ROADMAP FOR PRIORITIZING POPULATION GROUPS FOR VACCINES AGAINST COVID-19

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

27 September 2020 Draft

Introduction

As countries prepare to implement their respective COVID-19 immunization programs, SAGE has undertaken a three-step process to provide guidance for overall program strategy as well as vaccine-specific recommendations:

1. A Values Framework. The WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination, issued on 14 September 2020, outlines the general principles, objectives and related (unranked) target groups for prioritization.

2. A Prioritization Roadmap (this document). To support countries in planning, the Roadmap suggests public health strategies and target priority groups for different levels of vaccine availability and epidemiologic settings.

3. Vaccine-specific recommendations. Once market authorized vaccines become available, vaccine-specific recommendations will be issued; these recommendations may be updated as additional evidence of vaccine effectiveness and safety, and additional vaccines and other interventions become available.

Rationale

Given the urgency and wide-ranging effects of the COVID-19 pandemic, SAGE has developed a proposed approach to help inform deliberation around the range of recommendations that may be appropriate under different conditions once safety and efficacy evidence from phase 3 trials of candidate vaccines become available. To be clear, the SAGE consensus is that currently available evidence is too limited to allow any recommendations for use of any specific vaccine against COVID-19 at this time. This document should be regarded solely as a Roadmap for planning purposes.

This Roadmap builds on the WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination. The Framework listed over 20 population sub-groups that, if prioritized, would advance one or more of the principles and objectives identified in the Framework. It is recognized that the prioritization of these and other groups could not be simply read off of the Values Framework. Rather, specific priority group recommendations for specific vaccines as they become authorized for use will require the integration of these values objectives with evidence and information about: 1) the status of the pandemic in the proposed implementation area (i.e., the epidemiologic setting in terms of the degree of ongoing SARS-CoV-2 transmission, COVID-19 burden); 2) the overall public health strategy for each epidemiologic setting; 3) the amount and pace of vaccine supply; 4) specific characteristics of
the available vaccine(s); and 5) the benefit-risk assessment for the different population groups at the time vaccination is being considered for deployment; as well as other standard criteria used in developing SAGE recommendations (e.g., feasibility, resource use, values and preferences). To advance the effort in drafting recommendations for use of vaccines against COVID-19, SAGE proposes herein a Roadmap of use cases that considers priority populations for vaccination by epidemiologic setting and vaccine supply scenarios in the context of the overall public health strategy for each epidemiologic setting (Table 1).

Guiding Considerations

The following considerations guided the development of this Roadmap:

- This Roadmap must remain fully aligned with the WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination that preceded it.
- To be useful in driving discussions at all levels (i.e., global, regional, and national), the Roadmap needs to be kept “as simple as possible, but no simpler”.
- The Roadmap needs to be revisited through: 1) rolling review as new information becomes available; and 2) on-going dialogue with RITAGs and NITAGs.

Key Assumptions

- The Roadmap assumes the vaccine is fully licensed and has met all the minimal or critical criteria in WHO Target Product Profiles (TPP) for COVID-19 vaccines. Less conclusive evidence on benefit-risk, as expected for an emergency-authorized product, might lead to more restricted recommendations.
- The current degree of uncertainty of and the potential difference between vaccine candidates’ induction of age-independent vaccine efficacy were considered (e.g., a scenario in which the vaccine is assumed to induce age-independent protective immunity, and another scenario in which the vaccine is assumed to have much lower efficacy in older adults). However, the Roadmap relies on the simplifying assumption, supported by current modelling, 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 (Moore et al., 2020). If vaccine efficacy in older adults relative to other age groups was so low that individual protection and public health impact become significantly sub-optimal, the older age group individuals in each scenario would likely be moved to a lower rank.
- Similarly, it was assumed that there would not be substantive differences in protective immune responses in subpopulations (e.g., underlying disease, HIV-positive, pre-existing immunity, etc.).
- Although the vaccine’s effect on interrupting or reducing transmission is an important consideration in the recommendations for use, direct evidence of impact on transmission will likely not be available when the first vaccines are authorized for use. Priority populations in Table 1 were based on the simplifying assumption that vaccine would reduce transmission to an extent sufficient to justify prioritizing vaccination of some groups on the basis of their role in transmission.
Epidemiologic Setting Scenarios

