



# LAB CULTURE

ADVANCING THE LABORATORY PROFESSION AND NETWORKS IN AFRICA

## Bringing diagnostic testing closer to communities

**Malaria rapid test**



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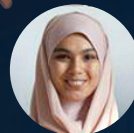
**HIV early infant diagnosis/viral load**



**Tuberculosis testing**



**Essential diagnostics**



### In this issue

Improving access to diagnostics at the community level:  
How can national Essential Diagnostics Lists help?

Disease testing in the community: the under-utilized opportunity.

Accelerating detection and early action for outbreaks:  
Role of decentralized testing capacities.



# LAB CULTURE

June 2022 | Issue 27

ADVANCING THE LABORATORY PROFESSION AND NETWORKS IN AFRICA

## Editors Note

**4** Communities are key for delivery of diagnostic services

by Collins Otieno

## FEATURED TOPIC

**6** Improving access to diagnostics at the community level: How can national Essential Diagnostics Lists help?

by Kenneth A Fleming, Susan Horton, Michael Wilson

## Q & A

**10** What is community-based testing?

by Marguerite Massinga Loembé

## FEATURED TOPIC

**12** Community roles in routine viral load testing: Going beyond demand creation to effecting change

by Bactrin Killingo, Helen Etya'le, Pontsho Pilane, Susan Perez

**15** Disease testing in the community: The under-utilized opportunity

by Zibusiso Ndlovu

## PERSPECTIVE

**18** Viewpoint of a virologist in the era of COVID-19: Impacts on communities, lessons learned and where do we go from here

by Aabida Khan

**22** Accelerating detection and early action for outbreaks: Role of decentralized testing

by Christopher T. Lee

## LABORATORY NEWS

**24** Global Fund Laboratory eTools Repository

by Natalie Martinez

**25** Workshop to finalize Integration Readiness Assessment Tool

by Collins Otieno

## LEADERS FROM THE BENCH

**26** Meet Varsatile Varster Nkwinika

### Contribute to Lab Culture

ASLM is currently accepting article and photo submissions for upcoming issues of **Lab Culture**. We publish timely, informative, inspirational articles relevant to the unique challenges faced by laboratories in resource-limited settings. We are interested in articles on the critical aspects of laboratory medicine, best practices, success stories, leaders in the field, industry news, etc.

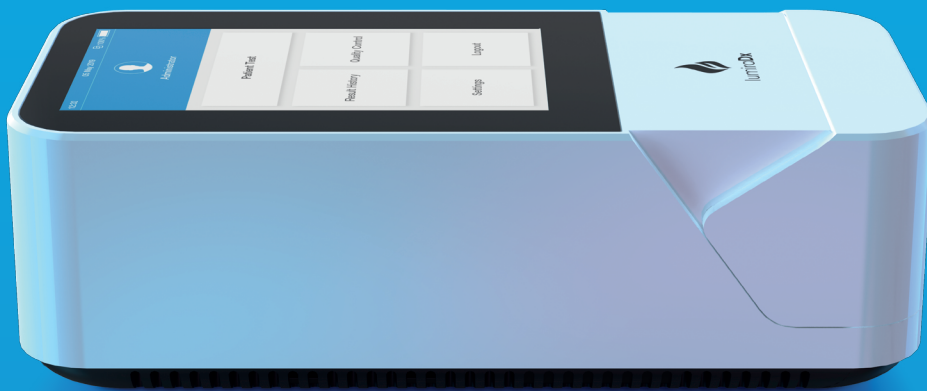
To submit article or photo proposals, please contact the Editor at [newsletter@aslm.org](mailto:newsletter@aslm.org).

**Lab Culture**. Established along with ASLM in 2011 as a member newsletter, **Lab Culture** relaunched in 2017 as ASLM's magazine for laboratory medicine in Africa. Dedicated to bringing timely, informative articles relevant to the unique challenges faced by African laboratories, **Lab Culture** seeks to be Africa's premiere resource for laboratory professionals and other stakeholders working on with the continent. Published six times a year as a digital edition, **Lab Culture** includes features on critical aspects of laboratory medicine and best practices in resource-limited settings, success stories from the continent, industry news, and more.

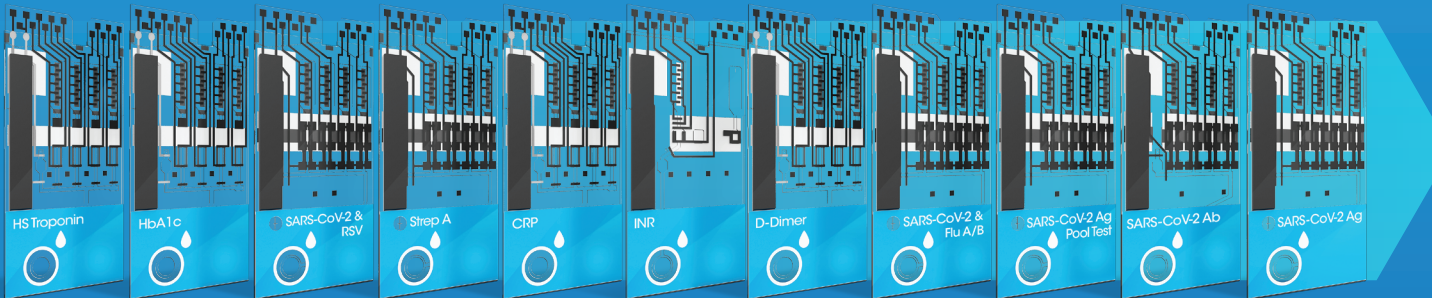


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*Lab Culture* is produced in  
partnership with *Medical  
Laboratory Observer*.



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# Communities are key for delivery of diagnostic services

'Community' has contributed immensely towards innovation and advancement in healthcare services, including treatment and accompanying diagnostics. Who is a community in the context of healthcare services? A community is a group of people who share an identity-forming narrative. It can be you and me, and any other person identified as seeking healthcare services. The concept of community is at the centre of any healthcare response. According to Prof L-G Bekker, in her presentation at the ASLM 2021 conference,<sup>1</sup> community has historically played four key roles in accessing better healthcare, including diagnostics: **Activism**; **Advocacy** for improved services; **Education** and information; **Action** and provision of services. The history of HIV outlines the role of the community in supporting the advancement in treatment options and access to diagnostics, including provision of patient-centred healthcare services.

While great strides have been realised in achieving global targets in well-funded disease programmes, like HIV and tuberculosis programmes, there is still lack of access to basic diagnostics at the community level. The recent *Lancet* Commission study<sup>2</sup> revealed a lack of access to diagnostics at the lowest tier of the healthcare system, the community, where the highest population in need of services exist, but only 47% globally have access. The article by K. Fleming, et al. in this issue (page 6) highlights the

glaring gap in access to essential diagnostic tests in low- and middle-income countries, where 81% have no access at the primary healthcare level, indicating that more needs to be done.

Even in these well-funded programs, like HIV programmes where diagnostics have been decentralized beyond clinical laboratories, with nurses and lay health workers among other cadres involved in supporting rapid HIV testing services, access to additional tests in the recommended diagnostic package for people living with HIV remains a challenge. The article by B. Killingo, *et al.* in this issue (page 12) cites a lack of awareness about the importance of a viral load test and the need for community groups to educate their members on accessing this vital test for monitoring the success of treatment. They call for a community-led monitoring initiative to assess the availability of diagnostic services at the community level. This initiative involves engagement of key stakeholders to share findings with an aim to co-create solutions to identified service delivery gaps.

With the rising incidence of non-communicable diseases, best practices in access to diagnostics for communicable diseases can be implemented to address diagnostic access gaps in the former. The article by Z. Ndlovu in this issue (page 15) proposes some proven solutions for delivery of diagnostics that can be leveraged to address



the growing problem of lack of access to non-communicable disease diagnostics. Thought must be given to involving the communities themselves in supporting diagnostic testing given the limited resources and laboratory personnel at the community level. Our Q&A article by M. Massinga-Loembe (page 10) outlines the potential of community testing by formally trained community healthcare workers in enhancing early detection of infectious disease outbreaks to inform faster implementation of control measures. Laboratory regulatory authorities need to provide guidelines on how

quality testing can be scaled up with appropriate training and licensure for lay health workers.

The need to involve communities in addressing healthcare gaps was perhaps best stated by Prof L-G Bekker when she said:

**“Communities do not want to be managed and medicalized. They want to contribute to their own care and have a seat at the table. They are the true innovators of health care delivery.”**

## References

<sup>1</sup> ASLM2021 virtual conference. <https://aslm2021.org/>

<sup>2</sup> Fleming KA, Horton S, Wilson ML, et al. The Lancet Commission on Diagnostics: Transforming access to diagnostics. *Lancet*. 2021;398(10315):1997-2050.

### Citation

Otieno, C. Communities are key for delivery of diagnostic services. *Lab Culture* 2022, No. 27, Pages 4-5



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## Mapping Antimicrobial Resistance and Antimicrobial Use Partnership (MAAP) Continental Dissemination Meeting

Data on antimicrobial resistance (AMR) and antimicrobial use (AMU) in Africa have been scarce. But, since 2019, the MAAP project has consolidated large amounts of data on AMR and AMU in Africa, initially focusing on 14 countries. This represents the first large-scale effort to collect, digitize and analyse such data retrospectively. Given the importance of the data to health policy decision-making in the region, and its potential to shape antibiotic use, ASLM will be sharing the findings of the research with policymakers and donors, as well as other key stakeholders at this critical meeting.



**Stay tuned for upcoming dates in Q3 2022!**



**African Union  
Addis Ababa, Ethiopia**



# Improving access to diagnostics at the community level:

## *How can national Essential Diagnostics Lists help?*

### Overview of *Lancet* Commission on Diagnostics findings

Realisation of the goal of Universal Health Coverage (UHC) as part of the Sustainable Development Goals will require countries to have national plans for delivery of basic packages of healthcare services, as well as the necessary investment. As part of this, countries will need to provide access to diagnostics to help guide provision of medical care, provide the necessary data on the prevalence of diseases and conditions, and to help support public health initiatives. However, as the coronavirus disease 2019 pandemic has shown, access to diagnostic services is too often inadequate, inequitable, and not adequately funded in many areas of the world.

There are several areas of investigation that provide objective evidence for this lack of access. A first example is the concept of cascades of care, where each disease or medical condition has a specific multi-step process required for diagnosis, treatment, and monitoring. These can be identified or measured. In the report of the *Lancet* Commission on Diagnostics, cascades of care were reviewed for seven common medical conditions, all of which had diagnosis as the largest gap in the cascade.<sup>1</sup> A second piece of evidence relates to how the combined issues of how available (i.e., present and usable in a health facility) and accessible diagnostics are for populations. In our analysis, we defined 'access' as being within two hours walking time of primary care and the diagnostic being available at the facility when surveyed. When this approach was applied to essential diagnostic tests

(eight laboratory tests and ultrasound, from the World Health Organization (WHO) antenatal care recommendations<sup>2</sup>), the findings were sobering: only 47% of the global population had access to these key diagnostics, and in low- and middle-income countries this dropped to 19%.<sup>1</sup> It is important to remember that these figures, as extraordinary as they are, are for basic diagnostic tests and examinations. The availability and access to more complex testing, especially diagnostic imaging, is even more limited.

