WHO SAGE ROADMAP FOR PRIORITIZING USE OF COVID-19 VACCINES

An approach to optimize the global impact of COVID-19 vaccines, based on public health goals, global and national equity, and vaccine access and coverage scenarios

First issued 20 October 2020 Updated: 13 November 2020 Updated: 16 July 2021 Latest update: 21 January 2022



Preamble

This interim guidance constitutes a major revision of the *WHO SAGE roadmap for prioritizing uses of COVID-19 vaccines*, first issued October 2020, and updated in November 2020 and July 2021. It is based on work conducted by the SAGE Working Group on COVID-19 Vaccines and SAGE members, from October 2021 to January 2022, including consultation with RITAG¹ chairs, and dedicated discussions at extraordinary meetings of the Strategic Advisory Group of Experts (SAGE) on Immunization on 7 December 2021 and 19 January 2022 (1).

This revised Roadmap takes into account increasing vaccine availability, vaccine coverage rates, and the evolving epidemiological situation including COVID-19 variants of concern. Scenarios in which vaccination coverage exceeds 50% of the population are considered, as are topics such as vaccine use in children and adolescents and prioritization of additional and booster doses in relation to vaccination coverage rates. To assist countries in developing recommendations for optimized use of vaccines against COVID-19, priority-use groups for vaccination (both primary series and booster doses) are identified based on epidemiological scenarios, public health goals, and vaccine coverage scenarios (in accordance with <u>WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination (2))</u>.

This Roadmap is complementary to the <u>Strategy to achieve global Covid-19 vaccination by mid-2022</u> (3) issued in September 2021, which was developed by WHO in collaboration with its COVAX partners and key regional and national stakeholders, and which specifies national vaccine coverage categories. The Roadmap emphasizes the importance of prioritizing the distribution of increasingly available vaccine supply to optimize impact on health, socioeconomic conditions, and equity, and focuses on in-country vaccine policies.

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.

¹ RITAG: Regional Immunization Technical Advisory Group

Executive summary

By the end of December 2021, about 12 months after the first COVID-19 vaccine received WHO Emergency Use Listing (EUL), more than 9 billion COVID-19 vaccine doses had been administered globally and 48% of the global population had received the primary vaccination series. However, profound inequities in vaccine access and coverage remain worldwide, with some countries reporting vaccination coverage rates below 5%, and others above 80%. Because millions of people in many countries have been left behind in completing a primary vaccination series, globally-coordinated efforts and funding must be strengthened to achieve equitable distribution to, and uptake of, vaccines in all countries. In 2022, more vaccine doses will become available, enabling many countries to achieve high vaccination coverage by mid-2022. Achieving high vaccine access and coverage rates depends not only on vaccine supplies, but also vaccine acceptance and a country's capacity to roll out available supply.

This Roadmap builds on WHO's <u>Strategy to achieve global Covid-19 vaccination by mid-2022 (3)</u> which highlights four objectives for vaccination programmes to achieve the overall goal of full recovery from the COVID-19 pandemic to: i) minimize deaths, severe disease and overall disease burden; ii) curtail the health system impact; iii) fully resume socioeconomic activity; and iv) reduce the risk of new variants. These four objectives are interdependent, and each is important. Currently available COVID-19 vaccines have a modest impact on reducing transmission in the context of SARS-CoV-2 Variants of Concern (VoCs), particularly Omicron. Therefore, averting severe disease and deaths, and protecting health systems remain the primary objectives of vaccine use in the context of the global COVID-19 response, while also reducing morbidity including post COVID conditions. This Roadmap also considers vaccine use in resuming socioeconomic recovery, particularly the priority of maintaining uninterrupted education to keep children connected and learning.

Countries are in different stages of the pandemic and vaccine roll-out, and have different population age structures. To guide country decision-making on how to optimize the public health and social impact of available vaccine supplies and absorptive capacity to administer primary vaccination series and booster doses while attending to equity considerations, the Roadmap identifies priority-use groups and accounts for vaccination coverage rates of the primary series and time since the start of the vaccination programme, in accordance with the <u>WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination</u> (2).

In most countries, groups at higher risk of severe disease and death were first to receive the primary vaccine series; these groups are therefore among the first to show evidence of declining vaccine effectiveness over time. Emerging evidence indicates that vaccine effectiveness against SARS-CoV-2 infection and any symptomatic COVID-19 declines significantly over a period of six months after completion of the primary series, likely resulting from waning protective vaccine-induced immunity, compounded by lower vaccine-induced neutralizing antibody activity against VoCs, including the Delta and Omicron variants. By contrast, vaccine-induced protection against severe COVID-19 outcomes remains relatively better maintained for at least six months after completion of the primary vaccination series, with some declines from maximum protection after completion depending on vaccine platform and VoC. In the short-term, a third dose (booster dose) may fully or partially restore vaccine effectiveness. Variant-adapted COVID-19 vaccines, while in development, are not yet available, hence their potential use is not considered in this Roadmap.

Given that achieving high rates of primary series coverage among the groups at higher risk of severe disease and death remains a critical priority to optimize the impact of available COVID-19 vaccine supply, this Roadmap is built upon two key findings derived from modelling and vaccine effectiveness data:

- 1. *Within a priority-use group*, increasing the primary vaccination series coverage rate has a greater impact on reducing hospitalizations and deaths per dose than use of equivalent vaccine supply to increase the booster dose coverage rate.
- 2. Across priority-use groups, increasing the booster dose coverage rate for higher priority-use groups will usually[†] yield greater reductions in severe disease and death than use of equivalent vaccine supply to increase the primary vaccination series coverage rates of lower priority-use groups.

[†]In some circumstances, there may be a relatively close trade-off in optimizing the impact of vaccine use between offering booster doses to older adults to avert more hospitalizations and deaths versus offering primary series doses to the remaining adults, adolescents, and children, that depend on country conditions, including supply and rollout timelines, past epidemic dynamics and infection-induced immunity, vaccine product, vaccine effectiveness, and waning of protection.

WHO recommends for low, moderate, and high primary series coverage rates in higher priority-use groups (see also **Table 1** below) that:

1. *Countries with low rates of primary series coverage* should first achieve high primary series coverage rates among the higher priority-use groups before offering vaccine doses to lower priority-use groups.[†]

Note: As older adults comprise a large fraction of the highest priority-use group, settings unable to access or deliver vaccines to older adults should consider prioritizing new delivery systems specifically to achieve high coverage rates in this subgroup.

