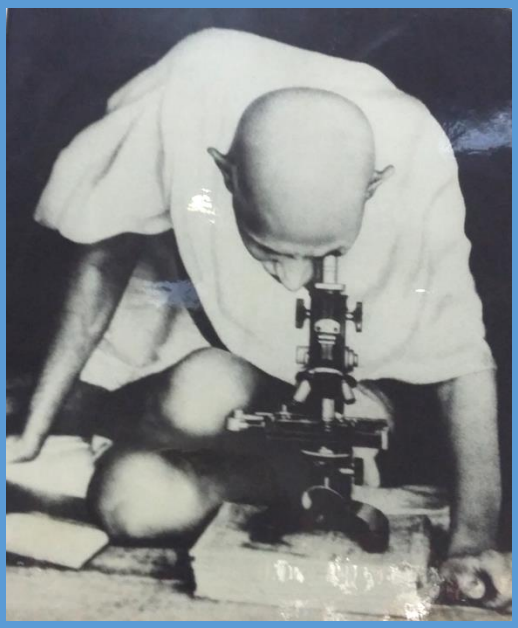
Ministry of Health and Family Welfare
Government of India

Final Report
Joint Assessment of the Tuberculosis Diagnostic Network of India

October 30 – November 10, 2017



Mahatma Gandhi viewing *Mycobacterium leprae* through a microscope at Sevagram Ashram, Maharashtra India 1940

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Executive Summary

Introduction

India continues to be the highest TB burden country in the world[1]. India accounts for a little more than a quarter of the global burden of TB and has the largest number of multidrug-resistant TB (MDR-TB) patients worldwide. Mortality due to TB is the sixth leading cause of years of life lost (YLLs), in the country. The estimated incidence (new TB patients per year) was nearly 2.8 million patients in 2016 (211 per 100,000 population). The estimated mortality due to TB is 423,000. In 2016, India detected and notified approximately 1.8 million new TB patients – 63% of the estimated burden. This means that slightly more than 1 million TB patients in India are either not detected or not notified to the program after diagnosis.

India's National Strategic Plan for Tuberculosis Elimination 2017-2025[2] (NSP) is aligned with WHO's End TB Strategy, but is much more ambitious. The NSP proposes bold strategies with commensurate resources to decrease rapidly TB incidence and mortality in India by 2025, five years ahead of the global End TB targets and Sustainable Development Goals to attain the vision of a TB-free India. The NSP calls for the use of digital technologies to improve TB reporting and care, the engagement of the private sector, the roll-out of rapid molecular tests to diagnose TB and drug resistance, universal DST, new anti-TB drugs, and shorter MDR-TB regimens to combat drug-resistant TB. Achieving universal access to TB care is also a key component of India's campaign for a TB Free India.

The TB diagnostics landscape in India has been transformed in recent years with the scale up of free rapid TB diagnostics and treatment all across the country. However, the Revised National Tuberculosis Control Program (RNTCP) recognizes that continuation of prior efforts alone will not accelerate the progress towards ending TB fast enough to meet NSP targets.

New interventions have been developed and integrated into the four strategic pillars:[2]

- **Detect**: Find all DS-TB and DR-TB patients with an emphasis on reaching TB patients seeking care from private providers and TB in high-risk populations,
- **Treat**: Initiate and sustain all patients on appropriate anti-TB treatment,
- **Prevent**: Prevent the emergence of TB in susceptible populations,
- **Build**: Build and strengthen enabling policies, empowered institutions, human resources with enhanced capacities, and financial resources to match the plan.

The **Detect** pillar focuses on creating a comprehensive, high-quality TB diagnostic network to accurately and rapidly diagnose TB and link confirmed TB patients to appropriate and timely treatment.

[1] Global tuberculosis report 2017. Geneva: World Health Organization; 2017. Available at: http://www.who.int/tb/publications/global_report/en/

[2] Revised National Tuberculosis Control Programme. National Strategic Plan for Tuberculosis Elimination 2017-2025. Available at https://tbcindia.gov.in/WriteReadData/NSP%20Draft%2020.02.2017%201.pdf

Objectives

The RNTCP, with USAID support, invited a group of international and national laboratory, diagnostic network, and TB program experts to assess the TB diagnostic network in India. The assessment was conducted from October 30 to November 10, 2017. The main objectives of the assessment were to holistically 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 NSP.

Methods

The assessment consulted with the RNTCP and other stakeholders at the national level and covered 5 national reference laboratories (NRLs), 11 intermediate reference laboratories (IRLs), 5 other culture/drug-susceptibility testing (DST)/line-probe assay (LPA) laboratories, 23 cartridge-based nucleic amplification test (CBNAAT) facilities, and 46 designated microscopy centers (DMCs). In summary, TB diagnostic services were reviewed in 90 TB diagnostic facilities in 19 geographic areas to inform the assessment. The Central TB Division (CTD) and State TB Program Officers (STOs) identified assessment states, districts and sites with the aim of including a range of laboratories at varying levels of the health system. The assessment utilized a new assessment tool that was developed based on the framework of the African Society of Laboratory Medicine/Association of Public Health Laboratories National Laboratory Network Assessment (LABNET) Score Card. The tool was customized for use in India in collaboration with CTD. The tool used 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.

General Findings

- There has been extraordinarily strong commitment for a TB Free India from the highest levels of the Government of India, which has led to the development of an ambitious NSP to eliminate TB by 2025.
- TB program and laboratory personnel throughout the country and at all levels were found to be committed and open to new approaches to strengthen TB diagnostic services.
- Recruitment of contractual positions for laboratory personnel has been delayed – over 20% of these positions have been vacant (up to 40% in some states). In addition, about 300 laboratory personnel are deployed in culture/DST (C/DST) laboratories across the country by a human resource agency (SAMS) contracted by FIND as a sub-recipient of CTD for the current Global Fund Grant (ending December 31, 2017). These personnel contribute greatly to delivery of rapid TB diagnostics services including LPA and liquid culture. The assessment team observed HR issues critical for sustaining C/DST laboratory services which require urgent attention.
- NSP targets are unlikely to be met with deployment of the new diagnostic algorithm in the public sector only. Some private and academic institutions are functionally integrated in the network; however programme needs to intensify efforts for engagement of private sector health facilities.
- Considerable variability in the quality of the diagnostic network and diagnostic testing was observed across the various parts of the country included in the assessment.

- A system of regulated supervision is in place from reference laboratory tiers to lower levels within the public sector but challenges with resourcing, focus on technical aspects of testing, implementation and follow-up of on-site supervisory evaluation visits and blinded rechecking activities limit impact on quality improvement.
- Nikshay has great potential to facilitate laboratory data management, hence programme may take initiatives to review and analyze the data. The usability of Nikshay is hampered by a lack of user-oriented design and collection of large volumes of diagnostic data, some of which is not used for decision-making. Furthermore, the assessment team observed challenges that hampered implementation of the current overall Nikshay system including insufficient server capacity. Issues around data confidentiality and data security were observed at all levels.

Recommended Key Interventions and Priority Actions

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

1. Accelerate implementation and monitor progress

Estimate the contribution of increasing the use of the new NSP diagnostic algorithm in the private sector and in priority populations to detect TB and for universal access to DST for all smear-positive patients to meeting NSP targets. Monitor the impact of the scale up of the new diagnostic algorithm in both public and private sectors and revise algorithm if needed to reach targets. Improve engagement with the private sector (recommendation 2) and develop state-specific plans for implementation of the new diagnostic algorithm (recommendation 3).

2. Translate public-private mix (PPM) policy into implementable activities within the diagnostic network

Develop and implement specific guidelines to engage private providers and laboratories within the TB diagnostic network. Set targets, adequately resource and mainstream monitoring of key indicators to measure process and impact. Ensure the quality of private sector TB laboratory testing (*e.g.*, participation in external quality assurance (EQA), training, and certification).

3. Develop state-specific performance improvement plans

Work with state TB program officers to develop evidence-based performance improvement plans for their TB diagnostic services that will enable well-functioning states to move quickly and lagging states to catch up. Bolster advocacy at state level to minimize human resource (HR) and funding bottlenecks for TB diagnostic services.

4. Urgently address the laboratory human resource issues and impending service-interruption crisis

Fill presently vacant laboratory positions and work to build a sustainable HR strategy with adequate numbers of trained, competent staff at all levels working under appropriate remuneration and in safe facilities and working conditions. Ensure uninterrupted support of HR for C/DST laboratories in the short term and ensure sustainable support through establishment of appropriate mid- to long-term mechanisms.

5. Simplify, refocus and reinvigorate supportive supervision

Optimize the schedule of senior TB laboratory supervisor (STLS) and senior treatment supervisor (STS) visits to peripheral facilities (DMCs and CBNAAT sites) and simplify supervision to capture essential elements for service quality improvement. Prioritize visits by need and use simple electronic data systems to collect key information needed for action as well as facilitate centralized monitoring of network performance. Ensure adequate resourcing to carry out supervision and oversight functions and ensure that supervision includes patient cascade, and not just laboratory technical aspects. Conduct a needs assessment of NRL and IRL supervision, and based on the assessment findings, strategically reorganize NRLs and IRLs (considering the possible need for additional NRLs or IRLs).

6. Deploy electronic data systems across all diagnostic and laboratory levels

Ensure that the system is user-friendly and allows people to do their jobs better and more efficiently. Streamline laboratory/diagnostic data collection to focus on data that will be used and analyzed to inform decisions. Consider a near-term upgrade of the Nikshay server capacity to effect immediate benefit in usability. Deploy a data connectivity solution to connect all CBNAAT sites to facilitate remote monitoring of test and network performance.

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 testing.
- Deploying what is available now, while planning for the future 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.
- 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 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 CTD 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.

India is on the right track to end TB, with state-of-the-art tools, an ambitious, imaginative NSP and high level political commitment. The recommended key interventions and priority actions described in this report will assist India to reach its TB diagnostic goals with the ultimate aim to end TB in India.

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Abbreviations

ACF	Active Case Finding
AFB	Acid-Fast Bacilli
AMC	Annual Maintenance Contract
APHL	Association of Public Health Laboratories
ASLM	African Society of Laboratory Medicine
BSC	Biosafety cabinet
BSL	Biosafety level
CBNAAT	Cartridge-Based Nucleic Acid Amplification Test
CTD	Central TB Division
CXR	Chest X-ray
DMC	Designated Microscopy Centre
DR-TB	Drug-Resistant Tuberculosis
DST	Drug-Susceptibility Testing
DTC	District TB Centre
DTO	District TB Officer
EQA	External Quality Assessment
FM	Fluorescence Microscopy
EPTB	Extra-pulmonary TB
FQ	Fluoroquinolone (*e.g.*, Ofloxacin, Levofloxacin, Gatifloxacin or Moxifloxacin)
GDF	Global Drug Facility
GLI	Global Laboratory Initiative
GPS	Global Positioning System
GOI	Government of India
HIV	Human Immunodeficiency Virus
HR	Human Resources
INH	Isoniazid
IQC	Internal Quality Control
IRL	Intermediate Reference Laboratory
KPI	Key Performance Indicator
LC	Liquid Culture
LED	Light-Emitting Diode
LPA	Line Probe Assay
LIMS	Laboratory Information Management System
LJ	Lowenstein-Jensen media
LT	Laboratory Technician
MDR-TB	Multidrug-Resistant Tuberculosis
MGIT	Mycobacteria Growth Indicator Tube
MoHFW	Ministry of Health & Family Welfare
MTB	*Mycobacterium tuberculosis* complex bacteria
NABL	National Accreditation Board for Testing and Calibration Laboratories
NGO	Non-Governmental Organization
NRL	National Reference Laboratory
NSP	National Strategic Plan for Tuberculosis Elimination
OSE	On-site Evaluation
PHI	Peripheral Health Institution
PLHIV	People Living with HIV/AIDS

PMDT	Programmatic Management of Drug-resistant TB
PPE	Personal Protective Equipment
PPM	Public-Private Mix
PT	Proficiency Testing
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
RBRC	Random Blinded Rechecking
RIF	Rifampicin
RNTCP	Revised National TB Control Program of India
RR	Rifampicin-Resistant
SLID	Second-Line Injectable anti-TB drug (*i.e.*, Kanamycin, Capreomycin or Amikacin)
SL-LPA	Second-Line Line Probe Assay
SM	Sputum Smear Microscopy
SOP	Standard Operating Procedure
SRL	Supranational Reference Laboratory
STLS	Senior TB Laboratory Supervisor
STO	State TB Officer
STS	Senior Treatment Supervisor
TB	Tuberculosis
TU	TB Unit
USAID	United States Agency for International Development
WHO	World Health Organization
WRD	WHO-recommended Rapid TB Diagnostic
ZN	Ziehl-Neelsen

Introduction

"Compared to the world we have a large number of TB patients in India. We have to defeat TB in India."

Shri Narendra Modi, Honorable Prime Minister of India,
"Mann Ki Baat"; radio address to the nation; March 27th 2016

The TB Burden in India

Though the available data suggest that the TB epidemic may be on the decline, India continues to have the highest TB burden of any country in the world. India accounts for a little more than a quarter of the global burden of TB and has the largest number of multidrug-resistant TB (MDR-TB) patients worldwide. Mortality due to TB is the sixth leading cause of years of life lost (YLLs), in the country. TB alone contributes to 3.3% of disability adjusted life years (DALYs) attributable to all-cause premature mortality and morbidity in the country. The estimated incidence of new TB patients was nearly 2.8 million patients in 2016 (211 per 100,000 population)[3]. In 2016, India detected and notified approximately 1.8 million new TB patients – 63% of the estimated burden. This means that slightly more than 1 million TB patients in India are either not detected or not notified to the program after diagnosis. Furthermore, only about 54% of the notified patients were bacteriologically confirmed, which greatly limits the ability to detect MDR-TB patients.

India's National Strategic Plan for Tuberculosis Elimination, 2017-2025

Alignment with the WHO End TB Strategy

India's National Strategic Plan for Tuberculosis Elimination, 2017-2025 (NSP)[4] proposes bold strategies with commensurate resources to decrease rapidly TB incidence and mortality in India by 2025 to attain the vision of a TB Free India. The NSP calls for engagement of the private sector, roll-out of rapid molecular tests to diagnose TB and drug resistant (DR) TB, universal DST, new anti-TB drugs, shorter regimens to combat DR-TB, and use of digital technologies to improve TB reporting and care. Universal access to TB care is a key component of India's campaign for a TB Free India.

[3] Global tuberculosis report 2017. Geneva: World Health Organization; 2017. http://www.who.int/tb/publications/global_report/en/

[4] Revised National Tuberculosis Control Programme. National Strategic Plan for Tuberculosis Elimination 2017-2025. https://tbcindia.gov.in/WriteReadData/NSP%20Draft%2020.02.2017%201.pdf

India's NSP is aligned with WHO's End TB Strategy, but, admirably, is much more ambitious. The End TB Strategy aims to end the global TB epidemic, with targets to reduce TB deaths by 95% and new patients by 90% between 2015 and 2035 and to ensure that no family is burdened with catastrophic expenses due to TB[5]. TB Free India calls for reaching the End TB targets 5 years earlier, *e.g.*, reducing the number of new cases by 80% by 2025 instead of by 2030.
The End TB Strategy highlights the critical role of laboratories in the post-2015 era and emphasizes that in order to meet the targets of the End TB Strategy, WHO-recommended rapid TB diagnostics (WRDs) should be available to all persons with signs or symptoms of TB; all bacteriologically confirmed TB patients should receive drug-susceptibility testing (DST) at least for rifampicin (RIF); and all patients with rifampicin-resistant (RR)-TB should receive DST at least for fluoroquinolones (FQs) and second-line injectable drugs (SLIDs). WHO emphasizes that all national TB control programs need to prioritize the development of a network of TB laboratories that use modern diagnostics, have efficient referral systems, use standard operating procedures (SOPs) and appropriate quality assurance (QA) processes, and have adequate biosafety and sufficient human resources. These priorities should be comprehensively addressed in national strategic plans and adequately funded.

Strategic Pillars of the NSP: Detect

The NSP recognizes that continuation of prior efforts alone, which yielded inadequate declines in TB incidence, will not yield sufficient progress towards ending TB. New, comprehensively deployed, locally-adopted interventions are required to accelerate the rate of decline of the incidence of TB to the targeted 10-15% annually. The requirements for moving towards TB elimination have been integrated into the four strategic pillars of "**Detect – Treat – Prevent – Build**" (DTPB).

The NSP envisages "Early identification of presumptive TB cases, at the first point of care be it private or public sectors, and prompt diagnosis using high sensitivity diagnostic tests to provide universal access to quality TB diagnosis including drug resistant TB in the country". The Revised National Tuberculosis Control Program (RNTCP) is currently challenged to attain this vision because of limitations in their laboratory services and diagnostic network. In the NSP, the RNCTP described multiple challenges in the provision of TB laboratory services including:

- Establishment of safe TB containment laboratories at state level
- Transportation of specimens from hard to reach areas (*e.g.*, hilly, tribal, deserts)
- Collection of appropriate specimens from children and presumptive extrapulmonary TB (EPTB) patients and referral for laboratory testing at the district level
- Procurement of equipment from original manufacturers from outside the country who have restricted or no in-country post sales services
- Sub-optimal supervision of laboratories
- Limited human and financial resources for on-site evaluations (OSE)
- Increasing workload due to expanding Programmatic Management of Drug-Resistant TB (PMDT) services
- Tedious paper-based monitoring system
- Delayed reporting and limited analysis, troubleshooting and capacity to take timely corrective actions

[5] The End TB Strategy - global strategy and targets for tuberculosis prevention, care and control after 2015. http://www.who.int/tb/strategy/End_TB_Strategy.pdf

- Retention of trained laboratory staff and poor and variable compensation packages

The **Detect** pillar encompasses the key activities of the NSP needed to address these and other challenges to make the vision of early detection and universal access a reality:

	Aim	Interventions
Detect	Find all DS-TB and DR-TB patients with an emphasis on reaching TB patients seeking care from private providers and undiagnosed TB in high-risk populations	• Scale up free, highly sensitive diagnostic tests and algorithms • Scale up effective private provider engagement approaches • Universal testing for drug-resistant TB • Systematic screening of high risk populations

One of the NSP's strategic approaches under the **Detect** pillar is a new national integrated diagnostic algorithm that expands access to rapid molecular testing for the laboratory confirmation of TB and DR-TB. Implementation of the new algorithm is an opportunity to review the structure of the existing tiered network of TB diagnostic services and laboratories; the linkages between laboratories and clinical services at all levels; the minimum package of TB diagnostic services for each level of the network; and the systems for referring specimens to the appropriate level for tests that are not available at lower level laboratories. To ensure universal access to high quality diagnostic testing, and given the extensive role of the private sector in health service provision, the TB diagnostic network should include facilities and providers in both the public and private sectors.

NSP Key Detect Indicators and Targets

The following are selected indicators and targets described in the NSP under the **Detect** pillar, using 2015 as the baseline year. The targets represent substantial increases in the indicators over a short time. For example, by 2018 India is targeting an 87% increase in TB patient notifications compared to 2015 – including an almost 7 times increase in the number of TB patients notified by the private sector. The number of presumptive and diagnosed patients to be offered a rapid molecular test is targeted to increase from 0.4 million to 5 million in 2018.

Indicators	2015 (Baseline)	2016 (Target)	2017 (Target)	2018 (Target)	2019 (Target)	2020 (Target)
Total TB patients (pts) notified	1,607,983	1,745,000	2,650,000	3,000,000	3,350,000	3,600,000
No. TB pts notified by private sector	184,802	325,000	1,200,000	1,500,000	1,550,000	1,600,000
No. of presumptive TB pts to be offered bacteriological test (sputum microscopy)	9,132,306	9,200,000	9,300,000	10,125,000	11,550,000	12,600,000
No. of presumptive and diagnosed TB pts to be offered rapid molecular test	400,000	2,000,000	4,000,000	5,000,000	6,500,000	7,000,000
Proportion of notified TB pts offered DST	25%	30%	50%	60%	70%	80%
No. of presumptive MDR-TB pts to be examined	341,395	444,933	600,000	700,000	900,000	1,100,000

No. of MDR/RR TB patients notified	29,057	36,000	55,620	66,000	78,975	92,000

The strategic approaches laid out in the NSP are designed to allow India to attain to reach these ambitious **Detect** targets.

TB Diagnostic Network

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

The diagnostic process starts with the person experiencing symptoms and deciding to seek care (*i.e.*, passive case finding) or a health care worker identifying a person to be evaluated for TB (*i.e.*, active case finding). The process continues with the ordering of an appropriate test by a health care worker, 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 health care worker, 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.

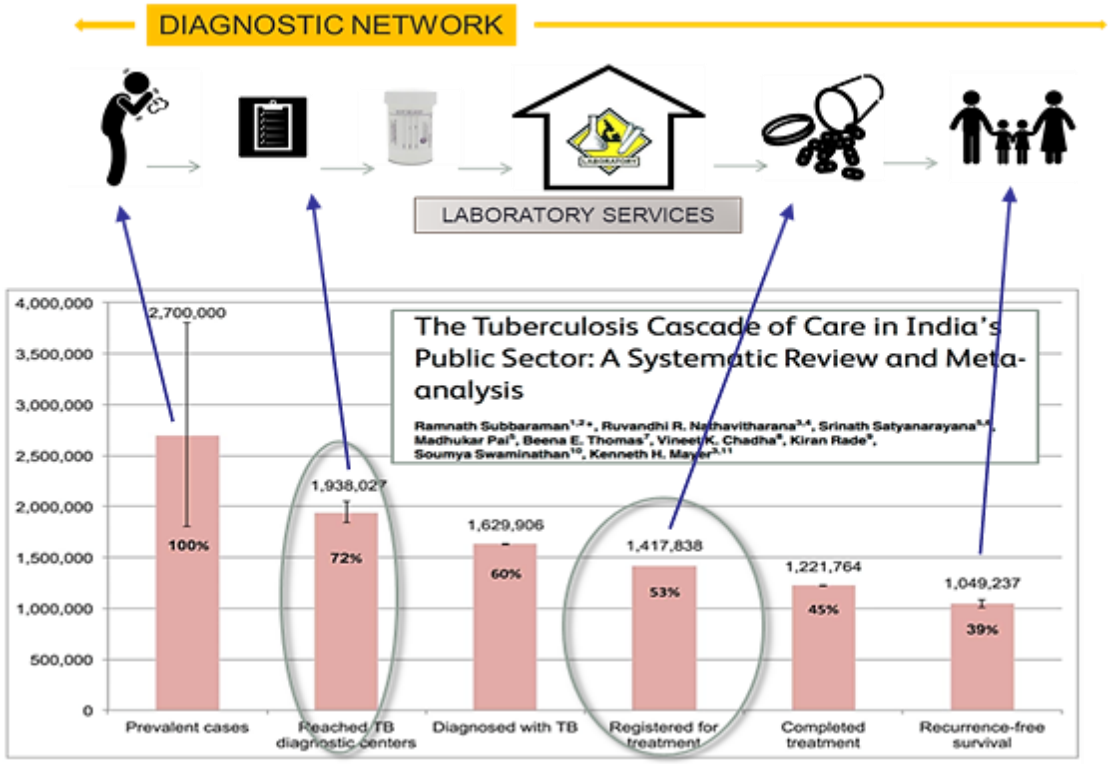


Figure 1. The TB Diagnostic Cascade and Attrition in TB Diagnostic Cascade in India

A recent study[6] of the TB diagnostic cascade in India revealed that in 2013, only 39% of the estimated 2.7 million new TB patients complete the entire patient pathway to achieve a sustained cure. Significant losses along the patient pathway include 1) only 72% of estimated TB patients reach a TB diagnostic center, 2) of these only 84% are diagnosed with TB, 3) of these 87% are registered for treatment, and 4) of these only 74% achieve a sustained cure (Figure 1).

[6] Subbaraman R, Nathavitharana RR, Satyanarayana S, Pai M, Thomas BE, Chadha VK, et al. (2016) The Tuberculosis Cascade of Care in India's Public Sector: A Systematic Review and Meta-analysis. PLoS Med 13(10): e1002149. https://doi.org/10.1371/journal.pmed.1002149

Strengthening the entire diagnostic network and patient pathway can produce dramatic reductions in the time from the ordering of a test to a clinician making a patient care decision, reduce loss to follow up, and increase access to laboratory services for all patients.

The diagnostic network is a shared responsibility between a TB program and all levels of the TB or general laboratories within the network. The network encompasses all points where community members seek care – both within the public and private sectors, and among formal and informal providers.

India's Tiered Network of TB Laboratories

India has a vast countrywide TB laboratory diagnostic network of designated microscopy centers (DMCs), CBNAAT (Xpert MTB/RIF) laboratories, intermediate reference laboratories (IRLs), other culture/drug-susceptibility testing (C/DST) laboratories and national reference laboratories (NRLs) (Figure 2). The diagnostic network also includes District TB Centers (DTCs) which are responsible for managing the TB program, treatment and laboratory services in the District and sub-District Tuberculosis Units (TUs) which are responsible for treatment programs and ensuring the quality of laboratory testing in DMCs through supervisory visits and random blinded rechecking.