Consideration of the relative benefits and potential risks of vaccination and the public health strategy for use of vaccines depends upon the burden of disease and incidence rate of infection (i.e., epidemiology) in a setting at the time vaccination is being contemplated for deployment. The three proposed epidemiologic settings are: (i) widespread transmission, (ii) localized or limited transmission, and (iii) countries with no reported cases but at risk for an outbreak (Table 1).

Vaccine Supply Scenarios

Because vaccine supply will not be immediately available to immunize all who could benefit from vaccination, three scenarios of constrained vaccine supply were considered: a Stage I scenario of very limited vaccine availability (ranging from 1-10% of each country’s total population) for initial distribution of vaccine supply; a Stage II scenario as vaccine supply increases but availability remains limited, (ranging from 11-20% of each country’s total population); and a Stage III scenario as vaccine supply reaches moderate vaccine availability (ranging from 21-50% of each country’s total population). As expressed in the Global Equity principle of the Values Framework, all countries of the world should have access, not only to vaccine for 50% of their populations, but to as much vaccine as is needed to control the threat of SARS-CoV-2 and even to eliminate it, if that becomes feasible. How each of these three vaccine supply scenarios could be used in considering recommendations for use in priority populations is illustrated in Table 1.

The Roadmap recognizes that many countries’ prioritization decisions will be tied in part or in whole to vaccine distribution through the COVAX facility. Stages I and II in the Roadmap correspond to the latest draft of the WHO Fair allocation mechanism for COVID-19 vaccines through the COVAX facility Phase 1 supply of up to 20% of each country’s population. The Roadmap’s Stage III scenario falls under the Allocation Framework’s Phase 2 supply of more than 20% population coverage (Appendix 1). As already noted, the Roadmap will be extended to include a Stage IV (greater than 50%) as vaccine supply becomes more available.

Overall Public Health Strategy by Epidemiologic Setting and Vaccine Supply Stages

SAGE recommends overall public health strategies, grounded in the Values Framework, for each of the three epidemiologic scenarios. The strategies accommodate the dynamic nature of vaccine supply in each country.

Widespread Transmission: When vaccine supplies are severely constrained, what is feasible to achieve with limited product justifies an initial focus on direct reduction of morbidity and mortality and maintenance of most critical essential services, while considering reciprocity towards groups that have taken disproportionate risks to mitigate consequences of this pandemic (e.g., health workers). As vaccine supplies increase, the strategy expands to reduction in transmission to further reduce disruption of social and economic functions. Special attention is paid to functions that disproportionately impact children and to the
reduction of morbidity and mortality in disadvantaged groups, in keeping with the SAGE Values Framework principles.

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

Countries with no Reported Cases but at Risk for an Outbreak: This epidemiologic setting applies to countries that have managed to achieve substantial control of transmission through non-pharmaceutical interventions. When vaccine supplies are severely constrained, the initial focus is on prevention of community transmission from importation of cases, and reciprocity. As vaccine supplies increase, the strategy expands to preserve control of transmission and reduce reliance on burdensome non-pharmaceutical interventions. This strategy does not reflect a lower value for morbidity and mortality reduction, but rather assumptions about the most efficient approaches that are most likely to protect those at risk of severe disease and death in this type of epidemiologic setting.