The implications from lack of access at the community level are profound. Meeting the goals of UHC will not be possible without substantial improvements in the availability and access to diagnostics. However, the *Lancet* Commission on Diagnostics does present solutions to the current barriers to access, providing a path forward to more widespread and equitable availability and access to diagnostics.

### Developing a national Essential Diagnostics List

To help address the problems identified above, we propose the development of evidence-based national Essential Diagnostics Lists (EDLs) – a concept analogous to the Essential Medicines List which was first published by the WHO in 1977. The EDL identifies those diagnostic investigations which should be present at the three main levels of healthcare – primary or community care, first-level or district hospital and referral hospital. It should provide the basic structure of an integrated network of pathology and laboratory medicine and radiology services within the country. The specific components will depend on



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# Essential Diagnostics List: 2nd Edition

## General *In vitro* Diagnostic Tests

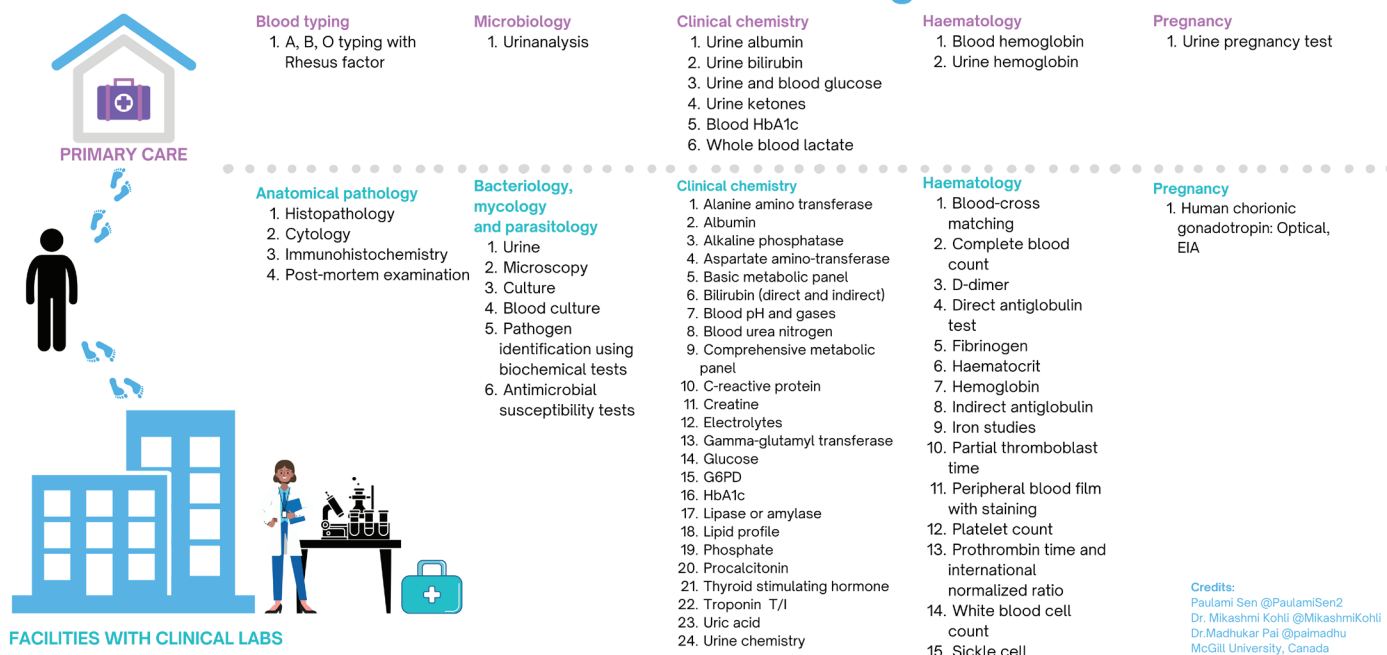


Figure 1. Summary of general in-vitro tests on WHO Essential Diagnostics List (second edition) for facilities with and without laboratories.

Source: Figure developed by Paulami Sen, Mikashmi Kohli and Madhukar Pai; used with permission.

the current and future burden of disease in the country and availability of workforce, and infrastructure such as equipment and supply chain. Efficacy and affordability are also relevant fac-

tors. A particular focus should be the provision of appropriate services at the primary/community level where the greatest deficiencies of diagnostics currently exist.

The WHO published its first EDL in 2018 with a revision in 2019 and a third edition in 2021.<sup>3</sup> The WHO list currently only considers *in vitro* diagnostics and only assigns the

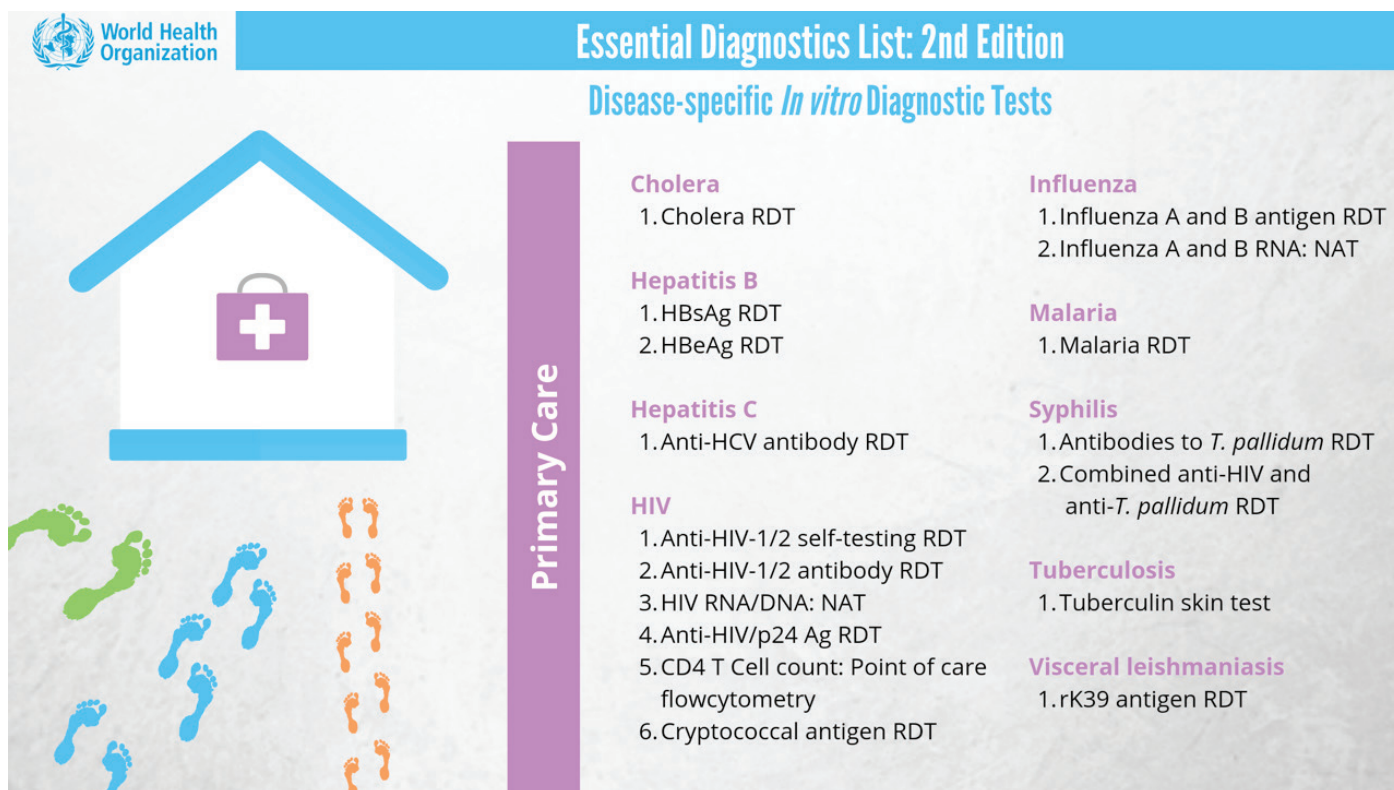


Figure 2: Disease specific in-vitro tests on WHO Essential Diagnostics List (second edition) for primary care.

Source: Figure developed by Paulami Sen, Mikashmi Kohli and Madhukar Pai; used with permission.



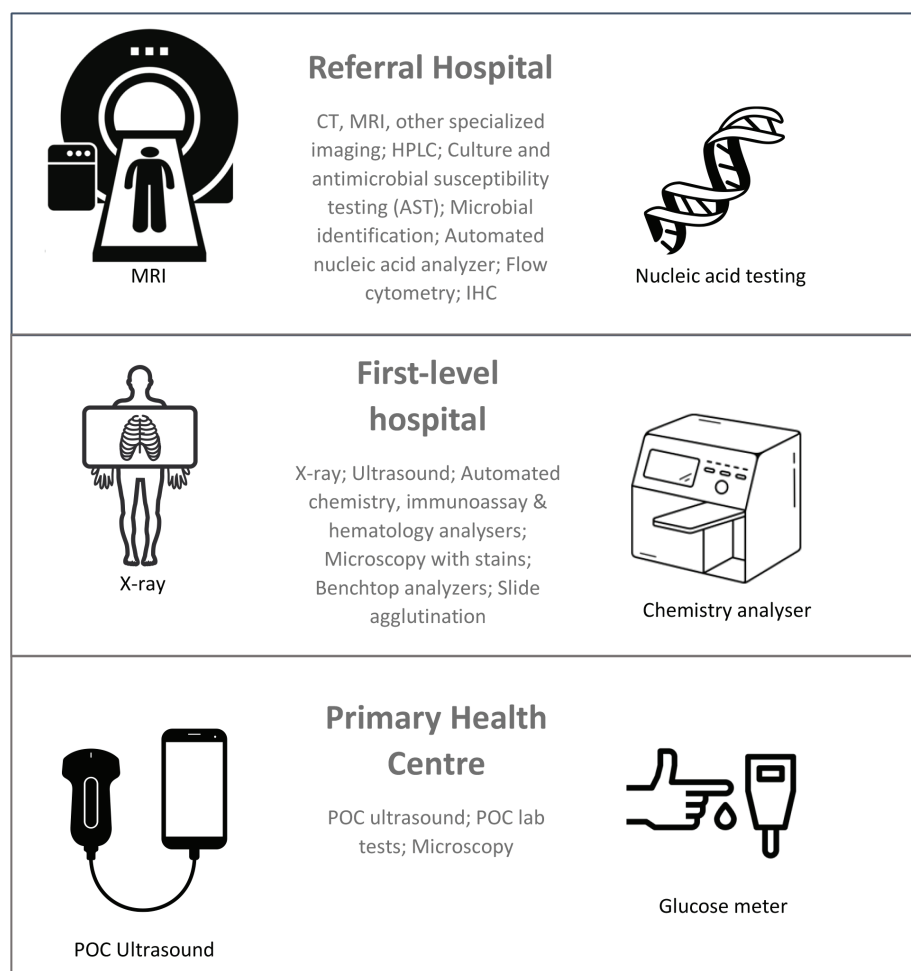


Figure 3. Diagnostics allocation by healthcare tier, *Lancet* Commission on diagnostics. Source: Ref. #1, Fleming A, et al.; used with permission.

tests to facilities with or without laboratories (**Figure 1**). It categorises tests as either general laboratory tests or disease-specific tests (**Figure 2**). The first edition contained 62 test categories, the second 122 test categories and the third added a 'Do Not Do' recommendation. For each group of tests, the EDL specifies the test's name, purpose, [assay](#) format and type of specimen.

