WHO Concept for fair access and equitable allocation of COVID-19 health products

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An allocation framework for fair and equitable access to COVID-19 health products

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Introduction

COVID-19 has taken lives and exacted a toll on individuals, families, communities and entire nations. The pandemic has overwhelmed health systems and badly shaken economies around the world, showing that health and economic outcomes are interdependent. Its effective and efficient control will require sustained public health measures and access to affordable, safe, efficacious, assured quality vaccines, along with therapeutics, diagnostics and other health products.

As at the time of writing, there are no effective treatments or cures for COVID-19, and countries have resorted to public health and social measures such as physical distancing and quarantine to contain the spread of the causative virus SARS-CoV-2. These measures have proven highly effective when instituted early. However, they can carry harsh social and economic consequences when maintained for a prolonged time.[1]

Health products must be available when and where they are needed, contextually and culturally appropriate, quality-assured, safe, efficacious and affordable. In past pandemics, some countries have had trouble accessing therapeutics, vaccines and other essential health products. Moreover, access to life-saving medicines and other health products in low- and middle-income countries tends to be very delayed compared with wealthier countries. Overwhelming demand, scarce manufacturing capacity, high-costs and the lack of a global allocation mechanism, have played a role in those delays.

Owing to the unprecedentedly high demand, many countries are facing extreme difficulties in accessing essential medical supplies such as personal protective equipment, mechanical ventilators and diagnostics for COVID-19 disease.

It is expected that access to novel COVID-19 health products, once they are available, will most likely be limited by short supply due to insufficient manufacturing capacity coupled with extraordinarily high demand. The world is responding with unprecedented efforts to accelerate the development and production and to ensure equitable access to vaccines, diagnostics and therapeutics for COVID-19 disease.

The recently established Access to COVID-19 Tools (ACT) Accelerator (Annex 1) is currently the largest global collaboration working to accelerate development and production and to ensure equitable access to new COVID-19 technologies.

Even though the solidarity and collaboration of global stakeholders will help to ensure the availability of safe, quality-assured and efficacious products, more is needed. Scaling up manufacturing, facilitating procurement, maximizing public health benefit and optimizing the use of financial resources to ensure sustainable and affordable supply requires continuous coordination among stakeholders across the globe.

All countries – regardless of their developmental or economic status - should have access to a share of these products once they are available. For this principle to be realized, the world needs a clear, transparent and broadly accepted framework and mechanism for access and allocation based on objective criteria. The framework should guide the mechanisms used to allocate **scarce** products (whether new or repurposed) among countries in order to provide fair and equitable access.

[1] United Nations. Shared responsibility, global solidarity: responding to the socio-economic impacts of COVID-19. New York: United Nations; 2020 (https://www.un.org/sites/un2.un.org/files/sg_report_socio-economic_impact_of_covid19.pdf, accessed 5 September 2020).

The WHO Secretariat, following both long-standing and recent mandates from WHO Member States,[2] is being tasked with developing the basis to ensure fair, equitable and timely access to scarce novel or repurposed COVID-19 health products. Three deliverables are envisaged for the completion of this task:

(1) a set of overarching principles for access to and allocation of health products for COVID-19;
(2) a global framework to ensure equitable and fair access and allocation of COVID-19 health products; and
(3) fair and equitable allocation mechanisms for each product stream, developed in collaboration with relevant partners.

The overarching principles and general framework could be applicable to all types of health products, but allocation of vaccines, therapeutics and diagnostics will require tailored approaches reflecting the different specificities inherent in their use.

This document describes the overarching principles and the framework for the equitable access and allocation of COVID-19 health products (deliverables (1) and (2) above).

[2] On 19 May 2020, the Health Assembly adopted resolution WHA73.1 on COVID-19 response, in which it calls for "the universal, timely and equitable access to, and fair distribution of, all quality, safe, efficacious and affordable essential health technologies and products, including their components and precursors that are required in the response to the COVID-19 pandemic".

Towards equitable access and fair allocation of COVID-19 health products

Overarching principles for equitable access and fair allocation of COVID-19 health products

A commitment to equity across all countries and for all populations in need remains the foundation for a global fair allocation framework. The WHO Secretariat has defined overarching principles to promote access to and allocation of essential COVID-19 health products based on equity and fairness. These principles are grounded in the *right of every human being to the enjoyment of the highest attainable standard of health without distinction of race, religion, political belief, economic or any other social condition*.[3] To attain this right, therapeutics, vaccines, diagnostics and other health products for COVID-19 must be affordable, available, appropriate, and of assured quality for all of those who need them.