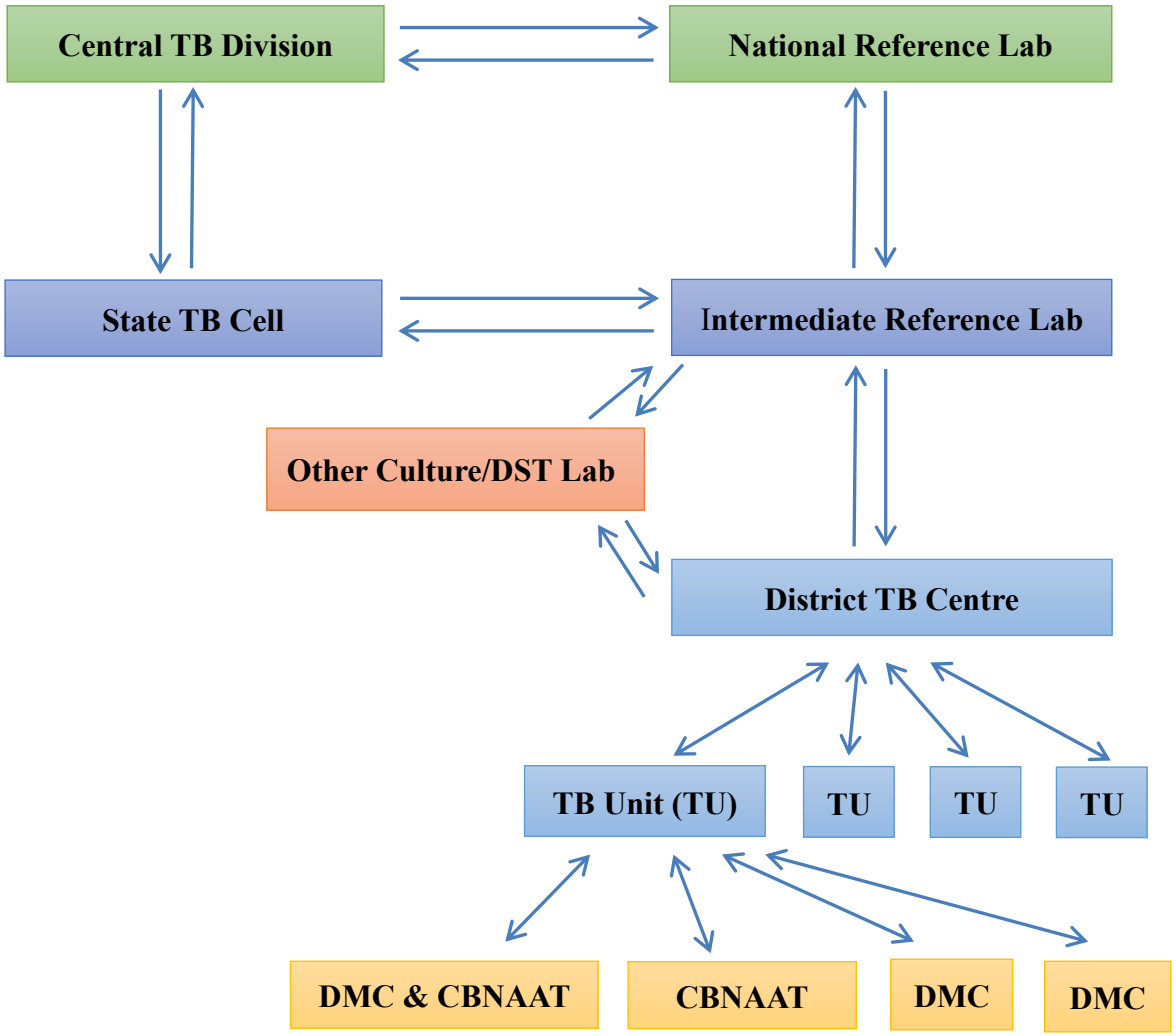
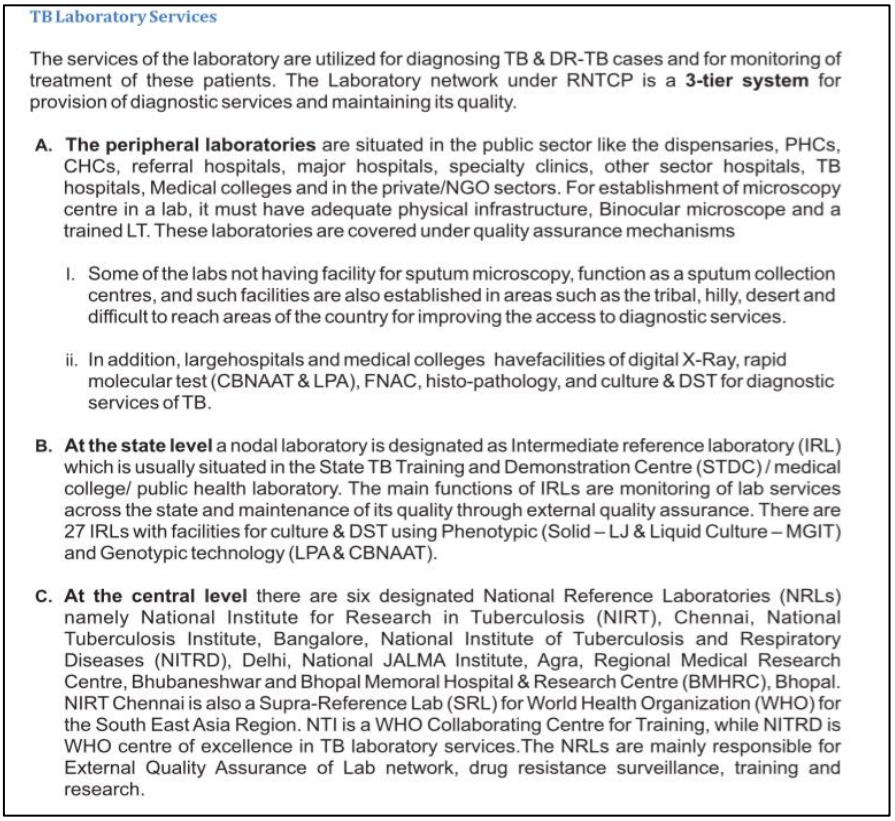


Figure 2. Laboratory Services and Diagnostics in India

India's *Revised National TB Control Program Technical and Operational Guidelines for Tuberculosis Control in India* (2016) describes the TB laboratory services (Figure 3) at each of the tiers of the network. The Guidelines also define acceptable methods for microbiological diagnosis of TB including:

- Sputum smear microscopy for AFB including Zeihl-Neelsen and fluorescence staining methods
- Culture including:
    - Solid media, *i.e.*, Lowenstein Jensen (LJ) media
    - Automated liquid culture systems (*e.g.*, MGIT 960)
    - Drug-susceptibility testing
    - Modified proportion sensitivity testing for MGIT 960 system (both first-line and second-line drugs)
    - Economic variant of proportion sensitivity testing (1%) using LJ medium (as a backup when indicated)
- Rapid molecular diagnostic testing including line probe assay for detecting *Mycobacterium tuberculosis* complex bacteria (MTB) and isoniazid (INH) and RIF resistance and CBNAAT (Xpert MTB/RIF using the GeneXpert system)

Where available, chest X-ray is to be used as a screening tool to increase the sensitivity of the diagnostic algorithm. Standardized tuberculin skin testing may be used as a complementary test in children (Interferon-Gamma Release Assays are not recommended). The use of serological tests to diagnose TB was banned in India in 2012. The guidelines briefly describe the process of specimen collection and transport. A revised algorithm (shown in Annex 1) is described in the new NSP; however, scale-up of the new algorithm will begin in 2018.



TB Laboratory Services

The services of the laboratory are utilized for diagnosing TB & DR-TB cases and for monitoring of treatment of these patients. The Laboratory network under RNTCP is a **3-tier system** for provision of diagnostic services and maintaining its quality.

A. **The peripheral laboratories** are situated in the public sector like the dispensaries, PHCs, CHCs, referral hospitals, major hospitals, specialty clinics, other sector hospitals, TB hospitals, Medical colleges and in the private/NGO sectors. For establishment of microscopy centre in a lab, it must have adequate physical infrastructure, Binocular microscope and a trained LT. These laboratories are covered under quality assurance mechanisms

   i. Some of the labs not having facility for sputum microscopy, function as a sputum collection centres, and such facilities are also established in areas such as the tribal, hilly, desert and difficult to reach areas of the country for improving the access to diagnostic services.

   ii. In addition, largehospitals and medical colleges havefacilities of digital X-Ray, rapid molecular test (CBNAAT & LPA), FNAC, histo-pathology, and culture & DST for diagnostic services of TB.

B. **At the state level** a nodal laboratory is designated as Intermediate reference laboratory (IRL) which is usually situated in the State TB Training and Demonstration Centre (STDC) / medical college/ public health laboratory. The main functions of IRLs are monitoring of lab services across the state and maintenance of its quality through external quality assurance. There are 27 IRLs with facilities for culture & DST using Phenotypic (Solid – LJ & Liquid Culture – MGIT) and Genotypic technology (LPA & CBNAAT).

C. **At the central level** there are six designated National Reference Laboratories (NRLs) namely National Institute for Research in Tuberculosis (NIRT), Chennai, National Tuberculosis Institute, Bangalore, National Institute of Tuberculosis and Respiratory Diseases (NITRD), Delhi, National JALMA Institute, Agra, Regional Medical Research Centre, Bhubaneshwar and Bhopal Memoral Hospital & Research Centre (BMHRC), Bhopal. NIRT Chennai is also a Supra-Reference Lab (SRL) for World Health Organization (WHO) for the South East Asia Region. NTI is a WHO Collaborating Centre for Training, while NITRD is WHO centre of excellence in TB laboratory services.The NRLs are mainly responsible for External Quality Assurance of Lab network, drug resistance surveillance, training and research.

Figure 3. India's TB Laboratory Services, Revised National TB Control Program Technical and Operational Guidelines for Tuberculosis Control in India (2016)

The Joint National TB Diagnostic Network Assessment

The RNTCP, with USAID support, invited a group of international and national laboratory, diagnostic network, and TB program experts to assess of the TB diagnostic network in India. The main objectives of the assessment were to assess the current status of the diagnostic network and the extent to which it meets the diagnostic needs of the NSP, and to make recommendations for interventions to optimize the TB diagnostic network to provide more efficient and effective services to meet the goals and targets of the NSP.

Objectives

The main objective of the assessment was to evaluate India's current laboratory and program diagnostic practices and identify issues that may limit the overall diagnostic network from performing efficiently and effectively. The assessment aimed to determine if the existing laboratory and diagnostic network would enable the RNTCP to reach the NSP targets and, if not, propose evidence-based short and medium-term interventions to improve access, capacity and quality of the TB diagnostic network as a way of reaching the targets.

Expected Outputs

Two major outputs were expected to be delivered by the team at the end of the assessment including:

1. Evidence of the strengths and limitations of the TB diagnostic network at all levels of the health system to contribute to RNTCP priorities and to reach the NSP targets, and
2. Evidence-based and result-oriented recommendations that can be operationalized for a strengthened TB diagnostic network.

Areas that were assessed included:

- Utilization of all currently available TB laboratory tests, especially rapid molecular tests, and mechanisms for evaluation and future integration of upcoming technologies
- Interplay of the diagnostic algorithm and tier-specific TB testing packages to create a strong, 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 and strategies to improve capacity for SL-DST in line with the scale-up of Bedaquiline (BDQ) and shorter MDR-TB regimens
- Capability of TB referral mechanisms to ensure increased service uptake, reduce turn-around time, and optimize the available laboratory diagnostic capacities
- Planning, deployment, and use of human resources at all levels of care
- Policies and procedures for ensuring the quality of diagnostic services throughout the network, including quality assessment programs (*e.g.*, proficiency testing or OSE)
- 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
- Laboratory and diagnostic commodities and logistics system
- Policies and guidelines for laboratory biosafety and mechanisms to ensure adherence to guidelines at all levels of the health system

The Assessment Team

The assessment was conducted by a group of external TB laboratory, diagnostic network, and TB program experts as well as internal program and laboratory experts associated with the national programme or laboratory network of India (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. External consultants came from a variety of international and national organizations or were independent, and each is considered a leader or expert in their field. Internal (*i.e.*, RNCTP affiliated) assessors represented the many levels of the RNTCP including CTD, NRLs, multilateral/technical agencies and organizations, and private hospitals. 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

Name	Organization	Name	Organization
Thomas Shinnick	Independent (team lead)	Sunil D Khaparde	DDG-TB
Heidi Albert	FIND/SA (team lead)	V. S. Salhotra	ADDG-TB
Amy Piatek	USAID/W (coordinator)	Nishant Kumar	DADG –TB
Umesh Alavadi	USAID/I (coordinator)	P Kumar	NTI Bangalore
Patricia Campbell	CDC/Atlanta	Rohit Sarin	NITRD Delhi
Martina Casenghi	Independent	N.S. Gomathi	NIRT Chennai
Kenneth Castro	USAID/Washington	Prabha Desikan	BMHRC Bhopal
Sarabjit Chadha	rGLC chair/Union	Dasarathi Das	RMRC Bhubaneswar
Sujatha Chandrasekran	Independent	Avi Bansal	JALMA Agra
Anh Innes	USAID/Washington	Ranjani Ramachandran	WHO India
Chris Macek	SystemOne	M. Hanif	IRL Delhi
Sundari Mase	WHO India	Lakshmi R	NTI Bangalore
Christiaan Mulder	KNCV	Jyoti Arora	NITRD Delhi
Kameko Nichols	Independent	Ameeta Joshi	JJ Hospital Mumbai
Daniel Orozco	Partners in Health	Camilla Rodrigues	Hinduja Hospital
Sushil Pandey	SRL Queensland	Nerges Mistry	FMR Mumbai
C.N. Paramasivan	rGLC member/indep.	Urvashi Singh	AIIMS Delhi
Imran Syed	Union/Challenge TB	Sunita Upadhyaya	CDC India
Elisa Tagilani	SRL Milan	Jyoti Jaju	CTD
Manoj Toshniwal	Independent	Anand S	CTD
Maarten Van Cleeff	Independent	Yogesh Patel	CTD
Wayne Van Gemert	GDF	Lalit Mehandru	CTD
		Sanjeev Saini	CTD
		Bhavin Vadera	CTD
		Almas Shamim	CTD
		Shanoo Mishra	CTD
		Amit Koregaonkar	CTD
		Himanshu Jha	CTD
		Shailaja H	CTD
		Amit Sahu	CTD

Sites and Facilities Visited

The assessment covered the RNTCP and other stakeholders at the national level, 5 NRLs, 11 IRLs, 5 other Culture/DST/LPA laboratories, 23 CBNAAT facilities, and 46 DMCs (Table 2) for a total of 90 facilities. TB diagnostic services were reviewed in 19 geographic areas to inform the assessment. States, districts and facilities were selected by the CTD and state program officers with the aim of including a range of laboratories at varying levels of the health system including private sector and non-governmental organization (NGO) TB diagnostic facilities. The sites visited are listed in Annex 4.

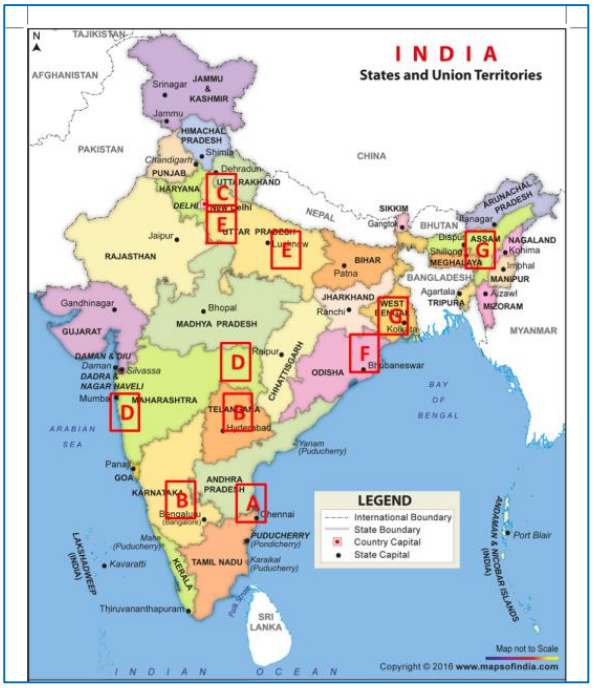


Table 2 Sites visited during Joint Assessment of TB Diagnostic Network

Team	Sites	Laboratories Visited
A	Chennai, Puducherry, Nellore	NRL – 1, IRL – 2, C/DST/LPA – 1 (NGO), CBNAAT – 3 (1 private), DMC – 4
B	Bangalore, Hyderabad	NRL – 1, IRL – 2, CBNAAT – 4, DMC - 5
C	Delhi, Noida	NRL – 1, IRL – 1, CBNAAT – 4, DMC – 6
D	Mumbai, Nagpur	IRL – 1, C/DST/LPA – 3 (2 private), CBNAAT – 3, DMC - 6
E	Mathura, Agra, Lucknow	NRL – 1, IRL – 2, C/DST/LPA – 1, CBNAAT – 2, DMC – 8
F	Bhubaneswar, Cuttack, Dhenekal	NRL – 1, IRL – 1, CBNAAT – 3, DMC – 7
G	Kolkata, Guwahati, Nalbari Goalpara	IRL – 2, CBNAAT – 4, DMC – 10
	TOTAL (90):	**5 NRLs, 11 IRLs, 5 other Culture/DST/LPA laboratories, 23 CBNAAT facilities, and 46 DMCs**

The Assessment Process

The assessment was conducted in three stages:

- Pre-assessment data collection and analysis
- Self-assessment scoring of TB diagnostic network core capacities by India
- Review of self-assessment and in-country verification by the assessment team

Together, the information and data gathered from the three parts collectively informed the final assessment findings and recommendations.

1. Pre-assessment data collection and analysis

National and sub-national data on diagnostic and laboratory variables were provided by the CTD before the assessment. The data were compiled, analyzed and presented by an external consultant to the assessment team before the site visits. All external consultants signed a non-disclosure agreement before reviewing the data because some of the data was not publicly available.

Data included:

- Notification data (*e.g.*, pulmonary vs. extrapulmonary, microbiologically vs. clinically confirmed, pediatric vs. adult, public vs. private) at state and district level from the 2016 national database
- Number and type of staff at NRL and IRLs and whether the positions were sanctioned or vacant
- Microscopy volumes, positivity and EQA results by state and district (2016)
- CBNAAT data by state (2015, 2016, 2017 1st and 2nd quarter only)
- C/DST laboratories certified for different diagnostic technologies
- Number of tests done at C/DST laboratories: liquid culture and DST (2012-2017; 2017 1st and 2nd quarter only); LPA (2012-2017; 2017 1st and 2nd quarter only); second line DST (2016-2017; 2017 1st and 2nd quarter only)
- DR-TB patient finding (2012-2017; 2017 1st and 2nd quarter only)

The CTD also calculated country-specific targets for microscopy, WHO recommended diagnostics (including Xpert MTB/RIF), culture and DST capacity according to the WHO template (Annex 2).

Official RNTCP documents and reports were reviewed prior to the assessment including the new NSP, the most recent annual report, the revised technical and operational guidelines (2016), diagnostic algorithms, and other recording and reporting forms.

Because there were many facilities and sites to visit, where possible, the assessment planned to have facility/site-specific data collected and key variables analyzed and compiled in a usable format for the assessment team prior to the site visits.

2. Self-assessment of TB diagnostic network core capacities by India

The country performed a self-assessment of their capacity in key diagnostic network areas by identifying their capability stage according to pre-defined criteria (components and questions) for each core capacity (Table 3). The self-assessment was performed two weeks prior to the in-country external assessment by a small technical group consisting of the CTD, NRL, IRL and other national level laboratory expert.

TB Diagnostic Network Assessment Tool

Background

There are many tools available to evaluate individual components of a laboratory system or individual laboratories within a diagnostic network; however, there is currently no single comprehensive tool available to assess holistically a complex TB diagnostic network like the one in India. To meet this need, a 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.

The framework of the India assessment tool (hereafter referred to as the "Tool") was based on two previously developed tools: 1) the African Society of Laboratory Medicine (ASLM)/Association of Public Health Laboratories (APHL) National Laboratory Network Assessment (LABNET) scorecard[7], developed by ASLM, APHL, the Royal Tropical Institute (KIT) and the Amsterdam Institute of Global Health and Development (AIGHD) and 2) the National TB diagnostic network standards and assessment tools developed and piloted by the Global Laboratory Initiative (GLI) and partners[8], which were based on an earlier GLI assessment tool focusing on TB microscopy laboratory networks[9]. Parts of the Tool were customized to meet the local context of India's complex health system in collaboration with CTD.

Diagnostic Network Standards, Core Capacities and Components

The 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. The original nine LABNET core capacities were developed for evaluating national laboratory networks in Africa with respect to achieving global health security targets according to the International Health Regulations (IHR), Global Health Security Agenda (GHSA), Integrated Disease Surveillance and Response (IDSR), and WHO Global Strategy for the Containment of Antimicrobial Resistance. The core capacities used in the assessment of the TB diagnostic network in India (Table 3) are based on the nine LABNET core capacities but adapted to respond to the set of standards that define minimum performances needed for a quality TB diagnostic network. Components are used to describe the essential functions of the diagnostic network across the core capacities.

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[7] 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.

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

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

Table 3. Diagnostic Network Standards, Core Capacities and Components

	Standard	Core Capacity	Components
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.	Political, legal, regulatory and financial framework	- Legislation - National policies and plans - Governance - Financing
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.	Structure and organization of the diagnostic network	- Network structure - Coordination and management
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.	Coverage	- Diagnostic network coverage - Sample referral system - Rapid response and preparedness
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	Diagnostic algorithm and laboratory-clinical interface	- Algorithms - TB diagnosis - Drug-resistant TB - Linkages - Surveillance - Research

	Standard	Core Capacity	Components
	treatment.		
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.	Biosafety	- Facilities - Biosafety manual - Biosafety systems - Specimen storage - Waste management
6	Testing is performed with state-of-the-art and well-maintained equipment and an uninterrupted supply of quality reagents and consumables.	Equipment and supplies	- Supply chain management - Equipment
7	Adequate numbers of competent, well-trained and motivated technical and managerial staff are available at all levels of the diagnostic network.	Workforce	- Education and training - Staffing - HR development strategy
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.	Diagnostics data management	- Data collection - Data analysis and sharing - Reporting - Surveillance/epidemiology - Security and confidentiality of information
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.	Quality of the diagnostic network	- Quality assurance - Quality management systems - Certification and accreditation

Questions and Stages

Within the Tool, standardized "questions" are used to assess to what degree each component is present to meet 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 Measurement Model (CMM)[10], 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.

The stages of capability are defined as:

- *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.

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

Determining the capability stage and progress towards achieving core capacities

A capability stage is determined for every "question" of a component, and the overall capability stage assigned to the component is the lowest stage assigned to any of the questions used to evaluate that component. In this sort of qualitative analysis, the overall stage for each component reflects the "weakest link" of the component. Figure 4 illustrates how the component stage is determined. In the example, because the response to the last question was equivalent with stage 1, the overall component capability stage is 1 – even though higher stages were determined through the other component questions.

Component	Questions	0	1	2	3	4	5
Algorithm			**Overall stage 1**				
	Is a clear national TB diagnostic algorithm available that is responsive to the epidemic, patient-centred, based on international best practice?	No	National diagnostic algorithms for TB are available at some laboratories but not current or complete.	National diagnostic algorithms and SOPs are available at all facilities in the public sector, but not current or complete.	Current national diagnostic algorithm available, but not at all public facilities. ☑	Current national diagnostic algorithm available at all public facilities and some private labs.	Current national diagnostic algorithms available at all public and private facilities and regularly updated.
	Does the algorithm focus on the whole diagnostic cascade, from screening to treatment completion?	No	The algorithm focuses only on the laboratory testing but is not current or complete.	The algorithm focuses on laboratory testing and does not address the whole diagnostic cascade.	The algorithm at least partially addresses the whole diagnostic cascade.	The algorithm addresses the whole diagnostic cascade.	The algorithm addresses the whole diagnostic cascade and is regularly updated. ☑
	Does the diagnostic algorithm define the role of symptom screening, clinical presentation, patient history, and X-ray in the diagnostic cascade?	No	A national algorithm is available but is rarely followed and there has been little training of clinicians in the algorithm.	National diagnostic algorithm is followed by some clinicians in the public sector. ☑	National diagnostic algorithm is followed by all clinicians in the public sector in some districts.	Stage 3 with all public sector in all districts and some private sector.	National, standard-of-care guidelines for evaluating patients and using X-ray findings are followed by all clinicians.
	Are health care workers provided with standardized sensitization content (e.g., algorithm diagrams, brochures, training materials)?	No	Sensitization content is available at some facilities but not current or complete. ☑	Sensitization content is available at all facilities in the public sector, but not current or complete.	Current sensitization content is available, but not at all public facilities.	Current sensitization content is available at all public facilities and some private labs.	Current sensitization content is available at all public and private facilities and regularly reviewed and updated.

Figure 4. Determining a component's capability stage

This qualitative analysis can provide a quick visual assessment of the status of the overall diagnostic network core capacities at the country level and identify areas that need intensified strengthening. However, a 'weakest link' staging system does not provide a complete assessment of the progress towards achieving a strong diagnostic network. To do this, progress towards reaching stage 5 (or 100% capability) for all components within a core capacity can be determined.

Figure 5 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 under Algorithm contributes 3 points, question 2 contributes 5 points, etc.
- Add up the points for all of the questions within the core capacity. In the example, the total number of points is 62
- 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 calculated as: [62/(18x5)]x100 = 69%

Core Capacity: Diagnostic algorithm and laboratory-clinical interface

Standard: 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.

Components	Stage
Algorithms	
Question 1	3
Question 2	5
Question 3	5
Question 4	4
Question 5	2
Question 6	1
Question 7	4
TB Diagnosis	
Question 1	4
Drug resistant TB	
Question 1	3
Question 2	4
Linkages	
Question 1	4
Question 2	4
Question 3	2
Surveillance	
Question 1	1
Question 2	1
Question 3	5
Research	
Question 1	5
Question 2	5
Total	62

Figure 5. Determining Progress Towards 100% Capability for a Core Capacity

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

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

During the period of October 30 – November 10, 2017, the assessment team reviewed and verified the country's pre-assessment stages for each component. Data for verification were gathered during visits to pre-determined diagnostic facilities at each level of the TB diagnostic network (NRL, IRL, other C/DST laboratories, DMC, CBNAAT laboratories) (see Table 2 for the details) 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:

- Access to services (specimen collection and transport; regional perspective and special populations)
- Use of chest X-ray as a screening tool for entry into the new diagnostic algorithm and for the clinical diagnosis of TB

Table 4. Assessment checklists

Checklist	Audience	Purpose
CTD Verification Checklist	CTD, partners	To verify the self-assessment done by the national program
NRL Verification Checklist	NRL	To verify the self-assessment done by the national program
IRL Verification Checklist	IRL, C/DST laboratories	To verify the self-assessment done by the national program
DMC Verification Checklist	DMC	To verify the self-assessment done by the national program
CBNAAT Verification Checklist	CBNAAT Lab	To verify the self-assessment done by the national program
Program Verification checklist	State and district TB officers (STOs, DTOs)	To verify the self-assessment done by the national program
Supervisory Laboratory Checklist	NRL, IRL	To evaluate the system of external quality assessment and on-site supervisory visits
Microscopy checklist	DMC	To assess microscopy services
CBNAAT Checklist	CBNAAT laboratories	To assess CBNAAT services
Specimen referral checklist – national	CTD, partners	To assess specimen referral networks
Specimen referral checklist – subnational	NRL, IRL, C/DST, DMC, CBNAAT laboratories	To assess the specimen referral processes
Diagnostic Data Management - national checklist	CTD, partners	To assess data management processes
Diagnostic Data Management - subnational checklist	NRL, IRL	To assess data management processes
Chest X-ray Supplemental Checklist	CTD, STOs, DTOs, clinicians, partners	To assess the availability and quality of chest X-ray

Each field team was provided a set of tools (including the main assessment tool and accompanying checklists) specific for the types of facilities and individuals planned to be assessed or interviewed within their allocated state or region. The consultants were responsible for collecting the data and verifying the collected information.

Members of the assessment team interviewed national level stakeholders and agencies (*e.g.*, CTD, technical partners, clinicians, program committee, and heads of NRLs) and collected data and information according to the main assessment tool and supplemental checklists.

Analysis

Feedback on findings from each state 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 state level and national level assessments informed the team's final findings and recommendations.

Site- or state-level reports were compiled by the assessment teams based on data gathered using the various assessment tools, and informed key findings and recommendations (Annex 4).

An interim assessment report was presented to Ministry of Health and Family Welfare (MoHFW) officials, the CTD and other stakeholders and key partners at a national stakeholder debriefing meeting on 10 November 2017.

As assessment team observed HR issues critical for sustenance of C-DST lab services which required urgent actions, an interim summary of assessment was submitted to CTD highlighting the urgency of immediate intervention.

Following compilation of all data and in-depth analysis, the assessment team prepared the full assessment report.

Findings and Recommendations

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

1. Pre-Assessment Data Analysis Results
2. National TB Diagnostic Network Assessment Results
3. Key Findings, Interventions and Priority Actions
4. Detailed Findings and Recommendations by Capacity and Thematic Area
5. General Considerations for Strengthening the Diagnostic Network and Thematic Areas

Site-specific key findings by facility are described in detail in Appendix 5.

1. Pre-assessment Data Analysis Results

Below are selected compiled graphs from the pre-assessment data analysis. For each graph, data is presented for all states, the assessment states only, or per laboratory

Bacteriological confirmation

The percentage of notified new and previously treated TB patients from the public sector with bacteriological confirmation was 54% nationally in 2016 (Figure 6). The percentage bacteriological confirmation was highest in the state of Gujarat (64%) and lowest in the state of Mizoram (32%).

