Strengthening pandemic preparedness: Build the vaccine manufacturing capacity in low- and middle-income countries

Wu Zeng a,*, Daana Bajnauth b, Eva Jarawan a, Haksoon Ahn c, Guohong Li d,e, Yuyang Cai d,f, Ling Yang g, Jie Shen h,i

a Department of Global Health, School of Health, Georgetown University, Washington, DC, USA
b Georgetown University, Washington, DC, USA
c School of Social Work, University of Maryland, Baltimore, MD, USA
d School of Public Health, Shanghai Jiao Tong University School of Medicine, Shanghai, China
e China Hospital Development Institute, Shanghai Jiao Tong University, Shanghai, China
f China Institute for Urban Governance, Shanghai Jiao Tong University, Shanghai, China
g Department of Geriatrics, Xinhua Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai, China
h School of Public Health, Shanghai Jiao Tong University School of Medicine, Shanghai, China

It has been over two years since the World Health Organization (WHO) declared COVID-19 a global pandemic on March 11, 2020. The COVID-19 virus continues to mutate and spread, causing many countries to experience multiple waves of the pandemic. Although non-therapeutic protective measures have slowed the spread of the virus and decreased case numbers, the COVID-19 vaccines are taking precedence as the leading measure of therapeutic protection against the virus.

Low- and middle-income countries (LMICs), however, face challenges and uncertainty regarding vaccine access, despite the growing supply of COVID-19 vaccines. This paper describes the unequal access to COVID-19 vaccines, argues that vaccine nationalism and fragmented COVID-19 vaccine procurement are key reasons for the unfair distribution of COVID-19 vaccines, and advocates for building vaccine manufacturing capacity in LMICs and establishing South-North partnerships to improve vaccine access and prepare for future pandemics.

1. Unequal access to COVID-19 vaccines

The development of effective COVID-19 vaccines has improved the outlook of the pandemic. Studies show that the coverage of COVID-19 vaccines is strongly associated with the incidence of COVID-19 and the associated deaths [1]. The mutations of the virus and breakthrough cases challenge the efficacy of the vaccines and requires periodical vaccination across populations. COVID-19 vaccines are vital in mitigating the health impact of the COVID-19 virus. However, the availability of COVID-19 vaccines varies drastically across the world. Countries that have the vaccine manufacturing capacity, such as the United States, Germany, China, India, and the United Kingdom, have exceeded 100 doses per 100 people. As of April 14, 2022, an estimated 11.4 billion doses of COVID-19 vaccines were administered globally [2].

According to the estimation from Our World in Data and using the World Bank categorization of countries’ income level, high-income countries had administered, on average, about 200 doses per 100 population, in comparison to 22.3 doses per 100 population in low-income countries, while the 50 least wealthy countries measured by gross domestic product per capita only had 8.2% of the population receiving at least one dose of vaccination [2]. The vaccine coverage among the least wealthy countries is far below the target of 70% COVID-19 immunization coverage by mid-2022. COVID-19 vaccination among migrants and refugees is even more challenging [3].

2. Vaccine nationalism and procurement of COVID-19 vaccines for LMICs

During the first year of distribution, the supply shortage of COVID-19 vaccines increased the competition for procurement among countries. High-income countries used their market and political power to make bilateral agreements directly with manufacturers to secure a supply of vaccines. This has raised the concern for ‘vaccine nationalism’, when wealthier countries prioritize vaccine procurement through private deals to benefit their population. As of March 15, 2021, high-income countries such as the United States, United Kingdom, Canada, France, and other countries in the European Union represent only 16% of the global adult population but have procured 54% of available vaccine...
doses [4]. In contrast, LMICs account for 81% of the global adult population but have only been able to purchase 33% of the available vaccine doses in the same period. This generates an access gap for LMICs that have already suffered from a vaccine supply deficit and relied on international organizations to provide the bulk of their doses. It was reported that only 1% of COVID-19 vaccines administered in Africa were produced in the region as of April 2021 [5]. The shortage of and, particularly, access inequity to COVID-19 vaccines during the early COVID-19 pandemic highlights the necessity of building vaccine manufacturing capacity in LMICs to mitigate such problems. The international community had hoped to have more coordinated and equitable procurements of COVID-19 vaccines. WHO, The Global Alliance for Vaccines and Immunizations (GAVI), and CEPI established the Access to COVID-19 Tools (ACT) Accelerator, a global collaborative partnership dedicated to achieving equitable access to COVID-19 tests, treatments, and vaccines. COVAX is the vaccine pillar of the ACT Accelerator and has been instrumental in providing LMICs with access to COVID-19 vaccines. Despite tremendous effort, COVAX failed to meet its original goal of providing fair and equitable vaccine access across the globe in 2021. The large demand for COVID-19 vaccine doses and high vaccine prices when the COVID-19 vaccines were initially released placed COVAX in fierce competition with high-income countries. As a result, COVAX shipped only a small share (~10%) of the administered vaccine doses globally. COVAX distributed 1 billion COVID-19 vaccine doses to 144 countries, in comparison to approximately 10 billion doses administered globally as of January 2022 [6]. The continued emergence of COVID-19 variants creates a sense of urgency for scaling up vaccine administration to protect vulnerable and underserved populations (e.g., refugees, migrants, and impoverished populations) in LMICs.

