

The Global Inequity of COVID-19 Diagnostics: Challenges and Opportunities

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WORD COUNT: 1732

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SUMMARY BOX

1. The COVID-19 pandemic has demonstrated that rapid diagnostic innovation and scale-up is achievable, but inadequate, without equitable global access to these tools.
2. Global COVID-19 testing rates are driven by country income group, with an average of 6.07 tests per 1000 people per day in high income countries, compared with just 0.08 tests per 1000 people per day in low-income countries.
3. Decades of national and international efforts have failed to invest in sustainable diagnostic infrastructure, local manufacturing, and innovation in many low-income and lower middle-income countries (LMICs), contributing to the persistent low testing capacity for SARS-CoV-2.
4. Despite these challenges, many LMICs have used the COVID-19 pandemic to invest in laboratory capacity, develop and manufacture novel SARS-CoV-2 diagnostics, leverage existing infrastructure and international partnerships to implement diagnostic and surveillance capabilities, and vastly expand genomic sequencing capacity.
5. Investments supporting LMIC-based diagnostics innovation, physical infrastructure and support capabilities, and public-private partnerships in genomic sequencing and other diagnostic technologies will improve and sustain diagnostic equity.

Diagnostics for COVID-19 have advanced at an unprecedented pace over the last two years. Testing is a critical pillar of pandemic control, and is required for epidemiological tracking, treatment, and surveillance. Despite high quality SARS-CoV-2 viral diagnostic capability, there are vast global inequities in access. The Virology, Immunology, and Diagnostics Working Group (WG) of the COVID-19 Clinical Research Coalition (CRC) brings together experts in immunology, infectious diseases, and microbiology to advocate for equity-based COVID-19 research, prioritising solutions driven by communities in low-income and lower middle-income countries (LMICs).¹ This commentary shares the unique perspective of the WG on the asymmetry in COVID-19 diagnostic access between low-income and high-income settings, the barriers to these disparities, and highlights opportunities to remedy these inequities.

Two COVID-19 pandemics

Two parallel COVID-19 pandemics are occurring. High and upper-middle income countries have widespread and affordable access to testing and high vaccination rates. In contrast, LMICs have minimal access to affordable testing and generally lower vaccination rates. The disparities are stark. In most high-income countries (HICs), SARS-CoV-2 testing is widely available, free, or affordable. For these countries, diagnostics have been a conduit to the rapid return of pre-pandemic life, enabling leisure and social activities, reopening businesses and schools, and allowing the resumption of mass gatherings. In most LMICs however, the return to pre-pandemic life has been slow. Testing remains expensive and restricted to where it is deemed essential, such as for symptomatic individuals, healthcare workers, cross-border essential workers, and international travellers. Outside of these indications, if molecular testing is available, it is often prohibitively expensive. The World Health Organization (WHO) regional office for Africa estimates that 85% of COVID-19 cases remain undetected across the continent.²

SARS-CoV-2 testing metrics illustrate testing disparities between high- and low-income countries. The COVID-19 Tools Accelerator (ACT-A), established in April 2020 by the WHO, has set a benchmark for testing of at least 1 test/1000 people/day. Between May 10, 2021 to May 10, 2022, on average, 6.07 tests/1000 people/day were conducted in high-income countries, compared with just 0.08 tests/1000 people/day in low-income countries.³ The cumulative testing rate per 1000 people (the total number of tests performed per 1000 people since the January 2020), demonstrates the vast differences in testing at a country income level, with figures ranging from <10 tests/1000 people, to >20,000 tests/1000 people (Figure 1).

Barriers to achieving equity in diagnostics

The reasons for low testing rates in LMICs are complex. In mid-2021 the CRC undertook a survey among its membership of institutions and individuals ranging from research centres, laboratories, and foundations to physicians, academics, and pharmacologists, to provide a snapshot of SARS-CoV-2 testing.⁴ Two-hundred and seventy respondents from seventy-four countries, predominately LMICs, identified a number of challenges. These included insufficient tests and reagents, scarce testing locations, high costs of procuring testing kits, and inadequate testing capacity. Over 30% of respondents felt that diagnostic capacity was either given a low priority or was not prioritised, and most (88%) reported a need for increased access to diagnostics.

