

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 on epidemiological setting and vaccine supply scenarios

First issued 20 October 2020

Latest update: 16 July 2021



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Background

This interim guidance was initially issued in October 2020, based on advice from the Strategic Advisory Group of Experts (SAGE) on Immunization; it has been updated following the discussions at an extraordinary meeting of SAGE on [29 June 2021](#). Declarations of interests were collected from all external contributors and assessed for any conflicts of interest. Summaries of the reported interests can be found on the [SAGE meeting webpage](#) and [SAGE Working Group webpage](#).

Abbreviations and acronyms used in this document

ACT	access to COVID-19 tools
Allocation Framework	fair allocation mechanism for COVID-19 vaccines through the COVAX Facility
COVAX	the vaccines pillar of the access to COVID-19 tools (ACT) Accelerator
COVID-19	coronavirus disease
DART	developmental and reproductive toxicology
EUL	emergency use listed
ICU	intensive care unit
MIS-C	multisystem inflammatory syndrome in children
NITAG	National Immunization Technical Advisory Group
RITAG	Regional Immunization Technical Advisory Group
SAGE	Strategic Advisory Group of Experts on Immunization
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
VOC	variant of concern
WHO	World Health Organization
YLL	years of life lost

Preamble

The objective of this Prioritization Roadmap is to support countries in prioritizing population groups for COVID-19 vaccination in situations of limited vaccine supply, building on the current best understanding of the burden of disease and generally accepted values and preferences. It is not meant to guide the setting of coverage targets or country goals for disease control. The World Health Organization, in collaboration with its COVAX partners and key regional and national stakeholders, is currently updating its initial goals for 2021 towards a WHO Global COVID-19 Vaccination Strategy for 2021–22. The Vaccination Strategy will consider global goals against COVID-19 and describe different strategies and resources needed to pursue the various goals. The Prioritization Roadmap and the Vaccination Strategy are two distinct documents complementary to one another.

Introduction

To support countries in implementing their respective coronavirus disease (COVID-19) vaccination programmes, the Strategic Advisory Group of Experts (SAGE) on Immunization of the World Health Organization (WHO) has developed a three-step process to provide guidance for overall programme priorities 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). To support countries in planning vaccination programmes, the Prioritization Roadmap suggests public health strategies and identifies target groups for prioritization for COVID-19 vaccination (referred to as “priority-use groups”) in the context of different levels of vaccine availability and epidemiological settings. The first version of the Prioritization Roadmap was published on 7 October 2020 and updated on 13 November 2020. This current update is more substantive and reflects data that have become available from clinical vaccine studies, as well as lessons learned from the early implementation of programmes. The Prioritization Roadmap will be updated, as necessary, to accommodate the dynamic nature of the pandemic, greater availability of vaccines and evolving evidence about vaccine impact.

Step 3: Vaccine-specific recommendations. As conditionally authorized vaccines become available, specific recommendations for the use of these vaccines will be issued. Currently, six vaccines have been recommended for emergency use, and interim recommendations on the use of these products have been issued. These recommendations are being updated as additional evidence on effectiveness, safety, and booster needs becomes available, and as epidemiological and other contextual conditions evolve (2).

Rationale

Given the urgency and wide-ranging effects of the COVID-19 pandemic, SAGE has developed an approach to help inform national policy deliberations on the range of recommendations that may be appropriate under different epidemiological and vaccine supply conditions. COVAX(3) and other donor and bilateral procurement mechanisms have facilitated unprecedented implementation of COVID-19 vaccination programmes. Nevertheless, most middle- and lower-income countries still face a limited and often unreliable vaccine supply, and vaccination still needs to be prioritized in a pragmatic and ethical manner. While all currently recommended COVID-19 vaccines have similar broad indications for use, countries may decide to consider specific product attributes when prioritizing vaccine use in certain populations.

This Prioritization Roadmap builds on the *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination*, which lists over 20 population subgroups. If vaccine use needs to be prioritized because of limited supply, vaccination of these subgroups would advance one or more of the Framework’s principles and objectives. The Values Framework does not rank the subgroups in any order. Specific priority-use group recommendations will require the ethical principles detailed in the Values Framework to be integrated with evidence and information about: (i) the status of the pandemic in the proposed implementation area (that is, the epidemiological setting in terms of the level of SARS-CoV-2 transmission and the severity of the COVID-19 burden); (ii) the amount and timing of vaccine supply and availability; (iii) specific product characteristics of the available vaccine(s); and (iv) the benefit–risk assessment for the different population subgroups at the time the vaccine is being considered for deployment. Other standard criteria used in developing SAGE recommendations, e.g. feasibility, acceptability and resource use, will also need to be considered. All of these factors will provide a guide to an appropriate public health strategy for deployment of specific vaccines.

To assist in developing recommendations for use of vaccines against COVID-19, the WHO SAGE Prioritization Roadmap suggests priority-use groups for vaccination based on epidemiological setting and vaccine supply scenarios. These suggestions are set in the context of the overall public health strategy for each epidemiological setting (Table 1).