3. Strengthen manufacturing capacity to produce COVID-19 vaccines in LMICs

LMICs with existing vaccine production capacity can divert resources toward manufacturing COVID-19 vaccines to shrink the access gap. There are some initiatives to build manufacturing capacity that have begun. Brazil, for example, houses two major vaccine producers, the Instituto Butantan and Bio-Manguinhos/Fiocruz. Sinovac, a Chinese pharmaceutical company, has manufactured its COVID-19 vaccine with the Instituto Butantan. India has a large pharmaceutical industry and its private manufacturers have dominated the global market with their vaccine development and production. The Serum Institute of India is the world’s largest vaccine producer by volume with over 20 WHO-approved vaccines. In September 2020, The Serum Institute of India, Gavi, and the Bill & Melinda Gates Foundation pledged to accelerate production capacity by 100 million doses. The vaccines are supplied by AstraZeneca and Novavax, priced at $3 per dose compared to $19.50 for Pfizer/BioNTech and $37 for Moderna [7], and have contributed to approximately 90% of the vaccine doses administered in India [8]. Serbia has collaborated with China to produce the Sinopharm COVID-19 vaccine. China and the United Arab Emirates helped Serbia build a production facility to ensure the volume of vaccines can support Serbia and its neighboring countries. With this goal, Serbia is hoping to produce 24 million doses annually. These collaborations have significantly improved the supply of the vaccine in respective countries if COVID-19 vaccines have been produced, as shown in the case of India, or would strengthen the capacity of those countries to be prepared for the future epidemics of pandemics of diseases.

COVID-19 vaccine patent waivers and technology transfers would allow more LMICs to take part in manufacturing vaccines to meet their own public health needs but demand intricate resources and regulatory guidance needed to manufacture COVID-19 vaccines. We have seen that AstraZeneca transferred its COVID-19 vaccine formulation to the Serum Institute in India and produced Covishield. The production of Covishield has significantly improved the availability of COVID-19 vaccines in India and beyond [7]. Recently, the United States planned to share U. S. government-devised coronavirus technologies, including vaccine development, with the WHO to help other countries battle against the pandemic. However, this does not include the technology on mRNA-based vaccines from Pfizer/BioNTech or Moderna [9]. Neither company has relinquished its intellectual property (IP) rights for reverse engineering. Acknowledging that IP rights will hinder COVID-19 vaccine technology transfers and production in LMICs, WHO and its partners launched the COVID-19 Technology Access Poll (C-TAP) in May 2020 to provide a platform for developers of COVID-19 related health products to share their IP, knowledge, and data. Establishing South-North partnerships to address IP constraints during the pandemic will be a large step toward a global scale-up in bio-products (e.g., vaccines) for controlling the pandemic. Once LMICs have access to vaccine technology and begin production, this framework used to produce COVID-19 vaccines sets a baseline for LMICs to better tackle future public health crises. At the same time, it is critical to educate the public and generate demand for effective vaccines. Africa CDC warns that the lack of demand in Africa would jeopardize the production of COVID-19 in South Africa [10].

4. Address potential challenges in building vaccine manufacturing capacity

There are challenges associated with building vaccine manufacturing capacity in LMICs. One challenge is facilitating vaccine technology transfers between large pharmaceutical companies and manufacturers in LMICs, which entails educating manufacturers and research & development teams in LMICs [11]. Some are concerned about insufficient financial and talent capacity for manufacturing vaccines in LMICs [12]. This would require long-term investment in education and infrastructure (e.g., vaccine production line and infrastructure for functional supply chain) in identified LMICs for vaccine production after the assessment of vaccine manufacturing readiness. Governments and international development partners need to work together to ensure that such investment is implemented in the identified LMICs.

Also, to ensure the safety and quality of vaccines manufactured in LMICs, national regulatory authorities (NRAs) in each country are essential for vaccine production. As of May 2021, only 13 LMICs have NRAs to effectively regulate medical products [13]. Many of the countries with their own NRAs are already manufacturing vaccines through licensing agreements or are in the midst of developing their own vaccine. For LMICs who are not currently manufacturing COVID-19 vaccines, they will need to have the necessary NRAs. Building capacity on NRAs in LMICs would facilitate the engagement of LMICs in producing quality vaccines.

5. Summary

The rise of increasingly contagious COVID-19 variants (Omicron) makes it harder for LMICs to contain the spread without adequate access to vaccines. Some countries are experiencing continued surges of COVID-19 cases and deaths. In the 28 days prior to April 16, 2022, more than 34 million new COVID-19 cases were confirmed and 123,036 COVID-19 related deaths occurred [14]. It is important for high-income countries, international organizations, and pharmaceutical manufacturers to support countries with low COVID-19 vaccine coverage by facilitating partnerships that increase vaccine availability and production opportunities. The Quad Vaccine Partnership, an alliance between the United States, India, Australia, and Japan, will work toward financing, manufacturing, and delivering 1 billion vaccine doses in the Indo-Pacific region by the end of 2022 [15]. This collaborative effort will be a significant step toward improving vaccine access in LMICs affected by COVID-19 and its variants. There are many factors that affect the access to COVID-19 vaccines in LMICs, such as vaccine hesitancy, poor health literacy, broken supply chain, and shortage of human resources for health. Nevertheless, strengthening the vaccine
manufacturing capacity in LMICs will increase their resilience against future pandemics.

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