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Expanding the **diagnostic toolkit** for tracking *Mycobacterium tuberculosis*

In this issue:

To recover from the impact of the pandemic, we must urgently improve tuberculosis case detection

TB-CAPT: Optimising molecular testing for tuberculosis

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Table of Contents

**Expanding the diagnostic toolkit for tracking
*Mycobacterium tuberculosis***

November 2022
Issue 28

EDITORIAL 4

To recover from the impact of the pandemic, we must urgently improve tuberculosis case detection

Mikashmi Kohli and Madhukar Pai

FEATURED TOPIC 11

Deploying Truenat 'super-users' to fight tuberculosis

Emily Nink and Tom Price

FEATURED TOPIC 17

Expanding access to near point-of-care molecular testing for tuberculosis in Nigeria using the Truenat testing system

Nkiru Nwokoye, Jamiu Olabamiji, Austin Ihesie, et al.

FEATURED TOPIC 25

Integration of medium-to-high throughput platforms for tuberculosis diagnosis

Herry Mapesi and Edwin Muiruri

LEADERS FROM THE BENCH 33

Meet Dissou Affolabi

National Tuberculosis Programme of Benin

FEATURED TOPIC 7

TB-CAPT: Optimising molecular testing for tuberculosis

The TB-CAPT Consortium

FEATURED TOPIC 14

Strengthening access to molecular diagnostics: Challenges and lessons learned from the Zimbabwe Truenat implementation

Phoebe Nzombe, Moe Moore, Fungai Kavenga and Raiva Simbi

Q&A 22

What is diagnostic network optimization?

Sam Acellam, Juhi Gautam and Heidi Albert

FEATURED TOPIC 29

Stopping disease outbreaks with integrated disease surveillance and response

Emily Nink and Tom Price

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.

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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To recover from the impact of the pandemic, **we must urgently improve tuberculosis case detection**



Figure 1. Newer non-sputum-based sampling techniques for tuberculosis detection.
Image courtesy: FIND, Geneva.

The coronavirus disease 2019 (COVID-19) pandemic has had a devastating impact on tuberculosis services, especially in high-burden tuberculosis countries.^{1,2} The 2021 World Health Organisation (WHO) Global Tuberculosis Report shows that due to disruptions of healthcare services during the pandemic, tuberculosis case notifications have substantially decreased.³ In 2020, more than 4 million of the estimated 10 million people with tuberculosis were either undiagnosed or unreported. Tuberculosis deaths have also increased for the first time in over a decade, rapidly diminishing the chances of meeting global tuberculosis targets.

Given the huge drop in case notifications, improving case detection is one of the biggest priorities to get back on track. To achieve this, we must leverage COVID-19 investments and systems, implement active case finding, push for greater access to rapid molecular diagnostics, and continue to develop novel diagnostics usable at the point of care.

Leverage COVID-19 investments and systems

Although the COVID-19 pandemic has been devastating, it did result in many innovations, investments and systems, which can be leveraged and repurposed to improve tuberculosis case finding.⁴ Nearly every country used mobile-phone-based apps and digital tools (e.g., WhatsApp, chat-bots) to educate people on COVID-19, triage people for testing and referral, and even do contact tracing. For example, India's Arogya Setu app reached over 100 million downloads in 40 days. There is no reason why such tools cannot be repurposed to include tuberculosis, given their massive reach.

Both tuberculosis and COVID-19 are airborne infections and stigma is a concern. Innovative methods of self-sampling and self-testing increased during the pandemic, which normalised testing in homes, schools and workplaces. If we can do this for COVID-19, this can be leveraged for tuberculosis as well (Figure 1). Diagnostics for COVID-19 started with nasopharyngeal swabs, which were difficult and uncomfortable to obtain. This transitioned rapidly to oral swabs and self-swabbing, which increased access to testing. These sampling methods are now showing promise for tuberculosis detection.^{5,6} Face mask sampling is another innovative method of detecting tuberculosis, which leverages the current health practice of increased use of facemasks during the pandemic.⁷

Targeted active case-finding initiatives, guided by precision public health (i.e., using predictive analytics and artificial intelligence), could help identify tuberculosis hot spots and missed tuberculosis cases that occurred during the pandemic. The need to provide medical care during lockdowns led to significant telehealth advances, including the use of digital adherence technologies and e-pharmacies combined with the home delivery of medicines. All of these can be repurposed for tuberculosis, which will help to scale up tuberculosis care.

“ During the pandemic, every country scaled-up molecular testing capacity for COVID-19 ”

Push for greater access to molecular diagnostics

Ensuring that $\geq 90\%$ of notified tuberculosis patients are tested with a WHO-recommended rapid diagnostic as the initial test by 2025 is an End TB Strategy target. According to WHO, the achievement was only 33% as of 2020, despite the Xpert MTB/RIF (Cepheid Inc, United States) being WHO-endorsed since 2010. The TrueNAT (Molbio, India) is also now endorsed by WHO.⁸ While both technologies were extensively used for COVID-19 testing, they have yet to scale up tuberculosis testing.⁹ Many high-burden countries are still reliant on smear microscopy.

During the pandemic, every country scaled-up molecular testing capacity for COVID-19; globally, billions of PCR tests were done. This expanded capacity for molecular testing must be used for tuberculosis testing, combined with validation using simpler, non-sputum samples. Better integration of tuberculosis and COVID-19 testing is also necessary, since both are respiratory syndromes (Figure 2).¹⁰ Beyond COVID-19, there is a need for better integration of tuberculosis testing with other conditions, especially since molecular platforms can be used to test for multiple diseases. Diagnostic network optimisation is a valuable process to accomplish this.¹¹

Establishment of mobile laboratories in countries like India increased access to COVID-19 testing. These mobile laboratories can now be used for rapid molecular testing and as X-ray vans for tuberculosis testing. Additionally, country investments in COVID-19 sequencing technologies and next-generation sequencing has excellent potential not only for tuberculosis surveillance but also for improving management of drug-resistant tuberculosis by rapidly providing clinically relevant data.¹²

Continue to innovate

Although WHO-recommended rapid molecular tests are available, there is a need for molecular point-of-care solutions, especially in primary care settings. Several such technologies are under development, which, when combined with simple, easy-to-collect samples such as oral or tongue swabs,^{5,6} will enable earlier diagnosis, especially at the primary care level. Although oral swabs are less sensitive than sputum samples, they are always feasible to collect compared to sputum samples.

In addition, efforts are underway to develop rapid antigen detection tests (e.g., urine LAM antigen detection tests).¹³ Although many biomarkers have been evaluated for active tuberculosis,¹⁴ urine LAM was the only commercial antigen test at the time of this publication. A more sensitive urine antigen detection test could greatly help decentralise tuberculosis testing.

Lastly, significant advances have been made to develop highly portable digital X-ray technologies combined with artificial intelligence-based software for reading.¹⁵ Making these technologies more affordable will scale up tuberculosis screening and active case finding, as they will serve as essential, primary care-level diagnostics.



Figure 2. Integrated testing for COVID-19 and tuberculosis at a laboratory in Lima, Peru. Image courtesy: Dr César Ugarte-Gil, Universidad Peruana Cayetano Heredia.

“... there is a need for molecular point-of-care solutions, especially in primary care settings.”

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Editor

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Featured Topic

TB-CAPT: Optimising molecular testing for tuberculosis

Rapid molecular tests for tuberculosis and drug-resistant tuberculosis can be a game-changer in the tuberculosis epidemic. However, diagnostic technologies only have an impact if they are accessible to patients and provide results in a timely manner. The [‘Close the gap, increase Access, Provide adequate Therapy’](#) or [‘TB-CAPT’](#) project is funded by the European and Developing Countries Clinical Trials Partnership and is implementing three clinical trials focused on optimising the use of different molecular testing tools in sub-Saharan African settings.

In 2020, nearly 10 million people fell ill with tuberculosis, over 4 million of whom were never diagnosed or whose diagnosis was not reported¹. The gap between incident and notified cases can be attributed to access to diagnostic tests and provision of results within a timely manner². There is, therefore, an urgent need for accessible, improved tuberculosis tools and diagnostic technologies that can not only detect disease but can also identify strains that are resistant to the tuberculosis medications that are available. Containing the emergence of drug-resistant tuberculosis is critical, if we are to have a chance to beat the disease while the medicines that we have still work.

Molecular diagnostic testing was anticipated to become a game-changer for tuberculosis control, but its usual reliance on laboratory infrastructure, often complex workflows, and in some cases limited implementation guidance has left diagnostic gaps remaining. Next-generation tests need to be placed at the point of care at the level of microscopy centres, fully integrated into the diagnostic and treatment network, connectivity enabled, more sensitive and able to perform expanded drug susceptibility testing.

Coordinated by FIND, the global alliance for diagnostics, TB-CAPT includes a series of clinical trials in Tanzania, Mozambique and South Africa that will evaluate the impact of novel diagnostic interventions on outcomes, including the impact of expanding tuberculosis testing strategies among people living with HIV. All three trials included in the project take local epidemiology and existing infrastructure into consideration and will compare new strategies with current standards of care.



Tanzania: TB-CAPT CORE trial laboratory technologist is pipetting the elute sample for an MTB test on the Molbio Truenat instrument. Photo: NIMR.

