

VIEWPOINT

Sharing Technology and Vaccine Doses to Address Global Vaccine Inequity and End the COVID-19 Pandemic

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Although COVID-19 cases are declining rapidly in the US, they have reached record highs in low- and middle-income countries (LMICs). The nucleus of the pandemic has shifted decidedly to the global south. The South-East Asia region and Latin America now represent 75% of global weekly deaths.¹ On June 22, the Latin America region reported more than 1 million weekly new cases and 30 000 new deaths. Latin America has the highest deaths per capita, where deaths in countries such as Brazil, Argentina, Mexico, and Peru have reached 177 to 564 per hundred thousand.¹ The Africa region has had increasing numbers of cases, with Uganda and Zambia experiencing 10 000 and 17 000 new weekly cases, respectively. Increasingly, the pandemic is where the vaccines are not.

Approximately 1.2% of the global vaccine supply has been received by low-income countries and just 14% by lower-middle-income countries, which account for nearly 40% of the world's population.² In contrast, more than half the US adult population is fully vaccinated, including most health workers and individuals from vulnerable populations. Yet sub-Saharan Africa has doses to cover only an estimated 18% of health workers and older individuals. South Asia has not vaccinated all priority groups, and vaccine supplies would fully vaccinate just 9% of the total population.

Vaccine inequity is driven by insufficient supply and unfair allocation. Powerful high-income countries pre-purchased sufficient doses for their entire populations, sometimes twice the number needed. In contrast, COVAX, a global initiative to procure and equitably allocate vaccines, failed to secure enough doses even for its modest goal of covering 20% of lower-income country populations this year.³ Pfizer, for example, agreed to sell COVAX only 40 million doses, and had delivered just over 1 million by mid-May.⁴

On June 13, the G7 countries pledged to share 1 billion vaccine doses, half of which would come from the US. But this represents only a fraction of the approximately 11 billion doses needed to vaccinate the world. Support for LMICs to enable them to produce vaccines for their populations and significantly more donations are necessary to vastly increase supplies and ensure equity. The US and allied governments could take several steps to overcome barriers to vaccinating the world.

Waiving Intellectual Property

One important step is an intellectual property (IP) waiver. The Biden administration recently reversed US policy and was joined by France in endorsing a proposal by India and South Africa to temporarily waive countries' World Trade Organization (WTO) obligations to enforce IP on COVID-19 technologies. The proposal still faces nego-

tiations over its scope and opposition by certain high-income countries.

A WTO waiver would not remove US patents on vaccines. It would simply give governments the option to allow local manufacturers to produce, import, and export SARS-CoV-2 vaccines. Investments in production facilities could occur without concern about lawsuits or prosecution for IP infringement. Although countries have rights to issue compulsory licenses under the Trade-Related Aspects of Intellectual Property Rights (Article 31) agreement, the rules are legally complex. Messenger RNA (mRNA) vaccine technologies are covered by more than 100 patents, with many different patent holders.⁵ Procedures on importation of medical technologies for countries without manufacturing capacity are so cumbersome they have been used only once, by Canada and Rwanda, in a process that took years. A blanket waiver would eliminate complex regulations to facilitate vaccine manufacture.

There are some concerns that a waiver could threaten innovation. Yet COVID-19 vaccines were developed with significant public funding, also yielding high profits. Monopoly protection in every country is unnecessary for innovation. Patents have not incentivized companies to provide vaccines to LMICs. Intellectual property waivers could actually spur new discoveries and better vaccines, such as single-dose vaccines. Giving countries the freedom to produce vaccines could address both market and ethical failures.

With the pandemic escalating in LMICs, a broad, simple IP waiver that covers all IP, including patents and trade secrets, and extends to all COVID-19 technologies is urgent. Negotiators must avoid delay. Waiver negotiations among WTO members in 2003 took 9 months and governments have so far been slow in negotiating the current IP waiver proposal. Movement toward a waiver also might support voluntary action. Following President Biden's announcement supporting an IP waiver, Moderna and Pfizer-BioNTech both pledged additional doses to LMICs, a welcome sign that waiver negotiations might incentivize sharing.