This Prioritization Roadmap is primarily intended to serve as guidance when preparing for vaccine prioritization decisions within countries. While the Values Framework includes the principle of global equity, this Prioritization Roadmap does not directly address global allocation decisions, which is the remit of the COVAX Facility allocation mechanism for countries participating in the COVAX Facility (4).

In addition, the Prioritization Roadmap does not propose vaccine coverage targets. Previous versions of the Prioritization Roadmap assumed that initial supply would be limited, and considered stages of vaccination of 0–10%, 11–20%, and 21–50% of the population. More ambitious coverage targets have since been called for, and some countries have indeed reached higher coverage levels. WHO is in the process of developing a Global Vaccination Strategy, which will consider possible goals and ambitions for COVID-19 vaccination and the necessary resource requirements. The Prioritization Roadmap here is intended to aid prioritization within the coverage goals set by the country. Both the Prioritization Roadmap and the Global Vaccination Strategy emphasize the importance of prioritizing the distribution of initial limited supplies of vaccine to optimize impact on health, socioeconomic conditions and equity. Opening vaccine eligibility to the whole population without first achieving the desired coverage among older age groups and other high-priority groups will reduce the impact that could otherwise be secured with the initial limited vaccine supply.

Process of Prioritization Roadmap development

The Prioritization 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, which includes the chairs of all six Regional Immunization Technical Advisory Groups (RITAGs) as well as several SAGE members. The draft table was then revised and reviewed several times. A similar process was used to develop the narrative sections of the Prioritization Roadmap. Prioritization took account of emerging modelling information exploring the effectiveness and optimal impact of different vaccination strategies and the best available epidemiological information from the scientific literature as well as various surveillance organizations. A penultimate round of review by a number of SAGE members resulted in further substantive changes to the Prioritization Roadmap, followed by a final review by the full SAGE committee.

The current update was initiated in June 2021 to incorporate new evidence and the evolution of the pandemic. Using methods similar to those used to develop the original Prioritization Roadmap, data on vaccine efficacy, effectiveness, immunogenicity and safety, as well as new developments, such as SARS-CoV-2 virus variants of concern (VOCs), have been incorporated. The updated Prioritization Roadmap has been reviewed by the SAGE Working Group on COVID-19 Vaccines and by RITAG chairs, and endorsed by SAGE.

Guiding considerations

The following considerations guided the development of this Prioritization Roadmap and its update.

- This Prioritization Roadmap must remain fully aligned with the [WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination](#).
- To be useful in driving discussions at regional and national levels, the Prioritization Roadmap needs to be kept as clear and concise as possible.
- The Prioritization Roadmap will be revisited through rolling review, as new information becomes available, and ongoing dialogue with RITAGs and National Immunization Technical Advisory Groups (NITAGs).

Key assumptions

- The Prioritization Roadmap assumes that any vaccine deployed has received emergency use listing or full regulatory approval and has met all the minimal or critical criteria in [WHO target product profiles \(TPP\) for COVID-19 vaccines](#) (5). Estimates of efficacy and data on effectiveness indicate that currently available vaccines perform differently in different population subgroups (for example, people with comorbidities that increase the risk of severe COVID-19, such as HIV-positive status), but not to an extent that affects prioritization.

- There are still many unknowns related to the vaccines that have been deployed, for example, the duration of protection and need for additional doses (i.e. booster doses), therefore these issues have not been addressed in this update. As additional data becomes available, updates will be issued.
- The Prioritization Roadmap assumes that public health and social measures (PHSM) remain in place to varying degrees as vaccines are introduced and coverage expands.
- Emerging evidence suggests that at least some vaccines reduce SARS-CoV-2 transmission. Therefore, vaccination of some groups has been prioritized based on those groups' contribution to transmission (6-8).
- The Prioritization Roadmap does not take into account variations in population seropositivity rates or the degree of naturally acquired protection within countries or communities that may have already experienced a high level of community transmission.
- In the development of this update, the risk of severe disease was considered to be closely correlated with the risk of death. Because evidence on post-COVID-19 condition (9) is still emerging, the impact of vaccines on long-term sequelae of SARS-CoV-2 infection has not been included.
- Data on vaccine efficacy and effectiveness against VOCs continue to evolve. To date, most vaccines exhibit reasonable effectiveness against VOCs, especially after two doses. For some VOCs, effectiveness appears to be lower against symptomatic illness not associated with hospitalization and asymptomatic infection, but remains relatively high against severe disease (hospitalization), admission to an intensive care unit (ICU) and death (10-12).

Epidemiological setting scenarios

The epidemiological setting scenarios used here take into consideration the relative benefits and potential risks of vaccination. The public health strategy for use of vaccines will depend on the burden of disease and the local epidemiology, including circulation of VOCs, and in particular the incidence rate of infection in the specific setting at the time vaccination is being contemplated. WHO has revised the transmission categories to include seven different categories, four of which are community transmission but reflect different levels of transmission intensity (13). For this Prioritization Roadmap we have used three broad epidemiological settings: (i) community transmission, (ii) sporadic cases or clusters of cases, and (iii) no cases (Table 1).