The overarching principles are:

1. **Solidarity.** Solidarity is at the heart of the global community's endeavor to join forces to confront this unique challenge together and collaborate to overcome this pandemic. The allocation of scarce resources must be done in a spirit of global solidarity.
2. **Accountability.** Clearly defined roles and responsibilities are needed to ensure procedural justice. Clearly defined objectives, targets, processes, roles, responsibilities and decisions will be critical for accountability on all initiatives related to equitable and fair access to health products.
3. **Transparency.** Trust needs to be built and maintained. Transparency of and access to timely, robust and relevant information related to the discovery, development and delivery of health products are essential for establishing accountability, improving efficiency, maintaining trust, enabling stakeholder participation and reducing risks related to undue influence and inappropriate use.
4. **Responsiveness to public health needs.** Health products must be carefully selected and allocated to address the public health need. COVID-19 health products should be selected on the basis of their safety and effectiveness to reduce mortality, reduce morbidity, prevent infection, facilitate prompt diagnosis and contribute to delivery of optimal care. Health products need to be affordable, available and appropriate for the individual and setting in which they are used. Ensuring access to COVID-19 health products should not compromise equitable access to health products that are essential for other public health needs.
5. **Equity and fairness**. The allocation process is driven by public health needs and informed by these qualities. Equitable and consistent allocation procedures, informed by ethical values and public health needs, are needed to maximize public health benefits and ensure that scarce health products are available and accessible to those in need, on the basis that the public health goals for COVID-19 control take into consideration epidemiological factors and vulnerabilities, among other aspects.
6. **Affordability.** Consideration needs to be given to pricing and procurement strategies to improve affordability of health products. It is crucial that costs do not pose a barrier to access, while sustainability of both health systems and manufacturers is safeguarded. New approaches to

[3] Constitution of the World Health Organization (https://www.who.int/governance/eb/who_constitution_en.pdf, accessed 5 September 2020).

procurement and pricing are needed as well as innovative strategies for preventing proprietary rights placing hurdles to access to essential products and/or expanding manufacturing and supply.

7. **Collaboration. C**ollaborative efforts among relevant global and national stakeholders must is enhanced to accelerate and scale-up the response. A coordinated global approach is needed for the discovery, development and fair allocation of safe, affordable and effective health products and timely access to them. Collaborations are essential to accelerate research and development, rapidly scale up manufacturing (through, for instance, transfer of technology and know-how), to define criteria for equitable allocation, to build capacity for the use of laboratory testing, reagents and supporting materials, essential medical supplies, new diagnostics, medicines and COVID-19 vaccines, and to strengthen supply chains for their distribution.
8. **Regulatory and procurement efficiency.** Agile and comprehensive regulatory and procurement approaches are used to improve timely access to safe, efficacious and quality health products for all countries in need[4]. Agile regulatory processes are needed to support the timely development or repurposing of health products while the safety, efficacity and quality of the products remains assured. Efficient procurement process will ensure timely access to the available products.

These principles are relevant for ensuring that the allocation process enables equitable access and fair allocation of vaccines, therapeutics and/or diagnostics. Although universal, the principles allow for tailoring of the allocation mechanisms according to different contexts and product use and characteristics and with particular focus on reaching those populations at high-risk, living in conditions of vulnerability, and who carry out functions essential for the well-being of others and society.

Ethical values informing allocation of scarce resources

Following recent guidance from WHO Working Group on Ethics and COVID-19,[5] ethical values such as equity and fairness will guide the proposed allocation of scarce resources for COVID-19. The stage of pandemic, the type of product and related considerations will further inform prioritization and critical judgements needed during the allocation.

When public health goals are used to steer the allocation of scarce resources, the aim can be to achieve the best outcome, to do the most good or to minimize the harm with the scarce resources available. This implies the prioritization of certain populations over others and treating similar populations the same way.

A more articulated explanation of the ethical considerations underpinning this proposed framework is provided in Annex 2, focusing on vaccines as an example.

[4] For example, WHO will support the assessment of the safety, effectiveness and quality of vaccines candidates through its PQ program and in collaboration with SRA and regulatory bodies. In addition, WHO will provide support to national regulatory authorities and other relevant national bodies to ensure efficient introduction and oversight of the vaccines at the national level.

