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# Challenges in addressing inequity in access to COVID-19 diagnostics, therapeutics and vaccines in Africa

**Significance:**

Although the global response to COVID-19 has demonstrated that some progress has been made in ensuring timely access to new medical interventions in Africa, much more needs to be done to strengthen the global systems that enable equitable access to health technologies during public health emergencies.

The development of COVID-19 diagnostics, therapeutics and vaccines has been a remarkable technical achievement. By the end of 2021, hundreds of diagnostic tests, including rapid antigen tests enabling self-testing, had received regulatory approval from national authorities. Multiple existing medicines had been repurposed and novel therapeutics had been included in World Health Organization (WHO) guidance for the treatment and prevention of COVID-19.<sup>1,2</sup> As at the end of February 2022, 14 WHO emergency use listings had been issued, covering ten vaccine products, and a further five vaccines were under review.<sup>3</sup>

However, access to these COVID-19 technologies has been slow and unequal in low- and middle-income countries (LMICs), and particularly in Africa. For example, while vaccine coverage is near universal in many high-income countries, only 10% of the populations in low-income countries have received at least one dose of a COVID-19 vaccine.<sup>4</sup>

Access has been hampered for a range of reasons. With limited supplies and global manufacturing capacity, manufacturers have prioritised high-income countries paying premium prices. Some countries have also imposed export restrictions on finished vaccines and/or raw materials. Despite modelling showing that, in the medium term, more lives would be saved by equitable global distribution, hoarding of COVID-19 vaccines by high-income countries has been the norm.<sup>5</sup>

Affordability is a key barrier. The average cost of a dose of COVID-19 vaccine varies between USD2 and USD40, while distribution costs average USD3.70 per double-vaccinated individual. It has been estimated that high-income countries have to increase their health expenditure by 0.8% to vaccinate 70% of their population but low-income countries have to increase it by 56.6%.<sup>6</sup>

Local obstacles to the introduction of COVID-19 vaccines have also played a role in limiting access. A lack of health system preparedness in countries with weak healthcare systems, as well as limited local evidence, for example on the effectiveness of different vaccines or the nature of circulating strains, has contributed to delayed availability of vaccines, which has contributed to significant vaccine hesitancy in Africa.

This Commentary draws lessons from Africa's struggles for access to health technologies, including those for COVID-19. It identifies the interventions needed to enhance access, in order to strengthen pandemic preparedness and protect the health of the people of Africa.

## Lessons from history

Despite its high disease burden, Africa has typically been slow to gain access to new medical technologies. The object lesson was provided by the response to HIV/AIDS in the 1990s. Despite the development of combination antiretroviral therapy in the late 1990s, access to these medicines was hampered by their high and monopolistic pricing, protected by intellectual property provisions. In South Africa, access to affordable, generic antiretrovirals was enabled by remarkable grassroots activism, with the Treatment Action Campaign utilising a range of innovative tactics to shift opinion and change practices.<sup>7</sup>

A more recent example is provided by the 2009 H1N1 influenza pandemic. As concerns about the pandemic grew, high-income countries acted swiftly to secure supplies of newly developed H1N1-specific vaccine. The USA alone signed agreements accounting for up to 60% of global supply capacity.<sup>8</sup> LMICs had little opportunity to secure early supplies. H1N1-specific vaccines did not arrive in Africa through global mechanisms until 2010, once demand had declined (owing to the lower-than-expected severity of infections) and high-income countries were able to donate surplus vaccines for global distribution.

As H1N1 influenza was a global pandemic, high-income countries had an incentive to invest in rapid vaccine development. For infections of epidemic potential that primarily affect Africa, such as Lassa fever or Ebola virus disease, this incentive has been lacking. When Ebola struck West African countries in 2014, no vaccines or therapeutics were available. Lack of both preparedness and coordination led to significant delays in clinical trials of Ebola interventions, and only one vaccine trial was completed during the outbreak.

