

The silent and dangerous inequity around access to COVID-19 testing: A call to action

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The COVID-19 pandemic is a public health crisis of unprecedented proportions. Despite unparalleled rates of vaccination and mass testing in certain parts of the world, the virus rages on. Since SARS-CoV-2, the virus that causes COVID-19, was first isolated in Wuhan, China, on 7 January 2020, more than 243 million cases and 4.9 million deaths have been reported worldwide at the time of writing.¹

Widespread testing and timely diagnosis are critical for pandemic control and preparedness. This is especially true for SARS-CoV-2, as asymptomatic and pre-symptomatic individuals play a key role in spreading the virus.² Understanding COVID-19 epidemiology in each region of the world is essential to guide policy; however, this is not always feasible due to limited access to tests, poor laboratory infrastructure, insufficient personnel and strained health systems. In addition, the so-called COVID-19 “infodemic” has contributed to the dissemination of anti-science messages and negatively influenced testing and vaccine uptake worldwide.³

Alarming inequities have set the tone of this pandemic. Low- and middle-income countries (LMICs) have struggled to access existing tools to ease the impact of COVID-19 on their fragile health systems. By September 2021, 5.82 billion vaccine doses had been administered, although just 1.9% of individuals in LMICs had received at least one dose,⁴ while of the more than 3.2 billion tests performed worldwide, just 0.4% were in LMICs.⁵

Of the various types of tests available for SARS-CoV-2, antigen rapid diagnostic tests (Ag-RDTs) represent the most promising tools for the scale-up of testing. Ag-RDTs combine good performance with a rapid turnaround time, while not requiring sophisticated laboratory infrastructure or skilled personnel. This facilitates decentralized testing, so Ag-RDTs could potentially accelerate detection and responses to COVID-19 at scale in LMICs to help control the pandemic.⁶

When the first Ag-RDTs received World Health Organization (WHO) emergency use listing (EUL) in September 2020, global institutions called for improved access and affordability of these tests for LMICs.⁷ Since then, multiple tests have been developed and brought to

EClinicalMedicine

2022;43: 101230

Published online xxx

<https://doi.org/10.1016/j.eclinm.2021.101230>

eclinm.2021.101230

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market. Independent evaluation and real-time results sharing are essential to ensure quality standards are met and to build diagnostics literacy to guide countries' testing policies.⁸ FIND, the global alliance for diagnostics and others have played a key role in conducting such studies.⁹

The role of diagnostics has evolved throughout the COVID-19 crisis and will continue to do so. Enhanced access to testing will improve surveillance, generate real-world vaccine efficacy data, guide strategies, and

enable emerging variants to be monitored. As clinical trials targeting outpatients progress, improved access to tests will support demand-forecasting efforts and enable treatment adoption.

The pandemic has exposed the inadequacy of global supply chains to ensure access to the tools countries need to fight COVID-19. The reliance on a few diagnostics manufacturers has generated unfair competition for scarce resources and jeopardized the capacity of LMICs to scale-up testing coverage.

Availability
<p>Recommendations for the short-term</p> <ul style="list-style-type: none"> - Leverage current technology transfer agreements to ramp up manufacturing of high-quality antigen rapid diagnostic tests (Ag-RDTs) in low- and middle-income countries (LMICs) - Encourage quick rollout of tests in countries where vaccination rates are slow - Boost research and development (R&D) investments for the development of new diagnostic tools and field-adapted options (both antigen and molecular tests) in LMICs - Under multi-stakeholder collaborations, plan for timely scale-up of access to tests as part of market-shaping efforts to enable deployment of new treatment strategies targeting outpatient populations <p>Recommendations for the medium- to long-term</p> <ul style="list-style-type: none"> - Establish global collaborations and investments to build infrastructure for molecular testing in LMICs - Under the Access to COVID-19 Tools (ACT) Accelerator diagnostics pillar, drive the development and availability of affordable and innovative testing options - Define a global diagnostics agenda for emerging pathogens as part of overall pandemic preparedness - Develop a plan for future utilisation of newly built COVID-19 testing manufacturing capacity, to address endemic diseases and strengthen surveillance capability at a local level
Adoption
<p>Recommendations for the short-term</p> <ul style="list-style-type: none"> - Ensure timely dissemination of updated World Health Organization (WHO) testing guidelines to drive country policies - Define a global governance framework to maintain privacy and ensure efficient data management - Under global coordination, define implementation research priorities and policy applications of current and future diagnostics options - Establish multilateral collaboration to achieve regulatory approval and enable timely adoption of tests - Conduct qualitative studies to understand local acceptance and hesitancy regarding COVID-19 diagnostics, to guide recommendations - Ensure LMICs and civil society participation in setting priorities and design of tailored access strategies <p>Recommendations for the medium- to long-term</p> <ul style="list-style-type: none"> - Define an international agenda to drive overall diagnostics literacy and enhance communication efforts to improve confidence and scale-up access to essential diagnostics in LMICs
Financing
<ul style="list-style-type: none"> - Mobilise funds to sustain technology transfer agreements to enable the production of quality assured Ag-RDTs in LMICs - Secure investments to address the ACT-Accelerator funding gap for diagnostics - Secure catalytic funding to support market entry and deployment of tests in LMICs - Secure robust investments for multi-country validation studies, ensuring a variety of settings and diverse population profiles to better inform public health guidance and recommendations - Convene integrated platforms to improve resource mobilisation, allocation, and collaborative purchasing mechanisms
Panel 1: Priorities and Recommendations for COVID-19 Diagnostics Access