Priority Populations

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

While a narrative explication of the rationale for each of the priority groups is beyond the scope of this document, an example for one group, health workers at high to very high risk of becoming infected and transmitting SARS-CoV-2, for one epidemiologic and supply use scenario is provided in Box 1.
Box 1: Example of Rationale for Priority Groups by Use Case: Health Workers in Widespread Transmission Epidemiologic Setting

For the Widespread Transmission epidemiologic setting, health workers at high to very high risk of becoming infected and transmitting SARS-CoV-2 are included in Stage Ia. There are three values-linked reasons supporting this prioritization. First, protecting these workers protects the availability of the most critical of essential services to the COVID-19 pandemic response. Also, the indirect health effects of the pandemic beyond COVID-19 are likely to be much worse if such services are compromised or overwhelmed. Second, evidence suggests that health workers at high to very high risk of acquiring and transmitting infection are also at significantly increased risk of morbidity and mortality, and of onward transmission to people who are at similarly high risk of serious COVID-19 outcomes. Third, prioritization of these workers is also supported by the principle of reciprocity; they have had to 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 is also a fourth set of pragmatic reasons for prioritizing health workers at high to very high risk. Health workers already interact directly with health systems, which should facilitate effective deployment of a vaccine program, including if two doses need to be administered. Launching a vaccine program with a relatively accessible target population will allow more time for the development of delivery mechanisms to other priority groups.

How Supply Staging of Priority Groups Relates to Population Size

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

With the exception of Stages Ia and Ib, the priority groups within a vaccine supply stage are not rank ordered. The assignment of priority groups was based on rough assumptions about the size of different priority groups in high-, middle-, and low- income country settings. For some priority groups, even rough estimates were not available. Considerable national variation is expected. In some countries, the amount of vaccine projected for a vaccine supply stage may be insufficient to cover all the priority groups assigned to that stage and countries will have to determine within-stage prioritization.

As an example, consider Stage II in the Widespread Transmission epidemiologic setting. Receiving vaccine supply up to an additional 10% of population coverage in this stage may be insufficient to address all the groups assigned to that Stage, even if Stage I supply is sufficient to cover the groups assigned to Stage I. In deciding whether to defer some Stage II groups to Stage III, or proceed with offering all groups vaccine, countries may wish to consult the Values Framework for guidance. For example, in countries where diagnosis of comorbidities may be less common in disadvantaged sociodemographic groups, the principle of national equity would support prioritizing sociodemographic groups at significantly higher risk of severe disease or death over groups who are at significantly higher risk because of comorbidities, if vaccine supply is insufficient to cover all the groups assigned to Stage II.
Ongoing Activities and Next Steps

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

Acknowledgements

The WHO SAGE Roadmap for prioritizing population groups for vaccines against COVID-19 was prepared by the SAGE Working Group on COVID-19 vaccines. The drafting of the 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 (members: Folake Olayinka, Muhammed Afolabi, Celia Alpuche, Hyam Bashour, David Durrheim, Sonali Kochhar, Peter G Smith, Yin Zundong, Peter Figueroa, and Helen Rees) and Annelies Wilder-Smith and Joachim Hombach from the WHO Secretariat, with support of Matthew A. Crane from Johns Hopkins University School of Medicine. Hanna Nohynek leads the SAGE Working Group on COVID-19 vaccines.
Table 1. Epidemiologic setting and vaccine supply scenarios, and recommendations for priority use cases for vaccines against Covid-19. The labels in parentheses for each priority population indicate objectives outlined in the Values Framework (see legend below). For individuals in more than one priority group, the highest applicable priority group determines the order in which they should receive COVID-19 vaccine. Current modelling suggests that (given the many-fold higher mortality rate among older individuals) age-dependent vaccine efficacy would not significantly change the recommendations for priority use cases in older populations). If vaccine efficacy in older adults relative to other age groups was so low that individual protection and public health impact become significantly sub-optimal, the older age group individuals in each scenario would likely be moved to a lower rank (see model by Moore et al.).