Vaccine supply scenarios

As vaccine supply has not been sufficient to immunize everyone who could benefit from vaccination in all countries, three scenarios of constrained vaccine supply were considered: a stage I scenario of very limited vaccine availability (1–10% of the country's total population) for initial distribution (which most countries have now achieved); stage II, in which vaccine supply increases but availability remains limited (11–20% of the country's total population); and stage III, in which vaccine supply reaches moderate availability (21–50% of the country's total population). How each of these scenarios could be considered in recommendations for prioritized vaccination of specific groups is illustrated in Table 1.

The Prioritization Roadmap recognizes that prioritization decisions in many countries will be tied, in part or in whole, to vaccine distribution through the COVAX Facility. Stages I and II in the Prioritization Roadmap correspond to the phase 1 supply of up to 20% of each country's population, as detailed in the current working version of the [WHO fair allocation mechanism for COVID-19 vaccines through the COVAX Facility](#) (4). The Prioritization Roadmap's stage III scenario aligns with the Allocation Framework's phase 2 supply of more than 20% to 50% population coverage.

Overall public health strategies by epidemiological setting and vaccine supply stage

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

Community transmission setting: When vaccine supplies are severely constrained, it is justifiable to place an initial focus on direct reduction of morbidity and mortality and maintenance of most critical essential services, while considering reciprocity towards groups that have been placed at disproportionate risk to mitigate the consequences of the pandemic (for example, front-line health workers). As vaccine supplies increase, depending on the vaccine characteristics, the strategy can expand to reduction of transmission in order to 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 remains on direct reduction of morbidity and mortality, maintenance of most critical essential services and reciprocity. Special attention to reducing morbidity and mortality in disadvantaged groups in areas of high or anticipated high transmission is maintained. As vaccine supplies increase, the strategy can expand to substantially control transmission and further reduce disruption of social and economic functions.

No cases setting: This epidemiological setting applies to countries that have managed to stop transmission through PHSM and border controls. When vaccine supplies are severely constrained, the initial focus is on risk mitigation, by vaccinating those groups most at risk of severe disease in the event of an outbreak, alongside prevention of community transmission from importation of cases, and reciprocity for critical workers, particularly front-line health workers. As vaccine supply increases, the strategy expands to preserve control of transmission and, if possible, to reduce reliance on burdensome PHSM.

Priority uses of COVID-19 vaccines

The rationale for the inclusion of each prioritized vaccine use based on population subgroup is anchored in the principles and objectives of the Values Framework. For each priority-use group, the Values Framework objectives that would be supported by prioritizing vaccine use in this population are indicated in Table 1 by parenthetical abbreviations after the population description (for example, A1); the legend explaining these abbreviations is provided below Table 1.

While a detailed explanation of the rationale for each of the priority-use 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 use of COVID-19 vaccines**Example 1. Health workers at high to very high risk of becoming infected and transmitting SARS-CoV-2 in an epidemiological setting of community transmission**

In an epidemiological setting of community transmission, 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 for this, linked to the Values Framework. First, protecting these workers protects the availability of a critical essential service in the COVID-19 pandemic response. The indirect health effects of the pandemic beyond COVID-19 are also 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 (14). 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 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 vaccine use in 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 when 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-use groups.

Example 2. Sociodemographic groups at significantly higher risk of severe disease or death

In an epidemiological setting of community transmission, 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, other groups in the population may be at just as high a risk of these severe outcomes but 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 (15-18), as well as a higher prevalence of background states of poor health that increase their risk of severe COVID-19 (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 (20). Some individuals in these groups would probably qualify for prioritization of vaccine use if their comorbidities were known or ascertainable, but because of inequitable access to health care their conditions will often 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 of severe COVID-19 disease and death will be lacking or less clear than for 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 be included 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 (21). Table 1 provides examples of groups that, depending on the country context, may fall under this prioritization use category.

Example 3. Social/employment groups at elevated risk of acquiring and transmitting infection because they are unable to effectively physically distance

In an epidemiological setting of community transmission, 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 between the groups that should be considered in this category and the sociodemographic groups discussed in Example 2. 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 still be at increased risk (if not greatly increased risk) of severe COVID-19 for 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 (22, 23). They are disadvantaged relative to other groups in the population who benefit more from PHSM, in terms of both their own risk and onward transmission to close contacts, others in their community 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 of infection 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-use groups relates to group size

The staging of priority-use groups is sequential. If there is insufficient vaccine supply to cover the priority-use groups in stage I, the intention is that all these groups are offered vaccine before those included in stage II.

With the exception of stages Ia and Ib, the priority-use groups within a vaccine supply stage are not ordered for prioritization of vaccination. The assignment of priority-use groups was based on assumptions about the size of different priority-use groups in high-, middle- and low-income country settings. For some priority-use groups, even estimates of size 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-use groups assigned to that stage and countries will have to prioritize vaccine use within stages.

As an example, consider stage II in the epidemiological setting of community transmission. Even if vaccine supply is sufficient to cover the groups assigned to stage I, receiving supplies to cover an additional 10% of the population may be insufficient to vaccinate all the groups assigned to stage II. In deciding which groups in stage II to prioritize to receive vaccine, countries may wish to consult the Values Framework for guidance. Determining which ethical principles are most important to the country may help identify the groups that should be prioritized for vaccination.