 TB·CAPT



EDCTP

This project is part of the EDCTP2 programme supported by the European Union

Patient enrolment for the XDR trial completed in early 2022

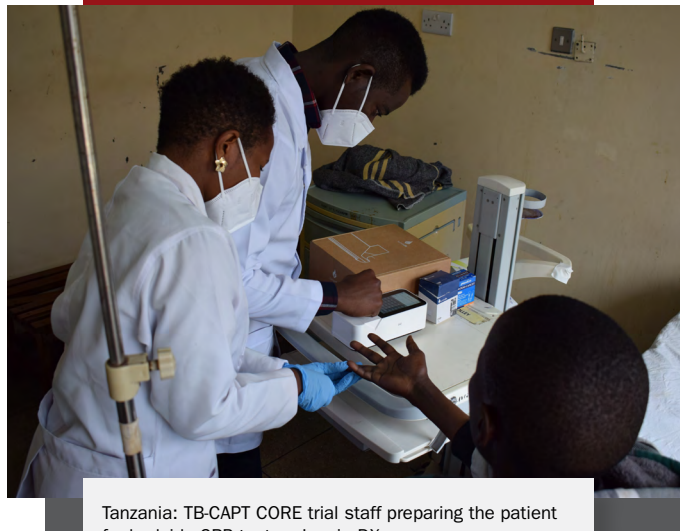
The first TB-CAPT trial to kick off was the XDR trial, led by Prof Helen Cox and Dr Chad Centner of the University of Cape Town. It was conducted at two laboratories in South Africa, one in Green Point and one in Gqeberha, both part of the National Health Laboratory Service. The laboratories began enrolment in June 2021 and completed the sample collection in March of 2022.

The XDR study is a laboratory-based feasibility study that aims at evaluating the accuracy of a new diagnostic test for drug-resistant tuberculosis, namely, the Xpert MTB/XDR 10-colour reflex assay on GeneXpert, on 753 samples from patients with rifampicin-resistant tuberculosis in South Africa. For the study, the TB-CAPT XDR trial team used residual samples that were leftover from routine testing in the two National Health Laboratory Service laboratories. This recruitment method enabled the team to complete enrolment much faster than if they had collected new samples directly from patients in tuberculosis clinics or hospitals. Even though the team did not work directly with participants, patient privacy was a central component of the enrolment process.

Beyond evaluating the accuracy of the Xpert MTB/XDR 10-colour reflex assay on GeneXpert, the TB-CAPT XDR trial also sought to evaluate a modified laboratory workflow and assess the feasibility of using residual samples for further testing for research purposes. The study procedure was designed to fit into the routine laboratory workflow and minimise interruptions to standard procedures, and while evaluation of the process is still ongoing, the initial perception from the study team is that this has worked well.

The trial team began preliminary data analysis during the enrolment phase in late 2021. One of the team's initial concerns was that the procedural samples that were saved from routine testing in the laboratories would not be sufficient for the MTB/XDR assay. However, preliminary results show that there is a sufficient remaining specimen in more than 97% of cases. Another concern was related to whether setting aside samples for a certain time period would reduce the detection rate of *Mycobacterium tuberculosis*, but the team found that they still had relatively good detection rates when they tested these samples.

The XDR trial team has also been able to demonstrate a reduction in turn-around time for tuberculosis drug resistance detection results. The MTB/XDR assay performs drug



Tanzania: TB-CAPT CORE trial staff preparing the patient for bedside CRP test on LumiraDX. Photo: NIMR.

susceptibility testing for three first-line drugs. Normally, the turn-around time for culture-based drug sensitivity testing is days to weeks, sometimes even months. With the new Xpert-based assay, the turn-around time can be reduced to just a few hours, as the MTB/XDR assay can immediately follow an Xpert Ultra test, each with a two-hour run period. The diagnostic accuracy analysis will begin when the reference standard testing has been finalised in late 2022.

This study will inform South African national tuberculosis guidelines, as well as guidelines in other high-burden countries, on the feasibility of implementing the Xpert MTB/XDR 10-colour reflex assay within the diagnostic algorithm. Adoption of the assay will lead to faster detection of drug-resistant tuberculosis, more rapid initiation of appropriate anti-tuberculosis treatment, and better patient outcomes.



Mozambique: CISM recruited the first participant for the TB-CAPT CORE trial in late August 2022. Photo: CISM.

Mozambique: A nurse at one of the sites where the CISM team is recruiting participants for the TB-CAPT CORE trial is using the Molbio TruePrep for tuberculosis diagnosis. Photo: CISM.

CORE trial kicked off patient recruitment in August 2022

Today, on-site rapid molecular testing for tuberculosis is not available in most primary healthcare clinics in many countries where the disease is widespread. As a result, due to offsite molecular tuberculosis testing, patients often need to wait for up to several weeks, sometimes more than a month, before they receive their results and, if positive, can start treatment. During this time, there is also a high risk of disease transmission and mortality.

The TB-CAPT CORE trial, led by Katharina Kranzer of Ludwig Maximilian University of Munich in Germany, aims at assessing the impact of making the Molbio MTB assays on the Truenat platform available at the primary healthcare level. This battery-powered rapid diagnostic instrument has the capacity to reduce the turn-around time for tuberculosis testing to a few hours, allowing patients who test positive to start tuberculosis treatment on the same day.

Participant enrolment for the CORE trial began in August of 2022. Overall, 28 primary healthcare level sites across Tanzania and Mozambique will enrol a total 4200 patients in the study before the end of October 2023.



Expanding tuberculosis testing for people with HIV

The third TB-CAPT trial, the HIV trial, kicked off recruitment in early September 2022. This trial aims at assessing the impact of an expanded testing strategy for diagnosing tuberculosis among people living with HIV, irrespective of signs and symptoms of tuberculosis, by using the highly sensitive Xpert Ultra assay, as well as the Abbott Determine-TB LAM antigen test. In total, 1172 participants across six hospitals in Tanzania and Mozambique will be included in the project.

People living with HIV are less likely to produce a sputum sample with sufficient quality to be used for tuberculosis diagnosis are therefore not well served by the current standard sputum-based diagnostic tests. The current standard of care in many countries is to only provide tuberculosis testing to HIV-positive patients who have tuberculosis symptoms or advanced HIV disease.

The five-year TB-CAPT project will provide insights into the clinical benefits of expanded tuberculosis diagnostic strategies in resource-limited settings and thereby improve public health in these contexts and decrease tuberculosis mortality and disease recurrence. Study findings will be shared and discussed with policymakers at the local, national and international levels to enable them to make more informed decisions on the implementation and scale-up of innovative technologies.

TB-CAPT capacity building

Capacity building is a central pillar in TB-CAPT. The TB-CAPT capacity building scheme, led by Dr Klaus Reither of Swiss Tropical and Public Health Institute, consists of three main components:

1 Training: The TB-CAPT consortium has developed both a comprehensive study-specific training programme, including sections on the implementation of new tuberculosis diagnostic tests and the use of novel data collection tools, and tailor-made training sessions for African partners. Following a consortium-wide needs assessment, which revealed a great need for the strengthening of knowledge and skills related to sequencing and bioinformatics in sub-Saharan Africa, TB-CAPT teamed up with the PanACEA and Seq&Treat projects to develop a four-day, free-of-charge training series on next generation sequencing for *Mycobacterium tuberculosis* complex titled ‘*Mycobacterium tuberculosis* complex next-generation sequencing made easy: data analysis step-by-step.’ The flexible training programme includes both pre-recorded webinars and interactive Q&A sections. A successful four-day training event was held in March 2022 and a one-day follow-up training session was held in July 2022. A second four-day training is planned for late 2022.

All recorded webinars and hands-on training sessions remain publicly available on the Galaxy platform: <https://gallantries.github.io/video-library/events/mtb-ngs/program.html>

2 Mentor-mentee programme: Including eight mentor-mentee pairs, the focus of the TB-CAPT mentorship programme goes beyond supporting junior researchers in learning specific skills or tasks. The programme is designed to create a climate of trust between the mentee and mentor, to allow the former to seek advice on all issues affecting their career.

3 Knowledge transfer: The TB-CAPT consortium consists of key experts from academia, clinical and laboratory research in Africa and Europe. These experienced professionals scientifically guide master’s and doctoral students in one-to-one meetings and share their expertise in tuberculosis diagnostics to foster the next generation of clinical scientists in Africa.

About TB-CAPT	
Full name:	Close the gap, increase access, provide adequate therapy
Runtime:	September 2019 – June 2024
Project lead:	Dr Morten Ruhwald, FIND, Switzerland
Countries involved:	Ethiopia, Germany, Italy, Mozambique, Spain, South Africa, Switzerland, Tanzania
Project website:	www.tb-capt.org
Funder:	The European and Developing Countries Clinical Trials Partnership (EDCTP)
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Grant agreement number:	RIA2017S-2007

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Featured Topic

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Deploying Truenat ‘Super-users’ to Fight Tuberculosis

In the global effort to stamp out tuberculosis, laboratories and community health clinics work together as disease detectives to discover tuberculosis infections and try to contain them before they spread to other people. This is a difficult job. Although preventable and treatable, tuberculosis infection stubbornly remains the world’s thirteenth most common cause of death and the second-leading infectious killer after coronavirus disease 2019. In 2020, [10 million people fell ill with tuberculosis](#), including 1.1 million children, and 1.5 million people died.

To prevent these needless deaths, it is often a race against time to provide test results that can speed up diagnosis and allow clinicians to initiate life-saving treatment. Rapid and accurate testing for tuberculosis remains out of reach in many of the areas that are most affected by the disease, mostly because of their hot, humid conditions and inconsistent access to electrical power, which thwart the use of many of the available diagnostic tools that can test for tuberculosis.

