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

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World Health Organization

Contents

Acknowledgements

Abbreviations

Allocation Framework	fair allocation mechanism for COVID-19 vaccines through the COVAX Facility
COVAX	COVID-19 Vaccines Global Access
COVID-19	coronavirus disease 2019
NITAG	National Immunization Technical Advisory Group
Prioritization Roadmap	WHO SAGE roadmap for prioritizing uses of covid-19 vaccines in the context of limited supply
SAGE	Strategic Advisory Group of Experts on Immunization
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
RITAG	Regional Immunization Technical Advisory Group
Values Framework	WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination
YLL	years of life lost
WHO	World Health Organization

Introduction

As countries prepare to implement their respective coronavirus disease 2019 (COVID-19) vaccination programmes, the Strategic Advisory Group of Experts (SAGE) on Immunization of the World Health Organization (WHO) is undertaking a three-step process to provide guidance for overall programme strategy as well as vaccine-specific recommendations.

> **Step 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 of COVID-19 vaccines.
>
> **Step 2: Roadmap for prioritizing uses of Covid-19 vaccines (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.
>
> **Step 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 of 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 (7 October 2020).** This document should be regarded as a Roadmap for planning purposes only.
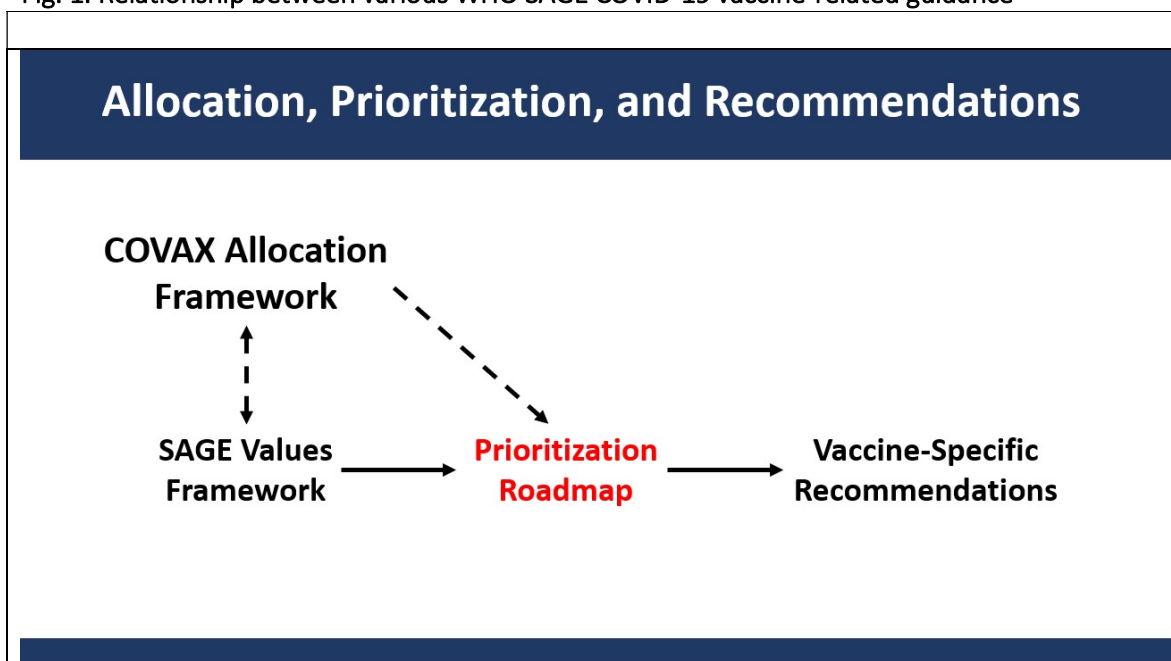
This Roadmap builds on the *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination*. The Values Framework listed over 20 population subgroups that, if vaccine use needed to be prioritized because of limited supply, would advance one or more of its principles and objectives. 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 ethical principles detailed in the Values Framework with evidence and information about: i) the status of the pandemic in the proposed implementation area (that is, the epidemiologic setting in terms of the degree of ongoing severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) transmission and COVID-19 burden); ii) the amount and timing of vaccine supply and availability, respectively; iii) specific product characteristics of the available vaccine(s); and iv) the benefit–risk assessment for the different population subgroups at the time vaccination is being considered for deployment; as well as other standard criteria used in developing SAGE recommendations (for example, feasibility, acceptability and resource use). 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 Prioritization Roadmap of COVID-19 vaccines that considers priority groups 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. A COVAX Facility allocation mechanism for countries participating in the COVAX Facility has been proposed *(2)*. Fig. 1 shows how it aligns with this Roadmap and the Values Framework.