## Making progress

Global health financing interventions, such as the Global Fund against AIDS, Tuberculosis and Malaria (GFATM), the President's Emergency Plan for AIDS Relief (PEPFAR), the President's Malaria Initiative (PMI) and Unitaid, have addressed access to health technologies in LMICs. Both the GFATM and PEPFAR have focused on the provision of quality-assured generic medicines, whereas Unitaid has sought to employ a range of market-shaping interventions to

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improve access to affordable diagnostics and preventive and therapeutic technologies, such as through the establishment of the Medicines Patent Pool and support of the WHO prequalification programme. Established in 2000, the Global Alliance for Vaccines and Immunization (now Gavi, the Vaccine Alliance) sought to lower vaccine prices for low-income countries by fostering predictable long-term markets. Mechanisms have been introduced to enhance affordability, including tiered pricing schemes and advance market commitment mechanisms, which pool demand from individual countries to help create a sustainable market. For pneumococcal conjugate vaccine (PCV), a donor commitment of USD1.5 billion stimulated the development of new vaccines that have been used to immunise over 150 million children, saving more than 700 000 lives.<sup>9</sup> These efforts have helped to ensure that, in the African region, 68% of infants received the third dose of PCV in 2020, compared to 3% in 2010.<sup>10</sup>

For new and emerging infectious diseases, efforts such as the WHO R&D Blueprint are coordinating research into pathogens of epidemic potential, while the Coalition for Epidemic Preparedness Innovations (CEPI) has been established to drive vaccine development for priority pathogens.

Collectively, these mechanisms have contributed to significant progress in enhancing access to new medical technologies in Africa, and in LMICs more generally. Ebola vaccines were available to be deployed during the 2018 Ebola outbreak in the Democratic Republic of the Congo and trials of multiple Ebola therapeutics were initiated. Global stockpiles have been established for Ebola vaccines, as well as for other new vaccines against diseases with epidemic potential affecting Africa, including yellow fever vaccine, typhoid conjugate vaccine and oral cholera vaccine. CEPI was already funding the development of vaccines for Middle East respiratory syndrome (MERS), caused by a coronavirus, which pivoted to focus on COVID-19. CEPI also supported work on novel vaccine platform technologies with the potential to accelerate vaccine development for emerging pathogens. CEPI has spearheaded the '100-day challenge' – to ensure a new vaccine is available within 100 days of the identification of a new pandemic threat.<sup>11</sup>

## Responding to COVID-19

In response to the COVID-19 pandemic, the global community set up the Access to COVID-19 Tools Accelerator (ACT-A), a multi-stakeholder partnership to support innovation and globally equitable access to COVID-19 vaccines, therapeutics and diagnostics.<sup>12</sup> ACT-A has separate 'pillars' aimed at improving access to diagnostics, treatment and vaccines, and strengthening health systems.

The vaccine pillar of ACT-A, COVAX, aims to support countries in meeting the 70% global vaccination target in 2022, building on the Gavi model. Although COVAX distributed its one billionth dose of COVID-19 vaccine by January 2022, it has not delivered as rapidly or as equitably as many had hoped. Its activities have been hampered by the slow pace with which some donor countries have provided their pledged financial support, but in particular by a lack of political commitment to global solidarity, despite multiple calls from the WHO's Director-General. With global supplies limited, many high-income countries have not only prioritised their own populations but have also procured many more vaccine doses than they actually need ('vaccine hoarding'). Furthermore, countries have donated vaccines nearing the end of their shelf life. Nearly 3 million doses donated to Africa expired before they could be used (although this is less than 1% of total donations).<sup>13</sup>

Affordability remains a major challenge. There is little transparency on COVID-19 vaccine costs globally. AstraZeneca pledged to make its ChAdOx1 vaccine available at cost during the pandemic, but prices vary internationally (and it has recently changed its policy and now intends to make a modest profit). There is some evidence that companies are charging high-income countries a premium. What is almost certainly true is that the manufacturing costs of commonly used vaccines (less than USD1 a dose) are substantially lower than the prices being charged (USD10–20, and possibly more).<sup>14</sup> Moreover, manufacturing costs might also be significantly lower in lower-cost environments such as

LMICs, and yet, pre-COVID, African vaccine manufacturers had received little investment.