[5] Q&A: Ethics and COVID-19: resource allocation and priority setting [website]. Geneva: World Health Organization: 20 April 2020 (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/ethics-and-covid-19)

An allocation framework for fair and equitable access to COVID-19 health products

An allocation framework is a vital piece of the broader agenda of work to ensure equitable access to COVID-19 health products, control the pandemic and fulfil the objectives behind the partnerships under the aegis of the ACT Accelerator and other initiatives working to improve access globally. These initiatives are providing essential support and coordination for research and development and improving the chances of having safe and effective vaccines, therapeutics and diagnostics in sufficient quantities to confront the pandemic. The framework aims at promoting access and guiding the allocation of new and repurposed products for which demand greatly outpaces supply. In addition, financial support, procurement and country-delivery arrangements are essential for ensuring that financial and/or logistical issues do not pose a barrier for access to all those who need COVID-19 health products.

This global allocation framework is intended to guide the process of timely allocation of COVID-19 products among countries (rather than within countries) and would then be applied and adapted to each product through specific allocation mechanisms.

The framework and enabling mechanisms are designed to be time-limited, potentially covering the period of supply constraint until production increases and supply meets global demand. At present, it is not possible to determine an exact duration of the allocation mechanisms that are being planned or set up owing to the uncertainty around the characteristics of the products in the pipelines and the evolution of the pandemic.

Crucially, achieving equitable access and fair allocation rests on the solidarity, political commitment and accountability of stakeholders globally, and will require complementary efforts that put systems in place to ensure availability, quality, affordability and rapid and effective delivery of products.

Strategies to ensure availability and affordability of health products for all countries are beyond the scope of this framework. However, the WHO Secretariat supports these efforts through other partnerships and programs such as the COVID-19 Supply Task Force and the ACT Accelerator.

The major components of the allocation framework for COVID-19 products are outlined in Figure 1.

Fig. 1. Major elements of the global allocation framework

Goals

In order to achieve the largest public health impact possible globally in supply-constrained conditions, it is necessary to focus initially on target populations. Prioritizing specific populations that are linked to specific public health goals should allow the world to achieve these goals in a resource-constrained environment. Eventually, as product supplies increase, access should be expanded to all who can benefit from them.

The overarching goals of protecting individuals and public health, while recognizing the need to minimize impact on societies and economies, should drive the allocation process of health products across different countries.

To inform the most effective strategy to achieve these goals, the Secretariat relies on emerging and evolving scientific evidence (see Box 1, Policy recommendations), its extensive know-how and that of partners and collaborating entities, and on the lessons learned from responses to previous pandemics.

The targeted use of limited resources and products for defined populations will help to maximize the public health impact of such limited supplies. As more supplies become available, expanding access to additional populations will achieve additional goals. Thus, it is necessary to focus on specific, highest priority public health goals in the initial stages for allocating a specific product.

Target groups

The strategy should define plausible scenarios and identify target groups for the use of resources as they become available, and take into consideration the complementarity of diagnostic, preventive and/or therapeutic products with public health measures.

The selection of target groups according to strategy and policy recommendations is of cardinal importance. For example, if the goal is to reduce mortality, those at the highest risk of dying should be prioritized for vaccination, and therapeutics may be reserved for potentially severe cases of illness. Similarly, rapid diagnostic tests and vaccines may be prioritized for essential workers in a scenario where the preservation of essential services is critical.

Timing

Based on the target groups for each type of product specified through the policy recommendations outlined in Box 1, the framework will then help to define the volumes that each country should receive in each allocation round,[6] and the pace at which they will receive them in order to cover the targeted groups. While products are in short supply compared to countries' overall demand, the allocation can proceed in a progressive manner as more quantities become available.

For certain types of products and/or eventually for some stages of the allocation process**, countries may need to be prioritized** according to clear, objective and transparent criteria that include the threat that COVID-19 poses to them and the vulnerability of their health systems. In general, countries with populations exposed to a higher threat and vulnerability might receive products at a

[6] An allocation round is when new volumes are made available by manufacturers for allocation to countries through global access mechanisms, and procurement and distribution are set up to deliver the products to countries.

faster pace. Depending on the product and its availability, a phase of proportional allocation to all countries may be introduced. In any case, all countries should receive at least a portion of the target volumes in each round.