While medicines and vaccines require complex technology transfer mechanisms, simple lateral flow tests can be easily manufactured in regions where test production is currently limited. Regional diversification of manufacturing capacity is urgently needed to contribute to countries' resilience and preparedness.⁸ Ongoing technology transfer agreements will expand regional capacity through partnerships and help ensure equitable access to diagnostics in LMICs.¹⁰

The emergence of variants of concern has highlighted the importance of genomic epidemiology and sequencing. However, the sequencing of new variants requires training, infrastructure and sustained reagent supply; both short- and long-term commitments are needed to reinforce regional capabilities to achieve this (see [Panel 1](#)).

There is an urgent need for further investments to develop and scale-up access to diagnostics, as LMIC populations have been uniquely vulnerable yet invisible, with their undocumented infections unable to demand the requisite attention or priority. The COVID-19 pandemic has underscored the chronically poor testing capacity in resource-limited settings and the need for improved national diagnostics strategies. It is critical that testing capabilities are increased to identify surges, assess vaccine effectiveness, promote innovative approaches including test and treat strategies, and to identify and monitor emerging variants.

The speed of scientific progress to develop tools to tackle COVID-19 has been remarkable. Such progress would not have been possible without collaboration, robust public and private investments and effective coordination. However, these achievements have not been made available equitably, and huge access asymmetries remain between rich and poor countries. Testing remains an essential pillar to help fight the COVID-19 pandemic and to ensure preparedness for future pandemics.

Contributors

CB, S-JL, EH wrote the initial draft. MEB and BL managed the process of review. All authors contributed equally and provided critical feedback, reference sources, and critical revisions for intellectual content and verified the information presented here.

Lancet Commission on COVID-19 Vaccines and Therapeutics Task Force

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Declaration of Interest

MEB and PJH are developers of a COVID-19 vaccine construct, which was licensed by Baylor College of Medicine to Biological E Ltd., a commercial vaccine manufacturer for scale up, production, testing and licensure. MG participates in one of eight SARS-CoV-2 vaccine development projects supported by The Scientific and Technological Research Council of Turkey (TÜBİTAK) since March 2020. MH is Founder and Managing Director of SaudiVax. JPF, GK and DCK are members of the WHO SAGE Working Group on COVID-19 vaccines. GK is independent director appointed by the Wellcome Trust, MSD Wellcome Trust Hilleman Laboratories Private Limited and Vice Chair of the Board, Coalition of Epidemic Preparedness Innovations (CEPI). DCK reports grants from Bill and Melinda Gates Foundation (BMGF) and grants from CEPI, JHK reports personal fees from SK biosciences. HL reports grants and honoraria from GlaxoSmithKline for training talks and from Merck as a member of the Merck Vaccine Confidence Advisory Board, grants from J&J outside the submitted work. AWS serves as Consultant to WHO. The views presented here reflect her views and not necessarily those of WHO. TS reports grants from National Institute of Allergy and Infectious Disease and Fast Grants and research contracts from GlaxoSmithKline, and ViiV Healthcare. SS reports grants from Ansun BioPharma, Astellas Pharma, Cidara Therapeutics, F2G, Merck, T2 Biosystems, Shire Pharmaceuticals, Shionogi, and Gilead Sciences, outside the submitted work; and personal fees from Amplyx Pharmaceuticals, Acidophil, Janssen Pharmaceuticals, Reviral, Intermountain Healthcare, Karyopharm Therapeutics, Immunome, Celltrion, and Adagio outside the submitted work. EH and S-JL are currently employed by FIND. All the other authors report no conflicts.

Acknowledgments

We thank Jeffrey Sachs, Chair of the Lancet COVID-19 Commission for his invaluable review and feedback.

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