India-based Molbio Diagnostics developed an alternative technology, called Truenat, that can be used in a variety of circumstances and low-resource settings. The Truenat tuberculosis technology is a chip-based, rapid molecular test. The test is run on the portable Truelab system, which can withstand high temperatures and operate up to eight

hours on its own power supply. At the time of its endorsement by the World Health Organization in 2020, India was the only country where Truenat was in regular use. Since then, the United States Agency for International Development (USAID) [Infectious Disease Detection and Surveillance project](#) (IDDS) has collaborated with other USAID projects and the Stop TB Partnership to install more than 300 Truelab devices and train and support their users in countries facing a high burden of tuberculosis.

It is not enough to simply deliver the Truelab devices and expect that laboratories and healthcare workers will be able to use them to improve tuberculosis testing in their communities. In fact, even with initial training and remote technical support, Truenat users still face challenges ranging from unknown error messages to maintenance and repair issues. Recognising these obstacles, IDDS came up with the idea of training Truenat ‘super-users’: end users who receive extra Truenat training to become experts and can pass on their troubleshooting skills to others. This model invests in local workforce capacity and builds connections across the public and private sectors.

Starting in 2022, IDDS developed a super-user support package to provide ongoing technical assistance, supervision, and mentorship to Truelab sites in supported countries until the sites can independently manage operations. During a pilot in Zimbabwe in early 2022, IDDS trained 14 participants through technical and hands-on sessions, gleaned lessons to inform rollout to other countries. IDDS also worked with SmartSpot, a company that provides quality control materials across Africa, to deliver verification panels of inactivated tuberculosis cultures to Truelab sites. These verification panels help to flag low-performing sites where super-user technical support might be especially needed. Twenty testing sites in Zimbabwe received an initial distribution of these panels.

The IDDS Project Director, Lisa Nichols, stated,

“ IDDS, together with our in-country partners, is working to bring fast, accurate tuberculosis testing as close as possible to anyone seeking care. ”

After seeing the benefits in Zimbabwe, IDDS rolled out the Truenat super-user training to four additional countries between April and June 2022, namely Cambodia, the Democratic Republic of the Congo, Kenya, and Uganda. In total, 83 participants completed super-user training consisting of two days of classroom instructions and three days of practical, hands-on training.

During the training in the Democratic Republic of the Congo, the super-users were taught how to assist the Truenat end users in the field with common technical problems during installation or other issues. After the training, the super-users began providing local support to Truenat end users in their home provinces, including participating in an external quality assessment.

‘We are in the process of adapting this new Truelab machine to overcome the difficulties encountered here in the city of Mbuji-Mayi with recurring failures of existing machines,’ said super-user Alphonse Lufulwabo, head of the provincial tuberculosis laboratory in Mbuji-Mayi, Kasai-Oriental province, the Democratic Republic of the Congo. ‘This training as a super-user will greatly help us to support the sites and solve the challenges encountered in the field.’



In Bangladesh, newly trained super-users will train 40 technicians from sites that have recently received new Truelab devices, teaching them how to process and test specimens using the Truenat platform. In addition, the trainers will support the national tuberculosis program (NTP) in the implementation, monitoring, and supervision of the Truenat rollout.

According to Dr Khurshid Alam, NTP line director,

“ Training will usher in a new era for NTP to boost early detection of tuberculosis in the remote areas of the country. ”



Truenat super-user training in the Democratic Republic of the Congo. Source: IDDS.

Looking ahead, IDDS will train super-users in three other countries in 2022: Vietnam, Nigeria, and the Philippines. In Cambodia, IDDS will repackage Truenat training materials, including job aids, and distribute them to Truelab sites. IDDS will also document best practices and user feedback and prepare a final report discussing the findings of the Truenat pilot. IDDS continues to engage the private sector in the effort to empower super-users. For example, the project engaged software company SystemOne to provide connectivity for Truelab devices in all countries that are receiving them through USAID’s Introducing New Tools Project. Further, IDDS is partnering with Molbio Diagnostics to install a software upgrade on the Truelab devices, which is necessary to connect them to a laboratory information system that can harness the data from the instruments to inform public health decision-making.

To meet the [Sustainable Development Goal of ending tuberculosis by 2030](#), it is essential to know where the disease is circulating and interrupt its spread. With new Truelab devices in hand and super-users at the ready to solve technical problems that may arise, the hope is that countries can soon unlock the full potential of Truenat to rapidly and accurately diagnose tuberculosis in high-burden areas where other tools do not work.

The [IDDS project](#) strengthens the ability of health systems in low- and middle-income countries to quickly detect, track and respond to infectious disease threats. Emily Nink and Tom Price are IDDS project staff at [ICF](#). The views expressed here are not necessarily those of USAID or the United States government.



Truenat super-user training in the Democratic Republic Biologist Alphonse Lufulwabo using Truenat at the provincial laboratory in Mbuji-Mayi, Kasai-Oriental Province, the Democratic Republic of the Congo. Source: IDDS.

Editors

Dr Marguerite Massinga Loembé, Africa CDC, and Mr Erkison Odih and Mrs Bethanie Rammer, African Society for Laboratory Medicine

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Strengthening access to molecular diagnostics:

Challenges and lessons learned from the Zimbabwe Truenat implementation

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Tuberculosis Diagnostic Networks

The adoption of GeneXpert as the initial diagnostic test for tuberculosis by Zimbabwe provided an opportunity for presumptive tuberculosis patients to access better diagnostic services and more favourable treatment outcomes. By 2020, Zimbabwe had deployed more than 140 GeneXpert machines at the national, provincial and district levels in both the public and private sectors. To understand potential gaps in coverage, Zimbabwe conducted a spatial analysis of laboratories in the Xpert diagnostic network in 2020 to determine its accessibility, availability and utilisation. The analysis evaluated the population-level coverage and accessibility of Xpert MTB/RIF testing services, with and without a specimen referral system, and analysed the geographic distribution of GeneXpert network testing capacity, as well as the utilisation of the instruments. The aim of the analysis was to identify priority geographic areas for intervention to improve access and coverage of

the diagnostic network. The assessment revealed that only a third of the population live within five kilometres of a GeneXpert facility, meaning that much of the population continues to lack access to GeneXpert testing.

To support Zimbabwe in increasing access to molecular diagnostics, the Stop TB Partnership, in collaboration with the United States Agency for International Development (USAID), donated 20 Truenat machines in December 2021. The placement of the Truenat machines was guided by the findings from the laboratory spatial analysis and focused on peripheral-level facilities located in hard-to-reach areas (Figure 1). The National Tuberculosis Control Programme also revised the national diagnostic algorithm to include the Truenat algorithm. Tuberculosis implementing partners will train all health care workers on the algorithm.

Benefits of Truenat Implementation in Zimbabwe

The rollout of Truenat at the peripheral level in Zimbabwe has increased access to molecular diagnosis through decentralisation and reduced the turn-around time for tuberculosis test results. Since its introduction, the new tool has become integrated into the tuberculosis diagnostic network and the number of tests conducted has increased (Figure 2). To date, a total of 125 patients (115 new pulmonary tuberculosis (PTB) cases, two previously treated PTB cases, one previously treated PTB case with unknown history, four PTB relapse cases, and three cases with rifampicin-resistant tuberculosis) have been diagnosed with tuberculosis using the Truenat platform.

Challenges

Despite the successful integration of Truenat into the diagnostic network, there have been many challenges, some of which were expected in the context of implementing a new diagnostic tool at the lowest level of the network. The most frequent challenges identified included personnel- and facility-related challenges.

Personnel-related challenges:

- Need for additional hands-on training to improve the proficiency of end users
- Lack of trained, competent staff to cover staff absences and ensure continuity of operations
- Gaps in awareness of quality management systems among end users
- Low number of specimens received due to newly established referral sites
- Poor specimen quality

Facility-related challenges:

- Inability to attend virtual training sessions and report proficiency test results online due to sporadic internet connection
- Prolonged power outages that impacted the ability to recharge the instruments

Zimbabwean laboratory personnel being trained on using Truenat machines. Source: IDDS.