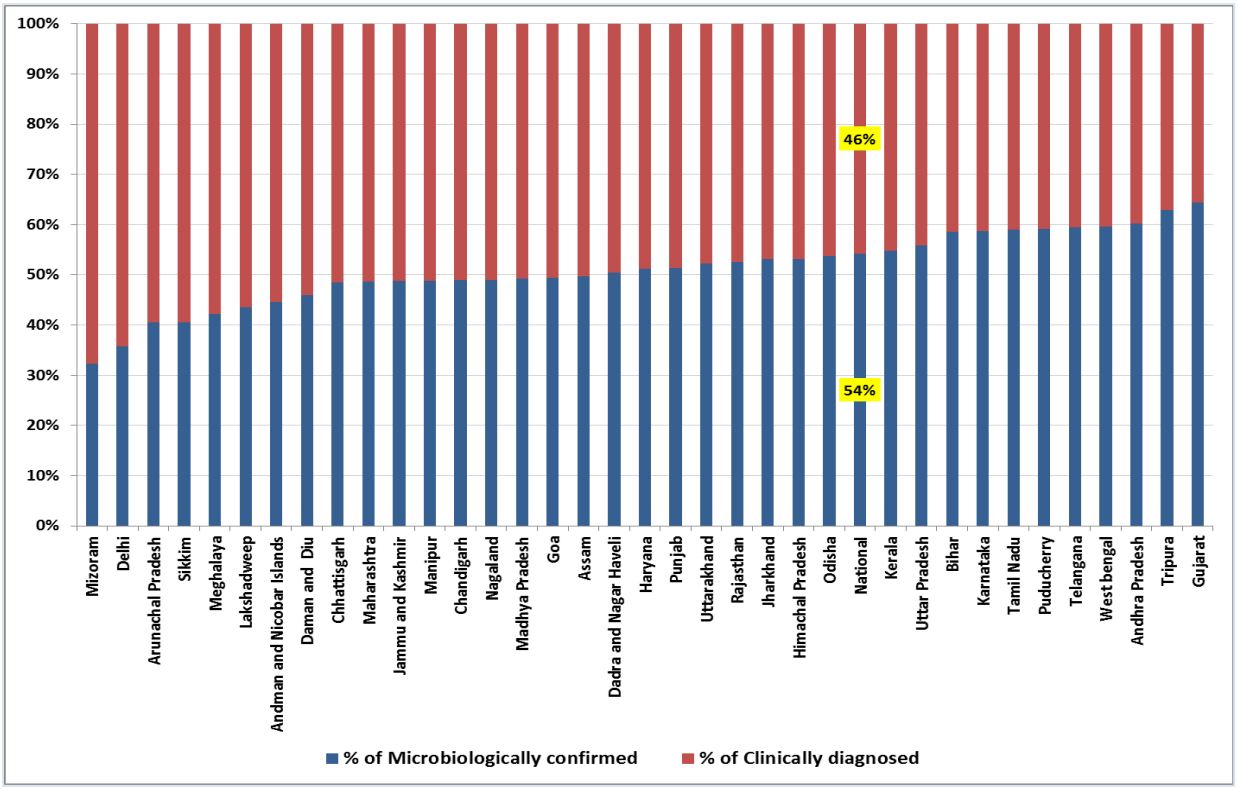


Figure 6. The proportion of notified new and previously treated TB patients with bacteriological confirmation from the public sector by state and on national level in 2016 (Source: *CTD-provided data file "National database 2016"*).

Sputum smear microscopy

There was large variation in the number of smear microscopy slides read between the states in 2016 (Figure 7). This ranged from 5,831 in Diu Daman (~2400 per 100,000 population) to up to almost 3,312,600 in Uttar Pradesh (~1600 per 100,000 population). Five states did not provide any data regarding the volume of smear slides for 2016. The smear microscopy positivity rate in most states was between 6% and 12% in 2016. The smear positivity rate was lowest in Kerala (4%) and Kashmir (4%), and highest in Nagaland (16%) and Rajasthan (13%).

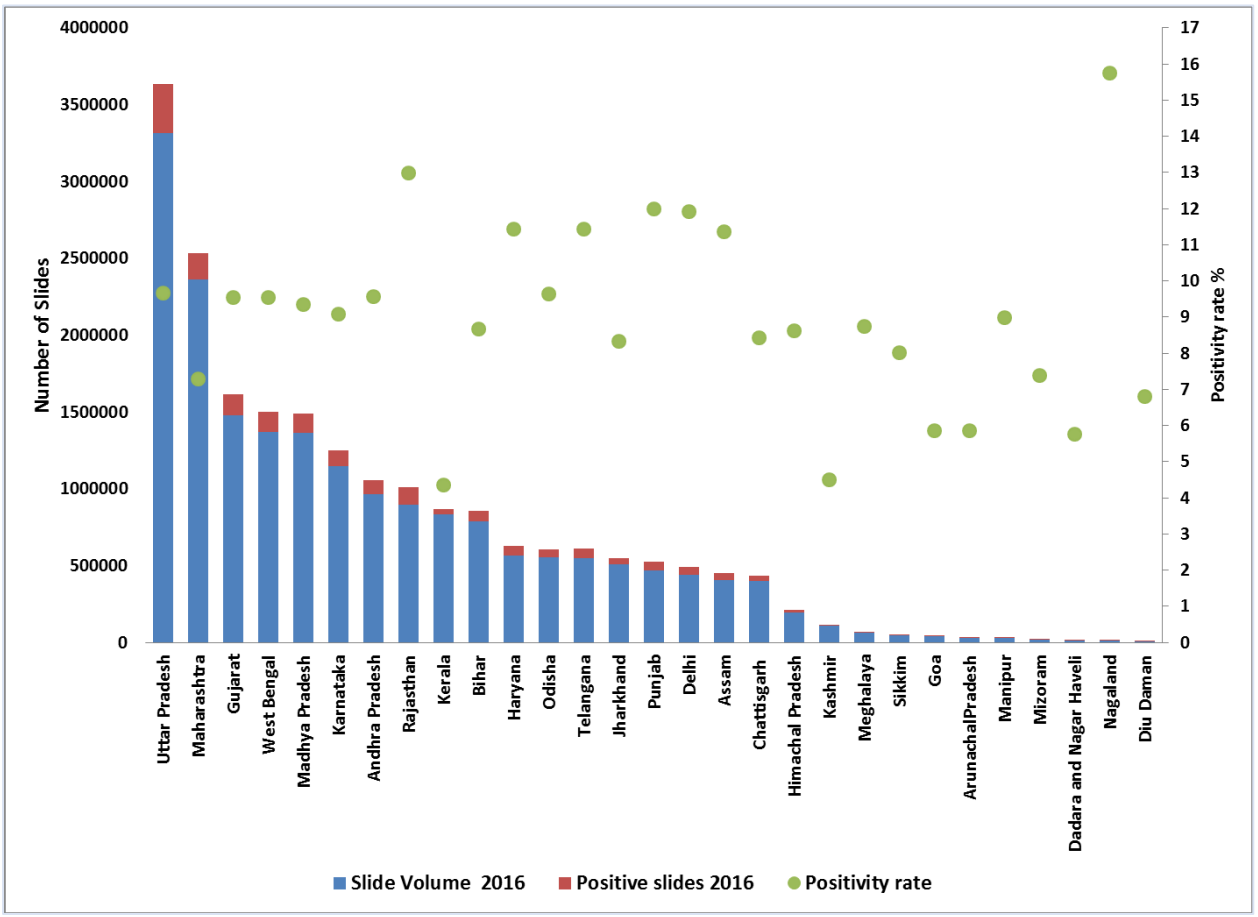


Figure 7. Number of sputum smear microscopy slides and the number of positive sputum smear microscopy slides and the positivity rate by state in 2016 (Source: *CTD-provided data file "Annexure G 2016"*).

Drug-susceptibility testing

The number of people with presumptive RR-TB or MDR-TB tested for DR-TB has been increasing in all states included in the assessment during the last 5 years (Figure 8).

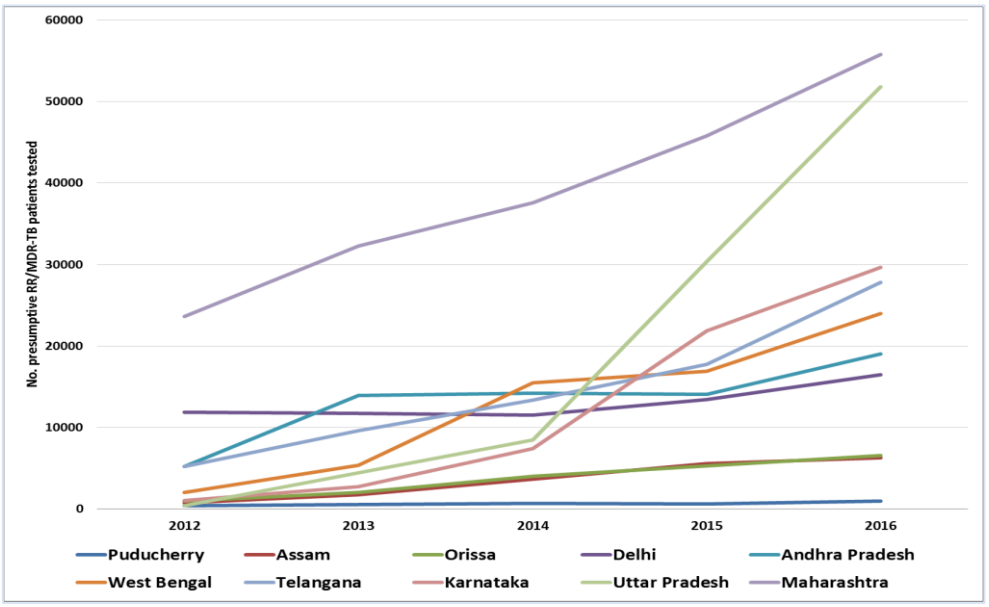


Figure 8. Number of people tested for DR-TB by all available methods by state (included in the assessment) from 2012 to 2016 (Source: *CTD-provided data file "DR-TB case finding 5 years"*).

The number and percentage of patients tested for DR-TB out of the total patients notified is presented in Figure 9. This percentage varied from 11% in Kerala to 70% in Manipur. At national level 25% of the notified TB patients were offered DST, which is just below the NSP target (30%).

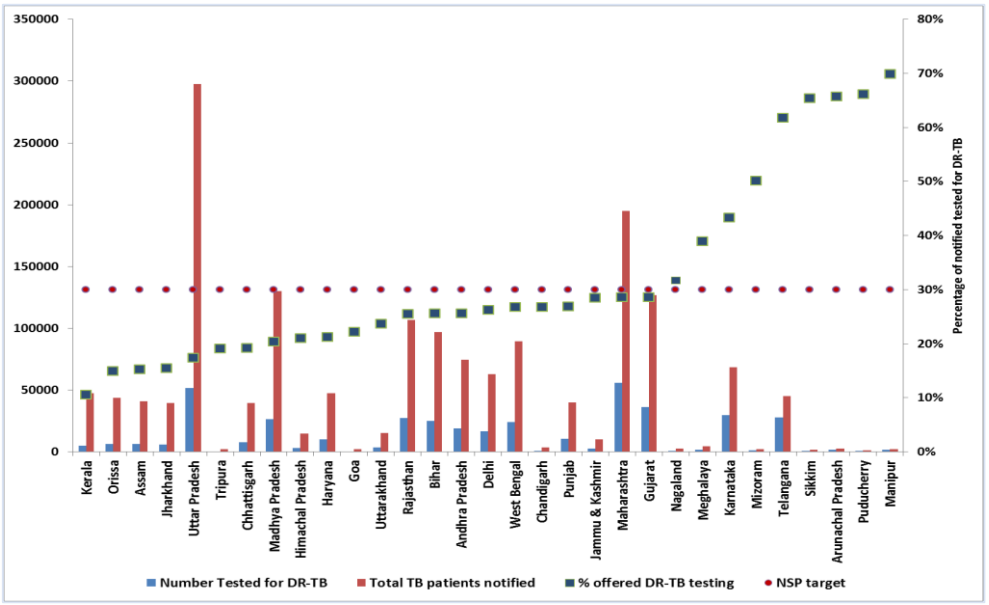


Figure 9. The percentage of notified patients tested for DR-TB per state in 2016 (Source: *CTD-provided data files "National database 2016"and "DR-TB case finding 5 years"*).

CBNAAT

The utilization of the CBNAAT machines by state in 2016 and 2017 is presented in Figure 10. This was calculated by dividing the number of tests performed per state by the number of available CBNAAT machines in that state, assuming that each machine was a 4-module machine which could run 12 samples per day for 240 working days. The number of tests performed in 2017 was extrapolated from Q1 and Q2 data. On national level the CBNAAT utilization rate increased from 32% in 2016 to 44% in 2017. The utilization rate increased in most states from 2016 to 2017, however, the rate of increase was varied considerably. (Source: *CTD-provided data files "CBNAAT_2016" and "CBNAAT_2017- 1 and 2 Q"*)

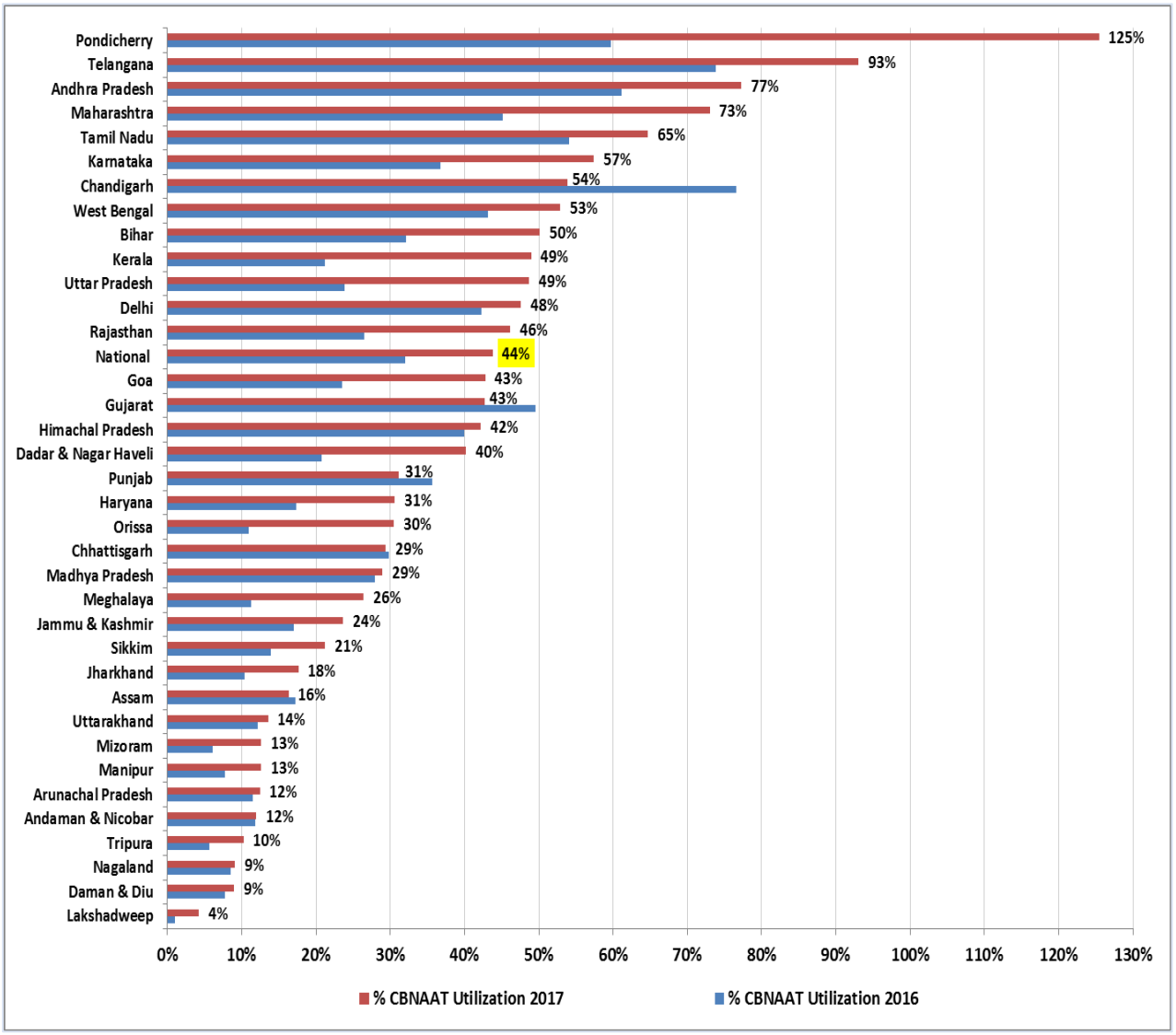


Figure 10. The utilization rate for CBNAAT by state in 2016 and 2017. The percentage refers to the 2017 value.

First Line LPA

The total number of first-line LPAs conducted in the laboratories reporting data increased from 71,316 in 2012 to 102,313 in 2016. In 14 out of the 19 laboratories conducting LPAs, and which participated in the Diagnostic Network Assessment, the number of LPAs increased between 2012 and 2016.

The estimated utilization rate for LPA testing for each laboratory in 2017 (based on data available for first two quarters) is presented in Figure 11. We assume that the maximum LPA capacity per lab was 7,680 based on an average 32 tests per day and 240 working days[11]. The utilization rate at national level was 28%.

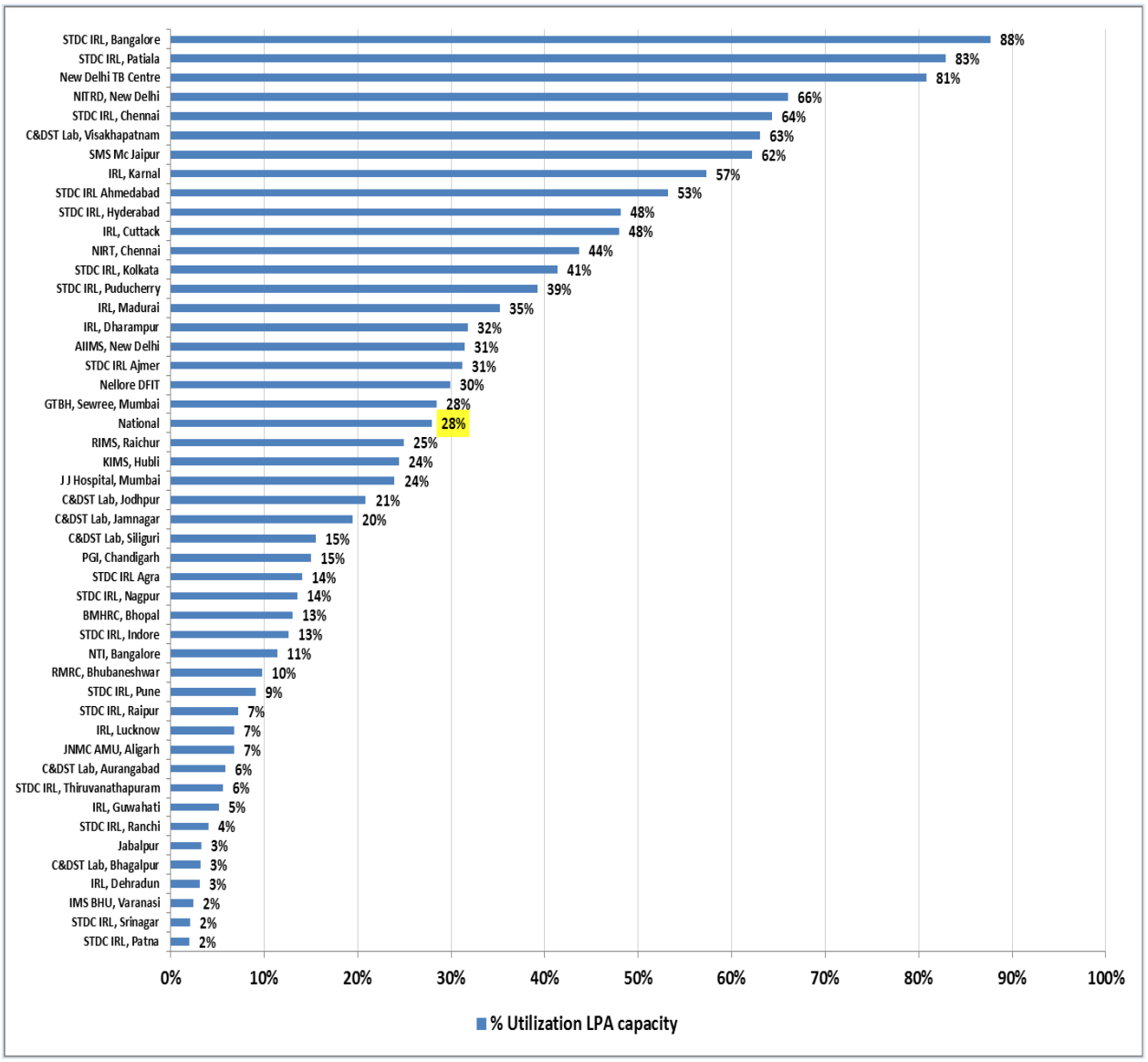


Figure 11. The estimated utilization rate (in %) of the LPA capacity per laboratory in 2017 (Source: *CTD-provided data file "LPA Data_MDRTB_2012-2Q2017"*).

[11] LPA lab capacity of 32 tests per day is based on the program assumption of two runs on 16-tube centrifuge/day.

Second-Line Liquid DST

The number of second-line drug-susceptibility tests as conducted through liquid culture in 2016 is presented in Figure 12. Out of the total 22,492 SL-tests conducted in 2016, five facilities processed close to 50% of those, 2,760 by NITRD (New Delhi), 2,230 by JJ Hospital (Mumbai), 1,788 by Hinduja Hospital (Mumbai), 1,771 by SMS Medical College (Jaipur), and 1,497 by BC Roy Hospital (IRL) Kolkata (West Bengal).

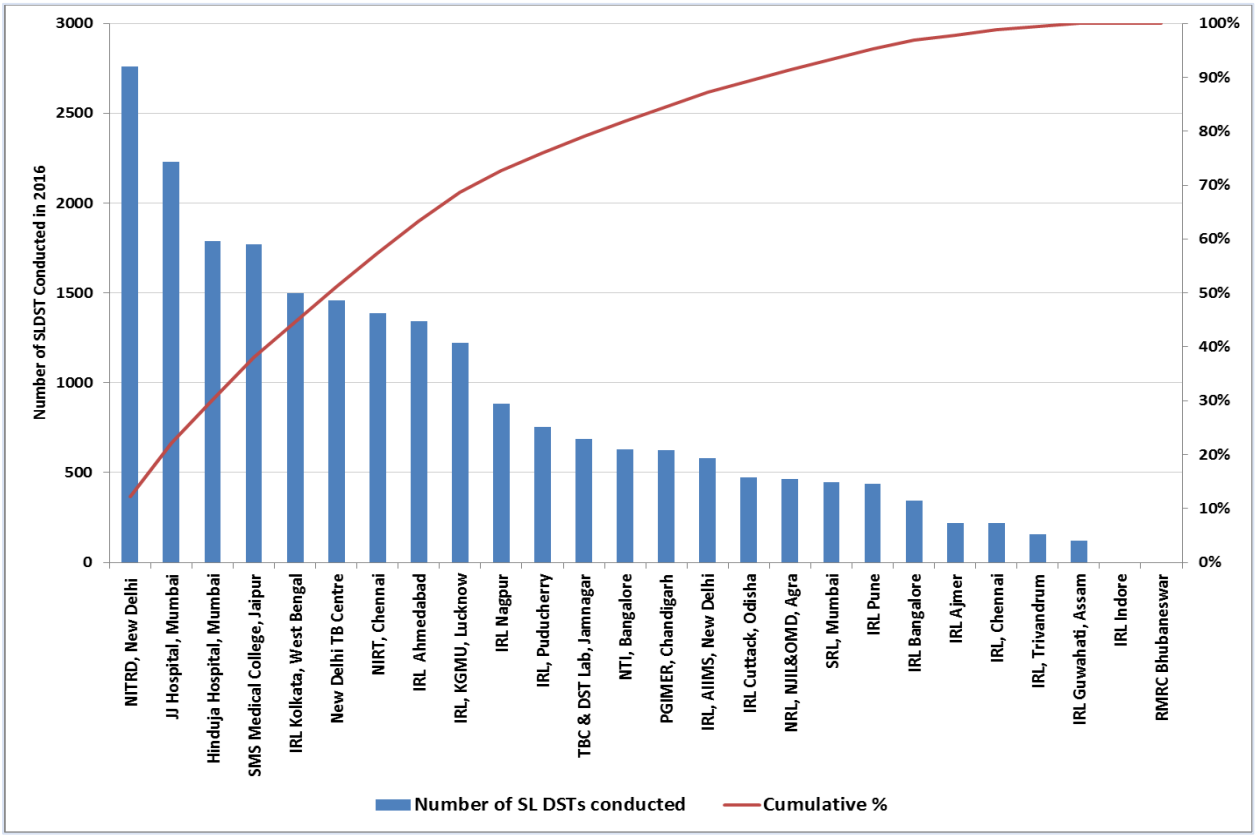


Figure 12. The number (and cumulative %) of second-line tests conducted by laboratory in 2016 (Source: *CTD-provided data file "LC SLDST 2016").*

Calculation of country-specific targets for microscopy, Xpert MTB/RIF, culture, and DST capacity

The WHO tool to calculate country-specific targets for diagnostics was used[12] to provide an estimate of future capacity needs to meet NSP targets (Annex 2). Here we briefly describe the analysis for Xpert MTB/RIF capacity.

By the end of 2018 CTD aims to have 1,380 functional 4-module CBNAAT machines. Assuming that these machines can run 12 tests per day for 300 working days, the estimated capacity is 4,968,000 tests per year (3,974,000 tests if assumption is 240 workdays per year). In collaboration with CTD, analysis done through the WHO Tool shows that 7,754,000 CBNAAT tests would need to be performed in 2018 to meet the 2018 NSP targets using the new diagnostic algorithm. If the instruments run at 100% capacity, India will miss the target by 36% (49% if 240 workdays) because there are not enough planned CBNAAT machines.

[12] http://www.who.int/tb/publications/labindicators/en/

Key conclusions from the pre-assessment data analysis

- There is a large variation between the volume of tests conducted per laboratory and district and the positivity rates found for the different diagnostic tests being used across the states.
- There is considerable variability in the performance of different states in meeting the goals of the NSP.
- A clear trend in increasing DST has been observed across the country, though the uptake varied from state to state.
- CBNAAT has been rolled-out across the country. Nevertheless, the current CBNAAT capacity is insufficient to meet the 2018 targets of the NSP.
- The estimated utilization rate of the available CBNAAT capacity has increased from 2016 to 2017, but could be further accelerated.
- The proportion of bacteriological confirmation by state seems to be positively associated with the uptake of CBNAAT.
- The estimated utilization rate of LPAs suggest that LPAs are not being used to its full capacity.

2. National TB Diagnostic Network Scorecard Results

Figure 13 shows the capability stages identified for the components of each core capacity by the assessment team following the field visits and discussions with key stakeholders, Table 5 compares the capability stages identified in the self-assessment and those identified by the assessment team, and Table 6 provides the progress towards 100% capability for each core capacity, calculated both for the self-assessment and team verification.

