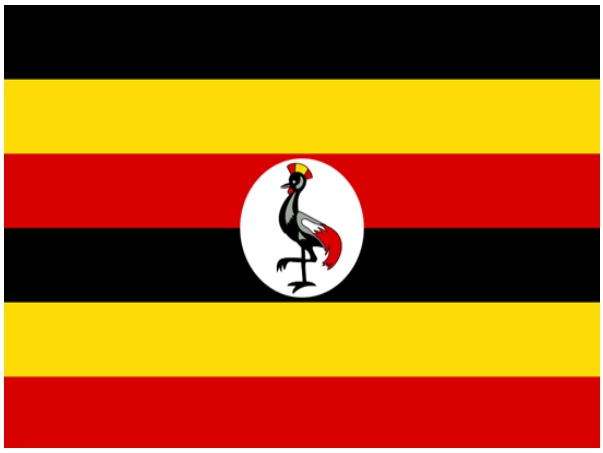
2nd Joint Assessment
of the Tuberculosis Diagnostic Network of Uganda

July 8-19, 2024

THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH



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Introduction

Uganda is among the 20 countries contributing to 83% of the missed TB cases globally with an estimated TB incidence of 198/100,000 population. Although Uganda was able to notify all the estimated TB cases in 2022 (WHO Global TB report, 2023), there is need to not only sustain but also intensify efforts to achieve the higher targets from WHO and United Nations High level meeting (UNHLM, 2023). It is estimated that 0.89% of the new TB cases have MDR/RR-TB and the country is conducting a second DR-survey to ascertain the actual burden of DR-TB. Access to molecular WHO-recommended rapid diagnostic (mWRD) testing among new and relapse TB patients stands at 70% with 74% of bacteriologically confirmed patients having access to drug susceptibility testing (DST) for at least rifampicin. Uganda has a TB/HIV co-infection rate of 33% and only 8.8% of PLHIV (newly enrolled in care) received preventive treatment in 2022.

The National TB Reference Laboratory supports the National Tuberculosis and Leprosy Control Program (NTLP) in achieving its mandate of policy formulations, resource mobilization and planning, training of health workers, conducting reference testing and research. The National TB Reference Laboratory (NTRL) received accreditation from the reputable South African National Accreditation System (SANAS) for 'Medical Testing Laboratory Tuberculosis and Molecular Tuberculosis' – ISO 15189 in May 2013; as well as further accreditation for 'Proficiency Testing by Inter-Laboratory Comparisons' – ISO/IEC 17043 in 2018 and accreditation for all the training program by the International Association for Continuing Education and Training in 2020. The NTRL through its SRL umbrella has supported accreditation of 11 NTRLs for ISO 15189 and one NTRL for ISO 17043 and supported seven countries to build the capacity in TB diagnostics and First Line Drug Susceptibility Testing (DST) and capacity to implement second line DST in five countries in the African region.

Objectives

The main objectives of the assessment were to review the diagnostic network, current practices and algorithms; identify challenges that prevent the overall diagnostic network from performing efficiently and effectively; and propose evidence-based interventions to improve the overall ability of the TB diagnostic network to meet the goals and targets of the National Strategic Plan (NSP).

A similar assessment of the TB Diagnostic Network of Uganda was conducted from August 25 to September 6, 2019. A comparison of the findings of the 2019 assessment and the 2024 assessment is presented in Annex 6. In general, good progress was made on addressing the key recommendations of the 2019 assessment, which has contributed to achieving the laboratory indicators for NTLP NSP (e.g., 69% of notified cases were tested by WRDs and 75% of bacteriologically confirmed cases have DST for at least rifampicin. In particular, strong progress was made in expanding the use of the Xpert MTB/RIF Ultra test as the initial diagnostic test for persons presumed to have TB; strengthening the system of supportive supervision; the use of Village Health Teams (VHTs) and mobile vans containing portable digital X-ray with Computer-Aided Detection (CAD) technology and a GeneXpert instrument for Xpert MTB/RIF Ultra testing to extend services to the community level and to find TB earlier, and improve linkages to testing and care; deploying a diagnostics connectivity system (LabXpert) to 89% of the Xpert MTB/RIF ultra testing sites; and optimizing the utilization of GeneXpert instruments by introducing multi-disease testing (e.g., Xpert testing for HIV Viral Load, EID, HPV, COVID-19, Chlamydia, TB and Hepatitis).

Methods

The assessment included consultations with the Ministry of Health (MoH), NTLP, NTRL, and other stakeholders at the national and sub-national levels. Site visits were also conducted to a total of 116 health facilities in 11 geographic areas (Annex 4). Regions, districts and facilities were selected by the NTP and NTRL with the aim of

including a range of laboratories at varying levels of the health system. The assessment utilized an assessment tool (TB-Net Tool) which uses semi-quantitative scoring to identify the stage of various aspects of the diagnostic network. The stages describe current capabilities and identify key areas for improvement. The assessment team reviewed the self-assessed staging conducted by the TB program, visited various facilities, and consulted numerous stakeholders to assess the functionality and performance of the national TB diagnostic network from the perspective of its ability to meet the needs of the country's NSP.

General Findings

- Dedicated and knowledgeable workforce were available at many sites.
- Well-established laboratory department [National Health Laboratory & Diagnostic Services (NHLDS)] that has oversight of laboratories across the entire network and strong collaboration with NTP. There is a strong National TB Reference Laboratory which performs essential clinical and public health supervisory and training functions.
- Community health workers are used to extend services to the community level and facilitate linkages.
- A highly integrated specimen referral system (Hub system) that covers all the districts.
    - Procedures for tracking of individual referred specimens and tracking of the return of results to the referring laboratory were either not available or not well implemented at some sites.
    - Challenge for the system is that the full Turnaround time (TAT) for mWRD results in certain areas is well over the 2-day target, possibly in part due to scheduled frequency of pick-ups.
- Service and maintenance contracts with Key performance indicators (KPIs) and targets are in place for some instruments. However, in 34% of sites, equipment was not being properly serviced, calibrated or maintained.
- 63% of assessed sites reported stock-outs during the past year because of challenges with the procurement and distribution system, including late deliveries especially in remote regions.
- Widespread availability of mWRD testing for all presumptive TB.
- The algorithm addresses the entire diagnostic cascade including DST for people with RR-TB, but DST for Isoniazid (INH) resistance among people with rifampicin-susceptible TB is not included.
    - Current TB diagnostic algorithms (version 2024) were not available at many of the visited facilities. Old versions (2017 and 2019) of the algorithm were still displayed.
    - Multi-disease testing using GeneXpert instruments is becoming common, but this is beginning to affect turnaround times for TB testing.
- TB tests are free in public sector facilities for people being evaluated for TB. There is limited availability of chest-X-ray; often it is not free to the patient and without CAD software
- Good progress with rollout of LabXpert, but it is not present and functional at all sites and does not include all digital diagnostic platforms. There is insufficient funding for IT infrastructure and systems at most levels and data backup is not possible at all sites.
- National procedures and Standard Operating Procedures (SOPs) have been developed; however, they were not widely distributed or incorporated into lab-specific SOPs. There is no centralization of document resources or guidelines.
- Weak implementation of biosafety practices in many facilities.

- 50% of laboratories reported that the available workforce is insufficient for diagnostic testing. For most staff, there were no records for in-service training and competency assessments. Private sector clinicians and laboratory staff are often not included in TB training.

Recommended Key Interventions and Priority Actions

The assessment team recommends that the NTLP and NTRL prioritize and consider immediate action to implement the following key recommendations. Specific, detailed recommendations are provided for each diagnostic network core capability in the report.

1. Build on the momentum of the existing robust integrated specimen referral system

The current Hub system is more mature and integrated than many systems and many key recommendations from the 2019 assessment have been addressed. However, persistent challenges remain including availability of triple packaging materials, cold chain equipment and SOPs. A challenge for the system is that the full TAT for mWRD results in certain areas is well over the 2-day target, which may be due in part to scheduled frequency of pick-ups (1x to 5x per week). At some sites, the hub system offers on-demand pickup for priority samples (TB included), but capacity is limited. There is a good procedure (printed barcodes) for tracking shipments but tracking individual specimens does not happen in real-time.

To address these challenges 1) conduct an analysis of full TAT, disaggregated by segment, for mWRD testing to identify bottlenecks and target interventions for areas that are not meeting the 48-hour TAT target from sample collection to receipt of results, 2) Identify funding for individual sample barcoding and/or consider alternative solutions for individual sample tracking/digitally registering samples upon collection and 3) consider conducting a cost analysis for scheduled vs. on-demand system and estimate current and predicted costs.

2. Ensure all equipment are properly serviced and maintained, and with a continuous supply of reagents

Service, maintenance and calibration are handled by the national calibration center (ISO certified and with a cadre of bioengineers, including with capacity to certify BSCs) in cooperation with manufacturers' service agents and a network of nine regional workshops. However, 34% of assessed sites found that laboratory equipment was not being properly serviced or maintained on time, including calibration. Procurement and distribution of commodities are managed through the National Medical Stores (NMS) and the Joint Medical Stores (JMS). 63% of assessed sites reported stock-outs during the past year (e.g., Xpert cartridges, PPE, LF-LAM tests, triple packaging materials) because of challenges with the procurement and distribution system.

To address these challenges 1) improve capacity of regional workshops and bioengineers to repair, service and calibrate instruments at testing sites; pursue increasing number of workshops to improve regional coverage, 2) ensure a comprehensively budgeted plan for service and maintenance of all equipment and its implementation in all regions and levels of testing sites, and make available spare parts, 3) execute service contracts with suppliers that include KPIs and targets and 4) improve reliability of the supply distribution system by strengthening national and regional NMS offices to facilitate timely deliveries to all sites and to handle emergency orders.

3. Expand availability of diagnostic tools including digital chest X-ray and CAD software, optimize access to mWRDs, strengthen TAT monitoring to improve linkage to care, reduce loss to follow-up and improve patient outcomes

There was widespread availability of mWRD testing for all presumptive TB and detection of rifampicin resistance, but DST for INH resistance among people with rifampicin-susceptible TB is not included in the testing algorithm. Also, there was limited availability of chest-X-ray, and it was often not free to the patient and without CAD software. About 68% of the population had access to microscopy services within a 5KM radius and 26.7% patients can access Xpert services as per the 2024 geospatial mapping report. Village health teams (VHTs) were used to extend services to the community level and facilitate linkages. Mobile vans with Xpert testing and X-ray were available in some regions to expand access to services.

To address these challenges 1) expand the use of Xpert MTB/XDR testing in the diagnostic algorithm to all bacteriologically confirmed TB cases to detect any INH-resistance 2) expand availability of digital chest X-ray and CAD software and ensure that it is used in accord with national guidelines, 3) optimize access to mWRD testing by expanding the hub system to increase % of population with access to molecular testing and reviewing existing data to optimize placement of GeneXpert and Truenat instruments based on anticipated workload and 4)expand utilization of community health workers and mobile vans to extend services to the community level, find TB earlier, and improve linkages to testing and care.

4. Develop end-to-end integrated connected systems

There has been good progress with the rollout of LabXpert, but it is not present and functional at all sites, is not being used to its full potential and does not include all digital diagnostic platforms. The LabXpert system would benefit from data integration and interoperability with ASLM-Laboratory Information System (A-LIS) and Uganda electronic medical record (EMR) systems. Overall, there is insufficient funding for IT infrastructure and systems at most levels, data backup not possible at all sites.

To address these challenges 1) develop integrated connected systems to facilitate patient transactions, data collation, KPI monitoring and to provide actionable data to various network roles from central management to facility departments, 2) expand availability and utilization of LabXpert, 3) build capacity of district TB and lab supervisors on use of LabXpert to be able to monitor and strengthen its utilization and 4) invest in human capacity to monitor data quality and usage as part of regular health network analysis.

5. Centralize and digitize all policies, guidelines and tools within a document control system

Although most sites generally observe good data management practices, dedicated guidelines and procedures governing data management, data security were not available. Also, there was a lack of documented SOPs available on site and no centralization of documented resources, processes, guidelines etc.

To address these challenges 1) centralize and digitize all policies, guidelines, Health Management Information System (HMIS) tools, SOPs within a document control system with easy access to all users to ensure that only latest versions of documents are visible and used and 2) create processes along with training on the central document hub (i.e., a document management system) and a stepwise program for increased compliance (i.e., receipt, acknowledgement & understanding of content, review cycles).

6. Strengthen the implementation of Biosafety and Biosecurity guidelines at all tiers

Biosafety manuals and SOPs containing biosafety information were missing in most facilities and were not consistently implemented when available. Not all laboratory staff were trained in biosafety and biosecurity. There was generally weak adherence to good biosafety practices, especially with respect to waste management. TB laboratory workers were not regularly screened for signs and symptoms of TB.

To address these challenges 1) review, update and distribute Biosafety manuals and national SOPs in line with ISO 15190:2019, 2) conduct trainings on Biosafety and Biosecurity for all laboratory staff, 3) implement proper biosafety practices, including waste management, and monitor compliance, 4) train all staff on the signs and symptoms of TB and screen all staff at least annually for TB and 5) provide a strategic plan and adequate budget for Biosafety and Biosecurity including provision of adequate PPEs and proper triple packaging materials.

The HVAC system at the NTRL is not functional. It is essential to expedite the maintenance of the HVAC system at NTRL.

7. Implement the Human Resources policies to recruit, retrain, and retain staff

Half of the laboratories visited reported that the available workforce was insufficient for diagnostic testing and that they were challenged by the increased workload during the Community Awareness, Screening and Testing (CAST-TB) campaigns. Although staff received pre-service training prior to starting work, refresher training or CME was often not available. Competency based job descriptions were found in only 68% of sites visited and annual competency assessments were not routinely done or documented.

To address these challenges 1) implement a staff retention plan based on the HRH Strategic Plan 2020-2030 to ensure the availability of adequate staff for diagnostic testing, supervisory roles and EQA activities and ensure continuity of funding for laboratory staff who are partner-supported, 2) develop a comprehensive training plan for all health workers on TB diagnostic procedures and continue updating the health workers through the CME, 3) disseminate standardized competency-based job descriptions and ensure that competency assessments are done annually, and results documented in personnel files

Implementation of the recommended key interventions and priority actions should be guided by several cross-cutting principles. These include:

- Finding efficiencies, optimizing test utilization and improving access to existing services to build a strong foundation for the rapid scale-up of laboratory and other diagnostic testing.
- Analyzing existing services and deploying what is available now, while planning and continuing to evaluate new tools and approaches (e.g., phenotypic and molecular DST, next generation sequencing).
- Emphasizing translation of policies into action and putting in place comprehensive systems with adequate resources to closely monitor implementation.
- Linking indicators of laboratory and diagnostic network strengthening with NSP goals and targets.
- Managing change within the diagnostic network and laboratory personnel to ensure the acceptance and effective implementation of the strengthened diagnostic network.

Next Steps

The findings and recommendations from the assessment are extensive and will require the MoH, NTLP and NTRL to lead and coordinate efforts among all stakeholders, including technical partners and donors. Recommended activities or interventions should be prioritized by establishing a detailed action plan with time-bound deliverables and specified roles and responsibilities of various stakeholders. The implementation of this plan should be reviewed periodically and adjusted as needed.

The recommended key interventions and priority actions described in this report will assist Uganda to reach its key TB diagnostic goals with the aim of eliminating TB.

Acknowledgements

We would like to thank Uganda's MoH, NTLP, NTRL, and UNHLS for the vision and support to conduct this joint Assessment of the TB Diagnostic Network Assessment of Uganda and for making available their staff to work alongside the assessment team prior to and throughout the visit. We especially appreciate the leadership and support of Dr. Susan Nabadda, Dr. Stavia Turyahabwe, Prof. Moses Joloba, and Dr Raymond Byaruhanga.

We would also like to acknowledge:

- Staff at health facilities, RRHs and NTRLs, and within the regional TB programs who welcomed the teams with overwhelming hospitality and spent considerable time with us openly sharing their data and experiences.
- The external and local assessment team members who dedicated their time and expertise before, during and after the assessment.
- Technical Partners and Donors who provided critical input throughout the assessment.
- JSI for providing excellent logistics support throughout the assessment.
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The Final Report was reviewed by External Assessment team members

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Abbreviations

List abbreviations used in the document.

AFB	Acid-fast bacilli
ALIS	African Laboratory Information System
BSC	Biosafety cabinet
BSL	Biosafety level
CAST-TB	Community Awareness, Screening and Testing for TB
CPHL	Central Public Health Laboratory
CXR	Chest X-ray
DR-TB	Drug-resistant tuberculosis
DST	Drug-susceptibility testing
DTFP	District TB focal person
DTLS	District TB and Leprosy Supervisor
DHO	District Health Officer
EPTB	Extra-pulmonary TB
EQA	External quality assessment
FM	Fluorescence microscopy
FQ	Fluoroquinolone (e.g., levofloxacin, gatifloxacin or moxifloxacin)
GLI	Global Laboratory Initiative
GoU	Government of Uganda
GPS	Global positioning system

HC	Health center
HCW	Health care worker
HIV	Human Immunodeficiency Virus
HR	Human resources
Hr-TB	Isoniazid-resistant, rifampicin-susceptible TB
ICF	Intensified case finding
INH	Isoniazid
IPT	Isoniazid preventive therapy
IQC	Internal quality control
IRL	Intermediate reference laboratory
KPI	Key performance indicator
LED	Light-emitting diode
LF-LAM	Lateral flow lipoarabinomannan assay
LPA	Line-probe assay
LIMS	Laboratory information management system
MDR-TB	Multidrug-Resistant Tuberculosis
MGIT	Mycobacteria Growth Indicator Tube
MoH	Ministry of Health
MTB	*Mycobacterium tuberculosis* complex bacteria
NACP	National AIDS Control Program
NMS	National Medical Stores
NTLP	National TB and Leprosy Control Program
NTRL	National TB Reference Laboratory
NSP	National Strategic Plan
OPD	Out-patient department
OSE	On-site evaluation
PFP	Private for profit
PLHIV	People living with HIV/AIDS
PNFP	Private not for profit
PPE	Personal protective equipment
PPM	Public-private mix
PT	Proficiency testing
QA	Quality assurance
QC	Quality control
QMS	Quality management system
RIF	Rifampicin
RR	Rifampicin-resistant
RRH	Regional Referral Hospital
RTLF	Regional TB and Leprosy Focal person
SL-DST	Second-line drug susceptibility testing
SL-LPA	Second-line line-probe assay
SOP	Standard operating procedure
SRL	Supranational reference laboratory
SRN	Specimen referral network
TB	Tuberculosis
UNHLS	Uganda National Health Laboratory and Diagnostic Services
USAID	United States Agency for International Development
WHO	World Health Organization
WRD	WHO-recommended rapid TB diagnostic
ZN	Ziehl-Neelsen

Introduction

Uganda is among the 20 countries contributing to 83% of the missed TB cases globally with an estimated TB incidence of 198/100,000 population. Although Uganda was able to notify all the estimated TB cases in 2022 (WHO Global TB report, 2023), there is need to not only sustain but also intensify efforts to achieve the higher targets from WHO and United Nations High level meeting (UNHLM, 2023). It is estimated that 0.89% of the new TB cases have MDR/RR-TB and the country is conducting a second DR-survey to ascertain the actual burden of DR-TB. Access to mWRD testing among new and relapse TB patients stands at 70% with 74% of bacteriologically confirmed patients having access to DST for at least rifampicin. Uganda has TB/HIV co-infection of 33% and only 8.8% of PLHIV (newly enrolled in care) received preventive treatment in 2022.

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TB Diagnostic Network

A comprehensive, high-quality TB diagnostic network is essential to diagnose TB accurately and rapidly and to link confirmed TB patients to appropriate and timely treatment. Laboratories and laboratory services are key components of a well-functioning diagnostic network; however, a laboratory test is just one part of the diagnostic process (Figure 1).

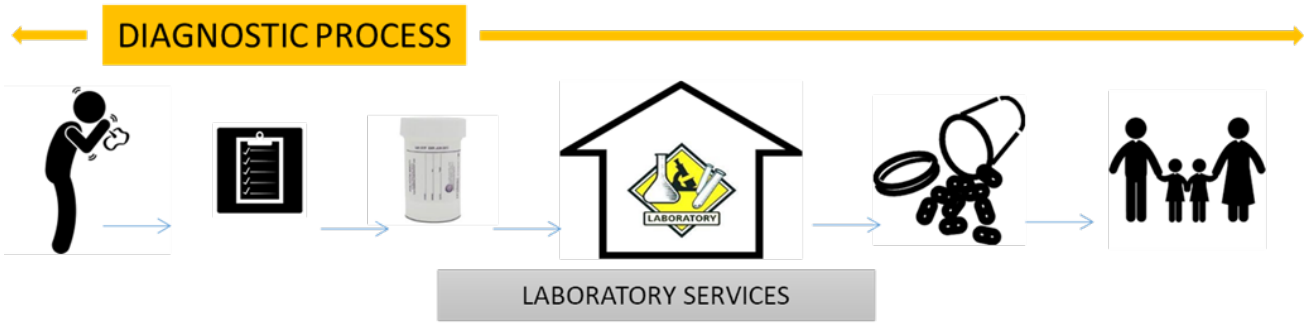

Figure 1. The TB Diagnostic Cascade

The diagnostic process starts with the person experiencing symptoms and deciding to seek care (i.e., passive case finding) or a health care worker (HCW) identifying a person to be evaluated for TB (i.e., active case finding). The process continues with the ordering of an appropriate test; timely and safe referral of the specimen under appropriate transit conditions to the laboratory for testing; accurate and quality-assured testing by the laboratory; return and receipt of the test results by the HCW; initiation of appropriate treatment; and monitoring of response to therapy. Attrition from or delays in any of the steps can reduce the clinical and public health impact of the laboratory test.

The diagnostic network is a shared responsibility between the TB program, TB laboratories, and clinicians at each level of the health system. The network encompasses all points where community members seek care – both within the public and private sectors and among formal and informal providers.

Tiered Network of TB Laboratories

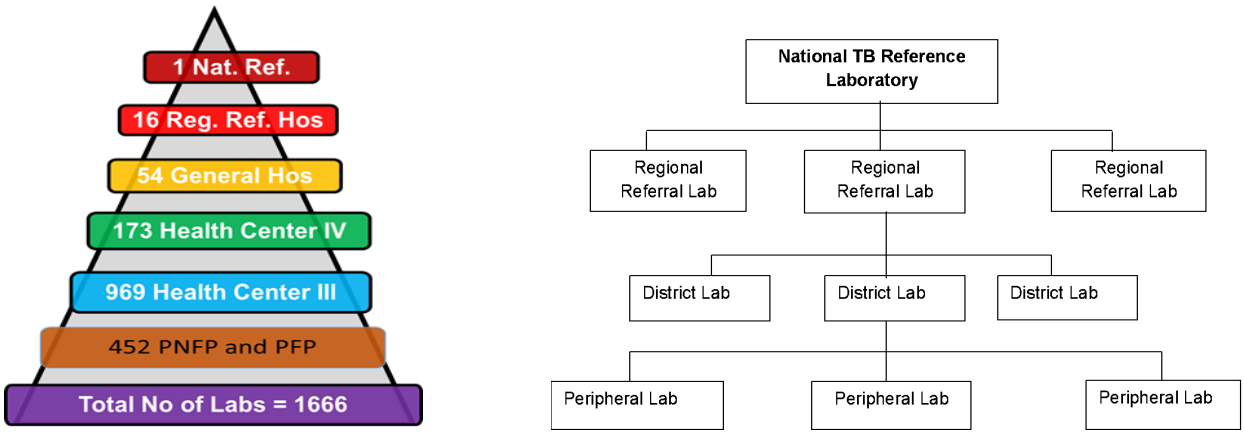

Figure 2. The TB Laboratory Network in Uganda

The TB Laboratory network in Uganda is organized at three levels or tiers and Uganda's TB Laboratory Network Manual (2019) describes the TB laboratory services at each of the tiers of the network.

