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Operational guidance:

Evidence-based decisionmaking process for developing national COVID-19 vaccination strategies

This document is part of a series of operational guidance modules developed to support WHO Member States in the European Region in preparing for and implementing COVID-19 vaccination. The modules were developed by a working group convened by the WHO Regional Office for Europe and consisting of experts from WHO, partner agencies, academia, Member States and other stakeholders.

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Objective

To provide guidance and tools to National Immunization Technical Advisory Groups (NITAGs) in developing recommendations on vaccination objectives and prioritization of population groups for COVID-19 vaccination.

Rationale

NITAGs or equivalent advisory bodies play a key role in enabling ministries of health to develop evidence-informed strategies for COVID-19 vaccination. The scientific advice from NITAGs, as independent advisory bodies, will increase the credibility and acceptance of decisions by ministries of health. NITAGs' recommendations will facilitate national planning and preparedness for COVID-19 vaccine deployment and vaccination including prioritization of population groups, especially at the initial phase when the vaccine availability is expected to be very limited.

In order to support the national planning process, the WHO Strategic Advisory Group of Experts on Immunization (SAGE) provided guidance on prioritizing target populations for different stages of vaccine availability and local epidemiological settings. SAGE has classified vaccine availability in three stages intended to cover 1–10% (Stage I – very limited vaccine availability), 11–20% (Stage II- limited availability) and 21–50% (Stage III- moderate availability) of national populations. The local epidemiological setting scenarios were categorized into the following transmission categories: no cases, sporadic cases or clusters of cases, and community transmission.

COVID-19 infection is currently widespread across the WHO European Region, with most countries in the community transmission category or likely to be when the first doses of vaccine become available. In the situation of very limited vaccine availability (Stage I), SAGE recommends that countries prioritize health workers at high to very high risk and older adults for vaccination. When more vaccine doses become available (Stage II), SAGE suggests additionally prioritizing individuals with comorbidities and sociodemographic groups that are at increased risk of developing severe disease and death, health workers engaged in immunization delivery, and high-priority teachers and school staff.

The European Technical Advisory Group of Experts on Immunization (ETAGE) has considered the available regional data on COVID-19 epidemiology and local demography and, based on robust modelling has adapted the SAGE recommendations to the context of the WHO European Region. ETAGE provided recommendations on the stages of very limited and limited vaccine availability in the category of community transmission. ETAGE has:

- recommended that in the initial stage of very limited vaccine availability, health
 workers at high and very high risk of acquiring the infection, transmitting infection
 to vulnerable people with high risk of severe disease outcome or developing severe
 disease themselves, and older adults, should be prioritized for COVID-19 vaccination;
- suggested additional criteria for defining the health workers at very high risk of either acquiring or transmitting the disease or at high risk of developing severe disease themselves;
- · recommended that residents and staff of long-term care facilities could be prioritized

for vaccination at the initial stages of vaccine availability;

- defined the regional age-specific cut-off for vaccinating older adults;
- recognized that, depending on vaccine availability, countries may choose to commence immunization of both health workers and older age groups simultaneously;
- outlined specific comorbidities associated with severe COVID-19 disease and death.

Key actions

1. Developing recommendations

NITAGs should provide scientific advice to their ministry of health during different stages of planning for COVID-19 vaccine deployment and implementation of COVID-19 vaccination. Initially, when available evidence on vaccines is limited, NITAGs should develop preliminary recommendations on prioritization of target populations for vaccination. When market-authorized vaccines become available, NITAGs will provide product-specific recommendations.

NITAGs may use either of the following approaches in developing preliminary recommendations on vaccination objectives and prioritization of target populations.

- **a.** use **routine** NITAG procedures to develop objectives and target populations for national vaccination; or,
- **b.** adapt recommendations on objectives and prioritized target populations provided by SAGE and/or ETAGE.

Regardless of the selected approach, NITAGs should apply outlined ethical principles in the SAGE values framework(2) to develop recommendations on priority access to COVID-19 vaccines and relate their recommendations to vaccine availability.

A. Using routine NITAG procedures

The WHO Regional Office for Europe encourages NITAGs to apply a systematic approach developed by SAGE when making evidence-based recommendations for routine vaccines. This approach includes the following steps:

- formulating a policy question
- defining and ranking criteria to be considered
- gathering and analysing evidence
- translating evidence into recommendations.

NITAGs will have to modify this approach for developing recommendations for CO-VID-19 vaccination because the current data on vaccine characteristics is limited and information on COVID-19 evolving. NITAGs should consider the data (if feasible) on local COVID-19 epidemiology, risk factors for acquiring and transmitting infection, risk of developing severe disease and death, availability of vaccines and accessibility and programmatic feasibility of vaccinating target population groups.