The general considerations outlined here provide the rationale for allocating new or repurposed therapeutics, vaccines or diagnostics that can help to combat the COVID-19 pandemic while their supply cannot match global demand. The uncertainties of the product characteristics and the inherent differences and interrelatedness of diagnostic, preventive and therapeutic health products require the development of specific allocation mechanism for each of these types of products.

Such a mechanism has been developed for vaccines associated to the COVID-19 Vaccines Global Access (COVAX) mechanism, and is under development for therapeutics and diagnostics (see Annex 3).

Box 1. Policy recommendations for the allocation of COVID-19 health products

In general, WHO provides policy recommendations for the use of specific health products based on the product profile, scientific evidence on the product's safety and effectiveness in different populations, the programmatic appropriateness and country contexts, the interrelatedness with other health products and other relevant information.

It is understood that countries, in their sovereign capacity, will ultimately decide national allocation of products based on their own context and assessed risk, but WHO will make specific recommendations for COVID-19 vaccines, therapeutics and diagnostics as they become available.

The populations that may benefit from these products will depend greatly on the safety and effectiveness profile of each product, and the policy recommendations may favour the prioritization of some populations over others. Hence, the policy recommendations for each product will greatly influence the specifics of allocation once the products become available.

Annexes

Annex 1: Access to COVID-19 Tools Accelerator (Work in progress)

The Access to COVID-19 Tools Accelerator (ACT-A) was launched on 24 April 2020, with the vision of creating an end-to-end global solution to expedite the end the COVID-19 pandemic, and restore full societal and economic activity globally. To do this, ACT-A will accelerate the development, regulatory approval, scale-up, delivery and equitable allocation of COVID-19 tests, treatments and vaccines.

ACT-A joins four Pillars (Vaccines, Therapeutics, Diagnostics and the foundational Health System Connector), co-convened by leading partners (CEPI, FIND , Gavi, The Global Fund, The World Bank, Unitaid, Wellcome, and World Health Organization), working with governments, civil society and industry. Additionally, cross-cutting workstreams further facilitate the work of the Pillars, such as Access & Allocation, that aims to ensure equitable access to tools across ACT-A, as well as support on topics such as norms & standards, regulatory/prequalification, and policy & technical guidance.

Vaccines: ~2 billion doses of vaccines fairly distributed by the end of 2021.

Development of vaccines is long, complex, risky and expensive. The vast majority of vaccines in early development fail. There are also significant supply constraints. When a new vaccine is successfully developed there will be greater demand than there is supply. This is the kind of market failure that only a globally coordinated approach can solve.

ACT-A's main goals in the area of vaccines are supporting the development of the most promising candidates while, in parallel, securing supply, scaling up the manufacturing capacity, establishing an allocation mechanism, formulating vaccine use policy, and rapidly establishing the readiness for delivery at scale. Other critical goals include working to ensure that regulatory conditions and coordination are in place to allow the smoothest, most efficient, and safest transitions between early stages of development through to licensure, large-scale use and long-term safety and impact monitoring. Given the rapid development of these vaccines, the post-authorization monitoring in the routine use setting are critical for further guiding their optimal use.

This will result in accelerated access to vaccines for all countries and will provide countries with enough vaccines to immunize health care workers and the vulnerable in 2021 (i.e. ~2 billion doses).

Therapeutics: ~245 million treatment courses within 12 months delivered to LMICs.

Therapeutics can play a role in all stages of the disease: to prevent infection in most-at-risk groups, to suppress and prevent symptoms and the spread of infection to others; to treat mild disease and prevent progression to moderate or severe symptoms; to speed up recovery and save lives for severe disease cases. Even when an effective vaccine exists, COVID-19 cases will continue to occur and require treatment as vaccines may not protect all population groups (e.g. the elderly), some people will not take them, and for others it may not provide 100% protection.

ACT-A's main goals in the area of therapeutics are to accelerate the development of new, safe and effective therapeutics, adapted to all countries including LMICs; and to ensure manufacturing, procurement and delivery of successful candidates for LMICs.

Diagnostics: ~500 million simple, accurate and affordable diagnostic tests used in LMICs by mid-2021.

Diagnostics to help control the pandemic are in our hands today. Widely available tests are a prerequisite for fully resuming international mobility, travel and trade, but there is a clear danger that LMICs will miss out. Diagnostic capacity is also critical to enabling test-and-treat strategies, and roll out of targeted vaccination campaigns.

