Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility

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Contents

Introduction

Vaccines with a broad safety and effectiveness profile would constitute powerful tools in preventing cases of COVID-19 and ending the pandemic. The unprecedented investments and global collaboration in research and development may result in a vaccine being available in the medium term. It is expected, however, that manufacturing, and scalability issues coupled with unprecedented demand will pose substantial hurdles to achieving immediate access to the vaccines for all who need them. Thus, once safe and effective COVID-19 vaccines become available the world will be confronted with the great challenge of ensuring equitable access and fair allocation among all countries.

Following on from the overarching provisions of the global allocation framework for fair and equitable access to COVID-19 health products, this document presents the proposed mechanism for fair allocation of vaccines.

This document describes the WHO Secretariat's proposal for the allocation of COVID-19 vaccines among countries (not within countries), specifically in the context of the COVID-19 Vaccines Global Access (COVAX) Facility access mechanism and developed in collaboration with the ACT-Accelerator vaccine partners. The overarching principles and the framework for the equitable access and allocation of COVID-19 health products are described in a separate document.

This working document may be adjusted in the future as new information about vaccines comes out.

COVAX access mechanism for COVID-19 vaccines

A global access facility for vaccines is being developed under the leadership of Gavi (The Vaccine Alliance), The Coalition for Epidemic Preparedness Innovations, WHO and other global partners in the Access to COVID-19 Tools Accelerator. **The COVAX Facility will bring all participating countries together, regardless of their income level, for the procurement and distribution of COVID-19 vaccines**.

The **COVAX Facility** is a mechanism through which demand and resources are pooled to support availability of, and equitable access to, COVID-19 vaccines for all countries. Therefore, all those parties are invited to participate, and all participating entities will benefit by securing access to vaccine supply made available through the Facility. The **COVAX Advance Market Commitment** (AMC), has been established to raise funding to enable Gavi to purchase doses of vaccine for the COVAX AMC eligible countries through official development assistance funding, as well as through support from foundations, private donors and concessional funds from multilateral development banks. The COVAX AMC helps to ensure that the COVAX AMC Eligible Economies can participate in the Facility and access vaccines through it. The remaining economies are expected to fully self-finance their participation in the Facility.

Recognizing that under a business-as-usual approach it could take years to develop effective vaccines and even longer to ensure that these vaccines reach everybody that needs them, the COVAX Facility will accelerate this timeline by enabling investments in a diverse and actively-managed portfolio of candidates, expansion of manufacturing capacity, technology transfer and vaccine production in advance of licensure. Furthermore, it will provide commitments of future vaccine procurement in order to increase the speed and scale of available vaccines once approved.

The goals of the Facility are:

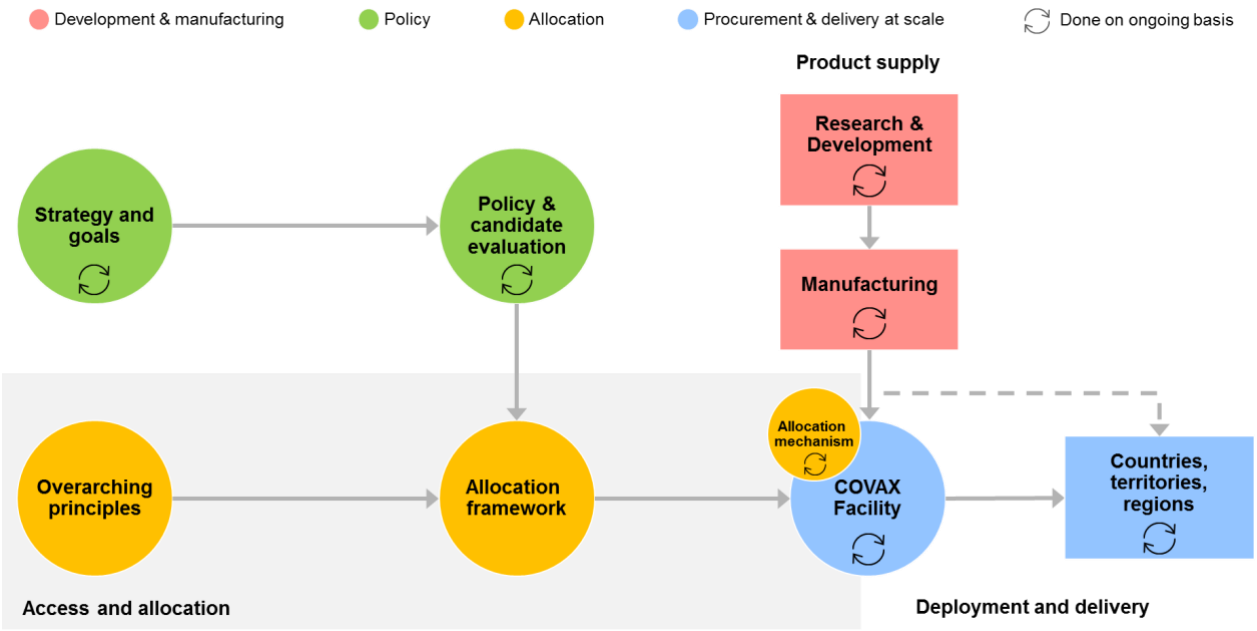
- to develop a large and diverse actively-managed portfolio of COVID-19 vaccine candidates to maximize the probability of success of several candidates, so that the best vaccines are ultimately made available and the supply will be sufficient for highest-priority populations globally for all self-financing participants and COVAX AMC Eligible Economies
- to deliver at least two billion doses of approved vaccines by the end of 2021
- to guarantee access to approved vaccines for every participating economy, and
- to end the acute phase of the pandemic by the end of 2021.

