Tanzania TB Diagnostic Network Assessment

Implementation overview
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USAID Infectious Disease Detection and Surveillance (IDDS)
Presentation coverage

- Introduction/Background
- Overview of TB DNA
- Methodology for TB DNA
- Findings
- Recommendations
- Lesson learned
- Next steps
- Acknowledgment
TB continues to be a major public health problem in the United Republic of Tanzania. The country is among the 6 high-burden TB countries in the world (WHO 2020).

Is High TB Burden?  
Yes (Y)

Is High DR-TB Burden?  
No (N)

Is High TB-HIV Burden?  
Yes (Y)

Eligible for Global Fund Funding (TB or TB/HIV)?  
Yes (Y)

Participates in GF Strategic Initiative to find missing people with TB?  
Yes (Y)

Active national TB MP Caucus?  
Yes (Y)

National StopTB Partnership?  
Yes (Y)

Estimated people who developed TB. Among them 22,000 were children.
Limited access to diagnostics remains a challenge

- The country has adopted WHO-recommended diagnostics, including AFB smear Microscopy, Xpert Mycobacterium tuberculosis (MTB)/RIF, line probe assay (LPA), and culture.

- The main challenge to attaining universal access to drug susceptibility testing (DST) is the limited access to rapid diagnostic tests using Xpert MTB/RIF and underutilization of available GeneXpert machines.
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.
- TB laboratory services in Tanzania are managed through the Central TB Reference Laboratory (CTRL) that is under the NTLP of the MOH.

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The TB diagnostic cascade

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End term review of NSP V (2016-2020) NTLP identified some major challenges

- Low bacteriological confirmation rate among the notified pulmonary TB cases.
- Limited number of TB tests accredited under ISO15189 standards to the CTRL and the zonal laboratories.
- Meeting biosafety and biosecurity standards (specify gap).
- Achieving universal access to WH-recommended TB diagnosis (specify gap).
- Receiving timely diagnosis and results feedback due to a fragmented specimen transportation system.
- Only 23% of the notified new and relapse TB were tested with rapid diagnostics at diagnosis.

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Trends for TB notifications and proportional of Bacteriologically positive among Pulmonary cases

TB notifications trend and proportion of bacteriological confirmation rate 2015-2020

<table>
<thead>
<tr>
<th>Years</th>
<th>Pulmonary TB notification</th>
<th>B+ pulmonary TB cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>62,180</td>
<td>24,290</td>
</tr>
<tr>
<td>2016</td>
<td>65,902</td>
<td>25,887</td>
</tr>
<tr>
<td>2017</td>
<td>69,819</td>
<td>28,687</td>
</tr>
<tr>
<td>2018</td>
<td>75,845</td>
<td>27,201</td>
</tr>
<tr>
<td>2019</td>
<td>82,166</td>
<td>27,705</td>
</tr>
<tr>
<td>2020</td>
<td>84,800</td>
<td>37,312</td>
</tr>
</tbody>
</table>

USAID Infectious Disease Detection and Surveillance (IDDS)
The challenges from the NSP -V performance review necessitated carrying out the TB Diagnostic Network Assessment.
Overview of Tuberculosis Diagnostic Network Assessment (TB DNA)

- Aims at comprehensively evaluating 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 NSP

**Key Objectives:**

- Evaluate the diagnostic network, current practices and algorithms
- Identify challenges that prevent the overall diagnostic network from performing efficiently and effectively
- Propose evidence-based short- and medium-term interventions to improve access, capacity and quality of the TB diagnostic network to increase detection of TB and MDR-TB as outlined in the NSP.
Methodology

- The assessment included consultations with the MOH, NTLP, Central TB Reference Laboratory (CTRL), and other stakeholders involved. A total of 35 TB diagnostic and clinical facilities in 12 geographical regions.

- Regions, districts, and facilities were randomly selected.

- The assessment used an assessment tool (TB-Net Tool) that uses semi-quantitative scoring.

- The tool helps to identify the stage of various aspects of the diagnostic network to describe current capabilities and identify key areas for improvement.

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# The assessment tool – Capacities and components

## 1. Political, legal, regulatory and financial framework
- Legislation and policies
- National TB Policy and plans
- Governance
- Financing and budget

## 2. Structure and organization of the diagnostic network
- Diagnostic network
- Coordination and management
- Programmatic and operational research

## 3. Coverage
- Diagnostic network coverage
- Sample referral system
- Linkages
- Emergency preparedness

## 4. Diagnostic algorithm
- Algorithms
- Detection of TB
- Detection of DR-TB

## 5. Biosafety
- Facilities
- Biosafety and biosecurity manual
- Biosafety systems
- Specimen Storage
- Waste Management

## 6. Equipment and supplies
- Supply chain management
- Equipment management

## 7. Workforce
- Education and training
- Staffing
- Human resources development strategies and plans
- Competency-based job descriptions

## 8. Diagnostic data management
- Data collection Forms
- Reporting
- Diagnostics connectivity and remote monitoring
- Data analysis and sharing
- Surveillance and Epidemiology
- Security and confidentiality of information

## 9. Quality of the diagnostic network
- Documents and document control
- Quality Assurance
- Quality management System
- Certification and Accreditation
Methodology...