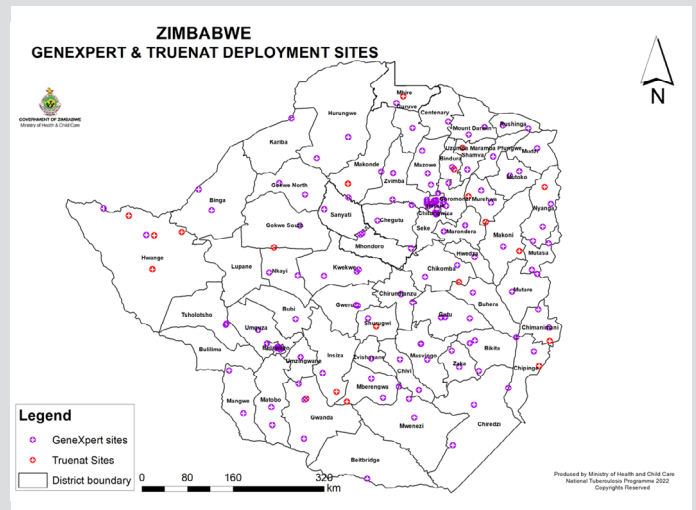


Figure 1. GeneXpert and Truenat sites in Zimbabwe

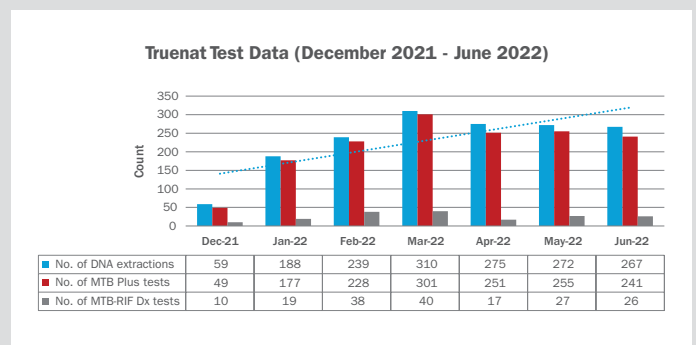


Figure 2. Truenat tests across 20 sites in Zimbabwe



Conclusions and Lessons Learned

The Zimbabwe experience demonstrates that the Truenat system to detect tuberculosis and rifampicin resistance can be successfully scaled up in peripheral-level laboratory settings with limited resources. In Zimbabwe, the laboratory technicians at the implementing sites have minimal or no experience with rapid molecular diagnostic tools, so providing refresher training and ongoing site supervision and mentorship will be important to ensure continual improvement. Key lessons learned include:

- Personnel training is key to ensuring quality testing in Truenat implementation. A trained group of ‘super-users’ is essential to support the implementation of quality practices and assist with external quality assurance (EQA) reporting. Also, additional training of end users at each laboratory is necessary to ensure the continuity of operations during staff absences or turnover. End-user in-person refresher training should include good laboratory practices, EQA, and quality management system sensitisation.
- Laboratories with prolonged power outages may need solar charging solutions.
- To create demand, workshops and specimen collection training should be conducted for local healthcare workers and the community to increase awareness and utilisation and to improve specimen quality.
- Establishing an end-user WhatsApp group was beneficial as it provided an opportunity for troubleshooting and sharing challenges and best practices among the users.
- The Truenat Global Laboratory Initiative-endorsed training modules discussed quality control practices; however, the laboratories lacked the consumables and equipment such as timers and micropipettes needed to implement quality control processes. The Infectious Disease Detection and Surveillance (IDDS) project will procure the equipment to ensure that the laboratories meet the required standards.

Editors

Dr Marguerite Massinga Loembé, Africa CDC, and Mr Erkison Odih and Mrs Bethanie Rammer, African Society for Laboratory Medicine

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About IDDS

The [IDDS project](#) strengthens the ability of health systems in low- and middle-income countries to quickly detect, track, and respond to infectious disease threats.



Laboratory personnel testing sputum specimens on a Truenat machine. Source: IDDS.

Acknowledgement

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The views expressed here are not necessarily those of USAID or the United States government.



Laboratory personnel testing sputum specimens on a Truenat machine. Source: IDDS.

Featured Topic

Expanding access to near point-of-care molecular testing for tuberculosis in Nigeria using the Truenat testing system

Background

Despite advances in rapid molecular diagnostics over the past decade, tuberculosis remains a major public health challenge and the second leading cause of death by an infectious disease.¹ Since 2013, although the World Health Organization (WHO) has issued recommendations for the use of rapid molecular tests as the initial diagnostic test for people undergoing investigation for tuberculosis,² smear microscopy remains the mainstay of tuberculosis diagnosis in most low- and middle-income countries, with only 33% of the 5.8 million reported cases in 2020 tested with a molecular test.¹

Furthermore, the coronavirus disease 2019 (COVID-19) pandemic disrupted access to tuberculosis diagnosis and treatment, leading to a drop in the number of people newly diagnosed, and, for the first time since 2005, an increase in tuberculosis deaths.¹ These effects are expected to persist for at least three more years, with potential increases in global tuberculosis incidence of 6.3 million cases and mortality of 1.5 million cases by 2025.³ Therefore, the scale-up of molecular WHO-recommended rapid diagnostics (mWRD) is now an urgent priority if countries are to increase tuberculosis case detection and get back on track to meeting global targets to end tuberculosis as a public health emergency.^{4,5} Increased bacteriological confirmation of tuberculosis by use of mWRDs that can test for resistance to rifampicin will also increase the number of people put on the correct treatment regimen early.

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The introducing New Tools Project (iNTP) was therefore designed to assist countries in Africa and Asia to meet the targets of the 2018 United Nations High-Level Meeting on Tuberculosis on tuberculosis diagnosis, treatment, and prevention.⁶ With funding from the United States Agency for International Development (USAID), the Stop TB Partnership has provided 11 countries with a high burden of tuberculosis with a package of interventions that includes digital technologies for tuberculosis screening and monitoring of tuberculosis treatment adherence, near point-of-care tests for tuberculosis diagnosis, tuberculosis preventive treatments, next-generation sequencing, treatment of drug-resistant tuberculosis and diagnostics connectivity solutions.

The project is the largest multi-country implementation of Truenat systems, providing Truenat instrument systems and MTB Plus and MTB-RIF Dx reagents to nine countries, including Bangladesh, Cambodia, the Democratic Republic of the Congo, Kenya, Nigeria, the Philippines, Uganda, Vietnam, and Zimbabwe. To help guide

countries in the roll-out of the tool, the Stop TB Partnership and USAID developed a [Practical Guide to Implementation of Truenat tests](#), which received Global Laboratory Initiative (GLI) endorsement. The Stop TB Partnership and USAID also collaborated with the USAID Infectious Disease Detection and Surveillance project to develop a package of training modules on Truenat for country adoption; this package also received GLI endorsement.

In this article, we spotlight an early implementer of Truenat MTB Plus and MTB-RIF Dx testing, Nigeria. Nigeria is one of the 30 countries with a high burden of tuberculosis, tuberculosis/HIV co-infection, and multidrug-resistant (MDR) tuberculosis, and is one of the eight countries that contributed 66% of the 7.7 million tuberculosis cases notified in 2020.¹ Nigeria also accounted for 8% of the estimated 4.3 million missing tuberculosis cases,⁷ with only 135 784 of an estimated 452 000 cases notified to the national tuberculosis program in 2020.¹ Furthermore, the diagnosis of drug-resistant tuberculosis is a persistent problem, and in 2020, only 7% of the estimated 22 000 people with MDR tuberculosis were diagnosed and started on appropriate treatment.¹

With the objective of bringing access to molecular testing to hard-to-reach populations and in collaboration with the implementing partners, the National Tuberculosis and Leprosy Control Program (NTBLCP) and USAID rolled out 38 Truenat instruments provided by the iNTP in peripheral sites across 14 Nigerian states. Implementing partner KNCV Nigeria carried out the Tuberculosis Local Organization Network (LON) Region 1 and Region 2 projects and the Institute for Human Virology Nigeria carried out the Region 3 project.

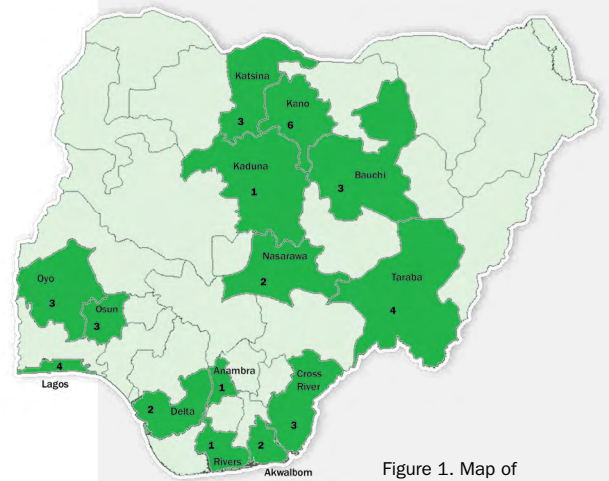
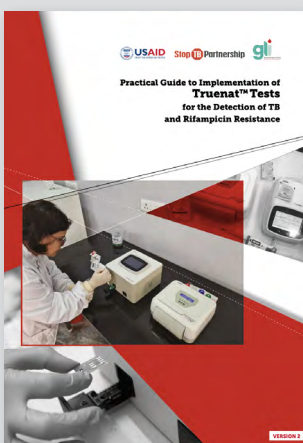


Figure 1. Map of Truenat sites in Nigeria

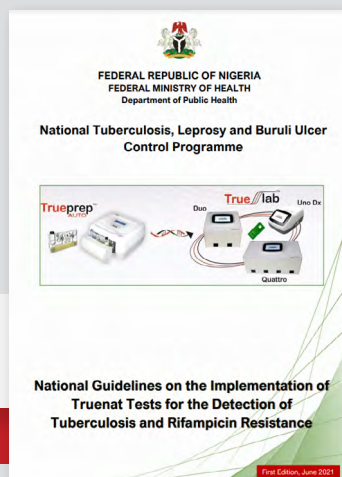
Feasibility assessment

Prior to implementing Truenat testing, sensitization and engagement meetings were held over a five-month period with senior leadership at the NTBLCP. An implementation roadmap and national Truenat implementation guideline were developed. With NTBLCP support and guidance, the 38 facilities were selected based on distance from other sites with an mWRD and the average number of tuberculosis cases seen at the facility (Figure 1). Selected facilities were predominantly microscopy sites, and the median distance from another mWRD site was 13.6 km (range: 2.1 km to 292 km). The project team also engaged the facility management to discuss site readiness and what upgrades were needed to the existing laboratory space. Whilst the Truenat instruments are lightweight, have minimal space requirements and can test at ambient temperatures up to 40° Celsius, in some sites minor upgrades were needed. Upgrades included installation of workbenches, partitioning of laboratory space to include a sample processing room and a Truenat room, painting, installation of burglary prevention devices on windows and doors, installation of plumbing to ensure water supply to the laboratory, provision of refrigerators for storage and provision of air conditioners for a suitable working environment. Community leaders were also engaged to raise awareness and interest in the new diagnostic tool.



