

A CENTRAL BARRIER TO DIAGNOSTIC TESTING

Traditional models of diagnostic testing are often characterized by a centralized approach. This is particularly true in low- and middle-income countries (LMICs), where limited financial, infrastructural, and human resources limit the majority of tests to hospitals and laboratories in urban settings.

Issues of distance, travel time, and cost can prevent many people from accessing central diagnostics. Furthermore, where new technologies for point-of-care (POC) testing exist, high prices and issues of acceptability are barriers to accessing testing. Developments are also limited by policies and processes that struggle to keep pace with this rapidly evolving landscape.

It is a situation that jeopardizes patient care and undermines disease surveillance and control, including for COVID-19. Here, rigorous and widespread testing proved key to bringing the virus under control. Yet in many LMICs, early diagnostic testing was restricted to a few central laboratories with the capacity to support it. This was not enough to meet the acute demand. With lockdowns, travel restrictions, and a fear of contracting the virus all limiting access to testing, the need to improve the availability and uptake of decentralized tools soon became urgent.



COMMON BARRIERS TO CENTRALIZED TESTING

- Cost
- Availability
- Distance
- Processing times
- Travel time
- · Fear and stigma

INTRODUCING THE ACT-ACCELERATOR

In early 2020, global partners came together to create the Access to COVID-19 Tools Accelerator (ACT-Accelerator). FIND, alongside the Global Fund, was named co-convener of the diagnostics pillar and tasked with the primary objective of ensuring equitable access to testing. Achieving this requires strengthening and expanding centralized models, while also moving to implement decentralized strategies that bring affordable, rapid, fit-for-purpose solutions closer to where people live and work.

Focusing on the latter, this case study will explore the processes and partnerships that drove progress from innovation to implementation — crossing boundaries, challenging norms, and breaking down barriers to essential diagnostic testing.

"This amazing spirit of human solidarity must become even more infectious than the coronavirus itself. Although we may have to be physically apart from each other for a while, we can come together in ways we never have before."

Dr Tedros Adhanom Ghebreyesus, WHO Director-General 1

STAGE 1 · ACCELERATING INNOVATION IN RESEARCH AND DEVELOPMENT

For a decentralized approach, diagnostic tests must be easy to use, adapted to the needs and resource constraints of the end-user, and deliver fast and accurate results.

Through the ACT-Accelerator, FIND and our collaborating partners have sparked a revolution in diagnostic testing. Condensing a process that took five years for HIV, together we refined and streamlined the product development pathway – with the first antigen detection rapid diagnostic test (Ag RDT) entering the market just eight months after the pandemic was announced. As more and more tests entered the market, FIND led the independent evaluation of different solutions. Not only did this bring much-needed transparency to the diagnostic landscape, but it also created a framework to assess the impact of new variants and guide test development. In 2021, FIND supported the evaluation of over 100 different products, for which listings and data are available through our COVID-19 Test Directory, with information used to support country-level procurement and guide local and global policy development.

Building on the success of this collaborative approach, FIND launched a US\$21 million investment scheme to support the development, manufacturing, and launch of new <u>multi-pathogen POC platforms</u> – an innovation that could <u>transform progress</u> towards universal health coverage by allowing clinicians to test for multiple diseases alongside COVID-19.



OUTCOMES

EXPEDITED PRODUCT
DEVELOPMENT AND
EVALUATION PATHWAYS

TRANSPARENT AND INDEPENDENT DATA TO GUIDE POLICY AND DECISION-MAKING

A ROBUST TEST ARSENAL FOR COVID-19 AND OTHER DISEASES









STAGE 2 · ENSURING EFFICIENT AND SUSTAINABLE TEST SUPPLIES

To ensure equitable access to diagnostic testing, countries must be able to procure and/or supply appropriate products at speed, wherever they are needed.