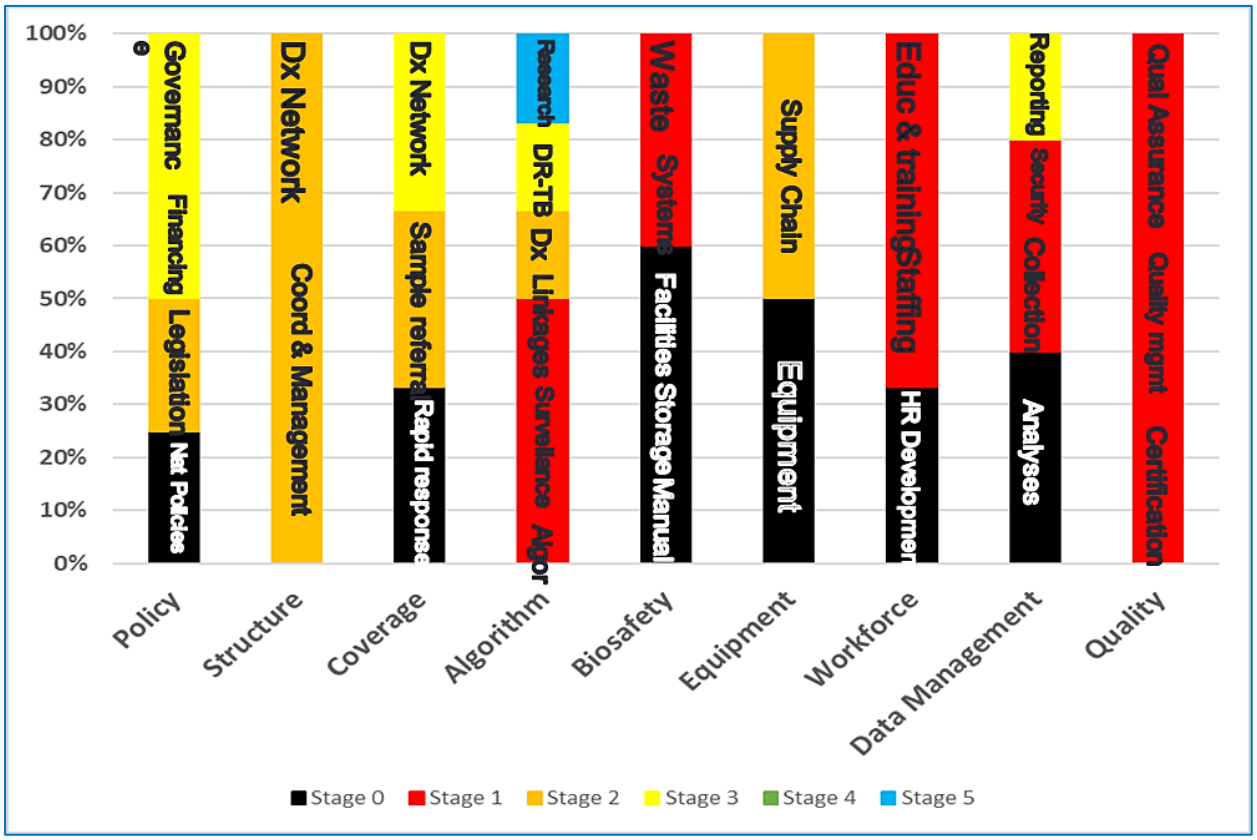


Figure 13. Verified capability stages for the components of each core capacity

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

Core Capacity		Stage		Stage determining factors considered by assessment team
	Component	**Self**	**Team**	
1. Political, legal, regulatory and financial framework				
1.A	Legislation	3	2	Biosafety waste management guidelines were included in the program guidelines, but no separate biosafety guidelines or biosafety policy for BSL-3 facilities were available. Surveillance policy for TB was not available.
1.B	National policies and plan	0	0	TB laboratory guideline exists as a standalone document. The laboratory scale-up plan includes modern diagnostics. EQA guidelines for all tests in program (except CBNAAT) exist. A TB laboratory operational plan was not available. Certification process exists, licensing does not exist.
1.C	Governance	5	3	There is no governing entity at MOHFW level. Coordination is managed at CTD level. Coordination with National AIDS Control Program (NACP) exists, but with other programs it is on an ad hoc basis.
1.D	Financing	3	3	There were differences between allocation and actual disbursed budget. All tests are available free to the patient in all public sector laboratories and in engaged private laboratories. Chest X-ray is free of charge in limited locations. There were central budgets and state budgets, with an expected ratio of 60% central funds and 40% state funds. A comprehensive laboratory specific budget was not available that addresses all of the laboratory activities, but different components are submerged in different budget lines (*e.g.*, EQA visits under supervision & monitoring, laboratory HR under HR-budget line, etc.).
2. Structure and organization of the diagnostic network				
2.A	Diagnostic network	3	2	Community screening was done in some districts or in some portions of a district. Laboratory services were available in most communities. Cost-effectiveness was not assessed.
2.B	Coordination and management	4	2	There was little or no communication within laboratory tiers. Meetings were not held at regular intervals, instead scheduled on an ad hoc basis. Communication between NRLs and IRLs varied by region. There was little evidence of review of quality indicators. Issues with supervision from NRL to IRL were noted. Corrective actions and follow-up were not working well in some sites.
3. Coverage				
3.A	Diagnostic network coverage	3	3	A line listing of public laboratories existed at 5/5 NRLs and 15/16 IRLs /C-DST labs visited. GPS-based maps were not included although the mapping exercise is currently being done. Testing appears to be available in most districts (including by referral), but capacity is a limiting factor for access in some diagnostic sites.

3.B	Sample referral system	4	2	CBNAAT/DMC staff training was variable, with many sites stating that no training had occurred. There were no standard training or SOPs available for couriers. Triple packaging was standardized, but there was variability between sites (7/55 stated challenges in this area).
3.C	Rapid response and preparedness	0	0	5/5 NRLs and 7/16 IRLs/C-DST labs cited back-up testing plans, but they are not formal or written and not necessarily for emergency situations. 9/16 IRLs/C-DST labs had no plan at all.
4. Diagnostic algorithm and laboratory-clinical interface				
4.A	Algorithms	1	1	The new diagnostic algorithm is in process of being implemented. Training of medical officers has taken place in many districts. Private sector clinicians were not trained. Not all clinicians followed new algorithm. The chest X-ray portion of algorithm was not followed by all. Health care workers were not provided with standardized sensitization content.
4.B	TB Diagnosis	4	2	WHO recommended rapid diagnostics were not being used for all priority groups. Tier-specific testing packages have been defined.
4.C	Drug resistant TB	3	3	In process of implementing or building capacity for first-line DST on site or by referral for bacteriologically confirmed TB patients at risk of having MDR-TB.
4.D	Linkages	2	1	There were no formalized procedures for linking patients to services in the private sector. Formal reporting to the DTO was observed, but some issues with finding patients, including migration and lack of documentation of attempts to find patients were noted. Gaps in tracing patients. Process was not efficient anywhere. Procedures were described but not completely implemented.
4.E	Surveillance	1	1	A drug resistance survey has been conducted, but not a prevalence survey; sentinel laboratory-based surveillance for TB and DR-TB is not conducted.
4.F	Research	5	5	Research currently underway or previously carried out for Truenat, NGS, newly-introduced molecular diagnostics, including CBNAAT validation and implementation research.
5. Biosafety				
5.A	Facilities	0	0	There are no national laboratory building requirements that include detailed standards for TB laboratories. 2/5 NRLs had issues in maintaining negative pressure in the BSL-3 rooms. 6/46 DMCs had inadequate ventilation.
5.B	Biosafety manual	0	0	There is no current national laboratory biosafety and biosecurity manual, however there were SOPs on safety.
5.C	Biosafety systems	1	1	2/5 NRLs, 11/16 IRLs or C/DST labs, and 41/46 DMCs do not have basic occupational health services available. 1/5 NRL and 2/16 IRLs/C-DST labs BSC cabinets were not routinely certified. Designated safety officers only appointed in facilities actively working toward NABL accreditation.

5.D	Specimen storage	0	0	No record or inventory of facilities that process or store TB or DR-TB strains.
5.E	Waste management	4	1	Variation in implementation of national standards for waste management exists at the DMC level. In particular, 2 DMCs located in rural area were not serviced by biowaste management company (open pits or incinerators used).
6. Equipment and Supplies				
6.A	Supply chain management	1	2	Post-market surveillance was not comprehensive across TB tests, unsystematic procedures for quality control of lots, weak monitoring of testing results, lack of SOPs for reporting complaints. Supply management and forecasting was done with Excel tools. FIND manages procurement of reference lab commodities; plans to devolve functions to states will need to be carefully monitored. GDF manages procurement of CBNAAT commodities. CBNAAT consumption was reported monthly to IRLs, which is aggregated and sent to CTD; forecasting seen in some districts.
6.B	Equipment	0	0	Discussions at national level to start allowing use of GeneXpert instruments for HIV viral load testing in 2018, where capacity allows; multi-disease testing not being performed at NRL/IRL/DMC yet. CBNAAT machines are under warranty. National annual maintenance plan for microscopes is ending in December; some microscopes were found to be in poor condition. Some maintenance plans are state-based and quality varies by state.
7. Workforce				
7.A	Education and training	1	1	There is no licensing or registration for laboratory workers at any level. Certification for staff is mostly at state level. There is no national body for certification of laboratory staff at the different levels. Staff mentioned accessing laboratory management trainings: Pre-service training: 3/5 NRLS; 15/16 IRLs/C-DST labs; 18/46 CBNAAT/DMCs.
7.B	Staffing	1	1	National tier-specific staffing plan was available. However, scale-up plan of CBNAAT network does not include provision of additional staff based on increasing workload. State also contributes to staffing plans separately from RNTCP. IRLs seem to be more constrained by the number of staff available at their level (as compared to the lower levels), primarily staff is lacking around data management and EQA.
7.C	Human resources development strategy	0	0	No national human resource development strategy was available. Only 45% of DMC/CBNAAT; 1/5 NRLs and 12/15 IRLs/C-DST labs reported having competency-based job descriptions available at their facilities.

8. Diagnostic Data Management				
8.A	Data collection	4	1	Tracking varied considerably by site ("WhatsApp", email, telephone, paper based, etc.). For 40% of the sites assessed, no system was visible to determine if results were received. Performance was not monitored.
8.B	Data analysis and sharing	0	0	No dedicated unit at the CTD level or NRL level. Although many data are reported, there is little evidence of appropriate or consistent analyzing of the data.
8.C	Reporting	5	3	Nikshay was not used in all laboratories, not used in a timely manner, and not used at all levels. No automated electronic system for reporting results.
8.D	Surveillance /epidemiology	2	0	System appeared to be informal and ad hoc. No automated data reporting at this time. In the future, Nikshay may be able to do this.
8.E	Security and confidentiality of information	4	1	Deficiencies noted at many sites. Back-up systems were ad hoc and not consistently applied in all laboratories.
9. Quality of the Diagnostic Network				
9.A	Quality assurance	5	1	Gaps in scope of quality indicator monitoring, analysis and use of data for quality improvement, especially at lower levels. No labs conduct internal quality control for smear microscopy (*i.e.*, use of known positive and negative slides with each batch of tests), as it is not required by RNTCP guidelines. EQA for microscopy is in place for DMC and IRL level. CBNAAT EQA consists of OSE only. 12/16 IRLs/C-DST labs received proficiency testing and OSE in the past year. 3/12 IRLs/C-DST labs did not receive timely feedback and corrective actions.
9.B	Quality management systems	3	1	Quality officer positions were only found in 4/16 IRLs/C-DST labs and 3/5 NRLs. At most NRLs and IRLs, quality management systems practices related to personnel, equipment and EQA were partially implemented, but not according to a structured approach.
9.C	Certification and accreditation	1	1	NABL is responsible for accreditation of medical laboratories in India. Only a few NRLs and IRLs were in the process of becoming accredited.

Table 6. Progress Towards 100% Capability

Core Capacity	Capability percentage	
	Self-Assessed	Team-Assessed
Political, legal, regulatory and financial framework	**70%**	**52%**
Structure and organization of the diagnostic network	**88%**	**68%**
Coverage	**69%**	**53%**
Diagnostic algorithm and laboratory-clinical interface	**69%**	**52%**
Biosafety	**40%**	**25%**
Equipment and Supplies	**64%**	**56%**
Workforce	**48%**	**34%**
Diagnostic data management	**80%**	**45%**
Quality of the diagnostic network	**84%**	**40%**

The most frequent discrepancy between the self-assessment and the assessment team verified stages in which the self-assessed stage was higher than the verified result was due to the fact that the self-assessment staging was done based on availability of policies and future plans, compared with the assessment team staging which was based on the current status of implementation. Further, the assessment team observed that the extent of the implementation of the policies and practices varied at the different levels of the diagnostic network. Typically, complete or near-complete implementation of policies and practices were observed at the NRL and IRL levels, but policies and procedures were absent or only partially implemented at the DMC and CBNAAT levels. This variation may have biased the self-assessment results due to stronger focus on the higher-level laboratories. The assessment team noted that due to the presence of policies and guidelines that address several of the key areas requiring strengthening, and initiation of implementation efforts, that a focus on accelerated implementation of existing plans is anticipated to drive progress to higher capability levels for many components in the relative short term.

3. 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:

Meeting the NSP targets will require a large scale and rapid expansion in the use of the new diagnostic algorithm in the public sector, and importantly, in the private sector.

Intervention: **Accelerate implementation and monitor progress**
Priority Actions:

- Using a simple modeling approach, estimate the contribution of increasing the use of the new NSP diagnostic algorithm in the private sector and in priority populations to enable meeting of NSP targets.
- Monitor the impact of the scale up of the new diagnostic algorithm in both public and private sectors and revise algorithm if needed to reach targets.
- Improve engagement with the private sector (see below).
- Develop adequately resourced, state-specific plans for implementation of the new diagnostic algorithm (see below).

Key Finding #2:

Overall there is limited and insufficient engagement of private sector laboratories and providers to find the missing 1 million TB patients. In 2016, 1.8 million of the estimated 2.8 million TB patients were reported to the RNCTP – and only 19% of the notified patients were through private providers.

Intervention: **Translate public-private mix (PPM) policy into implementable activities within the diagnostic network**
Priority Actions:

- Develop and implement specific operational guidelines to engage private providers and laboratories within the TB diagnostic network.
- Set targets, adequately resource and mainstream monitoring of key indicators to measure progress and impact.
- Expand private sector engagement and ensure the quality of private sector TB laboratory testing (*e.g.*, participation in EQA, training, certification) and reporting of TB patients to the TB programme.

Key Finding #3:

Considerable variability in the quality of the diagnostic network was observed across the various parts of the country included in the assessment.

Intervention: **Develop state-specific performance improvement plans**
Priority Actions:

- Work with state TB program officers to develop performance improvement plans for TB diagnostic services and for implementation of the new diagnostic algorithm that will enable well-functioning states to move quickly and lagging states to catch up.
- Bolster advocacy at state level to minimize human resource (HR) and funding bottlenecks for TB diagnostic services.

Key Finding #4:

Recruitment of contractual positions for laboratory personnel has been delayed – over 20% of these positions have been vacant (up to 40% in some states). In addition, about 300 laboratory personnel are deployed in C/DST laboratories across the country by a Human Resource agency contracted by FIND as a sub-recipient of CTD for the current Global Fund Grant (ending December 31, 2017). The assessment team observed HR issues critical for sustaining C/DST laboratory services which require urgent attention.

Intervention: **Urgently address the laboratory human resource (HR) issues and impending service-interruption crisis**

Priority Actions:

- Fill presently vacant laboratory positions and work to build a sustainable HR strategy with adequate numbers of staff at all levels working under appropriate remuneration and in safe facilities and working conditions.
- Ensure uninterrupted support of HR for various culture/DST laboratories in the short term and ensure sustainable support through establishment of appropriate mid- to long-term mechanisms for uninterrupted service delivery.

Key Finding #5:

A system of regulated supervision is in place from reference laboratory tiers to lower levels within the public sector but challenges with resourcing, implementation and follow-up of on-site supervisory evaluation visits and blinded rechecking activities limit impact on quality improvement.

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

Priority Actions:

- Optimize the schedule of supervisory visits to DMCs and simplify supervision to capture essential elements for service quality improvement. Prioritize visits by need and use electronic data systems to collect key data.
- Conduct a needs assessment of NRL and IRL supervision, and based on the assessment findings, strategically reorganize NRLs and IRLs (considering the possibility of additional NRLs or IRLs) and ensure adequate resourcing to carry out supervision and oversight functions.
- Ensure supervision includes entire patient cascade, not just laboratory technical aspects.

Key Finding #6:

Nikshay has great potential to facilitate laboratory data collection, but there is little evidence of analysis, review, or sharing of information. Problems exist with Nikshay adoption and use across country.

Rapid reporting of diagnostic data for both clinical and programmatic management is weak and there is no connectivity of CBNAAT machines currently.

Intervention: **Deploy electronic data systems across all diagnostic and laboratory level**

Priority Actions:

- Ensure that the data management system is user-friendly and is designed to allow people to do their jobs better and more efficiently.
- Streamline laboratory and diagnostic data collection to focus on data that will be analyzed and used to inform decisions.

- Establish data analysis unit at CTD or NRLs.
- Consider immediate upgrade of the Nikshay server capacity to effect immediate benefit in usability.

4. Detailed Findings and Recommendations by Capacity and Thematic Area

Since the objective of the assessment was to evaluate India's 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 nine capacities that encompass the standards of a comprehensive diagnostic network (Table 3). Two thematic areas are included in addition to the nine capacities: access to services (through a focus on specimen referral systems), and the use of chest X-ray as a screening tool for entry into the diagnostic algorithm.

Please note that there is overlap among the capacities – for example, findings and recommendations on optimal utilization of CBNAAT is both a network structure/organization issue and a network coverage/access issue.

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 enables continuous, country-wide availability of free, quality assured TB diagnosis according to the national guidelines.

The assessment found that policies/plans/regulations and/or legislation exists for some components of TB diagnosis, but not all. Components of TB diagnosis and laboratory services are incorporated into the NSP; however, India lacks a comprehensive, detailed and costed national TB laboratory/diagnostic network operational plan aligned with NSP targets and in harmony with similar plans at the state level (which are also lacking). While there are transparent mechanisms to certify and regulate laboratories that participate in the RNTCP diagnostic network, the process to ensure quality of private labs and enforce regulations is weak or lacking.

The specific findings and recommendations include:

Key findings	Recommendations
• Policy, plans, regulation or legislation exists for TB notification, private sector engagement and biomedical waste management, but are lacking for laboratory surveillance and biosafety • Clear mechanisms for certifying the laboratories that participate in the diagnostic network are available	• Develop a detailed, costed national TB lab operational plan and costed state level operational plans that are aligned with the NSP, and that includes private sector • Quickly engage states in development of state operational plans, use SMART[13] planning, and review and revise after 2 years

[13] Specific, Measurable, Achievable, Relevant, Time-Based

• Provisions for registration of laboratories exist, but mechanisms for licensing or renewal are not in place • National TB Laboratory policy and plan (and National Laboratory Policy) are not available, although components have been incorporated in various program documents • Diagnostic tests are provided free to the people being evaluated • National laboratory human resources policy is lacking • Facilities have dedicated budgets for the TB laboratory services which cover key routine laboratory activities; although issues related to delays in disbursement were observed	• Monitor and evaluate implementation of the plans and link indicators to NSP targets • Ensure availability of funds at national and state level to support implementation of approved plans • Strengthen and enforce regulations to ensure the quality of private sector laboratories that provide TB diagnostic services and facilitate their incorporation into the TB diagnostic network • Develop and implement a national policy on use of chest X-ray and ensure availability of quality radiology in public and private sector free of cost or by a reimbursement mechanism

It should be noted that individual countries are best positioned to decide if policies, plans or regulations are most appropriate for their country. For example, India may decide that a strong, well-enforced policy is a better approach than a regulation for ensuring the needed framework for the network.

Components of a TB laboratory strategic plan are included in the NSP. Implementation of the TB laboratory strategic plan will be greatly facilitated by having a detailed, costed, national TB laboratory operational plan that includes all components of a comprehensive TB diagnostic network. State-specific TB laboratory operational plans should be developed to tailor the national plan to their specific situation. This will allow well-performing states to move quickly towards accomplishing NSP targets and help develop interventions that will allow lagging states to catch up.

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 existing structure and organization of India's TB diagnostic network reflects the RNTCP's prior main strategy to use smear microscopy for detecting (mostly drug sensitive) TB. As the program's priorities and strategies shift to providing universal DST to all people and ensuring that second-line drug resistance results are informing treatment for MDR-TB, there is an urgent need for accessible, rapid and more sensitive technologies to test for TB and DR-TB. The existing network structure needs to adapt to fill this need, as evidenced by the current low CBNAAT capacity in the country and the under- or over-utilization of existing CBNAAT instruments. There are currently far too few private labs integrated or

engaged into the network for India to meet its ambitious case notification targets. Organizational and structural changes necessary to modernize the TB diagnostic network will need to occur throughout all tiers of the network from NRL to the community, and can be informed by optimal scenario planning combined with detailed mapping of the network.

The specific findings and recommendations include:

Key findings	Recommendations
• An organized and structured TB diagnostic network is in place with clearly defined tiers with specific roles and responsibilities • Some private and academic institutions are functionally integrated in the network, otherwise there is limited engagement of private sector laboratories • SOPs for all TB tests have been developed and are centrally available but information and implementation is inconsistent across the network • CBNAAT instruments are underutilized in some settings (<50 tests per month) and over utilized in some settings (>30 tests per day) • There is not enough current or planned CBNAAT capacity to reach the 2018 NSP targets (*i.e.*, 50% more CBNAAT instruments are required than are planned) • Some DMCs are characterized by low workload making it challenging to maintain staff proficiency and quality of testing	• Build capacity at NRLs and IRLs to manage the network - Map current and future need for network oversight (increased number of C/DST labs and private sector engagement) - Based on mapping exercise, determine whether to strengthen existing NRLs and IRLs or create additional NRLs and IRLs - Review and revise roles and responsibilities of NRLs and IRLs based on the current and future need and provide adequate resources to fulfill their mandate • Expand engagement of private sector laboratories and practitioners • Review the requirement for CBNAAT based on NSP targets and revise CBNAAT implementation plan as necessary • Review structure of the existing tiered network of TB diagnostic services, minimum package of TB diagnostic services for each level of the network, and the systems for referring specimens - Optimize placement of CBNAAT instruments and specimen transport systems - Low volume DMCs may be better utilized as specimen collection and referral hubs than as testing sites - Prioritize the establishment of an effective and efficient sample referral system to ensure timely access to diagnostic services • Use mapping data and network design software to model various scenarios for diagnostic network structure and to inform tier-specific testing packages and referral pathways to optimize network efficiency

- Note: the optimal network design will likely vary by geography and epidemiologic situation

The structure of the network and the testing packages available at each level of the network should be tailored to meet the needs of the community and the local epidemiology of TB (*i.e.*, demand-based rather than population-based targets). For example:

- In low-prevalence settings, having 1 DMC per 100,000 population may lead to low testing volumes and difficulty in maintaining proficiency. In such cases, it may be more effective to use existing DMCs as hubs to collect and rapidly refer specimens to testing centers.
- In high-prevalence settings, more or higher volume laboratories may be needed. For example, additional instruments (or higher throughput instruments) and resources should be provided to IRLs receiving more than 20 specimens a day for CBNAAT testing, perhaps by relocating GeneXpert instruments from DMCs that receive fewer than 30 specimens a month for CBNAAT testing to the IRL. Any relocation of instruments must include implementation of an efficient specimen referral system to ensure that patients at the DMCs have timely access to CBNAAT testing.
- If a rapid molecular test (*e.g.*, Truenat or Xpert MTB/RIF) is to replace smear as the initial diagnostic test for TB, optimal access to quality testing may be achieved by deploying the molecular test to all DMCs, or by using DMCs to collect specimens and then transport specimens to molecular testing centers through an efficient specimen referral system.

Tailoring of the network should be facilitated by using data from the recent drug resistance survey and data from the planned national prevalence survey. This data will provide important information for refining and optimizing the diagnostic network, minimal testing packages, resource deployment, specimen referral routes and service map.

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.

The network will need strong management support from the NRLs and IRLs in order to function efficiently. While building management capabilities at the NRLs and IRLs, the roles, responsibilities, resources and number of NRLs and IRLs should be reviewed and aligned with the map and structure of the diagnostic network.

India's current diagnostic network structure makes TB diagnosis available to the majority of the population; however, the accessibility and type of testing available is unknown or difficult to assess. (The assessment team did not have the opportunity to assess access for hard-to-reach populations). Community-level (or patient-centered) services to access modern TB tests are weak or non-existent throughout India. Information on services available through private

sector providers or laboratories is growing but still incomplete. While specimen referral mechanisms exist throughout the country, they are not patient-centered or efficient. Specimen transport systems are not properly monitored or tracked, and staff (including couriers) lack SOPs and training.
The specific findings and recommendations include:

Key findings[14]	Recommendations

• Lists of laboratories in the diagnostic network plus relevant tests/equipment were available, but a GPS-based map was not available
• A list of private providers and laboratories exists at many sites but completeness was uncertain
• Most, but not all, public facilities are covered by a specimen referral system
  - Most DMC/CBNAAT sites received specimens via a specimen referral system, in most cases a human carrier
  - Most DMC/CBNAAT sites referred specimens via either courier or human carrier
• States, districts or facilities pay for specimen transport
• Referral logs were in a majority of sites but were not always available or filled in properly or completely
• Most laboratory staff have been trained on proper specimen collection, packaging, transportation but SOPs were not available at all lower-level laboratories and refresher training was not done
• Courier staff has not been trained on biosafety or specimen handling
• Proper triple packaging is not used all the time but not due to lack of packaging materials
• There is inadequate involvement of community services in case finding and improving access to diagnostic testing
• Although there are informal or spoken agreements in place for backing up laboratories, there is no formal or written plan for emergency services
	• Understand access and coverage gaps and bottlenecks in current diagnostic network and cascade through expansion of national study (including patient-patient turnaround time and loss to follow up)
	• Ensure GPS-based map includes all public and private facilities/laboratories, equipment/testing capacity and referral linkages
	• Once a map is available, use network planning, simulation or optimization tools for design and planning with an emphasis on access to services and patient flow through the diagnostics cascade
	  - the optimal system design will likely vary by geography and epidemiologic situation
	• Assess specimen referral systems and ensure funding is available to fill gaps in specimen transportation
	  - Gaps vary per state, from urban to rural settings and at different levels
	  - Consider taking advantage of specimen referral mechanisms to manage and increase testing demand in various settings
	• Make payments to couriers at district level – not at individual sites
	• Aggregate all state-level demand for specimen transport services, including routes now covered by human carriers
	• Provide annual refresher training on specimen referral and document for staff files
	• Provide all courier companies standardized SOPs and guidelines for specimen referral and transport
	• Track triple packaging use indicator and provide follow up where there are challenges

[14] For some findings, the number of facilities that provided information may be less than the total number of facilities assessed by the team due to possible variations in the data collection process for each facility.

	• Strengthen the community level of the diagnostic network to ensure that patients can access services • Develop written continuity of operation plans for each laboratory

Strengthening the diagnostic network should rely on a systems approach which emphasizes access to quality-assured services and which optimizes the flow of specimens and information. An efficient specimen referral and results reporting system can help:

- Optimize access to services, utilization of instruments, maintenance of proficiency, and quality assurance
- Provide the program with a degree of control over specimen flow and referral pathways
- Facilitate linkage to care and capture of all detected patients in the TB surveillance system
- Provide solutions adapted to the local geography and epidemiology

In a systems approach, the patient-based turnaround time for testing (*i.e.*, time from ordering a test to the time the patient receives the results) must be minimized to avoid delays in diagnosis or loss to follow up. For example, once weekly pick up of specimens might add a long delay for getting the results of a rapid molecular test. The GLI Guide for TB Specimen Referral Systems is a good source of information for designing, implementing, and monitoring specimen referral and results reporting systems

The entire diagnostic cascade, patient pathway and linkages to testing and treatment must be improved to maximize impact on patient outcomes. That is, gaps in any of the steps in the diagnostic cascade (*e.g.*, screening, testing, diagnosis, reporting, treatment initiation, treatment monitoring, follow up and use of X-ray) can reduce the clinical and public health impact of diagnostic testing. Although it is usually difficult to routinely monitor the patient pathway and diagnostic cascade without an efficient tracking system such as barcodes, it should be noted that by expanding access to Nikshay and assigning a Nikshay identifier to a presumptive TB patient, one could use the power of Nikshay to track patients through the patient pathway in real time and thereby monitor the entire diagnostic cascade, patient pathway and linkages to care.

