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

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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.
WHO Coronavirus Disease (COVID-19) Dashboard

Data last updated: 2020/11/16, 2:59pm CET

7,858 new deaths
1,316,994 deaths
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

54,301,156 confirmed cases
Access to COVID-19 Technologies – Accelerator

ACT- A*

Launched 24 April 2020 co-hosted live event

With:

- UN Secretary-General
- Heads of State & Government
- Head of Agencies, Academia
- CSOs, Foundations, Industry

*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
- to ensure global equitable access to these tools

Diagnostics
- to enable rapid case isolation and targeted treatment

Vaccines
- to protect from disease, death and ideally transmission

Therapeutics
- to prevent and provide treatment for all forms of disease

Health systems
- to provide PPE to reduce transmission and protect health systems, supply O2 for severe disease, and support the delivery of safe, basic services

Asymptomatic & mild disease
- 80%

Severe disease
- 20%

COVID-19 Transmission

Hospital / ICU overload

Extreme physical distancing

Health, social & economic disruption

Asymptomatic & mild disease

Severe disease

Diagnostics

Vaccines

Therapeutics

Health systems
COVAX – the Vaccines Pillar – GAVI-CEPI-WHO
What 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
ALL vaccine candidates need to be evaluated*

- 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

* [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)

A Overarching principles for access
Global principles to ensure fair and equitable access to products

Presented in May 2020

B Global Allocation Framework
A global Allocation Framework for all COVID-19 products

Final working paper shared on 9 September 2020

C 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 scale-up 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

<table>
<thead>
<tr>
<th>Goals</th>
<th>Target groups</th>
<th>Timing</th>
<th>Boundary conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>What are the overarching goals of the response?</td>
<td>Which target groups should receive products in priority to help achieve this goal?</td>
<td>At what pace will countries receive products given:</td>
<td>What other factors will impact the allocation of specific products given to countries:</td>
</tr>
<tr>
<td></td>
<td>How should specific products be allocated given their characteristics?</td>
<td>• their vulnerabilities (health systems and population factors)</td>
<td>• Product characteristics</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• the dynamic nature of the threat?</td>
<td>• Country context?</td>
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**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?
We have developed an Allocation Mechanism for Vaccines

**Phase 1: Proportional allocation up to 20% of population**

Countries receive doses proportionally to their total population given the ubiquity of the threat

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.

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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%)
- Health workers at high to very high risk of acquiring and transmitting infection

Stage IA (initial launch)
- Older adults defined by age-based risk specific to country / region

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

Stage II (11-20%)
- Remaining teachers and school staff
- Other essential workers outside of health and education sectors
- Pregnant women
- Health workers at low to moderate risk of acquiring and transmitting infection
- Personnel needed for vaccine production and other high-risk lab staff
- Social/ employment groups at elevated risk 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*)

<table>
<thead>
<tr>
<th>Participant Engagement</th>
<th>Number of participants</th>
<th>Total Population, mn</th>
<th>Doses, mn</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fully Self-Financing</strong></td>
<td>63</td>
<td>2,594</td>
<td>461</td>
</tr>
<tr>
<td><strong>Team Europe</strong></td>
<td>29</td>
<td>445</td>
<td>90</td>
</tr>
<tr>
<td><strong>AMC92</strong></td>
<td>92</td>
<td>3'919</td>
<td>950*</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>184</td>
<td>6,958</td>
<td>1,601</td>
</tr>
</tbody>
</table>

*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

Presenter: Kate O’Brien
The Allocation Mechanism for Vaccines interacts directly with the COVAX Facility

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

**Input**
- Relevant to Allocation from Office of the COVAX Facility, WHO, Procurement agencies and Participants

**Implementation**
- Of the Allocation Decision by COVAX Facility, Procurement agencies and self-procuring Participants
Solidarity trial for vaccines

WHY an international RCT of several candidate vaccines?

- Evaluating several different candidate vaccines
  - permitting selected vaccines to enter the trial whenever ready
  - all vaccines selected for trial are eligible for testing at all sites
  - vaccines selection for trial assessed using a priori criteria
- Expeditiously enrolling participants at sites with high rates of COVID-19
  - flexible mix of fixed sites and pop-up sites
  - sufficient enrollment to assess efficacy and safety of all vaccines
  - adaptive design accommodates unanticipated circumstances
- Eliminating inefficiency of designing and conducting separate trials
  - shared placebo group increases efficiency and attractiveness
  - If placebo can no longer be used, another vaccine becomes comparator
  - ineffective vaccines don’t much hinder evaluation of better vaccines
- International collaboration and countries’ commitment
  - fosters participation of sites with high COVID-19 rates
  - any effective vaccines will be tested at all sites
  - paves the way for international distribution of effective vaccines

**Results**

- 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