Cover page of the Truenat Implementation Guide developed by USAID/ Stop TB and endorsed by the GLI

Cover page of Nigeria's National Guidelines on the Implementation of Truenat Tests for the Detection of Tuberculosis and Rifampicin Resistance



This created excitement about the new test, and in some sites the leaders were actively involved in the renovations of the laboratory space.

Operational lessons

The implementing partners customised the training material developed by the Stop TB Partnership and USAID and trained 110 healthcare workers, including 80 technologists and 30 supervisors. The training took place in two phases, an initial three-day centralised training that included end-users from the state where a training of trainers was conducted, supervisors, and other NTBLCP staff, followed by on-site training of end-users and installation of instruments by the Molbio local agent, Michael Weierstrass. This reinforced any concepts introduced during the initial training. The trainees were evaluated at the end of each training session to assess competency. Key elements needed for successful implementation are listed in Table 1.



A laboratory scientist at Health Affairs Lagos testing on the Truenat instrument system.
Source: Institute for Human Virology Nigeria, Nigeria

The king and community leaders donate a fridge and air conditioner to Osun State TB laboratory in preparation for the installation of a Truenat instrument system.
Source: Institute for Human Virology Nigeria, Nigeria



Table 1. Key elements for successful implementation of Truenat testing at peripheral facilities

Lesson	Key activities
1. Close collaboration with NTBLCP translates to ease of operation.	<ul style="list-style-type: none"> • Early and constant consultation with NTBLCP to increase ownership • Collaborative update of the national tuberculosis algorithm to include Truenat testing • Guidance from NTBLCP on site selection
2. Close monitoring of facilities aids timely response to challenges.	<ul style="list-style-type: none"> • Creation of a WhatsApp group for real-time reporting and resolution of issues • Close collaboration with a local agent who provided video consultation to guide end-users for resolution of errors • Creation of a weekly report to allow early identification of problems. • Monthly supervisory visits also provide ongoing support to end-users • Plans to connect the Truenat instruments using the Aspect connectivity solution (SystemOne, Northampton, United States). This will allow the NTBLCP to monitor the functioning of its Truenat and GeneXpert networks in real-time on an integrated online platform, and allow test results to be transmitted electronically to clinicians.
3. Engagement of key stakeholders, including community leaders and facility management, increases acceptability.	<ul style="list-style-type: none"> • Sensitization of healthcare workers to improve utilisation at sites • Creation of a plan for sample logistics to increase utilisation
4. Mentorship is needed to strengthen the quality management systems at Truenat facilities.	<ul style="list-style-type: none"> • During the initial period, establish plans for multiple onsite mentorships, trainings and standard operating procedures for sample storage, safety and waste management, quality control, and preventive maintenance
5. Strong support from the manufacturer ensures instrument uptime.	<ul style="list-style-type: none"> • Participation of the manufacturer Molbio's in-country agent not only in trainings, to ensure proficiency of end users, but also to troubleshoot problems virtually and travel to sites as needed, under Truenat warranty coverage

Impact of Truenat deployment on tuberculosis diagnosis

Between December 2021 and May 2022, a total of 21 825 samples from individuals undergoing investigations for tuberculosis were received at the Truenat facilities. Of these, 21 503 DNA extractions, 21 382 MTB Plus and 2 141 MTB-RIF Dx tests were conducted (Figure 2). The positivity rate was 10% (n=2 141) for MDR tuberculosis and 2% (n=43) for rifampicin-resistance detection. The average number of tests performed per month per instrument increased from 41 at inception to 114 tests in May 2022, representing a 178% increase in utilisation rate. The error rate for MDR tuberculosis testing decreased from 4.3% in December 2021 to 3.1% in May 2022, and remained at 1% or lower for the MTB-RIF Dx test (Figure 3). Comparing the period before and after Truenat implementation (Quarter 1 2021 vs Quarter 1 2022), both the percentage of new or relapsed tuberculosis cases tested with a mWRD test and bacteriologically confirmed tuberculosis cases increased to a median of 100% in Quarter 1 2022 (Table 2). The median percentage point increase was 25% for cases tested with a mWRD test (Quarter 1, Quarter 3: 0, 28.2) and 24% for bacteriologically confirmed cases (Quarter 1, Quarter 3: 0, 44.6).

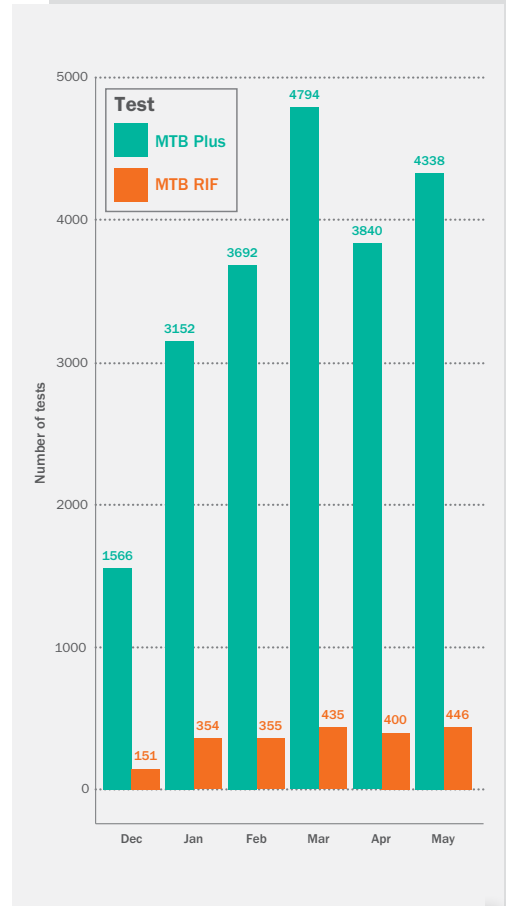


Figure 2. Number of Truenat MTB Plus and MTB-RIF Dx tests conducted in Nigeria between December 2021 and May 2022

Table 2. Change* in the number of new or relapsed tuberculosis cases tested with a mWRD and bacteriologically confirmed in Nigeria, 2021-2022.¹

Indicator	2021 Quarter 1			2022 Quarter 1		
	Median	Quarter 1	Quarter 3	Median	Quarter 1	Quarter 3
New or relapsed tuberculosis case tested with mWRD						
Number	6	4	12.5	20	16	30
Percentage ²	72.2	36.9	96.3	100	91.4	100
Bacteriologically confirmed new or relapsed tuberculosis						
Number	6.5	4.3	13	19.5	11.2	26
Percentage ³	73.6	52.6	100	100	95.7	100

- 1 Comparing paired data from 30 facilities
- 2 Number tested with mWRD divided by the number of new or relapsed tuberculosis cases.
- 3 Number bacteriologically confirmed tuberculosis cases divided by the number of new or relapsed tuberculosis cases.

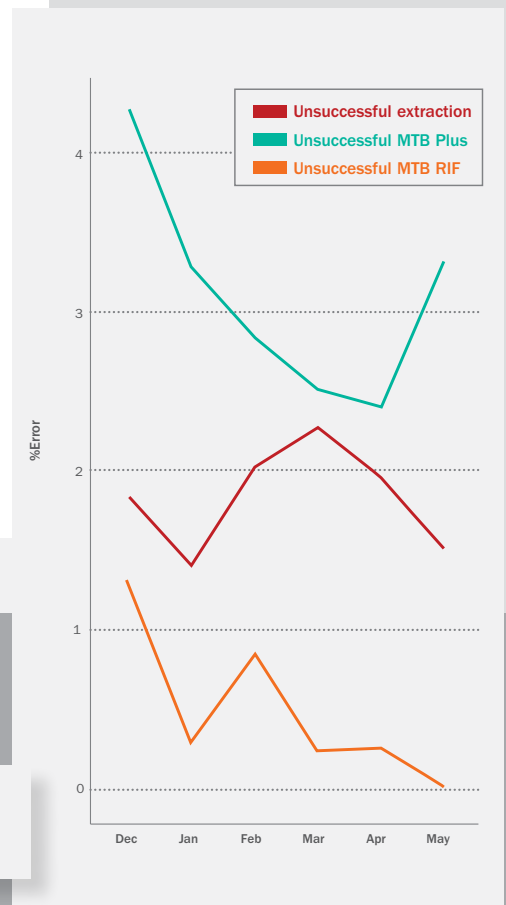


Figure 3. Truenat errors classified by stage at which error occurred in Nigeria between December 2021 and May 2022

Planned use of Truenat in community-based active case-finding

We have also started piloting the use of Truenat instruments together with ultraportable Delft Light digital X-ray systems provided under the iNTP. Outreach is currently planned in communities that are more than 10 km away from the nearest health facilities.

Conclusion

The battery-operated Truenat systems have the potential to impact tuberculosis case detection and facilitate rapid and near point-of-care detection of drug-resistant tuberculosis. Lessons learned from this project can be used to scale up efficient, high-quality tuberculosis diagnostic tools for the people who most need them.