- Peripheral level - consists of GeneXpert and microscopy centers based at sub-county (Health Centre IIIs), sub-districts (Health Centre IVs) and district levels (district Hospitals and other hospitals [PNFP, PFP and academic]). These laboratories are expected to:
    - Perform Xpert Ultra/ Truenat testing for diagnosis and AFB-smear microscopy for monitoring patients on treatment
    - Refer samples for culture and DST for all eligible retreatment and RR-TB patients
- Intermediate level – Intermediate laboratories are located at district hospitals or RRHs may act as a clinical as well as public health laboratories. Intermediate laboratories are expected to:
    - Perform all functions of the peripheral labs in addition to offering logistic and technical support of public and private health laboratories.
    - Train and build capacity of staff at peripheral laboratories.
    - Mentor, monitor and conduct on-site evaluation (OSE) of peripheral laboratories.
    - Perform quality control of smears performed at the microscopy centers (blinded rechecking).
    - Mentor the TB diagnostic centers in the district for quality improvement, data collection and troubleshooting.
- Central Level - National TB Reference Laboratory located in Butabika and Central TB Reference Laboratory based at NTLP compound. Core functions of an NTRL include:
    - Support the NTLP in Formulation and revision of policies and guidelines for TB diagnosis as per the WHO End TB strategy.
    - Carry out research with the appropriate programs in control of communicable diseases.
    - Reference and specialized testing.
    - Integrated Data Management.
    - Policy development.
    - Link the health laboratory services division with international laboratories.
    - Carry out research on control of TB diseases.

The TB Laboratory Network Manual (2019) also defines acceptable methods for microbiological diagnosis of TB including AFB-smear microscopy and rapid molecular testing as well as standard test requisition and results reporting forms. In addition, External Quality Assessment (EQA) systems are described including blinded rechecking and proficiency testing; checklists for on-site evaluation (OSEs); and the roles of the District TB and Leprosy Supervisor (DTLS), District Laboratory Supervisor (DLFP), Regional Laboratory Supervisor and NTRL staff in supportive supervision.

The National TB Diagnostic Network Assessment

Purpose:

Comprehensively evaluate a country's TB diagnostic network to assess the functionality and performance of the national TB diagnostic network from the perspective of the ability to meet the needs of the country's National Strategic Plan.

Objectives

- Holistically review of the diagnostic network, current practices and algorithms.
- Identify challenges that prevent the overall diagnostic network from performing efficiently and effectively.
- Do an evaluation of the progress made in the implementation of the 2019 TB DNA conducted in the Uganda network.
- Propose evidence-based short-and medium-term interventions to improve the overall ability of the TB diagnostic network to meet the goals and targets of the country's strategic plan.

Method:

- Use the TB Diagnostic Network Assessment Tool with semi-quantitative scoring to identify the stages of the various aspects of the diagnostic network, describe current capabilities, and identify key areas for improvement through a Self-assessment exercise.
- Review of the self-assessment by an experienced group of international laboratory, diagnostic network and TB program experts with support from in-country lab and TB experts, including site visits and other stakeholder meetings while in the country.
- Review of overall findings from the self-assessment and external assessors and development of recommendations and priority interventions.

Expected Outcomes:

- Evidence-based and results-oriented recommendations that inform the development of a TB diagnostic network operational plan as the roadmap for the MoH, NTP, NTRL, sub-national level program, donors, and technical partners.
- An understanding of the progress made on implementing the interventions and priority actions recommended in the 2019 TB Diagnostic Assessment.

The Assessment Team

The assessment was conducted by a group of external TB laboratory and diagnostic network experts as well as internal program and laboratory experts associated with the national program or laboratory network of Uganda (Table 1). Consultants were chosen to represent the range of diagnostic network components including laboratory services and testing algorithms, quality assurance, clinical linkages, public/private integration, diagnostic data management, specimen referral, commodity and logistics management, and biosafety. All efforts were made to ensure that there were no conflicts of interest for any of the assessors.

Table 1. Joint TB Diagnostic Network Assessment Team Members

External Assessor	Local Assessor	Observers	
Hebert Mutunzi	Joseph Nturo	Dr. Harriet Nakigozi	Henry Bediic
Ann Masese	George Lukyamuzi	Abdunoor Nyombi	Stephen Mutyaba
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Zilma Rey	Patrick Kakeeto	Raymond Byaruhanga	Mbonye Andrew
Fasil Tsegaye	Carol Asiimwe Mutabazi	Benjamin Niringiyimana	Emmanuel Tibenderana
Alex Durena	Resty Leonie Nanyonjo	Grace Nantege	Kenneth Musisi
Teresa Simiyu	Martha Pedun	Rebecca Nakidde	Robert Wagubi
Miriam Mulungi	Willy Ssengooba	Claire Nankoma	Mulomo Leabaneng
Chris Isaacs	Julius Mutagubya	Patrick Ademun	Sam Lwanga
Jeremiah Okari	Moses Katagwa	Denis Oola	Edeet Lamu
Thomas Shinnick	Simon Eladu	Christopher Okiira	Okao Ben
Grace Kahenya	Joyce Mbogo	Henry Byabajungu	Kayiwa Samuel
Andwele Mwansasu	Thomas Ssemakadde	Orena Beatrice	Faith Alikoba
Amos Kutwa		Moses Joloba	Fontiano Kolobe
Ali Kwizera		Newton Isaac Okebba	Annett Akello
Jean de Dieu Iragena		Kangave Fredrick	
Sarder Tanzir Hossain			
Farzana Begum			
Dr. Pronab Kumar Modak			

Sites and Facilities Visited

The assessment covered the NTP and other stakeholders at the national level, the NTRL, Regional Referral Laboratories and peripheral laboratories; a total of 116 facilities in 11 geographic areas to inform the assessment. Regions, districts and facilities were selected by the NLP and NTRL with the aim of including a range of laboratories at varying levels of the health system including private sector and non-governmental organization TB diagnostic facilities. The sites visited are listed in Annex 4.

Table 2. Checklists Administered during Assessment of TB Diagnostic Network

Team	Region	Checklists administered
A	Ankole	4 RTLS, 6 PL, 3 Program, 7 TB Clinics ,1 MDR-FP, 1 supervisory IRL, 1 non-supervisory IRL, 7 HIV clinics
B	Bunyoro	5 RTLS, 6 PL, 3 Program, 7 TB Clinics, 4 MDR-FP, 1 supervisory IRL, 1 non-supervisory IRL, 7 HIV clinics
C	East and Bukedi	3 RTLS, 7 PL, 2 Program, 7 TB Clinics, 2 MDR-FP, 1 supervisory IRL, 2 non-supervisory IRL, 7 HIV clinics, 3 Community
D	Kampala-A	1 NTRL, 1 PL, 1 NTP, 1 TB Clinic, 1 MDR-FP, 1 HIV clinics, 1 Community

E	Kampala-B	1 RTLS, 4 PL, 1 Program, 7 TB Clinics, 2 MDR-FP, 1 supervisory IRL, 1 non-supervisory IRL, 6 HIV clinics, 1 Community
F	Karamoja	4 RTLS, 5 PL, 1 Program, 6 TB Clinics, 2 MDR-FP, 1 supervisory IRL, 2 non-supervisory IRL, 6 HIV clinics, 1 Community
G	Kigezi	4 RTLS, 6 PL, 3 Program, 8 TB Clinics, 5 MDR-FP, 1 supervisory IRL, 2 non-supervisory IRL, 8 HIV clinics
H	Lango	3 RTLS, 6 PL, 3 Program, 7 TB Clinics, 2 MDR-FP, 1 supervisory IRL, 2 non-supervisory IRL, 7 HIV clinics, 2 Community
I	North Central	4 RTLS, 3 PL, 3 Program, 8 TB Clinics, 3 MDR-FP, 1 supervisory IRL, 4 non-supervisory IRL, 8 HIV clinics
J	South Central	5 RTLS, 5 PL, 5 Program, 8 TB Clinics, 4 MDR-FP, 1 supervisory IRL, 2 non-supervisory IRL, 8 HIV clinics
K	West Nile	5 RTLS, 5 PL, 5 Program, 8 TB Clinics, 4 MDR-FP, 1 supervisory IRL, 2 non-supervisory IRL, 8 HIV clinics
	Total: 331 Checklists	**1 NTRL, 1 NTP, 38 RTLS, 52 PL, 29 Program, 74 TB Clinics, 28 MDR-FP, 10 supervisory IRL, 17 non-supervisory IRL, 73 HIV clinics, 8 Community**

Table 3. Sites and Checklists

Team	Region	Facilities and checklists
A	Ankole	19 facilities, 30 checklists
B	Bunyoro	11 facilities, 34 checklists
C	East and Bukedi	10 facilities, 32 checklists
D	Kampala-A	9 facilities, 7 checklists
E	Kampala-B	8 facilities, 24 checklists
F	Karamoja	11 facilities, 28 checklists
G	Kigezi	11 facilities, 35 checklists
H	Lango	10 facilities, 31 checklists
I	North Central	11 facilities, 34 checklists
J	South Central	13 facilities, 38 checklists
K	West Nile	12 facilities, 38 checklists

Topics that were assessed included:

- Overall placement, quantity and utilization of appropriate diagnostic technologies.
- Availability and use of correct diagnostic algorithms, guidelines and policies.
- Interplay of the diagnostic algorithm and tier-specific TB testing packages to create a robust and resilient diagnostic network for efficient and cost-effective TB diagnosis and reporting.
- Incorporation of public and private TB diagnostic laboratories into a comprehensive network of TB diagnosis from the national level to the community level.
- Deployment of TB diagnostic technologies (e.g., Xpert Ultra) and strategies to improve capacity to reach the End TB goal of universal access to rapid molecular testing for all persons being evaluated for TB.

- Capability of specimen referral mechanisms to ensure increased service uptake, reduce turn-around time and optimize the available laboratory diagnostic capacities.
- Policies and procedures for ensuring the quality of diagnostic services throughout the network, including quality assessment programs.
- Laboratory information and data management systems for the diagnostic network to support robust and responsive data to inform TB diagnostic policies and program and clinical management.
- Management of laboratory and diagnostic commodities, logistics system, and equipment validation and maintenance.
- Policies and guidelines for laboratory infrastructure and biosafety and mechanisms to ensure adherence to guidelines at all levels of the health system.
- Integration/coordination with HIV program for TB/HIV diagnosis and shared diagnostic platforms.
- Quantity and quality of trained staff throughout the network and ability to build capacity of lower-level facilities.
- Identification of and linkage to testing for persons with presumptive TB and linkage to care for persons with laboratory confirmed TB.

Assessment of these topics and the TB Diagnostic Network relied on the use of the TB Diagnostic Network Assessment Tool.

TB Diagnostic Network Assessment Tool (TB-Net Tool)

Background

The TB Diagnostic Network Assessment Tool (hereafter referred to as the 'TB-Net Tool') was developed to assess the functionality of a national TB diagnostic network from the perspective of its ability to meet the needs of the country's NSP for TB. The tool uses semi-quantitative scoring to identify the 'capability' stage of various aspects of the diagnostic network to describe current capabilities and to help identify key areas for improvement.

Diagnostic Network Standards, Core Capacities and Components

The foundation of the TB-Net Tool is a set of standards that provide a measure of the quality and capabilities of a diagnostic network. The standards are based on the National TB diagnostic network standards and assessment tools developed and piloted by the Global Laboratory Initiative (GLI) and partners,[1] which were based on an earlier GLI assessment tool focusing on TB microscopy laboratory networks.[2]

For each standard, 'core capacities' and 'components' are used to define essential features and functions of a national diagnostic network designed to detect, assess, notify and respond to TB (Annex 1). The core capacities and components are adapted from the original nine LABNET[3] core capacities which were developed for evaluating national laboratory networks in Africa with respect to achieving global health security targets.

Questions and Stages

Within the TB-Net Tool, standardized "questions" are used to assess to what degree each component meets the diagnostic network standard. Attributes of each component are used to define six stages of capability from 'completely absent' to 'fully compliant with international standards. The stages, based on a Capability Maturity

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[1] Albert, H. Essential standards for a TB diagnostic network. ASLM2016

[2] TB Microscopy Network Accreditation. An assessment tool. Global Laboratory Initiative. 2013. http://www.stoptb.org/wg/gli/assets/documents/TBMicroscopy_Network_Accreditation_Web.pdf

[3] Ondoa, P. *et al.* A new matrix for scoring the functionality of national laboratory networks in Africa: introducing the LABNET scorecard. African Journal of Laboratory Medicine, 5, Oct. 2016. http://www.ajlmonline.org/index.php/ajlm/article/view/498/712.

Measurement Model (CMM),[4] are quantified using a scoring system (0–5) to provide a semi-quantitative measure of the stepwise progression towards complete fulfillment of each component of a core capacity:

- Stage 0: Absence of attributes that are considered key to the development of inputs and processes needed for the implementation of a functional diagnostic network.
- Stage 1: Foundational level. Includes attributes that are considered key to the development of inputs and processes needed for the implementation of a functional diagnostic network.
- Stage 2: Moderate level. Listed attributes including inputs and processes needed to build or maintain the diagnostic network.
- Stage 3: Strong technical or managerial or organizational capacity and a high level of performance of the diagnostic network with defined public health output and outcomes.
- Stage 4**:** Advanced level. Performance of the network is continuously measured and achieves national standards of capability.
- Stage 5: Attainment of international standards. Systems of revision are in place for continuously improving the diagnostic network.

The questions and stages by core capacity and associated components used in the assessment are listed in Annex 3.

Determining the capability stage and progress towards achieving core capacities

A capability stage is determined for every "question" of a component (Figure 3).

Core Capacity 4. Diagnostic Algorithm								
No.	**Questions**	**Stage**						
		0	**1**	**2**	**3**	**4**	**5**
Component 4.1. Algorithm							
4.1.1	Is a national TB diagnostic algorithm available that is responsive to the epidemic, patient-centered, and based on international best practice?				✓		
4.1.2	Does the algorithm address the laboratory goals of the End TB strategy to increase access to rapid detection of TB and to reach universal access to DST?					✓	
4.1.3	Does the algorithm focus on the whole diagnostic cascade, from screening to treatment completion?						✓
4.1.4	Are health care workers provided with standardized sensitization content (e.g., algorithm diagrams, brochures, training materials)?		✓				
4.1.5	Are diagnostic tests ordered according to standard diagnostic algorithms and based on national policy and patient factors?			✓			

Figure 3. Determining a capability stage for each question

This qualitative analysis can provide a quick visual assessment of the status of individual components and identify areas that need strengthening. To provide an assessment of the progress towards achieving a strong diagnostic network, progress towards reaching stage 5 (or 100% capability) is calculated for each core capacity.

[4] Watts Humphrey. Characterizing the software process. A maturity framework. Technical report CMU. SEI-87TR-11. ESD-TR-87-112. June 1987.

Figure 4 is an example of how to determine progress towards achieving 100% capability for the core capacity of diagnostic algorithm and laboratory-clinical interface:

- Translate each question's capability stage into points. For example, question 1 contributes 3 points, question 2 contributes 4 points, etc.
- Add up the points for all the questions within the core capacity. In the example, the total is 22 points.
- Calculate the capability percentage as: [(Total number of points for all questions within a core capacity) / (total number of questions x 5)] x 100. In the example, the percentage is: [22/(8x5)]x100 = 55%.

Core Capacity 4. Diagnostic algorithm	Component	Stage
Standard: Testing is performed in a manner and in facilities that guarantee safety for the staff, the customers, the community and the environment. Sufficient materials, means and skills are available throughout the system to ensure safe and secure procurement, handling, storage, transportation and disposal of samples and materials, both in routine as well as in emergency circumstances.	Algorithm:	
	Question 1	**3**
	Question 2	**4**
	Question 3	**5**
	Question 4	**2**
	Question 5	**1**
	Detection of TB:	
	Question 1	**3**
	Detection of DR-TB	
	Question 1	**3**
	Question 2	**1**
	Total	22

Figure 4. Determining Progress Towards 100% Capability for a Core Capacity

This type of analysis will provide practical information on the actions required to achieve 100% capability within each core capacity. Note that reaching 100% for each core capacity may not be appropriate for all countries.

The Assessment Process

The key objectives of the assessment of the TB diagnostic network were to:

- Review holistically the diagnostic network, current practices and algorithms.
- Identify challenges that prevent the diagnostic network from performing efficiently and effectively; and
- Propose evidence-based interventions to address the identified challenges and thereby improve the overall ability of the diagnostic network to meet the goals and targets of the NSP.

The assessment was conducted in three stages:

- Self-assessment of TB diagnostic network core capacities using the TB-Net Tool.
- Review of the results of the self-assessment and in-country verification by the external assessment team.
- Review of the findings, identification of strengths and weaknesses and development of evidence-based interventions to improve the TB diagnostic network.

1. Self-assessment scoring of TB diagnostic network

The country used the TB-Net Tool to perform a self-assessment of their capacities in key diagnostic network areas including determining their capability stage according to predefined criteria (components and questions) for each core capacity (Annex 3). The self-assessment was performed prior to the in-country external assessment by a technical group consisting of the NTLP, NTRL and other national level laboratory experts.

2. Review of self-assessment and in-country verification by the assessment team

During the period of July 8-19, 2024, the assessment team reviewed and verified the country's self-assessment stages for each component. Data for verification were gathered during visits to predetermined program staff and diagnostic facilities at each level of the TB diagnostic network and compiled by the team after the site visits.

A standard list of verification questions for each core capacity and component guided the process (Table 4). To ensure that the assessment team received enough detail on specific diagnostic network components, the verification process included a limited number of topic-specific checklists to supplement the verification questions. The additional thematic areas included:

- Specimen referral, transport and results return.
- Diagnostic Data Management.
- Private sector.
- Health Product Management

Table 4. Assessment checklists

Checklist	Audience	Number Administered
NTRL Verification Checklist	National TB Reference Laboratory	1
NTP Verification Checklist	National TB Program	1
IRL-sup Verification Checklist	Supervisory Intermediate laboratory	10
IRL-non-sup Verification Checklist	Non-supervisory Intermediate laboratory	17
PL Verification Checklist	Peripheral labs, e.g., microscopy centers	52
Program Verification Checklist	District TB Officer or District Health Officer	29
MDR FP Verification Checklist	MDR-TB Focal Person	28
RTLS Verification Checklist	Regional or District Lab supervisor	38
TB Clinic Verification Checklist	Health facility	74
Community Verification Checklist	Community Health Care Workers	8
HIV/TB Verification Checklist	HIV clinic	73

Each field team was provided with a set of tools (including the main assessment tool and accompanying checklists) specific for the types of facilities assessed and individuals interviewed within their allocated state or region. The consultants were responsible for collecting and verifying the data. Members of the external assessment team also interviewed national level stakeholders and agencies and collected data and information according to the main assessment tool and supplemental checklists.

3. Review of the findings of the assessment and development of recommendations

Feedback on findings from each state or region was compiled and a set of key findings and priority interventions were developed by group consensus among the external consultants. A mixed methods approach was followed including qualitative and quantitative data. Findings from both the regional level and national level assessments informed the team's final findings and recommendations.

Site- or region-level reports were compiled by the external assessment teams based on data gathered using the various assessment tools and informed key findings and recommendations (Annex 5).

An interim assessment report was presented to the Ministry of Health, NTP, NTRL and other stakeholders and key partners at a national stakeholder debriefing meeting on July 19, 2024. Following compilation of all data and in-depth analyses, the assessment team prepared the final report.

Findings and Recommendations

The assessment team analyzed national, intermediate, and peripheral level data and information for each facility. This section includes:

1. National TB Diagnostic Network Scorecard Results
2. Key Findings, Interventions and Priority Actions
3. Detailed Findings and Recommendations by Capacity and Thematic Area
4. General Considerations for Strengthening the Diagnostic Network and Thematic Areas
5. Region-specific key findings and recommendations by facilities are described in Annex 5.

1. National TB Diagnostic Network Assessment Results

The capability stages identified for the components of each core capacity during the self-assessment and by the assessment team following the field visits and discussions with key stakeholders are shown in Table 5. Table 6 provides the progress towards 100% capability for each core capacity, calculated both for the self-assessment and team assessment.

