greater risk of severe disease and death.^{40,41,42} Other groups, however, are experiencing disproportionately greater health and other burdens in this pandemic because of societal factors that are arguably unjust. Sometimes, but not always, the elevated risk in these groups is mediated by high rates of co-morbidities that are themselves causally connected to societal conditions, serving to compound further their disproportionate burden.

Although the evidence is not yet available globally, there are emerging reports that people living in poverty, especially extreme poverty, are suffering disproportionately during this pandemic, as they have done in past pandemics and in emergencies and disasters generally. It can be extremely difficult for people living in poverty to practice physical distancing in their living arrangements or at work;^{43,44,45,46} they are more likely to experience food and housing insecurity, both before and because of the pandemic, and to be in poorer health. They also have barriers to accessing quality health care. Systemic disadvantage associated with racism and other forms of denigrated group membership, sometimes but not always intersecting with poverty,^{47,48} is also associated with disproportionate pandemic burden. Promoting equity requires addressing higher rates of COVID-19 related severe illness and mortality among systematically disadvantaged or marginalized groups.

Reciprocity

Honor obligations of reciprocity to those individuals and groups within countries who bear substantial additional risks and burdens of COVID-19 response for the benefit of society

Obligations and norms of reciprocity can take many forms. In the context of the COVID-19 pandemic, when some show exceptional courage or face

exceptional risks that give the rest of society an opportunity to experience better health, physical security, and quality of life, those who benefit have an obligation to reciprocate accordingly.

Reciprocity, thus understood, is similar to but broader than the moral emotion of gratitude.⁴⁹ Expressions of gratitude, while welcome and appropriate, are not sufficient to discharge obligations of reciprocity. Offering vaccine to those who take or bear exceptional risks during a pandemic, often because of their occupations, is one way to honor obligations of reciprocity and also express gratitude.

Reciprocity and gratitude are not the only reasons to offer vaccine to occupational groups to whom duties of reciprocity are owed, however. Their being in good health is often critical to securing the well-being of others, which is why the designation “essential workers” is often used. That said, occupation groups judged to be essential differ in the degree of risk their jobs entail and therefore obligations of reciprocity do not apply evenly to all of them. Another reason for offering vaccine to front-line health and social care workers is that they often come into close contact with people who are biologically most likely to experience serious COVID-19 if infected and who might be afforded some level of protection if these workers were vaccinated.

The principle of reciprocity should be interpreted with caution to preempt inappropriate claims by people and entities with disproportionate power and resources to reciprocity-based entitlement to COVID-19 vaccine.

Legitimacy

Make global decisions about vaccine allocation and national decisions about vaccine prioritization through transparent processes that are based on shared values, best available scientific evidence, and appropriate representation and input by affected parties

Legitimacy in the context of COVID-19 vaccines and this pandemic refers to the appropriate authority to

articulation and incorporation of shared social values in the decision process and outcome; and appropriate representation, influence and input by affected parties, with no tolerance for personal, financial or political conflict of interest or corruption. In all cases, decision-makers must be able to defend their decisions by appealing to reasons that even those who disagree can view as reasonable, and not arbitrary or self-dealing.

From Values to Priority Groups

The “Values to Priority Groups” section of this document represents the first step in prioritizing groups for COVID-19 vaccination that is grounded in values principles and objectives (Table 2). Some groups appear more than once in this table because they are important to securing two or more values objectives. For example, health care workers at high to very high risk appear three times in the values to priority groups document in relation to three different values objectives: 1) reduce deaths and disease burden; 2) protect the continuing function of essential services (where they are included under health care workers); and 3) protect those who bear significant additional risks and burdens for the welfare of others. Final prioritization and specific vaccine recommendations will await more evidence, including a range of epidemiological, economic and clinical factors, specific characteristics of the vaccines, benefit-risk assessment data for particular priority groups (e.g. age specific vaccine efficacy and safety), as well as storage and supply chain requirements for a given product.

The Values to Priority Groups table can be a useful resource for countries as they decide on priority groups for COVID-19 vaccination. The document explicitly connects priority groups with specific value principles and objectives. Given country-specific nuances in epidemiology, demographics, and vaccine delivery systems, these priority groups will need to be further interpreted at a national level. This process should be led by national health experts/National Immunization Technical Advisory Groups (NITAGs) in wide consultation with stakeholders. Country-level decision making will require data collected, or at least collated,

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