The flowchart in Figure 1 shows the interactions between the various “systems” within the ACT-Accelerator Vaccines Pillar that will contribute to ensuring access to COVID-19 vaccines at country level.

The overarching principles for access and allocation (described in a separate document) will inform the definition of the goals and the identification of the response strategy. These will feed into the policies for vaccinations that will be based on the specific vaccines approved for use in specific populations and that will be recommended by the Strategic Advisory Group of Experts on immunization (SAGE).

The overarching principles have also informed the definition of the allocation framework that is being used to shape the mechanism for actual vaccine allocation. The COVAX Facility is envisaged as a global access mechanism, with linkages across areas of research, development and manufacture of vaccines, which aims to ensure deployment and delivery of approved vaccines to the participating countries.

Fig. 1. How the allocation framework and vaccines allocation mechanism contribute to global access to vaccines through the COVAX Facility



Goals

As outlined in the framework for allocation of COVID-19 pandemic health products, WHO proposes that the **overarching goals of protecting individuals and health systems and minimizing impact on societies and economies** should drive the allocation process for COVID-19 health products across different countries. A vaccination programme can help to achieve these goals by reducing serious morbidity and mortality and protecting even more broadly if a vaccine could protect against SARS-CoV-2 transmission. While resources remain scarce, immunization programs will have to prioritize certain groups over others before progressively expanding access to all who can benefit as supply increases.

At this point of the pandemic, a reasonable scenario would be that, while the supply of COVID-19 vaccines remains very scarce, countries should focus initially on reducing mortality and protecting the health system.

It is important to note that this is the current working assumption for a vaccine with a broad safety and effectiveness profile. **Formal policy recommendations will be issued by SAGE once specific vaccines become available** and are considered in terms of their safety and effectiveness in specific populations (see Box 1). These recommendations will also address the best use of different products if more than one vaccine is available. In addition, the WHO Secretariat is developing comprehensive guidance for countries on programme preparedness, implementation and country-level decision-making.

Box 1. SAGE and vaccine policy process

WHO issues policy recommendations on the optimal use of vaccines to guide and support country decision-making bodies, such as the National Immunization Technical Advisory Groups. Factors that are taken into consideration when making policy recommendations include: disease epidemiology and the clinical profile; the benefits and harms of the vaccine options; values pertaining to the importance of the desirable and undesirable effects; equity considerations; feasibility and resource implications, including economic considerations; social values and preferences, and acceptability; health-system opportunities; and interaction with other existing intervention and control strategies.

To issue such policy recommendations, WHO is advised by the Strategic Advisory Group of Experts on immunization (SAGE). A dedicated working group on COVID-19 is continuously reviewing emerging evidence and is charged with developing draft recommendations for consideration by SAGE.

Owing to the scarce vaccine supply, priority populations need to be defined according to a firm and transparent process. Therefore, SAGE is developing recommendations on the prioritization of populations, based on a framework of values and principles, and objectives of vaccination. Prioritization needs take into account the initially very limited supply of vaccine, with gradual increase over time.

In its policy-formulation process, SAGE will consider the priority populations in context of vaccine product-specific data. Given the broad spectrum of target populations for vaccination and the large variety of platform technologies used for the development of candidate vaccines, product-specific data on the performance of the vaccines in the different target populations and product labelling information, among others, will be considered, which may result in more restricted recommendations for certain populations. Vaccination policies will be updated as other products reach the market and more data on vaccine performance become available.

Target groups

In a reasonable scenario with an **initial focus on mortality reduction and protection of the health system,** the next step is the **identification of corresponding target groups** to maximise impact with limited supply. In supply-constrained situations, target groups are those identified through the goals and objectives for vaccination as those who should receive the vaccine sooner than others.

The definition of target groups should be based on the most thorough analysis of global epidemiological and scientific evidence, including differences across diverse geographical and social settings. Target groups are defined based on the specific product profile and are those for which a specific vaccine would be recommended.