Table 5. Capability stages identified in the self-assessment and team assessment

Key to staging: | | 1 | 2 | 3 | 4 | 5 |

Core Capacity		Stage		Stage Determining Factors Considered by the External Assessment Team
	Component	**Self**	**Team**	
1. Political, legal, regulatory and financial framework				
1.1	Legislation and policies	4	3	Policies, plans, regulation or legislation is in place for all key areas. Enforcement with respect to the private sector is lacking.
1.2	National TB policies and plans	1	1	Minimum standards for public sector labs to be licensed are not available.
1.3	Governance	4	4	No act mandates the NHLDS the role of laboratory coordination within Ministries.
1.4	Financing and budgets	3	2	Sustainable government funding has been improved, however more needs to be done with other local funding sources.
2. Structure and organization of the diagnostic network				
2.1	Diagnostic network	3	4	94 % Team findings, Community contributed to rapid TB case detection, Active VHT in TB care initiatives such as CAST.
2.2	Coordination and management	4	4	NTRL offers services to all tiers of the TB diagnostic network, including training, support supervision and research.
2.3	Programmatic and operational research	4	5	The uptake of GeneXpert informed by EAPHLN operational research, including Urine LF-LAM, Truenat, Xpert XDR.
3. Coverage				

3.1	Diagnostic network coverage	*3*	*2*	About 47% of sites (20 of 57 replied yes) reported that facilities were available within 5 km for >80% of the population. About 68% of the population had access to microscopy services within 5KM and 26.7% patients can access Xpert services as per the geospatial mapping report.
3.2	Sample referral system	0	2	75% of respondents (114/171 replied yes) said triple packaging used. About 30% (44 of 166 sites) experienced stockouts.
3.3	Linkages	1	3	81% (95/122 replied yes) reported that transfer-in and transfer-out forms were used to facilitate linkages. However, their use varied considerably between the regions visited.
3.4	Emergency preparedness	0	1	About 64% (68 of 121 replied yes) of sites reported that they had a list of local facilities. 77% of the lists contained contact information and 40% contained a list of services and equipment available at the sites.
4. Diagnostic algorithm				
4.1	Algorithms	2	1	About 82% of public sector laboratorians and clinicians, 53% of private sector laboratorians and clinicians, and 86% of program staff have had training on diagnostic algorithms testing methods and specimen referral. Old sensitization materials are available at 81% of visited facilities. Not all are trained, and most trainings do not cascade to the facility level, and there was no evidence at the visited facilities.
4.2	Detection of TB	3	4	81% of visited laboratories have the capacity to conduct all the tier-specific diagnostic testing required by the national algorithm. 91% of facilities reported mWRDs available for all presumptive TB cases and 95% reported availability of rapid molecular DST for Rifampicin. Xpert machines are available at 42 PNFP sites.
4.3	Detection of drug-resistant TB	3	3	The 2023 Uganda clinical guidelines outline risk factors for DRTB (pg. 375) and laboratory follow-up for patients on treatment (pg. 381). The diagnostic algorithm addresses all presumptive but is partially implemented.
5. Biosafety				
5.1	Facilities	1	1	The Country has National Infrastructure Guidelines dated 2021 but these are not implemented consistently across all facilities.
5.2	Biosafety and biosecurity manual	2	2	62% of the Facilities have manuals, others have SOPs.
5.3	Biosafety systems	1	1	Some safety equipment is available but with stockouts of gloves in most of the facilities. 53% of the laboratory Staff are screened and trained on the signs & symptoms of TB. In addition, the HVAC system at the NTRL is not functioning.
5.4	Waste management	1	1	NTRL & RRHs have access to both autoclaves and Incinerators. However, some RRHs had their autoclaves broken down.
6. Equipment and Supplies				
6.1	Supply chain management	2	2	Facilities monitor supply consumption and the data on consumption and remaining stock levels are reported to central

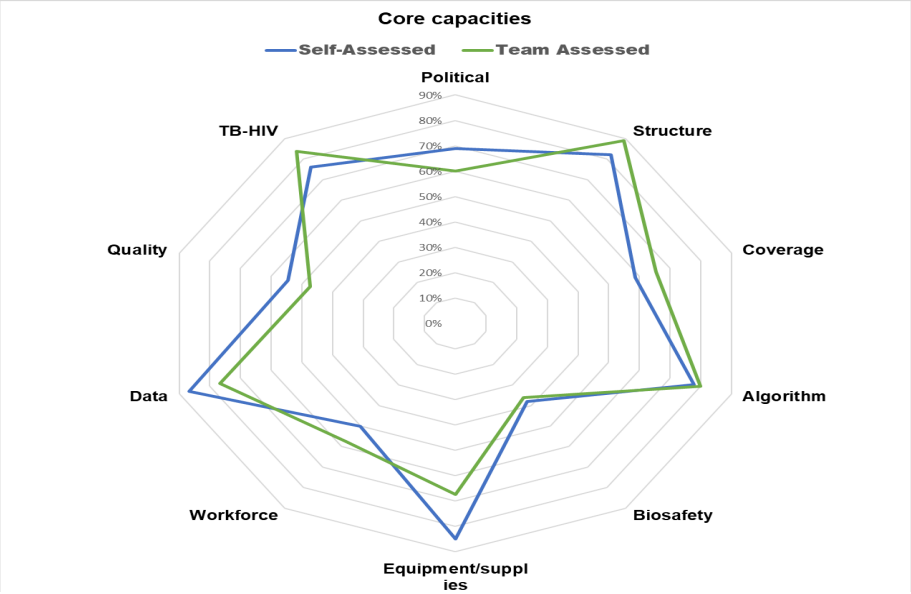
				level at the time of bi-monthly ordering using the NMS/JMS portals. However, there are occasional stock outs. Assessment found 63% of sites reporting stock-outs during the past year because of problems with the procurement and distribution system, for a variety of items: LF LAM tests, Xpert XDR, PPE, Xpert Ultra (less common). Also, assessment found 73% of sites had stock-outs because of inadequate forecasting or instances where reagents have exceeded their expiry dates during the past year.
6.2	Equipment management	4	3	A maintenance plan is in place for all equipment at the national level and some sub-national levels and includes some PNFPs. Also, there are contracts and engineers available at national and regional levels for some equipment (national calibration center is ISO certified and has capacity to certify BSCs), but contracts are not available for all equipment in some districts. There is a maintenance plan for all equipment at all levels in the public sector, but it is not being fully implemented and is not fully budgeted. Assessments found that 66% of sites did not have a maintenance plan (that covers spare parts, storage and disposal, warranty extensions) available and implemented for all laboratory equipment.
7. Workforce				
7.1	Education and training	3	3	LQMS trainings are irregular as commented by most regional teams. Survey CTO documents it at 57%, but training (SLMTA) was available at 41% of PLs, 87% of IRLs and at NTRL.
7.2	Staffing	1	2	Shortages of staff do exist due to high workload even more so during CAST-TB campaigns in all the regions with survey CTO reporting 66%.
7.3	Human resources strategies and plans	1	3	The following are some of the strategies that are addressed in Human Resources for Health Strategic Plan (2020-2030): 1) staff shortage, 2) distribution, 3) staffing norms, 4) private sector, 5) salaries, 6) retention, 7) staff deployment, 8) task-shifting, 9) trainings, 10) professional associations, 11) continuing professional development, 12) financing.
7.4	Competency-based job descriptions	3	3	Competency-based job descriptions reported by 68% in the survey CTO summaries. These are not done routinely for all staff in all the regions.
8. Diagnostic data management				
8.1	Data collection forms	4	3	HMIS TB 002 lacks indication of mandatory fields in line with policy. No provision on form for feedback in case of rejection. Use of HMIS 033b and HMIS 105, HMIS 106a but Lango team reported that some sites were using HMIS Lab form 004 which lacks HIV status.
8.2	Reporting	3	3	Standardized HMIS tools are used to collect test and demographic information. However, they are often not filled to completion and some sites are still using older Laboratory Request Forms. 59% of sites stated that there was an

				electronic system (e.g., LIMS) supporting the reporting of laboratory test data.
8.3	Data connectivity and remote monitoring	4	4	Diagnostic connectivity solution (LabXpert) is not implemented at all sites. Where connectivity has been implemented, some sites are not functional. There has been limited training on the use of LabXpert and LabXpert not being used to its full potential. 72% of labs reported having a diagnostic connectivity solution implemented. 88% of whom noted that data were remotely monitored and used.
8.4	Data analysis and sharing	5	5	The central unit that collects and analyzes TB laboratory data. It encompassed trained personnel at MOH, NTLP, NTRL and CPHL. The DHI oversees the Data Management of the MOH which is fed by all Divisions, HFs, Labs etc.) Records Officer, Biostats. HIAs at district and HF Levels whose capacity is built by DHI, Central Servers hosted at MOH, NTRL, NTLP, Data Transmission supported through IPs and Districts.
8.5	Surveillance and epidemiology	5	5	There is an up to date, implemented national plan for surveillance of TB and DR-TB, which defines the role of the laboratory. All these have been updated in the NTLP Manual.
8.6	Security and confidentiality of information	3	3	Whilst most sites generally observe good data management practices, dedicated guidelines and procedures governing data management, data security were not available. Only 54% of sites reported that SOPs for the back-up and retrieval of data were fully implemented.
9. Quality of the diagnostic network				
9.1	Documents and document control	3	3	Nationally approved SOPs were available in 67% of the testing labs, although 33% of the testing labs did not have national SOPs for all TB diagnostic methods.
9.2	Quality assurance	1	2	Quality indicators and performance measures are routinely monitored in 70% of the labs verified for some TB tests; however, data was infrequently analyzed.
9.3	Quality management system	3	3	About 63% of labs within the TB diagnostic network had designated quality officers with clearly defined roles and responsibilities documented in a job description.
9.4	Certification and accreditation	2		No Laboratory Certification Body exists.
10. TB-HIV				
10.1	Legislation and policies	2	4	TB diagnostic tests are provided for free in both Gov't and PNFPs for presumptive TB patients and at a cost in private facilities.
10.2	Structure and organization of the network	5	5	Observed multi disease testing to increase integration. Same GeneXpert machine used for HIV & TB testing.
10.3	Coverage	4	4	Presence of diagnostic algorithms and ART register (TB initiation column). There is availability of TB-diagnostic tests,

				multi-disease testing and LF-LAM in facilities either on site or by referral.
10.4	Diagnostic Algorithm	2	4	Rapid diagnostic tests for HIV are being used for all persons with signs and symptoms of TB.
10.5	Workforce	4	4	Trainings were done but were not current and not in all facilities.
10.6	Diagnostic Data Management	2	2	Standardized forms not used in all facilities.

Table 6. Progress Towards 100% Capability

Core Capacity	Capability percentage	
	Self-Assessed	Team-Assessed
1. Political, legal, regulatory and financial framework	69%	60%
2. Structure and organization of the diagnostic network	82%	89%
3. Coverage	59%	65%
4. Diagnostic algorithm	78%	80%
5. Biosafety	38%	36%
6. Equipment & Supplies	85%	68%
7. Workforce	50%	58%
8. Diagnostic data management	87%	77%
9. Quality of the diagnostic network	55%	47%
10. TB-HIV	76%	84%



There was good agreement between team assessment and self-assessment. Differences were minor and most likely related to variability in the implementation of national plans and policies at the county and sub-county levels and differences in interpretation of the TB-Net Tool staging criteria by the self-assessment team and the external team.

Pilot test of a Revised Capacity 8. Diagnostic Data Management

As part of this assessment, the external assessment team conducted a pilot evaluation of a new Capacity 8 with revised components which provides a much more in-depth analysis of Diagnostic Data Management. New checklists were developed for the Revised Capacity 8 and were also piloted as part of the assessment. The Revised Capacity 8 was not included in the self-assessment.

The data from the Revised Capacity 8 pilot was not incorporated into the analysis of the capability percentage for Core Capacity 8 (Table 6) or the spider chart. However, the data from the new checklists were used along with the data from the original checklists in identifying findings and developing recommendations for Capacity 8.

The Capability percentage for the Revised Capacity 8 was 74%. This is essentially the same as the capability percentage as the original Capacity 8, but with much more detail regarding the components of Diagnostic Data Management. The Revised Capacity 8 components and stage determining factors for the revised components are presented in Table 7.

Table 7. Capability stages of the Revised Capacity 8 identified in the external team assessment

Core Capacity		Stage	Stage Determining Factors Considered by the External Assessment Team
	Component	**Team**	
8.1	Program policy and procedure	4	HMIS TB 002 lacks indication of mandatory fields in line with policy. No provision on form for feedback in case of rejection.
8.2	Policy implementation in all levels and facilities	3	Lack of evidence at sites regarding data management
8.3	Requesting, testing and reporting data	2	Use of HMIS 033b and HMIS 105, HMIS 106a but Lango team reported that some sites were using HMIS Lab form 004 which lacks HIV status
8.4	Laboratory recording and maintenance of testing records	2	Some labs have access for unauthorized persons to the working areas where they may gain access to patient information. Not all drawers are lockable and keys are not available in some cases.
8.5	Test referral data - referring laboratory	2	Mixture of paper based and electronic reporting. No access to a dashboard to indicate results.
8.6	Results reporting	3	Interim reporting is available in ALIS and NTRL by email but not all sites are using this. No provision of interim reporting on HMIS TB 002.
8.7	Test referral data - clinical sites	2	Not all registers have provision for TAT
8.8	Data aggregation	2	Date and time from sample collection and test results are captured, but limited follow up

8.9	Local use of aggregated results to improve services	3	Areas such as management of budgets, procurement and system maintenance can be improved. Exampled by stock out, equipment breakdowns and slow servicing.
8.10	National use of aggregated results to improve services	4	Reported to happen in the Quarterly meetings and in the registers, however presumptive register not updated in some places following diagnosis.
8.11	Stakeholder use of aggregated data	4	Good level of data aggregation in DHIS2 but not all levels have access. Some aggregated data is outside DHIS2 which lower levels can't access.

2. Key Findings, Interventions and Priority Actions

The team assembled the composite data and information from the assessment into six key findings with associated recommended interventions and priority actions:

Key Finding #1:

The current Hub system is more mature and integrated than many systems and many key recommendations from the 2019 assessment have been addressed. However, persistent challenges remain including availability of triple packaging, cold chain equipment and SOPs. A challenge for the system is that the full TAT for mWRD results in certain areas (over 2d target) which may be due in part to scheduled frequency of pick-ups (1x to 5x per week). At some sites, the hub system offers on-demand pickup for priority samples (TB included) but capacity is limited. There is a good procedure (printed barcodes) for tracking shipments but tracking individual TB specimens does not happen in real-time.

Intervention: **Build on the momentum of the existing robust integrated specimen referral system**

Priority Actions:

- Conduct an analysis of the full TAT, disaggregated by segment, for mWRD testing to identify bottlenecks and target interventions for areas that are not meeting the 48h target from sample collection to receipt of results. Utilize digital solutions, e.g. LabXpert.
- Ensure collection sites have SOPs addressing specimen collection, packaging, storage and transport, including procedures for calling hub system 'on-demand'.
- Enable referring facilities to collect, monitor, and utilize data and KPIs around referrals.
- Ensure annual refresher training is conducted for clinicians, transporters, hub coordinators, laboratory staff and program managers, and documented for participants.
- Identify funding for individual sample barcoding and/or consider alternative solutions for individual sample tracking/digitally registering samples upon collection.
- Consider conducting a cost analysis for scheduled vs. on-demand systems and estimate current and predicted costs.

Key Finding #2:

Service, maintenance and calibration are handled by the national calibration center (ISO certified and with a cadre of bioengineers, with capacity to certify BSCs) in cooperation with manufacturers' service agents and a network of nine regional workshops. However, 34% of assessed sites found lab equipment was not being properly serviced or maintained including calibration. Procurement and distribution of commodities is managed through NMS and JMS. 63% of assessed sites reported stock-outs during the past year (e.g., Xpert cartridges, PPE, LAM tests, triple packaging) because of challenges with the procurement and distribution system.

Intervention: **Ensure all equipment are properly serviced and maintained, and with a continuous supply of reagents**

Priority Actions:

- Improve the capacity of regional workshops and bioengineers to repair, service and calibrate instruments at testing sites; pursue increasing number of workshops to improve regional coverage beyond the current nine regions.
- Ensure a comprehensively budgeted plan for service and maintenance of all equipment and its implementation in all regions and levels of testing sites and make available spare parts.
- Execute service contracts with suppliers that include KPIs and targets.
- Strengthen national and regional NMS offices to facilitate timely deliveries to all sites according to the delivery schedules and to handle emergency orders in case of stock-out. Use LabXpert to facilitate Xpert cartridge forecasting and supply management.
- Ensure supervisory support from district and regional levels to facilities on ordering and supply management, to improve facilities' capacity to use the NMS+ portal.

Key Finding #3:

There was widespread availability of mWRD testing for all persons with presumptive TB and detection of rifampicin resistance, but DST for INH resistance among people with rifampicin-susceptible TB is not included in the testing algorithm (Annex 2). Also, there was limited availability of chest-X-ray, and it was often not free to the patient and without CAD software. About 68% of the population had access to microscopy services within 5KM and 26.7% patients can access Xpert services as per the geospatial mapping report. Village health teams (VHTs) were used to extend services to the community level and facilitate linkages. Mobile vans with Xpert testing and X-ray were available in some regions to expand access to services.

Intervention: **Expand availability of diagnostic tools including digital chest X-ray and CAD software, optimize access to mWRDs, strengthen TAT monitoring to improve linkage to care, reduce loss to follow-up and improve patient outcomes**

Priority Actions:

- Expand the use of Xpert MTB/XDR testing in the diagnostic algorithm to all bacteriologically confirmed TB cases to detect any INH-resistance.
- Expand availability of digital chest X-ray and CAD software and ensure that it is used in accord with national guidelines.
- Increase the number of community and penitentiary screening events using X-ray/CAD to find TB earlier and use X-ray/CAD to assist in ruling out active TB among contacts before TPT.
- Optimize access to mWRD testing by expanding the hub system to increase % of population with access to molecular testing and reviewing existing data to optimize placement of GeneXpert and Truenat instruments based on anticipated workload.
- As multi-disease testing becomes more widespread, develop and implement a national strategy to optimize the use of GeneXpert instruments with respect to multi-disease testing and ensure adequate capacity for TB testing.
- Expand utilization of community health workers and mobile vans to extend services to the community level, find TB earlier, and improve linkages to testing and care.
- Monitor and evaluate the full TAT (time from sample collection to receipt of test result by clinician), disaggregated by segment, for the entire TB diagnostic cascade.

Key Finding #4:
There has been good progress with the rollout of LabXpert, but it is not present and functional at all sites, is not being used to its full potential and does not include all digital diagnostic platforms. The LabXpert system would benefit from data integration and interoperability with ALIS and Uganda EMR systems. Overall, there is insufficient funding for IT infrastructure and systems at most levels and therefore data backup is not possible at all sites.

Intervention: **Develop end-to-end integrated connected systems**

Priority Actions:

- Develop integrated connected systems to facilitate patient transactions, data collation, KPI monitoring and to provide actionable data to various network roles from central management to facility departments.
- Define KPIs at all tiers and ensure collection, analysis and use. Empower staff at all levels to benefit from data so they are motivated to ensure policies are followed.
- Expand availability and utilization of LabXpert.
- Build capacity of district TB and lab supervisors on use of LabXpert to be able to monitor and strengthen its utilization.
- Invest in human capacity to monitor data quality and usage as part of regular health network analysis.
- Ensure data backup capabilities and processes are available at all facilities.

Key Finding #5:
Although most sites generally observe good data management practices, dedicated guidelines and procedures governing data management, data security were not available. Also, there was a lack of documented SOPs available on site and no centralization of documented resources, processes, guidelines etc.

Intervention: **Centralize and digitize all policies, guidelines, and tools within a document control system**

Priority Actions:

- Centralize and digitize (if not already done) all policies, guidelines, HMIS tools, SOPs within a document control system with easy access to all users to ensure that only the latest versions of documents are visible and used.
- Disseminate national policies, SOPs, job aids, algorithms and tools and incorporate national SOPs and tools into laboratory-specific SOPs.
- Create processes along with training on the central document hub (i.e., a document management system).
- Create a stepwise program for increased compliance (i.e., receipt, acknowledgement & understanding of content, review cycles).

Key Finding #6:
Biosafety manuals and SOPs containing biosafety information were missing in some facilities and were not consistently implemented when available. Not all laboratory staff are trained in safety and biosecurity. There was generally weak adherence to good biosafety practices, especially with respect to waste management. TB laboratory workers are not regularly screened for signs and symptoms of TB.

It was noted that the HVAC system at the NTRL was not functional.

Intervention: **Strengthen the implementation of Biosafety and Biosecurity guidelines at all tiers**

Priority Actions:

- Review, update and distribute Biosafety manuals and national SOPs in line with ISO 15190:2019.
- Provide initial training and regular refresher training in biosafety and biosecurity policies and practices for staff at all levels of the diagnostic cascade, including the public and private sector.
- Implement proper biosafety practices, including waste management.
- Monitor and evaluate adherence to TB biosafety policies including the use of safe waste disposal methods to ensure staff and environmental safety.
- Train all staff on the signs and symptoms of TB and ensure that all laboratory and health care providers involved in TB testing are screened at least annually for signs and symptoms of TB using a standard checklist and referred for follow-up testing as needed.
- Provide a strategic plan and adequate budget for Biosafety and Biosecurity.
- Urgently expedite the maintenance of the HVAC system at the NTRL.

Key Finding #7:
Half of the laboratories visited reported that the available workforce was insufficient for diagnostic testing and that they were challenged by the increased workload during CAST-TB campaigns. Although staff received pre-service training prior to starting work, refresher training or CME was often not available. Competency-based job descriptions were found in only 68% of sites visited and annual competency assessments were not routinely done or documented.

Intervention: **Implement the Human Resources policies to recruit, retrain, and retain staff**

Priority Actions:

- Implement a staff retention plan based on HRH Strategic Plan 2020-2030 to ensure the availability of adequate staff for diagnostic testing, supervisory roles and EQA activities.
- Ensure that anticipated increases in TB workload are adequately addressed, for example, during the CAST-TB campaigns.
- Ensure continuity of funding for laboratory staff who are partner supported.
- Develop a comprehensive training plan for all health workers on TB diagnostic procedures and continue updating the health workers through the CME.
- Disseminate standardized competency-based job descriptions and ensure that competency assessments are done annually, and results documented in personnel files.

3. Detailed Findings and Recommendations by Capacity and Thematic Area

Capacity 1. Political, legal, regulatory & financial framework

Components: Legislation & policies; National policies & plans; Governance; Financing
Standard 1. The TB diagnostic network is built on a foundation of political, legal and regulatory frameworks which supports the achievement of the NSP, organizes and controls all public and private diagnostic services to support the NSP, and provides sufficient, dedicated and available funding at all levels of the network. Policies

are in place that enable continuous, country-wide availability of free, quality assured TB diagnosis according to the national guidelines.

Because the objective of the assessment was to evaluate the current laboratory and program diagnostic practices and identify issues that may limit the overall diagnostic network from performing efficiently and effectively, detailed findings and recommendations are presented below for each of the ten capacities that encompass the standards of a comprehensive diagnostic network (Annex 1). Please note that there is overlap among the capacities – for example, findings and recommendations on optimal utilization of Xpert Ultra is both a network structure/organization issue and a network coverage/access issue.

The assessment found that policies, plans, regulations and/or legislation exists for most components of TB diagnosis. National TB laboratory policy and guidelines for TB, HIV and PMDT or strategic plan are available and aligned. There is a well-established laboratory department (NHLDS) that has an oversight role for all laboratories across the whole network and strong collaboration with NTP. There is strong collaboration between NHLDS, the NTP, and NTRL. The National Strategic Plan for TB and Leprosy control, National TB laboratory Strategic Plan, TB diagnostic network manual, and guidelines for TB, HIV, PMDT are available.

Specific findings and recommendations include:

- No act mandates the role of NHLDS in laboratory coordination with other relevant Ministries.
    - *Make available an Act that mandates the NHLDS and recognizes the SRL role.*
- Sustainable government funding has improved, however, more needs to be done with other local funding sources. The budget for the TB diagnostic network (clinical diagnostic service and public health functions) is available but insufficient enough to make the network management function optimally.
    - *Advocate for the availability of more funding for the Integrated Laboratory (TB) diagnostic network, including the SRL.*
- Copies of the national policies and guidelines were often not available or fully implemented at the county and sub-county facilities.
    - *Disseminate national guidelines and plans and provide training to improve the understanding of the documents at all levels of the network. Use remote methods to expand access to training.*
    - *Emphasize implementation of policies and guidelines at all levels of the network and monitor progress in the implementation of policies and guidelines.*
- TB diagnostic tests are free, but Chest X-ray (CXR) is not widely available in public facilities and is not free of charge in the private sector.
    - *Expand availability of digital chest X-ray and CAD software and ensure that it is used in accord with national guidelines.*
    - *Remove cost barriers to TB diagnosis by reducing or eliminating the cost for CXR for the patient will become important if CXR becomes more widely used as a screening tool.*

Capacity 2. Structure and organization of the diagnostic network

Components: Network structure; Coordination & management

Standard 2. A sustainable, rational and efficient TB diagnostic network provides integrated, essential, quality diagnostic services for patient care and public health. The TB diagnostic network is coordinated by a national reference or public health laboratory and includes the public and private sector as well as community level diagnostic services. All facilities have clearly defined terms of reference and are adequately supervised.

