

26th Forum of National Ethics Councils and the European Group on Ethics in Science and New Technologies

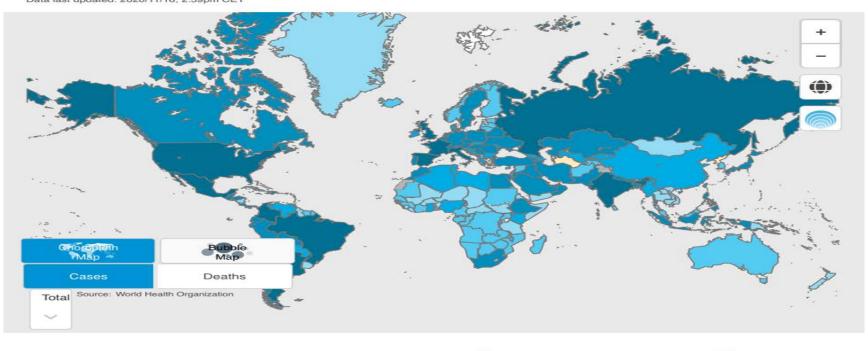
"Who First? Allocation of Vaccines against SARS-CoV-2"

COVAX a global response for equitable access to vaccines





WHO Coronavirus Disease (COVID-19) Dashboard Data last updated: 2020/11/16, 2:59pm CET



528,905 new cases 54,301,156 confirmed cases

1,316,994

Globally, as of 2:59pm CET, 16 November 2020, there have been 54,301,156 confirmed cases of COVID-19, including 1,316,994 deaths, reported to WHO.

Global Situation



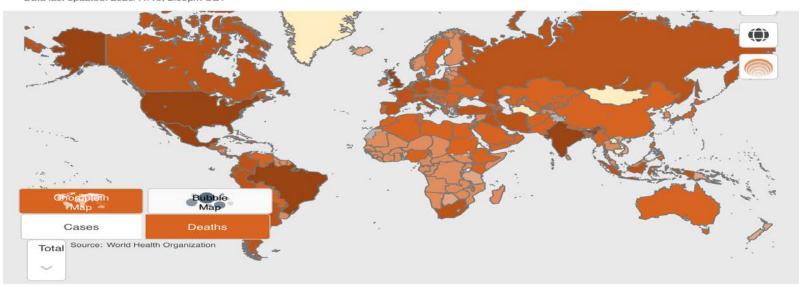






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WHO Coronavirus Disease (COVID-19) Dashboard Data last updated: 2020/11/16, 2:59pm CET



7,858 new deaths

1,316,994

54,301,156 confirmed cases

Globally, as of 2:59pm CET, 16 November 2020, there have been 54,301,156 confirmed cases of COVID-19, including 1,316,994 deaths, reported to WHO.

Global Situation





Weekly

54,301,156 confirmed cases



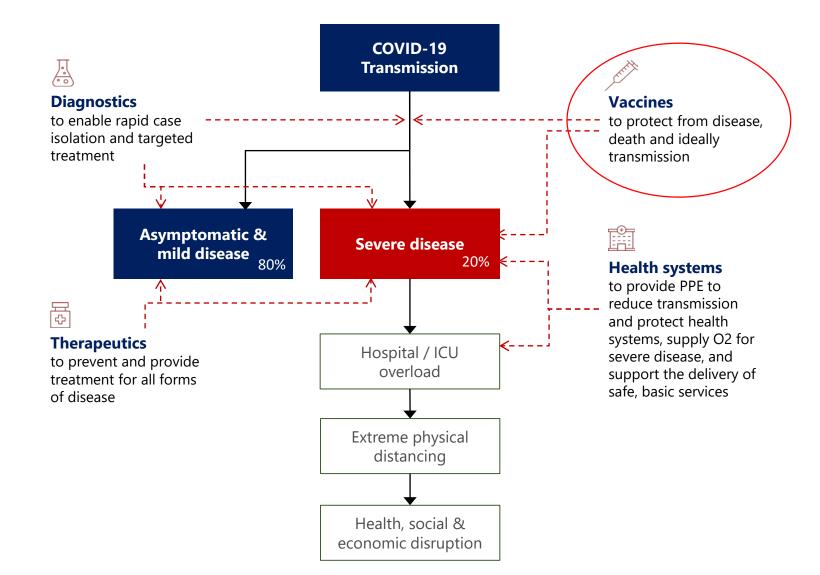
Access to COVID-19 Technologies – Accelerator ACT- A*