The *Lancet* Commission on Diagnostics<sup>1</sup> listed the development of a national EDL as one of its top recommendations. It also provided a model for developing an EDL using the Global Burden of Disease predictions for 2030 and 2040 and mortality and years of life lost as the metric (**Figure 3**). A key assumption was that diagnostic tests for a condition should ideally occur at the same level of the health system as where

the condition is managed. At lower levels in the system, tests for that condition would identify which individuals require referral for diagnosis. The Commission's EDL allocated diagnostics by tier. Primary care facilities are assumed to have the capability of running point-of-care (POC) tests, lateral flow tests, dipstick tests, tests requiring very basic equipment (e.g., haemoglobinometer or glucometer), and POC ultrasound. First-level hospitals are assumed to have basic automated analysers available, as well as ultrasound and X-ray. More advanced laboratory and imaging capabilities are assumed to be available at higher level hospitals. It is assumed that higher level facilities can undertake all tests available at lower levels. More details have been submitted for publication.<sup>4</sup>

Somewhat reassuringly, there are many similarities between the *Lancet* Commission EDL, the WHO EDL and the Indian national EDL. This is perhaps not unexpected as presumably all countries have a common core of disease, especially as infectious diseases become less prevalent and non-communicable diseases increase. The WHO is currently developing a fourth EDL, expanding the current range of tests. We suggest that in future, the possibility of including imaging and undertaking cost-benefit estimates should also be considered.

### The economic case for developing a national Essential Diagnostics List

Diagnostics are not just important for their role in better healthcare and better public health surveillance. They also have important economic benefits. Although it requires resources to undertake diagnostic investigations, testing reduces spending on unnecessary and inaccurate treatments. Diagnostics can also identify non-communicable diseases such as cardiovascular disease and cancer at earlier stages and help prevent the onset of severe disease which is both expensive to treat, and can cause morbidity, disability and premature death. This in turn helps to avert catastrophic health expenditure and premature death of adult earners in the household, thus helping to improve financial risk protection, another target of the Sustainable Development Goal for health.

The *Lancet* Commission undertook conservative estimates of the cost-benefit ratio for six basic diagnostic tests available at (or, for tuberculosis, close to) the primary healthcare level. These calculations suggested that each dollar invested in diagnostic tests yielded benefits ranging from \$2.40 (multi-drug resistant tuberculosis), \$3 (hepatitis

B), \$8.40 (hypertension in middle-income countries), \$8.60 (syphilis) and \$16.60 (HIV) to \$24.40 (drug-sensitive tuberculosis). These benefits represent reduced health-care costs and greater earnings due to morbidity and mortality averted. Yet we know that the availability of most of these tests (other than HIV and tuberculosis) is very limited at the primary healthcare level. The EDL can help to prioritise the provision of basic diagnostics at the primary healthcare level. Ideally, as countries develop their benefits packages as part of UHC, these basic diagnostics should be included. Likewise, community health insurance schemes should cover these basic diagnostics.

The Essential Medicines List (first published in 1977) has provided economic benefits. A study in China,<sup>5</sup> which introduced its Essential Medicines Policy in 2009, found that facilities which had implemented the policy used more essential medicines and provided them to patients at lower prices, than those which had not yet implemented the policy. Another study argued that in 2002 'the inclusion of antiretrovirals on the WHO's essential medicines list, among other steps, led to a series of activities and policies that reduced the costs of antiretrovirals by more than 90%',<sup>6</sup> and associated with positive health outcomes. It is anticipated that the Essential Diagnostics List may have similar consequences.

## National essential diagnostics lists

India was the first country to develop a national EDL,<sup>7</sup> following the introduction of the first WHO EDL. India's list is tailored to national disease burden, includes diagnostic imaging as well as in vitro tests, and also identifies

diagnostics according to different levels of and settings within the health system. The national EDL is part of a suite of policies aiming to improve access to diagnostics, which currently account for 10% of out-of-pocket expenditures of the Indian population.<sup>8</sup> These policies include an act requiring registration and regulation of private diagnostic laboratories, and the Free Diagnostics Initiative, which is one component of the Indian UHC initiative. Although it is too soon to assess the impact of this package of initiatives, the consensus procedures used to derive the EDL, and the careful assignment of tests to different levels and settings within the health system, may provide useful benchmarks for other countries developing their own lists.

Nigeria has invested in developing a national EDL with involvement of experts including Dr Anthony Emeribe, who served on the founding Strategic Advisory Group of Experts for developing the WHO EDL. Dr Emeribe notes that the draft has been completed and approved by the Minister of Health, and that implementation will be the next step. It is hoped that other countries will follow suit.

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### Editor:

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### Citation

Fleming A, Horton S, Wilson M. Improving access to diagnostics at the community level: How can national Essential Diagnostics Lists help?. *Lab Culture* 2022, No. 27, Pages 6-9.

# What is community-based testing?

Community-based testing has emerged as an essential strategy to **expand access to diagnostic services** with an approach that is more patient-centric. It aims to **bring testing closer to the individual**, removing the need to actively seek care in a healthcare facility and **minimizing barriers** related to distance to and cost of care.

## What role can community-based testing play in expanding access to care and improving health outcomes?

In the context of Universal Health Coverage, assuring the availability of health services within communities so that no one gets left behind is a central tenet towards achieving health equity.<sup>1</sup> Diagnostic service delivery at the community level increases the likelihood that everyone, everywhere can access testing whenever needed.

At its simplest, community-based testing consists of setting up diagnostic sites at closer proximity to communities – as exemplified for the COVID-19 response where SARS-CoV-2 testing has been provided in pharmacies, via drive-through services, etc.<sup>2</sup> The World Health Organization guidelines for integrated disease

surveillance,<sup>3</sup> go further, emphasizing the importance of community participation in the detection and response to public health threats. Testing at the community level (i.e., outside of a health facility), by formally trained community healthcare workers, can enhance early detection of new cases during an infectious disease outbreak or can allow monitoring of transmission to promptly detect resurgences (i.e., new wave of cases).<sup>4</sup> In regions faced with a disproportionate burden of transmissible diseases, such as Africa or South-East Asia, or in underserved populations in affluent countries, community-based testing is one of the key interventions proposed as part of active case finding strategies. Actively testing people with symptoms, or high-risk groups, within the community, allows earlier detection of cases and better linkage to treatment, which might limit the chain of transmission and lead to control of endemic infectious diseases such as HIV<sup>5</sup> or tuberculosis.<sup>6</sup>

## How is community-based testing performed?

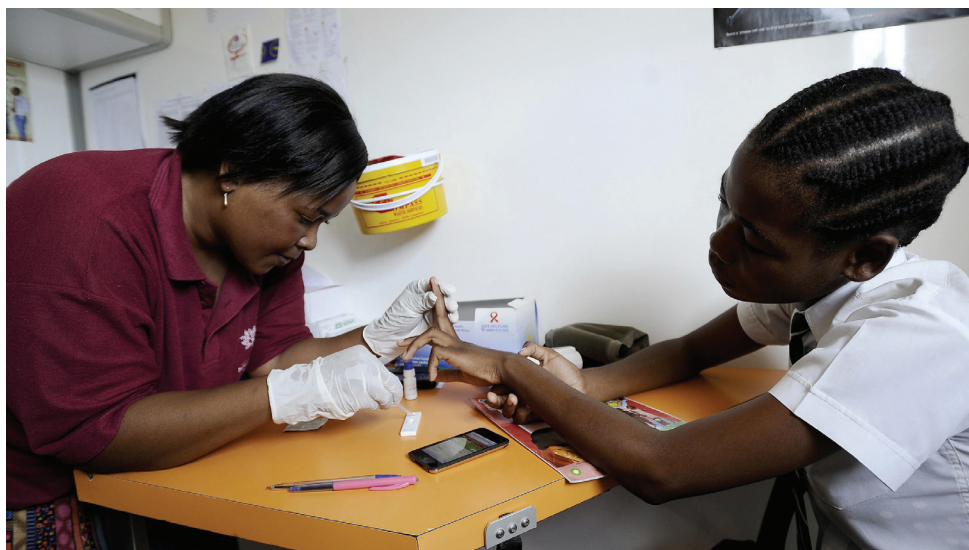
Community based testing relies on the use of low complexity assays, with a rapid turn-around time and which can



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easily be performed outside of a conventional laboratory. These include rapid diagnostic tests (RDTs), such as immunoassays (i.e., Ag RDT, Ab RDT) or molecular assays (i.e., Loop-mediated isothermal amplification, or 'LAMP'). Such tests are also known as point-of-care (POC), or near patient, tests.

Digital diagnostics, which aim to integrate additional functionalities such as connectivity or multiplexing to POC tests, all contained in a small handheld electronic device, represent the next step for community-based testing. Digital diagnostics have the potential to bring us closer to universal access to diagnostics services, even in resource-limited settings.

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# Community roles in routine viral load testing:

## *Going beyond demand creation to effecting change*

### Background

The World Health Organization (WHO) has recommended routine viral load testing (RVLT) to detect and confirm antiretroviral treatment failure since 2013.<sup>1</sup> On the global scale, RVLT is essential to achieving UNAIDS 2025 targets (diagnosing 95% of all people living with HIV, providing antiretroviral therapy (ART) for 95% of those diagnosed, and achieving viral suppression among 95% of those treated).<sup>2</sup> Viral load test results inform clinical decisions around changes in ART regimens and highlight the need for adherence counselling for recipients of care with unsuppressed viral loads; they also emphasize the importance of a suppressed viral load for better health outcomes and prevention of HIV transmission to partners. However, despite viral load testing scale up, recipients of care do not receive timely viral load test results and the use of viral load test results for ART management is suboptimal.<sup>3,4</sup> User fees for viral load tests, stockouts of reagents and consumables, machine malfunction,<sup>5</sup> and recently, coronavirus disease 2019 (COVID-19)-related disruptions to RVLT pose additional challenges.<sup>6</sup>

### Generating demand for RVLT through awareness campaigns

The community of people living with and affected by HIV have historically had an important and effective role in advocacy for access to care and treatment, which extends into laboratories. The International Treatment Preparedness Coalition (ITPC), a global group of people living with and affected by HIV, has mobilized around RVLT based on information gathered through community consultations and initiatives. ITPC's 2019 *Global Treatment Survey*,<sup>5</sup> which presented data collected from 14 low- and middle-income countries, covering seven global regions, found widespread lack of awareness about the importance of RVLT among recipients of care, which limited demand for, and uptake of RVLT – and imperiled individual health outcomes and progress towards global targets.