The TB laboratory network is an integral part of the TB diagnostic network, which also includes community-level services, private sector laboratories, linkages to care, etc. This core capacity focuses on the structure and

management of the TB laboratory network. Additional aspects of the TB diagnostic network are included in other core capacities (e.g., Capacity 3 – coverage).

Uganda's TB Laboratory Network Manual (2019) is the foundation of the TB laboratory network and describes an organized and structured TB diagnostic network with clearly defined tiers, and roles and responsibilities. The network is led by an internationally accredited National TB Reference Laboratory which performs essential clinical and public health functions, and which has developed policies, guidelines, SOPs, manuals, strategic plan and clinician's handbook that govern the provision of TB laboratory services in the network.

Specific findings and recommendations include:

- There is programmatically relevant operational research on new TB diagnostics or algorithms in the country and data are used to inform policy and practices.
    - *Increase visibility of the operational research done to guide uptake and roll-out of new TB diagnostics.*
- An organized and structured TB diagnostic network is in place with clearly defined tiers with specific roles and responsibilities that includes public, PNFP, research & academia, but rarely in PFP sector facilities.
    - *Strengthen the collaboration and coordination of TB services between public and private-for-profit sectors.*
- Draft policies and guidelines are being developed
    - *Expedite the finalization of the draft national guidelines and disseminate nation-wide i.e., SOP, biosafety manuals, diagnostic algorithm, multi-disease program coordination, and use of diagnostic tools.*

Capacity 3. Coverage

Components: Diagnostic network coverage; Sample referral system; Rapid response and preparedness
Standard 3. The national TB diagnostic network provides complete coverage and universal access to TB diagnostic services to the entire population of the country. Referral mechanisms exist to rapidly and safely refer specimens to the appropriate level for testing and to provide timely results to enable initiation of appropriate treatment.

There was widespread availability of mWRD testing for all presumptive TB and detection of rifampicin resistance, but DST for INH resistance among people with rifampicin-susceptible TB is not included in the testing algorithm (Annex 2). More than 90% of sites visited reported formalized procedures for linkage to testing and linkage to care. However, some regions reported issues with linkages. Village health teams (VHTs) and mobile vans were used to extend services to the community level in some regions. There were regular meetings of clinical, laboratory and program staff.

Specific findings and recommendations include:

- About 68% of the population had access to microscopy services within a 5KM radius and 26.7% patients can access Xpert services as per the geospatial mapping report. 47% of sites reported that >80% of the population was at a maximum of 5km from a health facility.
    - *Optimize access to mWRD testing by expanding the hub system to increase the percentage of the population with access to molecular testing and by reviewing existing data to optimize placement of GeneXpert and Truenat instruments based on anticipated demand and workload.*
- There was limited availability of chest-X-ray, which was often not free to the patient and without CAD software.

    - *Expand availability of chest X-ray with CAD and ensure that it is used in accord with national guidelines.*
    - *Increase the number of community and penitentiary screening events using X-ray/CAD to find TB earlier and use X-ray/CAD to assist in ruling out active TB among contacts before TPT.*
- There was limited utilization of testing for isoniazid resistance and the availability of second-line DST was challenged by stock outs of Xpert XDR cartridges.
    - *Incorporate DST for INH resistance among people with rifampicin-susceptible TB into the TB testing algorithm.*
    - *Determine root causes of the Xpert XDR cartridge shortages and address them.*
- Village health teams (VHTs) were used to extend services to the community level and facilitate linkages.
    - *Expand utilization of VHTs to find TB earlier and improve linkages to testing and care.*
    - *Integrate VHT/linkage facilitators with the HIV program to improve reliability of funding.*
- Mobile vans with Xpert testing and X-ray were available in some regions to expand access to services.
    - *Expand availability and utilization of mobile vans in all regions to extend services to the community level and improve linkages to testing and care.*
- At the national level, a map of facilities exists and includes GPS mapping. At local level, only 64% of sites had a list of testing facilities that included contact information and the services available.
    - *Local programs and laboratories should develop a list of facilities in their area that provide diagnostic services. The list should include contact information and details of the diagnostic services offered by the facility.*
- Continuity of operations plans were usually informal arrangements when they were available (infrequent).
    - *Develop and document written continuity of operations plans for every facility.*
- Multi-disease testing using GeneXpert instruments is common, but this is beginning to affect turnaround times for TB testing.
    - *Develop and implement a national multi-disease testing strategy to optimize the use of GeneXpert instruments with respect to multi-disease testing and ensure adequate capacity for TB testing.*

Thematic area: The specimen referral and results reporting system

The current specimen referral system (Hub system) is more mature and integrated than many systems and several key recommendations from the 2019 assessment have been addressed. 95% of sites reported coverage by the Hub System. However, persistent challenges remain including availability of triple packaging, cold chain equipment and SOPs.

Specific findings and recommendations include:

- A challenge for the hub system is that the full TAT for mWRD results in certain areas exceeds the 2-day target, possibly in part due to scheduled frequency of pick-ups.
    - *Conduct analysis of full TAT, disaggregated by segment, for mWRD testing to identify bottlenecks and target interventions for areas that are not meeting the 48h target from sample collection to receipt of results. Utilize digital solutions, e.g. LabXpert.*
- Most sites had a pickup frequency of 1-2 per week. At some sites, the hub system offered on-demand pickup for priority samples (TB included) but capacity is limited and based on vehicle/rider availability.
    - *Ensure hub schedule is available at every referring and receiving facility and standardize procedures for calling hub riders outside of schedule, including what to do if storage is necessary and provide SOPs to all sites. Include cold chain during storage and packaging, where necessary.*

- Lack of SOPs around sample collection, packaging, storage and transport, including defined roles and responsibilities.
    - *Ensure collection sites have SOPs around collection, packaging, storage and transport.*
- Referring facilities do not routinely monitor TAT and other KPIs and there is a lack of data collection forms, i.e. referral logs.
    - *Enable referring facilities to collect and monitor/utilize data and KPIs around referrals.*
    - *Standardize the M&E framework for the hub system across all disease programs and ensure agreed-upon KPIs are tracked down to collection facilities.*
- There is a good procedure (printed barcodes) for tracking shipments but tracking individual specimens does not happen in real-time as package is barcoded upon pickup, but individual samples aren't digitally recorded/allocated to that shipment until hub/testing lab level.
- *Identify funding for individual sample barcoding and/or consider alternative solutions for individual sample tracking/digitally registering samples upon collection.*
    - *Consider cost analysis for scheduled vs. on-demand systems - current and predicted costs.*
- Proper triple packaging is understood and done where possible, but stockouts of packaging material observed leads to improvisation.
    - *Determine and address the root causes of triple packaging material shortages .*
    - *Ensure annual refresher training is conducted for clinicians, transporters, hub coordinators, laboratory staff, and program managers and documented for participants.*
- Lack of documentation of training around specimen referrals.

Capacity 4. Diagnostic algorithm & laboratory-clinical interface

Components: Algorithms; TB diagnosis; Drug-resistant TB; Linkages; Surveillance, Research

Standard 4. A national TB diagnostic algorithm(s) that is responsive to the epidemic, patient-centered, includes appropriate use of diagnostic technologies, and is based on the current structure of the health system is enforced at all levels of the TB diagnostic network. A minimum package of tests and quality standards is defined for each level of the network. Laboratorians, health care workers, and TB program staff are trained in the application of the algorithm, and an efficient diagnostic-clinical interface allows for appropriate diagnostic tests to be ordered and performed and ensures the timely linkage of diagnosed patients to appropriate care and treatment

- *Ensure annual refresher training is conducted for clinicians, transporters, hub coordinators, laboratory staff and program managers and documented for participants.*

Uganda has adopted a state-of-the-art algorithm that incorporates the use of the Xpert Ultra or Truenat test as the initial diagnostic test for all persons presumed to have TB (Annex 2). mWRDs are implemented across all laboratory tiers. The NTLSP also includes a testing algorithm including LF-LAM to improve the detection of TB in HIV-infected persons.

Specific findings and recommendations include:

- Soft copies of the current TB diagnostic algorithm (version 2024) were available at some facilities. Other facilities were implementing the 2017/2019 versions.
    - *Disseminate new TB guidelines, algorithms and sensitization materials to both public and private facility clinicians, laboratorians, community peers and VHTs.*
- Not all health care providers (public and private) are trained on the current algorithm, test methods, specimen collection, labeling & specimen referral.
    - *Include all health care cadres involved in TB diagnostic cascade in trainings, and mentorships both at public and private facilities.*
    - *Disseminate standardized and up to date sensitization materials.*

- The algorithm clearly addresses laboratory aspects of the entire diagnostic cascade including DST for people with RR-TB, but DST for INH resistance among people with rifampicin-susceptible TB is not included.
    - *Use the findings of the upcoming drug resistance survey to decide on an optimal approach to expanding access to rapid DST for INH resistance among people with rifampicin-susceptible TB and at risk of INH monoresistance (Hr-TB).*
- Private-for-Profit clinicians do not always follow the diagnostic algorithms.
    - *The TB program should actively engage PFP hospital executives for their involvement in TB diagnostic and treatment activities.*
- Testing for latent TB infection (LTBI) using IGRAs has been piloted.
    - *Introduce MTB infection testing for detection of LTBI among household contacts over 5 years old; pursue new technologies including MTB-specific skin tests and near-POC IGRAs that are more affordable and feasible for use than conventional IGRAs.*

Capacity 5. Biosafety

Components: Facilities; Biosafety manual; Biosafety systems; Specimen storage; Waste management
Standard 5. Testing is performed in a manner and in facilities that ensure safety for the staff, the customers, the community and the environment. Sufficient materials, means and skills are available throughout the system to ensure safe and secure procurement, handling, storage, transportation and disposal of samples and materials, both in routine as well as in emergency circumstances.

Adherence to biosafety standards within TB testing facilities is critical for ensuring the safety of laboratory staff and patients and for protecting the environment. National biosafety policies and procedures are available and are well implemented at the NTRL. However, biosafety manuals and SOPs containing biosafety information were missing in some facilities and were not consistently implemented when available. There was generally weak adherence to good biosafety practices, especially with respect to waste management. TB laboratory workers are not regularly screened for signs and symptoms of TB.

Specific findings and recommendations include:

- National Biosafety guidelines/ Manuals and SOPs for TB are available in few facilities and missing in many facilities.
    - *Review, update and distribute Biosafety manuals and SOPs in line with ISO 15190:2019.*
- Biosafety officers are appointed and regular trainings on biosafety and biosecurity were conducted in only a few facilities.
    - *Provide initial training and regular refresher training in biosafety and biosecurity policies and practices for staff at all levels of the diagnostic cascade, including the public and private sector.*
- There was weak implementation of biosafety practices (waste management, stockouts of PPEs and triple packaging materials) in many facilities. Waste Management SOPs (waste collection, segregation, storing, and disposal) not available for some facilities.
    - *Implement proper biosafety practices, including waste management.*
    - *Monitor and evaluate adherence to TB biosafety policies including the use of safe waste disposal methods to ensure staff and environmental safety.*
- TB laboratory workers are not regularly screened for signs and symptoms of TB.
    - *Train all staff on the signs and symptoms of TB and ensure that all laboratory and health care providers involved in TB testing are screened at least annually for signs and symptoms of TB using a standard checklist and referred for follow-up testing as needed.*

- There was inconsistent adherence to National Infrastructure Guidelines including lack of safety equipment, maintenance plans, and unreliable utilities at some facilities.
    - *Implement the National Infrastructure Guidelines, provide safety equipment and the relevant utility supply in all facilities.*
- It was noted that the HVAC system at the NTRL was not functional.
    - *Urgently expedite the maintenance of the HVAC system at NTRL.*
- Many sites reported that there were limited funds available for biosafety aspects of the testing.
    - *Provide a strategic plan and adequate budget for Biosafety and Biosecurity.*

Capacity 6. Equipment and supplies

Components: Supply chain management; Equipment

Standard 6. Testing is performed with state-of-the-art and well-maintained equipment, and an uninterrupted supply of quality reagents and consumables.

A standardized list of equipment and reagents exists for laboratories in the network. Service, maintenance and calibration are handled by the national calibration center (ISO certified, with a cadre of bioengineers and the capacity to certify BSCs) in cooperation with manufacturers' service agents and a network of nine regional workshops. Procurement and distribution are managed through NMS and JMS.

Specific findings and recommendations include:

- Service and maintenance contracts with KPIs and targets are in place for some instruments, including GeneXpert and Truenat instruments. However, 34% of assessed sites found laboratory equipment was not being properly serviced or maintained including calibration.
    - *Ensure a comprehensively budgeted plan for service and maintenance of all equipment is available and implemented in all regions and levels of testing sites and make available spare parts.*
    - *Ensure service contracts are in place with all suppliers that include KPIs and targets, and require them to capacitate national biomedical engineers at the national calibration center.*
    - *Improve capacity of regional workshops and bioengineers to repair, service and calibrate instruments at testing sites; pursue increasing number of workshops to improve regional coverage beyond the current nine.*
    - *Increase government funding to ensure sustainability of the national calibration center and the regional workshops.*
- 63% of assessed sites reported stockouts during the past year (e.g., Xpert cartridges, PPE, LAM tests, triple packaging) because of challenges with the procurement and distribution system, including late deliveries especially in remote regions, and surges in testing as observed during CAST-TB campaigns.
    - *Strengthen national and regional NMS offices to facilitate timely deliveries to all sites according to the delivery schedules and to handle emergency orders in case of stockout.*
- Some facilities face challenges with being able to order timely and accurately through the NMS+ portal.
    - *Ensure supervisory support from district and regional levels to facilities on ordering and supply management, to improve facilities' capacity to use the NMS+ portal to attain improved timeliness and accuracy of order placements.*
- LabXpert connectivity is not being used to its full potential to facilitate Xpert cartridge forecasting and supply management at district, regional and national levels.
    - *Use LabXpert as a tool for district, regional and central level supervisors to have real-time visibility of Xpert cartridge stock levels, which can facilitate forecasting and redistribution when there are stock shortages.*

- There were challenges with ensuring quality of supplies including 1) poor quality sputum containers in some regions and 2) only 43% of sites had SOPs for reporting complaints on quality of batches of laboratory supplies, and for corrective action, and only half of sites (51%) had lot verification.
    - *Strengthen post-market surveillance by ensuring SOPs are in place at all testing sites for reporting complaints on quality of batches of laboratory supplies and SOPs for corrective actions.*

Capacity 7. Workforce

Components: Education & training; Staffing; Human resources development strategy

Standard 7. Adequate numbers of competent, well-trained and motivated technical and managerial staff are available at all levels of the diagnostic network.

Uganda has a large, well-motivated laboratory staff to carry out the roles and responsibilities of the TB diagnostic network.

Specific findings and recommendations include:

- About half of the laboratories visited reported that the available workforce was insufficient for diagnostic testing and that they were challenged by the increased workload during CAST-TB campaigns.
    - *Implement a staff retention plan based on HRH Strategic Plan 2020-2030 to ensure the availability of adequate staff for diagnostic testing, supervisory roles and EQA activities.*
    - *Ensure that anticipated increases in TB workload are adequately addressed, for example, during the CAST-TB campaigns.*
    - *Ensure continuity of funding for laboratory staff who are partner supported.*
- Although staff received pre-service training prior to starting work, refresher training or CME was often not available.
    - *Develop and implement a comprehensive training plan for all health workers on TB diagnostic procedures and continue updating the health workers through the CME.*
    - *Use of a virtual or remote training system to reduce travel-related costs of on-site trainings.*
    - *Individual training sessions or topics should include a clear description of how it relates or fits into the algorithm.*
    - *Ensure that laboratory and clinical staff are well-trained on the TB diagnostic algorithm and provide copies to sites.*
    - *Include PFP staff (both laboratory & clinical) in all TB-related training.*
- Competency-based job descriptions were found in only 68% of sites visited and annual competency assessments were not routinely done or documented.
    - *Disseminate standardized competency-based job descriptions and ensure that competency assessments are done annually, and results documented in personnel files.*
    - *Ensure that the laboratory staff receive on-the-job support and mentorship.*
- Training on the TB algorithm was rarely reported, but the algorithm is followed by almost all clinical and laboratory staff and there was a lack of sensitization materials, posters, job aids, in most sites.
    - *Provide trainings and sensitization materials to clinical and laboratory staff on latest guidelines, algorithms, procedures, etc.*

Capacity 8. Diagnostics data management

Components: Data collection; Data analysis & sharing; Reporting; Surveillance / epidemiology; Security and confidentiality of information

Standard 8. Inter-operable and inter-connected electronic recording and reporting systems are in place that generate reliable data that are monitored and analyzed in real time. These systems comply with international

standards to allow the rapid exchange of information in standardized formats at national and sub-national level. A laboratory information management system provides up to date information about the status of the laboratories and is linked to the Health Management Information System of the country.

Specific findings and recommendations include:

- Whilst most sites generally observe good data management practices, dedicated guidelines and procedures governing data management and data security were not available.
    - *Assess national policies and guidelines for adequacy and expansion of data management practices, procedures and systems (electronic and manual) to ensure needs of the current and future NSPs.*
- Lack of documents and SOPs available on site and no centralization of documented resources, processes, guidelines etc.
    - *Centralize and digitize (if not already) all policies, guidelines, HMIS tools, SOPs within a document control system with easy access to all users. This ensures that only the latest versions of documents are visible and used and that all needed tools are available to all users.*
    - *Create usage and processes (SOP) along with training on a central document hub (document management system).*
    - *Create stepwise program for increased compliance i.e. receipt, acknowledgement & understanding of content, review cycles.*
- Standardized HMIS tools are used to collect test and demographic information. However, they are often not filled to completion and some sites are still using older Laboratory Request Forms.
    - *Reinforce the data completion for all tools and introduce KPIs to monitor completeness.*
    - *Print, distribute and orient the health workers on the available tools for complete documentation and provide KPIs at facility level.*
    - *Issue a memo to confirm the current version of the tools in the facilities and retire the old ones.*
    - *Provide refresher training for local, district and regional facilities, strengthen the ability (knowledge and understanding of needs/benefits) to be able to analyze data and use it to identify problems and improve performance.*
- Forms were not regularly reviewed, or quality controlled by laboratories and there was no formal method to provide feedback i.e. rejection and associated reasons.
    - *Modify HMIS TB 002 to include rejection and associated reasons and interim reporting.*
- Not all levels of facilities were monitoring KPIs. Data analysis was mostly taking place at the regional and national levels.
    - *Reinforce training for KPI monitoring and expand the number of facilities participating in QMS programs.*
- The Program supports data and information systems (TB-ALIS, LabXpert) although GeneXpert software and TB-ALIS are not integrated.
    - *Integrate diagnostic test results with TB-ALIS. Ensure relevant data from GeneXpert and other platforms are populated to reduce manual transcription.*
- The established diagnostic connectivity solution (LabXpert) was not implemented at all sites. Where connectivity has been implemented, some sites were not functional. There has been limited training on the use of LabXpert which was not being used to its full potential.
    - *Expand LabXpert to all facilities including other equipment that are not yet connected.*
    - *Capacitate district lab officers and regional lab supervisors to monitor LabXpert, including GeneXpert site utilization and LabXpert's use by lab staff (e.g., sending SMSs to clinicians and patients) to maximize its benefits.*
    - *Build capacity of laboratory staff in troubleshooting LabXpert connections.*

- Insufficient funding was available for IT infrastructure and systems at most levels. Data backup was not possible at all sites.
    - *Provide dedicated funding to strengthen IT infrastructure, software and policy.*
    - *Equip all sites with access to electronic data backup and recovery processes.*
    - *Deploy the developed electronic sample tracking in LabXpert, currently piloted in 5 sites, and ensure integration with HIV program.*
    - *Identify upcoming funding needs and incorporate into dedicated budgets.*

Capacity 9. Quality of the diagnostic network

Components: Quality assurance; Quality management systems; Certification and accreditation

Standard 9. High quality diagnostic services producing accurate and reliable results are available throughout the network. Continuous quality improvement targets all facilities within the network and includes quality indicator monitoring, external quality assurance, and regular on-site supervision. A system of national certification is in place for all public and private laboratories within the network; reference and referral level laboratories are accredited according to national or international standards.

In the network, there are 71 Laboratories that are accredited and 4 that are recommended for accreditation to ISO 15189 standards. The NTRL is accredited to ISO 17043 for EQA/PT provider and IACET for Training. QMS implementation was observed at the national, hubs and some PNFP facilities. The NTRL has up-to-date policies and guidelines which are available. Most laboratories were participating in TB EQA (blinded rechecking for AFB microscopy, and GeneXpert/Truenat panels) and had results with corrective actions.

Specific findings and recommendations include:

- Limited implementation of QMS at the lower tier facilities (HCIVs, HCIIIs).
    - *Strengthen QMS implementation at all tiers of the diagnostic network. Utilize available QMS training tools, e.g., SLMTA.*
- Not all national standard operating procedures, job aids and forms were widely distributed or incorporated into laboratory-specific SOPs
    - *Disseminate national policies, SOPs, job aids, algorithms, tools across the TB diagnostic network.*
    - *Incorporate national SOPs and tools into laboratory-specific SOPs to ease implementation.*
- Most staff lacked pre-service records as well as records for in-service training and competency assessments.
    - *Provide initial training and regular refresher training in policies, practices and procedures for staff at all levels and document training in personnel files.*
    - *Ensure that competency assessments are done annually, and results documented in personnel files.*
- Regular support supervisory visits are performed. However, there were no records and feedback reports for some facilities.
    - *Ensure that supervisory feedback reports are provided to the laboratories to facilitate follow-up actions and continuous quality improvement.*
- There was a knowledge gap in the importance of Internal Quality Control (IQCs) for all tests in 70% of the facilities visited.
    - *Strengthen the use of Internal Quality Controls for all TB tests in lower facilities through training.*
- Quality indicators were not monitored in regional, district and peripheral laboratories in the diagnostic network.
    - *Support regional, district and peripheral laboratories to monitor lab KPIs and to use the data for improvement.*

Capacity 10. TB/HIV

Components: Legislation and policies, Structure and organization of the network, Coverage, Diagnostic Algorithm, Workforce, Diagnostic Data Management

Standard 10. A comprehensive approach is needed to combat the twin epidemics of HIV/AIDS and TB. All persons being evaluated for TB should receive free HIV testing and if found positive referred to appropriate counseling and care. All HIV+ persons should be screened for TB and linked to appropriate diagnostic testing. Coordination and communication between the National AIDS Control Program and the National TB Control Program are essential. The TB diagnostic network should collaborate with the HIV diagnostic network regarding laboratory and diagnostic services (e.g., specimen transport, shared diagnostic platforms, referrals for testing, etc.).

The MoH has a dedicated organizational unit in charge of coordination between the TB laboratory network and the HIV/AIDS laboratory network. Coordination of the NACP and NTLP is accomplished through monthly technical working group meetings and the secondment of staff between the programs. The TB diagnostic network and HIV diagnostic network collaborate extensively regarding specimen transport and referrals for testing. TB, HIV, and TB-HIV statistical data are reported, analyzed, used for decision making purposes at the national level and there is a surveillance system for TB/HIV. HIV testing and TB testing is free in all public facilities and private laboratories associated with the network. National policy on TPT is implemented across all facilities visited.