Fig. 1. Relationship between various WHO SAGE COVID-19 vaccine-related guidance

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 chairpersons of all six Regional Immunization Technical Advisory Groups (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 regional and national levels, the Roadmap needs to be kept as straightforward and concise as possible.
- The Roadmap may be revisited through i) rolling review as new information becomes available; and ii) ongoing dialogue with RITAGs and National Immunization Technical Advisory Groups (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_ (3). 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 (for example, 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 _(4, 5)_, even a vaccine with relatively low efficacy in older adults would not significantly change the recommendations for priority use cases in older populations _(6–8)_. If however it were determined that vaccine efficacy in older adults relative to other age groups were so low that individual protection and public health impact became significantly suboptimal, the individuals in older age groups 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 subgroups (for example, 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) *(9).*

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 groups 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 Phase 1 supply of up to 20% of each country's population detailed in the latest draft of the WHO *Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility*. The Roadmap's Stage III scenario aligns with the Allocation Framework's Phase 2 supply of more than 20% population coverage (Annex 1).

Overall public health strategies by epidemiologic setting and vaccine supply stage

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 setting: 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 (Annex 2) 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 (for example, 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 principles of the SAGE Values Framework.

Sporadic Cases or Clusters of Cases setting: 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 epidemiologic 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 (for example, 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 setting: 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 group, the Values Framework objective(s) that would be supported by prioritizing this population for vaccination are indicated by parenthetical abbreviations after the population description (for example, A1); the legend that links these abbreviations to the objectives is provided below Table 1.

While a detailed explanation 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. Three 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 the 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 reasons, linked to the Values Framework, supporting this prioritization. First, protecting these workers protects the availability of a critical essential service in 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 are at high risk of acquiring infection and possibly of morbidity and mortality *(10, 11)*. 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.

In a second step (Stage Ib), older adults defined by age-based risk specific to country or region are included.

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 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. However, 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 because of crowded work or living conditions over which they have no effective control *(12–15)*, as well as a higher prevalence of background states of poor health that increase their risk of severe COVID-19 *(16)*. 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 *(17)*. 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 to include in Stage II. While broader 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 *(18)*. 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 due to the reasons related to inequity discussed above. Groups that have no choice but to work without physical distancing or access to personal protective equipment, or no choice but to live in high-density homes in high-density neighbourhoods fall into this category *(19, 20)*. 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 people 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 being incarcerated.

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 be 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 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 Stage Ia and Stage Ib, the priority groups within a vaccine supply stage are not 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 prioritize groups within stages.

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 groups in Stage II to prioritize, countries may wish to consult the Values Framework for guidance. For example, determining which ethical principles 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 *(4, 21).* 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.

Addressing pregnant women

Pregnant women warrant particular consideration, as this group has 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 comorbidities, and may be at elevated risk of adverse pregnancy and birth outcomes as well *(22–25)*. 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 *(26)*.

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 for pregnant women and their children.

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 children 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.

Addressing lactating women

Historically, lactating women 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. 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.

Addressing children

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 *(27, 28)*. 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 *(29)*. 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 *(30–32)*.

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 vaccine prioritization

The evidence on specific comorbidities and the increased risk of severe COVID-19 is increasing. What is already clear is that i) several comorbidities increase this risk; ii) the increase in risk varies between specific comorbidities, and thus equity concerns would arise if all comorbidities were to be given similar weight; iii) 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; and iv) the list of relevant comorbidities will be location dependent *(4, 21, 33)*.

Based on these considerations, countries should use relevant local and regional data to identify the comorbidities associated with different levels of risk from COVID-19 (for example, significant versus 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 *(34)*. As evidence develops, further guidance from SAGE on comorbidities and risk associated with severe COVID-19 will be communicated. Moreover, the SAGE Working Group on COVID-19 Vaccines is currently 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. 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 vaccine development and prioritization processes. Examples of such strategies include i) culturally and linguistically accessible communications made freely available regarding COVID-19 vaccination; ii) recruitment of community opinion leaders to improve awareness and understanding of such communications; and iii) Inclusion of diverse and affected stakeholder opinions in decision-making. Efforts towards community engagement and effective communication are additionally important in subpopulations which may be unfamiliar with or distrustful of health-care 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 a candidate vaccine does not meet these assumptions, 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.

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[a]

(a) Epidemiologic setting scenario: Community Transmission – defined in Legend 2

Overall public health strategy for this 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) (C2) (D1)** – labels explained in Legend 1	

Vaccine supply scenario	Priority groups
Stage I (very limited vaccine availability, for 1–10% nat. pop.)	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, for 11–20% nat. pop.)	• Older adults not covered in Stage I. **(A1) (C1)** • Groups 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) (C2)** • 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; people living with disabilities; people living in extreme poverty, homeless and those living in informal settlements or urban slums; low-income migrant workers; refugees, internally displaced persons, asylum seekers, populations in conflict settings 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) (C2)** • 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: preschool 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) (C2)**

Stage III (moderate vaccine availability, for 21–50% nat. pop.)	• Remaining teachers and school staff. **(A2) (A3) (B1) (C1) (C2)**
	• Other essential workers outside health and education sectors (examples: police officers, municipal services, child-care 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 text under *Addressing pregnant women*). **(A1) (B1) (B2) (C1)**
	• Health workers at <u>low to moderate risk</u> 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 laboratory staff. **(A1) (A2) (A3) (D1)**
	• Social/employment groups at <u>elevated risk</u> 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, incarcerated people, 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 such as mining and meat processing). **(A1) (B1) (B2) (C1)**