The main goal is to enable access to simple, accurate and affordable diagnostic tests which will be game changes for the COVID-19 response. This will include developing 2–3 affordable, well-performing antigen (Ag) rapid diagnostic tests (RDTs), building a supplier base to meet global needs with substantial price reductions. Furthermore, 500m tests will be procured for LMICs for the next 12 months, and laboratories will be strengthened in 20+ countries to support the operational introduction of these new types of tests.
Establishing equitable access to simple, accurate and affordable diagnostic tests will save 9 million lives and avoid 1.6 billion further infections.

Health Systems: Help countries use new tools as they become available and supply Personal Protective Equipment (PPE) and Oxygen

Health Systems act as a connector between the three Pillars. ACT-A's main goal under the Health Systems Connector is to build the required capacity and support the health infrastructure needed to deploy the new tools effectively and efficiently when they are ready, and to make oxygen and personal protective equipment available as high priority commodities.

Countries will be supported on key enablers, such as front-line service delivery capacity, supply chains, laboratory capacity, integrated monitoring of service capacity in highly affected countries, health financing, private sector engagement and integrated clinical care. This will involve knowledge-sharing, coordination and best practice transfers. Finally, this area of work also looks to support the introduction of innovative non-pharmaceutical interventions to complement the rollout of the ACT-A tools – including contact tracing tools, physical distancing approaches, isolation guidelines and community engagement needed to sustain them.

Access & Allocation: Attain a fair and equitable allocation

The main objective of this workstream is to enable equitable allocation of COVID-19 tools through a global allocation framework, which will be concretized in the form of mechanisms to allocate each of the tools where they are needed the most. This will enable the groups most vulnerable to the virus get the protection and help they need, wherever they are. This global allocation will also be key to enabling economic recovery, which will only be possible if all interconnected economies are able to restart at the same time

Annex 2: Ethical foundations of a global vaccine allocation framework for COVID-19: high-level overview

Considerations from WHO Working Group on Ethics and COVID-19
Geneva, 16 July, 2020

The importance of ethics in a global vaccine allocation framework

Frameworks for the allocation of scarce resources reflect a *choice* about how we think resources should be allocated when there is not enough to satisfy everyone's needs.[1] Out of the many ways that we might choose to allocate scarce resources, this choice represents the objective that is being *valued* most, e.g., using available resources to produce the best outcomes, to address the greatest needs, and so forth. Science and/or evidence alone cannot tell us which choice or aim is 'correct' or which aim society should value most. This requires a value judgement, which is the domain of ethics. Hence, frameworks for the allocation of scarce resources do not simply have an 'ethical dimension' or 'raise ethical considerations'. Rather, they address inherently ethical questions about which values we should prioritize using scarce available resources, as different values dictate different allocations. Consequently, the first step in developing a framework for the allocation of scarce resources requires explicit consideration and clarification of ethical values—values that technical considerations and mechanisms should subsequently operationalize. It is equally important to morally justify *who* is to make these decisions.

Basic assumptions

- When a vaccine is developed, there will not be enough to vaccinate everyone, at least not immediately. A choice will need to be made about how to allocate available vaccines, which entails choosing who should be prioritized for vaccination.
- All humans are of equal moral value and possess the same rights by virtue of being human..[2-3] Consequently, vaccines should not be allocated on the basis of irrelevant characteristics over which humans have no control and which are arbitrary from the moral point of view. Such characteristics include race, colour, ethnic origin, place of origin, ancestry, citizenship, sex, gender identity and expression, sexual orientation, creed, family status, marital status, or ability to pay.
- Any allocation should strive to be equitable and fair. Equity and fairness are ethical values whose normative requirements need to be explicitly articulated. Equity requires that similar cases be treated similarly, i.e., if the vaccine is allocated on the basis of need, those with similar needs should be treated similarly.[3] There are many competing, yet nonetheless reasonable, views about what fairness means and requires. An account of fairness that is intended to guide allocation must be explicitly articulated and defended, and then applied in a consistent manner.
- The COVID-19 pandemic is a global problem that requires a global perspective and global approach to vaccine development, production, and allocation. A co-operative global solution based on a robust idea of global justice between countries, requiring sacrificing some degree of national benefit, is supported by appeals to a wide range of different reasons and ethical theories, such as ideas of health security, self-interest, public goods, shared benefits (e.g. travel, trade etc.), prevention of harms, and so forth.[4]
- Allowing practices and structures to inform how we allocate available vaccines—structures that are largely based on a market, shaped by power and price,[4] will only lead to unethical and inhumane outcomes, particularly since a few (high-income) countries with the capacity to manufacture (or purchase) vaccines will secure the bulk of the supply at the expense of global justice and fairness. A reassessment of the current market-based concept of value which equates the value of a good with the price that someone is willing to pay, may be required. As we do not know which country will be the first to produce a vaccine, it is in everyone's interest to commit to cooperation and solidarity.