Specific findings and recommendations include:

- LF-LAM is being implemented in many sites. However, there was some variability in adherence to the national algorithm and SOPs. EQA for LF-LAM was being implemented at some hub laboratories.
    - *Standardize LF-LAM request and reporting forms; expand the EQA program for LF-LAM.*
    - *Provide training to laboratory and clinical staff on the LF-LAM testing algorithm, procedures, test limitations, interpretation, and quality assurance.*
- Linkage procedures of PLHIV with TB testing and persons with presumptive TB and diagnosed TB to HIV testing were available. However, implementation was not uniform across all facilities.
    - *Ensure that TB and HIV clinical and laboratory staff are cross trained in the national testing algorithms for TB and HIV.*

General Considerations for Strengthening the Diagnostic Network and Thematic Areas

Implementation of the recommendations should be guided by several cross-cutting principles. These include:

- Developing aggressive bold policies and interventions in alignment with End-TB strategy and mobilize commensurate resources while finding efficiencies.
- Emphasizing translation of policies into action.
- Linking indicators of laboratory and diagnostic network strengthening with NSP goals and targets.
- Optimizing test utilization and improving access to existing services to build a strong foundation for the rapid scale-up of laboratory testing, deploying what is available now, while planning and continuing to evaluate new tools and approaches.
- Shifting the focus of diagnostic TB services from the health system to the patient including the complete cascade from screening to treatment completion.
- Putting in place comprehensive systems with adequate resources to closely monitor implementation.

- Managing change within the diagnostic network and laboratory personnel to ensure the acceptance and effective implementation of the strengthened diagnostic network.

Next steps

The findings and recommendations from the assessment are extensive and will require the NTLP and NTRL to lead and coordinate efforts among all stakeholders, including technical partners and donors. The NTP and NTRL should review the findings and recommendations of the assessment, empower a national Laboratory Technical Working group or an ad hoc workgroup to address the findings and recommendations.
Recommended activities or interventions should be prioritized, and a costed work plan developed with clearly defined and prioritized activities, responsibilities, deliverables and timeline. The implementation of this plan should be reviewed periodically and adjusted as needed.

Uganda is on the right track to meet the End TB targets of universal access to rapid diagnostic tests and universal DST for rifampicin. The recommended key interventions and priority actions described in this report will assist Uganda to reach its TB diagnostic goals with the aim of a Uganda free of TB.

Progress since the 2019 TB Diagnostic Network Assessment

An assessment of the TB Diagnostic Network of Uganda was conducted from August 25 to September 6, 2019. The assessment utilized an earlier version (2019 version) of the TB-Net Tool and the same general process of verification visits and staging. The 2019 assessment covered the NTLP and other stakeholders at the national level, the NTRL, 9 Regional Referral Hospitals, 11 PNFP hospitals, 3 General or District hospitals, 3 PFP hospitals, 1 clinic, 1 academic hospital, 9 HC IIIs, 2 Prison HC IIIs, 1 Police HC III, 5 HC IVs and 2 Military HC IVs for a total of 49 facilities in 10 geographic areas to inform the assessment.

The information gathered from the 2024 TB Diagnostic Network Assessment was used to assess the progress made on addressing the key recommendations of the 2019 assessment and contributions to improving the TB diagnostic network and achieving the laboratory indicators for NTLP NSP.

In general, good progress was made on addressing each of the key recommendations of the 2019 assessment. In particular, strong progress was made in expanding the use of the Xpert Ultra test as the initial diagnostic test for persons presumed to have TB; strengthening the system of supportive supervision; expanding the use of Village Health Teams (VHTs) and mobile vans containing portable digital X-ray with CAD and a GeneXpert instrument for Xpert Ultra testing to extend services to the community level, find TB earlier, and improve linkages to testing and care; deploying a diagnostics connectivity system (LabXpert) to 89% of the Xpert testing sites; and optimizing the utilization of GeneXpert instruments by introducing multi-disease testing (e.g., Xpert testing for HIV Viral Load, EID, HPV, COVID-19, Chlamydia, TB and Hepatitis).
This progress has contributed to strengthening the TB diagnostic network and achieving the laboratory indicators for NTLP NSP (e.g., 69% of notified cases were tested by WRDs and 75% of bacteriologically confirmed cases have DST for at least rifampicin when compared to the xx% and yy% reported in 2019.

A comparison of the TB-Net tool stages assigned in the 2019 assessment and the 2024 assessment revealed that improvements in capability percentages were noted for six core capacities with large improvements in Capacity 8 (Diagnostic Data Management) and Capacity 6 (Equipment & Supplies).
Capability percentages for the other four capacities were similar in the two assessments. With respect to the components (i.e., essential functions or activities) that make up the core capacities, the staging for 4

components declined (2 because of changes to the component stages between 2019 and 2024), while 19 remained the same and 18 improved.
A detailed discussion of the progress made since the 2019 assessment is presented in Annex 6.

Annexes

Annex 1. Diagnostic Network Standards, Core Capacities and Components

The TB-Net Tool's foundation is built around a set of standards that provide a qualitative measure of quality or attainment of a comprehensive TB diagnostic network. "Core capacities" and "components" of the Tool are linked to each of the standards and refer to the overarching capabilities of a national TB diagnostic network to detect, assess, notify and respond to TB. Components are used to describe the essential functions of the diagnostic network across the core capacities.

Standard 1. The country has a fully endorsed political, legal and regulatory framework in place which supports the achievement of the NSP and that organizes and controls all public and private diagnostic services to support the NSP, with sufficient dedicated funding available. Policies are in place that enable continuous, country-wide availability of free, quality assured diagnosis according to the national guidelines.

- **Core Capacity:** Political, legal, regulatory and financial framework
- **Components:** Legislation and policies, National policies and plans, Governance, Financing and budgeting

Standard 2. A sustainable, rational and efficient TB diagnostic network provides integrated, essential, quality diagnostic services for patient care and public health. The TB diagnostic network is coordinated by a national reference or public health laboratory and includes the public and private sector as well as community level diagnostic services. All facilities have clearly defined terms of reference and are adequately supervised.

- **Core Capacity:** Structure and organization of the diagnostic network
- **Components:** Diagnostic Network, Coordination and management, Programmatic and operational research

Standard 3. The national TB diagnostic network provides complete coverage and universal access to TB diagnostic services to the entire population of the country. Referral mechanisms exist to rapidly refer specimens to the appropriate level for testing and to provide timely results to enable initiation of appropriate treatment. An efficient diagnostic-clinical interface allows for appropriate diagnostic tests to be ordered and ensures the timely linkage of diagnosed patients to appropriate care and treatment.

- **Core Capacity:** Coverage
- **Components:** Diagnostic network coverage, Sample referral system, Linkages, Emergency preparedness

Standard 4. A national TB diagnostic algorithm(s) that is responsive to the epidemic, patient-centered, includes appropriate use of diagnostic technologies, and is based on the current structure of the health system is enforced at all levels of the TB diagnostic network. A minimum package of tests and quality standards is defined for each level of the network. Laboratorians, health care workers, and TB program staff are trained in the application of the algorithm.

- **Core Capacity:** Diagnostic algorithm
- **Components:** Algorithms, Detection of TB, Detection of drug-resistant TB

Standard 5. Testing is performed in a manner and in facilities that ensure safety for the staff, customers, community and environment. Sufficient materials, means and skills are available throughout the system to ensure safe and secure procurement, handling, storage, transportation and disposal of samples and materials, both in routine as well as in emergency circumstances.

- **Core Capacity:** Biosafety
- **Components:** Facilities, Biosafety and biosecurity manual, Biosafety systems, Waste management

Standard 6. Testing is performed with state-of-the-art and well-maintained equipment and an uninterrupted supply of quality reagents and consumables using standardized testing methods throughout the country.

- **Core Capacity**: Equipment and supplies
- **Components**: Supply chain management, Equipment management

Standard 7. Adequate numbers of competent, well-trained and motivated technical and managerial staff are available at all levels of the diagnostic network.

- **Core Capacity: Workforce**
- **Components: Education and training, Staffing, Human resources strategies and plans, Competency-based job descriptions**

Standard 8. Inter-operable and inter-connected electronic recording and reporting systems are in place that generate reliable data that are monitored and analyzed in real time. The systems comply with international standards to allow the rapid exchange of information in standardized formats. A laboratory information management system provides up to date information about the status of the laboratories and is linked to the Health Management Information System of the country.

- **Core Capacity: Diagnostics data management**
- **Components:** Data collection forms, Reporting, Diagnostics connectivity and remote monitoring, Data analysis and sharing, Surveillance and epidemiology, Security and confidentiality of information

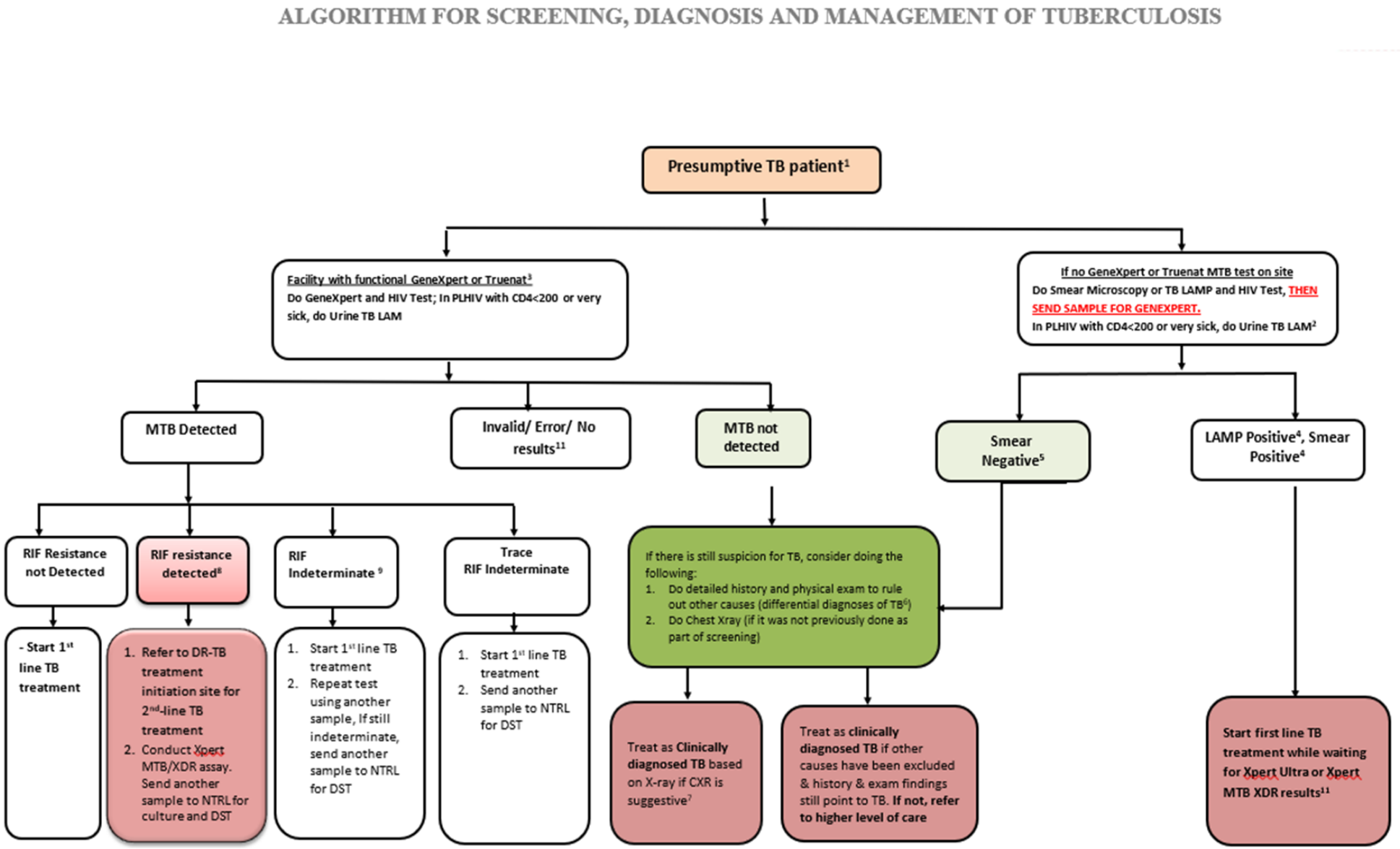
Standard 9. High quality diagnostic services producing accurate and reliable results are available throughout the network. Continuous quality improvement targets all facilities within the network and includes quality indicator monitoring, external quality assurance, and regular on-site supervision. A system of national certification is in place for all public and private laboratories within the network and reference and referral level laboratories are accredited according to national or international standards.

- **Core Capacity:** Quality of the diagnostic network
- **Components:** Documents and document control, Quality assurance, Quality management system, Certification and accreditation

Standard 10. A comprehensive approach is needed to combat the twin epidemics of HIV/AIDS and TB. All persons being evaluated for TB should receive free HIV testing and if found positive referred to appropriate counseling and care. All HIV+ persons should be screened for TB and linked to appropriate diagnostic testing. Coordination and communication between the National AIDS Control Program and National TB Control Program are essential. The TB diagnostic network should collaborate with the HIV diagnostic network regarding laboratory and diagnostic services (e.g., specimen transport, shared diagnostic platforms, referrals for testing, etc.).

- **Core Capacity:** TB/HIV
- **Components:** Legislation and policies, Structure and organization of the network, Coverage, Diagnostic Algorithm, Workforce, Diagnostic Data Management

Annex 2. Diagnostic Algorithms



Annex 3. Questions and Stages by Core Capacity and Components

See attached file “TB Network Assessment – Final”

Annex 4. Sites Visited

	Name	Level of facility	Type	Diagnostic tests performed
	Ankole			
	Mbarara DHO		GOV	
	Mbarara RRH	RRH	GOV	Xpert Ultra/ MTB/RIF. LF-LAM
	Makenke Military (2nd Division)	Health Centre III	Military	Xpert Ultra/ MTB/RIF
	Bushenyi DHO			
	Ishaka Adventist Hospital	HospitaL	PNFP	Xpert Ultra/ MTB/RIF, Microscopy, LF-LAM
	Bushenyi Medical centre	Health Centre III	PNFP	Microscopy, LF-LAM
	Isingiro DHO		GOV	
	Rwekubo HCIV	Health Centre IV	GOV	Truenat, Xpert Ultra/ MTB/RIF, Microscopy, LF-LAM
	Rugaaga HCIII	Health Centre III	GOV	Microscopy
	Nakivaale HCIII	Health Centre III	Refugee	Xpert Ultra/ MTB/RIF, Microscopy, LF-LAM
	Kakiika Prison HCII	Health Centre II	GOVT	LF-LAM
	Bunyoro			
	Hoima CHO			
	Hoima Regional RRH	RRH	GOVT	Xpert Ultra, Xpert MTB/XDR, LF-LAM, ZN Microscopy
	Azur Health Centre IV	Health Centre IV	PNFP	TB-LAMP, ZN Microscopy
	Kikuube DHO			
	St. Ambrose Charity Health Centre IV		PFP	GeneXpert, LF-LAM, ZN Microscopy
	Kyangwali Health Centre IV	Health Centre IV	GOVT	Xpert Ultra, LF-LAM, ZN Microscopy
	Kigorobya Health Centre IV	Health Centre IV	GOVT	GeneXpert, LF-LAM, ZN Microscopy
	Kagadi DHO		GOVT	
	Kagadi General Hospital	Hospital	GOVT	Xpert Ultra, LF-LAM, ZN Microscopy
	Kakumiro DHO			
	Kisiita HCIII	Health Centre III	GOVT	TrueNat, ZN Microscopy
	East & Bukedi			
	Soroti CHO	City Health Office	GOV	NA
	Soroti RRH (Teso)	RRH	GOV	Xpert
	Soroti Prison HC III	Health Centre III	PNFP	SMM

	Soroti Medical Associate Nursing Home (Teso)	Health Centre III	PFP	SMM
	Princess Diana HCIV (Teso)	Health Centre IV	GOV	TB LAMP
	Tororo DHO	DHO	GOV	
	Rubongi Military General Hospital	Hospital	Military	SMM
	Mulanda HC IV	Health Centre IV		Xpert
	Osukuru Health Centre III	Health Centre III		SMM
	Tororo Police Health Centre II	Health Centre II		SMM
	Kampala A			
	NHLDS	National		N/A
	NTRL	National Lab		All
	NTLP	National		N/A
	STOP TB	Partner		N/A
	NMS	National warehouse		N/A
	WHO	Partner		N/A
	JMS	National warehouse		N/A
	KOFIH	Partner		N/A
	Makerere University Hospital	Gov		
	Kampala B			
	City Health Office			NA
	Makerere Biomedical Research Center		Private	Microscopy, Xpert Ultra/XDR, Culture, FL&SL DST and LF LAM
	Nakareso Hospital		Private	Truenat
	Mulago Ward 5&6			Xpert Ultra/XDR
	Ebnezzer Labs		Private	
	Muchision Bay	Hospital	Prisons	Xpert Ultra/XDR
	Kiswa HCIII	Health Centre III	GOV	Xpert
	Alive Medical Services	Health Centre IV	PNFP	Xpert
	Nsambya Police HC IV	Health Centre IV	GOV	Xpert
	Kawempe Home Care	Health Centre	PNFP	SMM
	Karamoja			
	Moroto DHO	DHO		

Moroto RRH	RRH	GOVT	GeneXpert Ultra, TB LAM, Microscopy, Chest X-ray, HTS, U/S
Moroto Prisons	Health Centre III	GOVT	Microscopy, GeneXpert Ultra, TB LAM, HTS
St. Pius Kidepo Health Centre	Health Centre III		Microscopy, HTS, TB LAM
Nabilatuk DHO			
Nabilatuk HC IV	Health Centre IV	GOVT	Microscopy, GeneXpert Ultra, TB LAM, HTS
Lolachat HC III	Health Centre III	GOVT	Microscopy, TB LAMP, TB LAM, HTS
Lolengwedwat HC III	Health Centre III	GOVT	Microscopy, r GeneXpert, TB LAM, HTS
Napak DHO			
Matany Hospital	Level 5 hospital	PNFP	Microscopy, Chest X-ray, GeneXpert Ultra, TB LAM, U/S, HTS
Lopeei HCIII	Health Centre III	GOVT	Microscopy, , TB LAMP, TB LAM, HTS
Namaendela HCII	Health Centre III	GOVT	HTS
Kigezi			
DHO Kabale	DHO		
Kabale RRH	Hospital		Xpert Ultra (16 module) + MTB/XDR (new), microscopy, LAM, (no X-ray)
Kihefo Clinic	Private for profit		Xpert Ultra, microscopy, LAM
Rukungiri DHO			
Kebisoni HC IV	Health Centre IV		Microscopy, LAM
Rukungiri Prisons	Penitentiary		Microscopy, LAM
Kisiizi COU Hosp	Health Centre IV	PNFP	Xpert Ultra, microscopy, LAM
DHO Kisoro	DHO		
Kisoro Hosp	Hospital		Xpert Ultra (16 module) + MTB/XDR (new), microscopy, LAM, No Xray
Busanza HCIV	Health Centre IV		Xpert Ultra, microscopy, LAM
Kyahafi HC III	Health Centre III		Xpert Ultra, microscopy, LAM
Chahafii Health Center IV	Health Centre IV		Microscopy, LAM
Lango			
Lira DHO			
Lira RRH	RRH	GOV	Xpert Ultra, LF-LAM
Lira Prison	Health Centre III	GOV	Xpert Ultra, LF-LAM
Abala HC III	Health Centre III	GOV	Microscopy, LF-LAM, (Xpert ultra by Referral)
Lira Medica Centre	Health Centre III	PFP	Microscopy, LF-LAM, (Xpert ultra by Referral)

	DHO Oyam			
	Aber Hospital	Hospital	PNFP	Xpert Ultra, LF-LAM
	DHO Apac			
	Apac Hosp	Hospital	GOV	Xpert Ultra, LF-LAM
	Ibuje HC III	Health Centre III	GOV	Xpert Ultra, LF-LAM
	North Central			
	Mukono DHO			
	Mukono Hosp	General Hospital		Microscopy, Xpert Ultra, LF-LAM
	Kojja HC IV	Health Centre IV		Microscopy, Xpert Ultra, LF-LAM
	Kauga Prison HC III	Health Centre III		Microscopy, LF-LAM
	St. Francis Nagalama Hospital	PNFP		Microscopy, Xpert Ultra, LF-LAM
	Kayunga DHO			
	Kayunga RRH	RRH		Microscopy, Xpert Ultra, Xpert XDR, LF-LAM
	Luwero DHO			
	Bishop Asili Hosp	PNFP		Microscopy, Xpert Ultra, LF-LAM
	Bombo Hospital	Military		Microscopy, Xpert Ultra, LF-LAM
	Kalagala HC IV	Health Centre IV		Microscopy, LF-LAM
	South Central			
	City Health Office	DHO	GOV	NA
	Masaka RRH	RRH	GOV	Xpert MTB/RIF Ultra, LF LAM, Microscopy
	Uganda Cares Masaka	Health Centre IV	PNFP	SMM
	Masaka Police	Health Centre III	Police	Microscopy, LF LAM
	Byansi Hospital		GOV	Microscopy
	Masaka DHO		GOV	NA
	Bukeeri HC III	Health Centre III	GOV	Microscopy, LF LAM
	Buwunga HCIV	Health Centre III	GOV	Microscopy, LF LAM
	Kalangala DHO			
	Kalangala HC IV	Health Centre IV	GOV	Xpert MTB/RIF Ultra, LF LAM, ZN microscopy
	Rakia DHO			
	Rakia Hospital	Hospital	GOV	Xpert MTB/RIF Ultra, LF LAM, ZN microscopy
	Lwamaggwa HC III	Health Centre III	GOV	Microscopy, LF LAM
	West Nile			
	Arua DHO			
	Arua RRH	Regional referral hospital	GOV	TB Microscopy, Xpert (ultra & XDR), LF-LAM, Rapid HIV, CD4

Arua Police	Peripheral	GOV	TB Microscopy, LF-LAM, Rapid HIV, CD4
River Oli HC IV	Health Centre IV	GOV	TB Microscopy Xpert (ultra), LF-LAM, Rapid HIV, CD4
Maracha DHO			
Maracha Hosp	Hospital	PNFP	TB Microscopy, Xpert (ultra), LF-LAM, Rapid HIV, CD4
Oluvu HC III	Health Centre III	GOV	TB Microscopy, LF-LAM, Rapid HIV, CD4
Koboko DHO			
Koboko Hosp	Hospital	GOV	TB Microscopy, Xpert (ultra), LF-LAM, Rapid HIV, CD4
Ayipe HC III	Health Centre III	GOV	TB Microscopy, LF-LAM, Rapid HIV, CD4
Yumbe DHO			
Bidibidi HC III	Health Centre III	GOV	TB Microscopy, Xpert (ultra), LF-LAM, Rapid HIV, CD4

Annex 5. Site Visit Summaries

Site Visit A: Ankole

Team A: Assessors: Alex Durena, Teresa Simiyu, Miriam Mulungi, Resty Leonie Nanyonjo
Observers: Claire Nankoma, Rebecca Nakidde, Mulomo Leabaneng, Wagubi Robert

Key findings- Strengths

- There was a laboratory operational plan being implemented at Mbarara Regional Referral Hospital although this was missing at lower-level facilities visited.
- Lab informs the district and national programs through reporting and monthly reviews are done.
- Hub system is in place and functional to ensure sample referral all over the region.
- The Region provides rapid diagnostic tests (WRDs) to all persons with signs and symptoms of TB.
- There is a collaboration between the HIV and TB programs although documentation to support linkage to testing and care for patients was missing.
- TB diagnostic tests are provided for free in both Gov't and PNFPs for presumptive TB patients.
- Standardized tools are used to collect information on key quality performance indicators, although tools are not filled completely.
- Most labs (80%) had adequate ventilation with running water and electricity (power backup available).
- There was adequate stock of lab logistics like cartridges, and reagents for microscopy, only a few had a stock out of TB LAM kits like Kakiika Prisons.
- Over 90% of the labs have an electronic ordering system (Client Self Satisfaction System) which was used to order the required supplies.
- Most labs were participating in TB EQA (Blinded rechecking for microscopy and panel testing for GeneXpert) and had results with corrective actions.
- A sample tracking system was observed with QR codes for scanning by hub riders placed at every facility to track shipment; however, lab staff and clinicians were not using the data.
- LabXpert is implemented but not functional in all facilities with WRD capacity visited.