Launched 24 April 2020 co-hosted live event



^{*}WHO has established an ACT-A Ethics and Governance working group to offer advice and support the ACT-A activities,

ACT-A's strategy - accelerate global access to tools that reduce the risks of severe disease, thereby ending the pandemic's acute phase & restoring societal and economic health



Access &

Allocation

COVAX – the Vaccines Pillar – GAVI-CEPI-WHOWhat are COVAX goals?

To support the largest actively managed portfolio of vaccine candidates globally

To deliver 2 billion doses by end of 2021

To offer a **compelling return on investment** by delivering COVID-19 vaccines as quickly as possible

To guarantee fair and equitable access to COVID-19 vaccines for all participants

To end the acute phase of the pandemic by the end of 2021

- 47 candidates in clinical phase
- **10** in Phase III trials

154 candidates in pre-clinical phase

The world needs efficient, speedy, and reliable evaluation of many candidate vaccines against COVID-19

^{* &}lt;a href="https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines">https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines

The Global Allocation Framework builds on the overarching principles, and informs Allocation Mechanisms for specific products

A

Overarching principles for access

Global principles to ensure fair and equitable access to products

Presented in May 2020



Global Allocation Framework

A global Allocation Framework for all COVID-19 products

Final working paper shared on 9 September 2020

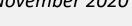


Fair and equitable Allocation Mechanisms

Mechanisms tailored for each product

Vaccines: shared 9 Sept 20

Initial view for Therapeutics: November 2020



Overarching principles to ensure equitable access to health products in the context of COVID-19



Solidarity: Joining forces to confront this unique challenge together and overcome this pandemic



Accountability: Clearly defined roles and responsibilities to ensure procedural justice



Transparency: To build and maintain trust



Responsiveness to public health needs: Health products are carefully selected and allocated to address the public health need



Equity and fairness: to inform the allocation process together with public health needs



Affordability: Consideration is given to pricing and procurement strategies to improve affordability of health products



Collaboration: Collaborative efforts amongst relevant global and national stakeholders is enhanced to accelerate and scaleup the response



Regulatory and procurement efficiency: Agile and comprehensive regulatory and procurement approaches are incorporated to improve timely access to safe, efficacious and quality health products for all countries in need

Major elements of the Global Allocation Framework for COVID-19 products

Goals

What are the overarching goals of the response?



Target groups

Which target groups should receive products in priority to help achieve this goal?
How should specific products be allocated given their characteristics?



Timing

At what pace will countries receive products given:

- their vulnerabilities (health systems and population factors)
- the dynamic nature of the threat?



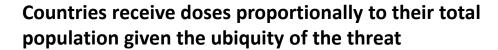
Boundary conditions

What other factors will impact the allocation of specific products given to countries:

- Product characteristics
- Country context?

We have developed an Allocation Mechanism for Vaccines

Phase 1: Proportional allocation up to 20% of population



Countries progressively receive doses until all countries reach 20% of their population (or less if they so requested).

The pace at which countries receive vaccines depends on country readiness¹ and the availability of doses (not on threat and vulnerability)

The allocation moves on to phase 2 once all countries have reached 20% coverage (or less if they so requested).

Phase 2 may start ahead of this if available doses are unable to be allocated due to lack of readiness, funding or territory issues



Phase 2: Weighted allocation beyond 20% (if supply severely constrained)

Timing may be based on consideration of vulnerability and COVID-19 threat:

In the case of a severely restricted supply, the timing of country shipments would be based on a risk assessment based on Threat and Vulnerability

Countries with a higher risk would receive the doses they need faster than others, although all countries will receive some doses in each allocation round

Threats and Vulnerabilities will be based on metrics defined closer to the end of phase 1, potentially related to the country's vulnerability to severe disease and its healthcare system.