While the product supply remains limited, **target groups should be grouped into tiers**[1] that would have progressive access to the vaccine, based on descending priority. **Tiers may be composed of different target groups** that are considered as having similar priority. **Tier 1 may be limited to a few**

[1] Tiers are combinations of different target groups considered to be of a similar priority.

target groups, but all population groups that could benefit from access to a vaccine should have access to the vaccination in due time and be included in subsequent tiers.

In the absence of product-specific information, **this document uses indicative target groups** and assumes that a vaccine has a broad safety and effectiveness profile (see Box 2). These target groups will need to be formulated by SAGE once, among others, specific products are available.

Box 2. Indicative target groups for vaccination

This document outlines a reasonable scenario of the target groups **to achieve the goal of reducing mortality and protecting the health system**, Tier 1 could *potentially* include the following target groups:

- frontline workers in health and social care settings
- people over the age of 65 years
- people under the age of 65 years who have underlying conditions that put them at a higher risk of death.

Frontline workers in health and social care settings could be prioritized as they are essential to treat and protect the population and come in close contact with infected individuals and provide care for high-mortality risk groups. Initial epidemiological data has shown that adults over 65 years of age and those with certain co-morbidities are at the highest risk of dying from COVID-19. However, this evidence may evolve as more data from different contexts is gathered and assessed.

For most countries, an allocation equal to 20% of the population would be enough to cover most of the population comprising initially prioritized target groups (whether those are the indicative target groups outlined above or other groups such as essential workers). By initially prioritizing these groups, a vaccination programme may achieve an enormous impact in reducing the consequences of the pandemic even in conditions of supply constraint.

WHO recognizes that the percentage of at-risk populations is variable across different countries; the 20% target is considered a floor for an initial allocation that should increase as soon as more product becomes available.

Timing

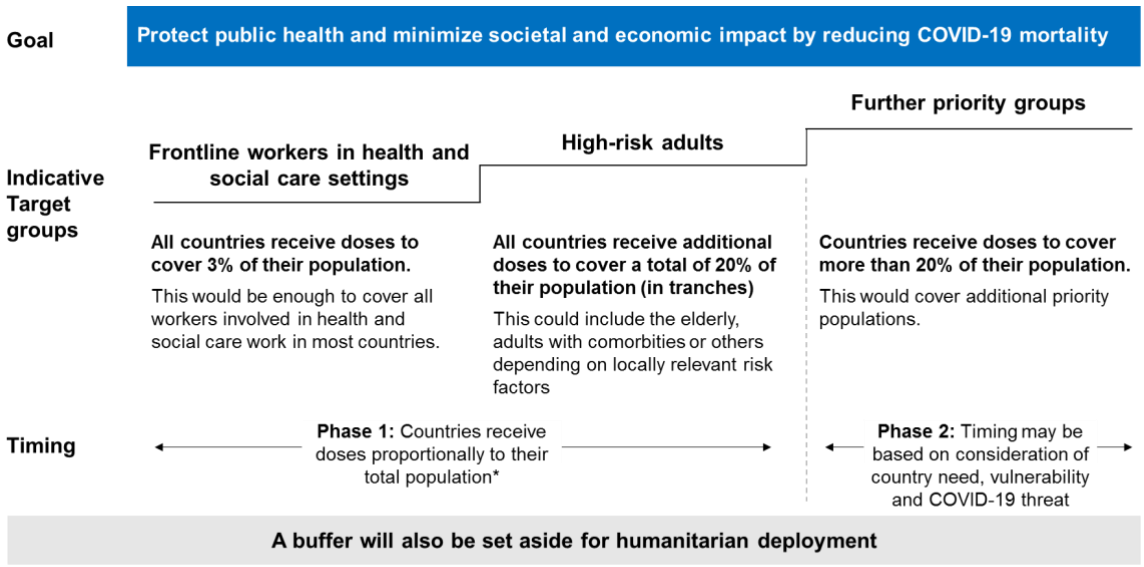
The impact of scarce vaccines will be greatest if the proposed access and allocation mechanism dictates the distribution of vaccines across all countries. For this reason, it is crucial that all countries have timely access to vaccines as they become available.

The fair allocation of vaccines will combine the principle of fairness to meet the basic needs of all countries at the same time in the initial stages (that is, based on proportional allocation), as well as the principle of equity to account for differences in risk profiles across countries.

Allocation prioritization across countries is proposed to be introduced in two phases (see Figure 2): in **phase 1** doses will be allocated proportionally to all participating countries and in **phase 2** consideration may be given to a country's risk to establish the pace at which they would receive additional volumes.