ITPC initiated awareness campaigns, a strategy which has been used successfully to address barriers to HIV prevention, testing, care and treatment services. The impact of awareness campaigns can be far-reaching; once recipients of



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**Figure 1. Be Healthy—Know Your Viral Load** – Communities leading campaigns to raise awareness and demand routine viral load testing scale-up. (Source: ITPC)



**Figure 2.** Youth activists in Kenya raise awareness of routine viral load testing through a radio program. (Source: NEPHAK)

care and their communities have been equipped with the right knowledge, they have demanded the health services they are entitled to. In 2015, ITPC and the AIDS and Rights Alliance for Southern Africa launched the *Be Healthy Know Your Viral Load*<sup>7</sup> campaign across multiple low- and middle-income countries, to create demand for RVLTL (**Figure 1**). ITPC also created an *Advocacy for Community Treatment* toolkit<sup>8</sup> for HIV treatment activists and community leaders. The *Toolkit* provided a community-friendly overview of the HIV cascade of care (spanning from HIV prevention to ongoing treatment and care, including RVLTL) to support low- and middle-income country HIV communities in identifying social, political, economic and other barriers to HIV services. It outlined a Community Demand Creation Model, which included treatment education and instructions on carrying out a baseline and endline assessment of gaps in access to and quality of services along the HIV care cascade, and on mobilizing and conducting advocacy. The *Toolkit* supported improved advocacy skills among PLHIV communities to be able to raise their voices more effectively in local and national decision-making fora.

Once they were empowered with information and skills, PLHIV communities used media and other online avenues to share personal stories and reach decision-makers. This civil society-led advocacy had a direct, positive impact on viral load testing scale-up, and pushed for additional research and development of cheaper, easier viral

load testing technology and point-of-care testing.<sup>9</sup>

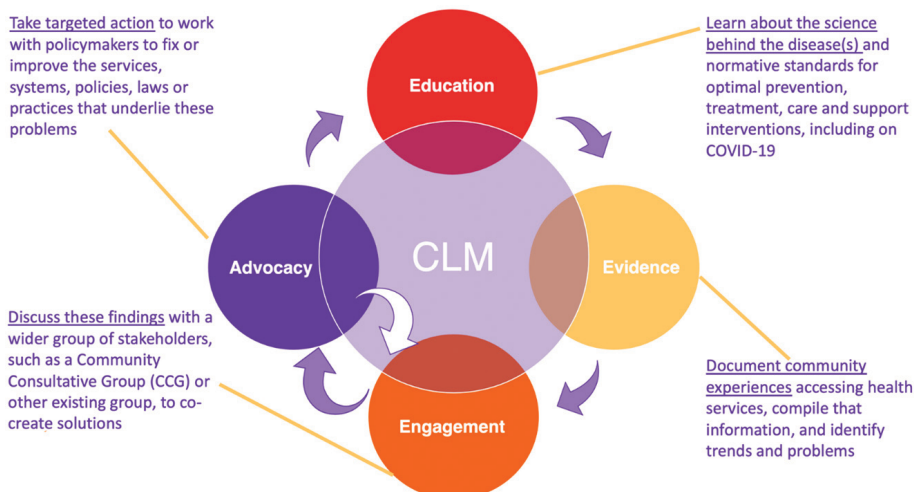
More recently, in 2020 through 2021, ITPC partnered with the African Society for Laboratory Medicine to support Laboratory Systems Strengthening Community of Practice, or ‘LabCOP’, country teams in initiating and scaling up hashtag campaigns to improve demand for RVLTL across six countries in Africa (Democratic Republic of Congo, Kenya, Malawi, Sierra Leone, South Sudan and Zimbabwe). These campaigns reached over an estimated 100,000 people through digital media (Facebook, Twitter, Instagram, WhatsApp) and TV,

radio, and in-person engagements across a wide range of audiences, including adult and young people living with HIV, expectant mothers, religious leaders and people who are members of key populations such as high-risk and high HIV prevalence groups (**Figure 2**).

A campaign impact assessment found that new behaviours were triggered among the target audiences, including getting a viral load test, telling a friend about RVLTL, and asking a healthcare worker about the results of a viral load test. Unfortunately, the campaign’s overall success was hindered by systemic barriers to viral load testing, including laboratory reagent stockouts, machine breakdowns and long turn-around times for test results.

## Addressing barriers to RVLTL through community-led monitoring and advocacy

In addition, HIV communities have documented the lived experiences of recipients of care and used this information for evidence-based advocacy to improve HIV services. In January 2017, ITPC launched the Regional Community Treatment Observatory (RCTO),<sup>10</sup> made up of networks of people living with HIV in 11 West African countries (Benin, Cote d’Ivoire, Gambia, Ghana,



**Figure 3.** Key components of ITPC’s community-led monitoring model: education, evidence, advocacy, engagement.



Guinea, Guinea Bissau, Liberia, Mali, Senegal, Sierra Leone and Togo), who identified quantitative and qualitative indicators based on their priorities and performed routine and systematic data collection on gaps in access to and quality of HIV services, a process called community-led monitoring (CLM). CLM involves four key quadrants: **education** on key elements of global HIV guidelines, indicators and on data collection, verification, storage and analysis (**evidence**), and **engagement** with key national and local stakeholders to share data and co-create solutions to identified shortfalls in service quality and access, and, when necessary, **advocacy** (Figure 3).

The RCTO collected data on the number and frequency of HIV viral load tests and documented barriers to testing across 125 health facilities (Figure 4). Qualitative data revealed that lack of knowledge was the primary reason for not undergoing RVLT. Beyond that, supply-side issues, including shortages of or malfunctioning machines, delays in returning results and laboratory reagent stockouts contributed to lack of access to RVLT.<sup>10</sup> Similar findings emerged from CLM in Malawi, Zambia and Zimbabwe: lack of knowledge about RVLT, inconvenient testing times, and long turn-around for results were identified as barriers.<sup>11</sup> After more than two years

of monitoring, consultation and advocacy across all eleven countries, the number of viral load tests performed increased from 16,532 in January-June 2018 to 33,376 during the same period just a year later. Viral suppression rates increased from 48.5% in 2018 to 77.4% in 2019, during the same period. Advocacy initiatives led by networks of people living with HIV also brought about a change to more convenient operating hours for target health facilities in Malawi.<sup>11</sup>

ITPC and its partners continue to monitor, document and advocate for improvements in access to, and quality of HIV services, including RVLT in the COVID-19 era.<sup>12</sup> Networks of people living with HIV in Nepal, Guatemala and Sierra Leone documented how COVID-19 led to a reduction in the number of viral load tests performed and longer turn-around times for test results – evidence used to inform national advocacy.<sup>13</sup>

## Communities and laboratory testing: beyond demand creation

The examples described here show the key role played by communities and recipients of care in improving access to RVLT, using demand creation and evidence-based advocacy approaches to effect targeted action at the local level and influence national-level policies. Keeping recipients of care at the center, as

active contributors in their own health, improved RVLT access at the health service site, national and regional levels. These same approaches can be applied to improving access to other laboratory and diagnostic services that communities

of people living with HIV need. In the era of universal healthcare, we have the opportunity to use these successful approaches to contribute to an integrated, holistic view of care that ultimately benefits recipients of care – and enables achievement of timebound HIV global targets and goals. However, while communities can make a contribution, their work must be met with concrete and actionable responses by decision-makers to resolve and correct service delivery, training and supply side issues so that community efforts are not in vain.

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### Editor:

Mrs Bethanie Rammer, African Society for Laboratory Medicine

### Citation

Killingo B, Etya'ale H, Pontsho P, Perez S. Community roles in routine viral load testing: Going beyond demand creation to effecting change. *Lab Culture* 2022, No. 27, Pages 12-14.



Figure 4. Community partners collecting quantitative data from health facilities. (Source: ITPC)

# Disease testing in the community:

## *The under-utilized opportunity*

### Introduction

Although sub-Saharan Africa remains the worst affected region by infectious diseases, there has been significant improvement in diagnostic support for HIV/AIDS, tuberculosis, and malaria over the past decades, although significant gaps persist in availability and quality.<sup>1</sup> Even worse, sub-Saharan Africa is now facing a rising surge of non-communicable diseases (NCDs) like diabetes mellitus, cardiovascular diseases, respiratory diseases and cancers.<sup>2, 3</sup> NCDs are, by far, the biggest killers of people worldwide as they kill 41 million people globally each year (equivalent to 71% of all deaths globally), and 77% of all NCD deaths occur in low- and middle-income countries (LMICs).<sup>3</sup>

Many health systems across LMICs remain weak, with poor disease integration, and are under-resourced and overburdened; certain key populations and geo-settings can hardly access existing health services. A *Lancet* Commission on diagnostics concluded that 47% of the world's population have little or no access to diagnostics and that the diagnostic gap (i.e., the proportion of the population with the condition who remain undiagnosed) is most severe at the primary healthcare level where only about 19% of populations in LMIC have access to the simplest diagnostic tests.<sup>4</sup>

Control and elimination of priority diseases could be enabled through complementing conventional health facility-based diagnostic testing by a variety of testing strategies that have more focus on patient convenience. Access to 'convenient diagnostic testing', which brings simplified, easy to use and affordable point-of-care (POC) diagnostics closer to people's homes while minimising long traditional diagnostic delays and tedious complex care pathways at health facilities, is long overdue for consideration in many LMICs. Within characteristics of a healthcare sys-

tem, communities (both in rural or urban, rich or poor) continue to expect ever-more convenient and patient-centric access to care, shaped by their preferences.

POC diagnostic testing is widely recognized as an essential component of ensuring access to health services, and advances in POC technology have made devices more accurate, easier to use and more accessible, particularly in hard-to-reach communities and in vulnerable groups. The advent of self-testing (self-sampling, performing and interpreting tests) such as for HIV and pregnancy together with self-monitoring tests for chronic conditions like diabetes mellitus and hypertension, allows individuals to conveniently use these tests. The coronavirus disease 2019 (COVID-19) pandemic has further re-shaped society's understanding of ideal healthcare delivery, placing more emphasis on patient convenience, including virtual care, self-diagnostic testing and telehealth. This fundamental shift from provider-driven care to individual driven care has slowly been expanding in many LMICs and opportunity exists to broadly include self or supervised testing in communities for glucose, cholesterol, syphilis, malaria, and hypertension, among others. Precedent self-testing (HIV, COVID-19) has helped to conveniently decentralize services to community sites and developed alternative entry points for accessing healthcare in LMICs, with pharmacy or retail networks and or community care providers who can distribute, supervise and support self-testing and facilitate follow-up and linkage to services.