[†]As more vaccine becomes available, lower priority-use groups should be offered vaccine, taking into account national epidemiological data and other relevant considerations. Lower priority-use groups should not be offered primary series doses before higher priority-use groups have been offered primary series doses, unless vaccine programmes encounter significant vaccine delivery or acceptability obstacles to uptake in higher priority-use groups that would result in vaccine wastage. In such cases, community engagement and social mobilization efforts to reach higher priority-use groups should be prioritized.

2. Countries with moderate-to-high rates of primary series coverage in higher priority-use groups should usually[‡]

prioritize available resources to first achieve high booster dose coverage rates in higher priority-use groups

before offering vaccine doses to lower priority-use groups.

[‡] In some circumstances, there may be a relatively close trade-off in optimizing the impact of vaccine use between offering booster doses to older adults to avert more hospitalizations and deaths versus offering primary series doses to the remaining adults, adolescents, and children, that depend on country conditions, including supply and rollout timelines, past epidemic dynamics and infection-induced immunity, vaccine product, vaccine effectiveness, and waning of protection.

 Table 1: Prioritized use of primary series and booster doses by vaccine coverage rates in higher priority-use (I & II)

 groups

Duiovitu uno granut	Vaccine coverage rates of <i>higher priority-use</i> (I & II) groups ^{//}
Priority-use groups [†]	Low $ ightarrow$ Moderate $ ightarrow$ High $ ightarrow$ Very high
I. Highest priority-use Older adults Health workers Immunocompromised persons	Primary series + Additional dose* / Booster**
 II. High priority-use Adults with comorbidities Pregnant persons Teachers and other essential workers Disadvantaged sociodemographic subpopulations at higher risk of severe COVID-19 	Primary series + Booster
III. <i>Medium priority-use</i> Remaining adults Children and adolescents with comorbidities	Primary series + Booster
IV. Lowest priority-use Healthy children and adolescents	Primary series + Booster (booster doses in children below the age of 12 years have not yet been assessed)

[†]*Priority-use groups*: The extent of risk of severe disease and death is the main determinant for assignment of a subgroup (or subpopulation) to a priority-use group. This criterion aligns with a specification of the human well-being principle in the *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccines*. In addition, other specifications of that principle, including reducing societal and economic disruption and protecting essential health services, as well as of the national equity and reciprocity principles, are also used to justify assignment of some of the subgroups to a priority-use group.

†† Vaccine coverage rates: The coverage rates relate to the very high and high priority-use groups. Specific thresholds are not provided as countries may have different abilities to reach these populations. As general guidance, very high coverage in the very high and high priority groups would be above 70%, and low coverage below 10%.

*Additional dose: Persons with moderate to severe immunocompromising conditions should receive an *expanded primary vaccination series* through an additional dose about 1–3 months after completion of the primary series (see <u>Interim recommendations for an extended primary series with an additional vaccine dose for COVID-19 vaccination in immunocompromised persons</u> (4). Such persons are also a high priority-use group for a subsequent (booster) dose.

**Booster dose: The optimal interval between completion of a primary series and administration of a booster dose has yet to be determined, and depends on epidemiological setting, vaccine product, targeted age groups, background seroprevalence, and circulation of specific variants of concern. As a general principle, dependent on vaccine product, an interval of 4–6 months since completion of the primary series could be considered for countries experiencing significant loss of vaccine effectiveness against severe disease in the context of an impending or ongoing major surge of cases, while a longer interval could be considered for those countries currently not experiencing, or at low risk of, an increasing incidence of cases. Healthy children and adolescents belong to the lowest priority-use group because of their relatively low risk of severe disease, hospitalization, and death. Vaccinating this age group is less urgent than vaccinating adults, particularly older adults. However, there are benefits of vaccinating children and adolescents that go beyond the direct health benefits, such as minimizing school disruptions. The decision to vaccinate healthy children and adolescents must account for prioritization to first fully protect higher priority-use groups (e.g., older adults and health workers) through primary vaccination series, and, as vaccine effectiveness declines with time, through booster doses. As such, before considering implementing a primary vaccination series in adolescents and children, using the vaccine supply to attain high coverage rates of primary series – and booster doses as needed based on evidence of waning and optimizing vaccination impact – in higher priority-use groups, such as older adults, must be considered.

Homologous schedules (both for primary series and booster doses) are considered standard practice based on substantial safety, immunogenicity, and efficacy data available for each WHO EUL COVID-19 vaccine. Nonetheless, increasing evidence shows that, for some vaccines, heterologous schedules may offer superior immunogenicity. WHO supports a flexible approach to the use of either homologous or heterologous vaccination schedules and boosters. WHO considers two heterologous doses of any EUL COVID-19 vaccine to be a complete primary series. Heterologous vaccination schedules should be implemented only after careful consideration of current vaccine supply, vaccine supply projections, and other access considerations, alongside the potential benefits and risks of the specific products being used.

The need for and optimal timing of the primary vaccination series and booster dose may be different in an individual who has had a prior SARS-CoV-2 infection or who has experienced a breakthrough infection after initiation of the primary series when compared to a previously uninfected individual. On a population level, the number of doses and interdose interval, as well as the need for booster doses, may differ in settings with high seroprevalence from infection-induced immunity. However, seroprevalence rates observed in population-based studies may not be representative of the entire population or certain subpopulations and age groups, and may also differ by population density. While there may be some benefit to account for the variations in population seropositivity rates in different priority-use groups and the degree of infection-induced protective immunity within countries or communities that may already have experienced high levels of community transmission, basing national vaccination policies on seroprevalence rates or individual pre-vaccination screening is currently not recommended. When more evidence is available, advice on if and how infection-induced immunity should be considered in national vaccination policies will be updated accordingly.

As there is modest impact of vaccines on transmission, and substantially less impact for the newly emerged Omicron variant, public health and social measures must continue, including use of effective face masks, physical distancing, handwashing, and other measures based on the epidemiology of SARS-CoV-2 and vaccine coverage rates. This advice will be updated as information on the impact of vaccination on virus transmission and indirect protection in the community accrues. Countries' strategies related to COVID-19 control should be designed to facilitate participation of children and adolescents in education and other aspects of social life, regardless of vaccination.

Introduction

To support countries in implementing their respective vaccination programmes against coronavirus disease (COVID-19), the Strategic Advisory Group of Experts (SAGE) on Immunization of the World Health Organization (WHO) developed a three-step process to provide guidance for overall programme optimization, as well as vaccine-specific recommendations.

Step 1: A values framework. The <u>WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination</u> (2), issued on 14 September 2020, outlines the general principles, objectives, and target groups for prioritizing the use of COVID-19 vaccine supplies.