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.
The entire assessment process...

Pre-assessment data collection and analysis (August to September 2019)

Self-assessment of the TB diagnostic network core capacities by the country using the TB-Net Tool (May 2021)

Review of self-assessment by team and in-country verification by a team laboratory experts during site visits and other stakeholder meetings while in country (June and July 2021)

Review of overall findings data gathered from parts 1–3 and development of recommendations and priority interventions (August 2021---)

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. USAID Infectious Disease Detection and Surveillance (IDDS)
TB DNA

General findings

- The findings were based on the 10 core capacities, in each core capacity there were capabilities with stages from 0 to 5.

- Semi-quantitative scoring procedures were used to identify capability stages for each component and identify areas for improvement.
## Scoring

### Core Diagnostic Network Capacities

The score reported below is for each component within a core capacity. Average percentage scores for each core capacity are provided on worksheet 11.

### 1. Political, legal, regulatory and financial framework
- Legislation and policies
- National TB policies and plan
- Governance
- Financing and budgets

### 2. Structure and organization of the diagnostic network
- Diagnostic network
- Coordination and management
- Programmatic and operational research

### 3. Coverage
- Diagnostic network coverage
- Sample referral system
- Linkages
- Emergency preparedness

### 4. Diagnostic algorithm
- Algorithms
- Detection of TB
- Detection of drug resistant TB

### 5. Biosafety
- Facilities
- Biosafety and biosecurity manual
- Biosafety systems
- Waste management

### 6. Equipment and Supplies
- Supply chain management
- Equipment management

### 7. Workforce
- Workforce
# Summary of self and team assessment scores

<table>
<thead>
<tr>
<th>Core Capacity</th>
<th>Capability Percentage</th>
<th>Self-assessed</th>
<th>Team-assessed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Political, legal, regulatory, and financial framework</td>
<td></td>
<td>64%</td>
<td>64%</td>
</tr>
<tr>
<td>2. Structure and organization of the diagnostic network</td>
<td></td>
<td>93%</td>
<td>80%</td>
</tr>
<tr>
<td>3. Coverage</td>
<td></td>
<td>69%</td>
<td>59%</td>
</tr>
<tr>
<td>4. Diagnostic algorithm</td>
<td></td>
<td>58%</td>
<td>69%</td>
</tr>
<tr>
<td>5. Biosafety</td>
<td></td>
<td>26%</td>
<td>42%</td>
</tr>
<tr>
<td>6. Equipment and supplies</td>
<td></td>
<td>48%</td>
<td>53%</td>
</tr>
<tr>
<td>7. Workforce</td>
<td></td>
<td>55%</td>
<td>45%</td>
</tr>
<tr>
<td>8. Diagnostic data management</td>
<td></td>
<td>58%</td>
<td>72%</td>
</tr>
<tr>
<td>9. Quality of the diagnostic network</td>
<td></td>
<td>58%</td>
<td>51%</td>
</tr>
<tr>
<td>10. TB-HIV</td>
<td></td>
<td>83%</td>
<td>79%</td>
</tr>
</tbody>
</table>
# Summary

## Core Diagnostic Network Capacities

The score reported below is for each component within a core capacity. Average percentage scores for each core capacity are provided on worksheet 11.

### 1. Political, legal, regulatory and financial framework
- **Legislation and policies**
  - Self: 4
  - Team: 3
- **National TB policies and plan**
  - Self: 1
  - Team: 2
- **Governance**
  - Self: 5
  - Team: 4
- **Financing and budgets**
  - Self: 2
  - Team: 2

### 2. Structure and organization of the diagnostic network
- **Diagnostic network**
  - Self: 3
  - Team: 3
- **Coordination and management**
  - Self: 5
  - Team: 3
- **Programmatic and operational research**
  - Self: 5
  - Team: 3

### 3. Coverage
- **Diagnostic network coverage**
  - Self: 2
  - Team: 2
- **Sample referral system**
  - Self: 2
  - Team: 2
- **Linkages**
  - Self: 4
  - Team: 3
- **Emergency preparedness**
  - Self: 0
  - Team: 1

### 4. Diagnostic algorithm
- **Algorithms**
  - Self: 1
  - Team: 2
- **Detection of TB**
  - Self: 1
  - Team: 1
General findings...