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 (24, 25). In many contexts, women are disproportionately represented in high-risk occupational groups and they often have direct responsibility for caring for the elderly. Also, in some contexts, women are structurally disadvantaged in terms of access to health care, political and social status, and decision-making authority. Prioritizing men or women for vaccination could exacerbate underlying gender-based inequities. For these reasons, the Prioritization Roadmap does not use sex or gender to prioritize vaccine use. 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-use group.

Pregnant women

Pregnant women warrant particular consideration, because the potential benefits and risks of vaccination apply not only to the health of the women themselves, but also to the health of their offspring. Historically, this group has been neglected in the testing and deployment of epidemic vaccines, including during the current pandemic. Evidence suggests that pregnant women with COVID-19 are at higher risk of developing severe disease compared with non-pregnant women of reproductive age, with an increased likelihood of admission to an ICU and invasive ventilation (26). Pregnant women who are aged 35 years and above or who have a high body mass index or an existing comorbidity, such as diabetes or hypertension, are at particular risk of serious outcomes from COVID-19. COVID-19 in pregnancy is also associated with adverse outcomes affecting the neonate (26, 27). Pregnant women with COVID-19 have an increased risk of preterm birth and of their newborns requiring neonatal intensive care, compared with pregnant women without COVID-19.

Developmental and reproductive toxicology (DART) studies in pregnant animals have been completed for all vaccines granted WHO Emergency Use Listing to date, and no harmful effects have been reported. The availability of data on the safety of COVID-19 vaccination in pregnancy varies by vaccine product. Post-introduction pharmacovigilance data on two mRNA vaccines have so

far not identified any additional acute safety signals; the reactogenicity and adverse events profile by age group is similar to that reported in non-pregnant populations (28). Data on safety in pregnancy for other vaccine products are still being collected (28, 29).

On the basis of previous experience with other vaccines used during pregnancy, the effectiveness of COVID-19 vaccines in pregnant women is expected to be comparable to that observed in non-pregnant women of the same age. Data from small studies have demonstrated that COVID-19 mRNA vaccines are immunogenic in pregnant women and that vaccine-elicited antibodies are transported in infant cord blood and breast milk, suggesting that the vaccines may give short-term early neonatal as well as maternal protection (29, 30).

In line with the equal respect principle in the Values Framework, pregnant women are included in stage II of all epidemiological scenarios of the Prioritization Roadmap, as part of the “Groups with comorbidities or health states determined to be at significantly higher risk of severe disease or death”. In many contexts, including the epidemiologic scenarios of both community transmission and sporadic cases or clusters of cases, these risks are likely to be greater than any theoretical risks posed by vaccination (the available evidence does not suggest any additional risks to date). WHO recommends that countries consult the section on pregnant women in the interim guidance documents for specific vaccine products when considering use of a vaccine during pregnancy.

Breastfeeding women

Historically, evaluation of benefit and risk in lactating women has also been overlooked in pandemic vaccine development and response. There is, as yet, little evidence on whether lactating women are at elevated risk of severe COVID-19. They have, therefore, not been prioritized in the Prioritization Roadmap because of lactation; however, some lactating women are included in other priority-use groups. Lactating women are as likely to benefit from vaccination as other people their age (29, 30). The limited data available for certain products suggest that immunization of lactating mothers poses no risk to the infant, although evidence on the safety of vaccination in lactating women continues to be gathered (31). Data from small studies have demonstrated vaccine-elicited antibodies in breast milk, raising the prospect of some short-term neonatal protection (29, 32). WHO does not recommend discontinuing breastfeeding because of vaccination.

Children

Children (i.e. those under 18 years of age) warrant special consideration for at least three reasons: (1) children are dependent on adults and the wider society for their well-being; (2) although severe COVID-19 is rare in children, it is occasionally observed; and (3) setbacks in well-being during childhood can have severe negative effects that can be lifelong.

Several trials of COVID-19 vaccine candidates in children have been completed or are ongoing. Regulatory authorization for some vaccines includes their use in children, and additional paediatric authorizations may follow. To date, the vaccines for which there are data sufficiently safe and efficacious in children (33).

While children are less likely to suffer from the direct impact of COVID-19 morbidity and mortality compared with other age groups, they do have a small risk of developing severe illness and complications from COVID-19 (34, 35)(34, 35)(34, 35)(34, 35)(34, 35)(34, 35)(34, 35). Children infected with SARS-CoV-2 are at low risk of developing multisystem inflammatory syndrome in children (MIS-C), a severe, potentially fatal multiorgan inflammatory condition with persistent fever (36). The long-term effects of infection with SARS-CoV-2 mild disease in children are yet to be determined (post-COVID-19 condition) and need to be studied to allow a better evaluation of the benefit of vaccinating children. In addition, infected children of all ages are capable of transmitting SARS-CoV-2 regardless of symptom status (37-40). The contribution of children under 10 years to transmission is uncertain; evidence is still evolving and may be context-specific.