Step 2: A roadmap for optimizing uses of COVID-19 vaccines based on priority-use groups (Prioritization Roadmap). This Prioritization Roadmap remains fully aligned with the <u>WHO SAGE values framework for the allocation and prioritization of</u> <u>COVID-19 vaccination (2)</u>. To support countries in planning vaccination programmes, this Roadmap suggests public health strategies and identifies target groups for optimization of COVID-19 vaccine use (referred to as "priority-use groups") in the context of different epidemiological settings, public health goals, and levels of vaccine access and coverage. The initial Roadmap, entitled <u>WHO SAGE roadmap for prioritizing uses of COVID-19 vaccines in the context of limited supply</u> (first published on 7 October 2020 and updated on 13 November 2020 and 16 July 2021), considered priority uses of vaccines at a time when vaccine supply was limited and deployment of the primary vaccination series was the only consideration. The focus of this current Roadmap is the optimization of vaccine use, including as a booster dose, and vaccination of adolescents and children. This update also reflects additional data from pre- and post-authorization studies, as well as lessons learned from COVID-19 vaccine programme implementation. The Roadmap will be updated, as necessary, to accommodate the dynamic nature of the pandemic, greater availability of vaccines, and evolving evidence about vaccine use and impact.

Step 3: Evidence to vaccine-specific recommendations. Specific recommendations for the use of EUL and WHO prequalified vaccines will be issued based on SAGE's *Evidence to recommendations for COVID-19: evidence framework (5)*. Currently, eight vaccines have been recommended by WHO for emergency use, and vaccine-specific interim recommendations on the use of these EUL vaccines have been issued (see: <u>COVID-19 vaccines technical documents: Product specific documentation</u>). These recommendations are updated as additional evidence on effectiveness, safety, and other needs (e.g., use of additional and booster doses) becomes available, and as epidemiological and other contextual conditions evolve.

Definitions

Throughout this Roadmap, "optimization" refers to policy considerations and decisions that aim to make the most effective and efficient use of COVID-19 vaccine supplies in specific epidemiological settings to achieve global and local public health goals.

The following definitions and terminology for additional doses and booster doses are used by WHO throughout its policy recommendations on COVID-19 vaccination.

- Additional doses of a vaccine may be needed as part of an extended primary vaccination series for target populations where the immune response rate following the standard primary series is deemed insufficient. The objective of an additional dose in the primary series is to optimize or enhance the immune response to establish a sufficient level of effectiveness against disease. In particular, immunocompromised individuals often fail to mount a protective immune response after a standard primary series. In addition, older adults may also respond poorly to a standard primary series with some vaccines.
- *Booster doses* are administered to a population that has completed a *primary vaccination series* (including additional doses in an extended primary series). The objective of a booster dose is to restore vaccine effectiveness when, with time, the

immunity and clinical protection of a primary vaccination series has fallen below a rate deemed sufficient in that population.

Epidemiological setting scenarios

The epidemiological settings used in this Roadmap take into consideration the relative benefits and potential risks of COVID-19 vaccine use (i.e., both primary vaccination series and booster dose). The public health strategy for optimizing vaccine use depends on the burden of disease and the local epidemiology, including transmission patterns, seroprevalence from infectioninduced immunity in the target population, circulation of specific variants of concern (VoCs), and the incidence rate of infection in the specific setting at the time vaccination is being contemplated.

Transmission patterns

WHO uses seven categories² to describe transmission patterns at national and subnational levels to guide decisions for preparedness, readiness and response activities (see: WHO's <u>Critical preparedness, readiness and response actions for COVID-19</u>). Although countries are in different epidemiological phases with different transmission patterns, essentially all are experiencing at least one of the four community transmission levels, which share common COVID-19 response aims: to slow transmission; to reduce case numbers; and to end community outbreaks. Hence, this Roadmap considers a single epidemiological scenario, community transmission.

Infection-induced immunity

Immunity derived from SARS-CoV-2 infection may provide variable protection against re-infection and severe disease. Infection-induced protective immunity may wane over time and be lower against new VoCs. Uncertainty remains as to the relative protection afforded by infection-induced, versus vaccine-induced, immunity, although initial evidence suggests that some COVID-19 vaccines provide higher levels of protective immunity than does infection, and that vaccination increases protective immunity in those with a prior infection. Preliminary evidence suggests that infection/vaccination-induced hybrid immunity from three exposures to Spike protein (i.e., one or more exposures from vaccination and one or more from SARS-CoV-2 infection, the latter either before or after vaccination) may provide superior neutralization capacity against VoCs, including Omicron, compared with two doses of vaccination, or previous natural SARS-CoV-2 infection without vaccination (6).

As such, the need for, and optimal timing of, the primary vaccination series and booster dose may be different in an individual who had prior SARS-CoV-2 infection(s), or who experienced a breakthrough infection after initiation of the primary series, when compared to a previously uninfected individual. On a population level, the number of doses and interdose interval, as well as the need for booster doses, may differ in settings with high seroprevalence from infection-induced immunity. Furthermore, seroprevalence is likely to help to inform future strategies and may be considered as part of comprehensive surveillance. However, under current conditions of limited serological testing capacity in many settings, pre-vaccination screening for past infection will increase logistical complexity and hamper the programmatic roll-out of vaccines and may not be cost–effective.

In addition, seroprevalence rates observed in population-based studies may not be representative of the entire population or certain subpopulations and age groups, and may also differ by population density (e.g., higher rates in urban settings than in

² The seven transmission categories defined by WHO are: 1. No (active) cases; 2. Imported/Sporadic cases; 3. Clusters of cases; 4. Community transmission (CT)1: Low incidence of locally acquired widely dispersed cases detected in the past 14 days; 5. CT2: Moderate incidence of locally acquired widely dispersed cases detected in the past 14 days; 6. CT3: High incidence of locally acquired widely dispersed cases in the past 14 days; 7. CT4: Very high incidence of locally acquired widely dispersed cases in the past 14 days; 7. CT4: Very high incidence of locally acquired widely dispersed cases in the past 14 days.

rural settings). While there may be some benefit to account for the variations in population seropositivity rates in different priority-use groups and the degree of infection-induced protective immunity within countries or communities that may have already experienced high levels of community transmission, basing national vaccination policies on seroprevalence rates or individual pre-vaccination screening is currently not recommended. When more evidence is available, advice will be updated accordingly on if and how infection-induced immunity should be considered in national vaccination policies.

