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

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World Health Organization

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

[*] 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 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.

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 Rights[31] 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.

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 make recommendations and governing decisions about who gets vaccine and when. Because different stakeholders, including different countries at the global level and different interest groups at the national level, are likely to have different views about vaccine allocation and prioritization, it is important that all concerned are aware that the recommendations and decisions are emanating from a legitimate body through a legitimate process.[1,]**Error! Bookmark not defined.**[,50]

What is required for decision-making bodies to be legitimate in the context of COVID-19 vaccine decision-making includes, but is not limited to:

transparency in decision processes, outcomes, and reasoning; reliance on best available evidence; 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, at the country-level. The Values to Priority Groups section can help countries identify where more local data are needed and where investment now might be required to ensure vaccine delivery platforms that can effectively reach prioritized groups. Moreover, this section may assist important regional discussions about the priorities, for example by Regional Immunization Technical Advisory Groups (RITAGs).

Of note, two principles that do not directly implicate particular priority groups have important implications for national prioritization processes. The equal respect principle requires that careful attention be given to the question of who should be eligible for inclusion in national immunization programs, so that no one is left out of consideration for unjustifiable reasons. The equal respect principle also requires that everyone who satisfies the criteria and reasoning supporting the prioritization of a certain group be included within that group. The legitimacy principle provides guidance on how the process of prioritization should proceed, with safeguards to ensure trust, and to help protect against corruption and self-dealing.

Also of note, the groups identified under the national equity principle may need to be further refined at the global level. Countries must ensure that vaccine access is equitable based on gender, race, socio-economic status, ability to pay, location and other factors that often contribute to inequities within population

The global equity principle applies to allocation at the global level. The considerations identified in Table 2 under this principle further characterize how countries can operationalize global equity obligations.

Table 2. Translation of values to (unranked) priority groups for COVID-19 vaccination. This table also includes equal respect, global equity, legitimacy considerations that apply to all groups

Principle	Objective	Groups & Other Considerations
Human Well-Being	Reduce deaths and disease burden from the COVID-19 pandemic	Populations with significantly elevated risk of severe disease or death: • Older adults defined by age-based risk - may vary by country/region, specific cutoff to be decided at the country level by national health experts/NITAGs based on differential mortality by age • Older adults in high risk living situations (examples: long term care facility, those unable to physically distance) • Groups with comorbidities or health states (e.g. pregnancy/lactation) determined to be at significantly higher risk of severe disease or death (list to be developed later) • Sociodemographic groups at disproportionately higher risk of severe disease or death Populations with significantly elevated risk of being infected: • Health workers at high or very high risk, as defined by interim guidance forthcoming from WHO and ILO • Employment categories unable to physically distance • Social groups unable to physically distance (examples: geographically remote clustered populations, detention facilities, dormitories, military personnel living in tight quarters, refugee camps) • Groups living in dense urban neighborhoods • Groups living in multigenerational households
	Reduce societal and economic disruption (other than through reducing deaths and disease burden)	• Age groups at high risk of transmitting SARS-CoV-2 • Non age-based population groups with significantly elevated risk of infection and transmission • School-aged children to minimize disruption of education and socioemotional development • Groups targeted as part of an emergency outbreak response using emergency vaccine reserves • Workers in non-essential but economically critical sectors, particularly in occupations that do not permit remote work or physical distancing while working
	Protect the continuing functioning of essential services, including health services	• Health workers • Essential workers outside health sector (examples: police officers and frontline emergency responders, municipal services, teachers, childcare providers, agriculture and food workers, transportation workers) • Government leaders and administrative and technical personnel critically needed for indispensable functions of the state (this group should be narrowly interpreted to include a very small number of individuals) • Personnel needed for vaccines, therapeutics, diagnostics production

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	The equal respect principle requires that careful attention be given to the question of who should be eligible for inclusion in national immunization programs, so that no one is left out of consideration for unjustifiable reasons. The equal respect principle also requires that everyone who satisfies the criteria and reasoning supporting the prioritization of a certain group be included within that group.
Global Equity	Ensure that vaccine allocation takes into account the special epidemic risks and needs of all countries; particularly low-and middle-income countries	Priority groups that are identified through this values framework process inform allocation decisions at the global level, with special attention to the needs of 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	Countries with sufficient financial resources should refrain from undermining vaccine access to low and middle-income counties by contributing to market conditions that substantially disadvantage countries with less economic power. Financially able countries should participate and support approaches to ensure access to COVID-19 vaccine for resource constrained populations, including multi-lateral (e.g. COVAX Facility), bilateral procurement mechanisms, and/or other means of support.
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	• People living in poverty, especially extreme poverty • Homeless people and those living in informal settlements or urban slums • Disadvantaged or persecuted ethnic, racial, gender, and religious groups, and sexual minorities and people living with disabilities • Low-income migrant workers, refugees, internally displaced persons, asylum seekers, populations in conflict setting or those affected by humanitarian emergencies, vulnerable migrants in irregular situations, nomadic populations • Hard to reach population groups
	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	• Health workers at high or very high risk, as defined by interim guidance forthcoming from WHO and ILO • Health workers at low or moderate risk, as defined by interim guidance forthcoming from WHO and ILO • Essential workers outside the health sector (see above) who are at high or very high risk of infection • Essential workers outside the health sector (see above) who are at low or moderate elevated risk of infection • COVID-19 vaccine clinical trial participants who did not receive an effective vaccine (examples: placebo recipients, recipient of vaccine products that did not show efficacy)
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	The legitimacy principle provides guidance on how the process of prioritization should proceed, with safeguards to ensure trust, and to help protect against corruption and self-dealing.

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WHO SAGE ROADMAP FOR PRIORITIZING USES OF COVID-19 VACCINES IN THE CONTEXT OF LIMITED SUPPLY

An Approach to Inform Planning and Subsequent Recommendations Based Upon Epidemiologic Setting and Vaccine Supply Scenarios

7 October 2020 Draft

Introduction

As countries prepare to implement their respective COVID-19 vaccination programmes, SAGE is undertaking a three-step process to provide guidance for overall programme strategy as well as vaccine-specific recommendations:

1. A Values Framework. The *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination*,[1] issued on 14 September 2020, outlines the general principles, objectives, and related (unranked) target groups for prioritization.
2. A Prioritization Roadmap (this document). To support countries in planning, the Roadmap suggests public health strategies and target priority groups for different levels of vaccine availability and epidemiologic settings. The Roadmap will be updated, as necessary, to accommodate the dynamic nature of the pandemic and evolving evidence about vaccine impact.
3. Vaccine-specific recommendations. As market-authorized vaccines become available, specific recommendations for the use of these vaccines will be issued. These recommendations may be updated as additional evidence of effectiveness and safety on market-authorized vaccines (as well as other interventions) becomes available, and as epidemiologic and other contextual conditions evolve.