Less visible progress has been made in ACT-A's therapeutics 'pillar'. As of January 2022, WHO had made 14 recommendations for COVID-19 therapeutics.<sup>15</sup> Some, such as dexamethasone, are widely available and relatively affordable. Others, such as the monoclonal antibodies, are only available in limited quantities and at high prices. Most also require intravenous administration, limiting their application in ambulatory care. Newer products, even when repurposed, such as baricitinib and tocilizumab, are still patent-protected in some LMICs. For example, although baricitinib was recommended by WHO in January 2022 for the treatment of severe or critical COVID-19, the available generic versions cannot be sold in many countries, including South Africa. In July 2021, the manufacturer's list price for baricitinib in the USA was more than USD2000 per treatment course.<sup>16</sup>

Access has also been limited by availability. A co-packaged presentation of nirmatrelvir and ritonavir received emergency use authorisation from the US Food and Drug Administration (FDA) in late 2021. However, advance purchase agreements concluded with high-income countries are likely to leave little or no stock available for LMICs. Although the initial prices charged in high-income countries would place the product out of reach for many LMICs, the manufacturer has committed to a tiered pricing approach and has indicated a willingness to discuss third-party manufacture.<sup>17</sup>

Another oral antiviral intended for the treatment of ambulant patients, molnupiravir, also received FDA emergency use authorisation in late 2021. Although the price demanded in high-income countries would be unaffordable to many LMICs, the manufacturer has entered into voluntary licence agreements with generic manufacturers in India<sup>18</sup> and has also licensed the UN-backed Medicines Patent Pool<sup>19</sup>. In South Africa, the generic versions will be restricted to the public sector, but both innovator and generic products are under review by the South African Health Products Regulatory Authority (SAHPRA). Through ACT-A, an agreement has been signed with UNICEF to distribute up to 3 million courses of molnupiravir in more than 100 LMICs in the first half of 2022.<sup>20</sup> ACT-A is also engaging with the developers of baricitinib and sotrovimab to ensure access in LMICs.<sup>21</sup>

Delayed access to effective COVID-19 therapeutics will hamper the ability of countries in the region to control COVID-19 in community settings. It will also likely lead to the use of ineffective alternatives, squandering resources and potentially leading to avoidable harm.

Diagnostic tests for COVID-19, initially dependent only on sophisticated laboratory-based polymerase chain reaction (PCR) testing, have posed particular challenges in Africa. By March 2020, 43 African countries had developed the competence to perform these tests, but access to the necessary reagents was limited.<sup>22</sup> Not only were the costs of diagnostics an issue, but national health systems were faced with a large number of potential suppliers, not all of which provided quality diagnostics. LMIC regulatory bodies were often ill-prepared to regulate diagnostics. The resultant level of testing was predictably lower than would be expected, given the continent's population.<sup>23</sup> Nonetheless, capacity for genome sequencing has increased dramatically, from two African laboratories at the outset to more than 900.<sup>24</sup>

Given the high prices demanded for novel diagnostics, vaccines and therapeutics, as well as limited production capacity, there have been calls to bypass intellectual property restrictions in order to advance access. In October 2020, India and South Africa proposed that a waiver be granted from the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for COVID-19 technologies. Although it is theoretically possible to rely on World Trade Organization (WTO) processes in times of public health emergencies, several high-income countries, including the United Kingdom and European Union, have repeatedly blocked the introduction of TRIPS waivers, and there has been little progress to date.<sup>25</sup>

It has been argued that there is insufficient capacity to manufacture complex products such as mRNA vaccines in LMICs, yet studies have



identified more than 100 possible sites, including seven in Africa.<sup>26</sup> Indeed, an mRNA vaccine manufacturing hub has been established in South Africa (see below). However, its freedom to operate may be compromised by the risk of intellectual property infringements. Although Moderna (one of the mRNA vaccine developers) has stated that it does not intend to enforce its rights in 92 COVAX countries to prevent COVID-19 mRNA vaccine production<sup>27</sup>, its position could change at any time.