Key findings – Challenges

- No dedicated budget for TB diagnostic services and a budget that completely covers operations related to routine lab activities.
- No documented terms of reference, no agreed upon mandate; test menu provided by the facilities not available.
- There was no proper triple packaging, mostly the packaging was improvised due to frequent stock outs of packaging materials.
- Not all the Standard operating procedures (SOPs) for specimen referral processes were available, and staff (clinical and lab) have not been trained in sample packaging, labeling, transportation among others.
- Biosafety manuals, SOPs were missing in some facilities and not all lab staff are trained in safety and biosecurity.
- Gaps observed in the implementation of biosafety practices especially in waste management and screening of TB service providers for signs and symptoms of TB.
- Long TAT of results at the testing Laboratories and sites without molecular diagnosis like Bushenyi Medical centre and Rugaaga HCIV hence affecting real time treatment initiation.
- Competency-based job descriptions and process of assessing staff competency were found in only 2 facilities (Makenke and Mbarara RRH), while the remaining facilities had these lacking.
- 5 out of the 8 labs had no documented contingency plan in case of emergencies like machine break down, stock outs etc.

- About 90% of the visited facilities had incomplete data entry on TB Laboratory request forms.
- Misuse of LF – LAM in 50% of the facilities visited.
- There were gaps in TB contact investigation at the community level.
- Most facilities (80%) lacked updated TB lab testing and diagnostic algorithms.
- About 60% of the visited labs had no quality management systems in place and no focal person trained.

Recommendations

- Increase WRD access especially in lower level HCIIIs and POCs.
- Develop Human resource policies to retain staff, maintain their motivation to execute the roles needed.
- Reinforce policies related to private public partnerships.
- Avail documented terms of reference and test menu for all labs.
- Ensure all lab staff are trained in biosafety and sample collection, packaging, labeling, and transportation processes.
- Ensure QMS implementation in all labs, identify and train HF focal persons.
- Support regional, district and peripheral labs to monitor lab KPIs and to use the data for improvement
- Support implementation of the recommended biosafety / biosecurity practices and adequate Warehouse Management.
- Ensure clinical and lab staff training / refresher in established guidelines for TB detection among HIV patients.

Site Visit B: Bunyoro

Team B: Assessors: Dr. Grace Kahenya, Julius Mutagubya
Observers: Beatrice Orena, Samuel Kayiwa

Prior email communication was sent out to the different District Health Offices notifying them of the activity. Hard copies were delivered by the team of assessors to the DHO's offices as scheduled on the travel plan. A district entry meeting was conducted to further explain the objectives of the activity and discuss the implementation of the activity. A Regional TB Laboratory Supervisor (RTLS) was assigned to the team of assessors to move to the facilities. Entry meetings were held at the facilities and authorization to engage the facility teams was received.

At the district Level, the District TB and Leprosy Supervisors, District Laboratory Focal person, and MDR Focal persons were interviewed. Health workers in the TB clinic, laboratory, data management units, Stores, and administration were interviewed using the electronic Survey CTO and hard copy checklists.

Key findings – Strengths

- All TB diagnostic tests are free.
- Established system of Reporting aggregated data in place.
- All labs offer services according to their level.
- A functional sample referral system found in the region with a formalized structure of communication through the hub system.
- All visited facilities were implementing LF LAM; staff was knowledgeable to LF LAM testing eligibility criteria.
- Over 80% district facilities had access to WRDs like GeneXpert, TrueNat and TB Lamp.
- Standardized documents, records and forms are accessible in most facilities.
- All facilities were enrolled in the EQA program.

Key findings – Challenges

- No dedicated budget for TB diagnostic services at the district and the laboratory.
- TB Laboratory strategic plan and operation plan are not in place (not implemented).
- No documentation to track referred samples.
- Most facilities had inadequate triple packaging materials.
- The current national TB diagnostic algorithm was not available in the laboratories but the HIV testing algorithm was available.
- Non-availability of SOPS for collection, storing, disposal of waste and reporting complaints for the quality of lab supplies.
- Most Labs were understaffed (managed by one staff).
- Gloves were out of stock in many facilities (except RRH and PNFPs).
- Absence of contingency plans for continuity of services during disasters, machine breakdown and stock outs.
- Only two facilities have multi disease testing platforms in the region.
- No equipment maintenance plan at the facilities.
- No refresher training to update on new technologies and guidelines.

Recommendations

- Distribute and orient laboratory staff on the current TB diagnostic algorithm.
- Disseminate the TB operational plan to all facilities.
- Orient district and laboratory staff on developing contingency plans for continuity of services.
- Train lab staffs not implementing QMS on SOPs for the different tests performed in the laboratory including biosafety.
- Implement biosafety and biosecurity measures in all labs (e.g. gloves).
- Provide written supervisory feedback reports for implementation of corrective actions in the labs.
- Provide specimen referral registers for tracking specimens at the facilities.
- Improve staffing levels at the different lab tiers.
- Expand electronic LIMS to support patient management and reporting.
- Improve engagement of private facilities through inclusion for trainings and Public Private partnerships.

Site Visit C: East and Bukedi

Team C: Assessors: Chris Isaacs, Jeremiah Okari, Martha Pedun
Observers: Patrick Ademun, Denis Oola, Christopher Okiira, Sam Lwanga, Edeet Lamu

Key findings

- Laboratory structure is functional.
- Good level of district supervisory visits reported.
- New MDR treatment center opened in Tororo General Hospital reducing referrals.
- Hub system is known and utilized, but formal documentation does not exist.
- Most facilities have good waste management procedures and practices in place.
- Good use of both public and private facilities - army, police and prisons etc. but private sector labs not updated on key policies and practices.
- Good linkage between TB and HIV. The HIV algorithm is up to date. Good use of resources.
- Lab staff were mostly familiar with processes, but SOPs were either unavailable or not used if found during the visits. Most sites lack quality officers.

- Data aggregation is regular and reported as scheduled. However, no evidence of facility level utilization.
- Lack of clear linkage between patient screening, diagnosis and treatment. Regular meetings between lab & clinical staff occur; however, poor screening leading to unnecessary presumption and testing. E.g. 120 tests with 0 positives at 1 site.
- Most sites are experiencing severe lack of reagents and testing supplies – MDR treatment site visited did not have XDR cartridges since January 24. Lack of visibility between laboratory and Central Stores on stock status and supply. Staff not able to determine if stock is available and often near expiry stock is delivered.
- Dissemination and implementation of the latest TB diagnostic algorithm has not taken place. Facilities are still using the 2017 or 2019 versions.
- Most sites visited could not perform the level of testing required for their level due non-operational equipment.
- No evidence of TAT monitoring for sample referral. No presence of sample/patient transfer logs – many sites missing results with difficulty to track those that are late or never delivered. Other registers present.
- At only 1 site did we meet an appointed lab manager, several sites were being run by lab assistants with sub-optimal experience and in some cases students with just 2 months of experience. Most sites are not adequately staffed.
- Equipment maintenance is not adequate, some equipment was not serviced since 2017.
- All but 1 site (Soroti RRH) were not able to indicate KPIs and were not actively monitoring them.
- No evidence of standard triple package containers witnessed. All sites were forced to improvise.
- Low evidence of training, certification, competency assessments. Informal knowledge sharing was evident.

Recommendations

- Conduct sensitization, capacity building and mentorship for clinicians to enhance TB detection.
- Increase visibility of stock status at the central level, quantification and forecasting with manufacturers and suppliers to support testing needs of the country, especially for mWRDs.
- Avail and rollout of the latest TB diagnostic algorithm including training.
- Equip facilities with mWRDs to perform tests expected for their level of care.
- Equip facilities with sample tracking logs and mentorship on their use.
- Advocate for further deployment and continuous training of laboratory staff.
- Adhere and ensure follow up of equipment maintenance schedules and document performance of equipment.
- Ensure the position of quality officer is filled and enforce quality and KPI monitoring/adherence at all sites. Implement QMS across the network.
- Procure adequate and sufficient triple packaging containers, ensure usage and supply monitoring at sites.
- Implement waste management protocol/guidelines.
- Deploy electronic test ordering and results return in LabXpert sooner rather than later.
- Consider allocation of further budget to better support laboratory operations.

Site Visit D: Kampala A:

Team D: Assessors: Ali Kwizera, Jean de Dieu Iragena, Thomas Ssemakadde
Observers: Fredrick Kangave, Akello Annet

The team visited the sites listed in Annex 4 with an aim of understanding the different perspectives of the TB leadership / management teams in the country. These sites and personnel interacted with were purposively selected to provide strategic information related to the TB network activities in the whole cascade. The teams also interacted with implementing partners and key influential donors that play key vital roles along the TB cascade right from case finding to treatment.

Specific findings and recommendations

1. National TB Reference Laboratory (NTRL):

The team assessed the National TB reference laboratory at Butabika and the backup laboratory at the National TB program in Wandegeya and below are the key findings and recommendations from the assessment that was done.

- The Uganda NTRL established under the NLTP of the MoH received accreditation from the WHO in April 2013, making it the first SRL in East Africa, and the second in Sub-Saharan Africa to achieve this status.
- Overall, the laboratory is well-structured and organized to execute its oversight role in supporting the laboratory network as it's the main referral point in the network.
- The NTRL operates under the National and Operational TB Laboratory Strategic Plan with a comprehensive budget, indicators, and targets to be monitored in a way to provide aggregated data that are linked to patient care.
- The NTRL has clear terms of reference stated in their policies and standard operating procedures and fulfills its mandate in providing public health and clinical diagnostic services.
- Roles and responsibilities in overseeing the network of public, private and academic laboratories are clearly defined and available
- The NTRL/SRL is implementing all the WHO-endorsed diagnostic technologies as they become available, starting by microscopy (LED and ZN), culture (solid and liquid), phenotypic and genotypic DST (1st and 2nd line LPA, Xpert Ultra and XDR and sequencing).

Key findings

- The NTRL/SRL Butabika facility has BSL3 (A: for culture and B: for DST), BSl2 where samples reach after reception, and 1 Molecular facility. The HVAC system does not work at Butabika, hence the facility of Wandegeya serves as a backup laboratory for now.
- Beside the BSL3 conditions in Butabika, samples are still channeled there before they are disseminated to different sections of the labs for testing. There is inconsistency in a way samples received are recorded in the register by a rider who has access to the reception facility. The access to that area is not restricted, which shows that anyone can access it without restriction. Indeed, some safety issues have been noticed in that area.
- An organized and structured TB diagnostic network is in place with clearly defined roles and responsibilities among staff and under a strong National Department of National Health Laboratory and Diagnostic Services (NHLDS) which oversees the NTRL and works closely with the NTLP program, to perform oversight roles for the TB diagnostic network.
- Collaboration between the HIV and TB programs is working very well and leading to excellent linkage to testing and care for patients.
- The laboratory network has many suitable and up-to-date policies and guidelines, which are reported to be implemented at all levels of the diagnostic network.
- Standardized forms are used to collect information on key quality measures and performance indicators, but the data are not routinely reviewed, analyzed by the laboratory staff, and used for improving laboratory testing.
- Specimen referral systems play a critical role in ensuring access to laboratory services. However, it was observed that proper triple packaging was not used for all specimen referrals, and there were frequent stockouts of packaging materials. Standard operating procedures for specimen referral processes were

not fully available, the quality of specimens received at the testing laboratory was a challenge in some settings.

- During verification visits, there were reports of stockouts of reagents for MGIT, first-line and second-line line probe assays, as well as triple packaging materials and GeneXpert cartridges. Also, laboratories do not routinely conduct lot-to-lot verification to ensure the quality of reagents.
- A National Biosafety and Biosecurity program is in place. However, there are still identified gaps in the implementation of biosafety practices especially in areas related to waste management and medical surveillance.
- There is some little evidence of the program support in Private laboratories being part of the network.
- A Laboratory Quality Management system is being implemented. However, not all policies are being adhered to especially in areas of safety.

Recommendations

- Address as a matter of urgency the mechanical issues of the BSL3 of Butabika NTRL/SRL.
- There is a need for improving the sample reception procedures at Butabika especially with registers located at the areas of reception.
- Expand the private sector engagement into the TB network assessment.
- Emphasize implementation of policies and guidelines. Ensure adherence to the waste management procedures across the different laboratory areas.
- Increase the GeneXpert coverage based on the recommendations from the Geo spatial Analysis report. An inventory of GIS-mapped TB laboratories (including current inventory of diagnostic tests and instruments) should be useful to the program for strategic planning, allocating resources, and planning for continuation of TB services in case of service disruptions. For example, the inventory of laboratories and current GeneXpert instruments and test volumes may identify under-utilized and over-utilized instruments and opportunities to redistribute instruments to improve the efficiency of testing.
- The NTRL laboratory reported having an adequate number of staff; however, most of these staff are on donor funded projects and few are government supported. This affects staff retention and motivation to execute the different roles.

2. Department of National Health Laboratory and Diagnostics Services (NHLDS):

The NHLDS is a department under the directorate of Public Health in the organogram of the Ministry of Health (MoH). It coordinates different reference laboratories (public, private and academia) including the NTRL/SRL which oversees the TB Laboratory network (from central to community levels) in Uganda (NTRL) and other African countries (SRL) through the regional TB laboratory project funded by the Global Fund GF (ending in June 2025). The NHLDS has recently been restructured in a way to diversify its coordination scheme of the integration and diversification by strengthening the regional hospitals. In its overseeing scheme, the NHLDS has strengthened different activities and gains including: LabXpert, sample transport system and tracking, integration (measures especially with EQA), service maintenance, inventory system and supply chain management.

Key findings

- Among the challenges expressed by the Commissioner, was the sustainability issue of the current Human resource. Recently, the country has conducted a workforce HR analysis especially for the NTRL/SRL to better mitigate this issue. The report will be available soon and the findings will be used to address this issue.
- Another challenge highlighted by the commissioner was the issue of sample tracking which doesn't capture/ track individual patient samples but rather tracks boxes.

Recommendations

- To advocate for the availability of more funding for the SRL Uganda beyond June 2025 allowing the TB regional Lab project to strengthen the lab system, by further addressing the challenge of AMR.
- To address the HR issues by retaining all the workforce the network succeeded to train so far.

3. National TB and Leprosy Program (NTLP)

Key findings

- The NTLP is a Division under the Department of communicable and noncommunicable diseases. It is well structured and headed by an Assistant Commissioner. The NTLP has a National Strategic Plan with a strong component of TB and closely works hands in hands with the NTRL in its operationalization of the NSP with regards to monitoring TB laboratory indicators and targets.
- Beside an improvement in collaboration with the NTRL, the TAT for TB results from the NTRL to clinicians for patient management is still a challenge that needs to be improved, especially for DR-TB.
- It is also a requirement of the NTLP to get a tracking system in place in a way individual samples can be tracked, from sample collection up to reporting.
- All TB lab tests including Chest XRay are not free everywhere, especially in private sectors where patients are requested to pay.
- Basic TB lab services such as TB screening, referral systems are decentralized to the community level, however, there is a way to go when it comes to private sector providers.
- The NTLP does not have a plan for continuation of TB services in emergency situations, however it adheres to the National plan for emergency preparedness and response when it comes to the maintenance of health services during emergencies.
- The guidelines using chest XRay are followed by clinicians, who are at least trained for it and diagnostic algorithms are followed accordingly especially in the public sector.
- The NTLP collaborates with the other programs, especially on the use of multi disease testing platforms that includes TB, HIV EID and VL as well as HPV. However, it is noted that for instance GeneXpert is used at 95% of its capacity for TB, while its use with the other diseases is not yet visible. Multi Disease testing guidelines at country level need to be developed and disseminated to strengthen that area.
- When it comes to HR strategies that address staffing, salaries, retention and career development, there is an improvement to be done, especially for the sustainability of the NTRL/SRL. Funding the SRL should continue as it allows at the same time strengthening TB program in Uganda.
- Beside there is an electronic system (LIMS) reporting lab data, there is no interface between LIMS and LabXpert (linked to GeneXpert instruments). Whatever lab data, once reached the NTLP, are used for decision making and program improvement. All the lab indicators are well analyzed by M&E focal point and reported.
- The NTLP has a national policy in place for TPT. TPT is administered to PLHIV 3 months after the start of ART (DTG). The guidelines are well followed. Data showed that PLHIV under TPT in Uganda is about 8,8% and these data seem not to be in line with what the NTLP has. Also, the number of TB patients tested for HIV at TB diagnostic and treatment centers seem not to be in line with what the NTLP has as data. The one stop shop seems to be for TB/HIV, from prevention, diagnostic, treatment and care. TB and HIV Program work together for the coinfection and all the procedures are formalized and linkage to patient care is evident. KPIs are collected, analyzed and reported routinely for decision making and program improvement.

Recommendations

- Improve the TAT of lab results by interacting with the NTRL/SRL and sharing concerns on a regular basis. This implies an improved sample referral system with ad hoc tracking of individual samples.

- Closely work with private facilities and discuss the way Chest XRay and some TB lab tests can be free of charge.
- To closely coordinate with the NHLDS the development of guidelines for use of multi testing diagnostic platforms across the TB lab network (beyond TB) and ensure its endorsement and wide dissemination; ensure the number of instruments can meet the needs.
- To advocate for continuity of the SRL funding mechanism, that not only will contribute to the sustainability of what has been achieved so far in the African countries but also will contribute to the improvement of the Ugandan TB Program.
- To coordinate with the NTRL/SRL the work that would allow interoperability between LIMS and LabXpert databases.
- To ensure data on PLHIV under TB and TB patients who know their HIV status are consistent with agreed and published national data.

4. Ministry of Health -Pharmacy Division (Supplies and commodities of the TB program): NMS

Key findings

- Two experts from the Department of Pharmaceuticals and Naturals Medicine were interviewed. This Department is under the Directorate of Curative Services.
- Quantification for the annual procurement plans is informed by many factors, including patient numbers, wastage and EQAs proportions also included.
- Supervision is performed at facility level by the National/Regional teams.
- Supply planning reviews are done quarterly with the aim of ensuring a 3-month stock-on-hand supply.
- There is a warehouse online report providing real-time information.
- All public commodities are supplied through NMS while JMS supplies commodities to PFNP.

Challenges

- There is a gap in accessing good quality, complete, and real-time data.
- Diagnostic capacity is reported to be over stretched e.g. Xpert over utilized.
- Funding for commodities-: TB preventive therapy in line with the WHO new recommendation, (Shorter ones- Gap in procurement- 4 million US dollars- Gap)- Currently running a donation for 50% from USAID. Similar Picture for the First Line treatment- No funding for the 4 months regimen, hence Uganda is still using the old and long regimen. DR- TB is well funded- roll out for this expected in November 2024.
- Long Procurement lead times: Distributions challenges- warehouses employ reimbursement mode (supply 3 times a year from the previous 6 times a year due to constraints in the funding). Facility can be understocked for close to 6 months. – MOH has engaged the Implementing partners to support the last mile delivery and ensure logistics redistributions.
- Central level stock- No Adult- RHZE and RH is stocked out at NMS, Pediatric formulations are available and the Scarcity of rifampicin globally- GDF- production is slowing down- active ingredient is limited. Orders placed with GDF.
- It has been noticed that LF-LAM tests have been misused by testing sites, and CRP for TB screening may be used for other testing than TB.

Recommendations

- To secure funds and implement the TPT regimen and shorter DS-TB regimen.
- To implement the shorter MDR-TB regimen.
- To monitor the use of LF-LAM and CRP, link to TB case finding for better planning.
- To use data, targets and check with goods at a storage facility.

5. Uganda Stop TB Partnership (UgSTP)

Key findings

- Uganda STP has around 200 members, supports CSO and private health facilities. It covers 13 districts including around 5 to 8 facilities per district. Its mandate is typically related to CSO (through monthly meetings), community and resource mobilization for TB. They are not only involved in the community-based activities but also in the outreach activities during World TB Day. On quarterly basis, STP staff participates in the supervision visits along with the NTLP in public and private sectors, including the lab facilities where STP is involved in supply chain management with distribution of reagents and consumables.
- On the advocacy, UgSTP interacts with different leaders, including MPs through caucus and is also involved in sample collection and referral system at community levels. On a quarterly basis, UgSTP convenes a meeting with CSOs and collects the update on the ongoing activities with KPIs through data reporting.
- It supports the umbrella of civil service organizations in the TB cascade, it offers support for 13 private health facilities mainly in advocacy related to increasing access and the uptake of TB services. The package includes support supervision to these facilities and can also provide logistics redistribution to drum up access to TB diagnostics services.
- Beside the UgSTP closely works with CSO and communities in strengthening TB case finding, it does not have data on the whole cascade of a TB case starting from case finding to the screening, testing, treatment and care.
- Also, the collaboration between CSO on TB and HIV seems not to be strong nor visible.

Recommendations

- To establish a link of collaboration between CSOs and the community on HIV and TB.
- To establish a mechanism that can track a case across the whole cascade from screening to treatment and care.

6. The AIDS Support Organization (TASO)

Key findings

- The teams discussed the assessment of Uganda's TB diagnostic network, focusing on challenges, interventions, and the roles of TASO in supporting treatment success.
- The discussion focused on the objectives, strategic priorities, and interventions, including contact tracing and food support for MDR TB patients.
- The teams further had a meeting on the selection focus on long-term impact and funding challenges.
- TASO has existed since 2018 and is involved in MDR treatment initiation through facility-based identification and notification, Regional Mechanisms support National TB management efforts through patient pick up and facility support.
- The teams discussed the TB treatment adherence challenges and food support for the MDR-TB patients, TB contact investigation and intensify screening in communities.
- The TASO team also highlighted the support they offer to 17 hospitals including also their involvement in creating awareness around the TB commemorative events during which screening for TB is provided.
- TASO functions under two schemes: PEPFAR funded and GF grant support, where MDR falls. As challenges, the cost of MDR is higher than sensitive TB, hence many challenges with DR-TB funding availability to improve quality.
- TASO is looking at innovative ways to empower the community in generating their income and address the issue of food availability and sustainability. However, not much progress has been made.