Rationale

Given the urgency and wide-ranging effects of the COVID-19 pandemic, SAGE has developed an approach to help inform deliberation around the range of recommendations that may be appropriate under different epidemiologic and vaccine supply conditions. **The SAGE consensus is that currently available evidence is too limited to allow any recommendations for use of any specific vaccine against COVID-19 at this time (6 October 2020).** This document should be regarded as a Roadmap for planning purposes only.

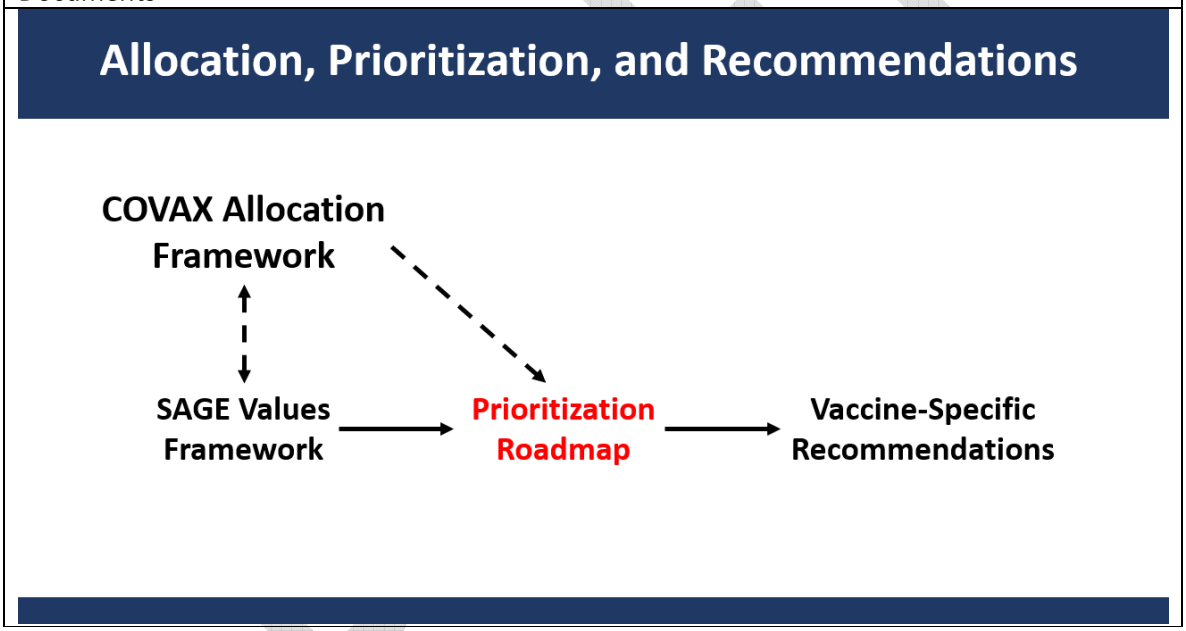
This Roadmap builds on the *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination*. The Values Framework listed over 20 population subgroups that, if vaccine uses needed to be prioritized because of limited supply, would advance one or more of its principles and objectives. The Values Framework did not rank the subgroups in any order. Specific priority group recommendations for each vaccine product as it becomes authorized for use will require the integration of these values objectives with evidence and information about: 1) the status of the pandemic in the proposed implementation area (i.e., the epidemiologic setting in terms of the degree of ongoing SARS-CoV-2 transmission, COVID-19 burden); 2) the amount and timing of vaccine supply and availability, respectively; 3) specific

product characteristics of the available vaccine(s); and 4) the benefit-risk assessment for the different population groups at the time vaccination is being considered for deployment; as well as other standard criteria used in developing SAGE recommendations (e.g., feasibility, resource use, values and preferences). These factors, together with the Values Framework, should guide the appropriate public health strategy for vaccine deployment of specific vaccines.

To assist in developing recommendations for use of vaccines against COVID-19, SAGE proposes a Roadmap for Prioritizing Uses of COVID-19 Vaccines that considers priority populations for vaccination based on epidemiologic setting and vaccine supply scenarios. These use cases are also set in the context of the overall public health strategy for each epidemiologic setting (Table 1).

This Roadmap is intended to serve as guidance on preparing for vaccine prioritization decisions within countries. Although the Values Framework does include the principle of global equity, this Roadmap does not directly address global allocation decisions. An Allocation Framework for countries participating in the COVAX facility has been proposed.[2]

Figure 1. Relationship Between Various WHO SAGE COVID-19 Vaccine-Related Guidance Documents



Process of Roadmap Development

The Roadmap builds on the population subgroups identified in the *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination* as significant for advancing the Framework's principles and objectives. After prioritization exercises by a subgroup of the SAGE Working Group on COVID-19 Vaccines, a draft of the prioritization table was developed and then critiqued by the full Working Group that includes the Chairs of the RITAGS as well several SAGE members. The draft table was then revised and reviewed multiple times. A similar process was used to develop the narrative sections of the Roadmap. Prioritization took account of emerging modelling information exploring the effectiveness and optimal impact of different vaccination strategies and best available epidemiologic information

from academic literature as well as various surveillance organizations. A penultimate round of review by multiple SAGE members resulted in further substantive changes to the Framework, followed by a final review by the full SAGE committee.

Guiding Considerations

The following considerations guided the development of this Roadmap:

- This Roadmap must remain fully aligned with the *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination* that preceded it.
- To be useful in driving discussions at the regional, and national level, the Roadmap needs to be kept as straightforward and concise as possible.
- The Roadmap may be revisited through 1) rolling review as new information becomes available; and 2) on-going dialogue with RITAGs and NITAGs.