Community based testing, through community healthcare workers (CHW) or self-testing, holds massive potential to enable a 'de-medicalised' approach to diagnostic testing access at the so-called last mile. There is an unprecedented opportunity to improve global health diagnostics, especially utilizing the frame-



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These pictures were taken in Beit-bridge in Zimbabwe among migrants in one of the communities. An MSF community health care worker is distributing HIV self test kits and demonstrating how to use them. Pictures: courtesy of Mr Israel (MSF)

work created by HIV self-testing and COVID-19 testing centres in the community; to accelerate progress toward universal health coverage.

## What it can look like

CHW programmes are embedded in communities and have been used extensively to provide household and community education, early screening, tracing and referrals for care and treatment for a range of health and social services.<sup>5</sup> As we previously wrote, many LMICs have insufficient healthcare providers to meet the needs of their populations, including diagnostic testing capacity.<sup>6</sup> Upskilling CHW to also conduct community-based diagnostic testing and monitoring for priority diseases like syphilis, malaria, diabetes and hypertension, especially with a focus on priority populations or geo-settings with the greatest gaps in testing, is a

way to meet this need.

Building on efforts to shift diagnostics away from healthcare facilities, and with the increasing importance of priority populations, sustainable systems could be developed for community-based testing delivery, especially in certain geographic locations, primarily rural or hard-to-reach areas. With the ongoing surge in NCDs in LMICs, expanding diagnostic screening and monitoring access points is critical for recruiting hard-to-reach populations. Experience from HIV programmes has shown that the ability to recruit and link patients into care within traditional health facility testing can reach a 'ceiling' whilst many people will still be left behind.

Innovations in expanding access to decentralized treatment is a way to improve linkage to treatment and prevention therapy among underserved groups and communi-

ties. Under the Pharmacy Initiated Management of Antiretroviral Treatment (PIMART) programme in South Africa, pharmacists holding the required permits prescribe and initiate HIV medicines without people first having to get scripts from doctors or nurses.<sup>7</sup> The PIMART model could be adapted for other priority diseases. Applying lessons from the HIV/AIDS experience could help shorten the learning curve for NCDs and other priority disease control.

Private pharmacies in the communities are a first port of call for many people seeking health services in many LMICs, including priority populations. Each of these visits provides an opportunity to offer supervised or unsupervised testing services, including secondary test distribution for priority diseases.

Regulatory authorities (especially the World Health Organization) should review evidence to assess the utility of self-diagnostic testing for other priority diseases like syphilis, hypertension, and malaria. Access to testing could be through self-testing (supervised or unsupervised) via local pharmacies, or through CHW mobile testing sites. In many LMICs, men who have sex with men, sex workers and other key populations are prevented from accessing sexual health services due to legal and cultural barriers, including the possibility of imprisonment. Approval of syphilis self-testing could aid its integration with HIV and/or pregnancy self-testing services and provide an opportunity for these and other key populations, including those in neglected geo-settings. Empowered and engaged communities can generate demand for self-care as seen with HIV and the COVID-19 pandemic, where self-testing has been successfully implemented, enabling communities to benefit from advances in science and medicine. Similarly, digital tools (smartphone apps and



chat-bots) can be used for interactive public education on priority diseases, linkage to care and treatment.

In some LMICs, HIV self-tests are still hardly available in communities with the greatest testing gaps and/or are expensive in the public or private retail sector (\$2.00–\$3.00 United States dollars [USD] and \$8.00–\$16.00 USD, respectively).<sup>8</sup> The availability of pregnancy testing products is usually through clinics or private retail settings, where they are usually not affordable for women from rural areas, yet these could be distributed through community-based programs just like condoms. With the expected

within context-specific disease priorities (which could include HIV/AIDS, sexually transmitted infections, malaria, tuberculosis, NCDs), but also consider the increasing importance of priority populations (younger people, ‘millennials’, men, older people, key populations) who face healthcare accessibility inequalities. Even though extensive social science research has demonstrated minimal social and physical harms of self-testing (mostly HIV), which was a major concern from the outset,<sup>9</sup> there is a need to empower patients to understand and manage their self-diagnosis with appropriate resources before introduction

of self-tests for other diseases. This approach requires efficient reporting of results, and rapid communication with health professionals using telemedicine or other virtual methods and referral to health facilities to maximise the advantages of self-testing.

Achieving community acceptance from local leaders and community

members will be critical to the success of implementing community testing across a variety of African settings and building diagnostic literacy through the media, policy makers, health workers and the public could help to communicate the agenda.

## Further research needed:

Because self-testing and or CHW-led testing could be expensive, it is important that its use be supported by robust evidence confirming its utility and efficacy. Research can help shed light on the feasibility and effectiveness of large-scale implementation of community-based testing, including determining the preferred distribution

channels, demand generation and implication for health systems more broadly. Of course, as with any paradigm shift, there will be numerous aspects to be resolved with regards to delivering community-based testing. This includes security measures being put into place that emphasize patient privacy, safety and a linkage-to-care framework.

## Conclusion

The sheer scale of the pandemics of infectious and NCDs in LMICs demands that we re-examine and complement current service delivery models with community-based self-testing and/or self-management. This is an area of high importance for investment in LMICs, as new tests and treatments will potentially enable further decentralization of essential healthcare to remote communities.

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### Editor:

Mrs Bethanie Rammer, African Society for Laboratory Medicine

### Citation

Ndlovu Z. Disease testing in the community: the under-utilized opportunity. *Lab Culture* 2022, No. 27, Pages 15–17



Mobile clinic in HIV/TB hotspots in Mozambique: tests conducted include HIV rapid test, CD4, urine TB LAM, Immy CrA

increase in use of self-testing products, their accessibility and affordability should be prioritized, especially in communities with testing gaps. Manufacturers should consider designing simplified self-test products for syphilis, tuberculosis, glucose, hypertension, and cholesterol, among others. Ideal self-testing products should be easy to use, including result interpretation, with clear instructions-for-use that are available in local languages and understandable at low literacy and education levels.

## What will it take?

Community-based diagnostic testing should be informed by testing gaps

# Viewpoint of a virologist in the era of COVID-19:

## *Impacts on communities, lessons learned and where do we go from here*

When I read the ProMED-mail notification on New Year's Eve 2019 regarding the emergence of a novel coronavirus, now known as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), no one could have anticipated the magnitude of the coming pandemic or its cataclysmic effects.<sup>1</sup> Coronaviruses have large RNA genomes and zoonotic potential, as evidenced by emergence of the first SARS coronavirus (SARS-CoV) in 2002 and Middle East respiratory syndrome coronavirus (MERS-CoV) in 2012. SARS-CoV-2 has spread rapidly worldwide and coronavirus disease 2019 (COVID-19) has disrupted all spheres of life. Despite loss of precious lives and economic hardship, with solidarity we can unite to preserve humanity. A big salute is due to all healthcare workers, including all laboratory personnel, for their hard work and sacrifice. The unprecedented pace of research and development is commendable, such that there are now evidence-based guidelines, validated diagnostics and vaccines available.

The recent pandemic has taught us the importance of outbreak preparedness and response, global scientific community collaboration and communication, government support, upscaling resources and skills, and improving capacity development.<sup>2,3</sup> It has also highlighted the stark disparities and inequities between regions, the powerful influence of social media and the irrevocable harm caused by misinformation and vaccine hesitancy.

Virologists like me were previously working under the radar. Now, we are in the spotlight with variants and vaccines being hot topics. This pandemic has highlighted the need for more

virologists to be working in the field, not only on SARS-CoV-2, but also on other public health concerns such as HIV, measles, Ebola, yellow fever, human papillomavirus-related cancers, rabies and viral hepatitis.

### COVID-19 has a zoonotic origin

The majority of emerging viral infections are zoonotic in origin.<sup>4</sup> The reservoir host for influenza viruses are wild aquatic birds. Currently, there are widespread outbreaks of highly pathogenic avian influenza in birds and poultry, with the ongoing threat of antigenic shift and emergence of another influenza pandemic. Bats are the reservoir host for coronaviruses, lyssaviruses, which causes rabies, and filoviruses such as Ebola virus and Marburg virus. Even HIV is zoonotic in origin. The One Health approach, which integrates human health, animal health and the environment in multi-sector cooperation, is a fundamental strategy in the prevention and control of emerging infections.<sup>5</sup> The investigation of the origin of SARS-CoV-2 and surveillance of susceptible animal species should not be neglected and, indeed, is necessary in order to gain understanding of the spillover event and potential intermediate hosts, identify strategies for prevention of zoonotic viral emergence and monitor viral evolution in infected animals such as mink and white-tailed deer.<sup>6</sup>

### Accessible testing is needed... but not only for COVID-19

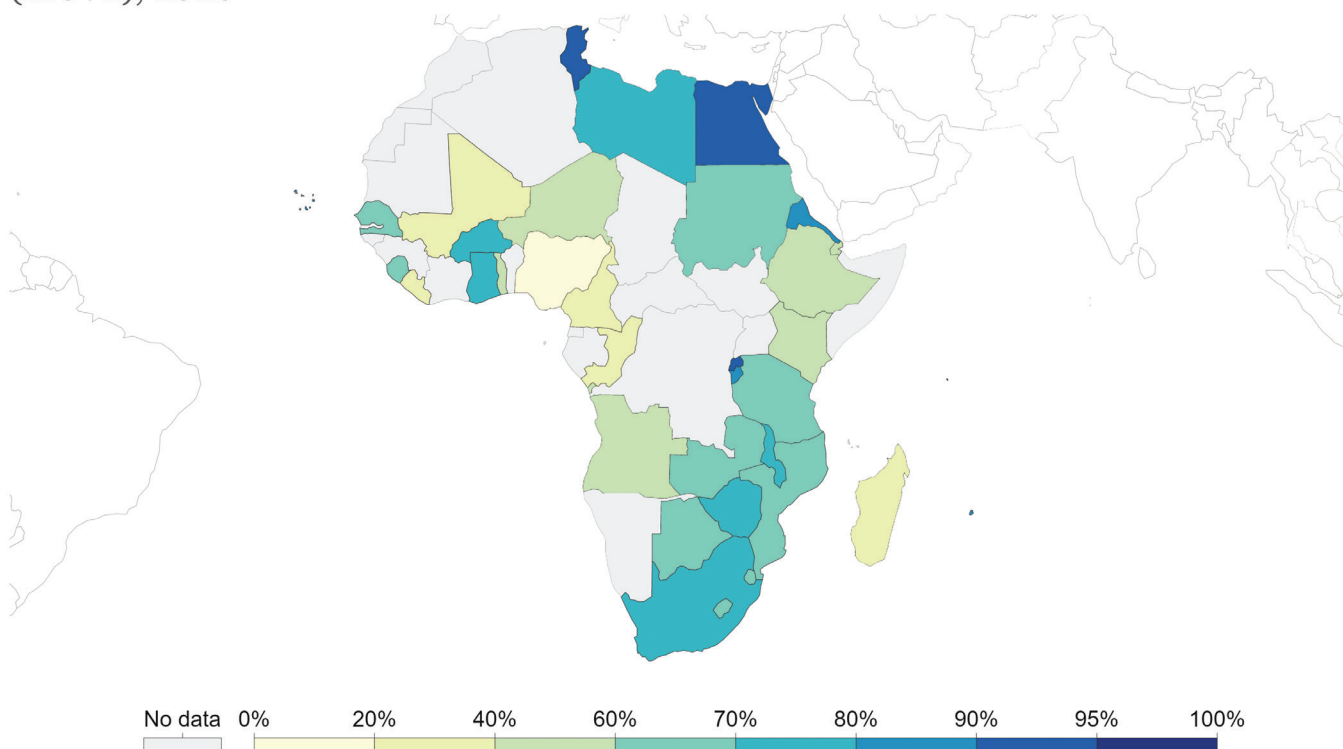
The collateral damage caused by the COVID-19 pandemic is insidious and underestimated. Patients have been unable to access basic healthcare in



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## Share of children vaccinated with the second dose of measles vaccine (MCV2), 2020

Our World  
in Data

Source: WHO, Global Health Observatory

OurWorldInData.org/vaccination/ • CC BY

Note: Measles is a highly contagious viral disease, most common in young children. Its effects include blindness, inflammation of the brain, severe diarrhoea, and severe respiratory infections such as pneumonia. Recommended child's age for MCV2 vaccination varies by country.