In addition, to ensure that sufficient supplies of vaccine are available to attend to and manage humanitarian situations, deployments and other emergency related situations, some doses of vaccine should be reserved as part of a "humanitarian buffer". This humanitarian buffer stock will be made available to implementing partners, humanitarian organizations and other relevant organizations which are in many instances the primary actors delivering vaccines in these contexts. The buffer is still under development, but it is envisaged to serve vulnerable populations, for example refugees and asylum seekers, and those dedicated to relieving their suffering. The allocation mechanisms will monitor in-country allocation decisions, to avoid "double-counting" of populations that may be serviced through either the general allocation mechanism or the humanitarian buffer. Access modalities, timing and financing of such a buffer will be determined with engagement of a broad array of relevant partners.

Fig. 2. Two phases of allocation with indicative target groups: some countries may be prioritized in Phase 2.



*The fundamental principle applies that all countries receive doses at the same rate to the extent possible, notwithstanding likely practical limitations to be further worked out (e.g. minimum delivery volumes)

Phase 1. Proportional allocation for all countries

Given the ubiquitous nature of COVID-19, all countries should receive, in Phase 1, an initial allocation of vaccines based on a proportional allocation scheme. Moreover, because of the uncertainty of when a vaccine will be available, the evolution of the pandemic in different regions and if and when other health products such as therapeutics will also become available, a proportional allocation should provide certainty to all countries abiding by the global allocation framework that they will receive a sizeable number of vaccine doses and will encourage a large number of countries to participate in a common mechanism and process.

Through the definition of target populations and demographic estimations, the WHO Secretariat considers that doses equivalent to 20% of the population of each country would cover most of those in initially prioritized target groups to help to prevent numerous deaths, reduce the societal and economic consequences, and potentially change the course of the pandemic. This is defined as the Tier 1 population. This fixed percentage represents a floor volume for allocation and ensures predictability for all participating countries in the COVAX Facility. Importantly, the fixed percentage

allows for flexibility in the use of these doses according to national needs and contexts and according to the recommendations issued by SAGE once vaccines are available.

Recognizing that vaccines will not be immediately available in sufficient quantities to reach the number of doses planned in Phase 1, a gradual allocation scheme is needed for distribution. In Phase 1, all countries should gradually receive tranches to cover each subset of Tier 1 target groups before other Tier 1 target groups are considered for an allocation. Thus, an initial tranche of doses will be made available to countries until they can cover 3% of the population.[2,3] This volume would enable, for example, the vaccination of frontline workers in health and social care settings[4] in most countries. By choosing to set a 3% benchmark, WHO wants to ensure that volumes meet the needs of well-resourced health systems while not penalizing countries with a lower proportion of health and social care workers. Additional tranches will follow gradually as more supply becomes available until 20% of the national population is covered in all countries.

It is preferable that countries follow SAGE's policy recommendations and use available doses for target groups defined by SAGE, but national contexts and characteristics may be taken into consideration for the use of a vaccine within each country. The WHO Secretariat recognizes the right of each country to decide how the vaccine will be used within their territory, but it encourages countries to consider these recommendations and to be transparent about their decision-making processes and ultimate use of the vaccine.

Given the uncertainty about when a vaccine will be available, the fact that vaccines are preventative, and uncertainty about other factors that may affect the course of the pandemic in the different regions, a proportional scheme represents a straightforward approach to ensure predictability for both participating manufacturers and countries, while optimizing impact. Manufacturers can have visibility on the potential demand for and geographical distribution of their products through the global COVAX Access mechanism. Countries may be more encouraged to adhere to the global allocation scheme knowing up front the potential number of doses they may have access to during the first phase.

Ideally, all countries will receive enough doses to cover the initial tranches and/or tier (in tranches up to 20% allocation in Phase 1) before other countries receive doses towards their next tranche and/or tier. All doses available for an allocation round will be allocated in a timely manner, ensuring that no doses go idle due to lack of readiness or funding in one country. Two main flexibilities are considered in this context to ensure that volumes are allocated efficiently:

- Exceptions can be made to allow countries to receive doses for their next tranche and/or tier, if there is an availability of stock that cannot be absorbed at that time by other countries. Once these technical issues are resolved, those countries that were unable to receive doses should receive them at an accelerated pace as additional products become available until they catch up.
- Exceptions on quantity per allocation round can be made for small States where it may be cost-effective to provide in one shipment more than the percentage of the tranche and/or tier under consideration, because of small overall populations *(the minimum threshold remains to be determined)*.

[2] The 3% mark was considered on the basis of data on doctors, nurses and midwives and community healthcare workers which indicated worldwide variability ranging from 0.0001% to about 3%. This is a potential first indicative global threshold and is not meant to signal that countries should not consider other types of health and social care workers or not expand vaccination to other essential workers as tranches are being distributed to countries.

[3] In a scenario where initial supply cannot guarantee a first tranche of 3%, considerations will be made to incrementally distribute a smaller percentage to all countries (still proportional to their populations – fir instance, 2%) so that all can have access to vaccines from the initial tranche.