Key Assumptions

- The Roadmap assumes any vaccine deployed is fully licensed and has met all the minimal or critical criteria in *WHO Target Product Profiles (TPP) for COVID-19 vaccines*. Less conclusive evidence on benefit-risk, as expected for an emergency-authorized product, might lead to more restricted recommendations.
- The current degree of uncertainty regarding age-independent vaccine efficacy of any specific vaccine was considered (e.g., a scenario in which the vaccine is assumed to have the same efficacy at all ages, and another scenario in which the vaccine is assumed to have much lower efficacy in older adults). However, the Roadmap relies on the underpinning assumption, supported by current modelling results, that, given the many-fold higher mortality rate among older individuals,[3-4] even a vaccine with relatively low efficacy in older adults would not significantly change the recommendations for priority use cases in older populations.[5-7] If however it were determined that vaccine efficacy in older adults relative to other age groups was so low that individual protection and public health impact became significantly sub-optimal, the older age group individuals in each scenario would likely be moved to a lower priority use case.
- Similarly, it was assumed that there would not be substantive differences in vaccine efficacy in subpopulations (e.g., people with comorbidities that increase the risk of severe COVID-19 such as HIV-positive status).
- The Roadmap assumes that non-pharmaceutical interventions are in place to varying degrees as vaccines are introduced and coverage expands. The Roadmap further assumes that vaccine efficacy will not deteriorate if use of non-pharmaceutical interventions is relaxed.
- Although a vaccine's effect on reducing transmission is an important consideration in the recommendations for use, direct evidence of impact on transmission will likely not be available when the first vaccines are authorized for use. The Roadmap assumes that at some point demonstrated evidence of vaccine effectiveness in reducing transmission will be available, sufficient to justify prioritizing vaccination of some groups on the basis of their role in transmission.
- The Roadmap does not account for variation in population seropositivity rates or existing degree of protection within countries or communities which may have already experienced a high degree of community transmission.

- Prioritization exercises undertaken for development of this Roadmap did not directly take account of severe disease as the risk of this will be closely correlated with the risk of death. Similarly, long-term sequalae from SARS-CoV-2 infection have not been taken into account as evidence on chronic morbidity is still emerging.

Epidemiologic Setting Scenarios

The epidemiologic setting scenarios used here take into consideration the relative benefits and potential risks of vaccination. Moreover, the public health strategy for use of vaccines depends upon the burden of disease and on the local epidemiology, particularly the incidence rate of infection in a setting at the time vaccination is being contemplated for deployment. The three proposed broad epidemiologic settings are: (i) Community Transmission, (ii) Sporadic Cases or Clusters of Cases, and (iii) No Cases (**Table 1**).[8]

Vaccine Supply Scenarios

As sufficient vaccine supply will not be immediately available to immunize all who could benefit from vaccination, three scenarios of constrained vaccine supply were considered: a Stage I scenario of very limited vaccine availability (ranging from 1-10% of each country's total population) for initial distribution; a Stage II scenario as vaccine supply increases but availability remains limited, (ranging from 11-20% of each country's total population); and a Stage III scenario as vaccine supply reaches moderate availability (ranging from 21-50% of each country's total population). How each of these three vaccine supply scenarios could be considered in recommendations for use in priority populations is illustrated in **Table 1**.

The Roadmap recognizes that many countries' prioritization decisions will be tied, in part or in whole, to vaccine distribution through the COVAX facility. Stages I and II in the Roadmap correspond to the latest draft of the *WHO Fair allocation mechanism for COVID-19 vaccines through the COVAX facility* Phase 1 supply of up to 20% of each country's population. The Roadmap's Stage III scenario falls under the Allocation Framework's Phase 2 supply of more than 20% population coverage (**Appendix 1**).

Overall Public Health Strategy by Epidemiologic Setting and Vaccine Supply Stages

SAGE recommends overall public health strategies, grounded in the Values Framework, for each of the three epidemiologic scenarios (**Table 1**). The strategies accommodate the dynamic nature of vaccine supply and epidemiologic conditions in each country.

Community Transmission: When vaccine supplies are severely constrained, what is feasible to achieve with limited vaccine availability justifies an initial focus on direct reduction of morbidity and mortality (**Appendix 2:** Reduction of Deaths vs. Reduction in Years of Life Lost) and maintenance of most critical essential services, while considering reciprocity towards groups that have been placed at disproportionate risks to mitigate consequences of this pandemic (e.g., front-line health workers). As vaccine supplies increase, depending on the vaccine characteristics, the strategy expands to reduction in transmission to further reduce disruption

of social and economic functions. Special attention is paid to functions that disproportionately impact children (see below) and to the reduction of morbidity and mortality in disadvantaged groups, in keeping with the SAGE Values Framework principles.

Sporadic Cases or Clusters of Cases: When vaccine supplies are severely constrained, the initial focus on direct reduction of morbidity and mortality and maintenance of most critical essential services, and reciprocity, remains. However, in contrast with the Community Transmission setting, this initial focus is concentrated in locations with high transmission or anticipated high transmission. In addition, some vaccine is allocated for emergency reserve use for outbreak response or mitigation (e.g., for localized outbreaks). Special attention to reduction of morbidity and mortality of disadvantaged groups in areas of high or anticipated high transmission is maintained. As vaccine supplies increase, the strategy expands to substantially control transmission and further reduce disruption of social and economic functions.

No cases: This epidemiologic setting applies to countries that have managed to stop transmission through non-pharmaceutical interventions and border controls. When vaccine supplies are severely constrained, the initial focus is on prevention of community transmission from importation of cases, and reciprocity to critical workers, particularly front-line health workers. As vaccine supply increases, older adults, the highest risk group for severe disease and death, are included to minimize harm should epidemic conditions change suddenly. Also, as vaccine supply increases, the strategy expands to preserve control of transmission and, if possible, to reduce reliance on burdensome non-pharmaceutical interventions.

Priority Uses of COVID-19 Vaccines

The rationale for the inclusion of each prioritized vaccine use case based upon population subgroup is anchored in the Values Framework principles and objectives. For each priority population, the Values Framework objective(s) that would be supported by prioritizing this population for vaccination are indicated by parenthetical abbreviations after the population description (e.g., A1); the legend that links these abbreviations to the objectives is provided in **Table 1**.

While a detailed narrative explication of the rationale for each of the priority groups is beyond the scope of this document, three examples of rationales are provided in **Box 1.**

Box 1: Examples of Rationales for Priority Uses of COVID-19 Vaccines

Example 1. Health Workers at High to Very High Risk of Becoming Infected and Transmitting SARS-CoV-2 in Community Transmission Epidemiologic Setting

For the Community Transmission epidemiologic setting, health workers at high to very high risk of becoming infected and transmitting SARS-CoV-2 are included in Stage Ia. There are three values-linked reasons supporting this prioritization. First, protecting these workers protects the availability of a critical essential service to the COVID-19 pandemic response. Also, the indirect health effects of the pandemic beyond COVID-19 are likely to be much worse if such services are compromised or overwhelmed. Second, evidence suggests that health workers at high to very high risk of acquiring and transmitting infection are also at high risk of morbidity and mortality.[9-10] There is also a risk of onward transmission to people who are also at high risk of serious COVID-19 outcomes. Third, prioritization of these workers is also supported by the principle of reciprocity; they play critical roles in the COVID-19 response, working under intense and challenging conditions, putting not only themselves but also potentially their households at higher risk for the sake of others.