Figure 1. Reduced measles vaccine coverage.

Source: Samantha Vanderslott, Bernadeta Dadonaite and Max Roser (2013) - "Vaccination". Published online at OurWorldInData.org. Share of children vaccinated with the second dose of measles vaccine (MCV2), 2020. Data source: World Health Organization, Global Health Observatory. Available from: <https://ourworldindata.org/vaccination> [Online Resource]professional qualifications

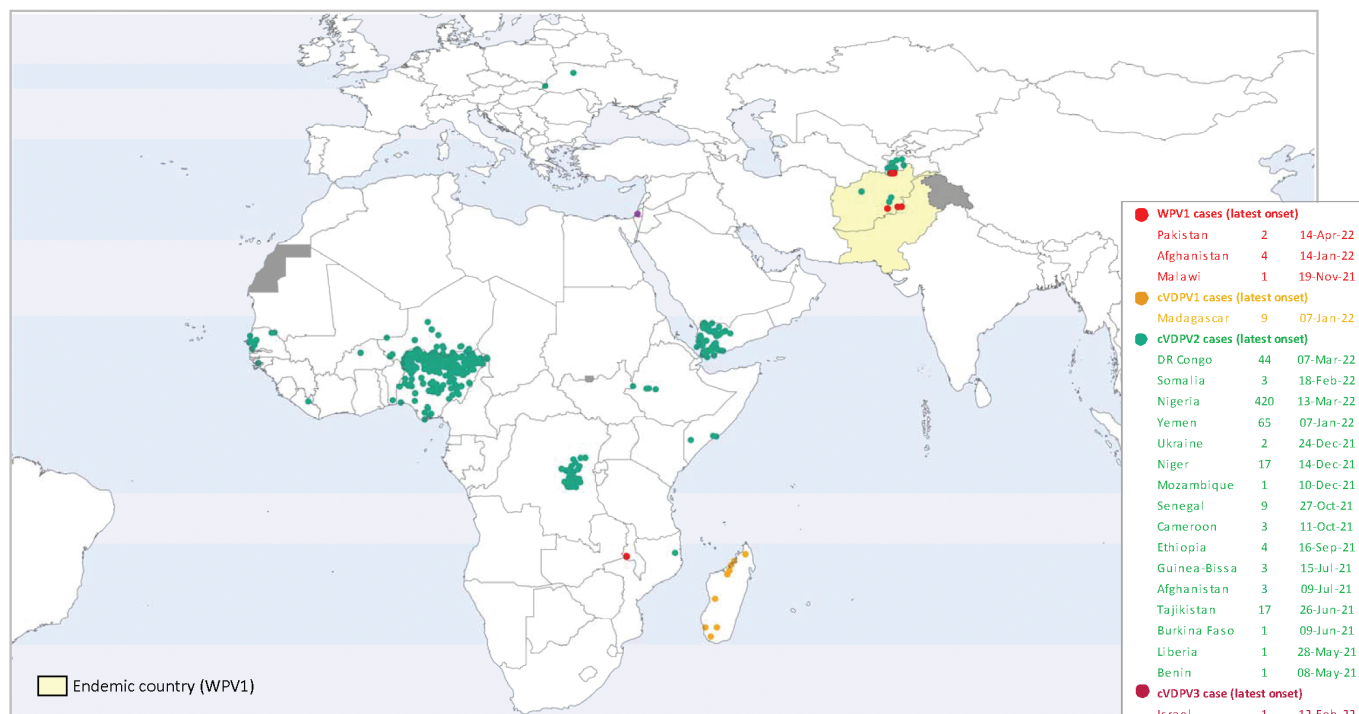
their communities, leading to undiagnosed or untreated diseases, reduced cancer screening and care, HIV treatment interruptions with the threat of drug resistance, reduced antenatal care and increased risk of adverse pregnancy outcomes, and reduced routine childhood vaccination (**Figure 1**).<sup>7-9</sup> In several countries in Africa, there have been circulating vaccine-derived polio outbreaks, as well as resurgence of measles (**Figure 2**). Besides COVID-19, there have been recent outbreaks of Ebola virus disease, yellow fever and Rift Valley fever in Africa. Therefore, there is a need not only to prioritize control of the pandemic but also to focus on improving all aspects of healthcare.

Another significant obstacle for effective healthcare delivery is reduced vaccine uptake due to lack of access and vaccine hesitancy due to mistrust and myths.<sup>10</sup> Community engagement, building trust and dispelling fears is important, as has been shown in control of Ebola outbreaks in central and western Africa (**Figure 3**). Qualitative research is needed to provide strategies to address issues such as vaccine hesitancy. Healthcare workers should be at the frontline of education and vaccine advocacy efforts. Community healthcare workers have played a critical role in the pandemic, and it is at the grass roots level in communities that education, empowerment and access is required.<sup>11</sup>

### COVID-19 testing strategies are moving targets

Technological advances have catapulted the diagnosis and surveillance of viral infections into the spotlight. The crucial role of laboratory medicine in outbreak control and management has been further highlighted by the COVID-19 pandemic.<sup>12</sup> The spectrum of test methodologies each has its own role (**Table 1**). Real-time PCR platforms streamline testing enabling high throughput. PCR assays with two or three gene targets are preferred to ensure sensitivity in the presence of variants. Point-of-care tests have the main advantage of fast turn-around times to facilitate case management and contact



Global WPV1 & cVDPV Cases<sup>1</sup>, Previous 12 Months<sup>2</sup>

<sup>1</sup>Excludes viruses detected from environmental surveillance; <sup>2</sup>Onset of paralysis 04 May 2021 to 03 May 2022

Data in WHO HQ as of 03 May 2022

Figure 2. Vaccine derived poliomyelitis outbreaks in Africa.

Source: World Health Organization. A map showing the latest number of wild poliovirus 1 and circulating vaccine derived poliovirus cases. Available from: <https://polioeradication.org/polio-today/polio-now/>

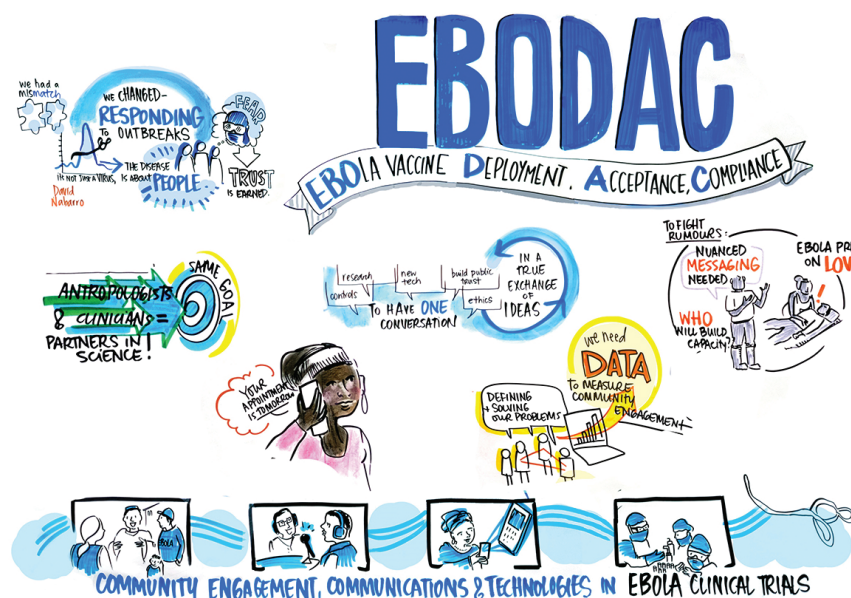
tracing to prevent spread. Rapid antigen tests are a great tool in this regard, as they are most sensitive early when viral load is highest dur-

ing the period of highest infectivity. Whereas PCR is highly sensitive, it can remain positive for several weeks to months after infection,

and detection of viral nucleic acid does not always equate to infectivity. Thus, there should be a balance between the 'catch-all PCR test' and 'quick-catch rapid antigen test' approaches, depending on the context and clinical decision making based on the test outcome.<sup>13</sup> Despite the obstacles faced, laboratories have risen to the challenge of providing timely, accurate, and quality-assured results.<sup>14</sup>

## Beyond surveillance, we need to adapt

This pandemic has brilliantly shown the importance of genomic sequencing in virus discovery and surveillance with tracking of viral evolution and identification of variants that impact on transmissibility, diagnostics, therapeutics and vaccines.<sup>15</sup> Sero-surveillance is also crucial in tracking the pandemic, especially since most cases are not tested due to being asymptomatic or mild.<sup>16</sup> Other forms of surveillance, such as wastewater



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Figure 3. Role of community engagement. Source: Open Access News, The role of anthropology and technology in the Ebola vaccine response, 20 December 2018, Adapted from EBODAC symposium 20-21 February 2017. Available from: <https://www.openaccessgovernment.org/anthropology-technology-ebola-vaccine-response/56084/>

Table 1. Role of methods for SARS-CoV-2 testing

Test method	Advantages	Disadvantages
<b>PCR</b>	<ul style="list-style-type: none"> <li>- Gold standard for diagnosis</li> <li>- High sensitivity and specificity</li> <li>- Automated platforms with high throughput available</li> <li>- Most have at least 2 or 3 gene targets</li> </ul>	<ul style="list-style-type: none"> <li>- Remains positive after period of infectiousness</li> <li>- Laboratory facilities and trained staff required</li> <li>- Higher cost than antigen test</li> <li>- Contamination risk</li> <li>- Impact of variants on detection</li> </ul>
<b>Rapid antigen test</b>	<ul style="list-style-type: none"> <li>- Can be done at the point of care</li> <li>- Laboratory facilities and equipment not required</li> <li>- Fast turn-around time</li> <li>- Positive during height of infectiousness</li> <li>- Most detect nucleocapsid protein, which is more conserved than spike proteins, and therefore less impacted by variants</li> <li>- Cheaper than PCR</li> </ul>	<ul style="list-style-type: none"> <li>- Less sensitive than PCR</li> <li>- Various assays with varying sensitivities and specificities available</li> <li>- Observer subjectivity in result interpretation</li> </ul>
<b>Antibody test</b>	<ul style="list-style-type: none"> <li>- Marker of exposure (nucleocapsid antibodies) or vaccination (spike antibodies only)</li> <li>- Useful for sero-surveillance</li> <li>- Can also be helpful in cases of inconclusive PCR or post-COVID-19 complications</li> </ul>	<ul style="list-style-type: none"> <li>- Not useful for diagnosis since antibodies take days or weeks to develop</li> <li>- Does not correlate with immunity</li> </ul>
<b>Genome sequencing</b>	<ul style="list-style-type: none"> <li>- Virus discovery</li> <li>- Molecular epidemiology: tracking of viral evolution, transmission networks, identification of variants</li> </ul>	<ul style="list-style-type: none"> <li>- Skilled staff required</li> <li>- Specialised laboratory facilities and equipment required</li> <li>- High cost</li> </ul>

detection and quantification of SARS-CoV-2, are useful for early detection and tracking.