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Editors

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Citation

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Q&A

What is diagnostic network optimisation?

Diagnostic network optimisation (DNO) is a form of geospatial network analytics approach used to analyse the current diagnostic network and recommend the optimal type, number and location of diagnostics and an associated sample referral network to achieve national health goals.¹

What key questions can be answered through DNO analysis?

DNO helps create a digital representation of diagnostic networks that can include multiple test types, devices, sites and referral linkages. While DNO analysis should be designed to address specific country needs, some common questions include: Can current testing capacity meet existing and future demand? Are new devices needed, and, if so, how many and where should they be placed? Is there spare capacity on existing multi-analyte devices and can testing integration bring improved patient access and system efficiency benefits?

DNO recommendations may lead to various interventions, including adding or relocating devices, integrating testing on multi-analyte platforms, establishing or altering sample referral linkages between health facilities and laboratories and shaping national policy and guidelines.²

How is DNO performed and how long does it take?

DNO consists of five main steps: (1) define scope, i.e. the questions to be addressed through DNO, (2) collate and prepare (existing) data, (3) run baseline analysis to identify gaps and opportunities for improvement, (4) run optimisation scenarios by making changes to the baseline, and compare across scenario, (5) select and implement outputs. DNO analyses typically take six to nine months, mainly depending on the availability and quality of existing data, the complexity of scope and the stakeholders' engagement. Implementation of DNO outputs can extend beyond this period depending on the nature of interventions selected during the analysis.

What data are needed to conduct DNO?

Who should be involved in the DNO process?

Key data inputs include geolocated information on testing sites (health facilities, hubs and laboratories or non laboratory sites), tests, devices, current and forecasted testing volumes, referral linkages and costs. Ideally, DNO should leverage existing data sources wherever available.

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The DNO process described above should be led and guided by ministries of health at each step, ideally by the national laboratory directorate, with the engagement of all key ministries, disease programmes and relevant implementing partners and donor agencies.

Where has DNO been performed, and how have DNO outputs informed diagnostic system strengthening?

DNO analyses have been conducted in a growing number of countries in Africa and Asia, many focussed on strengthening networks for improving access to [HIV and tuberculosis](#) molecular testing, while others addressed access to testing for [neglected tropical diseases](#) and strengthening antimicrobial resistance laboratory surveillance networks. DNO outputs have informed funding requests to donor agencies and shaped national strategic plans and guidelines.^{3,4} For example, the Philippines, India and Kenya have used DNO to inform GeneXpert procurement and device placement plans to best meet their national tuberculosis programme goals. DNO can also help support integrated diagnostic networks, for example, in Kenya national integrated sample referral guidelines were developed based on DNO recommendations. In Zambia, DNO demonstrated how centralised and decentralised testing could be optimally used to improve turn-around time for HIV viral load testing in priority populations, i.e., viral load testing for pregnant and breastfeeding women and children and early infant diagnosis. Findings suggested that GeneXpert devices with available capacity (that primarily conducted tuberculosis testing at baseline) could be leveraged for priority HIV testing where target turn-around time for HIV could not be assured with centralised polymerase chain reaction (PCR) testing, without negatively impacting tuberculosis testing.⁵ The integrated and optimised scenario would also reduce the combined cost of tuberculosis

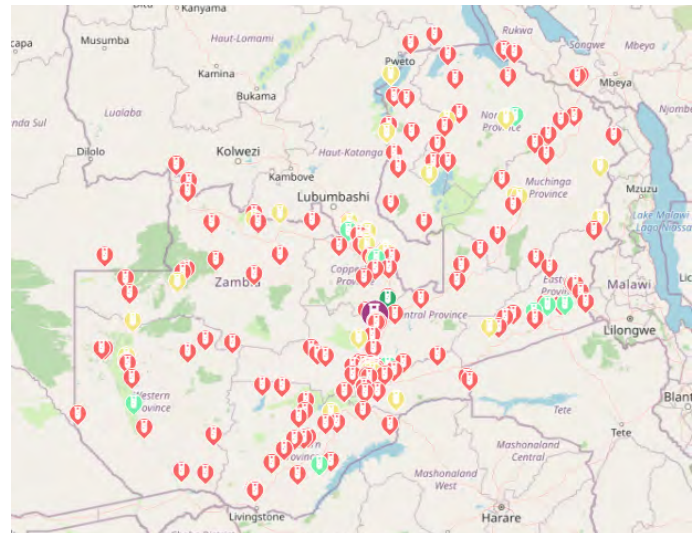


Figure 1. DNO in Zambia (baseline model). GeneXpert devices conducting tuberculosis testing were mapped using OptiDx software as a part of DNO analysis in Zambia. Most sites are red denoting low utilisation levels. HIV testing was conducted on centralised PCR devices (not displayed on the map) and samples travelled long distances, particularly from remote areas, leading to delays in test results.

“ DNO is increasingly being proposed to inform diagnostic system strengthening in low- and middle-income countries... ”

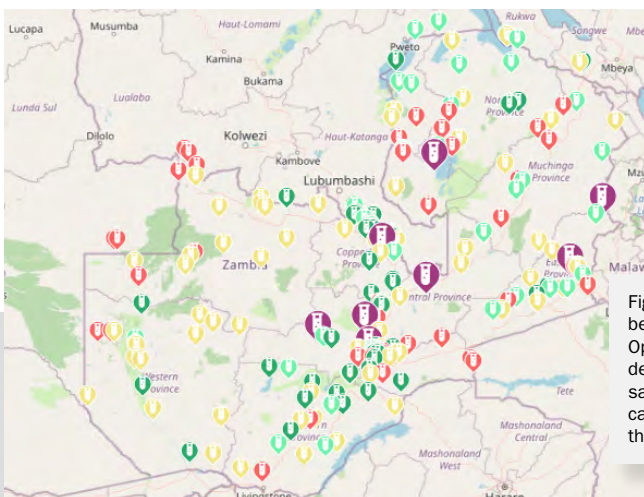
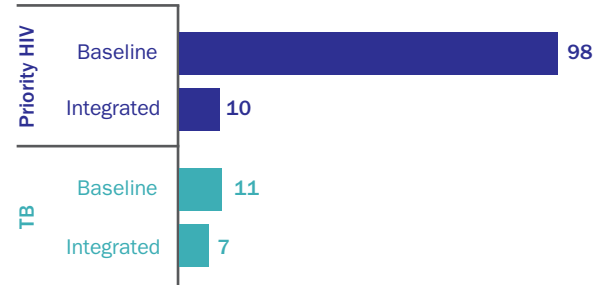


Figure 2. DNO in Zambia (optimised model). Feasibility and impact of integrated HIV-tuberculosis testing to improve turn-around times for test results was modelled using OptiDx software. The existing GeneXpert network was adequate to meet the combined demand of priority testing for HIV and tuberculosis. Compared to baseline, device utilisation would increase across most sites, while demand would exceed available testing capacity at some sites. Subsequent models were run to address overcapacity issues at these sites.

and HIV programmes by 2%, helping achieve both access and cost benefits. DNO is increasingly being proposed to inform diagnostic system strengthening in low- and middle-income countries and recommended by key donors including The Global Fund to Fight AIDS, Tuberculosis and Malaria and United States President's Emergency Plan for AIDS Relief (PEPFAR).^{6,7} The African Society for Laboratory Medicine (ASLM) and FIND have recently established the DNO sub-community of practice within ASLM's Laboratory Community of Practice (LabCoP), to promote the use of DNO and various applications of geospatial analysis in the region, for furthering evidence-based laboratory systems planning and decision-making.

Figure 3. Compared to baseline, in the optimised and integrated scenario average distance travelled by priority HIV samples decreases from 98 km to 10 km and for tuberculosis samples from 11 km to 7 km.

Average km travelled/sample



Suggested resources for further information:

- FIND's introductory YouTube video to [DNO](#)
- FIND's YouTube video on [OptiDx, an open access DNO tool](#)
- FIND's [landscape report](#) on various software tools to conduct DNO
- ASLM's webpage on the [DNO sub-community of practice](#)

Citation

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Featured Topic

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Integration of medium-to-high throughput platforms for tuberculosis diagnosis

Worldwide, about 2 billion people are infected with *Mycobacterium tuberculosis*, which is equivalent to a quarter of the world's population.¹ Compared to 2019, in 2020, the number of newly diagnosed tuberculosis patients dropped from 7.1 million to 5.8 million and there were an additional 100 000 deaths. During the same year, almost half of people who suffered from tuberculosis did not have access to care, and there was a significant drop in the number of people who were treated for multi-drug resistant tuberculosis, as well as in those receiving preventive therapy.¹ Disruptions of the healthcare systems due to the coronavirus disease 2019 (COVID-19) pandemic have reversed the progress to end tuberculosis by several years.¹

Among people with presumptive tuberculosis infection, the World Health Organization (WHO) recommends the use of molecular tests as the primary means of laboratory diagnosis, instead of sputum smear microscopy, due to high diagnostic accuracy of these tests in detecting tuberculosis and drug-resistant tuberculosis.² The microbiological detection of tuberculosis is critical for the definitive diagnosis of the disease and to predict or determine drug resistance, thereby ensuring the most effective treatment regimen is prescribed. Unfortunately, only 59% of people diagnosed with pulmonary tuberculosis were bacteriologically confirmed in 2020.¹ The other 41% of patients were diagnosed clinically either based on the presenting symptoms or other abnormalities on the chest radiography. Therefore, scaling up molecular testing can increase access of proper and more rapid diagnosis for patients and thus increase linkage to proper treatment.