Community organizations and workers can play critical roles in finding patients, facilitating access to testing (*e.g.*, community workers collect specimens and transport to a testing site), and monitoring treatment. A patient centric approach (*e.g.*, referring specimens not patients) is essential for reducing costs to patients and loss-to-follow up as well as improving linkages to care and treatment completion.

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.

The NSP 2017-2025 describes a revised diagnostic algorithm that allows for direct rapid testing with CBNAAT for identified key/vulnerable populations along with certain populations of confirmed TB patients most at risk for DR-TB. The revised algorithm explicitly includes second line DST for patients with confirmed RIF resistance. While the new algorithm increases access to CBNAAT for certain populations beyond the old algorithm, the NSP targets will not be met with deployment of the new algorithm in its current form in the public sector only. RNTCP has introduced universal access to DST for all notified TB patients since August 2017 in 19 states – a laudable effort to improve detection of DR-TB. With this effort will come the continued need to expand quality SL DST, including LPA, in accordance with the new algorithm.

The specific findings and recommendations include:

Key findings	Recommendations
• Access to DST for all notified TB patients is currently being phased in to improve detection of DR-TB • Initial improvements in detecting DS-TB focus on access to rapid and accurate molecular detection of TB in specific key populations and in the private sector • The new NSP includes active case finding (ACF) among high risk groups to enhance the detection of missing patients. • Testing algorithm relies on symptoms, clinical presentation, and radiology, but does not include screening of asymptomatic persons in (epidemiologically-defined; *e.g.*, household contacts) high risk groups to improve detection of missing patients • In the new algorithm, chest X-ray (CXR) is an important screening tool to	• Assess the landscape of private sector providers and laboratories and estimate their contribution to meeting NSP targets if the new algorithm is fully implemented • Accelerate implementation of new diagnostic algorithm and closely monitor progress towards targets • Focus on scaling up testing of key populations (including AFB smear negative with high TB suspicion) and decentralized molecular testing • Implementation of ACF needs to be scaled up and matched with access to rapid molecular tests • Expand the use of CXR screening and consider CXR screening of symptomatic and asymptomatic high-risk populations (e.g., close contacts) to improve case finding

identify patients eligible for CBNAAT, but there is little use of CXR in many settings and availability is a constraint • Recently approved the use of a rapid molecular near point-of-care test (Truenat) for the bacteriological confirmation of TB (replacement for smear microscopy) • First line and second line DST largely available by on-site or by referral; new PMDT guidelines describe to use LPA for DST for INH, fluoroquinolones and second-line injectable drugs; and liquid culture for Moxifloxacin, Kanamycin, Capreomycin, and Linezolid; and other drugs like Pyrazinamaide, Clofazimine, Bedaquilinie and Delamanid when tests are endorsed by WHO. However, there was little clarity or understanding of the second line DST panel at sites • Staff at all levels of the network are aware of the current/old diagnostic algorithm; sensitization to the algorithm in the new NSP is planned alongside introduction/scale up of the algorithm • Clinicians, especially those in private sector, order tests outside the algorithm • There are gaps in the patient pathway algorithm (and implementation of the algorithm) from identification of presumptive patients to diagnosis and treatment • Surveillance data, as defined by routine recording/reporting entered into NIKSHAY, are analyzed and are used to inform policy	• Deploy and evaluate the use of new, approved, near POC tests to improve the bacteriological confirmation of TB • Aspire to achieve rapid testing for all presumptive TB patients using a phased approach that takes into account local capacity and epidemiology and priority populations, for example, districts identified in the recent national DRS with high rates of DR-TB • With scale-up of the use of new drugs and shorter MDR-TB regimen, develop an accelerated scale-up plan for SL DST along with an efficient specimen referral system to ensure adequate capacity • Accelerate efforts to train private and public practitioners and community health care workers on the use of the new algorithm and linkages to care to close gaps in the patient pathway • Implement e-Nikshay, real-time entry on site (DMC) with urgency, including standardized reporting on key indicators and quantification of steps in the diagnostic pathway - Track presumptive TB patients in Nikshay and ensure linkage from diagnosis to care • Use data from the planned national prevalence survey and the recently conducted drug resistance survey to inform evolution of algorithm, resource utilization and mapping of services

Some additional findings and recommendations for **chest X-ray** include:

Key findings	Recommendations

• National guidelines for CXR in diagnostic algorithm do exist but implementation is not standardized (no SOPs) nor is it monitored by the RNTCP
• CXR is included in the diagnostic algorithm for presumptive TB patients, but its use varies in different states as well as for different types of patients, data on the use of CXR are limited
  - Unclear proportion of presumptive TB patients who present with CXR "in hand" from another facility Estimate is that a large proportion come to chest clinic with CXR in hand from private facility
• CXR to monitor TB treatment is less commonly done as sites reportedly rely on microbiology data to monitor treatment response
  - Sites reported that national guidelines do exist for using CXR to monitor treatment response
• System does not exist to track full process of CXR received, CXR abnormal, and patient requiring referral for testing (CBNAAT).
• System does not exist to link presumptive TB with abnormal CXR to CBNAAT testing
• Quality assurance is not standardized for conducting and interpreting CXR, nor is responsible party clearly defined
• Training is not standardized for conducting and interpreting CXR
• There are no clear national specifications for procurement
• CXR machines are available at several levels of health system, from tertiary referral centers to district level, sub-district level, and high volume primary health care centers
	• Standardize CXR utilization through clear standard operating procedures for TB screening, diagnosis and treatment monitoring
	  - Enforce and monitor adherence to algorithms.
	  - Once systematic monitoring is conducted and data are analyzed, additional recommendations can be made to improve CXR utilization
	• Develop systems:
	  - To track CXR conducted, CXR abnormal, and referral for further testing
	  - To link abnormal CXR with CBNAAT testing
	• Define roles and responsibilities for procurement, quality assurance, and training

Enforcing the use of the new national diagnostic algorithm throughout the TB diagnostic network will be essential for meeting the 'Detect" targets of the NSP. Important considerations are:

- To optimize uptake and proper use of the new algorithm, all public and private sector practitioners must be trained in the algorithm, when and how to order tests, where to send specimens for testing, how to interpret results, and how to use results for patient care decisions.
- Easily accessible, free-to-the-patient, high quality X-ray services will be needed for the planned use of chest X-ray as a screening tool for the diagnosis of AFB smear-negative TB and as an entry point to rapid molecular testing (*e.g.*, CBNAAT).
- The NSP target that all persons with bacteriologically confirmed TB (currently 54% of newly diagnosed patients) receive rapid DST will accelerate the detection of MDR-TB. To optimize the identification of MDR-TB patients, it will be necessary, where possible, to move toward rapid DST for all bacteriologically diagnosed and clinically diagnosed TB patients.
- The diagnostic algorithm must be adapted to local capacity, resources, and epidemiology. For example, in more advanced states or in the private sector, the testing of all persons with presumptive TB with rapid molecular test (WRDs, Xpert MTB/RIF, or other approved rapid molecular test) may be feasible.
- In regions with a high prevalence of INH resistance (according to the recent drug resistance survey results) or for persons at high risk of having INH-resistant TB, access to rapid DST (*e.g.*, FL-LPA) for INH for all bacteriologically confirmed TB patients will be needed to ensure that the patients are placed on an effective regimen.
- Timely DST (*e.g.*, SL-LPA) for key second-line TB drugs (FQs and SLIDs) for all patients with RIF-resistant TB will be essential for identifying patients eligible for the shorter MDR-TB regimens.
- To reach the NSP target of DST-guided treatment for all TB patients, adequate capacity for DST for first-line and second-line drugs must be available.

To meet the NSP goals of increasing patient finding and diagnostic testing, the network must be expanded to include private sector laboratories and providers. It is worth noting that 1) private sector laboratories can add value to the RNTCP by reporting of detected TB patients and providing laboratory testing capacity where needed, 2) RNTCP can add value to the private sector laboratories by including them in training and external quality assessment programs and 3) Certification of private sector laboratories by the RNCTP would help RNCTP ensure that only high-quality testing that meets RNCTP guidelines is conducted and help the laboratories by documenting the quality of their testing.

Chest X-ray is an important entry point into the new diagnostic algorithm, especially with respect to triaging smear-negative presumptive TB patients for further testing (*e.g.*, CBNAAT). Easily accessible, free-to-the-patient, high quality X-ray services will be essential.

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.

Biosafety within TB testing facilities is weak for many reasons – national policies are not enforced, no TB specific standardized guidance or manual, and a general culture of non-prioritization of occupational health for facility staff. Poor building infrastructure and lack of equipment or space for proper waste management also contribute to the lack of biosafety for laboratory staff. Although the current biosafety environment in many TB testing facilities is poor, new TB disease among lab and facility staff is not documented and workers are not routinely screened for TB.

The specific findings and recommendations include:

Key findings	Recommendations
• Variation was noted in implementation of national standards for waste management at DMC level - rural DMCs did not have access to proper waste disposal facilities and are using unsafe alternatives like pits and incinerators • No national policy exists on building standards for TB laboratories • Laboratory building biosafety requirements are not adequately applied to all facilities • All NRLs, most of IRLs and DMC facilities are adequately maintained and have all utilities available – issues were rarely noted • A TB biosafety and biosecurity manual is not available, but SOPs containing adequate information on TB biosafety are available at most sites	• Urgently enforce compliance with national regulations for waste management in all laboratories – management of infectious waste from processing TB specimens should also comply with international guidance and standards[16] • Develop a TB specific biosafety and biosecurity manual and implement at all levels including alternative, safe options to disposing wastes • Strengthen national TB specific biosafety policies, including building requirements, and monitor implementation during supervision visits, with support from trained biosafety officers • Enforce infection control and biosafety practices to protect health care workers • Conduct routine health care worker screening for signs and symptoms of TB, including chest X-ray as part of the screening algorithm

[16] WHO Tuberculosis Laboratory Biosafety Manual
http://apps.who.int/iris/bitstream/10665/77949/1/9789241504638_eng.pdf?ua=1

• Designated safety officers were available only in facilities working toward NABL accreditation • Basic occupational health services and TB screening of HCWs were not available in all facilities • BSC were not certified in some reference laboratories • Use of gloves is not mandatory at DMC level as is the international standard[15]

Ensuring safe working conditions in TB laboratories begins with developing national TB biosafety policies and manual and implementing and enforcing the policies at all levels of the laboratory network. Health care workers who come in contact with TB patients and those who work in the TB laboratory are at increased risk of acquiring an *M. tb* infection. As such, there should be a routine screening (at least yearly) program for signs and symptoms of TB. Chest X-ray may be included as part of the screening program. Health care workers with

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.

signs and symptoms of presumptive TB should receive a full diagnostic workup and those diagnosed with TB should receive appropriate therapy.

With support of external organizations, like FIND, the overall situation with laboratory equipment and commodities is positive – most instruments are maintained (issues with microscope maintenance were observed) and commodity stock-outs are rare. However, the stability of the existing system is threatened by future events including the phasing of the procurement functions from FIND to state labs, and the planned rapid scale-up of CBNAAT. A clear and swift plan is needed to build capacity in states to be able to manage laboratory equipment and supplies. Electronic tools for monitoring consumption and inventories are needed.

The specific findings and recommendations include:

Key findings	Recommendations
• The NSP identifies key areas for improvement including ICT solutions, annual maintenance contracts (AMCs), forecasting, etc.	• Accurately forecast the anticipated increase in equipment and supplies needed for scale-up and plan for the transition to increased demand

[15] Global Laboratory Initiative. 2013. Laboratory Diagnosis of Tuberculosis by Sputum Microscopy - The GLI Handbook. http://www.stoptb.org/wg/gli/assets/documents/TB%20MICROSCOPY%20HANDBOOK_FINAL.pdf

• A standardized list of equipment and reagents exists for laboratories in the diagnostic network • AMCs were largely in place • Maintenance of CBNAAT and NRL/IRL equipment is of a high standard • Maintenance of microscopes is not as strong in some states • Pre-service validation exists for some equipment; post-market surveillance is not comprehensive • Procurement is managed at various levels: CTD with GDF, FIND, State, District • Reports of stock-outs were rare • Supply management and forecasting tools used by CTD/FIND are Excel-based • Online modules for microscopy and CBNAAT supply management and forecasting are under development (DVDMS), making use of electronic data • Global Fund transitioning includes phased shifting of procurement functions from FIND to selected state labs for proprietary items (MGIT, LPA) and non-proprietary items	• Build capacities in states for managing procurement • Increase capacity of states for managing equipment maintenance, with clear plans and budgets • Expedite development of on-line diagnostic modules for all tests in '*Nikshay Aushadi*' (to be rolled out Q2 2018) • Monitor site-level CBNAAT capacity to initiate possible multi-disease testing in coordination with other disease program

Accomplishing the goals of the NSP will require a large scale expansion in the laboratory testing for TB, particularly molecular testing. The expected increase in the demand for equipment, supplies, and reagents will need to be carefully forecasted to avoid shortages and

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.

stockouts. Building capacity at the state level for monitoring consumables and managing procurement and for managing equipment maintenance should improve the functionality, reliability and robustness of the supply chain. For CBNAAT, remote monitoring systems have proven very useful for monitoring the supply chain as well as equipment performance and maintenance.

India has built a large, competent staff to carry out the roles and responsibilities of a massive laboratory and diagnostic network for the RNTCP. As the program and targets evolve, as stated in the new NSP, staff will need to evolve as well – both in terms of capacity and size.

The specific findings and recommendations include:

Key findings	Recommendations
• Certification of staff is mostly at state level. There is no national body for certification, licensing or registration for laboratory workers • Staff received training prior to starting work and are supervised by an experienced staff member prior to being assessed as competent • Laboratory staff have access to continuing education, however it is more sensitization than refreshing training and is limited by the availability of funds • Pre-service training available on laboratory management at IRL level • Most laboratories reported that the available workforce is sufficient, with the exception of NRLs where the scale-up of PMDT and additional testing for Bedaquiline containing regimens are stressing existing staff • IRLs appear to be more constrained by the number of available staff, primarily around data management and EQA • Competency based job descriptions not consistently available • The NSP clearly outlines the HR challenges that need to be addressed • Recruitment of contractual positions has been delayed - over 20% of these positions have been vacant (up to 40% in some states) • Salary payments have been delayed because of weaknesses in the financing system • Uncertainties around continuity of funding and continued employment and poor opportunities for career progression that threaten staff retention	• Work with states to fill all sanctioned yet vacant positions as soon as possible • Continue efforts to address ongoing salary support for contractual staff in C/DST/LPA laboratories to enable uninterrupted continuation of services • Conduct HR needs assessment, develop national staffing plan and ensure adequate numbers of appropriately trained and competent staff to perform all functions within the network • Address staff retention issues, under oversight of a national laboratory professionals body • Standardize competency based job descriptions, appraisals and documentation

Shortages of trained laboratory personnel will threaten the ability to provide the laboratory services needed for the implementation of the NSP. Current deficiencies (*e.g.*, delays in filling vacant sanctioned positions, ensuring continuity of funding and salary payments, insufficient staff for supervisory functions) must be addressed promptly. A national staffing plan with standardized competency based job descriptions and a national certification system are needed to ensure that there will be adequate numbers of appropriately trained and

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.

competent staff to perform all functions within the network as the new diagnostic algorithm is scaled up and the testing volume increases to meet the NSP goals.

The RNTCP has built an impressive program that is grounded by documented reporting of laboratory tests and results. Policies and guidance for TB diagnosis is informed through this massive amount of data generated each year. This system has been strengthened over the past several years by the introduction and scale-up of Nikshay. As the program matures and evolves to meet with targets of the new NSP, the data information and management systems must also be upgraded to meet these needs. Although the assessment focused on the laboratory and diagnostics aspects of data management, some findings and recommendations will be applicable to the system for the overall program.

The specific findings and recommendations include:

Key findings	Recommendations

• Good use of standardized request and result reporting forms
• Nikshay has great potential to facilitate data management, but there is little evidence of collection, analysis, review, or sharing of information
• Overall reporting of TB is working well, but there is no automated reporting of data
• There is no data analysis unit at CTD or NRLs
• The system to track sample referral and result reporting needs improvement
• Rapid reporting of diagnostic data for both clinical and programmatic management is weak
• There are inconsistencies with Nikshay adoption and use across the country
• No connectivity of CBNAAT machines currently
	• Fix resources immediately to impact usability of current system, e.g. increased server capacity
	• Ensure Nikshay version being implemented meets needs of users
	  - Shift approach from “system reporting to government” to “tool that helps users do their job’
	• Connect all diagnostic devices to Nikshay
	• Explore harmonization of Nikshay and Integrated Disease Surveillance Project Platform
	• Establish and adequately resource strategic data unit at CTD to lead use of data for action at all levels (electronic and manual)
	• Adopt a culture of paperless information system
	  - Address performance of Nikshay website so it is possible for users to enter data

• No procedures to integrate laboratory and epidemiological data to support real time surveillance • Confidentiality and protection of electronic patient data lacked policy and awareness among staff and was performed in ad hoc manner • Backup of electronic patient and diagnostic data lacked policy, awareness among staff, and was performed inconsistently	- Move ahead with Nikshay (tablet/smart phone interfaces) to motivate capture of patient enrollment at first contact - Expand the Nikshay team to enable fully functional user-friendly electronic system across diagnostic network - Use Nikshay fully and build in reporting mechanisms to automate (email, SMS, etc.) back to clinician, patient, and district or state program managers

Nikshay has great potential to facilitate laboratory data collection, but the system must become more user-friendly and function to allow people to do their jobs better and more efficiently. For example, by expanding access to Nikshay and assigning a Nikshay identifier to a presumptive TB patient, one could use the power of Nikshay to track patients through the patient pathway in real time and thereby monitor the entire diagnostic cascade and target interventions to improve patient outcomes. Also, data collection should focus on data that will be used to inform decisions, which should improve the timeliness of data analysis and usage as well as bolster confidence in the system by those collecting the data and by decision

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 and reference and referral level laboratories are accredited according to national or international standards.

makers. An enforced policy that ensures the confidentiality and protection of electronic patient information is needed to meet international standards of care and engender trust in the laboratory system. Similarly, electronic patient and laboratory data must be stored and secured in such a way as to avoid loss of information and loss of trust in the system.

One of the hallmarks of the RNTCP has been their comprehensive quality and supervision system – tenets of the original DOTS strategy. However, the quality and supervision systems must evolve in parallel with the planned revisions to the diagnostic algorithm and shifts within the network to optimize TB tests and processes to meet the NSP needs. The RNTCP needs to evaluate whether or not such “heavy” systems are providing the desired results, and if the data produced by these systems are informing the program. Also the focus and strengthening of quality and supervision needs to be in line with the staff and labs responsible for such efforts.

The specific findings and recommendations include:

Key findings	Recommendations
• Quality indicators are routinely monitored for all tests at some tiers, but infrequently analyzed • Internal quality controls are used in most testing; however, known positive and negative slides were not included with each batch of AFB smear microscopy tests as internal quality controls • A system of regulated supervision is in place from reference laboratory tiers to lower levels within the public sector • EQA is in place for public sector and collaborating private sector laboratories • Challenges with resourcing, implementation and follow-up of OSE visits and RBRC activities limit their impact on quality improvement • Frequency of NRL and IRL supervisory visits is limited by resources • Supervision is mostly focused on technical aspects and EQA. Other critical aspects (*i.e.*, biosafety, integrated data management) are not addressed • The position of quality or quality assurance officer is only filled in reference laboratories pursuing NABL accreditation • Quality Management System (QMS) activities are implemented in reference laboratories pursuing NABL accreditation using a structured approach • RNTCP certification standards are mandatory for all laboratories conducting TB testing in the public sector and collaborating private sector laboratories • Private labs not included under RNTCP do not require certification	• Simplify, re-focus, and re-energize supportive supervision and EQA - Leverage electronic systems to improve efficiency of data reporting and management and target on-site interventions - Monitor and evaluate the effectiveness and impact of supervision - Reduce DMC OSE visit frequency - Revise OSE activities and documentation, and update training to emphasize corrective action follow-up • Build capacity of NRLs and IRLs to be quality champions within the network (incl. by implementing QMS towards NABL accreditation) and re-establish regular supportive supervision to lower levels • Utilize quality assurance outreach activities as a key strategy for private sector engagement - Fast track RNTCP accreditation for private labs already accredited by NABL • Include quality of X-ray and clinical diagnosis in QA • Build capacity and expand proficiency testing programs for rapid molecular tests including CBNAAT

The quality of testing, specimen referral, and the network functions can be strengthened by building:

- Systems for effective implementation of a comprehensive quality assurance system that includes internal quality controls, external quality assessment, proficiency testing,

on-site supervision, blinded rechecking, continuous quality improvement processes, documentation, etc.

- A QA system and supportive supervision that addresses the entire patient pathway to maximize the impact of quality testing for the patient and programme
- A monitoring and evaluation system that assesses the impact of the QA system using key performance indicators (KPIs) of testing and of network functions
  - KPIs for TB tests and specimen referral are described in the GLI Guide to Laboratory Strengthening and the GLI Guide to TB Specimen Referral Systems
  - KPIs for diagnostic network include patient-to patient turnaround times, loss to follow up, timeliness of information flow, and completeness of reporting
- Electronic data systems (especially remotely monitored systems) to improve the efficiency of data reporting, management of the diagnostic network and resource utilization by targeting on-site interventions to facilities that can most benefit from the interventions
- A certification system that ensures all public and private sector laboratories meet the stringent requirements for RNTCP certification which should improve the quality of testing everywhere in the diagnostic network

5. General Considerations for Strengthening the Diagnostic Network and Thematic Areas

Implementation of the recommendations 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 testing
- Deploying what is available now, while planning for the future 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
- 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 diagnostic network and laboratory personnel to ensure the acceptance and effective implementation of the strengthened diagnostic network

Next steps

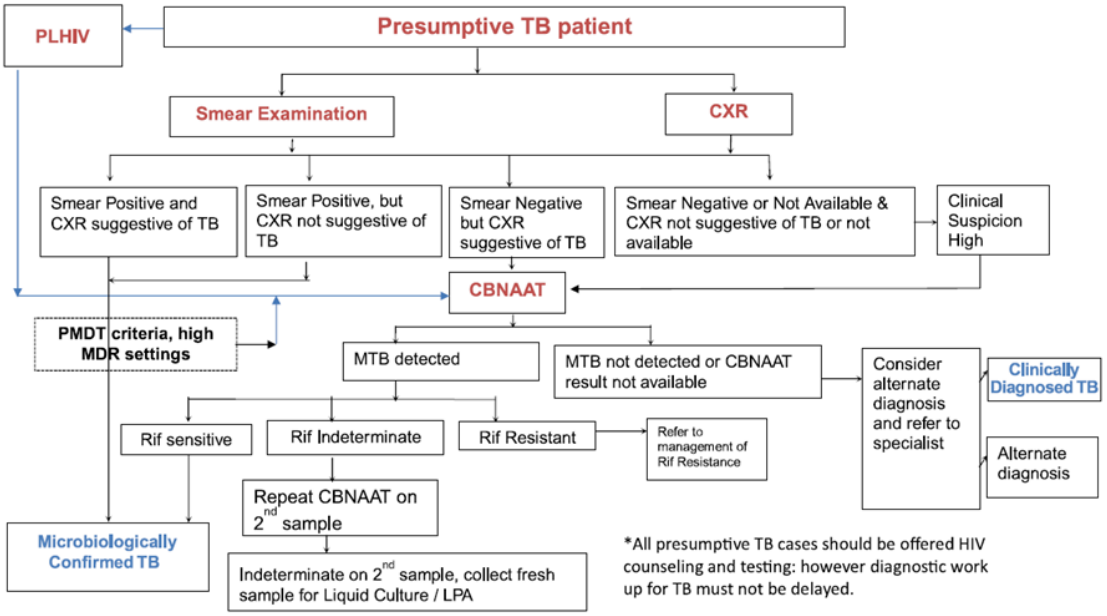
The findings and recommendations from the assessment are extensive and will require the CTD to lead and coordinate efforts among all stakeholders, including technical partners and donors. Recommended activities or interventions should be prioritized by establishing a detailed action plan with time-bound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

India is on the right track to ending TB, with state-of-the-art tools, an ambitious, imaginative NSP and high level political commitment. The recommended key interventions and priority actions described in this report will assist India to reach its TB diagnostic goals with the ultimate aim to end TB in India.

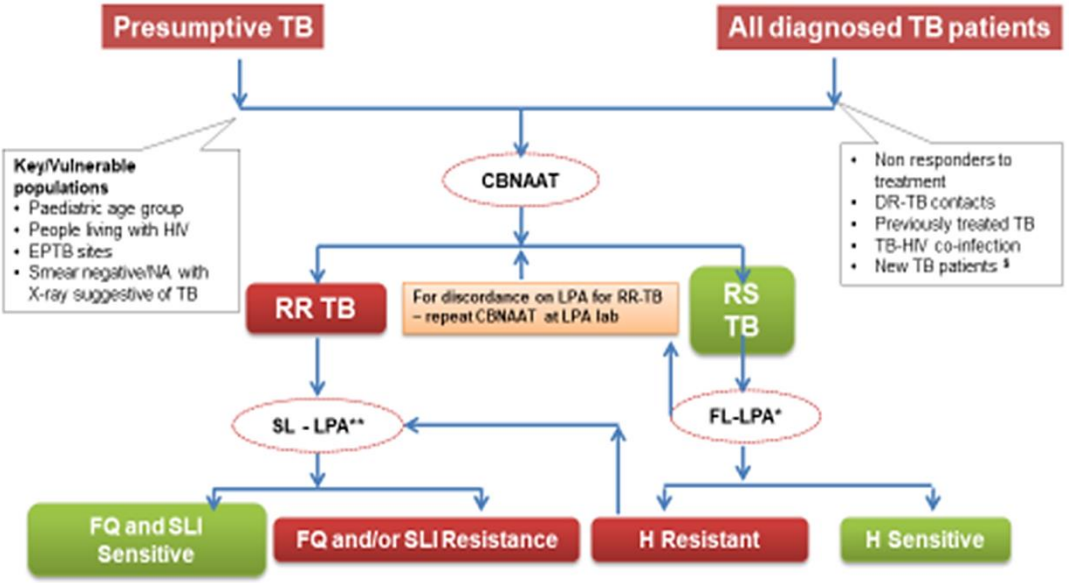
Annexes

Annex 1. Diagnostic Algorithms

"Current" Diagnostic Algorithm



New Diagnostic Algorithm in NSP 2017-2025



*Offer molecular testing for H mono/poly resistance to TB patients prioritized by risk as per the available lab capacity

**LC DST (Mfx 2.0, Km, Cm, Lzd) will be done only for patients with any resistance on baseline SL-LPA. DST to Z, Cfz, Bdq & Dlm would be considered for policy in future, whenever available, standardized & WHO endorsed.

