VIEWPOINT

COVID-19: BEYOND TOMORROW

The Equitable Distribution of COVID-19 Therapeutics and Vaccines

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Scientists from across the globe are racing to develop effective vaccines and therapeutics for coronavirus disease 2019 (COVID-19). On March 16, phase 1 clinical trials started with a vaccine candidate developed by a US-based company, supported by the National Institutes of Health and the Coalition of Epidemic Preparedness Innovations (CEPI). The next day, a Chinese biotechnology firm announced government authorization to begin clinical trials. Eight vaccine candidates are in clinical trials and more than 100 more are in preclinical development in more than 12 countries. Dozens of therapeutics are also in preclinical and clinical development.

Plans are beginning to emerge for ensuring the equitable worldwide distribution of vaccines and therapeutics resulting from biomedical innovations. Absent broad agreement and buy-in on those plans, governments may prioritize their own populations, resulting in inequitable distribution of medical products both within and among countries. During the 2009 influenza A(H1N1) pandemic, wealthy nations bought virtually all vaccine supplies.[1] Even after the WHO appealed for donations, supplies for low- and middle-income countries (LMICs) were limited.[2] The White House may have already sought exclusive access to a COVID-19 vaccine candidate.[3] European and Asian countries have imposed export controls on personal protective equipment and ventilators, with similar export controls likely to extend to COVID-19 vaccine and therapeutic stocks.[4]

The development and widespread distribution of COVID-19 medical treatments are a common global interest. Without effective vaccines, severe acute respiratory syndrome coronavirus 2 will circulate in humans unabated, threatening health and economic security. COVID-19 has caused scarcity of medical resources in health systems and has severely affected the global economy. Until effective medical interventions are developed and widely deployed, the novel coronavirus is likely to continue spreading.

An Opportunity for Equitable Distribution

A transformative therapeutic is months away, and a vaccine will take at least a year, likely longer. Once COVID-19 vaccines and therapeutics are approved, doses must be manufactured to scale. Now is the time to plan for manufacturing capacity, financing, and distribution infrastructure necessary to produce sufficient quantities to meet global needs in a fair, public health–driven manner.

Without the promise of equitable access, LMICs may be slow to share data and isolates for research and development. In 2007, Indonesia refused to provide influenza A(H5N1) virus samples to WHO and expressed concerns that the benefits would not be fairly shared. The WHO Pandemic Influenza Preparedness (PIP) Framework, concluded in 2011, granted researchers access to biological samples in exchange for financial or in-kind donation of products. The PIP Framework offers useful lessons, but it is nonbinding and does not apply beyond novel influenza viruses.[5]

Governments currently have the greatest incentive to collaborate while uncertainty remains as to which nations' vaccines and therapeutics will succeed. Over the last decade, research and development and manufacturing capabilities have become more globally distributed. The best treatments and vaccines against COVID-19 may be developed and manufactured outside traditional centers of pharmaceutical innovation. Wealthy countries cannot count on outbidding competitors if vaccine and therapeutic supplies are kept by countries that manufacture them. Cooperation remains a matter of necessity for and within all nations to ensure equitable distribution of therapies.

Framework for Distribution

Achieving global, equitable access to COVID-19 vaccines and therapeutics will be difficult. Amid rising populism, governments have resisted multilateral institutions and international agreements. Many countries have responded to this pandemic by turning inward: closing borders, hoarding medical resources, and scapegoating foreigners.

The world, however, is better prepared to respond than ever before. The following proposed framework leverages existing international forums to facilitate equitable distribution of COVID-19 countermeasures.

Flexible, Trusted Governance

Any governance framework to promote equitable access to COVID-19 countermeasures will need to earn the confidence of the international community. The framework requires rapid action, giving countries wishing to join a seat at the table (conditioned only by criteria relevant to pandemic control) and resisting undue political or commercial influences. Given the need for trust, reliability, and speed, leveraging well-established international forums is preferable to building something new.