Ethical values that should guide a global vaccine allocation framework

There are several options that we might choose from to inform an ethical allocation of vaccines, each capable of being characterized as 'fair', including, but not limited to: allocating the vaccine in whatever way will bring about the best outcome (e.g., to those with the greatest risk of becoming infected and transmitting the virus); allocating the vaccine to those at greatest need (e.g., to those at greatest risk of becoming seriously ill if infected); allocating the vaccine in a way that compensates for past actions (e.g., to those who participated in vaccine trials) or past injustice (e.g., to those who have been marginalized or who have not been able to access other measures to protect themselves from infection); allocating the vaccine to each country based on population; allocating the vaccine randomly; or a combination of the aforementioned options.[5-6] Whatever allocation scheme is chosen, it will need to be practically feasible and ethically justified.

Among available options, our first priority aim should be to allocate the vaccine in a way that will bring about the best outcome in relation to ending the pandemic. This means that the focus should be on the impact upon population health, which is justified by the fact that we are dealing with a pandemic and that this is best for everyone overall, even if individuals might benefit more from a different form of distribution. Even when individuals do not directly benefit, they will likely benefit from such an approach indirectly. Achieving this value will require judgments based upon the best available evidence related to who best to vaccinate (e.g., first responders) as a means of reducing transmission or producing other population benefits. Priority should be given to producing health benefits (e.g., reducing mortality and morbidity), but social and economic benefits (e.g., averting poverty, etc.) are also of importance and may be considered.

The second priority aim should be to allocate the vaccine to those at greatest need, with a focus on those at greatest risk of becoming seriously ill if infected. However, given the scale of the pandemic, the first priority must be tackling the pandemic as a whole. It is expected that achieving the first priority may to some degree overlap with this secondary priority (i.e., seeking to bring about the best outcome in relation to ending the pandemic may involve vaccinating at least some who are at greatest need), and will also likely indirectly benefit those at greatest need.

Procedural fairness

No matter which choice one makes when allocating scare resources, someone will lose out, and not simply because they do not have a legitimate moral claim to the resource. Any allocation decision will be challenging because it implies that not everybody will receive the vaccine despite their equal moral value. Consequently, for any choice about the global allocation of vaccines to be legitimate and fair, the choice itself, the moral justification for that choice, and the process through which that choice is made should be communicated publicly, inclusive of the perspectives of those affected by the choice, and subject to revision based on new evidence or other relevant circumstances or information.

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Annex 3: High-level overview of access mechanisms for vaccines and therapeutics

Mechanism for vaccines

Vaccines with a broad safety and effectiveness profile would constitute powerful tools preventing infection with SARS-CoV-2 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 and groups in need of protection.

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 COVID-19 Vaccines Global Access (COVAX) Facility will bring all participating countries together, regardless of their income level, for the procurement and distribution of COVID-19 vaccines.

A mechanism to allocate vaccines from the COVAX access mechanism is under development by WHO Secretariat together with the ACT-Accelerator COVAX Partners, and is described in a separate document.

Mechanisms for therapeutics

As with vaccines, effective and safe therapeutics for patients with COVID-19 would be a powerful intervention for mitigating the effects of the pandemic. As with vaccines, manufacturing and scalability issues and unprecedented demand will pose substantial hurdles to access for many countries and populations.

Therapeutics with potential utility against COVID-19 differ widely in cost, safety profile, availability, and indication; thus, forecasting the likely demand for specific agents will likely be highly complex, depending on a host of factors such as individual country regulatory requirements, patient population, prescribing practices, and financing mechanisms. As at the time of writing, dexamethasone[7] is the first WHO-recommended therapeutic for COVID-19 (indicated in severely ill patients). Other therapeutics will follow in due course; WHO will actively monitor clinical data on the efficacy and utility of specific clinical therapeutics and update guidance accordingly.