Recommendations

- To establish innovative solutions allowing the community to generate income for RR/MDR-TB patient support. This should apply also to DS-TB patients.

7. WHO meeting in TB Cascade

Findings

- WHO Uganda office expressed the need of being involved early enough in the preparation process of TB DNA to be able to commit for that.
- WHO has supported the country to ensure alignment with the NSP strategy focusing on the uptake of the new WHO molecular diagnostics to a current performance target of having 100 uptakes of the new WRD tests in all TB testing centers- (Use of Molecular tests as one of the initial diagnostics tests in the TB cascade); now Uganda is at 70% of cases using WRD as initial diagnostic test.
- Assessment in the uptake of the molecular diagnostics tests- results disseminated. reviewed bottle necks around having real time TB treatment since not all sites were GeneXpert sites and rely heavily on a functional TB sample and results transport network.
- WHO supported the roll out of the SOS (Single step test for stool) through the TIFA grant- challenges were noted in accessing funds to scale this up.
- Under reporting for the GeneXpert data in the different regions. Challenges were noted in TAT especially in sites that do not have a GeneXpert machine delaying the real time initiation of treatment. Those sites cannot implement the policy of using Xpert as an initial diagnostic test for presumptive TB. Those sites are using microscopy while transferring samples to Xpert sites for RR, and meanwhile start the treatment based on microscopy results if positive. With this sample transport system using hub spoke, results are not necessarily back to sending sites quickly, which is a challenge.
- WHO has done a study that indicates 20% of the clients die within the first 2 months of starting treatment indicating late initiation on Treatment for the clients. TAT is done differently for Xpert sites versus non Xpert sites.

Recommendations

- To involve WHO Uganda office in addressing TB Diagnostic challenges when needed and at the earliest stage. This will allow WHO Uganda office to coordinate with the implementing partners for a better outcome.

Site Visit E: Kampala B

Team E: Assessors: Andwele Mwansasu, Moses Katagwa
Observers: Faith Lydia Alikoba, Prof. Moses Joloba

Key findings

- Dedicated and motivated staff at all levels
- Accredited labs performed better than non-accredited ones.
- Laboratories report aggregate numbers to the Kampala City Council Authority and the TB program.
- Most sites reported having funding for diagnostic services, but the budget is not specific for TB diagnostics. Facilities (Private, not-for-profit) benefit more when they have implementing partners to support them.
    - One public clinic asked patients to buy face masks.
- TB testing services are available and accessible in public facilities at no cost, but not in private for-profit facilities. X-ray services are free for children in public facilities but not always for adults.

- Laboratories know their roles and responsibilities, although not all have written documentation.
- TB laboratory services are decentralized to the community level and are well implemented, especially in private, not-for-profit facilities.
    - Some private not-for-profits have Community-owned resource persons (COP) with a community focus and community linkage facility officer who is facility-based and implements Intensified Active Case Findings.
- Triple packaging is available, although not consistently used at all visited facilities; some reported stockouts of triple packaging material in the past year.
- Efficient specimen transport via the 'HUB system': Some facilities had a QR code to scan samples at pickup.
    - One of the hub riders (at Nsambya police station) commented that sometimes, the referring facility takes longer to get results due to the high workload at the GeneXpert site.
    - Microscopy sites also reported a long turnaround time.
- A current list of labs and facilities in the TB diagnostic network is available in some facilities- but not a GPS-based map of their locations. Facilities have backup plans for sample testing in case of machine breakdown.
- All persons with presumptive TB are offered an HIV test and referred to HIV counselors as needed, except for private facilities.
- Facilities do not have up-to-date National TB Algorithms. Most staff (public and PNFP) know the new guidelines, and some have soft copies.
- One site had two of the four GeneXpert modules functional; the site prioritizes adult samples and stores children's samples.
- Stool testing is not implemented at all sites.
- Private hospital clinicians do not follow recommended diagnostic algorithms, and there is a linkage to care.
- The private hospital is not able to follow up with contacts of confirmed TB patients and internally displaced people after repatriation.
- WRDs are available for all persons, depending on functional GeneXpert /Truenat on-site.
- Waste management is generally implemented with an autoclave mostly or through private vendors.
    - One facility (Murchison Bay) burns its cartridges.
- Biosafety cabinets are functional but not serviced at one of the visited facilities.
- Clinic and laboratory staff regularly screened for TB except at Nsambya police station.
- Stock out of LF LAM reported at one site, XDR cartridges at one site, and INH.
    - Pediatric formulations are near expiry (November 2024) at two facilities.
- Most staff received general training but lacked refresher training. Facilities have CME sessions for all staff, during which TB is discussed sometimes.
- Human resource shortage at public facilities.
    - Kampala City has secured a new health structure (which still needs to be in effect), and the number of staff per health facility will increase.
- Diagnostic connectivity solutions are implemented at all sites, but there is insufficient funding for IT infrastructure and systems (e.g., LIMS). Also, some reported connectivity challenges.
- Standardized reporting forms are used for all TB tests. Laboratories send results via printed copies and record them in lab registers.
- Laboratories receive feedback from supervisory visits, but reports are not left behind, and some corrective actions have not been implemented.
- Laboratories participate in EQA (Xpert and microscopy) and always get feedback.
- Consistent reporting from all levels on TB or DR-TB case detection to the local TB control program. Facilities also analyze their own data for improvement.

Recommendations

- Disseminate the updated TB diagnostic algorithms to all facilities.
- The TB program should actively engage senior consultants and hospital executives, such as the head of medical services. Their involvement can bring valuable expertise and leadership to the program, as seen in other successful health initiatives like malaria and cardiology.
- Upgrade GeneXpert machines for high workload (for example, Nsambya Police) labs to 16 modules machines and provide microscopy sites with WRDs. This upgrade can significantly improve the efficiency of TB testing, especially in facilities with a high patient load.
- Ensure continuous availability of triple packaging materials and other supplies.
- Facilities to take advantage of the mobile van to screen healthcare workers and conduct outreach services as needed.
- Provide waste management services to all facilities.
- Ensure all biosafety cabinets are periodically serviced.
- Strengthen supportive supervision by leaving documentation for follow-up.
- Most interventions are not best suited for the Kampala city context, where 99% of facilities are private. Assessments (such as this one) must consider Kampala's uniqueness in developing the tools.
- Government /MOH and Ips to increase the number of staff in public facilities to bridge the gap on work overload and reduce the TAT.
- Support more labs for accreditation.
- KCCA has cluster models staffed by a designated cluster operation officer. The officers follow up with the facilities in their clusters daily (HIV-specific). We can have a similar model for TB or even include TB screening in drug shops/pharmacies where patients first seek care.

Site Visit F: Karamoja

Team F: Assessors: Amos Kutwa, Simon Peter Eladu, Joyce Mbogo, Isaac Newton Okeba, Fontiano Korobe

Key findings

- Karamoja Region boasts of a well-structured TB Diagnostic network, starting from the community to the Level 6 health care system thus forming an essential component of the health care system.
- The network for TB care in Karamoja is spearheaded by a competent RTLS, with exceptional organizational and communication skills. We found dedicated healthcare workers at all levels. All had the requisite skill set to perform the TB care work. In most health facilities, the number of laboratorians was sub-optimal with some labs being operated by one lab assistant or technician.
- There was universal availability of WHO Recommended rapid molecular Diagnostics (mWRD). There were GeneXpert Ultra instruments in Health Centre Level 4, level 5, and 6 hospitals. Moroto Prisons Health Centre level III has a 10-color GeneXpert machine. TB LAMP machines in level 3 HCs besides microscopy and LF-LAM. Chest X-Ray in Matany Hospital, Kaabong Hospital and Moroto Regional Referral Hospital. The X-ray unit in Moroto Regional Referral Hospital was out of order during the assessment but with a functional CT scan. Patients requiring X-rays were referred to Matany Catholic Mission Hospital, a Private Not-For-Profit facility.
- All the TB clinics visited had TB guidelines, hard copies and soft copies, algorithms, and job aids. However, these were old versions (2019). District TB leprosy Supervisors (DTLS) had the current TB diagnostic algorithm (soft copy), courtesy of the RTLS. Hard copies have not been disseminated yet. There was evidence of training Laboratorians and clinicians on TB care in general.
- Karamoja has a robust Sample Referral System (SRS) in place. There are 9 Hubs in total: 6 main and 3 minors. SRS guidelines and SOPs were available. SRS is funded mainly by PEPFAR through implementing partners (PACT Karamoja, CUAMM, and USAID LPHS Karamoja & LSDA/UPMB), Global Fund, and the

Government of Uganda. SRS is well monitored, with site barcodes, and lists of facilities available, and handles all specimens including TB and HIV. SRS is an integrated specimen referral system using Motorcycles.

- Internal Quality Control (IQC) and External Quality Assurance (EQA) are regularly done in the visited health facilities. Including GeneXpert panel testing, Microcopy IQC, and HIV proficiency testing. The regional and national levels perform regular support supervision of the health facilities.
- Biosafety practices and SOPs were available in most of the labs visited in the three districts. National biosafety guidelines for TB laboratory services are available. The labs have appointed biosafety officers in place. Regular biosafety refresher trainings are held through CMEs.
- The roles and responsibilities are well documented.
- Waste segregation is done in all facilities visited in the districts. TB waste disposal guidelines were available in most if not all health facilities visited. Incinerators are fenced burn holes in some of the facilities we visited.
- Functioning Biosafety cabinets were at Moroto Regional Referral Hospital and Matany Hospital. BSC2s are certified and maintained regularly.
- Reliable power supply in Moroto RRH and Matany Hospital with backup generators. Nabilatuk HC IV does not have an electricity backup. Level 4, 3 & 2 HCs are connected to the national power grid, they however do not have reliable power backup.
- Service level agreement exists for the GeneXpert machines, service and repair for the other equipment like microscopes by regional equipment workshops. There is an established GeneXpert connectivity through the LabXpert system.
- Karamoja has had TB commodities, including GeneXpert cartridges in stock for over a year. Short expiry of the TPT regimen in the region. Clinical and laboratory staff meetings are regularly held to discuss performance. The team noted a malfunctioning Fluorescent Microscopy (FM) at Matany Hospital. TB LAMP is out of use at Lopeei HC III due to power interruptions and no solar backup.
- Simple one-step SOS) (Stool GeneXpert analysis) was done at Moroto RRH, Matany Hospital, and Nabilatuk HC IV. Other facilities refer samples through the hub system.
- TB/HIV integrated services were available in most of the facilities, with the provision of TPT using 6H and 3HP targeting health workers, TB contacts, and Prisoners (plus prison staff). HIV testing services for presumptive and notified TB patients are available. LF-LAM was rolled out in all ART-accredited health facilities visited.
- Presence of Community Health Workers/Volunteers that support the triaging of patients at facilities, recording, sample collection, contact tracing, patient linkage to treatment, and delivery of medicines.
- There is good documentation in the laboratory registers, and the existence of electronic data systems for reporting TB and TB/HIV diagnostic data; all mWRD sites have functional data connectivity solutions (LabXpert) that support real-time monitoring of equipment and for electronic transmission of results to clinicians through SMS and/or e-mails.
- Strong collaboration with private facilities (PNFPs - Matany Catholic Mission Hospital, St Pius Kidepo HC). This has improved TB case finding through these sectors.

Challenges

- Inadequate budgetary allocation for TB control activities for RTLS, DTLS, and DLFP.
- No power backup in Nabilatuk HC IV, Kotido Hospital, and Level 3 & 2 HCs.
- Nabilatuk HCIV has limited laboratory space.
- Service level agreement exists for the GeneXpert machines, service and repair for the other equipment like microscopes by regional equipment workshops.
- Malfunctioning FM at Matany Hospital.
- TB LAMP is out of use at Lopeei HC III due to lack of power backup systems.

Recommendations

- NTLP to disseminate new TB guidelines, algorithms, and other sensitization materials to HCWs (especially in TB care).
- Continue with cross-border TB care activities to ensure case holding is optimum among pastoralists (TB Manyatta) on either side of the Uganda-Kenya border.
- MoH to ensure optimization of staff establishment, especially at HC levels 2 and 3.
- Need for the country to implement the new schemes of service for the laboratory human resources.
- NTLP/MoH to provide VHT with transport preferably bicycles as an enabler.
- Improve Laboratory infrastructure design.
- Ensure all hub sites have a backup power supply.
- Make every district, especially in the Karamoja region a hub of its own, especially Karenga, Amudat, and Nabilatuk.
- Improve on structural design for Nabilatuk HCIV laboratory.
- Ensure there is adequate quarterly budget for laboratory supervision and mentorship by the RTLS, DLFP, and DTLS.
- Plan for TB culture DST lab requirements at all RRH including but not limited to the following:
    - Biosafety level 3 (BSL-3) facilities to handle potentially infectious materials.
    - Trained personnel with expertise in microbiology and molecular biology.
    - Specialized equipment: (Autoclave, Incubators, Microcentrifuges, Vortex mixers, Pipettes, Biosafety cabinets).
    - Culture media and reagents: (Lowenstein-Jensen (LJ) medium, Middlebrook 7H10/7H11 medium, Antibiotics and drugs for susceptibility testing).

Site Visit G: Kigezi

Team G: Assessors: Wayne Van Gemert, Kakeeto Patrick
Observers: Benjamin Niringiyimana, Raymond Byearuhanga, Emmanuel Tibenderana, Mbonye Andrew

Key findings

- Wide access to rapid molecular testing (Xpert) with Riders network generally performing well (at least 2 times weekly pick-ups); private and penitentiary facilities included in the network.
- Dedicated workforce at many sites, including lab staff and clinicians.
- GeneXpert machines are mostly functioning well, even in remote locations, with solar power and battery solutions.
- Strong integration with HIV program.
- Multi-disease testing on GeneXpert instruments for HIV EID, VL, HPV.
- Wide use of stool testing on GeneXpert, LAM testing.
- No microscopy reagent stockouts.
- Strong EQA system for all tests.
- Engagement of network of Village Health Teams (VHTs) / linkage facilitators for contact tracing and specimen collection.
- System of quarterly supervision from district and national level.
- Significant procurement and supply management challenges.
    - Irregular deliveries from NMS leading to stock outs (e.g., Xpert cartridges, LAM tests) followed by overstock of commodities with limited remaining shelf life.
    - Xpert cartridges delivered to sites without GeneXpert (2 instances described).
    - Poor quality sputum containers.
    - Lack of standard TB requisition forms.

- Very limited or no access to free X-ray (+ no CAD; rare mobile vans).
- Clinicians are not always trained on the latest algorithms (e.g., INH testing for patients failing at 2 months, Xpert Ultra Trace results, LAM criteria, Xpert MTB/XDR).
- Private sector clinicians and lab staff lack access to training.
- Limited or outdated hard copies of algorithms (pre-Ultra), guidelines, job aids.
- SOPs on all topics are often insufficient or out-of-date.
- Some referring sites are not yet able to send stool for Xpert testing.
- LabXpert is not being used to its full potential: clinicians waiting for paper copies of results, patients not informed, no district supervision.
- Service and maintenance shortcomings; reliance on central cadre of engineers.
- Sample transport packaging improvised.
- Inadequate biosafety putting health of lab staff at risk
    - BSC without replacement filter for year+ at RRH; one hospital with unused BSC; one hospital with innovative homemade ventilation hood.
- Absence of MTB infection testing (skin tests/IGRAs).

Recommendations

- Perform comprehensive root cause analysis to understand NMS delivery challenges; improve communications between facilities and NMS regarding what will be delivered & when.
- Increase access to free digital X-ray at health centers; introduce CAD; increase number of community/penitentiary screening events using X-ray/CAD to find TB earlier; free X-ray/CAD can also exclude active TB among contacts before TPT.
- Provide trainings/CMEs for clinicians + lab staff on new algorithms/tools, include private/penitentiary sector; avail of Zoom and widely disseminate recordings.
- Ensure hard copies are made available of updated algorithms, guidelines and job aids; include requisition forms in NMS.
- Fully capacitate cadre of regional engineers to provide preventative maintenance and repairs of all equipment; ensure budgeted national maintenance plan.
- Ensure adequate funding for the Rider's network including for backup riders.
- Sensitize/allow clinicians from all referring sites to send stool for Xpert testing.
- Plan for use of 10-color modules to detect INH and FQ resistance for all TB patients using Xpert MTB/XDR (at minimum RR-TB + TB patients failing treatment at 2 months): ensure clinicians at all sites are sensitized.
- Integrate VHT/linkage facilitators with HIV program, to improve reliability of funding
- Integrate digitalization of specimen referral system with HIV program, to improve specimen tracking and monitoring of TATs.
- Capacitate district lab officers and regional lab supervisors to monitor LabXpert, including GeneXpert site utilization and LabXpert's use by lab staff (e.g., sending SMSs to clinicians and patients) to maximize its benefits.
- Strengthen laboratory biosafety
    - Equip all hospitals with BSCs and ensure proper maintenance.
    - Ensure availability of N95s and triple packaging through NMS.
    - Train lower-level lab staff on safe practices (e.g., not facing incoming breeze from open windows when preparing smears) and supply window exhaust fans.
- Introduce new technologies for MTB infection testing: MTB-antigen specific skin tests or near-POC IGRAs when available.

Site Visit H: Lango

Team H: Assessors: Willy Ssegooba, Thomas Shinnick
Observers: Henry Byabajungu, Okao Ben

Key findings

- Dedicated knowledgeable staff.
- Xpert for all presumptive TB except in a few remote areas which still rely on AFB smear microscopy.
    - Immediate reporting of Xpert positive results by SMS.
- Most sites have adequate numbers of staff.
- Effective specimen transport system (Rider/Hub system) in many districts although ADHO estimated that about 30% of districts had issues with specimen referral.
    - System of tracking specimens is weak. Informing the referring laboratory of receipt of samples in the referral laboratory.
    - Issues with timeliness of pick-up schedule.
        - Samples collected on Tuesday may be "spoiled" before pickup on Friday (lack of refrigeration at some sites).
- Community health workers play important roles in facilitating linkage to testing and linkage to care.
- Mobile vans with chest X-ray and Xpert are used to extend services to the community level.
- Excellent integration of TB and HIV services. Many sites were one-stop shops.
- Some sites were using HMIS Lab form 004.
    - This form does not capture required information, e.g., HIV status.
    - Form 004 relies on manual entry, very few tick boxes.
    - Note that the nationally approved TB request form is quite good. Has been out of stock since May.
- Training in the TB algorithm was rarely reported, but the algorithm is followed by almost all clinical and laboratory staff.
- Lack of sensitization materials, posters, job aids, etc.
- Multi-disease testing is common but beginning to affect TB testing.
    - At one site there was a refrigerator full of samples waiting to be tested.
- Data routinely collected but limited analysis of data at the laboratory, district and region.
- Many sites did not routinely monitor performance indicators.
- Aggregate data reported to national level. Data available to local level by request.
- Little documentation of procedures was observed. Few facilities had written terms of reference or document control systems.
- Health screening of lab workers is rarely done.
- Emergency plans were infrequently available; most often were informal arrangements.
- Local Xpert sites are not taking advantage of the capabilities of diagnostic connectivity.
- Issues with (airflow, power) and biosafety observed at some peripheral sites.
    - At one site Xpert cartridges were burned in open pits.
    - One site had solar power that was sporadically non-functional.
    - TB Biosafety manuals were not available in most facilities.

Recommendations

- National program to distribute national TB request forms and ensure that local facilities use the national TB form.
- Ensure that laboratory and clinical staff are well-trained in the TB diagnostic algorithm and provide copies.
- Screen all TB workers at least annually for signs and symptoms of TB and document in personnel files.

- Ensure that local, district and regional facilities could analyze data and use it to identify problems and improve performance.
- Develop and implement a strategy to optimize the use of GeneXpert instruments with respect to multi-disease testing and ensure adequate capacity for TB testing.
- Ensure that Xpert testing sites are trained to take full advantage of diagnostic connectivity.
- Improve tracking of specimens. Implement a process to inform referring laboratories of the receipt of specimens.
- Ensure that all laboratories have written continuity of operations plans.
- Distribute national SOPs for TB testing, provide training as needed.
- District Laboratory Fiscal Person to work with laboratories to improve documentation of policies, procedures and processes in laboratories.
- Distribute TB Biosafety manuals to all facilities.

Site Visit I: North Central

Team I: Assessors: Ann Masese, Germine Nakayita
Observers: Abdunoor Nyombi, Tadeo Iga, Stephen Mutyaba, Joy Mary Kasumba

Key findings - Strengths

- Clinical and laboratory staff were well versed with the National policies and procedures of the TB program; only 27% of the visited sites had staff not versed with the policies and procedures.
- Strong collaboration between the TB/HIV programming; screening, testing and linkage to treatment and care.
- Availability and implementation of the TB Preventive Treatment (TPT) national guidelines.
- Multi-disease testing was done for GeneXpert: MTB/RIF, HPV, HIV Viral load HBV viral load (only Regional Referral Laboratory) and EID.
- mWRD tests were available and offered for free in all facilities visited on site or by referral.
- System in place to track samples and results; paper based and electronic system (QR codes for 2 Hubs; Mukono and Kayunga RRH) in 80% of the visited sites.
- Data is routinely analyzed and used for decision making (graphs, percentages and charts).

Key findings - Challenges

- Availability of TB diagnostic algorithm in most health facilities; however, outdated. Despite this, most Staff interviewed were well versed with the requirements.
- X-ray services were not available in all public facilities visited; however, it was available at the Bombo General Military hospital free of charge and at the PNFPs at a cost.
- Knowledge gap in test Internal Quality Control (IQCs) for all tests in 70% of the facilities visited. In addition, one facility didn't know how to access their Xpert EQA feedback reports.
- Knowledge gap in Internal Quality Control (IQCs) for all tests in 70% of the facilities visited.
- Poor documentation of TB testing; TB register HMIS TB010 was available but not consistently used in some of the facilities visited to document results.
- Lab staff had no documented competence-based training in TB diagnostics, safety and quality; specifically, those in the lower tier and not implementing Quality Management Systems (QMS).
- Sample referral system is in place; however, some spokes reported long TAT >1 week.
- LMIS available in all Xpert testing facilities (installed in the machines but not connected to the network); however, it was not implemented.
- Implementation of LF LAM; however, there was a stock out of testing kits in some facilities and PNFPs visited.

- Under-utilization of the 16 modules GeneXpert Machine at Bombo General Military Hospital for drug resistance testing.
- DRTB management is not provided in the regional referral hospital; referrals made to Mulago or Jinja.
- Some facilities had limitations in power back-up systems supporting the Xpert machines: cartridges are wasted in the process.
- Stock out of triple packaging materials e.g., cotton and Zip lock bags.
- PNFPs had challenges with equipment maintenance; biosafety cabinets (flagged red yet still being used in testing) and GeneXpert servicing.
- Regular support supervisory visits are performed; however, there were no records and feedback reports for some facilities specifically maintained in the laboratory.
- Standardized TB testing request form (HMIS TB 002) was not used in some facilities. Patients present books for every lab test request.
- No corrective actions conducted and documented for unsatisfactory EQA performance.