There are also pragmatic reasons for prioritizing health workers at high to very high risk of infection. Health workers already interact directly with health systems, which should facilitate effective deployment of a vaccine programme, particularly including if two or more doses need to be administered. Launching a vaccine programme with a relatively accessible target population will allow more time for the development of delivery mechanisms to other priority groups.

Example 2. Sociodemographic Groups at Significantly Higher Risk of Severe Disease or Death

For the Community Transmission epidemiologic setting, sociodemographic groups at significantly higher risk of severe disease or death are included in Stage II. The reasons for this prioritization are grounded in the principles of equal respect and national equity.

In keeping with the overall public health strategy that places an initial focus on direct reduction of mortality and morbidity, groups with comorbidities or health states that put them at significantly higher risk of severe disease or death are prioritized to Stage II. But there are other groups in the population who may be at just as high a risk of these severe outcomes but who are not captured in a prioritization solely by comorbidities. These groups disproportionately include those who are systematically disadvantaged with respect to social standing and economic and political power. In many contexts, disadvantaged groups are more likely to experience a higher burden of infection and consequent COVID-19 disease because of crowded work or living conditions over which they have no effective control,[11-13] as well as a higher prevalence of background states of poor health that increase their risk of severe COVID-19. They may also have less access to appropriate health care necessary for the diagnosis of high-risk conditions such as heart failure or chronic kidney disease.[14] Some individuals in these groups would likely qualify for prioritization if their comorbidities were known or ascertainable, but because of inequitable access to health care their conditions often will be undiagnosed and untreated. Which disadvantaged sociodemographic groups are at significantly higher risk of severe disease or death will vary from country to country. In many contexts, the evidence of

elevated risk for COVID-19 severe disease and death will be lacking or less clear than for the risk factors like age or comorbidities. Policy makers may have to decide which disadvantaged groups are likely to be sufficiently burdened by COVID-19 disease to include in Stage II. While broader health systems efforts must be made to reach out and identify risks among disadvantaged groups, these decisions may have to be based on reasonable assumptions about differential impact inferred from other relevant contexts, including past public health emergencies.[15, 16] Table 1 provides examples of groups that, depending on the country context, may fall under this prioritization category.

Example 3. Social/Employment Groups at Elevated Risk of Acquiring and Transmitting Infection Because They Are Unable to Effectively Physically Distance

For the Community Transmission epidemiologic setting, social/employment groups at elevated risk of acquiring and transmitting infection because they are unable to effectively physically distance are included in Stage III. There is considerable overlap in the groups that should be considered in this category and the Stage II sociodemographic groups category just discussed. The relevant difference is that for some disadvantaged groups there may not be good reasons to conclude that they are at significantly elevated risk of severe disease and death (and thus that they do not qualify under Stage II). However, these groups may nevertheless still be at increased risk (if not significantly increased risk) of severe COVID-19 disease for equity-concerning reasons. Groups that have no choice but to work without physical distancing or access to PPE, or no choice but to live in high-density homes in high density neighbourhoods fall into this category.[17, 18] They are disadvantaged relative to other groups in the population who benefit more easily and more significantly from non-pharmaceutical interventions, both in terms of their own risk and in terms of onward transmission to loved ones and co-workers. Incarcerated persons also fall into this category, although the rationale is somewhat different. Even if the restriction of their liberty is justified, that does not justify leaving unaddressed the elevated risk associated with compelled living in a congregate setting.

In an ideal world, policy makers could clearly distinguish, based on evidence regarding level of risk, which disadvantaged groups fall under Stage II criteria and which under Stage III criteria. In the real world, these decisions may have to made with only limited relevant data. Adherence to the principles of equal respect and equity will require a careful assessment to ensure that all relevant sociodemographic groups are given equal consideration for both Stages.

How Staging of Priority Groups Relates to Group Population Size

The staging of priority groups is sequential. If there is insufficient vaccine supply to cover the priority groups in Stage I, the intention is that all these groups are offered vaccine before groups enumerated in Stage II.

With the exception of Stages Ia and Ib, the priority groups within a vaccine supply stage are not rank ordered for prioritization. The assignment of priority groups was based on assumptions about the size of different priority groups in high-, middle-, and low- income country settings. For some priority groups, even estimates of the sizes of different groups were not available. Considerable national variation is expected. In some countries, the amount of vaccine

projected for a vaccine supply stage may be insufficient to cover all the priority groups assigned to that stage and countries will have to determine within-stage prioritization.

As an example, consider Stage II in the Community Transmission epidemiologic setting. Receiving vaccine supply up to an additional 10% of population coverage in this stage may be insufficient to address all the groups assigned to that Stage, even if Stage I supply is sufficient to cover the groups assigned to Stage I. In deciding which Stage II groups to prioritize, countries may wish to consult the Values Framework for guidance. For example, determining which Values Objectives are most important to the country at a given time may help identify which groups to privilege, if vaccine supply is insufficient to cover all the groups assigned to Stage II.

Gender Considerations

While there is evidence that the risk of severe disease and death is higher in males than in females, particularly in older age groups, this difference in risk is diminished when comorbidities and other factors are taken into account.[3, 19] In many contexts, women are disproportionately represented in high-risk occupation groups and they often have direct responsibility for caring for elders. Also, in some contexts, women are disadvantaged in terms of access to health care, political and social status, and decision-making authority due to social structural features in some communities. Prioritizing men or women for vaccination could exacerbate underlying gender-based inequities. For these reasons, the Roadmap does not use gender to identify prioritized vaccine use cases. The equal respect principle of the Values Framework underscores the importance of ensuring that immunization delivery systems place equal focus on reaching both men and women in every priority group.

How the Interests of Pregnant Women are Addressed

The interests of pregnant women warrant particular consideration as these groups have been disadvantaged with respect to the development and deployment of vaccines in previous pandemics. Also, specific to COVID-19, evidence is emerging that pregnant women are at elevated risk of serious disease, further increased if they have pre-existing co-morbidities, and may be at elevated risk of adverse pregnancy and birth outcomes as well.[20-24] However, it seems likely there will be relatively little data about the safety and efficacy of COVID-19 vaccines in these groups when Stage I and perhaps even Stage II vaccine supplies become available, making the prioritization of pregnant women in these early stages problematic. **It is imperative that data specific to pregnancy be generated now from, for example, pregnancy-specific safety and bridging studies and from participants who inadvertently become pregnant during Phase III trials**. Vaccine developers and funders should prioritize an assessment of vaccine safety and immunogenicity among pregnant women in their clinical development and of safety and effectiveness in post-marketing surveillance plans.[25]

Of particular concern is that several groups prioritized in the Roadmap, including health workers and teachers, are in age-groups likely to include significant numbers of women who are pregnant (including some who might not be aware of their pregnancy). Guidance on pregnant women in groups prioritized for vaccination before these urgently needed safety data are available will need to await information about the specific characteristics of the vaccines

authorized for use, as well as the latest evidence on risks of COVID-19 disease for pregnant women and their offspring.

