Country in Focus: Uganda

THE INTRODUCING NEW TOOLS PROJECT (iNTP)

Early Experience in Implementation of Truenat MTB Plus and MTB-RIF Dx Testing in Uganda

Background

Uganda is one of thirty high TB and TB/HIV burden countries, with an estimated 91,000 people falling ill with TB annually according to the World Health Organization (WHO)[1]. Despite achieving 82% TB detection and treatment coverage in 2021, limited access to WHO-recommended rapid molecular diagnostics (RMD) and the impact of COVID-19 have contributed to gaps in TB case finding.

To help improve access to RMD, the Stop TB Partnership provided 38 Truenat Duo systems and reagents for Uganda through the introducing New Tools Project (iNTP) funded by the United States Agency for International Development (USAID). The introduction of this new diagnostic tool by the Uganda National TB Reference Laboratory (NTRL) and the National TB and Leprosy Programme (NTLP) aimed to increase the detection of individuals with both rifampicin-susceptible and rifampicin-resistant TB, as well as reduce diagnostic and treatment delays. Implementation of activities was supported by the USAID Infectious Disease Detection and Surveillance (IDDS) Project.

[1] WHO Global Tuberculosis Report 2022: https://www.who.int/publications/i/item/9789240061729

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Figure 1: Map of 38 Truenat implementation sites (red dots) in Uganda

> Truenat testing has more hands-on work compared to GeneXpert. Since we are only 2 staff in the laboratory, it is going to be quite hard for us to manage the workload. However, due to the delays we have been experiencing when referring samples for GeneXpert testing, we see this as a better solution for our patients since we can now ensure same day diagnosis.
>
> Mr. Magada David | Laboratory Technologist, Buwasa HCIV

Implementation Experience

The phased implementation of Truenat testing in Uganda took the following steps:

01 Site Selection: Sites were selected based on the concept of universal health coverage to expand access to WHO-recommended RMDs among people in Uganda. The selection criteria also included the expected numbers of individuals with presumed TB, distance from other RMD sites, and strategic regional balance to cater for equitable distribution of resources among the population. In consultation with the NTLP and implementing partners, priority was, therefore, given to primary healthcare facilities (HCIVs & HCIIIs) with the highest outpatient department attendance and with longer distances from the nearest GeneXpert sites, across various regions of the country.

02 Centralized Training: Twenty-five (25) NTRL and NTLP staff, including laboratory personnel, medical officers, procurement and supply management personnel, and monitoring and evaluation staff, received training at the central level. This provided knowledge and skills on the role and use of Truenat technology for diagnosis of TB and rifampicin-resistant TB.

03 Superuser Training: Ten laboratory scientists from the NTRL completed a five-day advanced training program, which included theoretical and practical sessions, to enhance their competencies in the Truenat diagnostic technology. The training aimed to equip these "superusers" with technical and troubleshooting skills to support Truenat end-users with on- and off-site training and provide technical assistance.

04 Installation and On-site Training: Between June and July 2022, certified Molbio technical staff, supported by the NTRL team, performed the installation, and provided on-site training to laboratory staff, clinicians, data management staff, medical stores personnel and counsellors. This two-day knowledge and skills transfer activity was carried out per facility to provide the necessary competency among users. It covered aspects such as laboratory performance, inventory management, waste management, quality assurance, result interpretation, recording and reporting. In this way, users were educated on both the opportunities and challenges associated with Truenat technology.
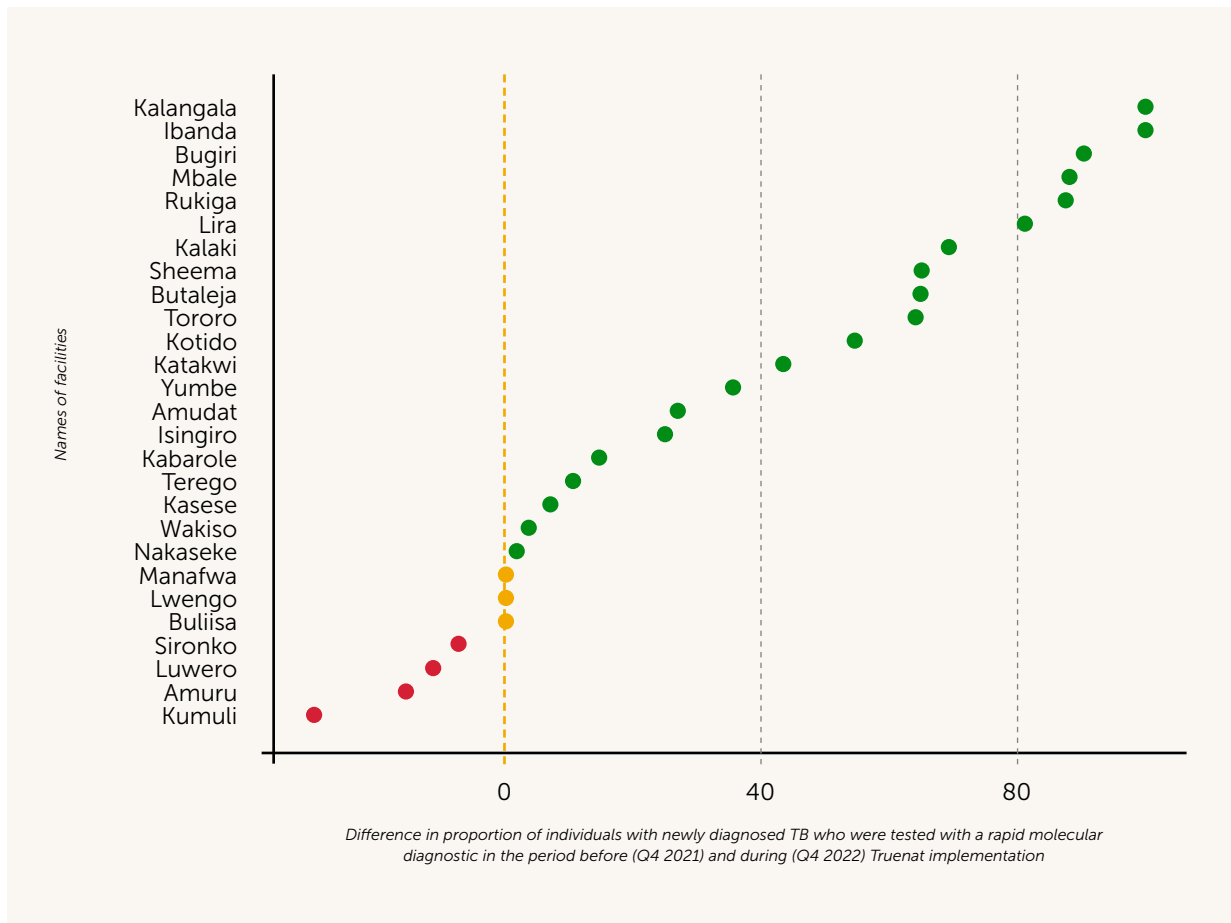
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Early Impact