Inequity in diagnostics has been an issue facing many LMICs for decades.⁵ The global diagnostic environment is set-up for investment in innovation and infrastructure to take place in high income settings. Even for diseases predominately occurring in LMICs, diagnostic innovations trickle down months, or even years later. Diagnostic tools for malaria are an example. In parts of Africa and Asia, malaria causes a significant disease burden. However, the bulk of malaria diagnostic tests

are not manufactured in endemic areas, nor is technology developed in these areas.⁶ National and international efforts have failed to invest in sustainable diagnostic infrastructure, local manufacturing, and innovation in LMICs, resulting in a lack of capacity to produce diagnostic tools.

The challenges of malaria diagnostics capacity and innovation mirrors that of COVID-19. Globally, there have been impediments to manufacturing capacity scale-up of SARS-CoV-2 tests due to insufficient production equipment, manufacturing techniques, and materials.⁷ Early in the pandemic, this was driven by fear of running out of reagents and tests, leading to stockpiling of these materials in some HICs.⁸ High COVID-19 case numbers and deaths in HICs further fuelled diagnostic nationalism and global protectionism, exposing the fault lines in global supply chains.⁹

The ACT-A Diagnostics pillar was designed to rapidly develop diagnostic capacity in LMICs and provide equitable access to testing. This initiative has had little success, providing only a fraction of the tests originally promised and little diagnostic infrastructure, with most funding directed towards vaccines and therapeutics.¹⁰ As a result, in-country and regional testing production remains low and many countries remain reliant on test kit importation to meet demand.⁸

Achievements in advancing diagnostics in low resource settings

Despite the pre-existing challenges around testing capacity and access in LMICs, valuable inroads have been made during the COVID-19 pandemic. In 2020, a Nigerian research team pivoted their work from Ebola and Lassa Fever to COVID-19, sequencing the SARS-CoV-2 viral genome in 72 hours.¹¹ University-based researchers in Vietnam collaborated with private sector partners to translate their test kits from innovation to certified products.¹² In Rwanda, pooled testing augmented diagnostic capacity to meet clinical demand when viral prevalence was low and asymptomatic cases were high.¹³

Continent-wide efforts, such as the Africa Centres for Disease Control and Prevention (CDC) Partnership to Accelerate COVID-19 testing (PACT), have expanded testing across the continent, providing over 95.5 million tests by February 2022.¹⁴ In 2022, PACT pivoted their testing strategy to scale-up the use of rapid antigen diagnostic tests. This enables rapid testing without the requirements for RT-PCR infrastructure and personnel, and increases the likelihood of individuals testing outside of healthcare settings. Through the Strategic Fund of the Pan American Health Organization (PAHO), pre-existing pooled procurement mechanisms were used to negotiate affordable pricing for SARS-CoV-2 diagnostic tests for member countries.¹⁵

In the early pandemic period, many LMICs leveraged existing diagnostics platforms for HIV and tuberculosis to meet SARS-CoV-2 testing demands. Some countries used SARS-CoV-2 testing using GeneXpert technology to bring SARS-CoV-2 molecular diagnostics on board.⁴ Currently, Africa CDC are encouraging practices established during the HIV pandemic around self-testing and partner notification for SARS-CoV-2 rapid self-testing at home.

Genomic sequencing capacity has been pivotal for public health surveillance of viral variants and test-to-treat programs. The Africa Pathogen Genomic Initiative (PGI), an initiative of Africa CDC, coordinates analysis of genomic sequencing data and builds the capacity of member countries to undertake genomic epidemiological surveys.¹⁶ In South and Central America, the COVID-19 Genomic Surveillance Regional Network, spearheaded by PAHO, are also harnessing genomic epidemiology to guide public health decisions on outbreak and response.¹⁷ SARS-CoV-2 genomic sequencing in Cambodia confirmed the first known COVID-19 case in the country, the result of a longstanding partnership between malaria researchers based in the U.S, and the Cambodian government.¹⁸

Leveraging opportunities for diagnostic equity

Although existing healthcare and diagnostic platforms for TB and HIV were frequently repurposed for SARS-CoV-2, there is scope to improve cooperation among intergovernmental agencies. Within many LMIC contexts, academic and research institutions are a source of highly trained and competent laboratory personnel, as well as providing elastic human resource capabilities through graduate students who can be quickly equipped with laboratory skills. Where academic institutions pivoted their diagnostic laboratories to support governments during the COVID-19 pandemic, testing was able to be augmented significantly. Academic and research institutions have great potential as resources, and policy changes are needed to ensure they can be rapidly incorporated in future pandemics. For example, coordination between the ministries of health and education, typically responsible for pandemic response and education respectively, may allow an academic laboratory or private research entity access to financial support traditionally provided only to ministries of health for pandemic purposes.