[4] Taking into consideration all relevant categories of workers (that is, not limited to physicians, nurses and technicians, but inclusive of other workers in these settings).

Phase 2. Weighted allocation based on risk assessment

Once 20% of population per country is covered (i.e. Tier 1), Phase 2 of the allocation process will progressively expand access to continue to cover a larger portion of the population in all countries.

At the time of phase 2, in case of protracted severe supply constraint, the allocation of vaccine doses will consider adjustments using the weighted allocation proposed below.
The use of clearly defined, transparent criteria will drive the allocation timing of doses once they become available. Increasing volumes will be allocated to all participating countries, allowing for vaccination of additional groups beyond the initial target groups. **Expanding target groups may help to consolidate the reduction of mortality and attain additional goals such as reducing morbidity and transmission and further promoting a sustainable workforce. Eventually, vaccine should be available and accessible to all those who would benefit.**

The prioritization and quantification of products for each allocation round should be based on a risk assessment through the evaluation of: **threat** – the potential impact of COVID-19 on a country, assessed using epidemiological data - and **vulnerability** – the vulnerability of a country based on health systems and population factors.

Using these criteria, the analysis will identify countries with the highest risk which should receive vaccines at a faster pace than those considered at lower risk. General considerations follow below, with a detailed description of the indicators and methodology included in Annexes 1 and 2. The choice of the most appropriate metrics to evaluate a country's risks is based on considerations of relevance, data quality and data completeness. **Adjustments can be foreseen once more information becomes available.**

Threat

Although the SARS-CoV-2 virus is now distributed globally, COVID-19 affects countries differently. Therefore, a prioritization would need to account for the evolving epidemiology of the virus and other factors that may exacerbate the pandemic's impact in a particular setting. Two analyses are proposed to assess the level of threat: (1) effective reproductive number and its trend and (2) co-circulation of influenza viruses. These analyses are detailed in Annex 1. Vulnerability
Pandemics stress system vulnerabilities and can significantly endanger the provision of essential care. These criteria aim to prioritize countries that are at increased risk due to weaknesses in their health system and/or the fact that the pandemic has overwhelmed existing capacities. Two analyses will be used to assess such vulnerability: (1) the health system capacity according to the universal health coverage index, and (2) occupancy of hospital beds. These analyses are detailed in Annex 1.

Other considerations on criteria

A special consideration will be given to countries that may suddenly face major outbreaks or national disasters throughout the allocation process.

The proposed set of criteria should allow consistency and comparability across all countries since most of these data are available and systematically reported to the WHO Secretariat. Additional reporting requirements for bed occupancy may be necessary but are not expected to impose a heavy burden on participating countries. Other potentially important factors such as excess mortality or mortality rates and the number of healthcare workers that may be registered as ill with COVID-19 were not included as they were considered to pose significant challenges due to lack or

variability of data and inconsistencies in reporting across the world. However, owing the uncertainties about the progression of the pandemic, the proposed parameters will be reviewed closer to the start of Phase 2 to assess their feasibility and relevance for the needed country risk assessment. It is foreseen that as the pandemic evolves together with country's testing and reporting capacity, different indicators may need to be added, like for example mortality rates by age group, to ensure a better representation of the country's threats.

Boundary conditions

Allocation of vaccines will also consider product and country-specific factors. This framework depends not only on available quantities of products, but also on the characteristics of the products, their safety and effectiveness profile, the logistical considerations around delivery, and timing. In addition, allocation should consider a country's context and capacity to absorb and use allocated doses. Country context will also be used to understand and inform decisions about which products will be most appropriate for which context. If country capacity limitations are identified as a hurdle for allocation and deployment, WHO and its partners will enable all necessary support to facilitate timely use. Efforts are under way to produce detailed guidance and training materials to support countries in rapid vaccine introduction, which will be adapted to local context and domesticCOVID-19 vaccine programme objectives. COVAX partners are exploring what financial support to provide to countries in need for technical assistance and delivery. The most time-sensitive element of delivery planning will likely be cold-chain equipment.

The allocation mechanism will strive to ensure, to the extent possible, a best match between available vaccines and country preferences and context suitability.

These boundary considerations can be considered in two categories and are further detailed in Annex 2 under two headings: product supply and characteristics and country context.

Governance considerations

The success of a global access and allocation framework and corresponding allocation mechanism will require accountability of all participating countries and organizations. Hence, creating a governance mechanism to oversee and manage the process is imperative. Transparency, consensus around clear success measures, regular reporting, dissemination of information to various audiences, effective programme management, and communications are critical for ensuring trust and adherence to established rules of engagement.

This section describes the proposed governance for the vaccine allocation mechanism. Governance for allocation of therapeutics and diagnostics will be discussed and set up as the need arises.