$ States to advance in phased manner as per PMDT Scale up plan for universal DST based on lab capacity and policy on use of diagnostics

Annex 2. WHO Lab Capacity Calculation tool – India 2017

Calculation of country-specific targets for microscopy, WRDs (including Xpert MTB/RIF), culture/DST capacity

Values in red should be entered or adjusted when possible based on actual country data and practices

TB epidemiology				
Pulmonary, bacteriologically confirmed	New cases:	1.266.279	Relapse cases:	172.173
Pulmonary, clinically diagnosed	New cases:	640.759	Relapse cases:	218.195
Extrapulmonary	New cases:	435.649	Relapse cases:	0
Total new cases notified		*2.342.688*	*Total relapse cases notified:*	*390.368*
Previously treated cases, excluding relapses	266.944			
Total cases notified	*3.000.000*			
% of TB cases that are children	5.00%		% of TB cases that are adult:	95.00%
% of TB cases that are HIV-positive	3.00%		% of TB cases that are HIV-negative/unknown:	97.00%
HIV-positive people clinically screened for TB	1.200.000			
Planned number of RR/MDR-TB cases to be detected (and treated):	59.000			

Programmatic assumptions				
% of patient population that will get microscopy or Xpert MTB/RIF as the initial diagnostic test	Microscopy	Xpert MTB/RIF	**HIV care**	
Previously untreated HIV-negative adults with signs and symptoms of TB	80%	20%	Number of times that clinical screening for TB is performed per person per year	12
People living with HIV (PLHIV) with signs and symptoms of TB	0%	100%	% of persons screened and found to have signs and symptoms of TB	5%
Children with signs and symptoms of TB	10%	90%	% coverage of WRD testing among screening sites	100%
People at risk of having drug-resistant TB	10%	90%	**Case detection**	
% of new TB cases getting Xpert MTB/RIF as a DST		60%	Ratio of people with signs and symptoms of TB: 1 bacteriologically confirmed (or smear-positive) notified case	12
Laboratory procedures			Ratio of children with signs and symptoms of TB: children notified with TB	10
Number of smears per person at time of initial diagnosis	2		Ratio of people with signs and symptoms of TB who have a history of previous succesful treatment: notified relapse cases	4
Total number of patient visits at which sputum specimens are given for treatment monitoring (for example, months 2, 5, 6)	2		Ratio of contacts per notified RR-TB case	3
Number of follow-up smears per patient per visit for treatment monitoring	1		**MDR-TB care**	
Average number of Xpert MTB/RIF tests per module per day	3		Average number of months of treatment	14
Average number of culture and DST examinations performed annually	10.000		Number of cultures per month of treatment	0.5
Number of working days per year	300			

Estimated number of annual diagnostic tests and required testing capacity	
Microscopy	
Annual number of smears	
For diagnostic purposes:	22.404.000
For patient follow-up (treatment monitoring):	4.594.800
Total annual number of smears:	**26.999.000**
Xpert MTB/RIF	
Annual number of Xpert MTB/RIF tests	
For PLHIV with signs and symptoms of TB:	720.000
For children with signs and symptoms of TB:	1.350.000
For people at risk of having drug-resistant TB:	1.849.300
For previously untreated HIV-negative adults with signs and symptoms of TB:	2.800.500
For TB cases for DST purposes (excluding those getting Xpert MTB/RIF as initial test):	1.034.100
Total annual number of Xpert MTB/RIF tests	**7.754.000**
Target number of GeneXpert modules	8616
Culture/DST	
Annual numbers of culture and DST examinations	
Numbers of cultures (for RR-TB case treatment monitoring)	454.300
Numbers of DST examinations	64.900
Total annual number of examinations (culture/DST)	**519.200**
Target number of culture/DST facilities	**52**

Annex 3. Questions and Stages by Core Capacity and Components

1. Political, legal, regulatory and financial framework

			Description of situation (stage)					
Question #	**Components**	**Questions**	**0**	**1**	**2**	**3**	**4**	**5**
1	**Legislation and policies** Legislation is the ideal situation to be achieved in order to ensure an adequate governing framework for all the key areas. However, policies, plans or regulations might have been developed in the absence of legislation and should be taken into consideration in the scoring.	Are the following key areas enforceable? - Roles and responsibilities of the NTP and health sector and links with other sectors (incl. financial flows) - TB notification - Private sector engagement - Biosafety/waste management - Surveillance	No policy, plan, regulation or legislation exists for any of the key areas.	Policy, plan, regulation or legislation exists for 1 or 2 key areas.	Policy, plans, regulation or legislation exists for 3 or 4 key areas.	Policy, plans, regulation or legislation is in place for all key areas.	Policy, plans, regulations. Or legislation in place and enforced.	Legislation in place enforced and regularly updated to reflect international standards.
2	**National policies and plans** National TB Lab plan should be developed in full alignment with the national laboratory policy, TB NSP and other key policies/guidelines (e.g. TB-HIV, PMDT etc.).	Is there a national TB laboratory policy, guideline or strategic plan? Is it fully aligned with other relevant policy documents including the national laboratory policy, National TB Strategic Plan and TB-HIV, PMDT policies and plans? Does the national plan prioritize the development of a network of TB laboratories that use modern diagnostics, have efficient referral systems, use standard operating procedures and appropriate quality assurance processes, and have adequate biosafety and sufficient human resources?	There is no National TB Laboratory policy, guideline, or /plan	There is a National TB Laboratory policy, guideline or plan but not approved and aligned with national laboratory policy and TB NSP.	The National TB Laboratory policy, guideline or plan is approved and aligns with the national laboratory policy and TB NSP. The plan describes development of a TB laboratory network.	All of before and up to date and partially implemented. The plan prioritizes the development of an efficient TB laboratory network.	Fully implemented. The plan prioritizes the development of a comprehensive TB laboratory network that encompasses both private-sector and public-sector laboratories.	Implemented and aligned with overall health strategic plan. Revised at least once.

1. Political, legal, regulatory and financial framework

Description of situation (stage)

Question #	Components	Questions	0	1	2	3	4	5
3	The operational plan can be a stand-alone document aligned with the NSP or an integral part of the national laboratory strategic plan. The operational plan guides day to day activities down to the district level. The plan should operationalize and budget for the achievement of the core capabilities of the laboratory network so that it aligns with the TB NSP. The plan should describe milestones, indicators and annual targets to measure progress.	Is there a current national plan describing how to operationalize the national TB laboratory strategies towards the achievement of the TB lab plan? Are indicators and annual targets described to monitor progress of implementation of the strategic and operational plan related to TB laboratory services?	There is no current (yearly) national laboratory operational plan either as standalone or as part of the NLSP	There is an operational plan or an operational section of the NLSP but it does not describe the how and/or the timelines and/or the associated budget required for the implementation of the NLSP.	The operational plan or operational section of the NLSP provides information on the how, the timelines and the budget associated with the implementation of the NLSP. Indicators and annual targets are described.	All of before and the plan describes milestones, indicators and annual targets to measure progress.	All of before and the plan is partly implemented (i.e. not distributed and used down to district level) and some indicators and annual targets are being monitored.	All of before, and the plan is fully implemented, prioritising some or all of the core capabilities, based on the NLSP, and all indicators and annual targets are being routinely monitored.
4	This question is to ensure that all laboratories in the private and public sector are authorized to practice under the same stringent criteria (hence not only registration, which is basically getting an ID number for the business). Re-licensing is to ensure that laboratories adapt to evolving regulatory framework for the laboratory sector or perform according to the standards.	Is there a licensing mechanism for laboratories in place?	No	One-time licensing is provided with registration and is legally required for all laboratories in the health sector. Licensing requirements are different for public versus private laboratories.	One-time licensing is in place and with similar requirements for all public and private laboratories in the health sector.	One-time licensing in place and enforced for public or private laboratories for health.	Licensing and re-licensing of all public and private laboratories for health are legally required.	Re-licensing is based on national certification standards and is legally required for all laboratories.
5	Relates to requirement for TB laboratories to inform the local program and national level of diagnosed TB cases. This may be policy or legislated.	Do labs inform the local and national programme of TB diagnosed cases? Is there a policy mandating labs to report detecting TB cases to the program?	No	Infrequently and on an *ad hoc* basis.	Informing the local or national programme is done directly by the laboratory at some tiers or some regions by public sector laboratories.	Regular informing of the programme at all tiers by public sector laboratories.	Informing the programme occurs at all tiers in the public sector and by some private sector laboratories.	Stage 4 with all tiers in the public and private sectors.

1. Political, legal, regulatory and financial framework

Description of situation (stage)

Question #	Components	Questions	0	1	2	3	4	5
6	**Governance** The question relates to the involvement of laboratory services at the top management level within the MoH. If the laboratory management unit is at a lower level and has to report to too many sub divisions under the MoH, it cannot be represented at the top management level with little involvement in the decision-making process, direct access to budget earmarked for laboratory-specific operations OR inter-ministerial coordination for relevant topics.	Does the Ministry of Health have a dedicated organizational unit in charge of laboratory coordination?	No	There are several entities in charge of laboratory coordination.	Dedicated entity but not at senior management level within the MoH. There is an official mandate, defined ToR and setting of targets.	Stage 2 plus coordination mechanisms with disease specific vertical programs and public health-related committees.	The entity is a directorate or a department, representing laboratory services at top management level of the MoH with the private sector included in oversight.	All of before, with interministerial coordination.
7	**Financing** Relates to access of the laboratory unit to budget dedicated to lab services. Only a unit directly under the MoH can have access to earmarked budget.	Is there a specific budget in place at national level for laboratory services within MoH?	There is no specific budget line for laboratory activities. Funding is indirectly available through the budget allocated to a higher administrative division of the MoH.	There is a specific budget line for laboratory services but not costed.	Yes, but ONLY partly covering operations related to key routine laboratory requirements.	Yes, completely covering operations related to key routine laboratory requirements.	All of the before and completely covers intersectoral functions and improvement as defined in operational plans.	All of the before with programs in place for monitoring and evaluation of finances, and improvement of cost efficiency for laboratory services.
8	Relates to the access to budget for laboratory activities at national an sub-national levels and for private sector laboratory services under NTP budget	Are there dedicated budgets for TB laboratory services available at all levels of the laboratory system and including public and private sector service provision under NTP?	No	Only for the reference and national public health laboratories.	For the reference, national public health and next level laboratories (IRLs).	Yes, but not for public health activities at primary health care level.	For public health activities at all levels of the health laboratory network(s).	For laboratories at all levels of the network and including public and private sector.

1. Political, legal, regulatory and financial framework

Description of situation (stage)

Question #	Components	Questions	0	1	2	3	4	5
9	Relates to the sustainability of laboratory services. There should be a progressive shift toward more government funding.	Is the budget for TB laboratory services covered by sustainable government funding and other local funding sources?	The budget does not include any government or local funding sources.	Government and local funding contribution to TB laboratory services includes only basic infrastructure and staff costs.	Stage 1 plus funding of basic supplies and reagents for some TB diagnostics (e.g. smear microscopy)	Stage 2 plus funding for supplies for advanced TB diagnostics and other costs (e.g. training, QA, equipment, maintenance etc.)	Government and local funding represents 100% of the total TB laboratory budget.	Stage 4 and 100% of the budget spent in the last 3 years.
10	Relates to a policy which provides for free TB diagnostics for all people being evaluated for TB, either free at point of service and/or reimbursement through medical insurance schemes	Is there a national policy which enables free diagnosis for all people being evaluated for TB, including all laboratory tests and X-ray as stipulated in the national algorithm?	No	Only limited diagnostics (e.g. smear microscopy) are provided free of charge in parts of the public sector only.	Several TB laboratory tests are available free of charge or reimbursed in public sector.	All TB laboratory tests are available free of charge or reimbursed in the public sector and some private sector facilities. Chest X-ray is free of charge or reimbursed in limited locations.	All laboratory tests are available free of charge or reimbursed in the public and private sector, Chest X-ray is available free of charge or reimbursed in the public sector and only in limited private sector facilities.	All TB diagnosis is free or reimbursed for all people being evaluated for TB in the public or private sector.

2. Structure and organization of the diagnostic network

			Description of situation (stage)					
Question #	**Components**	**Questions**	**0**	**1**	**2**	**3**	**4**	**5**
1	**Diagnostic network** To determine whether a network is in place and whether it adequately supports clinical and public health functions.	Is there a tiered TB diagnostic network in the country? Does each laboratory within the tiered TB diagnostic network have defined terms of reference and an agreed upon mandate to provide services for NTP under the MoH as part of an integrated TB laboratory network?	No	Only division into reference and other laboratories.	There is a TB diagnostic network with at least 3 tiers in the country without clearly defined roles and responsibilities.	There is a TB diagnostic network with at least 3 tiers in the country with partially defined roles and responsibilities.	There is a TB diagnostic network for public health functions OR for clinical functions with clearly defined tier-specific roles and responsibilities.	There is a TB diagnostic network for public health functions AND for clinical functions with clearly defined tier-specific roles and responsibilities for routine situations.
2	The question aims at determining whether other laboratories in the country participate in providing TB clinical or public health functions. How do they function together? What are their relationships? How do they collaborate and share information?	Do other types of laboratories (public, private, academic, military) link into the national TB laboratory network for clinical and public health functions?	No	Public laboratories perform TB clinical functions OR perform TB public health functions for the national TB diagnostic network. Non-public laboratories do not perform clinical or public health functions as part of the national TB diagnostic network.	Public laboratories perform TB clinical functions AND perform TB public health functions for the national TB diagnostic network. Non-public laboratories do not perform clinical or public health functions as part of the national TB diagnostic network.	Public laboratories perform TB clinical and public health functions for the national TB diagnostic network, AND some private, academic or military laboratories perform TB CLINICAL functions for the national TB diagnostic network.	Public laboratories perform TB clinical and public health functions for the national TB diagnostic network and some private, academic or military laboratories perform TB clinical functions for the national TB diagnostic network and SOME perform TB public health functions.	All laboratories in the public and private sector perform TB clinical and public health functions for the national TB diagnostic network.

2. Structure and organization of the diagnostic network

			Description of situation (stage)					
Question #	**Components**	**Questions**	**0**	**1**	**2**	**3**	**4**	**5**
3	This question relates to the institutionalization of community level services into the TB diagnostic network and the determination of best approaches to support the accessibility of good laboratory screening and diagnostic services to remote populations.	Does the organizational structure of the TB diagnostic network include decentralization of diagnostic services, e.g. screening to community level?	No networks in place	The organizational structure of the TB diagnostic network does not include community level.	A selection of basic TB laboratory services are decentralized to the community level in some districts.	Basic TB testing services are decentralized to the community level in most districts, including public sector and some private sector community-based providers. A process of formalizing linkages between community level and national health system has been initiated.	Community services are regularly monitored for quality and cost effectiveness AND for contribution to the rapid detection of TB. This approach is being scaled up in many districts with public sector community providers and some private sector integration.	Stage 4 with demonstrated quality and cost-effectiveness is scaled up nationwide and is incorporated into the organizational structure of the diagnostic network.
4	This question is to determine whether all tiers of the laboratory network have a defined minimal TB testing package, and whether these packages allow for the provision of all TB diagnostic services according to the national algorithms (either through local testing or referral)	Have tier-specific TB laboratory minimal testing packages been defined?	No tier-specific minimal TB testing packages have been defined.	Minimal TB testing packages are defined for <u>some</u> tiers of laboratories in the public sector.	Minimal TB testing packages are defined for <u>all</u> tiers of laboratories in the public sector.	Minimal testing packages are defined for all tiers laboratories in the public sector and engaged private sector laboratories.	Stage 3 with minimal testing packages for TB in all public and private sector.	All of before and the list has been revised at least once.
5		National standard operating procedures (SOPs) exist for all TB diagnostic technologies and procedures within the network and are accessible at all testing sites.	Nationally approved SOPs are not available.	National SOPs are available for some TB diagnostic procedures but are not widely accessible.	National SOPs are available for all TB diagnostic procedures and are accessible at most public sector testing sites.	National SOPs are available for all TB diagnostic procedures and are accessible at most public and private sector testing sites.	National SOPs for all TB diagnostic technologies are accessible at all testing sites	All of before and the list has been revised at least once.
6	**Coordination and management**	Is there a formalized system of communication within the TB diagnostic networks?	No	Formal communication from the top level to the lower tiers is in place	Formal communication between tiers on an *ad hoc* basis	Formal communication between tiers at a specified, regular basis	Formal communication between and within tiers on an *ad hoc* basis	Formal communication between and within tiers at a regular need basis

2. Structure and organization of the diagnostic network

			Description of situation (stage)					
Question #	**Components**	**Questions**	**0**	**1**	**2**	**3**	**4**	**5**
7		Is there a designated national TB reference laboratory (NRL) in the country? In large countries, there may be more than one designated laboratory that functions as an NRL, each with an assigned jurisdiction. - Is there a focal point at the national level that is responsible for managing the network of NRLs? - Do coordination meetings of the NRLs occur at least once a year?	No	An NRL has been designated. More than one NRL has been designated and each NRL has a clearly defined jurisdiction.	A NRL has been designated with clear ToR to coordinate public health functions of the national TB laboratory network. Each NRL has a clearly defined terms of reference.	A NRL coordinates public health functions of the national TB laboratory network and has informal links with the NTP (or other national agencies focusing on public health). A national-level unit is responsible for coordinating the activities of the network of NRLs.	Stage 3 and the links with the NTP (or other national agencies) are formalized through MoUs or similar. Coordination meetings of the NRLs occur at least once-a year	Stage 4 and formalized links with a supranational (international) lab.
8		Does the NRL provide essential TB public health functions?	The NRL is not designated or does not provide any of the essential TB public health functions.	<3 including at least TB disease prevention, control and surveillance.	Between 3-5, including at least TB disease prevention control and surveillance	Between 6-8 including at least TB disease prevention control and surveillance	NRL performs all essential TB public health functions, with inclusion of all public sector lab network and some private sector labs	Stage 4 with all public and private sector labs in the network included.
9	This question relates to collaboration of the TB diagnostic network/program with other disease-specific diagnostic networks and programs. Coordination of the overall network of laboratories is essential.	Does the TB diagnostic network collaborate with other disease-specific diagnostic networks (*e.g.* HIV, Diabetes, Tobacco) regarding lab and diagnostic services (i.e. specimen transport, shared diagnostic platforms, etc.)?	No	There is limited collaboration between TB and non-TB diagnostic networks either at the NRL level or program level.	Formal collaboration occurs on an *ad hoc* basis.	Formal collaboration and coordination mechanisms between TB and non-TB diagnostic networks take place at least annually.	Coordination mechanisms of TB and non-TB diagnostic networks occur at least once a year. A national level unit coordinates collaboration between TB and non-TB diagnostic networks.	Formal collaboration between TB and non-TB diagnostic networks and regular coordination meetings held. Review and analysis of collaboration on regular basis.

2. Structure and organization of the diagnostic network

			Description of situation (stage)					
Question #	**Components**	**Questions**	**0**	**1**	**2**	**3**	**4**	**5**
10		Is there a formal system of supportive supervision within the TB diagnostic network?	No	System of supervision defined but not routinely implemented.	<3 selected supervision elements routinely implemented only from the reference laboratory to the rest of the network.	<3 selected supervision elements routinely implemented from the higher (IRL) to lower tier laboratories (district or sub-district).	Routine supervision for all elements in place WITH the reference laboratory supporting all lower levels.	Routine supervision for all elements in place throughout the network i.e. each level supports the next lower level.

3. Coverage

Description of situation (stage)

Question #	Components	Questions	0	1	2	3	4	5
1	**Diagnostic network coverage** This relates to services or capacities being integrated within the network (not separate).	Are the TB program (i.e. disease specific) laboratory services fully integrated into the general tiered diagnostic network?	No integration at all.	Some collaboration takes place between TB program laboratories and other general public laboratories in the country.	Some general public laboratories perform selected TB testing.	The whole public general laboratory network performs selected TB testing.	The whole public general laboratory network and some private labs perform selected TB tests.	Full integration of all TB laboratory services into the national public and private laboratory network.
2	Relates to the overview of the facilities throughout the country. The information can be used for planning and for integrating rationally all available capacity into the network.	Is there a current map or list of laboratories that fall under the national TB diagnostic network? Is there a map of TB diagnostic tests (microscopy, Xpert MTB/RIF, culture, DST, etc.) and instruments within the existing diagnostic network?	No	A map or list of some laboratories that offer TB services exists in the public sector	A map or list of ALL laboratories that offer TB services exists in the public sector	A map or list of all laboratories that offer TB services exists in the public sector AND includes current inventory of diagnostic tests and instruments	All of before and includes incomplete GPS mapping	All of before and includes private, academia or military labs
3	This question relates to the geographic coverage of the network and is dependent on the availability of an up-to-date map and inventory of laboratories in the country. This also depends on an estimate of the country need for TB diagnostic services based on epidemiology, patient accessibility, specimen referral networks, national diagnostic algorithm.	Are laboratory facilities to meet the estimated needs for the basic TB testing package available in all districts or in such a way that >80% of the population is at a maximum of 5 km (or 1 hour travel time) from the lowest laboratory tier, in each district?	No because no TB testing package has been defined or no mapping was conducted.	Laboratory facilities to meet the estimated needs are not available at a distance < or = to 5km OR at a maximum of 1 hour travel time for 80% of the population in any district.	Laboratory facilities to meet the estimated needs are available at a distance < or = to 5km OR at a maximum of 1 hour travel time for 80% of the population in a district in less than <50% of the districts.	In 50-99% of the districts	Full coverage to meet the estimated needs and with continuous services in parts of the districts.	Full coverage and with continuous services accessible in all districts.

3. Coverage

Question #	Components	Questions	Description of situation (stage) 0	1	2	3	4	5
4	The question relates to the coverage of testing capacity for TB -by the country.	Is there access to TB testing for all priority groups identified in the NSP, including rapid diagnosis using WHO-recommended diagnostics (WRDs) in all districts?	There is no laboratory onsite testing and/or referral services in any of the districts.	Onsite testing and/or referral services are available for some defined risk groups in <10% of the districts	All of before in 10-49% of the districts.	All of before in >=50 % of the districts.	Onsite testing and/or referral laboratory services available in all districts for some defined risk groups.	Onsite testing and/or referral laboratory services available in all districts for all defined risk groups.
5	**Specimen referral system** This question relates to ensuring that all laboratory workers are trained for specimen referral in the course of their education and that they receive refresher trainings.	Is staff trained in TB specimen collection, referral, transportation and reception?	No	Yes, only through in-service trainings.	In-service training is available for some categories of workers and pre-service trainings are available at some levels.	In-service training is available for all categories of workers and is sanctioned by a certificate. Pre-service training with regular refresher trainings at some levels.	Yes, pre-service AND in-service training with regular refresher trainings for all workers and at all levels.	Stage 4 and regular competency testing and supervision at all levels
6	This question relates to specimens being potentially dangerous and should be transported using triple packaging.	Is triple packaging used for all national and international TB specimen transportation?	Concept of triple packaging is unknown OR triple packaging material not available at any tier.	Triple packaging is only used for international specimen transportation.	Triple packaging material is used at SOME tiers BUT there are regular stock outs.	Triple packaging material is used at ALL tiers BUT there are regular stock outs.	Triple packaging is used at all tiers with continuous supply of material.	No specimen is transported in the country if it is not triple packaged.
7	This relates to having written explanations about when, what, where and how to transport specimens. The persons sending and receiving the specimens and what they should do needs to be pre-defined.	Are there standardized procedures for national and international TB specimen transportation (including defined roles and responsibilities)?	No standardized procedures for specimen transportation in place.	Partially standardized procedures for specimen transportation in place at some levels but no roles and responsibilities defined.	Partially standardized procedures for specimen transportation in place at all levels with some roles and responsibilities defined.	Completely standardized procedures for specimen transportation in place at some tiers with tier-specific roles and responsibilities defined.	Completely standardized procedures for specimen transportation in place at all tiers with tier-specific roles and responsibilities defined.	Completely standardized procedures for national and international specimen transportation in place with tier-specific roles and responsibilities defined and regular rounds of improvement.

3. Coverage

Description of situation (stage)

Question #	Components	Questions	0	1	2	3	4	5
8	This relates to the coverage of the specimen referral system. Can any laboratory or facility refer any type of specimen to the appropriate level for testing or for confirmation?	Are national TB specimen referral and transportation systems in place?	No system in place for transporting specimens between tiers. Only *ad hoc* transportation takes place.	A non-structured specimen referral system exists between some tiers in some parts of the country.	A specimen referral system is in place to transport TB specimens from lower to appropriate higher tier laboratories in less than 50% of the districts.	A specimen referral system is in place to transport TB specimens from lower to appropriate higher tier laboratories in 50-80% of the districts.	A specimen referral system with national (>80% of the districts) coverage is in place to transport TB specimens from all lower to appropriate higher tier laboratories. A specimen tracking system is in place for some samples or in some part of the country.	An integrated specimen referral system with national coverage is in place for TB and non-TB specimens, connecting all tiers of the network with appropriate higher levels. A specimen tracking system is in place for multiple specimens throughout the country. The system can be used for emergency situations or for other purposes such as Proficiency panel testing distribution.

3. Coverage

Question #	Components	Questions	Description of situation (stage) 0	1	2	3	4	5
9	This is to ensure that adequate agreements are in place beforehand for the timely referral of TB specimens for testing outside the country (e.g. at SNRL) or importation of quality control materials.	Are there Material Transfer Agreements (MTAs), Memoranda of Understanding (MoUs) and an international specimen referral system in place for TB specimens that require testing outside of the country or for importation of quality assessment and control materials ?	No	MTAs and/or MoUs are in place for TB specimens.	MTAs and/or MoUs and international specimen referral systems are in place for TB specimens.	MTAs and/or MoUs are in place for routine and emergency situations for TB specimens.	MTAs and/or MoUs and international specimen referral systems are in place for routine and emergency situations for TB specimens.	All of before and a tracking system is in place for all international TB specimen referrals OR all TB specimens can be tested and confirmed in the country.
10	**Rapid response and preparedness** This question relates to the continuity of service plans under emergency situations. The plan should include the whole of the public sector as well as the private sector.	Are there plans for continuation of TB lab services in emergency situations, e.g. earthquake, floods, health worker strike, etc.?	No	Plans to ensure continuity of service are under development.	Plans have been developed but are incomplete or not approved. Essential resources (staff, materials, budget) are lacking for full implementation.	Plans are in place and budgeted for implementation in parts of the public sector.	Stage 3 plus all public sector and some private sector facilities.	Stage 4 plus all public and private sector. Plans and budgets are reviewed on a regular basis.
11	Relates to the integration of TB laboratory services under outbreak response protocols, such as the rapid emergence of new pathogens including those under epidemic conditions.	Are TB laboratory services included in outbreak response protocols?	There is no outbreak protocol.	There is an outbreak protocol in place but it does not mention laboratory services.	Laboratory services are a separate section of the outbreak response protocol, but TB is not specifically included.	Laboratory services are fully integrated in the outbreak response protocol(s). In case of multiple protocols in different ministries, they need to be harmonized.	All of before and the protocol is regularly (at least every 3 years) updated.	All of before and the protocol is part of regular (inter)national mock exercises for testing and improvement.

3. Coverage

			Description of situation (stage)					
Question #	**Components**	**Questions**	**0**	**1**	**2**	**3**	**4**	**5**
						Maintenance of TB laboratory services is fully addressed in case of an outbreak response that requires BSL-3 facilities.		