All countries will receive the total doses they have requested as rapidly as possible in phase 2.

^{1.} Readiness will be assessed using a very limited set of objective criteria (e.g., regulatory approval)

SAGE roadmap towards prioritization of target populations: example for community transmission

Strategy: Initial focus on direct risk reduction of morbidity and mortality and maintenance of most critical essential services; also, reciprocity. Expand to reduction in transmission to further reduce disruption of social and economic functions

Stage I (1-10%)

Stage II (11-20%)

Stage III (21-50%)

Stage IA (initial launch)

 Health workers at <u>high to very high</u> <u>risk</u> of acquiring and transmitting infection

Stage IB

 Older adults defined by age-based risk specific to country / region

- Older adults not covered in Stage I
- Individuals with comorbidities or heath states determined to be at significantly higher risk of severe disease or death
- Sociodemographic groups <u>at</u> <u>significantly higher risk</u> of severe disease or death
- Health workers involved in immunization delivery
- High priority teachers and school staff

- Remaining teachers and school staff
- Other essential workers outside of health and education sectors
- Pregnant women
- Health workers <u>at low to moderate</u> <u>risk</u> of acquiring and transmitting infection
- Personnel needed for vaccine production and other high-risk lab staff
- Social/ employment groups at <u>elevated risk</u> of acquiring and transmitting infection because they are unable to physically distance

COVAX Facility: 184 Participants representing over 85% of the world's population (additional participants expected)

Participant Engagement

	Number of participants	Total Population, mn	Doses, mn
Fully Self- Financing	63	2,594	461
Team Europe	29	445	90
AMC92	92	3'919	950*
Total	184	6,958	1,601

^{*}The precise number could vary up or down dependent on final variables.

Funding

> \$1 Billion received in prepayments from Self Financing Participants

\$7 Billion

Needed in total – approx. 2Bn have been raised so far

100m additional doses allocated to the Humanitarian Buffer

The Allocation Mechanism for Vaccines interacts directly with the COVAX Facility

Input

Implementation

Operations

Decision

Allocation Mechanism

Joint Allocation Taskforce

Composed of staff from WHO and Gavi's Office of the COVAX Facility

Prepares allocation proposal for the IAVG based on allocation model

Independent Allocation Validation Group

Composed of independent Experts nominated by COVAX members

Validates Vaccine Allocation
Decisions based on JAT proposal,
ensuring it is technically informed
and free to conflict of interest

Implementation of the Allocation Decision by COVAX Facility, Procurement agencies and self-procuring Participants

agencies and Participants

Input relevant

to Allocation

the COVAX

from Office of

Facility, WHO,

Procurement

Solidarity trial for vaccines

WHY an international RCT of several candidate vaccines?

Evaluating several different candidate vaccines

Expeditiously enrolling participants at sites with high rates of COVID-19

Eliminating inefficiency of designing and conducting separate trials

International collaboration and countries' commitment

permitting selected vaccines to enter the trial whenever ready

flexible mix of fixed sites and pop-up sites

shared placebo group increases efficiency and attractiveness

fosters participation of sites with high COVID-19 rates

vaccines selection for trial assessed using a priori criteria

sufficient enrollment to assess efficacy and safety of all vaccines

If placebo can no longer be used, another vaccine becomes comparator

any effective vaccines will be tested at all sites

all vaccines selected for trial are eligible for testing at all sites

adaptive design accommodates unanticipated circumstances

ineffective vaccines don't much hinder evaluation of better vaccines

paves the way for international distribution of effective vaccines

INCREASING THE LIKELIHOOD
OF FINDING SEVERAL
EFFECTIVE VACCINES

RAPID ACCUMULATION OF DATA TO SUPPORT RIGOROUS EVALUATION

RESULTS WITHIN 3-6 MONTHS
AFTER EACH VACCINE IS
READY FOR INCLUSION

FOSTERS INTERNATIONAL DEPLOYMENT WITH EQUITY OF ACCESS

Thank you