The Roadmap currently prioritizes pregnant women as specific groups in Stage III of two epidemiologic scenarios. By that time, there should be sufficient evidence to assess whether the net benefit of COVID-19 vaccination for pregnant women (with at least some vaccine candidates) outweighs the risks of community acquired infection and subsequent severe COVID-19. It is possible that as evidence accumulates the risks to pregnant women and to their offspring will be judged to be great enough to warrant offering vaccine even in the absence of pregnancy-specific evidence about vaccine risk, in which case pregnant women may be added as a priority group to Stage II. Similarly, if the pregnancy-specific risks of vaccines (which may vary with vaccine product) are determined to be higher than the risks from infection and disease, these groups will need to be prioritized for non-vaccine preventive interventions.

How the Interests of Lactating Women are Addressed

Women who are lactating have also been overlooked in pandemic vaccine development and response. There is, as yet, no evidence that lactating women or their infants are at elevated risk of severe COVID-19 disease. Therefore, they have not been prioritized in the Roadmap. Currently there are no data on any risks to the infant from immunization of their lactating mothers. As data become available, recommendations on lactating women may be provided for vaccine-specific recommendations. At least one manufacturer is enrolling lactating women. As with pregnant women, it is imperative that evidence on the safety of vaccination in lactating women be quickly gathered.

How the Interests of Children are Addressed

The interests of children also warrant specific consideration for at least two reasons. Children are dependent on adults and the wider society for their well-being and setbacks in well-being during childhood can have severe negative and sometimes permanent effects that can last a lifetime. Although children are less subject to direct morbidity and mortality impacts of infection from SARS-CoV-2 when compared to other age groups, they have suffered significantly in other ways during the COVID-19 pandemic.[26-27] Physical distancing measures designed to decrease or prevent community transmission of SARS-CoV-2 have included withdrawing children from in-person learning at schools or closing schools altogether. The extent of learning loss and its impact on life prospects is expected to be far greater for children living in poverty or in otherwise disadvantaged groups. Beyond poor learning and constraints of life prospects from disruption in school provision, students have lost social and developmental benefits afforded by in-person learning. Schools often also provide a number of additional functions important for child health and well-being such as social interactions, meal provision, and health services including immunizations and shelter from unstable or unsafe home living environments. These additional functions are especially important for children living in disadvantaged circumstances. Taken together, while all children are being harmed by educational disruptions, these effects are hitting the most disadvantaged children hardest, who also have less access to distance learning options, widening further existing inequities in child well-being.[28] The health of all children, and especially low-income children, is also being

threatened by COVID-19-related disruptions to routine immunization and other child health programmes.[29-31]

Although the pandemic has greatly impacted child well-being, children themselves are not directly prioritized as a population group in **Table 1** for two reasons. First, trials of COVID-19 vaccine candidates in children have not yet been initiated and thus data on safety and efficacy in this age group are not expected for some time. Second, as already noted, the low risk of severe COVID-19 and death in children does not make them a high priority for direct immunization. However, child well-being is addressed within this Roadmap through the prioritization of other groups that directly contribute to child well-being. Within the Community Transmission epidemiologic scenario, health workers engaged in immunization delivery are prioritized to ensure that routine childhood immunization delivery will be safely maintained. Teachers and other adult staff employed in school settings are prioritized within this epidemiologic scenario as well to facilitate the full reopening of in-school education.

Considering Comorbidities in Prioritization

The evidence on specific comorbidities and the increased risk of severe COVID-19 is increasing. What is already clear is that a) several comorbidities increase this risk, b) the increase in risk varies between specific comorbidities, and thus equity concerns would arise if all comorbidities were to be given similar weight, c) in many countries, if everyone with a comorbidity were to be prioritized in early vaccine supply scenarios, those eligible for vaccination would well-exceed supply,[19] and d) the list of relevant comorbidities will be location dependent.

Based on these considerations, countries should use the relevant local and regional data to identify the comorbidities associated with different levels of risk from COVID-19 (e.g. significant vs. moderate risk). One approach is to identify the additional risk associated with each comorbidity. Another approach is to prioritize individuals who have two or more relevant comorbidities.[32] As evidence develops, further guidance from SAGE on comorbidities and risk associated with severe COVID-19 disease will be communicated. Moreover, the SAGE Working Group on COVID-19 Vaccines is currently working on developing further guidance on comorbidities that put individuals at significantly higher risk.

Community Engagement, Effective Communication, and Legitimacy

Community engagement and effective communication are essential to the success of COVID-19 vaccine programmes. These elements are grounded in the legitimacy principle of the Values Framework.[1] This principle requires that prioritization decisions be made through transparent processes that are based on shared values, best available scientific evidence, and appropriate representation and input by affected parties. Adhering to the legitimacy principle is a way to promote public trust and acceptance of a COVID-19 vaccine.

When applied in practice, countries may embrace the legitimacy principle through practical strategies which improve the public's perception and understanding of the vaccine development and prioritization processes. Examples of such strategies include 1)

Culturally and linguistically accessible communications made freely available regarding COVID-19 vaccination; 2) Recruitment of community opinion leaders to improve awareness and understanding of such communications, and 3) Inclusion of diverse and affected stakeholder opinions in decision making. Efforts towards community engagement and effective communication are additionally important in sub-populations which may be unfamiliar with or distrustful of healthcare systems.

As outlined in the Values Framework, there must be no tolerance for personal, financial or political conflict of interest or corruption in the prioritization of groups to have access to COVID-19 vaccines. In all cases, decision-makers must be able to publicly defend their decisions and actions by appealing to reasons that even those who disagree can view as reasonable, and not arbitrary or self-serving. Countries should ensure that individuals are not able to use their social, financial, or political privilege to bypass country-level prioritization.