4. Diagnostic algorithm and lab-clinical interface

Description of situation (stage)

Question #	Components	Questions	0	1	2	3	4	5
1	**Algorithm** Relates to the nationally recommended tests and testing algorithm, referral and confirmation capacity as well as surveillance systems throughout the national diagnostic network.	Is a clear national TB diagnostic algorithm available that is responsive to the epidemic, patient-centred, based on international best practice and appropriate to the current structure of the health system?	No	National diagnostic algorithms for TB are available at some laboratories but not current or complete.	National diagnostic algorithms and SOPs are available at all facilities in the public sector, but not current or complete.	Current national diagnostic algorithm available, but not at all public facilities.	Current national diagnostic algorithm available at all public facilities and some private labs.	Current national diagnostic algorithms available at all public and private facilities and regularly reviewed and updated.
2	The algorithm should focus on the whole diagnostic process from screening through to treatment completion, and not just the laboratory testing workflow component.	Does the algorithm focus on the whole diagnostic cascade, from screening to treatment completion?	No	The algorithm focuses only on the laboratory testing but is not current or complete	The algorithm focuses on the laboratory testing and does not address the whole diagnostic cascade, from screening to treatment completion	The algorithm at least partially addresses the whole diagnostic cascade, from screening to treatment completion.	The algorithm addresses the whole diagnostic cascade, from screening to treatment completion.	The algorithm addresses the whole diagnostic cascade, from screening to treatment completion and regularly updated
3		Does the algorithm address the laboratory goals of the End TB strategy to increase access to rapid and accurate detection of TB and to reach universal access to DST?	No	The national algorithm incorporates the use of WHO-approved rapid diagnostics (WRDs) for some patients in some settings.	The national algorithm incorporates the use of WHO-approved rapid diagnostics (WRDs) for patients in some high priority groups (e.g., those at risk of MDR-TB, HIV/TB, or pediatric TB).	The national algorithm incorporates the use of WHO-approved rapid diagnostics (WRDs) for all patients in all high priority groups (e.g., those at risk of MDR-TB, HIV/TB, or pediatric TB).	The national algorithm incorporates universal access to WHO-approved rapid diagnostics (WRDs) for all patients.	The national algorithm incorporates universal access to WHO-approved rapid diagnostics (WRDs) for all patients and all persons being evaluated for TB.

4. Diagnostic algorithm and lab-clinical interface

Description of situation (stage)

Question #	Components	Questions	0	1	2	3	4	5
4		Does the diagnostic algorithm define the role of symptom screening, clinical presentation, patient history, and X-ray in the diagnostic cascade?	No	A national algorithm is available but is rarely followed and there has been little training of clinicians in the algorithm.	National diagnostic algorithm is followed by some clinicians in the public sector. Training is provided to some clinicians in the public sector but is not current or complete.	National diagnostic algorithm is followed by all clinicians in the public sector in some districts. Current and complete training is provided to all clinicians in the public sector in some districts	Stage 3 with all public sector in all districts and some private sector. Training is provided to all clinician in the public sector and some private sector.	National, standard-of-care guidelines for evaluating patients and using X-ray findings are followed by all clinicians in the public and private sectors.
5	Relates to the training of all health care workers in application of the national diagnostic algorithm.	Is comprehensive training on diagnostic algorithms, testing methods, specimen collection, test requisition forms and specimen referral provided to all laboratorians, clinicians and other providers (including non-NTP) and TB program staff?	No	Some training provided to some laboratorians/ clinicians/ providers in public sector in some districts but is not current or complete.	Training is provided to all lab and some clinicians/providers in the public sector but is not current or complete with updated guidelines	Current and complete training is provided to all lab staff / clinicians/providers in the public sector in some districts.	Stage 4 with training provided to all lab/ clinicians/providers in the public sector and some private sector.	All laboratorians, health care workers, and TB program staff are trained in the application of the algorithm, which is regularly reviewed and updated.
6	Relates to availability of sensitization materials for diagnostic services and algorithm.	Are health care workers provided with standardized sensitization content (e.g., algorithm diagrams, brochures, training materials, customer handbook)?	No	Sensitization content is available at some facilities but not current or complete.	Sensitization content is available at all facilities in the public sector, but not current or complete.	Current sensitization content is available, but not at all public facilities.	Current sensitization content is available at all public facilities and some private labs.	Current sensitization content is available at all public and private facilities and regularly reviewed and updated.
7	Relates to adherence to the national TB diagnostic algorithm when ordering tests.	Are diagnostic tests ordered according to standard diagnostic algorithms and based on national policy and patient risk factors and history? (as opposed to individual clinicians	No	National TB diagnostic algorithm is followed by some clinicians in the public sector for some	National diagnostic algorithm is followed by some clinicians in the public sector for all patient categories.	National diagnostic algorithm is followed by all clinicians in the public sector in some districts for all patient categories.	Stage 3 with all public sector in all districts and some private sector. Training is provided to all clinician in the	Stage 4 with all public and private sector clinicians.

4. Diagnostic algorithm and lab-clinical interface

Description of situation (stage)

Question #	Components	Questions	0	1	2	3	4	5
		deciding which tests to order based on their own criteria and patient preference)		patient categories.			public sector and some private sector.	
8	**TB diagnosis** Relates to the capacity of the diagnostic network to detect TB.	Is the diagnostic testing available (onsite testing or system in place for referral and confirmation) for all tests within the national TB diagnostic algorithm within the country? Is access to testing ensured for all patient categories within the NSP, including pediatric, extrapulmonary, PLHIV and high-risk populations (miners, slum dwellers etc.)? Are WHO-recommended rapid TB diagnostics (WRDs) available to all persons with signs or symptoms of TB?	Testing not available for any of the tests.	Diagnostic testing required by the TB diagnostic algorithm is taken into account in the definition of the tier-specific minimal testing package of the diagnostic network.	Stage 1 and the national laboratory network (all districts) has the capacity to provide full diagnostic testing required by the national algorithm. Rapid diagnostic tests (WRDs) are being used, according to the tier specific diagnostic strategy.	The national laboratory network has the capacity to conduct full diagnostic testing required by the national algorithm. Rapid diagnostic tests (WRDs) are being used according to the tier specific diagnostic strategy in all labs in public sector and some private labs.	Stage 3 plus access to testing is ensured for all priority patient categories. Rapid diagnostic tests (WRDs) are being used for all persons in priority risk groups (e.g., MDR-TB, HIV/TB) at the lowest tier possible and according to the tier-specific diagnostic strategy.	For all public and private sector labs and continuously fulfilling international standards and requirements. WHO-recommended rapid TB diagnostics (WRDs) are available to all persons in the public and private sectors with signs or symptoms of TB.
9	**Drug resistant TB** Relates to the strengthening of DR-TB prevention and control. The questions focus on reference testing.	Is DST for first-line anti-TB drugs (at least DST for rifampicin) available on site or by referral for all bacteriologically confirmed TB patients?	No	DST is available on site or by referral in reference laboratories for some patients.	DST is available on site or by referral for bacteriologically confirmed TB patients at risk of having MDR-TB.	Level 2 plus WRDs are used for DST for rifampicin.	Level 3 plus all bacteriologically confirmed patients in the public sector are tested for rifampicin resistance.	Level 4 plus all bacteriologically confirmed patients in the public and private sectors are tested for rifampicin resistance.
10		Is reference testing for resistance to the full panel of second-line (SL) anti-TB agents available on site or by referral throughout the network?	No SL DST available at reference laboratory.	Partial panel of SL drugs can be tested at reference level using reliable standardized assay. Panel	Partial panel of SL drugs (at least FQs and SLIDs) can be tested using reliable standardized detection assay; and DR-TB reference	Full panel of SL drugs can be tested using reliable standardized assay; and DR-TB reference services are available in	Full panel of SL drugs can be tested using reliable standardized assay; and DR-TB reference services are available in	Full panel of SL drugs can be tested using reliable standardized assay; and DR-TB reference

4. Diagnostic algorithm and lab-clinical interface

Description of situation (stage)

Question #	Components	Questions	0	1	2	3	4	5
				must include at least FQs and SLIDs.	services are available in <30% of the districts (molecular or phenotypic methods).	<50% of the districts (molecular and phenotypic methods).	<80% of the districts (molecular and phenotypic methods).	services are available in all districts (molecular and phenotypic methods).
11	**Linkages** Relates to the linkage of clinical and laboratory services to ensure efficient screening and referral for testing of persons with presumptive TB.	Are procedures in place to ensure efficient linkage of persons with presumptive TB to TB laboratory testing?	No	No formalized procedure; linkage is on an informal and irregular basis.	Formalized procedure is in place for some tests at some tiers of the network.	Formalized procedure is in place for all tests at all tiers in the public sector	Stage 3 with all public sector and some private sector facilities	Stage 4 with all public and private, with assessment of impact and review of procedures
12	Relates to the linkage of diagnosed TB patients to appropriate care in a timely manner.	Are procedures in place to ensure efficient linkage of persons diagnosed with TB and DR-TB to appropriate care and treatment?	No	No formalized procedure; linkage is on an informal and irregular basis.	Formalized procedure is in place for some tests at some tiers of the network.	Formalized procedure is in place for all tests at all tiers in the public sector	Stage 3 with all public sector and some private sector facilities	Stage 4 with all public and private, with assessment of impact and review of procedures
13	Relates to importance of patient-centered approach to TB diagnosis, with regular interaction between lab and clinical services to improve diagnostic cascade.	Do clinical and laboratory staff regularly meet to troubleshoot gaps in laboratory-clinical linkages, including specimen referral, results interpretation and reporting?	No	Meetings occur infrequently on an *ad hoc* basis.	Regular meetings occur at some tiers with public sector providers.	Regular meetings occur at all tiers with public sector providers.	Meetings occur regularly at all tiers and include all public and private lab and clinical providers.	Stage 4 with joint planning and impact assessment conducted, with regular reviews.
14	**Surveillance** Relates to the surveillance capacity of the laboratory network for TB and DR-TB.	Are laboratory-based surveillance procedures in place and implemented for TB and DR-TB?	No	A TB prevalence survey and a Drug Resistance Survey have been	Stage 1 plus laboratory-based surveillance for TB and DR-TB is conducted in sentinel sites	Stage 2 plus laboratory-based surveillance for TB and DR-TB is conducted in sentinel sites representing at	Stage 4 plus a system is in place for ongoing laboratory-based surveillance for TB and DR-TB in >30% of the high-	A system is in place for ongoing laboratory-based surveillance for TB and DR-TB throughout the country.

4. Diagnostic algorithm and lab-clinical interface

Description of situation (stage)

Question #	Components	Questions	0	1	2	3	4	5
				conducted within the past three years.	representing at least 30% of the country.	least 80% of the country.	prevalence districts in the country.	
15	Relates to the design of a laboratory/EPI-based surveillance plan, capable of generating nationally or sub-nationally representative data, which will be used for developing treatment guidelines.	Is there an up-to-date, implemented national plan for surveillance of TB and DR-TB, which defines the role of the laboratory.	No plan for TB laboratory surveillance exists. There is no policy that requires the laboratory to report data on TB or DR-TB cases to the local or national TB control program.	National plan for surveillance of TB and DR-TB explicitly describing the role of laboratory has been designed but not approved. A policy to require laboratory reporting of TB or DR-TB cases to the local or national TB control program has been designed but not approved.	National plan for surveillance of TB and DR-TB has been approved. A policy to require laboratory reporting of data on TB or DR-TB cases to the local or national TB control program has been approved.	National plan is being implemented. Designated sentinel sites are conducting surveillance of TB and DR-TB.	All of before. Designated sentinel sites have conducted surveillance of TB and DR-TB for at least 1 year. Data are made available to pertinent clinical organizations to guide local treatment decisions.	Designated sentinel sites have conducted surveillance of TB and DR-TB for 5 years with a system for continuous improvement.

4. Diagnostic algorithm and lab-clinical interface

Description of situation (stage)

Question #	Components	Questions	0	1	2	3	4	5
16	Reporting data to the epidemiology unit with evidence that data are acted upon is the final step to complete the surveillance cycle.	Are TB and DR-TB surveillance data reported to the epidemiology unit and used as per procedure?	Laboratory data on TB and DR-TB surveillance are not collected.	Some laboratory data on TB and DR-TB surveillance are collected but not reported to the national epidemiology unit.	Laboratory TB and DR-TB surveillance data are inconsistently reported to the epidemiology unit. There is no approved procedure for data reporting.	TB and DR-TB surveillance data are regularly reported to the epidemiology unit as per (approved) procedure.	Stage 3 and TB/DR-TB surveillance reports are regularly generated by the epidemiology unit.	Stage 4 with evidence that data have been used to update or draft national diagnostic and treatment guidelines .
17	**Research** Relates to conduct of programmatically relevant operational and implementation research on new diagnostic tests, platforms, algorithms and systems to inform national policies and guidelines.	Is programmatically relevant operational research and research on new TB diagnostics conducted in the country? Are data used from such research to inform national policy? Does research lead to adopting new diagnostics tools, review, validation, policy revision and implementation?	No	Limited high quality research is conducted in the country and is not used to inform national policy.	High quality research is conducted at reference and referral level only, and in few settings. Data are used to inform policy on an *ˆad hoc* basis.	Stage 3 plus some studies at lower levels of the network and various geographical settings. Data are used to inform national policy on an ad hoc basis.	Stage 4 plus all levels of the network and various geographical settings and some priority populations. Data are often used to inform national policy.	National policies on TB diagnosis are always informed by high quality research conducted in the country which reflects all levels of the network, various settings and priority populations.
18	Relates to design and conduct of operational research on TB	Are operational (implementation) research studies	No	Results from OR studies do not	Results from OR studies infrequently	OR studies often include patient-important	Stage 3 plus OR data used for scale up, although	OR studies always include patient-important

4. Diagnostic algorithm and lab-clinical interface

Description of situation (stage)

Question #	Components	Questions	0	1	2	3	4	5
	diagnosis that includes impact measurement. Outcomes of such studies should be analyzed at a national level and used to promote scale up of best practices to improve program performance.	designed in such a way as to measure standard patient-important outcome indicators? Is a mechanism in place for review of results of OR studies and promotion of best practices in scale up plans?		include patient-important outcomes.	include adequate patient-important outcomes. *Ad hoc* review of OR data by NTP.	outcomes. NTP reviews OR data on a regular basis but data-driven scale up of best practices is not common.	significant delays in dissemination of best practices occurs.	outcomes. The NTP plays an active role in review of study outputs and data on successful implementation models are rapidly disseminated and used to inform scale up.

5. Biosafety **Description of situation (stage)**

Question #	Components	Questions	0	1	2	3	4	5
1	**Facilities** Linking up building standards to acceptable international standards of biosafety and biosecurity.	Are there national laboratory building requirements that include detailed standards for TB laboratories?	There are no laboratory building requirements .	National requirements include ONLY general building standards.	National requirements include components of biosafety only.	National requirements include standards of biosafety and some standards of biosecurity but are not regularly updated.	National requirements include standards of biosafety and biosecurity but are not regularly updated.	Building requirements are aligned with international standards of biosafety and biosecurity and are regularly updated.
2	Ensures that both new and existing facilities comply with international and national laboratory standards or building codes.	Are laboratory specific building requirements consistently applied to all laboratory facilities?	There are no laboratory building requirements .	National requirements exist but they are not consistently applied.	National requirements exist and are consistently applied to all new buildings in the public OR private sector.	National requirements exist and are mandatory for new facilities in the private and public sector.	All new and existing laboratories facilities are aligned with national building requirements.	All new and existing laboratory facilities are aligned to national building norms and are regularly checked.
3		Are laboratory facilities regularly maintained and is there an uninterrupted availability of general utilities (water, energy, communication lines)?	No	Laboratories are sporadically maintained and some general utilities are available at some tiers .	Laboratories are periodically maintained and all utilities are available at some tiers.	Laboratories are periodically maintained and all utilities are available at all tiers with backup systems for at least electricity at some levels.	Ongoing preventive maintenance at some tiers and backup systems for at least electricity at all levels.	Ongoing preventive maintenance at all tiers and backup systems for all utilities are available regularly tested and replaced when necessary.
4	**Biosafety manual**	Is there a current national laboratory biosafety and biosecurity manual?	No	There is a manual that is out of date and/or that was never widely distributed.	There is a manual that is up to date that is covering biosafety but not biosecurity	There is an up to date manual covering biosafety and biosecurity (<2 years old) but it is not widely distributed.	There is an up to date manual covering biosafety and biosecurity (<2 years old) available at all facilities.	Stage 4 and the manual is regularly reviewed and updated according to the national guidelines.
5	The laboratory biosafety manual should be accompanied by separate SOPs covering all essential components. Sometimes SOPs are developed before manual is written, but the ideal situation is to have both a manual and the SOPs	Is the national laboratory biosafety and biosecurity manual implemented and incorporated into standard operating (SOP) procedures? Does the manual and/or SOPs contain adequate information on TB lab biosafety, or is there a separate TB lab biosafety manual?	There is no laboratory biosafety/ biosecurity manual and no SOPs.	There is a manual that is out of date with no current SOPs OR there are some out of date SOPs in place with no manual.	There is an up to date manual in place with no current SOP OR some current SOPs are in place with no manual	There is an up to date manual in place which is not fully incorporated into current SOPs	The manual is fully incorporated into current SOPs	All of before and the manual is regularly reviewed and updated.

5. Biosafety **Description of situation (stage)**

Question #	Components	Questions	0	1	2	3	4	5
6	The national biosafety and biosecurity manual should address key requirements for the safe handling and use of samples for TB testing and TB strains.	Does the biosafety and biosecurity manual cover key requirements for the safe handling of TB (specimens for testing, isolates/ strains) based on bio-risk assessment?	There is no biosafety manual.	There is a manual but *M. tb* is not explicitly addressed.	The manual explicitly addresses *M. tb* but covers only 1-2 key requirements. Includes risk assessment mainly in the perspective of safeguarding the laboratory staff (biosafety).	The manual addresses all elements, for both staff safety (biosafety) and the protection of the environment (biosecurity),	Stage 3 and documented risk assessments conducted at facility level.	Stage 4 and the manual is regularly reviewed and updated
7	**Biosafety systems** Relates to the health and safety of laboratory workers.	Are basic occupational health services available to all laboratory workers?	There are no basic occupational health services available for laboratory workers.	Some basic occupational health services available *ad hoc*.	<3 elements of basic occupational health services, including vaccination are systematically available to some workers.	>=3 elements of basic occupational health services including vaccination and prophylaxis are available to all laboratory workers including baseline examination and immunization.	All basic occupational health services are available to some laboratory workers.	All basic occupational health services available to all laboratory workers.
8		Is safety equipment available (e.g. biosafety cabinets, PPE)?	No	Some safety equipment available.	All safety equipment according to the national guidelines is available to some laboratory workers.	All safety equipment according to national guidelines available to all laboratory workers at some levels in the public sector.	All safety equipment according to national guidelines available to all laboratory workers at all levels in the public sector and some levels in the private sector.	All safety equipment available to all laboratory workers at all levels and regularly monitored and replaced when expired.
9		Are designated safety officers available in all facilities? (part-time or full time)	No designated safety officer at any facilities.	Some facilities at some tiers of the public sector have a designated safety officer.	All facilities at some tiers of the public sector have a designated safety officer.	All facilities at all tiers of the public sector have a designated safety officer.	All facilities of the public sector and some private sector have a qualified and designated safety officer who receives regular refresher trainings.	All facilities in the public and private sector have a qualified and designated safety officer that receive regular refresher trainings.

5. Biosafety **Description of situation (stage)**

Question #	Components	Questions	0	1	2	3	4	5
10	Biosafety cabinets should correspond to the biosafety level of the facilities to ensure protection of staff and the environment.	Are certified biosafety cabinets (BSC) available according to the facility biosafety level (BSL) wherever needed?	Certified BSC are needed but are not available in the country.	BSC are available according to BSL only at some tiers or in some facilities.	Certified BSC are available according to BSL at all facilities in need in the public sector but are not regularly serviced.	All of before and including some private labs and BSC are regularly serviced at some tiers but not by a certified body.	BSC are regularly serviced and certified at all relevant tiers by a certified body.	At all relevant tiers of the laboratory network in the public and private sector and these are regularly serviced and certified according to a national or institutional maintenance plan.
11	**Specimen storage** Relates to the reduction of the risk associated with the storage and handling of TB samples and strains.	Is the storage/archiving of TB and DR-TB strains done according to rules of biosafety and biosecurity?	No	Updated record and inventory of facilities that process or store TB/DR-TB is initiated.	Stage 1 plus pathogens control measures are being developed including standard for physical containment and operational handling and failure reporting system.	Stage 2 plus initiating the consolidation of TB/DR-TB storage in a minimum number of facilities	TB/DR-TB control measures, consolidation of TB/Dr-TB storage in a minimum number of facilities	Stage 4 and the system is regularly monitored.
12	**Waste management** Relates to the availability of clear descriptions (job aids or full procedures) on how waste should be handled from collection to final disposal according to standard of biosafety and biosecurity.	Are standardized procedures for collecting, storing and disposal of identified categories of waste implemented according to the national standards ?	No procedures or national standards exist.	Only job aids exist and they are not aligned with the national standards as described in the biosafety manual or in the legislation.	Some management procedures such as job aids aligned with national standards exist. Standardized procedures are only partially implemented.	All of before and full implementation of the standardized procedures. Conformance to waste management is partially monitored in accordance with level-specific biosafety and biosecurity requirements.	Waste management conformance is fully monitored in accordance with level-specific biosafety and biosecurity requirements in all public sector labs and some private sector.	All of before and in all public and private sector labs, plus follow up of non conformities.
13	Relates to the availability of autoclave and incinerators for the disposal of infectious waste that comply to national standards.	What are the methods used to safely dispose of infectious waste?	No (access to) autoclaves nor incinerators.	Some laboratories have access autoclaves and/or incinerators that may or may not comply with national standards.	All laboratories have access to autoclaves and some to incinerators that may or may not comply with national standards.	All laboratories have access to both autoclaves and incinerators that comply with national standards. Incinerators are not used for the disposal of all eligible waste.	All laboratories have access to autoclaves and incinerators. Incinerators comply with national standards, and are used for the disposal of all eligible waste in all public sector and some private sector labs.	All of previous and in all public and private sector labs and incinerators are designed to minimized air pollution.

6. Equipment and supplies **Description of situation (stage)**

Question #	Components	Questions	0	1	2	3	4	5
1	**Supply chain management**	Does the country have a standardization plan for laboratory testing reagents?	No	Yes but not in line with the tier-specific testing package.	Yes, in line with the tier-specific testing package but not regularly updated and not implemented at all levels.	Standardized testing reagents are used at all levels in the public sector, without regular monitoring and updating.	Standardized reagents are used at all levels within the public sector and some in private sector, with regular updating and monitoring	All laboratories in the public and private sector operate using state-of-the art standardized testing reagents that can be procured locally or regionally. Contract management capacity for reagents and supply is demonstrated in central laboratories.
2	Control of IVDs is to monitor the quality of reagents after they have been purchased. This would ensure that no counterfeit or defective reagents are being used.	Are there regulatory procedures in place for the control of in vitro diagnostics (IVD)?	No	Regulatory procedures are being developed.	Regulatory procedures are in place and a list of authorized IVDs is available.	The list of authorized IVDs is routinely updated. Post market surveillance is organized for some IVDs including those for TB.	The list of authorized IVDs and the regulatory procedures are routinely updated. In country post market surveillance include IVDs for TB.	Post-market control is done for all IVDs used in the country
3	Relates to the robustness of the system in place for reagent procurement. Supply of reagents and consumables should be continuous also for remote locations. The system should guarantee that supplies are adequately procured in case of emergency (time and volume).	Is there a procurement system allowing for the continuous supply of testing reagents in the country for public sector labs in the national TB diagnostic network?	No	System is in place for some supplies for some districts or tiers, but with regular stock outs.	System is in place for all supplies for some districts or tiers, but with regular stock outs in routine situations.	System is in place for all supplies and for all districts or tiers, with occasional stock outs during routine situations.	System is in place for all supplies and for all districts or tiers with no stock outs in routine situation.	The national procurement system ensures the continuous distribution of all needed supplies with a universal coverage. The system is regularly quality controlled.
4		Is there a procurement system allowing for the continuous supply of testing reagents in the country for private or academic laboratories that are in, or linked to, the national TB diagnostic network?	No	System is in place for some supplies in some laboratories, but with regular stock outs.	System is in place for all supplies for some laboratories, but with regular stock outs in routine situations.	System is in place for all supplies for all laboratories, but with regular stock outs in routine situations.	System is in place for all supplies for all laboratories, but with no stock outs in routine situations.	The national procurement system ensures the continuous distribution of all needed supplies with a universal coverage. The system is regularly quality controlled.

6. Equipment and supplies **Description of situation (stage)**

Question #	Components	Questions	0	1	2	3	4	5
5	Ensures that no stock outs or wastes are taking place. It is crucial that the system captures information on consumption from all levels. Forecasting is a step higher than monitoring consumption.	Is there a system to monitor and forecast supply consumption in the country?	No	Supply consumption monitoring is in place for some supplies.	Supply consumption monitoring is in place under routine conditions with occasional stock outs.	Supply consumption monitoring and forecasting systems are in place under routine conditions with no stock outs.	Real time supply consumption monitoring and forecasting systems are in place under routine conditions for procurement, storage and distribution.	All of before and the system is regularly monitored.
6	**Equipment**	Does the country have a standardized list of laboratory equipment?	No	There is a list of equipment for routine testing, but not fully aligned with tier-specific requirements.	There is a list of equipment for routine testing, aligned with tier-specific testing requirements, and the national reference laboratory is compliant with the list.	There is standardized list of equipment for routine testing, aligned with testing requirements for all tiers of the laboratory network.	There is standardized list of equipment for routine testing, aligned with testing requirements for all tiers of the laboratory network. The list is enforced within the public sector and some private labs and is regularly reviewed and updated.	There is standardized list of equipment for routine testing for all tiers of the laboratory network which is enforced and regularly updated in both public and private sectors. Contract management capacity for equipment is demonstrated in central laboratories.
7		Is there a procedure for validation of equipment?	No	There is pre-service validation of some pieces of equipment at national level.	There is pre-service validation of all pieces of equipment at national level.	There is pre-service validation of some pieces of equipment at all levels.	There is pre-service validation of all pieces of equipment at all levels in the public sector and some private labs. Operational validation (in service) is done for some. instruments at some levels.	There is pre-service and ongoing validation of all pieces of equipment at all levels in both public and private sector.

6. Equipment and supplies **Description of situation (stage)**

Question #	Components	Questions	0	1	2	3	4	5
8		Is there a national maintenance plan (covers spare parts, storage and disposal) for all laboratory equipment at all levels?	No	The national plan is in place only for essential or sophisticated equipment.	The national plan in place for all equipment at the national level.	The national plan is in place for all equipment at the all levels in the public sector. Contracts and engineers are available at national and regional levels for some equipment.	As before and including some private labs. Contracts and engineers are available for all equipment in some districts.	Companies are evaluated and contracts are reviewed, renewed or replaced. Coverage of all public and private labs. Engineers are available for all equipment in all laboratories.
9	Relates to integration of procurement, use and maintenance of diagnostic platforms across TB and other diseases (e.g. Xpert).	Are diagnostic platforms used for TB and other diseases, including planning, procurement, use and maintenance?	No	There are no guidelines on integration and it is conducted only in a limited number of facilities.	There are guidelines which advocate integration of services and it is implemented in some facilities.	Stage 2 plus shared planning and budgeting in some locations.	Stage 3 with shared planning and budgeting	Use of all diagnostic platforms is integrated across TB and other diseases, with joint planning and budgeting.

