

A proposal to establish a globally fair allocation system for COVID-19 vaccines
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Developing COVID-19 vaccines that can be used globally is a critical priority for ending the pandemic and restoring economic equilibrium. This effort should be guided by three goals that public health and social justice require be achieved simultaneously: the development of safe and effective vaccines at unprecedented speed, their manufacture and deployment at scale, and global access to such products.

CEPI estimates that developing up to three vaccines over the next 12-18 months will require an investment of at least US\$2 billion. This estimate includes the cost of development for up to three vaccines but does not include costs for manufacturing or delivery. Progress has been rapid: a candidate supported by the U.S. National Institutes of Health and CEPI initiated a Phase 1 trial on March 16, 2020, just 66 days after the SARS-CoV-2 genetic sequence was released, and clinical trials for other candidates will start soon.

Need for a Globally Fair Allocation System [since GFAS is meaningless, if we want a catchy acronym we could call it the Fair Allocations of Innovations for Pandemic Relief (FAIR) system]

This white paper focuses on the need, once such vaccines are developed, for a Globally Fair Allocation System to deliver them to persons at highest risk in rich, middle income, and poor countries. The need for vaccine during a pandemic is global and simultaneous, although differentially distributed within populations (assuming vaccine is prioritized for healthcare workers and those at greatest risk of severe illness and death), and we must avoid any scenario in which high-income countries monopolize the global supply. This risk is real: during the 2009 H1N1 influenza pandemic, rich countries negotiated large advanced orders for the vaccine, crowding poor countries out.ⁱ Seth Berkley, the CEO of Gavi, warns that COVID-19 vaccines could end up in just a handful of countries, which he asserts would be “a recipe for disaster, ensuring the disease continues to circulate globally, well after a means of stopping it is developed.”ⁱⁱ Such an outcome would result, in its public health and economic consequences, in a massively suboptimal allocation of what, at least initially, will almost certainly be a scarce resource.

A far better solution would be for governments to ensure that a globally fair allocation system is established. With sufficient political will and public sector financing, such a system could be established in a fairly straightforward manner, using existing instruments and institutions. The rudiments of the system would require a global purchasing agent or agents, a substantial but limited-term advance purchase commitment, and access through the system to financial instruments such as concessional loans or grants and indemnification from liability to offset the risks taken by participating private sector partners. Vaccine purchased through the system should be free at the point of care worldwide for prioritized segments of the population, with national allocations determined through a fair and objective process. Vaccine produced over and above the requirements of the advance purchase commitment could be made available commercially for those not in prioritized groups.

Fundamental requirements for a Globally Fair Allocation System

The fundamental requirements for a Globally Fair Allocation System are (1) the ethical and normative consensus that such a system is required; (2) the political will to implement or create such a system; and (3) the funding, financial instruments, and scale required to incentivize participation by public and private sector partners in such an arrangement.

- (1) Ethical and normative consensus: such a consensus could be articulated by international organizations such as the WHO, other UN partners (UN, UNICEF), Gavi and the Global Fund as well as civil society partners such as IFRC and MSF. This consensus exists; it merely needs to be captured and articulated.
- (2) Political will: the mobilization of political will to create and finance a Globally Fair Allocation System must emerge, first and foremost, from cooperative international intergovernmental organizations and forums such as the Group of Seven (G7) and the Group of Twenty (G20). The World Economic Forum could play an important advocacy role in helping to mobilize political will and private sector support for such a system.
- (3) Funding, financial instruments, and scale: the funding required to support such a system at the scale that will be required will likely be in the tens of billions of dollars over several years and should be provided through the coordinated action of governments, development banks, and (potentially, given the criticality of COVID-19 vaccines to restoring economic security) sovereign wealth funds. The system should be scaled to provide a minimum of 1-2 billion doses of vaccine per year for a minimum of three years. Critical to the success of the system, as described below, will be the coordinated use of financial instruments such as concessional loans, grants, advance purchase commitments (APCs), and potentially government-backed vaccine bonds to support the necessary scaling of manufacturing, procurement of vaccine, and delivery of product. The system should also address the outstanding concerns of private sector partners about liability and indemnification in the event of severe adverse events caused by licensed vaccines procured through the system. These financial instruments and the collective solution to the problem of indemnification should be reserved exclusively for private sector partners who agree to participate in the Globally Fair Allocation System. The restricted availability of such instruments and support will be the strongest incentive to participate in the system.