Between July and December 2022, Truenat technology was used to conduct 16,413 MTB Plus tests, resulting in the detection of 675 MTB positive samples (4.1% positivity rate) and 26 rifampicin-resistant samples (3.8% of MTB samples). The positivity rate was highest in July-August (6.6%) but reduced later due to testing from community outreach activities during the CAST TB (Community Awareness, Screening, Testing, and Treatment to end TB and Leprosy) campaign. The rate observed is comparable to the positivity rate observed with other RMDs used in Uganda including Xpert MTB/RIF Ultra (4.4%). Moreover, the impact of Truenat testing was evident in the significant increase in the proportion of individuals with newly diagnosed TB who received a RMD at project sites in the last quarter of 2022 compared to the same quarter in 2021, when Truenat had not yet been implemented. A median percentage point increase of 26.7% (IQR 0.9-67.2) was observed across all sites, with all but four sites showing a positive change (Figure 2).

Figure 2: *Change in the proportion of individuals with newly diagnosed TB tested with a rapid molecular diagnostic as the initial diagnostic test in the period prior to (Q4 2021) and during (Q4 2022) Truenat implementation*

Difference in proportion of individuals with newly diagnosed TB who were tested with a rapid molecular diagnostic in the period before (Q4 2021) and during (Q4 2022) Truenat implementation

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Lessons Learned

1. Training and Competence

Hands-on supportive visits were provided by superusers to address issues related to Truenat utilization, such as recording, internal control, preventive maintenance, contamination monitoring, linkage of individuals diagnosed with TB to treatment, waste management, and result turnaround time, demonstrating the positive impact of regular supportive supervision on adherence to good clinical laboratory practices. In November 2022, a refresher training organized for laboratory personnel further enhanced their competency in Truenat testing and provided a platform to share challenges and experiences. Whilst regular training and learning opportunities can improve the competence of personnel, addressing the challenge of understaffing will further optimize the utilization of the Truenat instruments.

2. Errors and Corrective Actions

The proportion of initial Trueprep errors was 1.3% (206/16,413), whilst the proportion of nondeterminate results (invalid, error or indeterminate) was 2.1% (341/16,413) and 4.3% (27/630) on the MTB Plus and MTB-RIF Dx assays respectively. The proportion of errors gradually reduced as users gained more hands-on competency with using the Truenat devices. Several issues were encountered during installation of Truenat devices (Table 1). The most common errors observed during field visits were Trueprep E1, E2, E4, E9 and E10 and Truelab E5.

Table 1: *Errors encountered during installation of Truenat devices and their resolution*

#	Issue	Machines that encountered the issue	Type: Major/ Minor	Frequency	How it was resolved	Recommendation
1	Failure to Elute DNA	Trueprep Auto V2	Major*	6	Field Service Engineer (FSE) flushed the device	Disperse test should be run before any installation
2	Printer failure to start	Bluetooth printer	Minor	4	Changed adapter	
3	Consistent invalid results	Truelab Duo	Major	2	Calibration of Truelab with standard chip to restore Bay reading to 3.41	Virtual troubleshooting with site before FSE field visit
4	Failure of back and home key to function	Truelab Duo	Minor	1	Only encountered in "power user" profile.	