Key principles that should be considered when identifying options for the governance of a vaccine allocation mechanism, to ensure accountability towards participating countries, include:

- ensuring representation of all relevant entities
- guaranteeing the independence of the decision-making process and body to ensure protection against undue influence
- safeguarding the transparency in the composition and functioning of each of the structure within the governance mechanism

- having strong accountability mechanisms
- making public all relevant inputs and decisions (background document, meeting minutes, final decision, individual members and their declaration of potential conflict of interest)
- being as lean and dynamic as possible to ensure timely decision-making.

On the basis of these considerations, the proposed governance for vaccine allocation makes use of WHO's and other partners organizations' existing decision-making bodies and their interplay with the COVAX Facility. Thus, the structure will be composed of two main bodies.

1. **Joint Allocation Taskforce.** The Taskforce will have primary responsibility for preparing the allocation proposals based on data-driven considerations. It will be formed by WHO and the Office of the COVAX Facility within the Gavi Secretariat to rapidly bring together the cross-organizational information needed to articulate joint allocation proposals. It is crucial that information is shared across the two organizations to ensure an accurate and efficient process across the multiple interfaces. The Taskforce will be supported by dedicated staff in the WHO Secretariat, which will have responsibility for coordination, organization, communication, running the preliminary allocation model and collecting data to enable monitoring and evaluation. This will allow for continuity and the ability to account for the interplay of the allocation of therapeutics, diagnostics and vaccines.
2. **Independent allocation validation group.** Composed of technical experts, this group will validate allocation proposals from the Joint Allocation Taskforce, ensuring they are technically informed, transparent and free from conflicts of interest. It is envisaged that the validation group will be comprised of independent experts jointly nominated by COVAX members (WHO, Gavi and The Coalition for Epidemic Preparedness Innovations) and other relevant partners and stakeholders, with observers from civil society organizations and representatives of countries participating in the COVAX Facility. The allocation decision is characterized as a strong decision/recommendation with some flexibility to enable adjustments for exceptional and clearly-defined reasons, such as specific operational considerations. This decision will be passed to the Office of the COVAX Facility for implementation with support from procuring agencies like UNICEF and the PAHO Revolving Fund.

Table 1 sets out a short description of responsibilities and oversight mechanisms of above-mentioned bodies and the COVAX Facility secretariat.

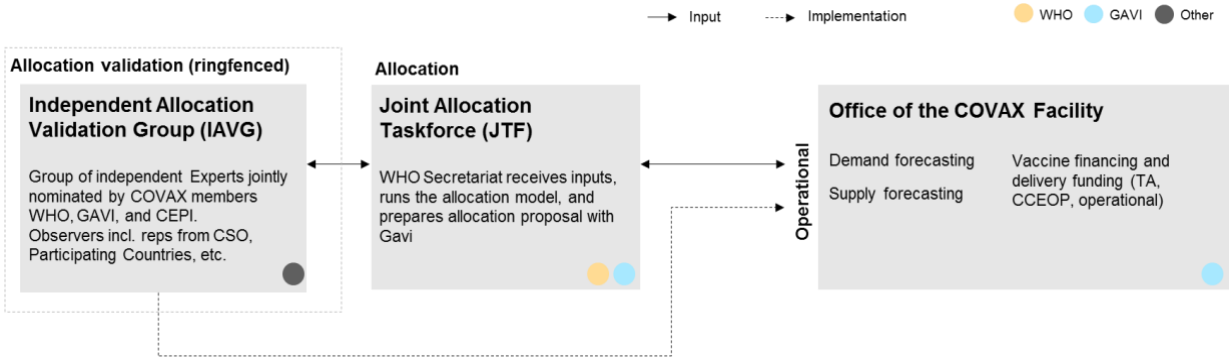
Table 1. Responsibilities and oversight for allocation as it relates to the COVAX Facility

Body	Description
Joint Allocation Taskforce	Responsibilities: • **provide allocation decision proposal** based on data-driven allocation model (coordinating inputs/communication across all stakeholders, running and maintaining the allocation model) • **support the independent allocation validation group** (convening the body, keeping the membership updated, ensuring transfer of relevant documentation) Composition: WHO and Office of the COVAX Facility (Gavi) Oversight by: • relevant agencies with transparency to all participants Supported by WHO and Gavi
Office of the COVAX Facility	Responsibilities: • **implement allocation decision** based on the validated allocation proposal • **provide input to Joint Allocation Taskforce** (including demand/supply forecasting, pricing and financing) Composition: Gavi Oversight by: • participating countries, as part of broader COVAX Facility governance
Independent allocation validation group	Responsibilities: • **perform validation** of data/documentation • **validate the allocation proposal** • **produce reports** to ensure transparency to governing bodies Composition: Independent experts

The overall governance of the COVAX Facility and the linkages between its bodies are still under development. As such, the Facility's relations with the various existing governance structures will be clarified at a later stage.