(b) Epidemiologic setting scenario: Sporadic Cases or Clusters of Cases – defined in Legend 2

Overall public health strategy for this 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) (C2) (D1)** – labels explained in Legend 1	

Vaccine supply scenario	Priority groups
Stage I (very limited vaccine availability, for 1–10% nat. pop.)	• 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 (for example, severe localized outbreak). **(A1) (A2)**
Stage II (limited vaccine availability, for 11–20% nat. pop.)	• 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) (C2)** • 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; people living with disabilities; people living in extreme poverty, homeless and those living in informal settlements or urban slums; low-income migrant workers; refugees, internally displaced persons, asylum seekers, populations in conflict settings 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) (C2)**
Stage III (moderate vaccine availability, for 21–50% nat. pop.)	• Primary and secondary teachers and school staff _in areas with high transmission or anticipated high transmission._ **(A2) (A3) (B1) (C1) (C2)** • 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, incarcerated people, 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 for example, 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 laboratory staff. **(A1) (A2) (A3) (D1)** • Pregnant women (see text under *Addressing pregnant women*). **(A1) (B1) (B2) (C1)**

(c) Epidemiologic setting scenario: No Cases – defined in Legend 2

Overall public health strategy for this 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) (C2) (D1)** – labels explained in Legend 1	

Vaccine supply scenario	Priority groups
Stage I (very limited vaccine availability, for 1–10% nat. pop.)	- 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 (for example, 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 (for example, isolation and quarantine managers, immunization deployment staff). **(A1) (A2) (D1)** - Emergency reserve utilization for focused outbreak response (for example, importation outbreaks). **(A1) (A2)**
Stage II (limited vaccine availability, for 11–20% nat. pop.)	- 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 (for example, importation outbreaks). **(A1) (A2)**
Stage III (moderate vaccine availability, for 21–50% nat. pop.)	- 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 school teachers and staff. **(A2) (A3) (B1) (C1) (C2)** - Other essential workers outside health and education sectors (examples: police officers, municipal services, child-care 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 disproportionate burdens of the COVID-19 pandemic on social groups	

that are systematically disadvantaged. **(C1) (C2)**

[a] For individuals in more than one priority group, the highest applicable priority group determines the order in which they should receive COVID-19 vaccine. <u>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</u> *(6–8, 35)*. <u>If vaccine efficacy in older adults relative to other age groups were so low that individual protection and public health impact became significantly suboptimal, the individuals in older age groups in each scenario would likely be moved to a lower rank.</u>

Legend 1. Health and equity objectives applied to priority groups

A. 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 made and implemented.
	(B2) Offer a meaningful opportunity to be vaccinated to all individuals and groups who qualify under prioritization criteria.
C. 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 priority populations have access to COVID-19 vaccines, and which ensures 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[a]	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 laboratory 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.

[a] 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

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 *(6–8, 35)*. If vaccine efficacy in older adults relative to other age groups were so low that the prioritization of older adults was expected to lead to substantially worse overall outcomes in number of lives saved, individuals in the older age groups 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. 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 subgroup. 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 (for example, masks, social distancing, hand washing, ventilation).
Risk profile of a previously identified high-risk group changes (for example, due to higher infection rate in earlier infection waves than in later waves)	The general structure of the Roadmap is unchanged. The relevant consideration is risk level; if a group is no longer high-risk it should be lowered in priority. However, due to equity concerns, as many of these groups are likely to be disadvantaged there must be a substantial level of evidence supporting the change, which the immunization programme/government should present to justify the change.
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 (for example, philanthropy, civil society organizations, pharmaceutical companies) should be sought to provide vaccination for those individuals.
Source: Adapted from National Academies of Sciences, Engineering, and Medicine's Framework for Equitable Allocation of COVID-19 Vaccine *(34)*, with permission.	

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In the interests of specificity during the COVID-19 pandemic – during which new data become available by the day – the references below that deal with COVID-19 or SARS-CoV-2 exceptionally include both the day and month of publication (where available). This is meant to assist the reader in quickly determining the exact date of publication.

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Annex 1. Alignment of the COVAX Facility allocation mechanism and Prioritization Roadmap

COVAX Facility allocation mechanism[a]		Prioritization Roadmap	
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%
[a] Note: the COVAX Facility allocation mechanism is still in draft form; further details from the current draft approach are available (here).			

Annex 2. Reduction of deaths versus reduction of 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. There are good ethics arguments for using YLL in many allocation contexts, *(1, 2)* including in this particular pandemic *(3)*. However, the particular epidemiology of the current pandemic supports using reducing deaths as a 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 *(4)*. 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 people relative to younger people 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 people by failing to address their disproportionately higher risk of death *(7)*.

YLL also does not address the primary equity challenges in prioritization of COVID-19 vaccines within countries and thus the commitment of the Values Framework to 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 influenza pandemic where young adults were a high-mortality risk group, 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. Standard expected years of life lost, a measure of disease burden often used for cross-national comparative purposes, can help illustrate the commitment of the Values Framework to global equity, as long as global inequities in access to testing and other surveillance technologies do not unfairly skew assessments of this metric.

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