*Major means that testing was interrupted

3. Quality Management System

A. Specimen Referral

The specimen referral system operates on the Hub and spoke model. The Hubs have designated spokes with formalized routing that is used for sample collection and result return. The NTRL is working with implementing partners to support formal routing of Truenat sites in the Hub routing. In areas where Truenat has been accommodated into the referral network, there has been notable decreases in driving distances, reduced wear and tear of motorcycles, reduced fuel consumption and reduced result turn-around times for RMD testing.

B. Results Management

Initially, gaps existed in the recording of results due to the use of current versions of Health Management Information Systems (HMIS) tools that do not entirely cover reporting of Truenat results. These challenges are expected to be solved when new tools are rolled out and with full-scale implementation of the LabXpert DS diagnostic connectivity solution.

C. Equipment and Maintenance

Equipment maintenance logs were created for each facility, and staff were tasked with conducting and documenting periodic preventive maintenance. The staff were also advised to monitor the battery charge to protect its lifespan (i.e., unplug the instruments when they are charged to 100% and plug them back in when they are around 50%). The Molbio agent (Science Logistics) routinely provides remote and onsite support in case there is breakdown of the Truenat devices. However, there were prolonged equipment downtimes of more than 10 days at some sites, reaching 40 days in some cases. Discussions are ongoing between the Stop TB Partnership's Global Drug Facility and Molbio to identify solutions to reduce these delays.

D. External Quality Assessment (EQA)

All sites participated in three rounds of a SmartSpot proficiency testing (PT) scheme, with centralized monitoring by regional coordinators based at the NTRL. Results were submitted online, and feedback reports downloaded from the website regularly for each round in 2022. At the same time, the NTRL developed a Truenat PT scheme using dried tube specimens and successfully passed validation in November 2022. Currently, all Truenat sites have been enrolled into this scheme, which will be added on the scope of the existing ISO 17043 accreditation. This will enhance capacity and minimize the resources required to manage and support laboratory quality management systems for this new molecular diagnostic test.

4. Connectivity System

With funding provided to the Makerere University Joint AIDS Program (MJAP) from USAID through the Stop TB Partnership, the NTRL has successfully rolled out the LabXpert DS diagnostic connectivity solution on all Truenat devices. This enables real-time monitoring of Truenat utilization, facilitates inventory management and allows for rapid return of results to clinicians. However, several challenges were faced during the implementation process (Table 2). Already the data transmitted has provided many interesting insights, that if well analyzed and utilized, can help to improve TB diagnostic services. Therefore, if these challenges can be overcome, the NTRL will be able to improve the functioning of the Truenat instrument network and provide better diagnostic services to individuals seeking care for TB.

5. Power and Backup Systems

Some facilities face prolonged power outages which results in interruptions in testing. There is a need for surge protectors to protect the instruments from damage due to power fluctuations, as well as power backup systems to support uninterrupted testing in settings with extended power outages.

Table 2: Challenges and lessons learned during implementation of the LabXpert DS connectivity solution

Challenge	Lesson Learned
Configuration of Truenat instruments	The Truenat connectivity process is more complex than that of GeneXpert, involving more back and forth with the manufacturer. Empowering local support teams with knowledge of configurations and troubleshooting will improve turnaround time (TAT) for Truenat connectivity.
Poor internet connectivity	Given the decentralized positioning of Truenat instruments, a major issue was poor internet connectivity in remote areas, which slowed down or even failed data transfer from Truenat instruments to the LabXpert DS. Nonetheless, internet routers should be made available in areas with poor network connectivity to boost data transfer.
Inability to retrieve data	Retrieving previous information was also problematic, as not all tests done prior to configurations automatically uploaded to the LabXpert DS server, affecting reporting.

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We initially thought that these machines would not work. However, we have found out that the use of Truenat sites at referral centers has reduced driving distances (by Hub riders), thus reducing the fuel consumption and motorcycle breakdown. Patients are now able to get results on the same day compared to the waiting that they had to endure during the time they were doing microscopy and then referring samples to Wakiso HCIV Hub for GeneXpert testing. I am very excited about it.

Mr. Kaketo Alex | District Laboratory Focal Person, Wakiso District

Looking Ahead

The NTRL and NTP are continuing to monitor the performance of Truenat at facilities including as part of active case finding activities to inform decision making around possible scale-up of the technology. The NTRL plans to collect additional evidence around acceptability, cost-effectiveness, and other benefits of decentralized use of Truenat compared to more centralized use of other rapid molecular tests.

Disclaimer: *The findings in this publication are those of the authors and do not necessarily represent the views of the U.S. Agency for International Development or the U.S. Government.*

For more information on the introducing New Tools Project, visit:

🔎 https://www.stoptb.org/accelerate-tb-innovations/introducing-new-tools-project