## Learning the lessons from COVID-19

The COVID-19 pandemic has highlighted significant shortcomings in the global response to pandemics. Lessons need to be learned, in particular to ensure greater equity in access to new technologies during public health emergencies.

One important priority is to **strengthen global and regional health leadership**. WHO needs more authority to act in accord with global public health priorities, and clarity is urgently needed on the objectives and governance of the proposed new intergovernmental negotiating body for pandemic preparedness and responses.<sup>28</sup> The International Health Regulations system needs to be reviewed and updated to ensure that it is fit for purpose. Bodies such as the Africa Centre for Disease Control and Prevention (Africa CDC) need to be at the forefront of efforts to coordinate responses in Africa. Countries need to show political leadership with prioritisation of pandemic preparedness, transparency around data sharing, and strengthening of health systems and health research capacity, to enhance resilience to public health threats.

**Comprehensive surveillance** is essential for detecting and tracking the next pandemic threat. Surveillance systems need to be strengthened, including in areas such as laboratory capacity, genomic surveillance and wastewater monitoring. Systems must be in place to ensure rapid **sharing of data** with global repositories. Data sharing needs to be incentivised and geopolitical challenges to data sharing addressed. Precipitate reactions, such as the travel bans imposed on South Africa after the identification of the Omicron variant, are not evidence-based and do not encourage rapid sharing of data.

A commitment to equitable access must be more deeply embedded in **product development**. Public investments in basic research or clinical trials are critical to most new medical interventions. However, little support was offered to LMIC scientists for COVID-19 research – a pattern that should be addressed in future. While tiered pricing is needed, other mechanisms – such as licensing, patent pooling, technology transfer and IP waivers – must be considered. There may also be space for IP-free products, following the model adopted for the COVID-19 protein subunit vaccine Corbevax, developed by researchers at the Texas Children's Hospital Center for Vaccine Development and Baylor College of Medicine, and licensed to Indian company Biological E Ltd.<sup>29</sup>

There is also an urgent need to strengthen and diversify **manufacturing capacity**. Although centralisation generates efficiency savings, local manufacturing is vital to mitigate the risk of vaccine hoarding or export restrictions, as seen for COVID-19, and is therefore an essential aspect of pandemic preparedness. The tenth meeting of the International Health Regulations (2005) Emergency Committee urged WHO to continue working with industry on voluntary licence agreements and other approaches to increase access to vaccines, therapeutics and diagnostics.<sup>30</sup>

Despite accounting for 14% of the world's population, Africa is responsible for around 1% of the world's vaccine production. The Addis Declaration on Immunisation, signed by African heads of state in 2017, included a commitment to 'promote and invest in regional capacity for the development and production of vaccines'. The Partnership for African Vaccine Manufacturing (PAVM), set up by the African Union and Africa CDC in 2021, has set as a target that 60% of the continent's routine vaccine needs, or between 1.4 and 1.7 billion doses yearly, should be met by local manufacturing by 2040.<sup>31</sup>

One priority is implementation of a 'hub and spoke' model for mRNA vaccine technology transfer, coordinated by WHO, to transfer

a comprehensive technology package and provide training to manufacturers in LMICs. This could be expanded to other vaccine technologies. A technology transfer hub for mRNA vaccines is being built by a South African consortium comprising Biovac and Afrigen Biologics and Vaccines South Africa, with support from WHO, a network of universities, Africa CDC, and partners from COVAX to help boost and scale up vaccine production in Africa.<sup>32</sup>

Further strengthening of **regulatory systems** will also be essential. National capacity building is being supported by increased country and donor support, and greater international cooperation, for example through the African Vaccine Regulatory Forum (AVAREF) and WHO. Capacity for clinical trials approval and monitoring, health product licensing and post-marketing surveillance needs to be bolstered. Greater collaboration between regulatory authorities, including data sharing, will be critical. The nascent African Medicines Agency could play an important role.