Variants of concern

The level of initial protective immunity achieved and the degree of waning of vaccine effectiveness, and hence the need for a booster dose, may differ depending on the circulating SARS-CoV-2 viruses, particularly VoCs, in the population. The protection conferred by vaccination also depends on the severity of the clinical outcome. While evidence shows that vaccine effectiveness against symptomatic SARS-CoV-2 infections wanes significantly during the six months following vaccination, vaccine effectiveness against hospitalizations and death wanes only modestly during the same period. This extent of waning is variant-dependent and may further depend upon the vaccine product(s) in use, and the priority-use group(s) (e.g., older adults, immunocompromised persons, those at high risk of exposure).

The Omicron variant which emerged in November 2021 is highly transmissible; it rapidly becomes the dominant variant where it circulates, and is spreading globally. Evolving evidence suggests that the Omicron variant is associated with less severe clinical disease compared with previous VoCs. Currently available COVID-19 vaccines continue to protect against severe disease, hospitalizations and death due to Omicron, albeit less so compared with other variants. Vaccine effectiveness following a primary vaccine series is low for mild infections due to Omicron. A booster dose enhances vaccine effectiveness against severe disease and hospitalizations (6) but vaccine impact on preventing mild disease, asymptomatic infections and viral shedding is modest and short-lived even with a booster dose. The emergence of Omicron re-emphasizes the urgent need to achieve very high vaccination coverage rates in the higher priority-use groups. It remains unknown to what extent Omicron cross-protects against other circulating VoCs, and those that will potentially newly emerge. The extent to which infection-induced immunity will contribute to high rates of protection against severe disease, hospitalization, and deaths in populations with lower vaccine coverage rates may be an important consideration in setting vaccine coverage targets for those populations. Variant-adapted COVID-19 vaccines, while in development, are not yet available, hence their potential use is not considered in this Roadmap. This Roadmap will be updated when more data accumulate.

Vaccine access and coverage

Vaccine supply has increased exponentially since January 2021. By the end of December 2021, 9 billion doses had been administered, and >48% of the global population fully vaccinated with a primary series. However, vaccine distribution remains grossly inequitable: some low-income countries have achieved less than 5% vaccine coverage, and only 9% of people in low-income countries have received at least one dose. As long as there is inequitable vaccine distribution with associated low coverage rates in some countries, the burden of mortality will remain inequitably distributed, and the risk of emergence and spread of new VoCs will likely remain high. Globally-coordinated efforts, and funding to fully enable COVAX, need to be strengthened to achieve equitable vaccine distribution to, and uptake in, all countries.

Vaccine coverage rates are determined not only by vaccine supply, but also by community vaccine acceptance, and the absorptive capacity by countries to implement vaccination programmes and other logistical constraints. WHO's <u>Strategy to achieve global</u> <u>Covid-19 vaccination by mid-2022</u> (3) describes the following stratified vaccination coverage rates: low (<10%); medium (10–40%); high (41–70%); and very high (>70%).

Public health goals scenarios

The <u>Strategy to achieve global Covid-19 vaccination by mid-2022 (3)</u> highlights four objectives for vaccination programmes to achieve the overall goal of full recovery from the COVID-19 pandemic: i) to minimize deaths, severe disease and overall disease burden; ii) to curtail the health system impact; iii) to fully resume socioeconomic activity; and iv) to reduce the risk of new variants. These four objectives are interdependent and each is important. However, currently available COVID-19 vaccines have modest impact on reducing transmission in the context of VoCs. Therefore, the emphasis on averting severe disease and deaths, and protecting health systems continues in the context of the global COVID-19 response. Hence, older adults, immunocompromised persons and health workers are the highest priority. Using vaccine to minimize the overall disease burden (including post COVID conditions), as well as other strategic uses of vaccine, also contributes to the objective of fully resuming socioeconomic activity, including ensuring stability of education for children and adolescents.

Priority-use groups

This Roadmap identifies four priority-use groupings, from highest to lowest priority-use, based largely on risk of severe disease, hospitalizations, and death. This health risk criterion aligns with a specification of the human well-being principle in the *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccines.* In addition, other specifications of that principle, including reducing societal and economic disruption and protecting essential health services, as well as of the national equity and reciprocity principles, are also used to justify categorization of some priority-use groupings. For example, teachers and other school staff are highlighted as a priority-use subgroup of particular importance to advancing the well-being of children, and societal functioning. Similarly, as regards to equity, this Roadmap also identifies, for special consideration, adults from disadvantaged communities experiencing higher rates of poor health and inadequate health care, as well as higher risks of SARS-CoV-2 infection from living and work conditions. The Values Framework goals and principles which underpin the placement of priority-use subgroups in each of the priority-use groupings can be found in Annex 1; the explanation of the four priority-use groupings in Annex 2; and the risk stratification for health workers in Annex 3.

A major lesson learned from vaccine roll-out during this pandemic is that overly complicated or prescriptive prioritization schema are difficult to implement and thus have limited use. For example, some countries use an age-descending approach only. In this Roadmap, the four priority-use groupings are populated by a limited number of commonly identified subgroups (Annex 2).

Optimized use of COVID-19 vaccines

Primary vaccination series

Achieving high primary series coverage among the priority-use subgroups at higher risk of severe disease and death remains a critical priority to optimize the impact of available COVID-19 vaccine supply.

Countries with low coverage rates of the primary vaccination series should first achieve high rates among the subgroups at higher risk of severe disease and death (i.e., most subgroups in the highest and high priority-use groups). As more vaccine becomes available, additional priority-use groups should be vaccinated, taking into account national epidemiological data and other relevant considerations. Primary series doses should not be offered to lower priority-use groups without first being offered to higher priority-use groups unless there is adequate justification to do so. Justification may include significant vaccine delivery or acceptability obstacles to uptake in higher priority-use groups that would result in vaccine wastage; in such cases, social mobilization efforts to reach higher priority-use groups should be prioritized. The programmatic need in geographically isolated or hard to reach locations to provide vaccine at the same time to lower priority-use groups as well as higher priority use groups may also be adequate justification.

As older adults comprise a large fraction of the highest priority-use group, settings unable to access or deliver vaccines to older adults should consider prioritizing new delivery systems specifically to achieve high coverage rates in this subgroup. WHO has published tools, guidance, national deployment and vaccination plans and training resources (7-9).

Booster doses

With many countries having implemented a primary vaccination series more than 6 months ago, waning of clinical vaccine effectiveness over time has been demonstrated, further compounded by lower vaccine effectiveness in the context of Delta and Omicron VoCs due to immune escape mechanisms of these variants and likely other virological factors (e.g., tropism, incubation period, force of infection). Current evidence underpins that waning vaccine effectiveness is moderate for severe disease, hospitalizations and death, but more significant for asymptomatic and mildly symptomatic SARS-CoV-2 infections. It is particularly important to monitor for loss of sufficient vaccine effectiveness among those at highest risk of severe disease or death. Because these higher risk groups may have been vaccinated first, they may be among the first groups to show evidence of loss of sufficient vaccine effectiveness due to the longer elapsed time since completion of their primary series.