Guidance Development and Decision Making under Conditions of Considerable Uncertainty

The Roadmap was developed with only limited information, under conditions of considerable uncertainty. The novelty of the SARS-CoV-2 pathogen and evolving epidemic, economic, and social circumstances present challenges in making decisions about priority groups for vaccine use at this time. Aside from unknown factors of clinical and epidemiologic importance, this document makes a number of plausible assumptions regarding vaccine characteristics. If these assumptions are not met by a candidate vaccine, the selection of priority groups may warrant reconsideration to best fulfil the principles and objectives adopted within the *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination*. Moreover, nuanced models of various prioritization scenarios are only now starting to emerge, and modelling-based evidence is rapidly evolving. For all these reasons, the Roadmap may be amended in light of evolving evidence.

Another limitation of the Roadmap is that it is unable to address all possible contingencies. Table 2 considers the implications of some changes in circumstances that could affect use of the Roadmap.

Ongoing Activities and Next Steps

To assess both the usefulness and robustness of the Roadmap in a variety of settings worldwide, RITAGs and NITAGs will be engaged in reviewing and critically assessing the Roadmap. It is anticipated that refinements of the Roadmap will be needed after the engagements of and feedback from national and regional stakeholders, including potentially further prioritization within priority groups.

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Table 1. Epidemiologic setting and vaccine supply scenarios, and recommendations for priority use cases for vaccines against Covid-19 in the context of limited supply.

The labels in parentheses for each priority population indicate objectives outlined in the Values Framework (see **Legend 1** below). For individuals in more than one priority group, the highest applicable priority group determines the order in which they should receive COVID-19 vaccine. Current modelling suggests that (given the many-fold higher mortality rate among older individuals) age-dependent vaccine efficacy would not **significantly** change the recommendations for priority use cases in older populations for a strategy based on mortality reduction[5-7, 33]. If vaccine efficacy in older adults relative to other age groups was so low that individual protection and public health impact become significantly sub-optimal, the older age group individuals in each scenario would likely be moved to a lower rank.

Epidemiologic Setting Scenario: Community Transmission (Legend 2) **Overall public health strategy for epidemiologic setting:** Initial focus on direct reduction of morbidity and mortality and maintenance of most critical essential services; also, reciprocity. Expand to reduction in transmission to further reduce disruption of social and economic functions. (A1) (A2) (A3) (B1) (B2) (C1) (D1)	
Vaccine supply scenario	**Priority populations**
Stage I (very limited vaccine availability, ranging from 1-10%)	Stage Ia (Initial Launch) - Health workers at *high to very high risk* of acquiring and transmitting infection as defined by interim guidance forthcoming from WHO (A1) (A3) (D1) Stage Ib - Older adults defined by age-based risk specific to country/region, specific age cut-off to be decided at the country level (A1) (C1)
Stage II (limited vaccine availability, ranging from 11-20%)	- Older adults not covered in Stage I (A1) (C1) - Individuals with comorbidities or health states determined to be at *significantly higher risk* of severe disease or death. Efforts should be made to ensure that disadvantaged groups where there is underdiagnosis of comorbidities are equitably included in this category. (A1) (C1) - Sociodemographic groups at *significantly higher risk* of severe disease or death (depending on country context, examples may include: disadvantaged or persecuted ethnic, racial, gender, and religious groups, and sexual minorities and people living with disabilities, people living in extreme poverty, homeless people and those living in informal settlements or urban slums, low-income migrant workers, refugees, internally displaced persons, asylum seekers, populations in conflict setting or those affected by humanitarian emergencies, vulnerable migrants in irregular situations, nomadic populations, and hard to reach population groups such as those in rural and remote areas) (A1) (B1) (B2) (C1) - Health workers engaged in immunization delivery (routine programme-specific and COVID-19) (A1) (A2) (B2) (C1) (C2) (D1) - High priority teachers and school staff (depending on country context, examples may include: pre- and primary school teachers because of the critical developmental stage of the children they teach, teachers of children where distance learning is very difficult or impossible) (A2) (A3) (B1) (C1)

Stage III (moderate vaccine availability, ranging from 21-50%)	- Remaining teachers and school staff (A2) (A3) (B1) (C1) - Other essential workers outside health and education sectors (examples: police officers, municipal services, childcare providers, agriculture and food workers, transportation workers, government workers essential to critical functioning of the state not covered by other categories) (A2) (A3) (D1) - Pregnant women (see accompanying text on pregnant women) (A1) (B1) (B2) (C1) - Health workers at *low to moderate risk* of acquiring and transmitting infection as defined by interim guidance forthcoming from WHO (A1) (A3) (D1) - Personnel needed for vaccine production and other high-risk lab staff (A1) (A2) (A3) (D1) - Social/employment groups at *elevated risk* of acquiring and transmitting infection because they are unable to effectively physically distance (depending on country context, examples may include: people living or working in detention facilities, dormitories, informal settlements or urban slums, low income people in dense urban neighbourhoods, homeless people, military personnel living in tight quarters, and people working in certain occupations e.g. mining, meat processing) (A1) (B1) (B2) (C1)
Epidemiologic Setting Scenario: Sporadic Cases or Clusters of Cases (Legend 2) **Overall public health strategy for epidemiologic setting:** Initial focus on direct reduction of morbidity and mortality and maintenance of most critical essential services; also, reciprocity. Expand to substantially control transmission and minimize disruption of social and economic functions. (A1) (A2) (A3) (B1) (B2) (C1) (D1)	
Vaccine supply scenario	**Priority populations**
Stage I (very limited vaccine availability, ranging from 1-10%)	- Health workers at *high to very high risk* of acquiring and transmitting infection as defined by interim guidance forthcoming from WHO, *in areas with high transmission or anticipated high transmission* (A1) (A3) (D1) - Older adults defined by age-based risk specific to country/region, specific age cut-off to be decided at the country level, *in areas with high transmission or anticipated high transmission* (A1) (C1) - Emergency reserve of vaccines for utilization for outbreak response or mitigation (e.g. severe localized outbreak) (A1) (A2)
Stage II (limited vaccine availability, ranging from 11-20%)	- Health workers at *high to very high risk* of acquiring and transmitting infection as defined by interim guidance forthcoming from WHO, *in the rest of the country* (A1) (A3) (D1) - Older adults defined by age-based risk specific to country/region, specific age cut-off to be decided at the country level, *in the rest of the country* (A1) (C1) - Groups with comorbidities or health states determined to be at *significantly higher risk* of severe disease or death *in areas with high transmission or anticipated high transmission*. Efforts should be made to ensure that disadvantaged groups where there is underdiagnosis of comorbidities are equitably included in this category. (A1) (C1)