It is probable that SARS-CoV-2 will become endemic, similar to seasonal influenza. However, there is always a pervading threat that another deadly pandemic will emerge. We must use the lessons learnt from COVID-19 for pandemic preparedness and to improve healthcare infrastructure and service delivery, in order to protect the lives and livelihoods of our people.<sup>17,18</sup> Translational research and development in areas such as local vaccine production, diagnostics, therapeutics and surveillance must garner support. Let us follow the spirit of 'umuntu ngumuntu ngabantu' – 'I am because you are'.

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## Editors:

Dr Pascale Ondoa and Mrs Bethanie Rammer, African Society for Laboratory Medicine

## Citation

Khan A. Viewpoint of a virologist in the era of COVID-19: Impacts on communities, lessons learned and where do we go from here. *Lab Culture* 2022, No. 27, Pages 18-21.

# Accelerating detection and early action for outbreaks:

## *Role of decentralized testing capacities*

### Thinking in Systems

The recent spread of the monkeypox and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viruses globally indicates the critical importance of finding and controlling disease threats at their source – before they become epidemics. We have proposed ‘7-1-7’ as a global metric for early outbreak detection, notification, and response (**Figure 1**), whereby every suspected outbreak is identified within 7 days of emergence, reported to public health authorities with initiation of investigation and response within 1 day, and effective outbreak control measures initiated within 7 days.<sup>1</sup>

This metric simplifies a systems approach to understanding key capacities to find and control outbreaks: patients must have access to care in their communities, diseases must be recognized and then tested, and results must be made available at all levels of the health system so that it can mount an effective response. The business processes for disease detection to response have been mapped and used successfully to identify priority interventions to accelerate disease control during previous disease outbreaks in Nigeria, the Democratic Republic of Congo, and Sierra Leone.<sup>2</sup> The 7-1-7 metric simplifies further the required milestones for business process mapping and bottleneck identification, and enables clear and simple communication for advocacy and accountability.

We have piloted the 7-1-7 approach in five countries to date, and have identified common bottlenecks to disease detection, which in all countries most frequently originate at the community and health facility levels. Most often, health workers are ill-equipped to identify new disease threats, resulting in

delays in diagnosis, specimen collection, and reporting of outbreaks.

### Decentralized Testing Capacity

The capacity to rapidly identify pathogens through laboratory diagnostics is an essential component of effective outbreak detection and response. Tiered diagnostic strategies, including expansion of point-of-care and rapid diagnostic testing, can help accelerate disease control efforts by quickly identifying new outbreaks and initiating appropriate case management and infection prevention and control measures where they matter most (in communities) and when they matter most (before outbreaks become epidemics). In addition to facilitating outbreak detection, community-based testing has been used to control malaria and other endemic diseases.<sup>3</sup>

Over the years, we have seen that improved laboratory testing capacity in countries has accelerated the detection and control of new and emerging pathogens including monkeypox, viral hemorrhagic fevers, and yellow fever. However, because most of these tests require specialized laboratory capacity, clinical diagnosis can be challenging for health workers in the early days of infection when signs and symptoms can be vague and potentially misinterpreted. Improved access to point-of-care diagnostics can help health workers distinguish between epidemic-prone diseases and ensure that public health authorities are notified promptly and patients are managed correctly.

This was exemplified in the coronavirus disease 2019 (COVID-19) response, where SARS-CoV-2 testing has been provided at various community locations as well as through rapid self-admin-



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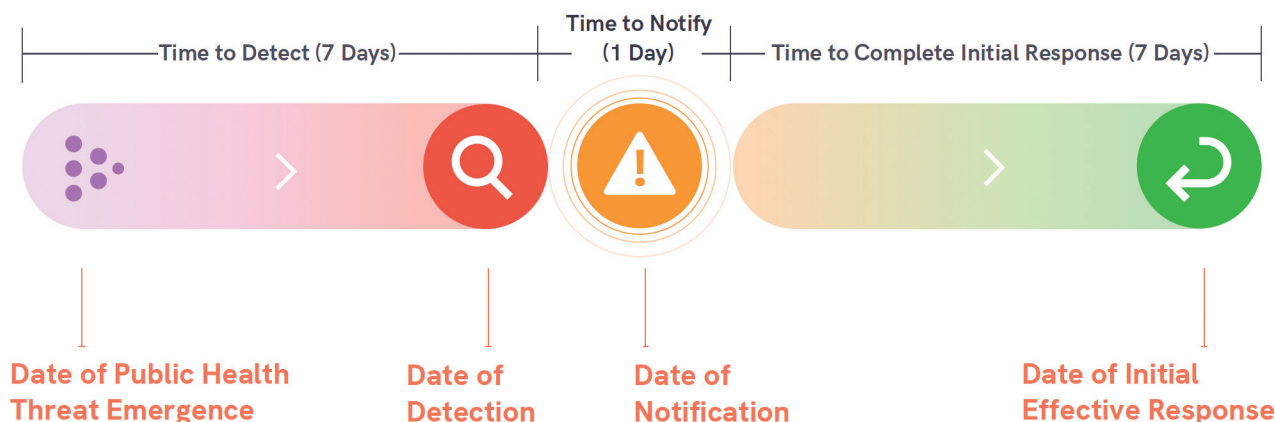


Figure 1. The '7-1-7' framework for early outbreak detection, notification, and response.

istered tests.<sup>4</sup> Community-based testing benefits patients through rapid confirmation of infection and facilitating isolation and initiation of treatment where indicated. Health systems, health facilities, and health workers benefit from prompt recognition and initiation of appropriate infection prevention and control measures. And our public health benefits from being able to rapidly identify cases, isolate infected individuals, notify potential contacts, and initiate rapid response. As the COVID-19 pandemic has demonstrated, we can't wait for days or weeks for results to be available, as the infection will continue to spread.

### Barriers to Decentralized Testing

There are currently significant barriers to expanding community-based testing as a strategy to improve active case finding. Primary health centers are often under-resourced and understaffed, especially in low-resource settings. In particular, training on case definitions and disease recognition is often lacking. Testing on specimens that are collected can be delayed by challenges transporting specimens to reference laboratories, both in the time required for transport as well as avoiding contamination or spoilage of specimens. Additionally, rapid or point-of-care tests are not currently

available for many epidemic-prone diseases in the African region. When available, including for SARS-CoV-2, the results of these tests (both positive and negative) must feed into routine surveillance systems, which has been an additional challenge during the COVID-19 pandemic.

### Conclusion

Our experience has shown that delays to outbreak detection are often experienced at the local health facility level, even though this is the most likely environment for identification of index cases. Increasing the availability of rapid diagnostic tests through research and development, procurement, and implementation strategies, as well as strengthening tiered laboratory networks, can help to alleviate this bottleneck by providing the resources that front-line health facilities need to ensure rapid case identification.

Until rapid diagnostic tests are available for more pathogens, we must continue to improve specimen transportation systems and map required laboratory capacities at all levels of the system, which will continue to play an important role for confirmatory diagnostics.

By making continued investments in research and development, human resources for health including adequate training of health

workers to identify cases and implement infection prevention and control measures, and building community trust in public health and healthcare systems, we can strengthen our capacities to rapidly detect and respond effectively to disease outbreaks.

Returning to the value of systems thinking, we must consider the business processes from disease emergence to response when planning investments and interventions. In public health, populations are our clients, but outbreaks will start communities; strengthened detection and response capacities must be decentralized so that outbreaks will end in those same communities before they become global threats.

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#### Editors:

Mrs Bethanie Rammer, African Society for Laboratory Medicine

#### Citation

Lee C. Accelerating detection and early action for outbreaks: Role of decentralized testing capacities. *Lab Culture* 2022, No. 27, Pages 22-23..

## Global Fund Laboratory eTools Repository

In the ever-changing landscape of laboratory medicine and to keep up to date with the current digital health trajectory, health leaders are on a quest for laboratory tools that contribute to efficiency and quality improvement. Tools are also needed to meet the data demands of laboratories and their stakeholders, by providing sustainable, interoperable solutions that enable exchange of data within and outside the laboratory. However, health and laboratory leaders are often challenged by the volume and complexity of information they must dig through to find the laboratory tool that best fits their needs. This sometimes results in selecting a laboratory tool based on secondhand knowledge, opting for word-of-mouth recommendations or choosing the lowest cost option.

To address these needs, The Global Fund through its Service Delivery Initiative Strategic Initiative (SDI-SI) laboratory component, in a collaborative effort with the Association of Public Health Laboratories (APHL), has created a global repository with frequently needed information on laboratory tools. This repository serves dual purposes: 1) It provides a platform for laboratory tool providers to share information on their product and make it available to a global audience of potential users. 2) It enables country health leaders to visit one location and view, filter, and acquire information on a variety of laboratory tools.

Tools in the repository are categorised (**Table 1**) based on literature searches conducted by APHL to identify over 600 types of laboratory e-tools providers. Current tools include freezer management, sample referral, laboratory information systems, proficiency testing and more and comprise both open-source and commercial tools that have been vetted. The repository is continuously growing and additional categories of laboratory e-tools can be inserted as more tool providers and/or

1.	Proficiency Testing(PT)/External Quality Assurance(EQA)
2.	Equipment Management
3.	Data Integration Engine
4.	Sample Referral
5.	Instrument Data Capture
6.	Data Centralization
7.	Data Analytics for Laboratory Data
8.	Freezer Management
9.	Laboratory Information Management System (LIMS)/ Laboratory Information System (LIS)

health leaders express a need for additional tool types.