Recommendations

- Disseminate the current guidelines/TB diagnostic algorithm to all health facilities and conduct sensitization.
- Strengthen Internal and External Quality Assurance of TB testing services in lower facilities through training.
- Operationalize all the certified DRTB management units / decentralize DRTB services.
- Conduct competency-based training for all health workers involved in TB testing and treatment.
- Maximize usage of the Xpert/XDR testing capacity at Bombo General Military Hospital.
- Capacity build laboratory staff in troubleshooting of labXpert connectivity solution.
- Collaboration with PNFP's to solve challenges with equipment maintenance.
- Enhance the use of TB HMIS tools through distribution and training of health workers in the use of the tools.
- Distribution of power backup systems (UPS, solar batteries) to avert cartridge wastage and prevent interruption in testing.
- Increase access to chest X-rays.
- Strengthen supportive supervision; document corrective actions and incorporate a continuous quality improvement approach in support supervision.

Site Visit J: South Central

Team J: Assessors: Zilma Rey, Fasil Tsegaye Kassa, Carol Asiimwe Mutabazi
Observers: Grace Nantege, Kenneth Musisi

Key findings

- Availability of WRDs at respective laboratory tiers for TB diagnosis. GeneXpert Ultra found at all Xpert sites and multi disease testing for HIV, HIV EID, HIV VL and HPV at Rakai hospital and Masaka RRH. LF-LAM used at all sites.
- Enrollment onto TB EQA schemes (blinded rechecking for microscopy and Xpert panels for Xpert Ultra).
- Integrated specimen referral system using the national sample transportation network (hub system). In Kalangala district, the hub system is only on the main Island and not on other smaller islands which rely on boats to refer samples.
- Wastage of Xpert cartridges (test aborted, no result test outcome) during power fluctuations; Xpert has no back up batteries.
- Use of outdated and incomplete documents such as SOPs, job aids and manuals.

- Under-utilization of the private sector (PFPs) for TB diagnosis.

Recommendations

- Supervisory feedback reports should be filed in the laboratory for root cause analysis and corrective action.
- Procure back up batteries or Uninterrupted Power Source (UPS) for Masaka regional referral hospital.
- Sensitization of facility clinicians on the specimen types that can be analyzed on Xpert Ultra for pediatric and extra pulmonary diagnosis.
- Training of laboratory personnel on SOPs development, review and operationalization.
- Expand Xpert usage to PFP facilities.

Site Visit K: West Nile

Team K: Assessors: Hebert Mutunzi, Joseph Nturo, George Lukyamuzi
Observers: Dr. Harriet Nakigozi, Henry Bediic

Key findings

- The government provides funding for human resources, servicing of equipment, and laboratory infrastructure. Some health workers are supported by implementing partners and this resulted in an improvement in the staffing levels although shortages were reported in 5 of the 8 facilities visited.
- TB and HIV diagnostic services are offered free of charge except for X-ray services which are mostly available in the private sector for a fee.
- National policies, guidelines, request forms, logbooks, SOPs were available but not at all levels. There were no hard copies of the current TB diagnostic algorithm distributed in 2024. Available policies and guidelines are not fully implemented at all levels of the diagnostic network.
- There is a well-defined structure with the region offering a wide range of services; administrative and technical oversight in the region with strong partner support at the regional level such as Infectious Disease Institute (IDI) which supports diagnostic activities and human resources.
- A specimen referral system (SRS) exists through the Hub system operating in all districts covering most public and including private facilities. Sample tracking system is mainly paper-based but is being implemented very well in Koboko District using the QR-coding system. However, this is done per batch of the specimens shipped to the testing hub and not individual specimens.
- All facilities visited had the older versions of the TB diagnostic algorithms. Ordering of tests being done according to the policy; pediatric TB algorithm was available in all facilities and the Simple One-Step (SOS) stool testing is being implemented mainly at GeneXpert sites.
- Waste management and personal protective equipment were available and in use for all facilities visited. Color-coded bins and bin liners were available, and most facilities had access to an incinerator in addition to green label picking highly infectious materials that cannot be burnt within the region. Similarly, cleaners were available to pick waste from different service points to the storage area awaiting final disposal.
- Most HCIII laboratory buildings are old and do not meet the national laboratory building standards; Bio-safety manuals were not available in all facilities; health screening/medical evaluations are irregular or non-existent to laboratory staff. Power back-up systems were either insufficient, unavailable or malfunctioning at several of the (6/8) facilities visited.
- The National Equipment Calibration Centre conducts calibration services of most equipment. There is also a service and maintenance plan for the GeneXpert instruments through a Service Level Agreement (SLA) with Cepheid. The regional workshop is used for servicing, repair, and maintenance of all other equipment. However, servicing and maintenance schedules were not regular.

- Ordering of reagents and supplies is done on a bi-monthly basis but it was reported that the National Medical Supplies (NMS) does not always meet the distribution cycles resulting in shortages and over-stocking when the deliveries are made. Shortages of sputum cups and Xpert cartridges were reported during the Community Awareness, Screening and Testing for TB (CAST-TB) campaigns which also resulted in some specimens being discarded.
- The staff that was interviewed was dedicated and very knowledgeable. However, many facilities reported a lack of refresher training for staff and that there was not a system in place to assess and document the competency of staff. Trainings are conducted through the Continuous Medical Education (CMEs) but not competency-based for all staff. Competency-based assessments are not always being conducted with noted gaps in the majority (6/8) of the facilities visited. Overall, re-licensing of the laboratory practitioners is also not based on the same.
- Standard laboratory request forms were in use but not available at all facilities (Yumbe HCIII and Koboko District Hospital). At Oluvu HCIII, health care workers use patient cards/books to order and report results. There was also no documented evidence on trainings on the use of the LabXpert DS data connectivity system. In addition, monitoring of the quality performance indicators is not happening at HCIIIs.
- TB and HIV services are offered free of charge; with a strong collaboration between the TB and HIV programs; multi-disease testing being implemented on the GeneXpert platform. LF-LAM is available but is not used for all recommended categories of patients; there is also a shortage of standard requisition/report forms.

Recommendations

- The Ministry of Health should implement a human resource scheme of service to recruit, deploy and retain the skilled laboratory staff including clinicians at all levels of services including the community level.
- Provide budgets to enable regions to conduct regular supportive supervisory visits to all labs in the region and procure basic laboratory supplies.
- Scale up digital X-ray and CAD in all districts to improve TB case detection and build capacity of health workers in the use of X-ray and interpretation of X-ray results for TB diagnosis in addition to Integrating of X-ray screening and laboratory testing by pairing mWRD platforms with X-ray screening to ensure same day diagnosis and treatment initiation.
- Expand the hub system to all public (HC II's) and private clinics that offer TB screening, and specimen collection. Implement the electronic sample and results tracking system (RESTRACK) to all districts and facilities in the region including the private facilities.
- Decentralize XDR testing to district laboratories (even though DR-TB management is centralized to regional level) by deploying more 10-color module GeneXpert machines. Use the results from the TB-Drug Resistance Survey to prioritize the deployment of these equipment to increase INH-resistance testing for all RIF-susceptible cases identified.
- Deploy higher throughput GeneXpert machines to cater for surges in test volumes, e.g., during the CAST-TB campaigns.
- Print and distribute the current national diagnostic algorithm and conduct sensitizations/trainings of health care workers.
- Implement the National Laboratory Infrastructure Guidelines (2021) especially at HCIII and HCIV to ensure the building lay-out/designs of the laboratories meet the minimum standards for biosafety, biosecurity, fire safety and chemical safety. These guidelines clearly provide guidance on the minimum space requirements to assure quality services in laboratories at the different levels based on the staffing norms and the prescribed testing menus for these levels.

- Print, distribute and train laboratory staff on the Biosafety manuals to make sure they are followed and implemented in all facilities. In addition, health care workers should receive health screening/medical evaluations on an annual basis.
- Develop a comprehensive training plan for all health workers on TB diagnostic procedures; and continue updating the health workers through the CME session; conduct annual competency-based assessments as a condition for re-licensing of the laboratory practitioners.
- Print and distribute standardized test requisition forms to all facilities and capture all indicators; install and implement digital connectivity solutions at all levels including the ARRH which supervises other facilities.
- Establish a system that mandates all laboratories to monitor and report key performance indicators on a regular basis. The system should ensure all staff are trained using all feasible methods (physical or virtual).
- There is a need for a wide-ranging and quality assurance program to be implemented to enable Laboratories to achieve and maintain high levels of accuracy and proficiency in testing, to ensure the reliability and reproducibility of results, and thus to influence confidence in clinicians and patients who are users of the laboratory services.
- TB LF-LAM should be used according to the national policy and algorithm for the recommended categories of patients according to global standards.

Annex 6. Improvements in the TB Diagnostic Network of Uganda since the 2019 Assessment

An assessment of the TB Diagnostic Network of Uganda was conducted from August 25 to September 6, 2019. The assessment covered the NTLP and other stakeholders at the national level, the NTRL, 9 Regional Referral Hospitals, 11 PNFP hospitals, 3 General or District hospitals, 3 PFP hospitals, 1 clinic, 1 academic hospital, 9 HC IIIs, 2 Prison HC IIIs, 1 Police HC III, 5 HC IVs and 2 Military HC IVs for a total of 49 facilities in 10 geographic areas to inform the assessment. Regions, districts and facilities were selected by the NTLP and NTRL with the aim of including a range of laboratories at varying levels of the health system including private sector and non-governmental organization TB diagnostic facilities.

Team	Region	Facilities Visited
A	Arua	RRH, District hospital, HC III, PNPF hospital, HC IV
B	Gulu	RRH, PNFP hospital, Prison, PFP hospital
C	Moroto	RRH, PNFP hospital, PNFP HC III, HC III, Military HC IV
D	Soroti	RRH, PNFP hospital, HC IV, HC III
E	Mbale	RRH, PNFP hospital, PFP hospital, HC III, HC III, HC IV
F	Jinja	RRH, HC III, Prison HC III, HC IV
G	Kampala	NTRL, HC III, PNFP hospital [2], General hospital, PFP hospital
H	Masaka	RRH, Police HC III, HC IV, PNFP hospital, General hospital, clinic
I	Mbarara, Bushenyi	RRH, UPDF HC IV, HC III [2], PNFP hospital, Academic hospital
J	Fort Portal	RRH, PNFP hospital [2], HC III
	TOTAL	**49 Facilities**

The assessment utilized an assessment tool (TB-Net Tool, 2019 version) which uses semi-quantitative scoring to identify the stage of various aspects of the diagnostic network to describe current capabilities and identify key areas for improvement. The assessment team reviewed the self-assessed staging conducted by the program, visited various facilities, and consulted numerous stakeholders to assess the functionality and performance of the national TB diagnostic network from the perspective of its ability to meet the needs of the country's NSP.

Progress on the Key Findings and Recommended Interventions of the 2019 Assessment

In 2019, the assessment team identified six key findings and proposed interventions and priority actions for each. Overall, good progress has been made on each of the recommendations.

Key Finding #1:
Meeting the NSP targets will require an expansion in the use of the 2019 diagnostic algorithms that incorporate the use of Xpert Ultra and LF-LAM. The algorithm addresses laboratory aspects of the diagnostic cascade. The role of chest X-ray in the diagnostic process is not clearly described.

Intervention: **Accelerate implementation of the 2019 TB diagnostic algorithms and monitor progress**

Progress:

- The 2019 algorithm was finalized, approved and disseminated to all Facilities and Health workers were trained on the algorithm. The 2019 algorithm is being revised to include the most recent WHO recommendations for TB diagnostic testing.
- The Xpert Ultra test is the initial diagnostic test for all persons presumed to have TB in more than 90% of sites visited in 2024 and more than 93% of the interviewed clinicians order tests based on the algorithm.
- The availability of the LF-LAM test increased from 67% of sites in 2019 to 94% of sites in 2024.
- The availability of tuberculosis preventive therapy increased from 61% to 90%.
- A technical working group of experts (ACF TWG) was convened to define the role of chest X-ray in the diagnostic process.
- Portable digital X-ray instruments with CAD software are available in 17 facilities and there are 5 mobile clinics (vehicle) which have a portable digital X-ray with CAD and a GeneXpert instrument for Xpert Ultra testing. More than 20,000 individuals were screened with chest X-ray in 2022-2023. This is a good start, but more effort and resources will be needed to expand availability of digital chest X-ray and CAD software and ensure that it is used in accord with national guidelines.
- Uganda has begun to explore implementation of latent TB infection testing for detection of LTBI among household contacts over 5 years old and other high-risk groups. It will be important to pursue new technologies including MTB-specific skin tests and near-POC IGRAs that are more affordable and feasible for use than conventional IGRAs.

Key Finding #2:

The National TB Laboratory Network Manual describes a system of regular supportive supervision from the NTRL to intermediate laboratories and from intermediate laboratories to peripheral laboratories within the public sector. However, intermediate laboratories do not have the staff, resources or training needed to conduct supervision. The supervision system also faces challenges related to resourcing, focusing on technical aspects of testing, implementation and follow-up of on-site supervisory evaluation visits and blinded rechecking activities. All of which limit its impact on quality improvement.

Intervention: **Simplify, refocus and reinvigorate supportive supervision**

Progress:

- An MOH supervision guide has been developed and is in use at all levels.
- The current supervision guide covers the entire patient cascade, and the Supervisions are done jointly between the Lab and clinical teams at both District and Regional Levels.
- Resources for supportive supervision have been mobilized under government and partners (GF, USAID.CDC.GIZ, KOFIH). In 2024, 100% of the RRHs (intermediate reference laboratories) reported that they carried out supervisory visits, an increase from 72% in 2019. Furthermore, all these supervisory visits in 2024 included all elements of supportive supervision.
- About 90% of Regional and District Laboratory Supervisors reported that they carried out supervisory visits in 2024.
- Oversight has been strengthened through NHLDS and the TB Lab Network has strengthened through the Regionalization of Key TB Lab activities.
- The skills and knowledge needed for supportive supervision are being developed through trainings at District and Regional Levels (trainings held in 5 out of 17 Regions). District trainings have been done through the ACF Mechanism.
- Despite these excellent achievements and advances, only about 70% of peripheral laboratories received regular supervisory visits. More work will be needed to ensure that all laboratories receive regular supervisory visits and written feedback.

Key Finding #3:
Meeting NSP targets for rapid testing and access to DST for rifampicin will require an increase in the availability of Xpert Ultra testing and improvements in patient-important TATs. Turnaround time from collection of a specimen to receipt of results varied greatly – TAT for patients at an Xpert testing site was 2 to 24 hours whereas TAT for patients whose specimens are referred for Xpert testing was 2 days to 2 weeks. Priority actions should focus on improving access of patients to testing, shortening patient-important turnaround times (TATs) (especially time from sample collection to receipt of test result by clinician), improving linkage to care, reducing loss to follow-up and improving patient outcomes.

Intervention: **Expand the accessibility and promptness of Xpert Ultra testing**

Progress:

- The Xpert Ultra test is the initial diagnostic test for all persons presumed to have TB and 92% of sites visited in 2024 (up from 80% in 2019) had Xpert Ultra testing available on site or by referral.
- There has been an increase in the deployment of mWRDs in the Network to improve coverage and access (263 GeneXpert machines to 320 GeneXpert machines, 40 Truenat instruments and 16 TB LAMP instruments).
- The change in algorithm and increase in testing capacity has contributed to improving coverage and access to WRDs and achieving laboratory indicators for NTLP NSP, e.g., 69% of notified cases are tested by WRDs, 75% of bacteriologically confirmed cases have DST for at least rifampicin.
- The Laboratory has optimized use of Xpert machines for Multiplexing for HIV Viral Load, EID, HPV, COVID, Chlamydia, TB and Hepatitis. Multi-disease testing has increased from 23% in 2019 to 86% in 2024.
- The increase in multi-disease testing threatens to impact the capacity and turnaround times for TB testing. It will be essential to develop and implement a national strategy to optimize the use of GeneXpert instruments with respect to multi-disease testing and ensure adequate capacity for TB testing.
- The Program conducted a Spatial analysis that assesses Referral, distribution and Number of WRD machines. According to a 2019 geospatial mapping report, about 68% of the population had access to microscopy services within 5 kilometers and 26.7% patients were able to access Xpert services within 5 kilometers. WRD access improvements are documented in the most recent Laboratory Spatial Analysis conducted in June 2024.

Key Finding #4:
A clear national laboratory testing algorithm that incorporates the use of rapid diagnostics tests forms the bases of TB diagnostic services. The algorithm clearly addresses laboratory aspects of the diagnostic cascade, but it does not fully address the patient pathway from identification of presumptive patients (screening) to diagnosis and treatment. Actions are needed to quantify the gaps at each step of the diagnostic cascade and patient pathway, strengthen community engagement in the identification of persons with presumed TB and strengthen the clinician-laboratory interface and linkage to care and treatment monitoring.

Intervention: **Monitor and evaluate the entire diagnostic cascade and patient pathway**

Progress:

- Village health teams (VHTs) have been used to extend services to the community level in many regions.
- Community services were expanded by deploying five mobile clinics which have a portable digital X-ray with CAD and a GeneXpert instrument for Xpert Ultra testing.

- Community and penitentiary screening events using X-ray/CAD have been used to find TB earlier and use X-ray/CAD to assist in ruling out active TB among contacts before TPT.
- 93% of sites (up from 83% in 2019) reported formalized procedures for linkage to testing and linkage to care. However, some regions reported issues with linkages.
- One gap in the diagnostic cascade identified in the 2019 assessment was that a critical shortcoming of the integrated specimen referral system is that turnaround times (TATs) from specimen collection to receipt of results for Xpert tests through the specimen referral system may be as long as 14 days. The program has significantly reduced the TAT by increasing the frequency of specimen pickup and notifying referring laboratories of positive Xpert results by phone or digitally. Priority action to further improve TATs are listed in Capacity 3 of the 2024 assessment.

Key Finding #5:
Standardized forms are used to collect information on key quality measure indicators and performance indicators, but the data are not routinely reviewed and analyzed by the laboratory staff. Mechanisms to link and jointly review clinical and laboratory data such as regular meetings to review patient and laboratory registers are lacking. The timeliness, completeness and correctness of laboratory data reported to NTRL is not monitored and evaluated.

Intervention: **Strengthen data collection and analysis to measure the effect of interventions**

Progress:
- NTRL has worked closely together with the NTLP M&E teams to strengthen Lab M&E systems, deploy connectivity, and participate in performance reviews at all Levels.
- NTRL has piloted Clinical Laboratory Interface Quality improvement Project which demonstrated that joint review of the presumptive register, Laboratory register, and TB unit register improves Result TAT, Linkage to treatment and eventual Patient outcomes.
- The monitoring of key performance indicators has increased to being routinely done in 60% of peripheral laboratories, 75% in non-supervisory intermediate reference laboratories and 100% of supervisory intermediate references laboratories and the NTRL. Staff at all levels must be empowered to collect, analyze, and monitor key performance indicators and use that data for decision making and continuous quality improvement.

Key Finding #6:
Currently, reporting of diagnostic data for both clinical and programmatic management is primarily paper-based and there is little or no connectivity of GeneXpert instruments. Electronic data systems can facilitate patient transactions, data collation, monitoring of key performance indicators and provide actionable data to all levels of the laboratory network.

Intervention: **Develop end-to-end integrated interoperable connected systems and deploy electronic data systems across all diagnostic and laboratory levels**

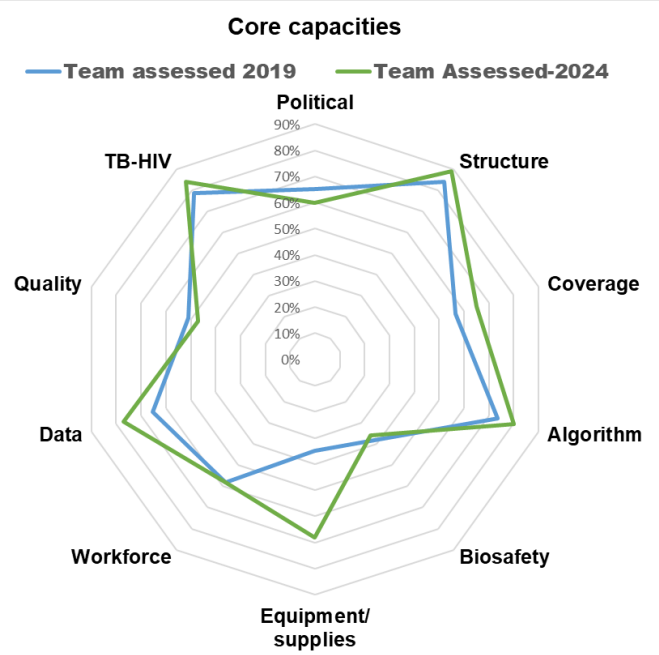
Progress:
- The use of electronic data systems to report results to clinicians has increased from 17% in 2019 to 57% in 2024.
- The use of electronic data systems to report diagnostic data to local and national program has increased from 16% in 2019 to 68% in 2024.
- The collection, analysis and use of remotely collected digital data has increased from 41% in 2019 to 85% in 2024.

- The LabXpert connectivity system has been deployed to 258 of the 290 (89%) of the Xpert testing sites and 74% (189/258) are actively using the system. The system utilizes SMS alerts to notify clinicians of results.
- There has been good progress with the rollout of LabXpert, but in 2024, it is not being used to its full potential and does not include all digital diagnostic platforms. The LabXpert system would benefit from data integration and interoperability with ALIS and Uganda EMR systems.
- The 2024 assessment noted the need for increased funding for IT infrastructure and systems at most levels, in part to ensure that data backup is done at all sites at all sites.

Comparison of Staging of Core Capacities and Components of the 2019 and 2024 Assessments

A comparison of the TB-Net tool stages assigned in the 2019 assessment and the 2024 assessment revealed that improvements in capability percentages were noted for six core capacities (in bold in the table below) with large improvements in Capacity 8 (Diagnostic Data Management) and Capacity 6 (Equipment & Supplies). Capability percentages for the other four capacity were similar in the two assessments. With respect to the components (i.e., essential functions or activities) of that make up the core capacities, the staging for 4 components declined (in red in table below; 2 because of changes to the component stages).

Core Capacity	Capability percentage	
	2019 Team-Assessed	2024 Team-Assessed
1. Political, legal, regulatory and financial framework	65%	60%
2. Structure and organization of the diagnostic network	84%	**89%**
3. Coverage	57%	**65%**
4. Diagnostic algorithm	73%	**80%**
5. Biosafety	38%	36%
6. Equipment & Supplies	35%	**68%**
7. Workforce	58%	58%
8. Diagnostic data management	65%	**77%**
9. Quality of the diagnostic network	51%	47%
10. TB-HIV	79%	**84%**



A review of the responses to the verification questions shows significant increases in capacities and capabilities related to rapid mWRD testing for all persons with presumptive TB, linkage to testing and care, TB preventive therapy, availability of LF-LAM testing, electronic data systems, monitoring of remotely collected data, use of standardized forms available for collecting laboratory statistics, and multi-disease testing.

Decreases in some capabilities and capacities were noted including the adequacy of the budget for diagnostic services, procurement (increase in stockouts), TB Biosafety, national maintenance plans for equipment, availability of competency-based job descriptions, availability of national SOPs and job aids, and the use of QMS tools such as SLMTA.