Depending on the therapeutic, countries may opt for a national access mechanism (that is, a nationally-led strategy to negotiate access with the manufacturer), grouped access mechanisms (multiple countries negotiating a regional or other access initiatives) or a global access mechanism. For example, procurement of dexamethasone is largely amenable to national solutions, as it is a generic medicine on the WHO Model List of Essential Medicines, with a favorable safety profile and whose use is generally well understood. Other therapeutics, such as monoclonal antibodies, are still investigational and thus subject to closer regulation, more restricted availability and generally higher cost, all of which may argue for a regional or global access mechanism if results of clinical testing warrant large-scale deployment during the COVID-19 pandemic. Global access mechanisms, where indicated, should operate according to the basic tenets of the global allocation framework governing vaccines and therapeutics (solidarity, accountability, transparency, responsiveness to public health needs, equity and fairness, affordability, collaboration, and regulatory and procurement efficiency).

[7] Other steroids may also be effective, see WHO guidance issued 2 September 2020. https://www.who.int/publications/i/item/WHO-2019-nCoV-Corticosteroids-2020.1

If the global community determines that a global allocation mechanism for one or more COVID-19 therapeutics is indicated, it may be set up along lines similar to the proposed mechanism for the COVAX access mechanism, under the broad organizational principles of the global allocation framework.

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

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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.

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:

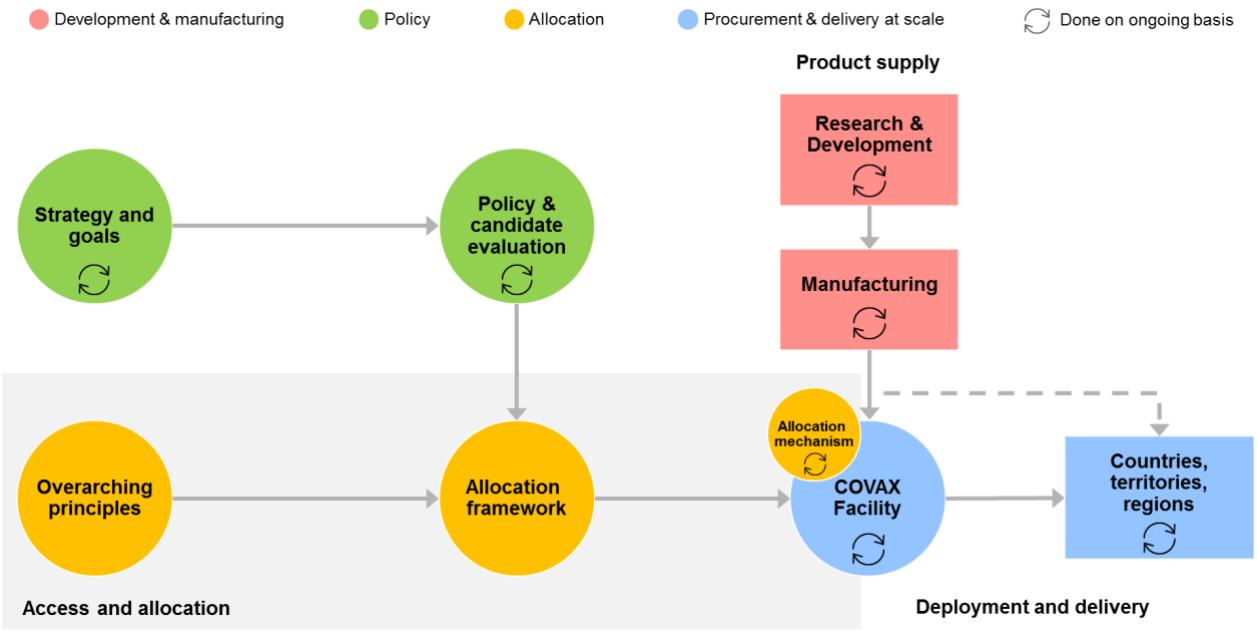
- to develop a large and diverse actively-managed portfolio of COVID-19 vaccine candidates to maximize the probability of success of several candidates, so that the best vaccines are ultimately made available and the supply will be sufficient for highest-priority populations globally for all self-financing 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**[8] 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**