“ *The microbiological detection of tuberculosis is critical for the definitive diagnosis of the disease and to predict or determine drug resistance...* ”

The Stop TB Partnership’s Global Plan to End TB 2023–2030 has a target to treat 50 million people, including 2.2 million with drug-resistant tuberculosis.³ In order to achieve these targets, a people-centred approach using the latest approved diagnostic tests, treatment regimens, and clinical monitoring is key. This will not only increase access to molecular testing for tuberculosis diagnosis for patients but also improve surveillance of tuberculosis and drug-resistant tuberculosis in communities. Additionally, it can reduce the turn-around time for reporting of results to clinicians, leading to timely diagnosis and treatment. To improve tuberculosis diagnosis, the WHO endorsed the use of four additional novel nucleic acid amplification tests to be used as initial tests for tuberculosis diagnosis.² These new tests can not only detect both rifampicin and isoniazid resistance, but are fully automated, ‘walk-away’ methods, with medium to high throughput.⁴ This is of public health importance, since around 13% of patients (1.1 million) diagnosed with rifampicin-susceptible disease have isoniazid resistance; this additional information has a significant impact on treatment outcomes and prevention of the development of additional drug resistance.^{5,6}

Additionally, some of these new tests offer detection of fluoroquinolone and pyrazinamide resistance.⁴ These new technologies allow integration of multiple testing for other infectious diseases of public health concern, such as HIV and hepatitis, using the same diagnostic platforms in the laboratories, improving patient access to diagnostics and to more timely interventions for better disease management (Figure 1).

“ ... a people-centred approach using the latest approved diagnostic tests, treatment regimens, and clinical monitoring is key. ”

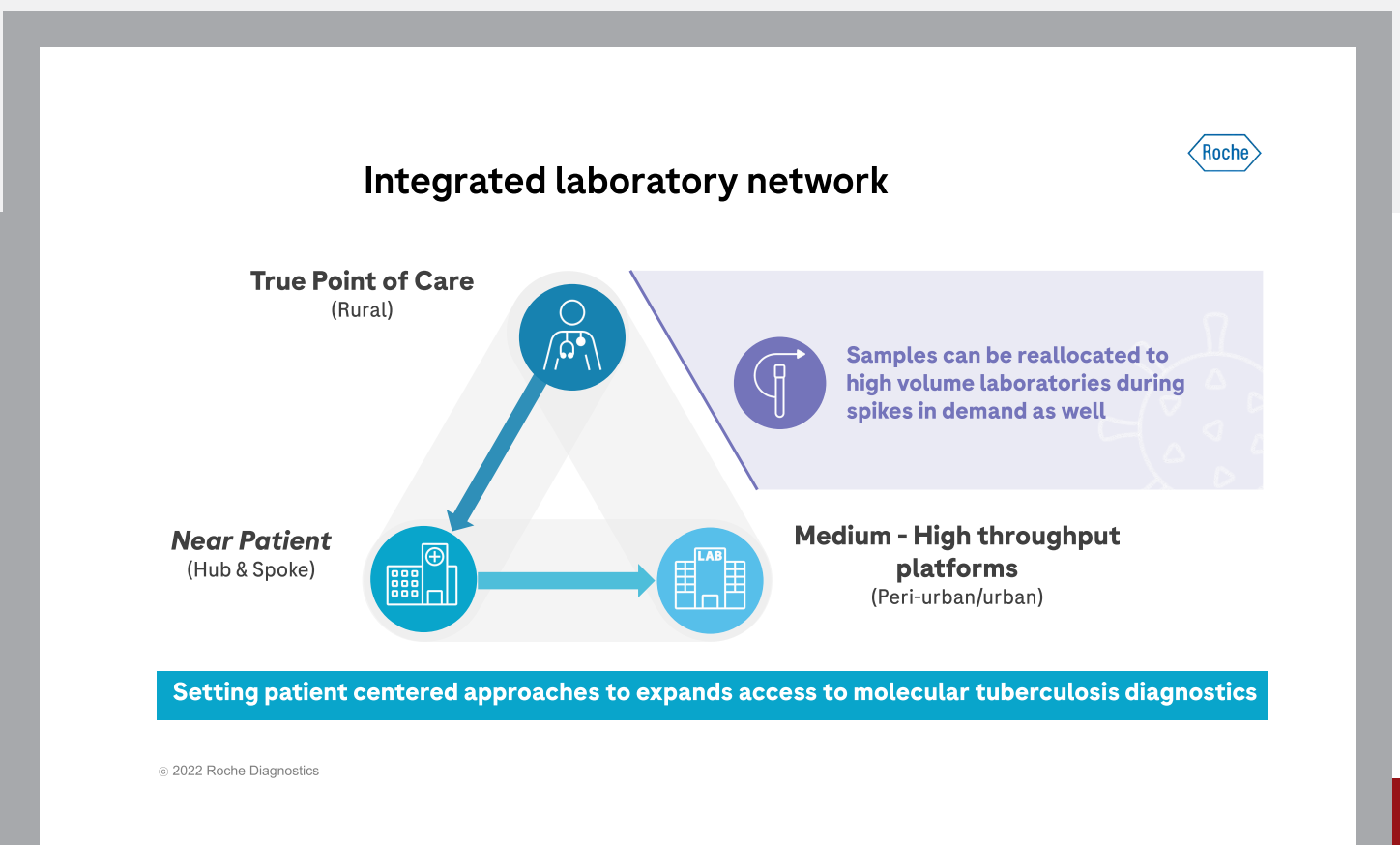


Figure 1. Leveraging the power of the diagnostic continuum to bring testing to people who need it in developing countries.

“*The new guidelines also strengthen head nurses' abilities to analyse and interpret disease surveillance data.*”

What lessons do we take from the healthcare system disruptions caused by the COVID-19 pandemic, which led to reduced care for tuberculosis services? First, running multiple tests in a single medium or high throughput system is key to enable high quality diagnostics not only for tuberculosis but also for other pathogens, such as coronaviruses, HIV, hepatitis B virus and hepatitis C virus, using the same systems and similar workflows to process the specimens. This approach is critical, especially in urban and peri-urban settings, where healthcare systems tend to have in place microbiology laboratories for drug resistance testing and the large populations served may require medium to high throughput platforms to enable adequate turn-around times. Second, there is a need to address the diagnostic network as a whole with the right solutions for integrated specimen collection and diagnostics tailored to each specific level of the tiered laboratory system (Figure 1). Integration of services supports all key elements of diagnostic services, such as laboratory capacity, laboratory workforce, commodity management and quality assurance. Third, there is an urgent need for more digital solutions to support patients and their communities beyond the test result. The digitalization of laboratory networks improves patient management by ensuring timely diagnosis, and hence management, of disease by clinicians. This can also improve patient education through increased awareness, adherence to medications regimens and reduced turn-around times for receipt of results. Taken together these benefits can lead to more efficient use of donor funds and help laboratories to become more efficient.

To achieve the WHO's End TB Strategy and the United Nations' Sustainable Development Goals, access to diagnosis, treatment and care for tuberculosis patients must be increased.^{1,7,8} The existing gaps in healthcare services delivery, such as access to high quality diagnostics, must be addressed. We can achieve this by the deployment of the additional nucleic acid amplification tests, endorsed by the WHO, and by considering the benefits of leveraging medium-to-high throughput platforms for diagnosis of tuberculosis and other co-infections, thus cutting across disease silos and diagnostic network tiers. This is a pivotal moment to close this gap and improve the outcomes of millions of patients affected by this debilitating disease in lower- and middle-income countries.

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Featured Topic

Stopping Disease Outbreaks with Integrated Disease Surveillance and Response

Stopping the next pandemic or other dangerous infectious disease outbreak is possible, but it requires public health agencies, private laboratories, and community partners to closely coordinate their responses to emerging threats. That's the idea behind the Integrated Disease Surveillance and Response (IDSR) framework, first established in Africa in 1988. Created by the World Health Organization's Africa region, the IDSR framework helps these groups decide when and how to act—by recommending thresholds for action on dangerous infectious diseases, determining events and conditions that merit a public health response, and establishing alert systems that help to contain infectious diseases.

The African Ministers of Health adopted the [Regional Strategy for IDSR 2020–2030](#) during the 69th Regional Committee for Africa in Brazzaville, Congo, in August 2019. Thus, all member states must implement the [third edition of the IDSR Technical Guidelines](#). These guidelines detail required actions at each health system level to promptly detect, surveil, respond to, and report infectious disease outbreaks (among other public health threats). Given the scope and complexity of the new guidelines, the United States Agency for International Development's (USAID) [Infectious Disease Detection and Surveillance](#) (IDDS) project is helping to roll out the new requirements through training and guidance, specifically in Senegal and Cameroon.

In Senegal, emerging and re-emerging infectious diseases such as Ebola virus disease, poliomyelitis, measles, and yellow fever continue to challenge the country's public health system. As a result, to build capacity, the country began implementing community-based epidemiological surveillance in 2015, which involves community members participating in detecting, monitoring, and responding to local health events and reporting information to their local authorities. For example, a schoolteacher might report an abnormally high number of children reporting sick on the same day.

The new IDSR guidelines aim to support these community-based activities by providing clear instructions for incorporating community members into public health surveillance—for instance, by deploying volunteers. The volunteers report any unusual health event (such as the sick school children example above) and help health workers with outbreak investigation and contact tracing.