Under the aegis of the ACT-Accelerator, FIND was able to boost demand for - and mitigate financial barriers to - POC test procurement. Convening and mobilizing a consortium of partners, we helped support the development of a 120 million Ag RDT volume guarantee by ACT-Accelerator partners to ensure access to LMICs at a maximum price of US\$5 per unit. We additionally worked to introduce new suppliers to the market - creating competition and driving price-points for Ag RDTs further down to US\$2.50 (ex-works). Concurrently, FIND also worked to generate demand by supporting the development of national COVID-19 testing strategies (see Stage 3) as well as exploring the potential of non-traditional market channels like pharmacies in Indonesia, Kenya, and Viet Nam. Critically, in 2021 FIND helped boost test production in LMICs by supporting expanded manufacturing capacity in countries like India, and facilitating RDT technology transfers and partnerships in Brazil, Senegal, and South Africa. This collective effort will help secure the sustained supply of essential diagnostics and aims to see ex-work costs for Ag RDTs fall as low as US\$2.00 in some instances.

Working along the value chain, in July 2021 FIND collaborated with partners to launch a 12-month <u>trade finance and governance initiative</u> that would optimize diagnostic supply chains, support innovative finance mechanisms and create much-needed efficiencies/savings. Together with a manufacturing and volume guarantee that sees COVID-19 self-tests made available to LMICs for <u>US\$1-2 per unit</u> (ex-works), these programmes will help sustain the supply of affordable, fit-for-purpose diagnostics – strengthening fragile supply chains and closing a critical gap in diagnostic testing.



OUTCOMES

A MORE VIBRANT AND COMPETITIVE DIAGNOSTIC MARKETPLACE

REDUCED DEPENDENCE
ON INTERNATIONAL
SUPPLIERS

INCREASED
AVAILABILITY OF HIGHQUALITY, LOW-COST
DIAGNOSTICS





STAGE 3 · SUPPORTING ROBUSTNATIONAL POLICY DEVELOPMENT

Decentralized testing depends on the development of context-appropriate diagnostic strategies supported by an enabling policy environment.

With its end-to-end model, FIND is committed to helping countries turn international guidance into bespoke COVID-19 testing policies. There is no one-size-fits all approach. To truly democratize access to testing, FIND understands the importance of working in partnership with local stakeholders to create fit-for-purpose solutions. This includes work in resource limited settings like Somalia, where a three-way partnership between the Federal Ministry of Health and Human Services, WHO and FIND led to the development of national policies, protocols and training packages for the rapid roll-out of Ag RDTs. FIND is also working to provide COVID-19 testing to health workers and communities in conflict-affected areas – in partnership with key stakeholders, including the International Organization for Migration, to develop and deliver testing algorithms/strategies that work for complex and fragile settings like Iraq, Jordan, Lebanon, and north-west Syria.

Underpinning this approach is an absolute commitment to research and evidence – the foundation on which such strategies are built, implemented and evolve. It is only by working to understand the reality on the ground that we can expand access to testing. Our work to validate the potential of bidirectional TB-COVID-19 testing in India is an important case-in-point here. Supporting the implementation of pilot models in select tertiary hospitals, together with our partners, we generated key learnings and recommendations to support the operationalization of national policy guidelines. To this end, in September 2021 FIND launched a new COVID-19 Operational Research Unit with the aim of identifying and validating community-based testing strategies to support in-country policy development and inspire replication across geographies and sociocultural contexts.



OUTCOMES

PARTNERSHIPS TO DEVELOP LOCALLY RELEVANT TESTING STRATEGIES

OPERATIONAL RESEARCH
TO VALIDATE THE
POTENTIAL OF LOCALLY
LED SOLUTIONS AND
USE CASES

NEW LEARNING TO SUPPORT LOCAL AND GLOBAL PROGRESS IN COVID-19 TESTING

STAGE 4 · MOBILIZING COMMUNITY-BASED AND SELF-TESTING STRATEGIES

For diagnostics to be truly decentralized, countries should be prepared to push boundaries and find new ways to integrate testing into daily life.

Expanding access to the very last mile, FIND is working with partners to leverage the potential of existing health programmes, utilize the services of healthcare professionals and volunteers, and integrate diagnostic testing into communities. This includes the delivery of Ag RDTs during routine antenatal care in South Sudan, the introduction of COVID-19 testing for *boda boda* (motorbike taxi) riders in Kenya and at taxi ranks in South Africa, as well as household testing in Rwanda. As part of our new Operational Research Unit, FIND is also working to test the effectiveness and acceptability of integrated malaria and COVID-19 outreach services in Suriname. With activities focused on the establishment of continuous testing in remote migrant and mining communities, this innovative venture is one of the 16 projects working to validate the potential of a local 'test-treat-isolate' response in 13 different countries.