The G7 (Canada, France, Germany, Italy, Japan, the UK, and the US) has historically raised the political profile of global health and could host international negotiations. A decade ago, the G7 negotiated an advance market commitment (AMC) to develop, manufacture, and deliver pneumococcal vaccines in LMICs.[6] The World Bank and the Gavi Alliance helped design and launch the $1.5 billion pilot, guided by an advisory group of experts and stakeholders including from national ministries of health and civil society organizations. That AMC has led to 3 vaccines, with immunization of an estimated 150 million children in 60 countries and saving an estimated 700 000 lives.[7]

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Developing a framework for fair and equitable distribution of COVID-19 vaccines and therapeutics is far more complex and will require coordination of multiple institutions, funders, governments, and pharmaceutical companies. The recently launched, European Commission–backed Access to COVID-19 Tools (ACT) Accelerator is a step in the right direction, an initiative devoted to rapid development and equitable deployment of therapeutics, vaccines, and diagnostics. More than a dozen countries and philanthropies pledged financial support to this initiative, but it has yet to attract contributions from major pharmaceutical powers such as China, India, and the US. This early progress should be expanded on at the June 2020 G7 summit, incorporating G20 states, particularly those developing COVID-19 countermeasures.

WHO must play a central role in planning and coordinating the implementation of the framework. WHO has indispensable expertise, credibility, and experience in promoting equitable access to medical technologies. This planning strategy should also engage entities that develop vaccines, treatments, and diagnostics and support pooled procurement in LMICs, including CEPI, Gavi, and the Global Fund.

Adequate, Predictable Financing

A financing mechanism to provide revenue for research and development and deployment of vaccines and therapeutics in LMICs is vitally important. Financing mechanisms would include advance purchase commitments (APCs) for COVID-19 products distributed under WHO's allocation guidelines and target product profiles, establishing technical criteria for products to be eligible under APCs.

The substantial funds required would include a mix of country and philanthropic contributions, leveraged to raise additional funds on capital markets, similar to bond offerings used to fund immunization in LMICs. Global leaders have recently pledged roughly $8 billion to the ACT Accelerator for COVID-19 product development and distribution. Other country contributions could be subscription based, with the cost of participation in the APC tied to the country's ability to pay. Participation of low-income countries would be heavily subsidized or free. Gavi and the Global Fund have analogous country eligibility policies based on income classification and disease burden.

The terms of the financing commitment must be clear, predictable, and multiyear to reduce uncertainty. Manufacturers will be hesitant to participate without indemnification, product liability insurance, or a capped injury compensation program to mitigate risk. A transparent regulatory pathway for approval of COVID-19 products will instill global confidence, reduce development costs, and expedite access in less remunerative markets. Regulators may leverage networks, such as the International Coalition of Medicines Regulatory Authorities, to share information with peers and collaborate on global regulatory challenges.

The World Bank could act as a host of the financing mechanism, with Gavi and the Global Fund as co-leaders on vaccines and therapeutics, respectively. The World Bank never successfully implemented its Pandemic Emergency Financing Facility, but that failure should not erase the bank's positive track record with pneumococcal vaccine AMCs, its experience operating dedicated trust funds, and its credibility. A board composed of governments, technical agencies, funders, and civil society could oversee an APC fund.

Open Collaboration and Evidence-Based, Health-Driven Allocation

Global allocation of COVID-19 therapeutics and vaccines should be guided by accurate and comprehensive information about the size, distribution, and risk profiles of affected populations, country capacities to implement immunization campaigns, and essential (sometimes politically sensitive) health surveillance data. Success rests on countries collecting and sharing data.

With benefits should come obligations. Participation in this global allocation plan should require commitment to open scientific collaboration, transparency, and sharing data and biological samples. Participants should adopt common guidelines for product oversight and share data on premarket and postmarket safety and effectiveness. Participating governments should commit to forgo export restrictions on vaccine and therapeutic stocks.

It is likely that a successful vaccine or drug treatment will be in limited supply, and any agreement should also include a commitment to ensure equitable distribution. Under ordinary circumstances, medical technologies are priced within many nations, including the US, at what the market will bear and available to those able to pay. Vaccines and key therapeutics against COVID-19 must be deployed broadly to prevent infection, reduce transmission, and build herd immunity. Governments must take all measures necessary to ensure that these medical products are affordable, equitably accessible by vulnerable and marginalized groups, and distributed according to public health need. This will require governments to set clear guidelines for the fair and equitable distribution of treatments for their own populations.

If nations pursue a competitive race to develop effective vaccines and therapeutics, there will be only be losers, no winners. The threat posed by the novel coronavirus knows no borders. Only a well-coordinated global plan that harnesses the best science and delivers it to everyone in need can effectively counteract the COVID-19 scourge and future pandemics.

ARTICLE INFORMATION

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