Booster doses should be offered based on evidence that doing so would optimize impact against severe disease, hospitalization, and death, and to protect health systems. The order of implementing booster doses should follow that for primary vaccination series – i.e., booster doses should be prioritized first to the higher priority-use groups before extending to lower priority-use groups, unless there is adequate justification not to do so. Such justification may include significant vaccine delivery or acceptability obstacles to uptake in higher priority-use groups that would result in vaccine wastage. In such cases, strategies should be prioritized to improve vaccine delivery, community engagement, and social mobilization efforts to reach higher priority-use groups.

Within a given priority-use group, primary series vaccination will have greater impact per dose than booster doses. Across priorityuse groups, the benefits of booster doses for higher priority-use groups versus primary series doses for lower priority-use groups may be a relatively close trade-off that depends on country conditions, including supply and roll-out timelines, past epidemic dynamics and infection-induced immunity, vaccine product, vaccine effectiveness, and waning of protection. When high primary series coverage rates have been achieved among subgroups at higher risk of severe disease and death (e.g., older adults), booster doses for these subgroups may yield greater reductions in severe disease and death than use of equivalent vaccine supply for primary series vaccination of lower priority-use groups.

The optimal interval between completion of a primary series and administration of a booster dose has yet to be determined, and depends on epidemiological setting, vaccine product, targeted age groups, background seroprevalence, and circulation and frequency of specific VoCs. As a general principle, an interval of 4–6 months since completion of the primary series could be considered for countries experiencing loss of vaccine effectiveness against severe disease in the context of an impending or ongoing major surge of cases, especially in the context of Omicron, while a longer interval could be considered for settings currently not experiencing, or are at low risk of, an increasing incidence of cases.

Some countries are implementing a 2nd booster dose for their highest risk populations 3–4 months after an initial booster dose. More data on the waning of protective immunity and vaccine effectiveness against severe disease and hospitalization after an initial booster dose is required before a recommendation may be made on additional booster doses.

 Table 1: Prioritized use of primary series and booster doses by vaccine coverage rates in higher priority-use (I & II)

 groups

Driority use groupst	Vaccine o	overage rates of	higher pri	ority-use (I & II) groups
Priority-use groups [†]	Low \rightarrow	Moderate \rightarrow	High	ightarrow Very high
I. Highest priority-use				
Older adults	Primary se	eries + Additiona	l dose* / Bo	ooster**
Health workers	,			
Immunocompromised persons				
II. High priority-use				
Adults with comorbidities				
Pregnant persons				
Teachers and other essential workers	Primary series + Booster			
Disadvantaged sociodemographic subpopulations at higher risk of severe COVID-19				
III. Medium priority-use				
Remaining adults			Primary	series + Booster
Children and adolescents with comorbidities			T THILE Y	
IV. Lowest priority-use				Primary series + Booster
Healthy children and adolescents				(booster doses in children below the age of 12 years have not yet been assessed)

[†]*Priority-use groups*: The extent of risk of severe disease and death is the main determinant for assignment of a subgroup (or subpopulation) to a priority-use group. This criterion aligns with a specification of <u>the human well-being principle</u> in the *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccines*. <u>In addition</u>, other specifications of that principle, including reducing societal and economic disruption and protecting essential health services, as well as of the national equity and reciprocity principles, are also used to justify assignment of some of the subgroups to a priority-use group.

†† Vaccine coverage rates: The coverage rates relate to the very high and high priority-use groups. Specific thresholds are not provided as countries may have different abilities to reach these populations. As general guidance, very high coverage in the very high and high priority groups would be above 70%, and low coverage below 10%.

*Additional dose: Persons with moderate to severe immunocompromising conditions should receive an *expanded primary vaccination series* through an additional dose about 1–3 months after the completion of the primary series (see <u>Interim recommendations for an extended primary series with an additional vaccine dose for COVID-19 vaccination in immunocompromised persons</u> (4). Such persons are also a high priority-use group for a subsequent (booster) dose.

**Booster dose: The optimal interval between completion of a primary series and administration of a booster dose has yet to be determined, and depends on epidemiological setting, vaccine product, targeted age groups, background seroprevalence, and circulation of specific variants of concern. As a general principle, dependent on vaccine product, an interval of 4–6 months since completion of the primary series could be considered for countries experiencing significant loss of vaccine effectiveness against severe disease in the context of an impending or ongoing major surge of cases, while a longer interval could be considered for those countries currently not experiencing, or at low risk of, an increasing incidence of cases.

Heterologous primary vaccination series and booster doses

Homologous schedules are considered standard practice based on substantial safety, immunogenicity, and efficacy data available for each WHO EUL COVID-19 vaccine. Increasing evidence shows that, for some vaccines, heterologous schedules offers superior immunogenicity. Therefore, WHO supports a flexible approach to the use of either homologous or heterologous vaccination schedules and boosters. WHO considers two heterologous doses of any EUL COVID-19 vaccine to be a complete primary series. Heterologous vaccination should only be implemented with careful consideration of current vaccine supply, vaccine supply projections, and other access considerations, alongside the potential benefits and risks of the specific products being used.

Rapidly achieving high vaccination coverage with a primary vaccine series in higher priority-use groups should continue to be the focus while vaccine supply remains constrained. Either homologous or heterologous schedules should be used. The process of vaccination should not be delayed over considerations regarding the potential benefits of heterologous versus homologous schedules.

For countries considering heterologous schedules, WHO makes the following recommendations on the basis of equivalent or favourable immunogenicity or effectiveness for heterologous versus homologous schedules (7):

- Depending on product availability, countries implementing WHO EUL inactivated vaccines for initial doses may consider using WHO EUL vectored or mRNA vaccines for subsequent doses.
- Depending on product availability, countries implementing WHO EUL vectored vaccines for initial doses may consider using WHO EUL mRNA vaccines for subsequent doses.
- Depending on product availability, countries implementing WHO EUL mRNA vaccines for initial doses may consider using WHO EUL vectored vaccines for subsequent doses.

Recommendations as to the relative risks and benefits of homologous versus heterologous primary and booster doses will be reviewed as additional data become available.

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 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.

Public health and social measures

As there is modest impact of vaccines on transmission, and substantially less impact for the newly emerged Omicron variant, public health and social measures must continue (8), including use of effective face masks, physical distancing, handwashing, and other measures based on the epidemiology of SARS-CoV-2 and vaccine coverage rates. This advice will be updated as information on the impact of vaccination on virus transmission and indirect protection in the community accrues. Countries' strategies related to COVID-19 control should be designed to facilitate participation of children and adolescents in education and other aspects of social life, irrespective whether the child is vaccinated or not.