Current evidence suggests that children with certain underlying medical conditions and infants (age <1 year) are at increased risk of severe illness from SARS-CoV-2 infection (41-44). In line with the equal respect principle in the Values Framework, children and adolescents with severe chronic comorbidities that place them at significantly higher risk of severe disease are included for vaccine prioritization in stage II in the epidemiological scenarios of both community transmission and sporadic cases/clusters of cases. This subset of children and adolescents joins the adult groups with significant comorbidities who are younger than adults identified as priority in stage I (age cut-off determined at the country level). Where there is evidence that the adults in these groups are at higher risk than those aged 12–18 years, the adults should be vaccinated first. Whether children and adolescents with severe chronic comorbidities are eligible for vaccination will depend on the local availability of vaccines that have been authorized by regulatory authorities for use in paediatric populations.

The negative impacts experienced by children during this pandemic go well beyond their personal direct risk of COVID-19 and burden of SARS-CoV-2 infection (45, 46). Physical distancing measures designed to decrease or prevent community transmission of SARS-CoV-2 have included withdrawing children from school or closing schools altogether. The resultant learning loss and its

impact on lifetime prospects are expected to be far greater for children living in poverty or in otherwise disadvantaged groups. Beyond poor learning and constrained life prospects resulting from disruption in school attendance, students have also lost the social and developmental benefits afforded by in-person learning. Schools often also provide many additional functions important for child health and well-being, such as social interaction, meals, health services including immunizations, and shelter from unstable or unsafe home environments. These additional benefits are especially important for children living in disadvantaged circumstances. Taken together, while all children are harmed by educational disruptions, these effects hit hardest the most disadvantaged children, who also have less access to distance learning options, further widening existing inequities in well-being (47). The health of all children, especially in low-income settings, is also threatened by COVID-19-related disruptions to routine immunization and other child health programmes (48-50).

Child well-being (including health, development and educational opportunities) is addressed in the Prioritization Roadmap through the prioritized vaccination of other groups that directly contribute to child welfare. In the epidemiological scenario of community transmission, vaccination of health workers engaged in immunization delivery is prioritized in stage II (limited vaccine availability), to ensure that delivery of routine childhood vaccines is safely maintained. To facilitate the full reopening of in-school education, vaccination of some teachers and other adult staff employed in school settings is also prioritized in stage II, as are remaining school staff in stage III (moderate vaccine availability). However, there is substantial evidence that schools can reopen safely without vaccinating children, particularly in the presence of other risk mitigation strategies (51, 52).

Considering comorbidities in vaccine prioritization

The evidence that specific comorbidities increase the risk of severe COVID-19 is compelling. It has been shown that: (i) several comorbidities increase the risk of severe COVID-19; (ii) the increase in risk depends on the specific comorbidities, thus equity concerns would arise if all comorbidities were given equal weight; (iii) in many countries, if everyone with a comorbidity were prioritized in early vaccine supply scenarios, the number eligible for vaccination would exceed supply; and (iv) the list of relevant comorbidities will depend on location and other local factors (24, 25, 53-55).

Countries should use relevant local and regional data to identify the comorbidities associated with different levels of COVID-19 risk (for example, significant versus moderate risk). One approach is to identify the additional risk associated with each comorbidity. Another approach is to prioritize vaccine use in individuals who have two or more relevant comorbidities (56).

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 are made through transparent processes 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 that 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) engagement of community leaders and trusted community representatives to contribute to communications; and (iii) inclusion of diverse and affected stakeholder groups in decision-making and planning processes. Community engagement and effective communication are especially important in subpopulations that may be unfamiliar with or distrustful of health-care systems. To complement this work, the routine gathering of local data on the behavioural and social drivers (BeSD)(57) of vaccination will offer valuable insights to guide the implementation of effective strategies to achieve high confidence and uptake.

As outlined in the Values Framework, personal, financial or political conflicts of interest or corruption should not be tolerated in the prioritization of groups for COVID-19 vaccination. In all cases, decision-makers must be able to publicly defend their decisions and actions with 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.

Table 1. Epidemiological setting and vaccine supply scenarios, and recommendations for priority use of vaccines against COVID-19 in the context of limited supply^{a,b}

(a) Epidemiological setting: community transmission – defined in Legend 2

Overall public health strategy for this epidemiological setting: Initial focus on direct reduction of morbidity and mortality, maintenance of most critical essential services and reciprocity. Expand for further reduction of mortality and morbidity and to contribute to reduction in transmission, to reduce disruption of social and economic functions. (A1) (A2) (A3) (B1) (B2) (C1) (C2) (D1) – labels explained in Legend 1

Vaccine supply scenario	Priority-use groups
Stage I (very limited vaccine availability, for 1–10% of national population)	<p>Stage Ia (initial launch):</p> <ul style="list-style-type: none"> Health workers at <i>high to very high risk</i> of acquiring and transmitting infection, as defined in Annex 2. (A1) (A3) (D1) <p>Stage Ib:</p> <ul style="list-style-type: none"> Older adults defined on the basis of age-based risk specific to country/region; specific age cut-off to be decided at country level. (A1) (C1)
Stage II (limited vaccine availability, for 11–20% of national population)	<ul style="list-style-type: none"> Older adults not covered in stage I. (A1) (C1) Health workers at <i>medium risk</i> of acquiring and transmitting infection, as defined in Annex 2. (A1) (A3) (D1) Groups with comorbidities^c or health states (such as pregnancy), determined to be at <i>significantly higher risk</i> of severe disease or death. Efforts should be made to ensure that disadvantaged groups in which there is underdiagnosis of comorbidities are equitably included in this category. (A1) (C1) (C2) Sociodemographic groups at <i>significantly higher risk</i> 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, the 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 programmes and COVID-19 vaccination). (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 for whom distance learning is very difficult or impossible). (A2) (A3) (B1) (C1) (C2)