In order to provide relevant information about the tools, APHL developed a maturity model that provides a series of levels to assess the capability of each tool and a basis for comparison across laboratory tools. The model has 10 main domains (**Table 2**), which were developed based on a review of

1.	System Infrastructure
2.	Utilization
3.	Country eHealth Strategy
4.	Roadmap
5.	Technical Support and Language
6.	Documentation - Technical and End User
7.	Implementation and Training
8.	Interoperability and Data Accessibility
9.	Security
10.	Installation Scalability

several models for assessing the maturity of digital health tools including [Digital Square's Global Goods Maturity model](#), [CAP Today's surveys](#), the World Health Organization's [Classification of Digital Health Interventions](#), [Elements of Digital Health Investment Review](#), APHL's 2005 Software Provider report, and MEASURE Evaluation's Maturity Model for Interoperability.

Each domain includes 5 levels of maturity (**Table 3**). This maturity model is based on the [Capability Maturity Model](#) which provides a framework for continuous improvement of the product on a five-level path growing

towards increasing maturity. For the full maturity model please refer to the posted [RFI](#).

Developers and providers of laboratory tools complete a self-assessment questionnaire based on these 10 domains and rank their tool on the maturity scale. Tool providers also supply detailed information on their organization, tool costs, hardware needed, that are not scored on the maturity scale. These data are received by APHL, reviewed and submitted to the web-based repository, which stores the data in a database. All tools are included in the repository regardless of scoring. Vendors are required to

Level	Maturity	Definition
Level 1	Nascent	Does not follow systematic process, isolated ad hoc effort
Level 2	Emerging	Defined structures but not systematically documented. No formal performance monitoring
Level 3	Established	Documented structures, structures are functional, metrics for performance monitoring are used systematically
Level 4	Institutionalized	Stakeholders use the product and follow standard practices
Level 5	Optimized	Developers/system providers regularly review needs and modify functionality to adapt to changing conditions

complete all questions in the questionnaire in order to be included in the repository.

To ensure the repository is widely known and utilized, APHL is establishing a Community of Practice (CoP). This CoP will be open to all interested in the information within the repository and enable potential end users of these laboratory tools to engage with each other across the globe. One of the goals of the repository is to have a more informed and empowered laboratory leadership across Africa,

Asia and South America, where the Global Fund has focused their efforts to strengthen laboratories. Greater participation from the CoP will result in enhancements to the repository, inclusion of more types of tools and details and alleviate the process of tool identification and selection.

APHL will collaborate with ASLM to ensure the information in the repository is widespread and countries have an opportunity to utilize the repository's information to inform future decisions. ASLM has established a robust CoP and this collaboration will enable laboratory scientists and professionals within Africa to become aware of this resource, utilize it and share it with others within their organizations.

The repository is located at <https://www.lab-etools.org/> and is freely available to all.

To ensure the repository captures balanced views, as a next step APHL will elicit input from end users of these laboratory tools in various countries. This input will be sought using similar domains as completed by the tool providers to enable for a comparison between information provided by tool developers and that provided by those who have experience with implementing and using the tool in their country's context. Additional domains may be added based upon the needs of the CoP.

#### For More Information:

-If you are a laboratory tool provider and would like your product to be considered

Or

-If you are curious to learn more about this project Please contact Natalie Martinez at APHL: [natalie.martinez@aphl.org](mailto:natalie.martinez@aphl.org)

This report was provided by Reshma Kakkar and Natalie Martinez, Association of Public Health Laboratories, United States

#### Citation

Kakkar R and Martinez N. Global Fund Laboratory eTools Repository. *Lab Culture* 2022, No. 27, Pages 24-25.

## Workshop to finalize Integration Readiness Assessment Tool

Integration of diagnostic services can contribute to improvement in the availability of and access to essential diagnostics in resource-limited settings. Ensuring that countries have sound plans and procedures to advance integrated testing and the systems underlying it will be a priority of future investments in Global Health.

The project team for ASLM's Laboratory Systems Strengthening Community of Practice (LabCoP), funded by the Bill & Melinda Gates Foundation, is working to move the diagnostic integration agenda forward. LabCoP is building a diagnostic integration framework that will help countries identify gaps and opportunities for integrating diagnostics throughout laboratory networks and toward significant clinical and public health outcomes. This framework is articulated around a scorecard complementing the arsenal of evaluation instruments used by LabCoP to inform countries' improvement interventions and funding requests annually.

On 5-6 April 2022, ASLM's LabCoP project team in collaboration with the

World Health Organization (WHO), convened a workshop in Geneva, Switzerland to finalize the diagnostic integration scorecard. The workshop was hosted at the Global Fund (GF) headquarters and was attended by representatives from the Clinton Health Access Initiative, FIND, the Global Fund, the United States President's Emergency Program For AIDS Relief, and the WHO. This is the first step towards a coordinated, structured and evidence-based consolidation of diagnostic integration. Countries and funders will be able to use the outcome of the scorecard assessment and plan for smart investments to improve integrated diagnostic services as recommended by the Maputo Declaration 13 years ago.

#### For more information:

Please contact Dr Collins Otieno at:

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This report was provided by ASLM staff.

#### Citation

ASLM. Workshop to finalize Integration Readiness Assessment Tool. *Lab Culture* 2022, No. 27, Page 25.



Members of the workshop team (left to right): Anafi Mataka (ASLM), Marguerite Massinga-Loembe (Africa CDC), Pascale Ondo (ASLM), Fatim-Cham Jallow (The Global Fund), Collins Otieno Odhiambo (ASLM), Juliet Bryant (The Global Fund) Patrick Royle (The Global Fund). Other members of the team joined the workshop virtually.



# Meet Varsetile Varster Nkwinika

*Ms Varsetile Varster Nkwinika, MSc, a doctoral candidate from the Sefako Makgatho Health Sciences University was awarded the ASLM Academy Award for Best Abstract at the ASLM2021 Conference in November 2021. Her abstract, entitled 'Human Papillomavirus Infections and The Impact of Viral Load In Women Attending the Gynecology Clinic at Dr George Mukhari Academic Hospital, South Africa', showcases her research on biomarkers of cervical cancer progression, a significant public health threat not only to women in South Africa, but also elsewhere on the continent. Ms Nkwinika is the Manager of the South African Vaccination and Immunisation Centre, a lecturer and a doctoral student at Sefako Makgatho Health Sciences University, both in Pretoria, South Africa. We sat down with her recently to learn more about her journey in laboratory medicine.*



Ms Varselite V Nkwinika, MSc (Courtesy of Ms Nkwinika)

## How or why did you choose a career in laboratory medicine?

Ever since I was diagnosed with rheumatic heart disease at the age of 6 years, I have wanted a career in the medical field so that I can help others. Despite my poor financial background, I was highly motivated and became one of the top 10 learners in my region (Ba-Phalaborwa, Mopani in Limpopo Province, South Africa). When I passed matric [final year of high school in South Africa] with merit, I was awarded a National Skills

Fund bursary to pursue my studies at a university. My undergraduate degree, a Bachelor of Science in Microbiology and Biochemistry, at the University of Venda, was meant to be a bridging course for me to study medicine. However, while studying microbiology, I discovered that my heart disease was caused by an autoimmune response to a bacterial infection. This was mind-blowing; there was a whole new world waiting to be discovered! I enjoyed learning about the science behind medicine, and was more

curious about what causes diseases and how to prevent them, than I was in clinical studies. I graduated with distinction, and then embarked on a Department of Science and Technology (DST)/ National Research Foundation (NRF) medical laboratory internship at the Department of Virology, Sefako Makgatho Health Sciences University (SMU). I then

obtained Department of Science and Innovation (DSI)-NRF funding for an honours degree in Medical Virology, and got a distinction for my research project. I then enrolled for a Master of Science degree in Medicine (Medical Virology), funded through a NRF-DAAD In-Country Scholarship, and passed Cum Laude. While doing my Master's, I also worked as a programme coordinator for the South African Vaccination and Immunisation Centre (SAVIC) at SMU. This exposure made me realise that my laboratory-based work can facilitate patient safety, improve patient outcomes, shorten patient journeys through the healthcare system, and lead to more cost-effective healthcare. I am now a doctoral candidate and a lecturer at SMU, through the NRF-New Generation of Academics Programme (nGAP).

## What subject areas are you studying and how are laboratories and laboratory infrastructure important to them? What do you hope to do after completing your degree?

My research focus is on the epidemiology of human papillomavirus (HPV). I am particularly interested in the identification of



Graduation from SMU in 2017 (Courtesy of Ms Nkwinika)



DST-NRF interns meeting at the Department of Virology, SMU in 2015  
(Courtesy of Ms Nkwinika)

HPV-related biomarkers that help predict women at high risk of cervical lesion progression. The use of laboratories and laboratory infrastructure is essential for achieving my research objectives, and access to quality tests and laboratory services is vital. My research area has the potential to contribute new knowledge for policy development, implementation of future interventions and patient management. I believe these areas are critical focal points for HPV cancer research in the next decade. Hence, I intend to continue learning, making a difference and contributing new knowledge to medicine. I plan to work on establishing an essential diagnostic list for the identification of women at risk of cancer development globally, and advocating for such tests to be available at point-of-care facilities and in laboratories in all countries to increase timely and life-saving diagnoses.

**Were you able to attend the ASLM2021 virtual conference? If so, aside from having won the Best Abstract Award (congratulations!), what did you learn from the conference / how did it help or benefit you?**

Yes, I did attend the ASLM2021 virtual conference and was able to learn about the latest technical and policy developments. I had the opportunity to hear from influencers and industry experts as they shared their experience in the field of laboratory medicine in Africa. I am happy that I attended the ASLM2021 virtual conference, because it helped improve my own skills and knowledge about my field. It was particularly interesting to learn about the need to reset quality management systems at the core of laboratory system strengthening, and the importance of considering locally relevant epidemiological data to determine disease burden. Hearing about all the success stories from other

presenters, while also recognising the need to increase diagnostic capacity in Africa, motivated me to achieve my own professional goals. The highlight of the conference for me was the sponsored presentation on the implementation of HPV testing across Africa: Practical partnering and experience-sharing to help achieve the WHO 2030 cervical cancer elimination targets. I learned a lot about practical ways to overcome challenges and to implement, scale-up and successfully sustain HPV testing across Africa as part of secondary cervical cancer prevention strategies, as well as the importance of the laboratory and the value of diagnostics for HPV screening programs.

**What advice do you have for younger people starting out in laboratory medicine?**

Medical laboratory science provides clues that are key in the diagnosis and treatment of disease, and laboratory scientists are the detectives of the health care world. It is a fulfilling field that requires extensive education and training – you are expected to pay meticulous attention to detail and produce highly reliable and valid results, even when under pressure. So as you are starting out in laboratory medicine, it is important to have a positive work ethic: you must be proactive, determined and self-motivated for you to excel and grow in the field.

**Interviewer & Editor:**

Mrs. Bethanie Rammer, African Society for Laboratory Medicine

**Citation**

Meet Varsetile Varster Nkwinika. *Lab Culture* 2022, No. 27, Pages 26-27.