Sharing Technology and Expanding Manufacturing Capacity

On June 21, South Africa, the World Health Organization (WHO), and the Africa Centers for Disease Control (CDC) announced an important new hub for producing mRNA vaccines for the African continent and asked the US and Europe to share the technology to make these vaccines. Waiving IP removes legal barriers, but sharing knowledge on how to make vaccines, including ingredients, methods, sourcing, and technologies, is a justice-oriented move that would help LMIC manufacturers

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move quickly. When Moderna needed added manufacturing capacity, it contracted Swiss company Lonza and transferred technology confidentially. Production started within a few months, showing that arguments suggesting local manufacturing will take too long are unfounded. But exclusive contract manufacturing agreements limit access. Sharing technology more openly could enable manufacturers in Africa, Asia, and Latin America to make vaccines for themselves. WHO created a platform for such technology transfer; however, US-based companies have thus far not shared vital information.

The Biden administration has leverage to incentivize sharing, given extensive public funding. mRNA vaccines are a prime target for sharing because manufacturing advantages make them rapidly scalable.⁶ The Moderna mRNA vaccine was developed jointly with the National Institutes of Health, which also holds key patents. Operation Warp Speed allocated Moderna \$2.5 billion, covering development and clinical trials. Public funding should come with ethical obligations to share knowledge for the global public good. If necessary, the Biden administration could use the Defense Production Act and government-owned patents to compel technology sharing or could pay companies to share technology.

If technology is shared, Senegal's Pasteur Institute has plans to make hundreds of millions of viral vector doses. Companies in South Africa, Vietnam, Brazil, India, and other countries could make mRNA vaccines with appropriate support for specialized processes involved. A Thai government-run manufacturer, which could be a model, is already working on mRNA vaccine production. A Chinese company will produce BioNTech's vaccine, although only for Chinese markets. Far more is achievable.

Quality control is critical, but arguments that LMIC producers cannot produce quality vaccines are misplaced. Many are global companies and government-run facilities with excellent records and strong oversight. WHO's prequalification/emergency use process can help ensure quality.

Sharing technologies openly could also allow scientists worldwide to collaborate on innovations; for example, on mRNA vaccine formulations stored at room temperature for lower-resource settings.

The US, WHO, and partners could support hubs to teach manufacturers how to make approved vaccines and fund expanded production in Africa, Asia, and Latin America, learning from efforts after influenza A (H1N1) outbreaks. Imperial College researchers

estimate a cost of \$2.2 billion to retrofit factories to produce 8 billion doses of COVID-19 vaccine.⁷ Expanding production of components such as disposable bioreactor bags to speed sterile production will also be needed.

Reallocating Procured and Ordered Doses

While production is expanded, the fastest way to vaccinate high-risk populations globally is reallocating doses already ordered by high-income countries. Of COVAX's 2-billion-dose goal for 2021, it has delivered only 88 million, less than a third of its forecast to reach even 3% of LMIC populations by June. A small number of companies are determining global allocation. Vaccine manufacturers could give priority to LMIC orders, whereas high-income countries could donate more doses already delivered. The MasterCard Foundation recently gave the Africa CDC \$1.3 billion for vaccine procurement and production, but African countries still need access to supplies. The US, for example, has shipped more than 350 million doses to states, but ordered 1.2 billion doses.⁸ Globally, 34 countries had donated doses by May, with hundreds of millions more pledged to COVAX.⁹ But LMICs account for 6.5 billion people; high-income countries have purchased 5.9 billion doses. Faster and broader donations could help vaccinate health workers and vulnerable populations globally.⁸

Equitable Allocation in Future Global Health Crises

Every US president since Jimmy Carter in 1976 has faced a pandemic.¹⁰ A broader COVID-era pandemic-response strategy guided by 3 principles could help avoid future shortages and inequities. First, pandemics require surge funding. COVAX was established rapidly without inclusive governance or sufficient funding. A more robust financing mechanism could be triggered by WHO's declaration of a public health emergency of international concern. Second, increasing funding to address today's multiple pandemics builds capacity for future responses; for example, through the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the President's Emergency Plan for AIDS Relief. Third, the US could back a more permanent solution at the WTO. A temporary waiver on IP need not be negotiated ad hoc in a crisis. Instead, an agreement to share technology and allow countries to waive IP in global public health emergencies could become the norm.

ARTICLE INFORMATION

Published Online: July 1, 2021.
doi:10.1001/jama.2021.10823

Conflict of Interest Disclosures: None reported.

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