Figure 3 schematically represents the envisaged interlinks between the COVAX Facility and the governance of the allocation mechanism.

Fig. 3. Governance of allocation mechanism as it relates to the COVAX Facility



Annex 1: Potential methodology proposed for the risk assessment

Details on the proposed analyses used as the basis for the country risk assessment are presented in this annex. A thorough analysis and expert consultation was undertaken for this proposal, but the criteria and methodology may evolve as new knowledge emerges that helps a better understanding of the risk of COVID-19 in different countries

Threat

Effective reproductive number and its trend

The effective reproductive number (R_t) represents the average number of secondary cases per primary case at calendar time (t) in a population consisting of both susceptible and non-susceptible hosts. Use of R_t and the trend in R_t is proposed as combined both variables offer insights on the dynamic of the COVID-19 epidemic in a country, rather than just at a specific point in time. Their joint interpretation will require a technical expert evaluation.

Detailed methodology

R_t is estimated in an area or cluster of interest (nationwide or at subnational level). This is performed with EpiEstim,[5] based on the number of daily cases reported by the country (confirmed, suspected or both) and the expected serial interval. The first day from a sequence of three consecutive days with a reported case is the starting point. R_t is estimated on sliding weekly windows, with a parametric serial interval mean of 4.8 days and a standard deviation of 2.3.[6, 7, 8]

Projections are run based on the estimated R_t, the estimated number of infectious cases, and other parameters including the implementation or lifting of certain public health measures at any given time. This is performed with CovidSIM[9]. This model is based on a standard deterministic SEIR model – "compartmental model" - for: susceptible [*S*], exposed [*E*], infectious *[*I], and recovered/removed [*R*] cases. This tool was developed specifically for COVID-19 by a modellers' group at the Institute of Clinical Epidemiology and Applied Biometrics of the Eberhard Karls University of Tübingen, Germany. Most of the parameters used are based on the most up-to-date literature identified. The parameters are intended to reflect the patterns of transmission of SARS-CoV-2 (phases and periods), taking into consideration population, severity, contagiousness, detection and interventions.

Limitations: The estimated R_t is based on observed reported cases and does not consider asymptomatic/unreported cases. The parameters used to model the patterns of transmission of SARS-CoV-2and severity of disease are based on review of current literature, which may not reflect the current behaviour of the virus in the country.

Co-circulation of influenza viruses or any other epidemic pathogens (for example, measles, respiratory syncytial virus and meningitis)

Although the seasonality of COVID-19 is uncertain, there is a concern that other respiratory viruses such as those that cause seasonal influenza will bring significant additional challenges for countries, as they may: (1) impact testing capacities and other health systems functions and (2) increase the risk profile of target COVID-19 population groups (for instance, older people). Therefore, an

[5] Cori A, Ferguson NM, Fraser C & Cauchemez S. A new framework and software to estimate time-varying reproduction numbers during epidemics. American Journal of Epidemiology, 2013; 178(9):1505–1512 (https://doi.org/10.1093/aje/kwt133).

[6] Liu Y, Funk S, Flasche S. The contribution of pre-symptomatic infection to the transmission dynamics of COVID-2019. Wellcome Open Research 2020, 5-58(https://doi.org/10.12688/wellcomeopenres.15788.1).

[7] Nishiura H, Linton NM, Akhmetzhanov AR. Serial interval of novel coronaviru)s (COVID-19) infections. International Journal of Infectious Diseases 2020; 93:284-286 (https://doi.org/10.1016/j.ijid.2020.02.060).

[8] Peak CM, Kahn R, Grad YH, Childs LM, Li R, Lipschitz M et al. Individual quarantine versus active monitoring of contacts for the mitigation of COVID-19: a modelling study. The Lancet Infectious Diseases, 2020; 20(9):1-25-1033 (https://doi.org/10.1016/S1473-3099(20)30361-3).

[9] MRC Centre for Global Infectious Disease Analysis, Imperial College London COVID-19 (https://covidsim.org/v2.20200903/)

additional indicator is proposed consisting of the hemispheric location of countries, albeit receiving less weight compared to other proposed indicators. This hemispheric location is in accordance with the influenza seasonality patterns. [10]

Vulnerability

Health system capacity

The proposed indicator to weight health systems' capacity is the universal health coverage service coverage index which combines several tracer indicators of service coverage into a single summary measure. The tracer interventions include reproductive, maternal, newborn and child health, infectious diseases, noncommunicable diseases, and service capacity and access, among the general and the most disadvantaged population.

Indicator reporting is performed on an unitless scale of 0 to 100, representing the geometric mean of 14 tracer indicators of health service coverage. It used as a measure for attainment of indicator 3.8.1. of Sustainable Development Goal 3 (Ensure healthy lives and promote wellbeing for all at all ages) and has a variable frequency of data collection (1-5 years).