Annex 1. Values Framework

Table A1. Values Framework: goals and principles*

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

* Extracted from: WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination.

Annex 2. Priority-use groups

Highest priority-use groups

Older adults

Older age is associated with a steep rise in risk for more severe disease, hospitalizations, and death. The risk of death related to COVID-19 is extremely high in older adults compared with that in younger adults. For example, in the United States of America, the mortality risk is estimated to be 90 times higher among adults aged 65–74 years than among those aged 18–29 years. A similar pattern of significantly higher mortality in older adults has been observed in other countries. The evidence to date from modelling analyses suggests that using years of lives lost³ instead of deaths would not substantially alter the priority-use ranking of older adults relative to younger persons when age is the only dimension considered.

Population age structures differ from country to country. In some countries, older adults, particularly those aged 60 years and older, constitute more than 20% of the populations; in other countries less than 5%. WHO recommends that very high vaccination coverage rates should be achieved for all older adults. The threshold for the definition of "older adults" may vary from country to country but is typically adults older than 60 years of age.

<u>Health workers</u>

Health workers are all people engaged in work actions whose primary intent is to improve human health. This includes health service providers, such as doctors, nurses, midwives, public health professionals, laboratory technicians, health technicians, 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. The International Labour Organization (ILO), together with WHO, published a risk stratification for exposure to SARS-CoV-2 (see: *Preventing and mitigating COVID-19 at work*). Linked to the Values Framework, health workers at high and very high risk of exposure (see Annex 3 and *COVID-19: Occupational health and safety for health workers: interim guidance*) are in the highest priority-use group for vaccination. The reasons for prioritizing health workers for vaccination are first, that protecting these workers protects the availability of critical essential services; second, evidence suggests that health workers are at high risk of acquiring infection and possibly of severe morbidity and mortality (health workers were among the first victims of the pandemic). There is also a risk of onward transmission to people and patients who are at higher risk of serious COVID-19 outcomes; and third, that prioritization is supported by the principle of reciprocity: health workers play critical roles in the COVID-19 response, putting not only themselves but also potentially their household members at higher risk for the sake of others.

Moderately and severely immunocompromised persons⁴

³ "Years of life lost" is a measure 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.
⁴ Persons are considered moderately or severely immunocompromised if they:

[•] are receiving active cancer treatment: Active immunosuppressive treatment for solid tumour or hematologic malignancy (including leukemia, lymphoma, and myeloma), or within 12 months of ending such treatment.

have received a transplant: Receipt of solid organ transplant and taking immunosuppressive therapy; receipt of stem cell transplant (within 2 years of transplantation, or taking immunosuppressive therapy).

[•] have an immunodeficiency condition: Severe primary immunodeficiency; chronic dialysis.

have an HIV infection with a current CD4 count of <200 cells/µl and/or lack viral suppression

Moderately and severely immunocompromised persons (ICPs) are at higher risk of severe COVID-19, regardless of age, although increasing age remains an important co-factor. For purposes of this Roadmap, moderately and severely ICPs include those with active cancer, immunodeficiency, transplant recipients, and those actively receiving treatment with immunosuppressives. This category also includes people living with HIV with a current CD4 cell count of <200 cells/µl; those with evidence of an opportunistic infection; and those not on HIV treatment, and/or with a detectable viral load (i.e., advanced HIV disease). (For further details, see: *Interim recommendations for an extended primary series with an additional vaccine dose for COVID-19 vaccination in immunocompromised persons (4)*.)

Available data for WHO EUL COVID-19 vaccine products suggest that vaccine effectiveness and immunogenicity are lower in ICPs compared to persons without immunocompromising condition. Emerging evidence suggests that an additional vaccine dose included in an extended primary series enhances immune responses in some ICPs. Reactogenicity data of an additional (third) dose given to ICPs, where reported, have generally been similar to those observed for the standard primary series of the vaccine being administered. Given the significant risk of severe COVID-19 for ICPs, if infected, WHO considers that the benefits of an additional (third) dose in an extended primary series outweigh the risks based on available data, although additional safety monitoring is required.

Available evidence suggests that an additional (third) dose should be given 1–3 months after the completion of the standard primary series in order to increase protection as quickly as possible in ICPs. The most appropriate timing for the additional dose may vary depending on the epidemiological setting and the extent and timing of immune suppressive therapy and course of the disease, and should be discussed with the treating physician. Additional booster doses may be necessary for ICPs. Information and, where possible, counselling about the limitations around the data on administration of an additional dose to ICPs should be provided to inform individual benefit–risk assessment.

Given that protection may remain inadequate in a portion of ICPs even after the administration of an additional dose, WHO further recommends that close contacts (particularly caregivers) of such individuals should be vaccinated if eligible. Additional public health and social measures at the household level to protect ICPs are also warranted depending on the local epidemic circumstances.

High priority-use groups

Adults with comorbidities

Several comorbidities such as diabetes, hypertension, chronic cardiac, lung and kidney diseases, neurodegenerative diseases, and conditions associated with immunosuppression are associated with a higher risk of severe disease, independent of age, but often further compounded by increasing age.

Pregnant women

Pregnant women with COVID-19 are at higher risk of developing severe disease, with increased risk of intensive care unit admission and invasive ventilation, compared to non-pregnant women of reproductive age. COVID-19 in pregnancy is also associated with an increased risk of preterm birth and of neonates requiring neonatal intensive care. It may also be associated with an increased risk of maternal mortality. Pregnant women who are aged 35 years or older, or 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.

Developmental and reproductive toxicology (DART) studies in pregnant animals have been conducted for all eight WHO EUL vaccines to date, and no harmful effects have been reported. Based on the severity of the risks of COVID-19 disease in pregnancy,

[•] are receiving immunosuppressive treatment: Active treatment causing significant immunosuppression (including high-dose corticosteroids), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents, tumour-necrosis factor (TNF) blockers, and other drugs that are significantly immunosuppressive; or have received immunosuppressive chemotherapy or radiotherapy in the previous 6 months.

WHO has concluded that the benefits of vaccination for pregnant women generally outweigh the risks. When considering use of a COVID-19 vaccine during pregnancy, a detailed discussion on the use of each specific WHO EUL COVID-19 vaccine product in pregnancy can be found in the section on pregnant women in the vaccine-specific interim recommendation documents (see: <u>COVID-19 vaccines technical documents: Product specific documentation</u>).