[8] 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

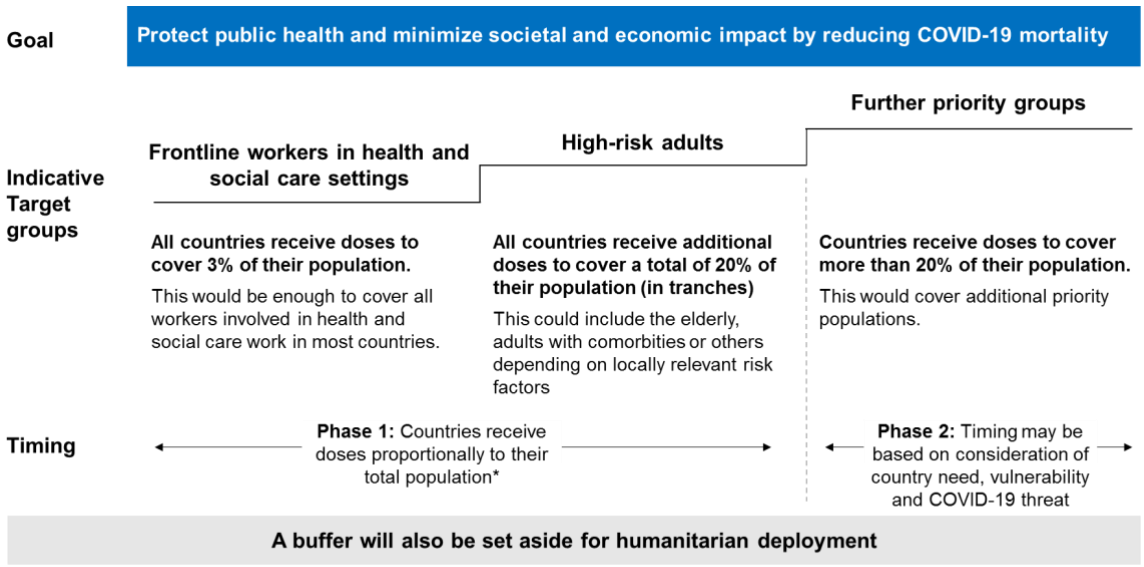
The impact of scarce vaccines will be greatest if the proposed access and allocation mechanism dictates the distribution of vaccines across all countries. For this reason, it is crucial that all countries have timely access to vaccines as they become available.

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.[9,10] This volume would enable, for example, the vaccination of frontline workers in health and social care settings[11] 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)*.

[9] 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.

[10] 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.

[11] 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.

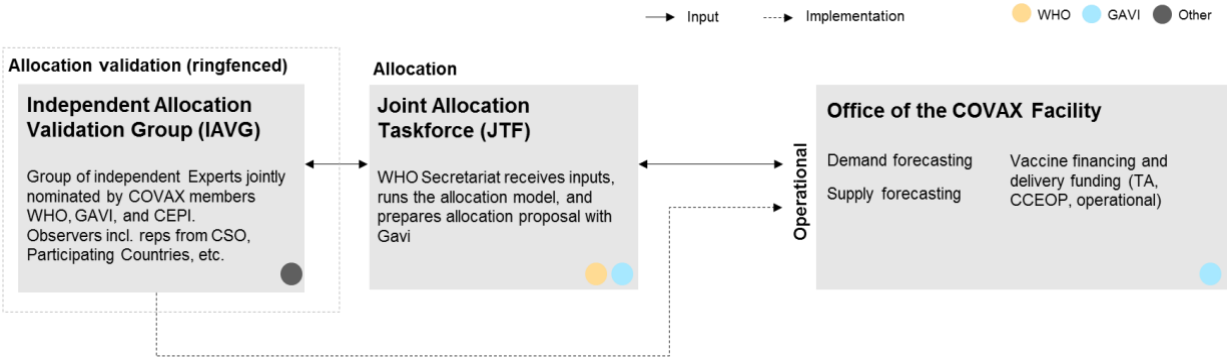
Table 1. Responsibilities and oversight for allocation as it relates to the COVAX Facility

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,[12] 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.[13, 14, 15]

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[16]. 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

[12] 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).

[13] 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).

[14] 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).

[15] 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).

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

risk profile of target COVID-19 population groups (for instance, older people). Therefore, an 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. [17]

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,[18] 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.

[17] 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).

[18] 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.