<table>
<thead>
<tr>
<th>Epidemiologic setting scenario</th>
<th>Overall public health strategy for epidemiologic setting</th>
<th>Vaccine supply scenario</th>
<th>Priority populations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Widespread transmission</td>
<td>Initial focus on direct reduction of morbidity and mortality and maintenance of most critical essential services; also, reciprocity. Expand to reduction in transmission to further reduce disruption of social and economic functions.</td>
<td>Stage I (very limited vaccine availability, ranging from 1-10%)</td>
<td>Stage Ia (Initial Launch) - Health workers at high to very high risk of acquiring and transmitting infection (A1) (A3) (C1) (D1)</td>
</tr>
<tr>
<td></td>
<td>(A1) (A2) (A3) (B1) (B2) (C1) (C2) (D1)</td>
<td>Stage Ib</td>
<td>- Older adults defined by age-based risk specific to country/region, specific age cut-off to be decided at the country level (A1) (C1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stage II (limited vaccine availability, ranging from 11-20%)</td>
<td>- Older adults not covered in Stage I (A1) (C1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Groups with comorbidities or health states determined to be at significantly higher risk of severe disease or death (in countries where the relevant comorbidities can be equitably assessed across the population) (A1) (C1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Sociodemographic groups at significantly higher risk of severe disease or death (A1) (B1) (B2) (C1) (C2)</td>
</tr>
<tr>
<td>Localized or limited transmission</td>
<td></td>
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</tr>
</tbody>
</table>
|  | Initial focus on direct reduction of morbidity and mortality and maintenance of most critical essential services; also, reciprocity. Expand to substantially control transmission and minimize disruption of social and economic functions.  
(A1) (A2) (A3) (B1) (B2) (C1) (C2) (D1) |  |  |
| Stage I (very limited vaccine availability, ranging from 1-10%) |  |  |
|  | - Health workers at *high to very high risk* of acquiring and transmitting infection, *in areas with high transmission or anticipated high transmission*  
(A1) (A3) (C1) (D1)  
- Older adults defined by age-based risk specific to country/region, specific age cut-off to be decided at the country level, *in areas with high transmission or anticipated high transmission*  
(A1) (C1)  
- Emergency reserve utilization for outbreak response or mitigation (e.g. severe localized outbreak)  
(A1) (A2) |  |  |
| Stage III (moderate vaccine availability, ranging from 21-50%) |  |  |
|  | - Primary and secondary teachers and school staff  
(A2) (A3) (B1) (C1)  
- Other essential workers outside health and education sectors (examples: police officers, municipal services, childcare providers, agriculture and food workers, transportation workers, government workers essential to critical functioning of the state not covered by other categories)  
(A2) (A3) (D1)  
- Health workers at *low to moderate risk* of acquiring and transmitting infection  
(A1) (A3) (C1) (D1)  
- Personnel needed for vaccine production and other high-risk lab staff  
(A2) (A3)  
- Social/employment groups unable to social distance (examples: detention facilities, dormitories, low income persons in dense urban neighbourhoods, homeless people and those living in informal settlements or urban slums, certain occupations e.g. mining)  
(A1) (B1) (B2) (C1) (C2) |  |  |
| Stage II (limited vaccine availability, ranging from 11-20%) | Health workers at *high to very high risk* of acquiring and transmitting infection, *in the rest of the country*  
(A1) (A3) (C1) (D1)  
- Older adults defined by age-based risk specific to country/region, specific age cut-off to be decided at the country level, *in the rest of the country*  
(A1) (C1)  
- Groups with comorbidities or health states determined to be at *significantly higher risk* of severe disease or death *in areas with high transmission or anticipated high transmission* (in countries where the relevant comorbidities can be equitably assessed across the population)  
(A1) (C1)  
- Sociodemographic groups at *significantly higher risk* of severe disease or death *in areas with high transmission or anticipated high transmission*  
(A1) (B1) (B2) (C1) (C2)  
- Age groups at high risk of transmitting infection  
(A1) (A2) |
| --- | --- |
| Stage III (moderate vaccine availability, ranging from 21-50%) | Essential workers outside the health sector who are *at high to very high risk* of infection *in areas with high transmission or anticipated high transmission*  
(A1) (A3) (D1)  
- Social/employment groups unable to social distance (examples: detention facilities, dormitories, low income persons in dense urban neighbourhoods, homeless people and those living in informal settlements or urban slums, certain occupations e.g. mining)  
(A1) (B1) (B2) (C1) (C2) |
| Countries with no reported cases but at risk for an outbreak | Initial focus on prevention of community transmission; also, reciprocity. Expand to | Stage I (very limited vaccine availability, ranging from 1-10%) | Health workers at *high to very high risk* of acquiring and transmitting infection  
(A1) (A3) (C1) (D1) |
<table>
<thead>
<tr>
<th>Stage II (limited vaccine availability, ranging from 11-20%)</th>
<th>Stage III (moderate vaccine availability, ranging from 21-50%)</th>
</tr>
</thead>
</table>
| - Essential travellers at risk for acquiring infection in a country with community transmission and reintroducing infection upon return to home country (e.g. students, aid workers)  
  (A2) (A3)  
  - Border protection staff screening for imported cases and workers for outbreak management (e.g. isolation and quarantine managers, immunization deployment staff)  
  (A1) (A2) (D1)  
  - Emergency reserve utilization for focused outbreak response (e.g. importation outbreaks)  
  (A1) (A2) | - All travellers at risk for acquiring infection in a country with community transmission and reintroducing infection upon return to home country  
  (A2)  
  - Emergency reserve utilization for outbreak mitigation (e.g. importation outbreaks)  
  (A1) (A2)  
  - Age groups at high risk of transmitting infection  
  (A1) (A2)  
  - Primary and secondary teachers and school staff  
  (A2) (A3) (B1) (C1)  
  - Social/employment groups unable to social distance (examples: detention facilities, dormitories, low income persons in dense urban neighbourhoods, homeless people and those living in informal settlements or urban slums, certain occupations e.g. mining)  
  (A1) (B1) (B2) (C1) (C2) |