Teachers and other essential workers in sectors outside of health

Teachers, school staff and other essential workers are also included as high priority-use groups because of the role these subgroups play in helping to maintain societal functioning and well-being, including for children, and because their occupations generally put them at a higher risk of SARS-CoV-2 exposure.

Disadvantaged sociodemographic subpopulations at higher risk of severe COVID-19 disease

Which disadvantaged sociodemographic subgroups are at higher risk of severe disease or death will vary from country to country but by and large these subgroups are characterized by limited economic and political power and often reduced social standing. In many contexts, the evidence of elevated risk of severe COVID-19 and death will be lacking or less clear than for risk factors such as age or medically diagnosed comorbidities. Policymakers may have to decide which disadvantaged groups are likely to be sufficiently burdened by COVID-19. While broader efforts must be made to reach out and identify risks among disadvantaged subgroups, these decisions may have to be based on reasonable assumptions about differential impact inferred from other relevant contexts, including past public health emergencies. Some individuals in socioeconomically disadvantaged subgroups would likely qualify for prioritization of vaccine use if their comorbidities were known or ascertainable, if they had better access to health care. In many contexts, disadvantaged subgroups 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, as well as a higher prevalence of background states of poor health that increase their risk of severe COVID-19.

Medium priority-use group

All remaining adults

This priority-use group includes all adults in neither the highest nor high priority-use groups.

Children and adolescents with comorbidities

Comorbidities such as diabetes, cardiac, lung and kidney diseases in children and adolescents are associated with a higher risk of severe COVID-19, but generally, this risk is still lower compared to adults with the same comorbidities, as increasing age is an independent risk factor for severe disease. All children and adolescents with moderate and severe immunocompromising conditions belong to the highest priority-use group (4). Down Syndrome and other neurodevelopmental diseases put children at higher risk of severe COVID-19; some countries may consider place such children and adolescents in the highest priority-use grouping

Lowest priority-use group

Children and adolescents

Children (i.e., those younger than 18 years of age) warrant special consideration for at least three reasons: i) children are dependent on adults and the wider society for their well-being; ii) although severe COVID-19 is rare in otherwise healthy children, it is occasionally observed; and iii) setbacks in well-being and education during childhood can have severe and lifelong negative effects. A recent <u>WHO Interim statement on COVID-19 vaccination for children and adolescents</u> reviewed the burden of disease in children and adolescents; the role of children and adolescents in transmission of SARS-CoV-2; the socioeconomic impact of the COVID-19 pandemic and pandemic response on children and adolescents; and the rationale for vaccinating adolescents and children. The statement concluded that countries should consider the individual and population benefits of vaccinating children and adolescents in their specific epidemiological and social context when developing their COVID-19 immunization policies and programmes. As children and adolescents tend to have milder disease compared to adults, unless they are in a subgroup at higher risk of severe COVID-19, it is less urgent to vaccinate this lowest priority-use group than older adults, those with chronic health conditions, and health workers.

Indirect protection of at-risk adults through vaccinating high-transmitting younger age subgroups against SARS-CoV-2 was an approach used for influenza. However, while the effectiveness of COVID-19 vaccines against asymptomatic infection (a proxy for transmission) was high for ancestral virus and the Alpha variant, it was reduced by around 20% against Delta (9) and is thought to be further reduced by Omicron (10). As vaccine effectiveness against infection and transmission wanes over time (while against severe disease it is relatively well maintained), potential use of COVID-19 vaccines for indirect impacts of vaccine strategies is limited.

Nonetheless, there may be benefits of vaccination that go beyond the direct health benefits to children and adolescents. Vaccination may minimize disruptions to education for children, and maintenance of their overall well-being, health and safety are important considerations. Countries' strategies related to COVID-19 control should facilitate children's participation in education and other aspects of social life, and minimize school closures, even without vaccinating children and adolescents. UNICEF and WHO have developed guidance on how to minimize transmission in schools and keep schools open, regardless of vaccination of school-aged children (11).

The decision to vaccinate adolescents and children must account for prioritization to first fully protect the higher priority-use groups through primary vaccination series, and, as vaccine effectiveness declines with time since completion of the primary vaccination series, through booster doses. As such, before considering implementing primary vaccination series in adolescents and children, attaining high coverage of primary series – and booster doses as needed based on evidence of waning and optimizing vaccination impact – in higher priority-use groups, particularly older adults, must be considered.

WHO recommends that countries that have achieved high vaccination coverage rates in the higher priority-use groups prioritize global sharing of COVID-19 vaccines (preferentially through the COVAX facility or alternative arrangements) before proceeding to vaccination of healthy children and adolescents who are at lowest risk for severe disease (see Table A2).

Priority-use groups	Subpopulations
Highest	 Older adults defined on the basis of age-based risk specific to country/region; specific age cut-off to be decided at the country level. Health workers.[†] Moderately and severely immunocompromised persons.*
High	 Adults with comorbidities or health states (such as pregnancy) that put them at increased risk of severe disease. Teachers and school staff. Other essential workers outside health and education sectors (examples include police officers, municipal service workers, child-care providers, agriculture and food workers, transportation workers, seafarers and air crews, government workers essential to the critical functioning of the state and not covered by other categories). Disadvantaged sociodemographic subpopulations at increased risk of severe disease and death because of higher burden of poor health, inadequate access to health services, underdiagnosis of comorbidities, and/or crowded living and working conditions. Efforts should be made to ensure that these groups are equitably included in this high priority-use category.
Medium	 All remaining adults in neither high nor highest priority-use groups. Children and adolescents with underlying medical conditions that put them at increased risk of severe COVID-19.
Lowest	• Healthy adolescents and children.

Table A2. Subpopulations in the four priority-use groups based on the extent of risk of severe disease, hospitalization and death, or disruption to health systems, education, or other essential services⁵

[†] COVID-19: Occupational health and safety for health workers: interim guidance. 2 February 2021. International Labour Organization and World Health Organization; 2021 (see: <u>www.who.int/publications/i/item/WHO-2019-nCoV-HCW_advice-2021.1</u>).
* Interim recommendations for an extended primary series with an additional vaccine dose for COVID-19 vaccination in immunocompromised persons: interim guidance. 26 October 2021. Geneva: World Health Organization; 2021 (see: <u>https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-immunocompromised-persons</u>).
Note: there is no intent of order within the priority-use groupings

Annex 3. Definition and risk stratification of health workers

Health workers are all people engaged in work actions whose primary intent is to improve human health. This includes health service providers, such as doctors, nurses, midwives, public health professionals, laboratory technicians, health technicians, 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).