		<ul style="list-style-type: none"> Seafarers and air crews who work on vessels that carry goods and no passengers, with special attention to seafarers who are stranded at sea and prevented from crossing international borders for crew change due to travel restrictions (58) (A2) (A3) (B1) (C1) (D1)
<p>Stage (moderate vaccine availability, for 21–50% of national population)</p>	<p>III</p>	<ul style="list-style-type: none"> 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) Personnel needed for vaccine production and other high-risk laboratory staff. (A1) (A2) (A3) (D1) Health workers at <i>low risk</i> of acquiring and transmitting infection, as defined in Annex 2 (A1) (A3) (D1) Social/employment groups at <i>elevated risk</i> 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, low-income people in dense urban neighbourhoods; military personnel living in tight quarters; and people working in certain occupations, such as mining and meat processing). (A1) (B1) (B2) (C1) (C2)

(b) Epidemiological setting: sporadic cases or clusters of cases – defined in Legend 2

Overall public health strategy for this epidemiological setting: Initial focus on direct reduction of morbidity and mortality, maintenance of most critical essential services and reciprocity. Expand to contribute to 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-use groups
Stage I (very limited vaccine availability, for 1–10% of national population)	<ul style="list-style-type: none"> Health workers at <i>high to very high risk</i> of acquiring and transmitting infection, as defined in Annex 2 (A1) (A3) (D1) Older adults defined in terms of age-based risk specific to country/region – specific age cut-off to be decided at country level (A1) (C1)
Stage II (limited vaccine availability, for 11–20% of national population)	<ul style="list-style-type: none"> Older adults not covered in stage I. (A1) (C1) Health workers at <i>medium risk</i> of acquiring and transmitting infection, as defined in Annex 2 (A1) (A3) (D1) Groups with comorbidities^c or health states (such as pregnancy) determined to be at <i>significantly higher risk</i> of severe disease or death. Efforts should be made to ensure that disadvantaged groups in which there is underdiagnosis of comorbidities are equitably included in this category. (A1) (C1) (C2) Sociodemographic groups at <i>significantly higher risk</i> 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, the 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) Seafarers and air crews who work on vessels that carry goods and no passengers, with special attention to seafarers who are stranded at sea and prevented from crossing international borders for crew change due to travel restrictions (58) (A2) (A3) (B1) (C1) (D1)
Stage III (moderate vaccine availability, for 21–50% of national population)	<ul style="list-style-type: none"> Primary and secondary teachers and school staff. (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). (A2) (A3) (D1) Social/employment groups at <i>elevated risk</i> 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, low-income people in dense urban

neighbourhoods, military personnel living in tight quarters, and people working in certain occupations, for example, mining, meat processing).

(A1) (B1) (B2) (C1) (C2)

- Health workers engaged in immunization delivery (routine programmes and COVID-19 vaccination).
(A1) (A2) (B2) (C1) (C2) (D1)
 - Age groups at high risk of transmitting infection by age-based risk specific to country/region; specific age groups to be decided at country level.
(A1) (A2)
 - Personnel needed for vaccine production and other high-risk laboratory staff.
(A1) (A2) (A3) (D1)
 - Health workers at *low risk* of acquiring and transmitting infection, as defined in Annex 2
(A1) (A3) (D1)
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(c) Epidemiological setting: no cases – defined in Legend 2

Overall public health strategy for this epidemiological setting: Initial focus on risk mitigation to protect those most at risk of severe outcomes in the case of a COVID-19 outbreak, prevention of community transmission and reciprocity. Expand to preserve control of transmission and reduce reliance on most burdensome public health and social measures.