B. Adapting SAGE and ETAGE recommendations

When adapting SAGE and ETAGE recommendations on prioritization of target populations, NITAGs should consider local data on COVID-19 epidemiology and risk factors (if available), national demography and predicted vaccine availability. Based on these data,

NITAGs should:

- define the health workers at high and very high risk of acquiring and transmitting COVID-19 infection and developing severe disease and death;
- determine the national age-specific cut-off for older adults and other priority populations based on the age-distribution of the population and available morbidity and mortality data;
- consider whether health workers at high and very high risk should be vaccinated first or alongside older adults;
- define comorbidities and sociodemographic groups that are at increased risk of developing severe disease and death.

For other target groups prioritized by SAGE in Stage II of vaccine availability, refer to SAGE roadmap.

2. Linking interim recommendations to the timetable of vaccine availability

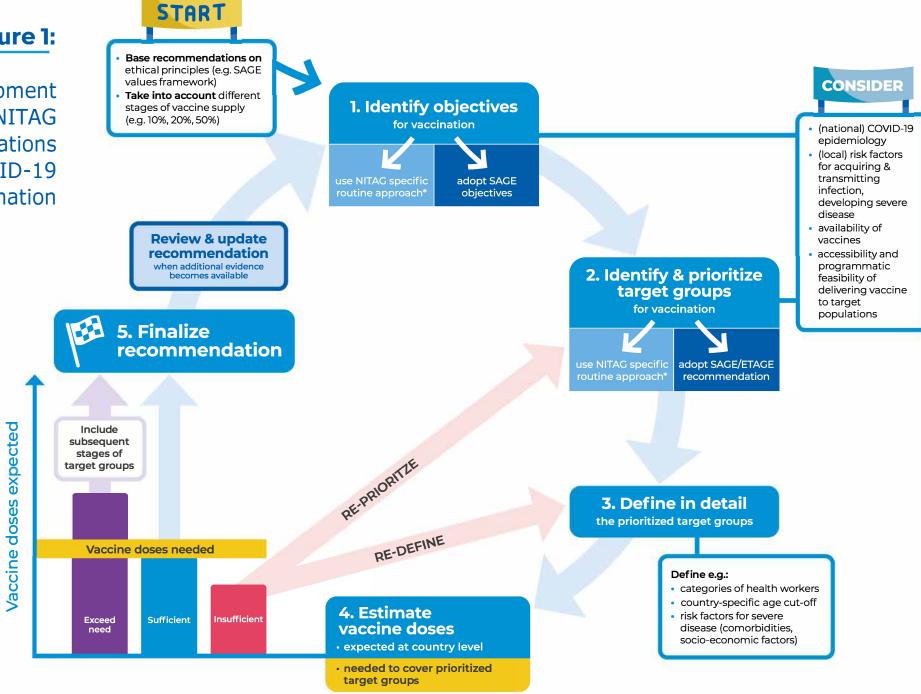
After NITAGs define the target population groups for vaccination, the National Immunization Programme should evaluate the expected vaccine availability based on estimated target population group size. If the expected number of vaccine doses is insufficient, NITAGs should further prioritize subgroups within the recommended target population groups. Conversely, if the number of vaccine doses is more than sufficient to cover the recommended target populations, NITAGs should expand the target population by including additional groups for subsequent stages of vaccine availability.

3. Reviewing recommendations

As additional evidence on COVID-19 epidemiology and vaccine characteristics becomes available, SAGE, ETAGE and NITAGs will need to periodically review their recommendations, update them accordingly and further develop vaccine-specific objectives and strategies.

Figure 1:

Development cycle of NITAG recommendations for COVID-19 vaccination



^{*} NITAGs routine approach: 1. Formulating policy question, 2. Defining (and ranking) criteria, 3. Gathering and analysing evidence, 4. translating evidence into recommendation.

Resources

- WHO SAGE roadmap for prioritizing uses of COVID-19 vaccines in the context of limited vaccine supply; published 13 November 2020; https://www.who.int/publications/m/item/who-sage-roadmap-for-prioritizing-uses-of-covid-19-vaccines-in-the-context-of-limited-supply
- 2. WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination; published 13 September 2020; https://www.who.int/publications/i/item/who-sage-values-framework-for-the-allocation-and-prioritization-of-covid-19-vaccination
- 3. ETAGE recommendations on prioritization of population groups in the WHO European Region; 23 September 2020; https://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/news/news/2020/11/health-workers-at-risk,-older-adults-and-residents-of-long-term-carefacilities-to-be-prioritized-for-covid-19-vaccination#:~:text=ETAGE%20recommends%20 that%20health%20workers,adapted%20according%20to%20local%20epidemiology

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