	- Sociodemographic groups at *significantly higher risk* of severe disease or death *in areas with high transmission or anticipated high transmission* (depending on country context, examples may include: disadvantaged or persecuted ethnic, racial, gender, and religious groups, and sexual minorities and people living with disabilities, people living in extreme poverty, homeless people and those living in informal settlements or urban slums, low-income migrant workers, refugees, internally displaced persons, asylum seekers, populations in conflict setting or those affected by humanitarian emergencies, vulnerable migrants in irregular situations, nomadic populations, and hard to reach population groups such as those in rural and remote areas) (A1) (B1) (B2) (C1)
Stage III (moderate vaccine availability, ranging from 21-50%)	- Primary and secondary teachers and school staff *in areas with high transmission or anticipated high transmission* (A2) (A3) (B1) (C1) - Other essential workers outside health and education sectors (examples: police officers, municipal services, childcare providers, agriculture and food workers, transportation workers, government workers essential to critical functioning of the state not covered by other categories) *in areas with high transmission or anticipated high transmission* (A2) (A3) (D1) - Social/employment groups at *elevated risk* of acquiring and transmitting infection because they are unable to effectively physically distance *in areas with high transmission or anticipated high transmission* (depending on country context, examples may include: people living or working in detention facilities, dormitories, informal settlements or urban slums, low income people in dense urban neighbourhoods, homeless people, military personnel living in tight quarters, and people working in certain occupations e.g. mining, meat processing) (A1) (B1) (B2) (C1) - Health workers at *low to moderate risk* of acquiring and transmitting infection as defined by interim guidance forthcoming from WHO *throughout the country* (A1) (A3) (D1) - Age groups at high risk of transmitting infection by age-based risk specific to country/region, specific age cut-off to be decided at the country level (A1) (A2) - Personnel needed for vaccine production and other high-risk lab staff (A1) (A2) (A3) (D1) - Pregnant women (see accompanying text on pregnant women) (A1) (B1) (B2) (C1)
Epidemiologic Setting Scenario: No Cases (Legend 2) **Overall public health strategy for epidemiologic setting:** Initial focus on prevention of community transmission; also, reciprocity. Expand to preserve control of transmission and reduce reliance on most burdensome non-pharmaceutical interventions, as well as to protect highest risk individuals in the event of importation-associated outbreaks. (A1) (A2) (A3) (B1) (C1) (D1)	
Vaccine supply scenario	**Priority populations**
Stage I (very limited vaccine availability, ranging from 1-10%)	- Health workers at *high to very high risk* of acquiring and transmitting infection as defined by interim guidance forthcoming from WHO (A1) (A3) (D1)

	- Essential travellers at risk for acquiring infection outside the home country and reintroducing infection upon return to home country (e.g. students, business travellers, migrant workers, aid workers). Countries should define essential travellers in a way that constrains the ability of economically and politically powerful individuals to exploit this priority group to their advantage. (A1) (A2) (A3) - Border protection staff screening for imported cases and workers for outbreak management (e.g. isolation and quarantine managers, immunization deployment staff) (A1) (A2) (D1) - Emergency reserve utilization for focused outbreak response (e.g. importation outbreaks) (A1) (A2)
Stage II (limited vaccine availability, ranging from 11-20%)	- Health workers at *low to moderate risk* of acquiring and transmitting infection as defined by interim guidance forthcoming from WHO (A1) (A3) (D1) - All travellers at risk for acquiring infection outside the home country and reintroducing infection upon return to home country (A1) (A2) - Emergency reserve of vaccines utilization for outbreak mitigation (e.g. importation outbreaks) (A1) (A2)
Stage III (moderate vaccine availability, ranging from 21-50%)	- Older adults defined by age-based risk specific to country/region, specific age cut-off to be decided at the country level (A1) (C1) - Age groups at high risk of transmitting infection by age-based risk specific to country/region, specific age cut-off to be decided at the country level (A1) (A2) - Primary and secondary teachers and school staff (A2) (A3) (B1) (C1) - Other essential workers outside health and education sectors (examples: police officers, municipal services, childcare providers, agriculture and food workers, transportation workers, government workers essential to critical functioning of the state not covered by other categories) (A2) (A3) (D1)
National Equity Considerations: Ensure that vaccine prioritization within countries takes into account the vulnerabilities, risks and needs of groups who, because of underlying societal, ethnic/racial, geographic or biomedical factors, are at risk of experiencing greater burdens from the COVID-19 pandemic. (A1) (B1) (B2) (C1) (C2)	

Legend 1. Translating Objectives to Priority Groups

A. Human Well-Being	A1. Reduce deaths and disease burden from the COVID-19 pandemic
	A2. Reduce societal and economic disruption (other than through reducing deaths and disease burden)
	A3. Protect the continuing functioning of essential services, including health services
B. Equal Respect	B1. Treat the interests of all individuals and groups with equal consideration as allocation and priority-setting decisions are being taken and implemented
	B2. Offer a meaningful opportunity to be vaccinated to all individuals and groups who qualify under prioritization criteria

C. National Equity	C1. 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
	C2. 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
D. Reciprocity	D1. Protect those who bear significant additional risks and burdens of COVID-19 to safeguard the welfare of others, including health and other essential workers

Legend 2. WHO Transmission Categories Corresponding to Epidemiologic Setting Scenarios

Transmission Category*	Definition
No Cases	Countries/territories/areas with no confirmed cases
Sporadic Cases	Countries/territories/areas with one or more cases, imported or locally detected
Clusters of Cases	Countries/territories/areas experiencing cases, clustered in time, geographic location and/or by common exposures
Community Transmission	Countries/area/territories experiencing larger outbreaks of local transmission defined through an assessment of factors including, but not limited to: • Large numbers of cases not linkable to transmission chains • Large numbers of cases from sentinel lab surveillance or increasing positive tests through sentinel samples (routine systematic testing of respiratory samples from established laboratories) • Multiple unrelated clusters in several areas of the country/territory/area.
Scenario transitions: From lower to higher transmission scenario: change to be reported at any time (in the next weekly update). From higher to lower transmission scenario: observe during a 28-day period before confirming downgrading of transmission.	