(A1) (A2) (A3) (B1) (C1) (C2) (D1) – labels explained in Legend 1

Vaccine supply scenario	Priority-use groups
Stage I (very limited vaccine availability, for 1–10% of national population)	<ul style="list-style-type: none"> Health workers at <i>high to very high risk</i> of acquiring and transmitting infection, as defined in Annex 2. (A1) (A3) (D1) Essential travellers at risk of acquiring infection outside the home country and reintroducing infection upon return (for example, seafarers and air crews who work on vessels that carry goods and no passengers, with special attention to seafarers who are stranded at sea and prevented from crossing international borders for crew change due to travel restrictions (58), 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-use group to their advantage. (A1) (A2) (A3) (B1) (C1) (D1) Border protection staff screening for imported cases and people working in outbreak management (for example, isolation and quarantine managers, immunization deployment staff). (A1) (A2) (D1) Older adults, defined in terms of age-based risk specific to the country/region; specific age cut-off to be decided at country level. (A1) (C1)
Stage II (limited vaccine availability, for 11–20% of national population)	<ul style="list-style-type: none"> Older adults not covered in stage I. (A1) (C1) Health workers at <i>medium risk</i> of acquiring and transmitting infection, as defined in Annex 2. (A1) (A3) (D1) All travellers at risk of acquiring infection outside the home country and reintroducing infection upon return. (A1) (A2) Groups with comorbidities^c or health states (such as pregnancy), determined to be at <i>significantly higher risk</i> of severe disease or death. Efforts should be made to ensure that disadvantaged groups in which there is underdiagnosis of comorbidities are equitably included in this category. (A1) (C1) (C2) Health workers engaged in immunization delivery (routine programmes and COVID-19 vaccination). (A1) (A2) (B2) (C1) (C2) (D1)
Stage III (moderate vaccine availability, for 21–50%)	<ul style="list-style-type: none"> Social/employment groups at <i>elevated risk</i> of acquiring and transmitting infection because they are unable to effectively physically distance <i>in areas with high transmission or anticipated high transmission</i> (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) (C2)

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| of national population) | <ul style="list-style-type: none"> • Age groups at high risk of transmitting infection based on age-based risk specific to country/region, specific age groups to be decided at country level. (A1) (A2) • Primary and secondary school teachers and staff. (A2) (A3) (B1) (C1) (C2) • Health workers at <i>low risk</i> of acquiring and transmitting infection, as defined in Annex 2 (A1) (A3) (D1) • 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) |
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National equity considerations: Ensure that vaccine prioritization within countries takes into account the disproportionate burden of the COVID-19 pandemic on social groups that are systematically disadvantaged. **(C1) (C2)**

^a For individuals in more than one priority-use group, the highest applicable priority-use group determines the order in which they should receive COVID-19 vaccine.

^b 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 (59-62). 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 probably be moved to a lower rank.

^c Comorbidities known to increase the risk of severe COVID-19 include diabetes, hypertension, obesity, neurodevelopmental disorders, cancer, conditions or therapies associated with immune suppression, persons living with HIV, sickle cell anemia, Down Syndrome, and chronic kidney disease. This list is not meant to be exhaustive and does not provide ranking.

Legend 1. Value objectives applied to priority-use groups

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| A. Well-being | <p>(A1) Reduce deaths and disease burden from the COVID-19 pandemic.</p> <p>(A2) Reduce societal and economic disruption (other than through reducing deaths and disease burden).</p> <p>(A3) Protect the continuing functioning of essential services, including health services.</p> |
| B. Equal respect | <p>(B1) Treat the interests of all individuals and groups with equal consideration as allocation and priority-setting decisions are being made and implemented.</p> <p>(B2) Offer a meaningful opportunity to be vaccinated to all individuals and groups who qualify under prioritization criteria.</p> |
| C. Equity | <p>(C1) Ensure that vaccine prioritization within countries takes into account the vulnerabilities, risks and needs of groups who, because of underlying societal, geographical or biomedical factors, are at risk of experiencing a greater burden from the COVID-19 pandemic.</p> |
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D. Reciprocity	<p>(C2) Develop the immunization delivery systems and infrastructure required to ensure that priority-use populations have access to COVID-19 vaccines, and that everyone in a priority-use group has equal access, particularly socially disadvantaged populations.</p> <p>(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.</p>
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Legend 2. WHO transmission categories corresponding to epidemiological 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 or geographical location and/or by common exposures
Community transmission	<p>Countries/area/territories experiencing larger outbreaks of local transmission, defined through an assessment of factors including, but not limited to:</p> <ul style="list-style-type: none"> • 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 epidemiological reports, using definitions published in the WHO interim guidance on public health surveillance for COVID-19 (63).

Annex 1. 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, including in this particular pandemic (64, 65). However, the epidemiology of the current pandemic supports using reducing deaths and hospitalization as a preferred strategy for within-country prioritization. The risk of death related to COVID-19 is extremely high in older age groups compared with that in younger age groups. For example, in the United States of America, the mortality risk has been estimated to be 90 times higher among 65–74-year-olds than among 18–29-year-olds (66). A similar pattern of significantly higher mortality in older age groups has been observed in other countries. The evidence 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 (59, 60)(59, 60)(59, 60)(59, 60)(59, 60)(59, 60)(59, 60)(59, 60)(59, 60)(59, 60). 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 use of YLL leads to the same conclusions about relative prioritization of vaccine use. 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 (56).

YLL also does not address the primary equity challenges in prioritization of COVID-19 vaccine use within countries and thus the commitment of the Values Framework to equity does not require use of YLL in this pandemic. 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.

Annex 2. Definition of health workers

Health workers (67) are all people engaged in work actions whose primary intent is to improve health. This includes health service providers, such as doctors, nurses, midwives, public health professionals, laboratory-, health- and medical and non-medical technicians, personal care workers, community health workers, healers and practitioners of traditional medicine. It also includes health management and support workers, such as cleaners, drivers, hospital administrators, district health managers and social workers, and other occupational groups in health-related activities. Health workers include not only those who work in acute care facilities but also those employed in long-term care, public health, community-based care, social care and home care and other occupations in the health and social work sectors as defined by the International Standard Industrial Classification of All Economic Activities (ISIC), revision 4, section Q: Human health and social work activities.