**Strengths**

- An organized and structured TB diagnostic network is in place with clearly defined tiers with specific roles and responsibilities and led by a strong CTRL, which performs essential clinical and public health functions.

- Collaboration between the HIV and TB programs is working very well and leading to excellent linkage to testing and care for patients. The detection of TB among people living with HIV could be improved by widespread use of the lateral flow lipoarabinomannan test.
## Some key Gaps & Recommendations

<table>
<thead>
<tr>
<th>Gaps</th>
<th>Recommendations</th>
<th>Responsible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Available policies and guidelines are not fully implemented at all</td>
<td>Enforce dissemination and implementation of policies and guidelines at all levels of the network</td>
<td>The MOH, NTLP, and the CTRL</td>
</tr>
<tr>
<td>levels of the diagnostic network.</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A national TB biosafety manual is not available, Biosafety cabinets</td>
<td>should accelerate development and dissemination of a national TB biosafety manual and provide training for</td>
<td>The MOH, NTLP, and the CTRL</td>
</tr>
<tr>
<td>at regional and local levels were out of repair or not recently</td>
<td>all biosafety officers throughout the network. A program should be conducting an annual screening of</td>
<td></td>
</tr>
<tr>
<td>certified. Biosafety officers at local facilities reported having</td>
<td>health care workers for signs and symptoms of TB.</td>
<td></td>
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<tr>
<td>minimal training.</td>
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<td></td>
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<td></td>
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<tr>
<td>Many facilities did not have a program for routine screening (at</td>
<td></td>
<td></td>
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<tr>
<td>least yearly) of workers for signs and symptoms of TB</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gaps</td>
<td>Recommendations</td>
<td>Responsible</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>----------------------------------------------------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>Diagnosis of pediatric TB was challenging in many settings because there was a lack of capacity for, and training in, collecting specimens from children</td>
<td>Mobilize resources to train and equip facilities to collect good specimens from children</td>
<td>The CTRL and the NTLP</td>
</tr>
<tr>
<td>There are different practices in handling specimen referral from one place to the other</td>
<td>Enforce implementation of integrated specimen referral system though out the diagnostic network</td>
<td>The CTRL and the NTLP</td>
</tr>
</tbody>
</table>
**Gaps & Recommendations...**

<table>
<thead>
<tr>
<th>Most laboratories reported having an adequate number of staff; however, there is <strong>no national staffing plan</strong> supported by workforce projections.</th>
<th><strong>Ensure availability of well-trained, competent laboratory workers.</strong> Priority actions should include developing a national staffing plan for TB laboratories supported by workforce projections and developing a comprehensive program to provide refresher training to all laboratory workers and to assess and document staff competency.</th>
<th>The NTLP and the CTRL</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data from KPI at facility level are not routinely reviewed.</td>
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<tr>
<td>----------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Build capacity to staff on data review and analysis</td>
<td></td>
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<tr>
<td>• Rolling out use of electronic information management system.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>There was a lack of dedicated staff for data management, as well as a lack of training on data management for laboratory staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stockouts of Laboratory reagents as well as triple packaging materials.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Routinely verification to ensure the quality of reagents.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CTRL and NTLP

Formalize reporting of stockouts and expiration and initiate corrective actions to identify the root cause of the challenges and determine whether they are regional or systemic. Need for proper forecasting and quantification.

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Lessons learned

- Country led coordination and ownership plays a key role in successful implementation of TB DNA
- Once capacitated, staff can provide cooperation to perform the assessment virtually for some of the components.
  - There were unprecedented delays of process implementation due to COVID-19 pandemic
- Contract and deploy local consultants
- Use of electronic tool
Next Steps

❑ Carry out a dissemination meeting with MoH, NTLP, CTRL, WHO, CDC, USAID and other stakeholders.

❑ MOH, the NTLP, and the CTRL to lead and coordinate efforts among all stakeholders, including technical partners and donors.

❑ Routine follow up of the action items developed from the recommendations.

❑ The recommended key interventions and priority actions described in this report will assist Tanzania to reach its TB diagnostic goals with the ultimate goal to eliminating TB.
Acknowledgement

• Tanzania’s Ministry of Health; the National Tuberculosis and Leprosy Program; the Central Tuberculosis Reference Laboratory; and the President's Office, Regional Administration and Local Government.

• Implementing partners and donors that provided critical input throughout the assessment, especially World Health Organization-Tanzania.

• PATH Tanzania through USAID Infectious Diseases Detection and Surveillance project for their technical and financial support.