Also important are greater use of **international standards in vaccine evaluation**, to aid comparisons across studies and meta-analyses, and harmonisation of regulatory approaches. Bodies such as the International Coalition of Medicines Regulatory Authorities have set an important example by developing guidelines to promote greater global consistency in the evaluation of COVID-19 vaccines.<sup>33</sup>

Despite significant challenges, **COVAX** has begun to deliver on its promises. Its long-term future now needs to be secured, given its potential to provide a mechanism to ensure access to vaccines against future pandemic threats and epidemic-prone diseases. A sustainable model and permanent home, for example within Gavi, are needed to maintain its operations during inter-pandemic periods. In parallel, the pandemic has highlighted the need for a strengthened WHO, able to assume an expanded leadership role to respond to future pandemics and other health emergencies.

Further strengthening of **pandemic preparedness** remains a high priority for Africa. Continued investment in laboratory and community surveillance infrastructure, as well as health workforce development and strategies to address chronic shortages in the health workforce, are needed to enable comprehensive surveillance and the ability to undertake clinical research in emergency situations.

Finally, efforts are needed to ensure that new interventions can be **rapidly implemented at scale and reach all populations**. This will require effective health systems strengthening, particularly of primary healthcare systems, as part of the drive towards universal health coverage. More generally, the Immunization Agenda 2030 (IA2030), the global immunisation strategy for 2021–2023, prioritises the strengthening of national immunisation programmes. **Civil society** has a crucial role to play in community mobilisation, in partnering with national programmes to deliver immunisation services, in holding governments accountable for their commitments, and in reminding the global community that equitable access is core to addressing pandemics.

## Conclusions

Despite some progress, the COVID-19 pandemic has highlighted a range of obstacles to timely access to new health technologies on the Africa continent. To address these obstacles, there is a need to strengthen existing structures and mechanisms of proven value, such as WHO, CEPI, Gavi, the Africa CDC and pandemic preparedness networks, as well as newly created platforms such as COVAX. This must be matched by country commitments to strengthen health systems so that they can deliver vaccines, therapeutics and diagnostics to all populations.

These structures need to be combined with imaginative solutions that acknowledge the limited purchasing power of LMICs. There have been some encouraging signs of progress during the COVID-19 pandemic, including AstraZeneca's initial decision to make its vaccine available at cost, Merck's moves to enhance the availability of molnupiravir, the licensing agreements with the Medicines Patent Pool, and the development of the 'open source' vaccine Corbevax.





As with all past public health crises, concerted efforts are still required to advance global equity in access to new health technologies. Collectively, the mRNA vaccine producers (Pfizer, BioNTech and Moderna) have projected profits of USD34 billion in 2021.<sup>34</sup> Their efforts to develop safe and effective vaccines have relied on public-sector investments in people, basic research and trials. Furthermore, it is reasonable to ask whether these enormous private gains are justified given the public health consequences – the lost lives, the life-long disability, and the lengthening of the pandemic – caused by limited and inequitable global access to critical health technologies.

## Competing interests

H.R. is a Member of the South African Ministerial Advisory Committee on COVID-19, the South African Ministerial Advisory Committee on COVID-19 Vaccines, and the National Essential Medicines List. A.G. is a Member of the South African Ministerial Advisory Committee on COVID-19, the National Essential Medicines List, the Ministerial Advisory Committee on COVID-19 Therapeutics, and a number of technical advisory committees at the South African Health Products Regulatory Authority, and Chair of the Proposal Review Committee at Unitaid.

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