*Note: Definitions correspond to those used elsewhere in WHO epidemiologic reports, using definitions published in the WHO interim guidance on public health surveillance for COVID-19 published on 7 August 2020 available (here)

TABLE 2. Summary Table of the Application of the Roadmap Under Various Contingencies. Adapted from National Academies of Sciences, Engineering, and Medicine's Framework for Equitable Allocation of COVID-19 Vaccine.[32]

Contingency	Change in the Application of the Roadmap
Number and Timing of Vaccine Doses	
Fewer vaccine courses available than expected	The Roadmap is unchanged. Some individuals receive vaccination later than they would otherwise.
Vaccine requires two doses, rather than one	The Roadmap is unchanged, but some individuals receive vaccination later.
Vaccine Efficacy	
Low vaccine efficacy among older adults or other population subgroup	Current modelling suggests that (given the many-fold higher mortality rate among older individuals) age-dependent vaccine efficacy would not significantly change the recommendations for priority use cases in older populations).[5-7, 33] If vaccine efficacy in older adults relative to other age groups was so low that the prioritization of older adults was expected to lead to substantially worse overall outcomes in number of lives saved, the older age group individuals in each scenario would likely be moved to a lower rank. Similar considerations apply for individuals with comorbidities.
Low vaccine efficacy in preventing transmission	The importance of high coverage of the most vulnerable groups is increased.
Vaccine Safety	
Unanticipated vaccine adverse events	Only prioritize individuals or groups for whom vaccine benefits continue to outweigh the risks.
Vaccine Uptake	
Vaccine acceptance and uptake is lower than expected	The Roadmap is unchanged. The community engagement and risk communication are enhanced.
Number of Vaccine Types	
More than one vaccine type available	The Roadmap is unchanged, but which vaccines are allocated to which population groups must take into account the benefits and risks of the vaccine for each population group. As authorized vaccines become available, SAGE will make vaccine-specific recommendations.
Epidemic Conditions and Immune Status	
Epidemic spread is continuing when the vaccine becomes available	The Roadmap is unchanged. Public health messages must continue to stress the need for personal protective measures (e.g., masks, social distancing, hand washing, ventilation).
Risk profile of a previously identified high-risk group changes (e.g. due to high infection rate in earlier waves)	The general structure of the Roadmap is unchanged. The relevant consideration is high-risk, and if a group is no longer high-risk it should be lowered in priority. However, due to equity concerns, many of these groups are likely to be disadvantaged, the evidentiary basis for any change in priority status must be high and the burden of proof should be on the immunization programme/government to meet.

Social, Economic, and Legal Contexts	
Some countries do not provide free vaccine access to non-citizens or people without documentation of legal status	The Roadmap is unchanged. This practice violates the principle of equity and the goals of public health. However, in such cases, other sources of financial support (e.g. philanthropy, civil society organizations, pharmaceutical companies) should be sought to provide vaccination for those individuals.

Appendix 1. COVAX Facility Allocation Mechanism Phases and Roadmap of Priority Use Cases Stages

COVAX Facility Allocation Mechanism*		Roadmap of Priority Use Cases	
Phase	*% country population to be covered by vaccine supply*	*Stage*	*% country population to be covered by vaccine supply*
Phase 1: Proportional allocation, to cover Tier 1 target groups	Indicative initial tranche: 3% Subsequent tranches to reach 20%	Stage I	1-10%
		Stage II	11-20%
Phase 2: Weighted allocation based on risk assessment	>20%	Stage III	21-50%
** Note: COVAX Facility Allocation Mechanism is still in draft form; further details from current draft approach are available (here).*			

Appendix 2. Reduction of Deaths vs. Reduction in Years of Life Lost

Years of Life Lost (YLL) is a measure that is thought by many to integrate a commitment to maximizing health benefit with a commitment to promoting equity, where equity is understood to include an obligation to ensure that younger people have a fair chance to reach later stages of life. Although there are good ethics arguments for using YLL in many allocation contexts,[34-35] in this particular pandemic, with its particular epidemiology, reducing deaths was considered the preferred strategy for within country prioritization. The risk of COVID-19 related mortality is extremely high in older age groups compared to that in younger age groups. For example, in the United States, the mortality risk has been estimated to be 90 times higher among 65–74-year-olds compared to 18–29-year-olds.[36] A similar pattern of significantly higher mortality in older age groups has been observed in multiple other countries. The evidence identified to date from modelling analyses suggests that using YLL instead of deaths would not substantially alter the priority ranking of older persons relative to younger persons when age is the only dimension considered.[5,6] Supplementary unpublished sensitivity analyses prepared for the WHO SAGE Working Group on COVID-19 vaccines support this finding. As priority rankings would not change, expressing the policy objective in terms of reduction in the number of deaths rather than YLL has programmatic advantages, even if YLL reaches the same conclusions about relative prioritization. Reduction of number of deaths is more easily understood by and communicated to the general public and is likely to be widely endorsed as an important objective at a time when securing public support for and confidence in vaccine programmes is critically important. A prioritization approach relying on YLL could be viewed as disrespectful to older persons by failing to address their disproportionately higher risk of death.[32]

YLL also does not address the primary equity challenges in within-country prioritization of COVID-19 vaccines and thus the Values Framework's commitment to national equity does not in this pandemic require use of YLL. In a pandemic with a mortality pattern similar to seasonal influenza where the very young as well as older adults have disproportionately high mortality, or that of the 1918 pandemic where young adults were a high mortality risk groups, equity considerations could well require a focus on YLL. Also, in the current COVID-19 pandemic the equity issues in allocation of vaccine between countries are markedly different from those in within-country prioritization. In the current COVID-19 pandemic the equity issues in allocation of vaccine between countries are markedly different from those in within-country prioritization. Standard Expected Years of Life Lost (SEYLL), a measure of disease burden often used for cross-national comparative purposes, can help instantiate the Values Framework's commitment to global equity, as long as global inequities in access to testing and other surveillance technologies do not unfairly skew SEYLL assessments.

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Category	Number of people		
	In areas with high transmission or anticipated high transmission	in areas with low to moderate transmission	in rest of the country
1 - Health workers at high to very high risk of acquiring and transmitting infection (i.e. those working in a COVID-19 treatement facility or performing AMET functions)			
2 - Other Health workers			
3 - Older adults (over 65)			
4 - Individuals with known comorbidities or health states (including diabetes) determined to be at significantly higher risk of severe disease or death			
5 - Sociodemographic groups at significantly higher risk of severe disease or death in areas with high transmission or anticipated high transmission, **and personnel living / working directly with these groups**, (examples include: refugees, internally displaced persons, populations in conflict setting or those affected by humanitarian emergencies, POC, and hard to reach population groups such as those in rural and remote areas)			
6 - Personnel at elevated risk of acquiring and transmitting infection because they are unable to effectively physically distance (examples include: people living or working in detention facilities, corrections, dormitories, UN provided-shared accommodation, military or police personnel living in tight quarters)			
7 - Other essential workers outside above mentioned sectors (examples: facilities/ infrastructure, security, etc)			