Occupancy of hospital and intensive care unit beds

As recommended in the public health criteria to adjust public health and social measures in the context of COVID-19,[11] countries are advised to continuously monitor whether the health system can cope with a resurgence of cases that may arise throughout the pandemic. This could be done through monitoring whether the number of new cases requiring hospitalization is smaller than the estimated maximum hospital and intensive care unit bed capacity of the health system (that is, the health system can cope with new hospitalizations without becoming overwhelmed while maintaining delivery of essential health services). In accordance with this recommendation and acknowledging the limited intensive care unit capacity in some countries, a combination of assessing occupancy both hospital and intensive care unit beds is suggested for the purposes of estimating health systems' vulnerability dynamically.

It is important to acknowledge that indicators such as R_t and the trend in R_t, and occupancy of intensive care unit and hospital beds (and potentially others as this framework progresses) require a qualitative evaluation by an independent technical expert assessment in view of correctly categorising the threat. Hence, it is important for the mechanism to rely on an independent, technical decision-making body that will provide full transparency on the process and rationale for decisions.

[10] HirveS, Newman LP, Paget J, Azziz-Baumgartner E, Fitzner J, Bhat N et al. Influenza seasonality in the tropics and subtropics – when to vaccinate? PLoS ONE, 2016; 11(4):e0153003 (https://doi.org/10.1371/journal.pone.0153003).

[11] WHO Public health criteria to adjust public health and social measures in the context of COVID-19 Annex to Considerations in adjusting public health and social measures in the context of COVID-19. Geneva: World Health Organization; 2020 (https://www.who.int/publications/i/item/public-health-criteria-to-adjust-public-health-and-social-measures-in-the-context-of-covid-19).

Annex 2: Detailed considerations for boundary conditions

Product supply

The allocation framework has been devised to provide objective criteria that would be applicable regardless of product supply. Product supply will remain uncertain given that products are still in the development phase and it is difficult to predict which ones will be judged to be safe and efficacious for human use. However, it is important to recognize that products will have distinct characteristics and may be more suitable for some population groups rather than others (for instance, some vaccines may be more or less appropriate for older persons). This will pose a bound on how products are used.

From a logistical standpoint, if a second dose of COVID-19 vaccine is needed, a country should receive the same vaccine it had previously been allocated. Avoiding co-circulation of products in countries is also less desirable as it may lead to medical errors and difficulties in tracking adverse events following vaccination. However, it may be necessary if different products are indicated for different populations and for supply constraint issues.

Finally, to maximize the product supply, recipient countries should report before the next tranche is shipped on their effective use of already-allocated products and current stocks. This will facilitate planning and avoid the holding of unused national vaccine stocks while the vaccine may be in dire need in a different setting. Avoiding such a situation is also recommended to pre-empt emergence of national stocks of expired vaccines or blocking the cold-chain that may be needed for other vaccines.

Although this boundary condition will not dictate per se the total number of doses to be allocated to one country, a minimum threshold of doses per shipment will be set, for reason of cost-effectiveness shipment practicalities. Therefore, for some countries with very small dose requirements, future shipments may be pulled forward to overcome this practical minimum beyond the expected tier allocation. In severely supply-constrained situations, there could be a maximum share of total vaccine supply that a single country can receive to ensure fair and timely access for others.

As greater supply and demand become clearer, a distribution plan will be compiled, containing planning of different phases based on emerging forecast data. This will be underpinned by good practices in inventory optimization.

Country context

As with all medical countermeasures, their import and usage need to be in line with national regulations. Therefore, each country will have to plan the deployment of products and campaign implementation and follow-up, considering their specific national requirements, practices, capacities and capabilities.

The following three main areas underscore these preparations.

- **Legal considerations:** these are usually in the form of agreements between the entity that supplies the products and the country that requests them. The agreement includes terms and conditions that apply to the products (either purchased or donated) and brings clarity on responsibilities of parties involved.
- **Regulatory requirements**: as timely regulatory authorization (or corresponding regulatory waiver) of vaccines will be needed before products are shipped, each country should be aware of the type of regulatory pathway it could use as well as the necessary documentation and the associated timelines to issue the relevant authorizations.

- **A national deployment and vaccination plan:** this will be needed to support deployment and vaccination operations. It usually provides clarity on vaccination strategies, management and organization of operations including necessary infrastructure, legal and regulatory planning, human resources and security needs including training, public communication and community-engagement strategies, supply chain and waste management, post-deployment surveillance and management of adverse events following vaccination and monitoring and evaluation practices. The plan will also help to enable technical support if needed. To this end, where technical assistance is needed, the NDVP should be shared in advance to allow review from technical partners; that will further ensure identification and surmounting of potential gaps in campaign implementation.