Moving on from this, 'self-testing' has come to represent the final step in the democratization process. A model that has proven pivotal to the field of HIV and is now recommended for Hepatitis C (HCV), self-testing is about making sure that every individual has the information they need to make positive, health-focused decisions. Advocates of self-testing for COVID-19, FIND and partners worked together to demonstrate <code>feasibility</code> and understand the <code>values</code> and <code>preferences</code> of different populations – with contributing evidence used to support the development of <code>global recommendations</code>. Turning theory into action, FIND is also working with partners to pilot self-testing models across priority user groups in Georgia, Brazil, India, Malaysia and Tanzania (e.g. health workers, students, school and factory employees) and to trial pharmacy-based distribution models in Cambodia and Viet Nam.

We have also joined forces with Unitaid to support partners implementing self-testing models in a number of countries across Africa, Asia and South America. Together we will build a body of evidence to aid the development of practical toolkits and resources that guide implementation and scale-up. We are also partnering with Boston University to assess the cost-effectiveness and value of self-test approach.

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All of the above is underpinned by a growing suite of digital tools that work to guide people through the testing process, simplify the care pathway, and mobilize an effective

public health response. All while generating the data and evidence needed to inform disease surveillance, guide public health action, and stem the spread of COVID-19.







OUTCOMES

NEW MODELS FOR INTEGRATED COMMUNITY TESTING

> SELF-TESTING STRATEGIES DEVELOPED AND IMPLEMENTED

SIMPLIFIED CARE
PATHWAYS LINKING
TO EFFECTIVE PUBLIC
HEALTH ACTION

Recognizing that such progress must take place within the context of a functioning health system, FIND came together with our partners to build capacity for COVID-19 testing at every level. From community sensitisation and diagnostic literacy to health worker training packages, staff secondments and institutional support, together we are sharing skills and building systems that

As part of the above, we helped pioneer digital training solutions that work across channels and borders to support the delivery and uptake of COVID-19 testing. This includes a **self-paced learning and implementation guide** developed in partnership with WHO to support the implementation of Ag RDTs across the diagnostic network, as well as a three-week foundational course on 'COVID-19 diagnostics and testing' (a collaborative venture with the London School of Hygiene and Tropical Medicine and African Society for Laboratory Medicine). With the latter representing a first in class digital training for diagnostics, this essential MOOC was available to local and global stakeholders alike – reaching over 20,000 people in 191 countries.



SUMMARY AND LEARNINGS

An unprecedented response to an unprecedented situation, the actions enabled through the ACT-Accelerator transformed access to COVID-19 testing. FIND is proud to be part of this process, and as we look back on the last two years, reflections reinforce the need for – and value of – decentralized testing models, with key learnings emphasizing the importance of:



INNOVATION AND CREATIVITY at every stage, from inception through to implementation



will stand the test of time.

PARTNERSHIPS AND COLLABORATION to drive, inspire and accelerate progress



LOCALLY LED AND CONTEXTUALLY RELEVANT SOLUTIONS to support national priorities and practice



APPROACH that recognizes and responds to the needs of local populations

A PARTICIPATORY



OPERATIONAL RESEARCH AND DATA to validate, guide and inform local and global pandemic response and policies

We must keep the momentum going. Because our drive to decentralize testing doesn't end with COVID-19. Across the field, we are seeing the advances made during the pandemic era bring forward opportunities that were decades away – with disruptive technologies driving innovation in POC multipathogen testing for TB, accelerating the uptake of self-testing strategies for HCV, and using genomic sequencing to improve the detection and control of antimicrobial resistance.

This is just the start. By democratizing strategies for diagnostic testing, we can break barriers to access and empower people to take control of their health – supporting local and global ambition for universal health coverage and ensuring that no one is left behind.



Bill Rodriguez, CEO, FIND



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