The following levels may be useful in assessing the risk of occupational exposure to SARS-CoV-2 for jobs or tasks of health workers, prior to introducing mitigation measures.

- a) **Low risk.** Jobs or work without frequent, close contact with the public or others, that do not require contact with people known to be or suspected of being actively infected with the virus responsible for COVID-19. Workers in this group have minimal occupational contact with the public and other co-workers, for example performing administrative duties in non-public areas of health care facilities away from other staff members, or telehealth services in individual offices.
- b) **Medium risk.** Jobs or tasks with close, frequent contact with the general public or others, but that do not require contact with people known to be or suspected of being actively infected with the virus responsible for COVID-19. In areas where COVID-19 cases continue to be reported, this risk level may apply to workers who have frequent and close contact with people in busy staff work areas within a health care facility and work activities where safe physical distance may be difficult to maintain, or tasks that require close and frequent contact between co-workers. In areas without community transmission of COVID-19, this scenario may include frequent contact with people returning from areas with known higher levels of community transmission. Examples include, providing care to the general public who are not known or suspected of having COVID-19, or working in busy staff work areas within a health care facility.
- c) **High risk.** Jobs or tasks with high potential for close contact with people who are known or suspected of having COVID-19, as well as contact with objects and surfaces possibly contaminated with the virus, e.g. direct patient care, domestic services or home care for people for people with COVID-19. Jobs and tasks that may fall under this category may include: entering the room of a known or suspected COVID-19 patient, providing care for a known or suspected COVID-19 patient not involving aerosol-generating procedures; transportation of people known or suspected to have COVID-19 without separation between the driver and the passenger.
- d) **Very high risk.** Jobs or tasks with risk of exposure to aerosols containing SARS-CoV-2, in settings where aerosol-generating procedures are performed on patients with COVID-19, such as tracheal intubation, non-invasive ventilation, tracheotomy, cardiopulmonary resuscitation, manual ventilation before intubation, sputum induction, bronchoscopy, spirometry, and autopsy procedures; and working with COVID19 patients in crowded, enclosed places without adequate ventilation.

Annex 3. Summary of major updates

Section	Rationale for update
Rationale	<p>The new version states that while vaccines are now licensed and available, the supply remains limited and unreliable in many settings. It further states that, while all currently recommended COVID-19 vaccines have similar broad indications for use, countries may decide to consider specific product attributes when prioritizing populations.</p> <p>The updated Prioritization Roadmap does not propose coverage targets for countries. The 2020 version of the Prioritization Roadmap worked with an initial target of 20% population coverage, based on the expected supply of vaccines. The updated Prioritization Roadmap provides guidance up to a population coverage level of 50%.</p>
Process of Prioritization Roadmap development	<p>The update reflects the methods and processes used to develop this version of the Prioritization Roadmap.</p>
Key assumptions	<p>A key assumption in 2020 was that COVID-19 vaccines would probably have an impact on transmission. There is now some evidence that supports this statement.</p>
Key assumptions	<p>Post-COVID-19 condition was noted, but as evidence is still emerging, the impact of vaccines on long-term sequelae from SARS-CoV-2 infection have not been included.</p>
Pregnant women, breastfeeding women and children	<p>Substantive changes have been made to these sections to reflect the recent evidence.</p>
Epidemiological settings	<p>The need to keep a vaccine reserve has been removed.</p> <p>Pregnant women have been moved to stage II.</p> <p>Seafarers and air crews have been added to stage II.</p> <p>Settings and geographical locations of high transmission have been removed.</p>

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Funding source

SAGE members and SAGE working group members do not receive any remuneration from the Organization for any work related to the SAGE. The SAGE secretariat is funded through core contributions to WHO.

Acknowledgements

This document was developed in consultation with:

External: Current members of the Strategic Advisory Group of Experts ([SAGE](#)) on Immunization and the [SAGE Working Group on COVID-19 Vaccines](#).

The drafting of the Prioritization Roadmap was led by Saad B. Omer, Ruth Faden, Sonali Kochhar, David Kaslow and Sarah Pallas, with input from the members of the Public Health Objectives Subgroup (Folake Olayinka, Muhammed Afolabi, Celia Alpuche-Aranda, Hyam Bashour, David Durrheim, Peter G. Smith, Yin Zundong, Peter Figueroa and Helen Rees), and support from Matthew A. Crane from the Johns Hopkins University School of Medicine. Hanna Nohynek leads the SAGE Working Group on COVID-19 Vaccines.

The update of the Prioritization Roadmap was led by Ruth Faden, Nick Grassley, Sonali Kochhar, David Kaslow, Saad B. Omer and Sarah Pallas, with input from other members of the Working Group.

WHO secretariat: Annelies Wilder-Smith, Joachim Hombach, Shalini Desai, Melanie Marti

WHO continues to monitor the situation closely for any changes that may affect this interim guidance. Should any factors change, WHO will issue a further update. Otherwise, this interim guidance document will expire 2 years after the date of publication.

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WHO reference number: WHO/2019-nCoV/Vaccines/SAGE/Prioritization/2021.1