**National Equity Considerations:** Ensure that vaccine prioritization within countries takes into account the vulnerabilities, risks and needs of groups who, because of underlying societal, ethnic/racial, geographic or biomedical factors, are at risk of experiencing greater burdens from the COVID-19 pandemic.  
(A1) (B1) (B2) (C1) (C2)

**Legend:** Translating Objectives to Priority Groups
<table>
<thead>
<tr>
<th>Category</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Human Well-Being</td>
<td>A1. Reduce deaths and disease burden from the COVID-19 pandemic</td>
</tr>
<tr>
<td></td>
<td>A2. Reduce societal and economic disruption (other than through reducing deaths and disease burden)</td>
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<tr>
<td></td>
<td>A3. Protect the continuing functioning of essential services, including health services</td>
</tr>
<tr>
<td>B. Equal Respect</td>
<td>B1. Treat the interests of all individuals and groups with equal consideration as allocation and priority-setting decisions are being taken and implemented</td>
</tr>
<tr>
<td></td>
<td>B2. Offer a meaningful opportunity to be vaccinated to all individuals and groups who qualify under prioritization criteria</td>
</tr>
<tr>
<td>C. National Equity</td>
<td>C1. Ensure that vaccine prioritization within countries takes into account the vulnerabilities, risks and needs of groups who, because of underlying societal, geographic or biomedical factors, are at risk of experiencing greater burdens from the COVID-19 pandemic</td>
</tr>
<tr>
<td></td>
<td>C2. Develop the immunization delivery systems and infrastructure required to ensure COVID-19 vaccines access to priority populations and take proactive action to ensure equal access to everyone who qualifies under a priority group, particularly socially disadvantaged populations</td>
</tr>
<tr>
<td>D. Reciprocity</td>
<td>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</td>
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</tbody>
</table>
### Appendix 1. COVAX Facility Allocation Mechanism Phases and Roadmap of Priority Use Cases Stages

<table>
<thead>
<tr>
<th>Phase</th>
<th>COVAX Facility Allocation Mechanism*</th>
<th>Roadmap of Priority Use Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1: Proportional allocation, to cover Tier 1 target groups</td>
<td>Indicative initial tranche: 3%</td>
<td>Stage I</td>
</tr>
<tr>
<td></td>
<td>Subsequent tranches to reach 20%</td>
<td>Stage II</td>
</tr>
<tr>
<td>Phase 2: Weighted allocation based on risk assessment</td>
<td>&gt;20%</td>
<td>Stage III</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stage IV</td>
</tr>
</tbody>
</table>

* Note: COVAX Facility Allocation Mechanism is still in draft form; further details from current draft approach available at: [https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility](https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility)
References