The elements of a Globally Fair Allocation System

Fairness, in this context, means procedural fairness. The goals of establishing a Globally Fair Allocation System are to create

- A fair and transparent system for prioritizing and allocating a scarce, life-saving resource
- A mechanism for the procurement of vaccine to support the vaccination of 1-2 billion people annually for a minimum of three years
- A mechanism for countries to draw on their allocation when and as they are prepared to do so, without fear of losing access

- An efficient and effective remedy that addresses private sector concerns about potential liability for injuries caused by newly licensed medical products
- Financial instruments to support and de-risk the scaling up of global manufacturing capacity
- Rewards for private sector partners that are commensurate with the risks and opportunity costs they have assumed in developing COVID-19 vaccines and participating in the system

These elements can be addressed mainly through or by adapting existing institutions. The international organizations best suited to implement and oversee such a system are Gavi, the Vaccine Alliance (Gavi) and the Global Fund for AIDS, TB, and Malaria (GFATM), working closely in coordination with each other and with WHO. Given their current focus on developing countries, the mandates of these organizations may need to be extended with respect to the COVID-19 response to include the provision of medical materiel and services to all affected countries.

Brief working proposals for operationalizing these elements follow.

Prioritization and Allocation

The supply of vaccine will be insufficient to cover the entirety of the global population for several years. Many countries, including the United States, have developed prioritization schemes for the initial allocation of pandemic influenza vaccine, typically to healthcare workers and first responders followed by the segments of the population deemed to be at greatest risk, and these could serve as a starting point for COVID-19 specific prioritization schemes. WHO should be in a position within the next several months to provide epidemiologically-based normative recommendations.

Gavi and GFATM both have transparent processes for allocating medical resources based on disease burden and other factors. An allocation scheme taking into account the size of the healthcare workforce, populations within identified risk groups, healthcare system capacity, and other factors as appropriate within different countries can be developed in coming months and facilitate the design and implementation of appropriately scaled national vaccination programs.

Manufacturing and Procurement

A global purchasing agent or agents would be designated. For vaccines, Gavi and/or UNICEF would be the most obvious candidates for this role, although any organization with a pooled purchasing mechanism (e.g., GFATM, PAHO) could provide capacity. The advantages of establishing a monopsony or at worst a coordinated oligopsony where price negotiation is concerned will be obvious. A pooled procurement mechanism, in addition to enabling a Globally Fair Allocation System, would provide numerous efficiencies, including access to competitive market terms, the elimination of procurement delays due to complicated tendering processes, and a guarantee that quality assured goods and medicines reach those most in need in a timely manner.

The procurement mechanism that appears best suited to incentivize participation in a Globally Fair Allocation System is a limited-term (perhaps three-year) APC of 1-2 billion regimens per year. An APC of this scale will

- Within 1-2 years provide sufficient regimens to vaccinate healthcare workers, first responders, and high-risk populations worldwide, and thereafter provide vaccine for a substantial portion of the world's population, contributing to the development of global herd immunity
- Provide a satisfactory return on investment and favorable P&L for vaccine manufacturers who invest in developing new manufacturing capacity to meet global needs

Eligibility for the limited-term APC should be made contingent upon agreeing to equitable access commitments such as tiered pricing for lower- and middle-income countries (LMICs) after the APC expires.

Draw-down Rights

Countries should have a simple mechanism by which to draw down vaccine from their allocation in an incremental fashion when and as they are ready to deliver it. Allocations of vaccine regimens to countries, once committed, should not be subject to withdrawal or reallocation.

As was the case in 2009, a framework and readiness scoring system for countries to receive, distribute, and dispense vaccine should be developed, with a defined threshold required for the release of a country's allocated vaccine. This system could be implemented now, would support the allocation scheme, and can build on GAVI and WHO work. The scoring will be transparent and countries can start building toward preparedness now, using funds for health system strengthening recently released by the World Bank as part of its COVID-19 Country Response. UNICEF could additionally support country readiness.