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Training Nurses

Senegal needs a well-trained and dedicated workforce equipped to activate the new IDSR guidelines to fully realise the benefits of decentralising and otherwise improving disease surveillance and response. Therefore, the IDDS used a train-the-trainer approach to engage the head nurses from three health districts of the Tambacounda medical region, advancing their technical knowledge of IDSR guidance on antimicrobial resistance, event-based surveillance; community-based surveillance; and human, animal, and laboratory surveillance.

According to Dr Bayal Cisse, Tambacounda regional medical officer, 'IDDS is the lead partner of the medical region on epidemiological surveillance. The project is already supporting the seven health districts of the region in improving the quality of data reports on priority diseases. Now it has provided support to implement the latest version of the IDSR through the training of nurses. This kind of training will help us to continuously strengthen the surveillance system.'

IDDS trained 59 head nurses for two weeks in November 2021, hosting sessions facilitated by the Senegal Ministry of Health's Directorate of Prevention. IDDS trained staff from three districts in East Senegal, Koumpentoum, Maka Colibantang, and Tambacounda, which included both urban and rural areas. By the end of the training, nurses' scores on a technical knowledge test had increased five-fold compared with their pre-training test scores. They will train the staff members in their health posts, such as assistant nurses and midwives, who are still using the outdated second-edition IDSR guidelines. Follow-up supportive supervision sessions were organised jointly with the Ministry of Health to assess the impact of the training. The findings show that the trained health districts improved the timeliness, completeness and quality of their reporting.



Training session in Maka Colibantang Health District #1, Senegal. Source: IDDS.



Training session in Tambacounda Health District, Senegal, from left to right: Dr. Gadiaga, chief medical officer, Tambacounda Health District; M. Bah, health informatics specialist, IDDS; M. Djiba, health informatics specialist, Ministry of Health. Source: IDDS.



Training session in Maka Colibantang Health District #2, Senegal. Source: IDDS.

Capturing Data for Surveillance

The new guidelines also strengthen head nurses' abilities to analyse and interpret disease surveillance data. The nurses enter data into the District Health Information Software version 2 (DHIS2), the IDSR reporting system. Through regular supervision and review of data quality in the DHIS2, the IDDS measures changes in data quality to determine how the IDSR training and coaching have improved nurses' data entry and analysis skills.

“ *The new guidelines also strengthen head nurses' abilities to analyse and interpret disease surveillance data.* ”

“ *With the adaptation and implementation of the third edition of the IDSR technical guidelines, there is potential for disease surveillance in Tambacounda to be greatly improved,* ”

says Dr Cheikh Gadiaga, Tambacounda Health District's chief medical officer.

In Cameroon, the IDDS held a train-the-trainer workshop for 34 participants (half were women) from the national and regional health system levels, including surveillance officers, on the new guidelines. Participants already knew the new guidelines, but post-test scores improved by a few points on average. Participants also rated the workshop as 'very relevant' and were highly satisfied with the training experience.

Looking ahead, IDDS plans to help remove all outdated IDSR guidelines from Senegal's regional offices and health districts, update data collection tools, and continue to organise regional training for nurses. In addition, the IDDS will monitor the impact of training to ensure that nurses are implementing the third-edition IDSR technical guidelines and orient the nurses on the analysis modules for DHIS2.

In Cameroon, IDDS will produce and implement training in all ten regions of the country, supervise IDSR actors at all health system levels, and help stakeholders access funding for the next steps in implementation.

Emily Nink and Tom Price are staff at [ICF](#) for the [IDDS project](#) funded by USAID. IDDS strengthens the ability of health systems in low- and middle-income countries to quickly detect, track, and respond to infectious disease threats. The views expressed here are the authors' and are not necessarily those of USAID or the United States government.

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Meet Dissou Affolabi

Dissou Affolabi is a medical doctor with a specialization diploma in laboratory medicine and Master of Science and doctorate degrees in Microbiology. He has been working in the National Tuberculosis Programme of Benin since 2004. He is currently a Professor of Microbiology at Abomey-Calavi University in Benin, the Director of the World Health Organization Supranational Reference Laboratory for tuberculosis in Cotonou, the Benin National Tuberculosis Programme manager and the Executive Secretary of The West and Central African Network for Tuberculosis Control. In addition, he coordinates a multicentre European and Developing Countries Clinical Trials Partnership-funded DIAMA project.



Thank you for taking the time for this interview, Prof Affolabi! What can you tell us about your current responsibilities and projects?

Apart from managing the clinical bacteriology and virology laboratory at the university teaching hospital Hubert Koutoukou Maga of Cotonou, the biggest hospital of the administrative capital city of Benin Republic, I am currently the head of the WHO Supranational Reference Laboratory (SRL) for tuberculosis in Cotonou. I have been working in this laboratory since 2004 and its performance has been gradually improved from 'SRL candidate' in 2012 to full membership in the SRL network in 2017. Since then, a network of 23 national tuberculosis reference laboratories (NTRL) in the West and Central African region has been created and is currently led by SRL Cotonou through the TB-Lab Project, which is funded by the Global Fund to Fight AIDS, Tuberculosis and Malaria. The SRL Cotonou for tuberculosis is currently the only such laboratory in the West and Central African region; others in the WHO African region include laboratories in Algiers, Algeria; Johannesburg, South Africa; and Kampala, Uganda.



What is the idea behind this network?

The goal is to enhance capacity for high quality diagnosis of tuberculosis in West and Central Africa, through support coordinated by SRL Cotonou. As tuberculosis knows no borders, it is essential that control of the disease be effective in all countries in the same geographical area by improving the quality of diagnosis and monitoring of tuberculosis endemic in the region.

What is the relationship of SRL Cotonou to expanding access to tuberculosis diagnostics in Africa?

SRL Cotonou oversees a number of projects and initiatives aimed at increasing capacity to perform diagnostic and disease control activities. One of these, the TB-Lab Project, started in January 2019 with the following objectives:

1. To establish a regional NTRL network in the West and Central African Region as a platform for partnerships, and exchange of best laboratory practices
2. To strengthen NTRL capacities by providing tailored training and on-site technical assistance
3. To build the technical capacity of the NTRLs of prioritised countries for disease monitoring surveys and laboratory-specific operational research studies
4. To strengthen the technical and administrative capacity of SRL Cotonou to become a training centre of excellence for NTRLs and the overall coordinator for the regional laboratory network

At the end of the three-year of the project, its main objectives had been achieved. In particular, a functional network had been built, and there had been great improvements in several aspects of the NTRL's activities, such as microscopy, GeneXpert, culture, drug susceptibility testing, molecular tests, and laboratory network management. In addition, a specific focus was put into improving quality management systems. In 2019, there were no ISO 15189-accredited NTRLs in the region, but by 2021 there were three. Based on the excellent performance of the project, it was renewed for another three years (2022-2024) with the aim of reinforcing these achievements and removing bottlenecks, such as sample transportation systems within countries and between countries and the SRL.

Another project managed by SRL Cotonou is the [DIAGnostic for Multidrug resistant tuberculosis in Africa](#) (DIAMA) project, which is funded by the European and Developing Countries Clinical Trials Partnership (NC03303963). The DIAMA project started in 2016 and will be completed in November 2022. It is coordinated by SRL Cotonou and involves nine African countries including Benin, Cameroon, Democratic Republic of Congo, Ethiopia, Guinea, Mali, Nigeria, Rwanda, and Senegal. The goal of the DIAMA project was to develop culture-free approaches for the diagnosis and management of patients with rifampicin-resistant tuberculosis. In fact, culture is still a reference standard for diagnosis and follow-up of drug-resistant tuberculosis. However, tuberculosis culture is rarely available in low resource and endemic countries due to several constraints. The main data from the project are still being analysed, but it has already contributed to the recent WHO recommendations on the use of the Xpert MTB/XDR on the GeneXpert 10-colour assay.

SRL Cotonou is under the umbrella of the [West and Central African Network for Tuberculosis Control](#). Among other activities, this organisation supports countries in the region to promote operational research. In particular, SRL Cotonou is used as a technical arm of the organisation to promote tuberculosis laboratory-related research within this geographical area.

Last but not least, since its ISO 15189 accreditation, SRL Cotonou is playing more and more roles in Benin, as well as in the West and Central African region, for improving quality management systems.



What will be the most important emerging challenges for public health in Africa over the next five years? How can ASLM work with SRL Cotonou to meet those challenges?

The coronavirus disease 2019 (COVID-19) pandemic showed that progress towards the targets of WHO's End TB Strategy can be jeopardised by emerging diseases. Therefore, it is of utmost importance that countries are well prepared to deal with such threats in the future. At the beginning of the COVID-19 pandemic, SRL Cotonou organised a series of webinars to train and to coach NTRLs to develop their contingency plans to mitigate the impact of this new disease on the tuberculosis laboratory network. Together with ASLM, SRL Cotonou can share lessons learned during this time for the future.

What is your best advice for the next generation of African laboratory scientists? How can they best equip themselves and their communities for the challenges to come?

New threats will emerge, with global impact; so, the next generation of laboratory scientists should be ready to deal with these challenges. Molecular tools, and whole genome sequencing in particular, will certainly play more and more roles, as well as connectivity and digital tools. So, scientists should be well trained, open-minded, and should develop multidisciplinary networks to be able to adequately tackle these challenges.



Interviewer

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