Public-private partnerships are another important tool that can be leveraged for diagnostic equity. During the COVID-19 pandemic some governments harnessed the capabilities of private laboratories to increase access to testing, using pre-existing private procurement relationships that were not available through the public procurement processes. These partnerships allow for an infusion of private funding into the pandemic response, improve the country-wide dissemination of testing centres, and create resources through testing platforms and skilled personnel that are available in-country for future clinical need.

There are many examples of local technological solutions that show great promise to increase diagnostic capacity. In India, researchers developed a low-cost, scalable, paper-based SARS-CoV-2 test primarily for home-based testing.¹⁹ Ghanaian scientists developed an antibody based rapid diagnostic kit to detect immune response to SARS-CoV-2 as an adjunct to molecular testing.²⁰ Thai researchers addressed the reluctance around nasal testing by developing a portable sweat test device for SARS-CoV-2.²¹ Local innovations for public health challenges should be encouraged through investment as they often provide solutions that are developed for local populations.

Through ACT-A and PACT, a \$21 million investment was made at the end of 2021 to bring molecular diagnostics for COVID-19 and other diseases to LMIC settings.²² The initiative sought to accelerate adaptable multi-disease diagnostic platforms, including for SARS-CoV-2, that were affordably priced and appropriate for primary health settings. While an excellent initiative, all the current awardees of this investment grant are based in HICs. This perpetuates the cycle of inequity in diagnostic development and innovation, and neglects crucial capacity and infrastructure building in LMICs. The 2021 Lancet Commission on Diagnostics report emphasises the critical role of physical infrastructure, support capabilities, and skilled staff in alleviating inequity in global diagnostics.²³ ACT-A and PACT funding, if administered to bolster these capabilities in LMIC settings, have tremendous potential to provide innovative diagnostic technologies to low-resource populations for current and future pandemics.

The development of a global genomic surveillance system may allow public health institutions to more rapidly address the spread of novel SARS-CoV-2 variants or future viruses. In discovering SARS-CoV-2 variants of concern, Africa PGI has already demonstrated that robust genomics networks can detect new mutations and variants in real time.²⁴ Genomic sequencing capabilities in Africa have been expanded largely due to Illumina and Nanopore sequencing technology, which has provided widespread scalable access for public health surveillance through public-

private partnerships. While the immediate aim is to address the COVID-19 pandemic, these technologies can be leveraged for other infectious diseases.

Conclusions

The speed of technical innovation, global collaboration, and public and private investment, to address COVID-19 has been unprecedented. However, the pandemic has highlighted longstanding inequities in access to diagnostics. Harnessing the diagnostic advances of COVID-19 has the potential to bridge wide gaps that persist, through establishing local infrastructure, encouraging the innovative capabilities of LMIC researchers and scientists, and augmenting regional partnerships.

Acknowledgments The members of the COVID-19 Clinical Research Coalition Virology, Immunology, and Diagnostics Working Group are: Ayouba Ahidjo, IRD and University of Montpellier, France; Derseree Archary, Centre for the AIDS Programme of Research in South Africa (CAPRISA), South Africa; Dharshan de Silva, Kotelawala Defence University, Sri Lanka; Améyo Dorkenoo, University of Lomé, Togo; Shymaa Enany, Suez Canal University, Egypt; Sophia Kitui, CDT Africa, Kenya; Blandina Mmbaga, Kilimanjaro Clinical Research Institute, Tanzania; Wolfgang Preiser, Stellenbosch University / NHLS Tygerberg, South Africa; Paramdeep Singh, Guru Gobind Singh Medical College and Hospital, Baba Farid University of Health Sciences, India; Aida Sivro, Centre for the AIDS Programme of Research in South Africa (CAPRISA), South Africa; and Misaki Wayengera, Makerere University, Uganda.

Contributors SN and BO contributed equally to this paper. SN, BO, and WM conceptualised the piece and prepared the initial draft. NE created the figure. All authors critically reviewed and edited the manuscript, and approved the final version for submission.

Funding The authors do not have a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing Interests None declared.

Data availability statement There are no data in this work.

Patient consent for publication Not required.

Ethics approval This study does not involve human participants.

Figure 1: Cumulative SARS-CoV-2 tests per 1,000 people since January 2020, by WHO country income group and country GDP per capita (PPP).^{3 25}

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