GFATM's online procurement tool, wambo.org, provides current GFATM partners an easy-to-use online platform that could be adapted to allow country health programs to place orders against their allocated vaccine, increasing visibility and situational awareness for end users, simplifying the ordering process, and improving administrative lead time.

Liability and Indemnification

Concerns about liability contributed to significant delays in delivering donated pdmH1N1 vaccine to developing countries in 2009-10 and have been a perennial concern of private sector partners engaged in the development of medical countermeasures against agents of bioterrorism and emerging threats. An insurance mechanism developed by WHO addresses liability concerns for investigational (unlicensed) products delivered in the context of a public health emergency under the provisions of the Emergency Use Listing (EUL) Procedure, but it provides no protection for licensed or registered products. Providing comprehensive

indemnification against harms caused by vaccines administered under the terms of the APC would greatly incentivize participation for private sector partners.

To eliminate the need for bilateral negotiations between countries and vaccine developers, which would significantly delay the delivery of vaccine, a small percentage of the World Bank funds released to LMICs as part of the COVID-19 Country Response could be set aside to fund a regional vaccine injury compensation fund and regional vaccine 'courts' or other scientifically based system to adjudicate claims of harm from vaccine. Vaccine injury compensation programs, first established in the United States, have now been adopted as the preferred mechanism to limit liability for vaccine manufacturers in many developed countries.

In the United States, the Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of the Department of Health and Human Services to issue a declaration that provides immunity from liability (except for willful misconduct) for claims of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined by the Secretary to constitute a present, or credible risk of a future public health emergency to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures. Model PREP Act legislation (which could be limited exclusively to COVID-19) has been drafted and could be adopted by individual countries in parallel with the establishment of regional vaccine injury compensation programs as described above.

Having liability/indemnification provisions such as these in place would contribute significantly to a country's 'readiness score' to receive vaccine and thus contribute to fair and transparent global allocation.

Appropriate Financial Instruments

Funding for late stage development for promising vaccine candidates will require the coordinated use of financial instruments such as concessional loans, grants, and potentially government-backed vaccine bonds to support the necessary scaling of manufacturing, globalization of capacity, procurement of vaccine, and delivery of product.

Different instruments will appeal to differently situated partners depending on their peculiar needs or the expectations and requirements of their respective investors or shareholders. Relevant instruments are offered by a number of regional development banks, IFFIm, CEPI, and others.

These financial instruments and the collective solution to the liability problem described above should be reserved exclusively for private sector partners who agree to participate in the Globally Fair Allocation System. The restricted availability of such instruments and support will be the strongest incentive to participate in the system.

Financial Rewards for Private Sector Participants

Even if grants and other sources of public sector funding were to cover all of the nominal costs of research and development, private sector vaccine developers would still be taking huge risks and paying significant opportunity costs to divert their enterprises from scheduled activities to the fulltime pursuit of a COVID-19 vaccine. It is wholly appropriate to reward those who are willing to take risks in the public interest, particularly if they are willing to participate in the cooperative management of a (time-limited) global public good.

The proposed APC would terminate at the end of three years, after which the vaccines delivered under its auspices would become normal commercial products with tiered pricing arrangements for LMICs. If, as many epidemiologists anticipate, SARS-CoV-2 becomes endemic and continues to circulate widely, particularly if natural immunity wanes over time, the value of COVID-19 vaccines will be high. Additionally, any manufacturing capacity funded as part of the scale-up or scale-out of COVID-19 vaccines would be granted to the private sector partner at the expiry of the APC (albeit with contingencies to return it to public service in the event of future pandemics).

The grand bargain struck between the public and private sectors in the effort to vanquish COVID-19 and to establish a Globally Fair Allocation System should be a fair deal for everyone.

ⁱ Fidler DP. Negotiating equitable access to influenza vaccines: global health diplomacy and the controversies surrounding avian influenza H5N1 and pandemic influenza H1N1. *PLoS Med* 2010; 7(5): e1000247.

ⁱⁱ <https://www.gavi.org/news/media-room/gavi-board-calls-bold-engagement-respond-covid-19>