According to the Prioritization table above, all health workers are currently allocated to the highest priority-use group for ease of vaccine roll-out. However, countries may find the following levels useful in assessing the risk of occupational exposure to SARS-CoV-2 for jobs or tasks of health workers, prior to introducing mitigation measures (see <u>COVID-19</u>: <u>Occupational health and</u> <u>safety for health workers: interim guidance, 2 February 2021</u>).</u>

- 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, for example, 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 aerosolgenerating 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 COVID-19 patients in crowded, enclosed places without adequate ventilation.

Annex 4. Summary of major updates

Update 19 January 2022

Section	Rational for update
Title	Shortening of title: from WHO SAGE Roadmap For Prioritizing Uses Of Covid-19 Vaccines In The Context Of Limited Supply To WHO SAGE Roadmap For Prioritizing Use Of Covid-19 Vaccines.
	Change of subtitle: from An approach to inform planning and subsequent recommendations based upon epidemiologic setting and vaccine supply scenarios to An approach to optimize the global impact of COVID-19 vaccines, based on public health goals, global and national equity, and vaccine access and coverage scenarios.
	These changes are made to reflect the increasing vaccine supply globally.
Preamble/Introduction	This revised Roadmap takes into account increasing vaccine availability and vaccine coverage rates. Scenarios in which vaccination coverage exceeds 50% of the population are considered.
	It further considers additional topics such as vaccine use in children and adolescents and the administration of booster doses.
Definitions	Definitions to guide the user were added (e.g. additional doses, booster doses).
Epidemiological setting scenarios, including variants of concern and infection-induced immunity	The scenarios were updated taking into account the current epidemiology, transmission patterns, variants of concern and their impact on vaccine performance, as well as the increasing population-level immunity.
Public health goals scenarios	The <u>Strategy to achieve global Covid-19 vaccination by mid-2022</u> was added and referred to.
Optimized use of COVID-19 vaccines	A major overhaul of this section was conducted. The priority-use groups for COVID- 19 vaccination were revisited and are reflected in Table 1. Further information on priority-use groups was added in the respective sections on page 9 and in Annex 2. Primary as well as booster dose schedules were considered.
Heterologous primary vaccination series and booster doses	The section was added and current WHO guidance was referenced.

Update 16 July 2021

Section	Rationale for update
Rationale	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. 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%
Process of Prioritization Roadmap development	The update reflects the methods and processes used to develop this version of the Prioritization Roadmap.
Key assumptions	A key assumption in 2020 was that COVID-19 vaccines would probably have an impact on transmission. In July 2021, there was some evidence that supported this statement.
Key assumptions	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.
Pregnant women, breastfeeding women and children	Substantive changes have been made to these sections to reflect the recent evidence.
Epidemiological settings	The need to keep a vaccine reserve has been removed. Pregnant women have been moved to stage II. Seafarers and air crews have been added to stage II. Settings and geographical locations of high transmission have been removed.

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 (<u>SAGE</u>) on Immunization and the <u>SAGE Working Group</u> on <u>COVID-19 Vaccines</u>.

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

The update of the Prioritization Roadmap was led by David C. Kaslow, Ruth Faden, and Sarah Pallas, with input from other members of the SAGE Working Group on COVID-19 vaccines.

WHO secretariat: Annelies Wilder-Smith, Joachim Hombach, Melanie Marti, Shalini Desai, Katherine O'Brien.

References

- 1. WHO. Extraordinary meeting of the Strategic Advisory Group of Experts on Immunization (SAGE) 19 January 2022. (<u>https://www.who.int/news-room/events/detail/2022/01/19/default-calendar/extraordinary-meeting-of-the-strategic-advisory-group-of-experts-on-immunization-(sage)-19-january-2022, accessed 21 January 2022).</u>
- WHO. WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination, 14 September 2020. Geneva: World Health Organization; 2020 (<u>https://www.who.int/publications/i/item/who-sage-values-framework-for-the-allocation-and-prioritization-of-covid-19-vaccination</u>, accessed 28 May 2021).
- WHO. Strategy to Achieve Global Covid-19 Vaccination by mid-2022. 2021 (<u>https://www.who.int/publications/m/item/strategy-to-achieve-global-covid-19-vaccination-by-mid-2022</u>, accessed 14 January 2022).
- 4. WHO. Interim recommendations for an extended primary series with an additional vaccine dose for COVID-19 vaccination in immunocompromised persons. 2021 (<u>https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-immunocompromised-persons</u>, accessed 26 October 2021).
- 5. WHO. Evidence to recommendations for COVID-19 vaccines: evidence framework: a framework to inform the assessment of evidence and formulation of subsequent COVID-19 vaccine recommendations, 10 December 2020. Geneva: World Health Organization; 2020 (<u>https://www.who.int/publications/i/item/WHO-2019-nCoV-SAGE-Framework-Evidence-2020-1</u>, accessed 27 May 2021).
- 6. Ulrike P, Paul W, Marcel S, Alina P, Annika W, Giovanni A et al. Superior immunity that allows neutralization of all SARS-CoV-2 variants of concern develops in COVID-19 convalescents and naïve individuals after three vaccinations. Nature Portfolio. 2022. doi: 10.21203/rs.3.rs-1226339/v1.
- 7. WHO. Interim recommendations for heterologous COVID-19 vaccination schedules. (<u>https://www.who.int/news/item/16-12-2021-interim-recommendations-for-heterologous-covid-19-vaccine-schedules</u>, accessed 21 Dec 2021).
- 8. WHO. Considerations for implementing and adjusting public health and social measures in the context of COVID-19. (https://www.who.int/publications/i/item/considerations-in-adjusting-public-health-and-social-measures-in-the-context-of-covid-19-interim-guidance, accessed 10 January 2022).
- 9. Singanayagam A, Hakki S, Dunning J, Madon KJ, Crone MA, Koycheva A et al. Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study. Lancet Infect Dis. 2021. doi: 10.1016/s1473-3099(21)00648-4.
- 10. Lyngse FP, Mortensen LH, Denwood MJ, Christiansen LE, Møller CH, Skov RL et al. SARS-CoV-2 Omicron VOC Transmission in Danish Households. medRxiv. 2021:2021.12.27.21268278. doi: 10.1101/2021.12.27.21268278.
- 11. UNESCO, UNICEF, World_Bank, World_Food_Programme, UNHCR. Framework for Reopening Schools. 2021 (<u>https://www.unicef.org/documents/framework-reopening-schools</u>, accessed 14 January 2022).

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.

© World Health Organization 2022. Some rights reserved. This work is available under the <u>CC BY-NC-SA 3.0 IGO</u> licence.

WHO reference number: WHO/2019-nCoV/Vaccines/SAGE/Prioritization/2022.1