7. Workforce **Description of situation (stage)**

Question #	Components	Questions	0	1	2	3	4	5
1	**Education and training** Relates to the availability of educational curricula that generates competent laboratory workers, according to national standards.	What is in place in terms of the pre-service education?	There are no educational curricula in place.	Educational curricula are available for various categories of laboratory workers but are not regularly reviewed and updated.	Competency-based educational curricula are in place.	As previous and there is a mechanism in place for regular reviewing and updating of the educational curricula.	As previous and are in line with national standards.	As previous and regularly reviewed by an independent national or internal certification or accreditation body.
2	Relates to the capacity of the training institute to offer hands on practicums in classic and modern laboratory techniques during internship.	Is practical training part of the pre-service curriculum?	No	Practical training is only organized outside the training institute.	Practical training is organized inside the training institute but consist mainly of observation/ demonstration.	Practical training is organized inside the training institute and consists mainly of hands-on practicals on classic techniques.	Hands on practicals inside the training institutes cover both classic and modern techniques.	Hands on practical trainings in all methods used in the laboratories are regularly reviewed and updated with input from the end users (lab managers).
3	The scoring relates to the availability of all levels of education, from basic certificate upwards. This is to determine whether adequately educated individuals are available.	Are there separate educational programs for different levels of laboratory workers?	No	There is only basic level education laboratory education.	There is college, certificate, diploma, BSc and Master in Science (MSc), Medical doctors (MD) level laboratory education.	All of the previous plus some specializations for pathologists and medical microbiologists.	All of the before plus possibilities for in-country PhD* degrees in laboratory sciences.	All of the before plus basic, intermediate and advanced specializations for pathologists, and medical microbiologists. Appropriately educated supervisors are available at all levels.
4		Are quality, biosafety, biosecurity and quality practices separate topics in laboratory educational curricula?	There is no education or training available for neither biosafety, biosecurity nor quality practices.	Some pre-service educational curricula include quality or biosafety or biosecurity management.	All pre-service educational curricula include quality, biosafety and biosecurity management.	Same as previous plus in-service and refresher trainings are available for quality, biosafety and biosecurity management.	Same as previous and all pre-service education include competency testing.	Same as previous plus all educational and training curricula are regularly reviewed and updated.

7. Workforce **Description of situation (stage)**

Question #	Components	Questions	0	1	2	3	4	5
5		Is there a training program for laboratory management in place?	No	Sporadically, courses on aspects of laboratory management (i.e. leadership course) are available.	Regular courses on aspects of laboratory management are available for upper level laboratory managers.	A training program for laboratory management at all levels, either separately or as a specialized track in a broader program, is functional.	All of previous and the program(s) is(are) available up to Master (MSc or MBA) programs.	All of previous and the programs are regularly reviewed and updated.
6	Relates to the perennial organization of in-service training that keeps the laboratory professional up-to-date with recent development of laboratory medicine technology and guidelines.	Are there continuous education training programs in place?	No	There are continuous education trainings organized by the program, local partners or international partners on an *ad hoc* basis.	There are continuous *ad hoc* or unofficial education trainings organized by the government or training institutes.	There is an official national program and annual plan for continuous education, which is partially functional.	All of previous and the program is regularly reviewed and updated. There is an official national program plan for continuous education, which is fully functional.	All of previous and personal development plans for laboratory workers are based on this program which is updated annually.
7	Ensures that re-licensing takes continuous education and competency into consideration.	Is the licensing of laboratory workers based on education, continuous education and competency?	There is no licensing mechanism in place.	One time licensing is automatically issued with registration or graduation for some categories of laboratory workers.	Stage 1 for all categories of workers.	Stage 2 and there is a regular re-licensing system in place.	There is a re-licensing mechanism in place based on qualification, continuous education and national standard of competency.	All of previous and the content of the re-licensing requirements are regularly reviewed and updated.
8	**Staffing** Relates to the establishment of clear and relevant targets for the development of human resources for laboratory.	Is there a national staffing plan for the TB diagnostic network that is based on workload forecasting?	No	There is a national staffing plan but it is not based on workload forecasting.	A workload forecasting -based staffing plan is being developed.	A workload forecasting based staffing plan is being implemented at some tiers.	There is an implemented staffing plan for all tiers based on workload forecasting.	There is an implemented staffing plan for all tiers based on workload forecasting with procedures for surge capacity.

7. Workforce **Description of situation (stage)**

Question #	Components	Questions	0	1	2	3	4	5
9	Most countries define their staffing needs based on administrative position available per type of facility. The recommended approach is to make the transition to forecast of workload-based staffing norms.	Are numbers of different categories of laboratory workers sufficient to cover the workload needs at all levels?	There are no numbers or figures available to quantify the availability of shortage of staff.	Shortages based on positions available exist for all categories of laboratory workers. Needs based on workloads are not defined.	All positions available are not filled for some categories of laboratory workers or in some districts or at some tiers. Needs based on workload are defined at some facilities or at some tiers.	All available positions are filled but shortages exist based on the workload-based staffing norms.	Positions available are based on workload-based norms and are all filled.	There is a sufficient number of all categories of laboratory workers based on current and anticipated workload and assist during surge capacity needs.
10	Integration of staff scope of work to cover TB and non-TB diagnostic testing is encouraged as a means to improve efficiency of services.	Does the scope of work for laboratory staff include diagnostic testing for both TB and other diseases?	There is no scope of work for laboratory staff available.	Laboratory staff that process TB specimens do not do diagnostic testing for other diseases.	The majority of personnel conduct only TB diagnostic testing.	The majority of personnel conduct diagnostic testing for TB and other diseases in a limited number and type of facility.	The majority of personnel conduct diagnostic testing for TB and other diseases at all levels.	Scope of work for laboratory staff is fully integrated across TB and other diagnostic testing at all levels and in public and private sector facilities
11	**Human resources development strategy** Relates to the alignment of the laboratory-specific and health HR strategies.	Is there a national human resource development strategy addressing laboratory workers?	No	There is a health strategy that addresses the development of the laboratory workforce but this is not up to date.	There is an updated health strategy that addresses the development of the laboratory workforce but it is not aligned with the national laboratory strategy.	There is an updated health strategy that addresses the development of the laboratory workforce and that is fully aligned with the laboratory strategy.	The national laboratory workforce development strategy is fully implemented.	The national laboratory workforce development strategy is fully implemented and regularly revised based on forecasted laboratory services needs.
12		Does the national laboratory strategic plan address key issues of the laboratory workforce?	There is no strategy (either stand alone or as an integral part of a larger health strategy) for the development of the laboratory workforce.	The strategy addresses <3 key issues.	The strategy addresses 3-6 key issues.	The strategy addresses 7-10 key issues with clear targets.	The strategy addresses all issues and some HR strategies exist at facility level.	The national strategy addresses all key issues with clear targets that are revised based on monitoring and evaluation. All facilities have HR strategies at institutional level.

7. Workforce **Description of situation (stage)**

Question #	Components	Questions	0	1	2	3	4	5
13	Competency-based job descriptions is one way to define staff roles while still allowing for evolution. Enunciating behavioral competencies facilitates personnel selection, role comprehension, and performance evaluation.	Are competency-based job descriptions available for all positions in the laboratory?	No job descriptions at all.	Non-standardized job descriptions available for some positions.	Non-standardized job descriptions are available for all positions.	Standardized and competency-based job descriptions are available for some positions and are non-standardized for some other positions.	Standardized and competency-based job descriptions are available for all positions, including support staff positions.	All of the before and regular review and updating.

8. Diagnostic data management **Description of situation (stage)**

Question #	Components	Questions	0	1	2	3	4	5
1	**Data collection**	Are request forms standardized for all testing and being used at all levels throughout the country?	No	Request forms are standardized for some tests only at national level.	Request forms are standardized for some tests only at national level and some lower levels OR in some parts of the county.	Request forms are standardised for ALL tests at national level and some lower levels OR in some parts of the country	Stage 3 and the request forms are fully used at all levels. Data on test request are captured by laboratory, verified and used in the testing process	Stage 4 and request forms are regularly reviewed. Data on test request are captured in logbooks/online in realtime/LIMS and regularly reviewed and analyzed.
2	Relates to the coverage of the sample referral system.	Is there a system in place that allows for a sample to be tracked from the submitting lab to the referral/reference lab and for the results/reports to be received by the referring labs?	No	Tracking system for referral is informal, irregular and not consistent.	Formal tracking system for referred samples exists at the national level only.	Stage 2 also at some lower levels.	Stage 3 also at all levels. Tracking system for referred samples provides reports on a timely basis	Online real-time tracking system for referred samples provides reports on a timely basis and referred data are routinely or regularly reviewed.
3	Relates to the standardized reporting of diagnostic results	Are reporting forms for all TB tests standardized and according to best practice, and include information on interpretation of results? Are they being used at all levels throughout the country?	No	Reporting is not standardized for any tests and reports do not include all essential data.	Reporting is standardized for some tests and reports do not include all essential data.	Reporting is standardized with all essential data for all tests at national level and some lower levels OR in some parts of the country in the public sector.	Stage 3 at all levels in public sector and some private sector facilities.	Standardized reporting forms are used in all public and private sector facilities.
4	**Data analysis and sharing**	Is there a fully functional laboratory data unit with adequate trained personnel, hardware and software that receives laboratory data from all levels, analyzes the data and generates reports?	No unit	There is a unit but no staff.	Stage 1 but not fully equipped or trained.	There is a unit with staff, which is equipped but not fully operational.	Stage 3 and fully operational.	Laboratory data unit is able to generate reports on a regular basis.

8. Diagnostic data management **Description of situation (stage)**

Question #	Components	Questions	0	1	2	3	4	5
5		Are statistical data reported, analyzed, used for decision making purposes and shared within MoH and other government agencies?	No	Data aggregated on an informal and irregular basis.	Only the national laboratory can report aggregate data to the MoH.	Data are aggregated at some laboratories but not reported to national level.	Data are aggregated from all levels. Procedures are in place for data sharing. Reports are sent to the national unit and data are collated and analyzed nationally.	National data reports are written, distributed and shared with other sectors within the government.
6	**Reporting**	Is there a national standard for patient reports and do labs follow this standard for reporting?	No	There is a standard for patient reports for some tests only.	There is a standard for patient reports for all tests and this is followed at the national level only.	There is a standard for patient reports and this is followed at the national level and some lower levels.	There is a standard for patient reports and this is followed at all levels.	Stage 4 and reports are routinely archived and reviewed routinely or regularly.
7	Relates to the rapid reporting of diagnostic data for clinical management.	Is there an electronic system supporting the reporting of diagnostic data to clinicians for patient management?	No	Electronic reporting is functional in reference laboratories only.	Stage 1 and functional at regional levels laboratories.	Stage 2 and functional at some lower levels.	Stage 3 and functional to all referring clinicians at all levels in the public sector and some private facilities.	Electronic reporting is fully functional to all referring clinicians at all levels in the public and private sector.
8	Relates to the rapid reporting of data for program management.	Is there an electronic system that enables reporting of diagnostic data to local and national program? Do local and national programs analyze and use data routinely for decision-making and program improvement, including network management and equipment maintenance, supply chain, quality assurance?	No	Electronic reporting for programme purposes is functional in reference laboratories only.	Stage 1 and functional at regional levels laboratories.	Stage 2 and functional at some lower levels and analysed for a limited range of purposes.	Stage 3 and functional at all levels in the public sector and some private sector labs. Data are analysed routinely for multiple purposes.	Stage 4 plus all public and private laboratories. Data are routinely analysed and used for full range of purposes.

8. Diagnostic data management **Description of situation (stage)**

Question #	Components	Questions	0	1	2	3	4	5
9	**Surveillance/ epidemiology**	Are there procedures to integrate laboratory and epidemiology data implemented and used to support real time surveillance?	No	Integrated reporting of laboratory and epidemiology surveillance data managed in an informal and irregular manner.	Procedures for integrating laboratory and epidemiology data and surveillance reporting are drafted but not approved.	Stage 2 and procedures approved but implemented only at national level.	Stage 3 and fully implemented at all levels.	Stage 4 and procedures are reviewed routinely or regularly. Analyzed data is used for policy making decisions.
10	Relates to automated reporting of diagnostics data for surveillance purposes.	Are electronic diagnostics data routinely captured and analysed for surveillance of TB and DR-TB?	No	Electronic reporting for program purposes is functional in reference laboratories only.	Stage 1 and functional at regional levels laboratories.	Stage 2 and functional at some lower levels.	Stage 3 and functional at all levels in the public sector and some private sector labs.	Stage 4 plus all public and private laboratories.
11	Relates to reporting of TB to MoH.	Is there a standard procedure for reporting results of notifiable diseases (including TB), to the MoH or specific entity in the MoH?	No procedure	TB is reported on an informal and irregular basis.	A standard process for reporting TB to MoH is developed but not approved.	A standard process for reporting TB is developed and approved but is only reported from public sector to national levels.	There is a standard process to report TB to the national level which is fully used at all levels in the public sector and some private sector, and has been in place for at least 1 year.	There is a standard process to report TB to the MoH which is fully used at all levels in private and public sector.
12	**Security and confidentiality of information**	Are there policies and procedures governing the security of laboratory data and confidentiality of patient data, whether paper based or electronic?	No	Security of laboratory data is managed in an informal and inconsistent way.	Policies or procedures for laboratory data security and patient data confidentiality are drafted but not approved.	Stage 2 and policies or procedures are approved but implemented at national only, not lower levels.	Stage 3 and policies and procedures are fully implemented at all levels in public sector and some in private sector.	Stage 4 and policies are fully implemented at all levels in public and private sector, and procedures are regularly reviewed.
13		Are there SOPs and policies in place to support the back up and retrieval of data ?	No	Back up and retrieval of laboratory data is managed in an informal and inconsistent manner.	Policies for laboratory data back up and retrieval are drafted but not approved.	Stage 2 and policies and procedures are approved but implemented at national only, not lower levels.	Stage 3 and policies and procedures are fully implemented at all levels in public sector and in some private sector labs.	Stage 4 and policies and procedures are fully implemented in all levels in public and private sector and are regularly reviewed.

9. Quality of the diagnostic network **Description of situation (stage)**

Question #	Components	Questions	0	1	2	3	4	5
1	**Quality assurance** Relates to the routine monitoring of quality (performance) indicators of TB testing.	Are quality indicators and performance measures monitored and evaluated for all TB tests?	No	Quality indicators and performance measures are not routinely monitored for all tests.	Quality indicators and performance measures are routinely monitored for all tests at some tiers, but infrequently analyzed.	Quality indicators and performance measures are routinely monitored and evaluated for all tests at all tiers of the public sector. Results are reported to the supervisory laboratory.	Stage 3 with corrective actions routinely taken for non-conformities identified by the quality indicators and performance measures for all tiers of public sector and some private sector.	Stage 4 for all public and private sector labs. Includes regular review of quality indicators and monitoring systems.
2	Relates to the day-to-day monitoring of precision and accuracy of all assays. There are implications regarding the acceptability of test data.	Do all laboratories have internal quality controls in place for all tests?	No	Internal quality controls are included in some testings.	Locally produced internal quality controls are included in all testings.	Standardized internal quality controls are included in all testings.	Internal quality control procedures are standardized throughout the network for all testings in the public sector and some private sector.	Internal quality control procedures are standardized throughout the network for all tests and reviewed to detect and correct trends. Includes all public and private sector labs.
3	Completes previous question with a notion of external check and inter-laboratory comparison to improve the quality of test results.	Are there national EQA programs in place for all TB diagnostics at the different tiers?	No	There are plans to develop an EQA program.	An EQA program for some tests at some tiers is in place with feedback of results in the public sector.	An EQA program for some tests at all tiers in the public sector is in place with feedback of results.	An EQA program for all tests is in place at all tiers in the public sector and some private sector labs with feedback of results and action for improvement.	No testing is permitted that does not have an EQA component for all public and private sector labs.
4	All testing from the reference laboratories should undergo EQA with proof of compliant results.	Do reference laboratories participate in international EQA (internationally certified/or accredited EQA-ISO 17043) programs where available?	No	Yes, but not for all EQA programs available.	Yes, for all EQA programs available.	Yes, for all EQA programs available and with action plans for improvement after each round.	Stage 3 and with compliant results for some of the programs for at least the last 3 years.	Stage 4 and with compliant results for all programs for at least the last 3 years.

9. Quality of the diagnostic network **Description of situation (stage)**

Question #	Components	Questions	0	1	2	3	4	5
5		Is there a system of laboratory supervisory oversight in place?	No	*Ad hoc* supervisions are organized in case of problems.	<3 selected supervision elements routinely implemented only from the reference laboratory to the rest of the network.	A system of regulated (with a protocol and a schedule) supervision is in place from the reference laboratory tier to the lower levels in the public sector.	Routine supervision for all elements in place with the reference laboratory supporting all lower levels in the public sector and some private sector.	A system of regulated supervision is in place from all tiers of the laboratory network to the lower tiers. The system includes staff competency evaluation and covers all public sector and private sector labs.
6	**Quality management system**	Is the position of quality or quality assurance officer filled in in each laboratory? (part-time or full-time)	No	Only in reference laboratories	Only in reference laboratories with clearly defined role and responsibilities documented in a job description.	In reference laboratories and lower tiers in the public sector with clearly defined role and responsibilities documented in a job description.	In all laboratories in the public sector.	In all laboratories in the public and private sector.
7		Are quality management activities implemented in all laboratories providing TB testing?	No	Not according to a structured approach.	Only in reference laboratories using a structured approach with QMS implementation tools (e.g. GLI, LQSI, LQMS, SLIPTA, SLMTA, mentoring)	In reference laboratories and some lower tiers in the public sector using a structured approach with QMS implementation tools (e.g. GLI, LQSI, LQMS, SLIPTA, SLMTA, mentoring)	In all laboratories in the public and some private sector labs.	In all laboratories in the public and private sector.
8	**Certification and accreditation** All laboratories should be certified to be allowed to operate.	Are there national certification standards for laboratories?	No	There are approved national certification standards for some TB tests.	There are national certification standards that are mandatory for some laboratories.	There are national certification standards that are mandatory for all laboratories conducting TB testing in the public sector.	All of previous and including some private sector, and enforced.	All of previous and fully aligned with ISO standards
9	Accreditation should be mandatory for laboratories at national and reference level in the public sector. Private laboratories can be accredited on a voluntary basis.	Are there mandatory accreditation standards for laboratories and are they implemented?	No	There are national accreditation standards.	There are national accreditation standards that are implemented for laboratories at the national level.	There are national accreditation standards that are implemented for laboratories at national and reference levels in the public sector.	All of before and enforced, and including some private sector labs	All of before and including all public and private sector labs at national and reference level, and fully aligned with ISO standards

Annex 4. Sites Visited

Sites Visited				
NRL	**IRL**	**Other C-DST Laboratory**	**DMC**	**CBNAAT**
Chennai-Puducherry-Nellore				
NIRT, Chennai	IRL Chennai	DFIT Nellore	Institute of Thoracic Medicine, Chennai	Institute of Thoracic Medicine, Chennai
	IRL Puducherry		Govt. Chest Clinic, Puducherry	Hindu Hospital, Chennai
			DTC Nellore	JIPMER, Puducherry
			ACSR Medical College, Nellore	
Bangalore-Hyderabad				
NTI Bangalore	IRL Bangalore		Rajajinagar Maternity Home, Bangalore	KC General Hospital, Bangalore
	IRL Hyderabad		Broadway DMC, Bangalore	Bowring Hospital, Bangalore
			ESI Rajajinagar, Bangalore	Osmania General Hospital, Bangalore
			District Hospital, Hyderabad	District Hospital, Hyderabad
			Telangana State Government Chest Hospital, Hyderabad	
Delhi-Noida				
NITRD, Delhi	IRL Delhi		Employee State Insurance Hospital, Noida	Rajan Babu Institute of Pulmonary Medicine and TB, Delhi
			Rama Krishna Mission, Delhi	Safdarjung Hospital, Delhi
			Lok Nayak Chest Hospital, Delhi	Lok Nayak Chest Hospital, Delhi
			Jeewan Park, Delhi	Ambekdar District Hospital, Noida
			Goyla Dairy, Delhi	
			Kingsway Camp Center, Delhi	

Mumbai-Nagpur				
	IRL Nagpur	SRL Diagnostics (Private), Mumbai	GT Hospital, Mumbai	GT Hospital, Mumbai
		Hinduja Hospital (Private), Mumbai	Khar TB Clinic, Mumbai	GMC, Nagpur
		JJ Hospital, Mumbai	GMC, Nagpur	IGMC, Nagpur
			IGMC, Nagpur	
			Takalghat, Nagpur	
			Hingana, Nagpur	
Mathura-Agra-Lucknow				
JALMA, Agra	IRL Agra	Dr. Ram Manohar Lohia Institute of Medical Sciences, Lucknow	Health Visiting Training Centre (HTVC), Agra	DTC Mathura, Mathura
	IRL Lucknow		DTC Agra, Agra	DTC Rajender Nagar, Lucknow
			Peeli Phokar, Agra	
			Baraoli Aheer, Agra	
			DTC Mathura, Mathura	
			DMC Thakurganj TB Hospital, Lucknow	
			DTC Rajender Nagar, Lucknow	
			Lok Bandhu Raj Narayan Combined Hospital, Lucknow	

Bhubaneswar-Cuttack-Dhenkanal			
RMRC Bhubaneshwar	IRL Cuttack	RMRC ,Bhubaneswar KIMS, Bhubaneswar Capital Hospital, Bhubaneswar DTC, Cuttack DTC, Dhenkanal Sriramchandrapur, Dhenkanal Aanlabereni, Dhenkanal	RMRC, Bhubaneswar Pediatric College, Cuttack DTC, Dhenkanal
Guwahati-Nalbari-Goalpara-Kolkata			
	IRL Guwahati IRL Kolkata	DTC Nalbari, Assam Chamata, Assam Ghograpara, Assam Goalpara DTC, Assam Krishnai BPHC, Assam Duodhnoi, Assam DTC Tangra, Kolkata Maniktala, Kolkata RG Kar Medical College, Kolkata Baghbazaar, Kolkata	DTC Nalbari, Assam Goalpara DTC, Assam DTC Tangra, Kolkata RG Kar Medical College, Kolkata

Annex 5. Site Visit Summaries

Site Visit A: Chennai-Puducherry-Nellore

Team A (Chennai -Puducherry): Elisa Tagliani (Team lead), Wayne Van Gemert, N.S. Gomathi, Bhavin Vadera,
Team B (Chennai -Nellore): Maarten Van Cleef (Team lead), Sanjeev Saini, Umesh Alavadi

Key Findings

- Dedicated and motivated staff at all levels
- Diagnostic network is well structured with all facilities linked to a reference laboratory
- Diagnostic technologies are properly placed and most instruments were utilized at full capacity, *e.g.*, 12 tests per day per 4-module GeneXpert instrument.
- Good laboratory infrastructure and practices
- Good laboratory management (functional diagnostic supply chain)
- Significant challenges in terms of human resources (vacant posts take long to fill; reliance on FIND managed staff for key posts at NRL and IRL)
- Insufficient private sector engagement (*e.g.*, notifications fall short of state targets)
- Weak quality assurance: Insufficient OSE performed by NRL and IRL; weak system for monitoring of performance indicators for CBNAAT; poor performance of microscopy staff (STLS); unsystematic corrective actions at DMC level
- Limited/unmonitored access to CXR under the RNTCP which in turn reduces access of SM negative presumptive TB patients to CBNAAT testing
- Lack of public awareness of CBNAAT free testing at RNTCP sites
- Specimen referral systems are not always optimal causing delays in sample referral
- Some CBNAAT facilities are working at maximum of their capacity causing delays in testing and reporting

Recommendations

- Take emergency measures to ensure sustainability of FIND managed HR
- Build staffing capacity and ensure funding of NRL, IRLs and SLTS to fulfill mandate of EQA (OSE)
- Retrain IRLs in monitoring CBNAAT performance and emphasize need for corrective actions at all levels
- Procure and install more digital X-ray equipment and improve link with CXR facilities
- Improve public awareness of availability of CBNAAT at RNTCP sites including awareness and use by private sector practitioners
- Increase number of specimen collection centers, contract courier services and investigate a system using barcodes to better track specimens
- Extend the use of CBNAAT to additional facilities
- Expand private sector engagement using CBNAAT (only way to access to concessional prices) and engage also Ayush providers and pharmacists

Site Visit B: Karnataka (Bangalore) and Telangana (Hyderabad)

Team Bangalore: Sushil Pandey (Team Lead), Kameko Nichols, V. S. Salhotra, Lakshmi R, Almas Shamim

Key Findings

- Dedicated and motivated staff at all levels
- KPIs regularly collected and sent up to respective levels
- Specimen referral/transport systems were in place
- Specimen packaging was standardized and in use
- Infrastructure is in place to carry out respective diagnostic tests and space at NRL/IRL is more than adequate for expansion
- WRD available; culture and DST/LPA available at IRL/NRL
- State receives significant managerial/technical support and training from NTI and CTD
- Budget is available to implement diagnostic activities
- PPE are available
- OSE and EQA was conducted as required
- Biosafety: not adequate at all levels, i.e. no staff health check, autoclave not present in BSL-3, gowns taken home for laundering, no tailored biosafety manual for India (implementation gap of policy), no biosafety responsibility assigned to officer, lack of training targeted at biosafety, facility/equipment maintenance issues related to biosafety
- Data systems: LIMS system not yet in place at all levels, data quality checks and data security not in place
- Human resources: staff retention plan not available, issues with state disbursements of salaries
- Specimen referrals: lack of biosafety training for couriers, potential overburden of STLS/human carriers as testing is scaled up

Recommendations

- Implement annual health checks, maintain facilities/ equipment, assign health and safety responsibilities to officer, develop/implement/sensitize on lab-specific biosafety manual
- Develop and implement HR retention plan including regular salary payments
- Data quality and security procedures and policies should be strengthened/ implemented
- Implement LIMS system as soon as possible
- Centralize agreements (not payments) for specimen transport couriers at state-level for pricing advantages/transparency
- As testing scales up, consider transitioning from human carriers to couriers if possible

Team Hyderabad: Patricia Campbell (Team Lead), Sujatha Chandrasekran, P Kumar, Sunita Upadhyaya

Key Findings

- Workforce
  - Programmatic (state/ district)/ lab (IRL) staff all knowledgeable and actively analyze network patient data for improvement
  - STLS key for network functioning, oversight of activities, transport of specimens, and routinely conducted OSE visits
  - Insufficient human resources due to bifurcation of districts (IRL), STLS scope of work (district), LT rotations (CBNAAT/ DMC), and budget
- National Policy and Guidance
  - Case reporting to program consistently done at IRL/ CBNAAT/ DMC
  - Standardized algorithms, request/ report, and OSE forms always used
  - Reporting of performance/ quality indicators routinely completed
- TB Laboratory Budget
  - Sufficient to ensure a continuous supply of reagents and commodities
- Sample Packaging/ Transport
  - Excellent quality, and frequency, of sample packaging/ transport
- Private Sector Engagement
  - Strategies for private sector lab (referral strengthening) and NGO-supported lab (testing support) present with formal documentation (MOU)
- Coverage
  - Mapping of hard-to-reach and key populations and targeted interventions to improve case detection are ongoing at IRL
- Biosafety:
  - Lack of appropriate PPE at CBNAAT/ DMC level and certified equipment at all levels (all out of date)
  - Lack of health screening across all levels
- Data Management:
  - Performance and quality indicators (all levels) are not completely monitored, documented and followed-up
  - Patient data is not confidential/ secure
  - Unclear procedures, roles and responsibilities, and documentation for pre-diagnostic and diagnostic presumptive/ TB patient follow-up
- Quality:
  - QC of reagents not done/ not done according to national policy (IRL)
  - In-service training, competency testing, EQA supervisory visits, and EQA panels, and documentation review from NRL and IRL infrequent and lack coverage of the supervisory network(s)

Recommendations

- Increase advocacy for support (*e.g.*, salaries, continuity of service) for laboratory staff by RNTCP and state
- Decentralize STLS responsibilities to LTs (reagent QC, patient follow-up)
- Institute biosafety policy, designate biosafety officer responsibilities (IRL), train all staff of biosafety practices and importance of equipment certification, and introduce annual health screenings for all lab and programmatic TB staff
- Urgently re-establish supervisory visits and EQA visit analysis (NRL/ IRL)
- Re-introduce QC/ QA practices for all tests (all levels) according to national guidelines
- Implement daily SSM QC for low-volume DMCs
- Revise documentation to improve quality monitoring, introduce referral register and SOPs for patient monitoring and follow-up
- Secure patient data
- Routinely monitor indicators from reporting sites and follow-up on unexpected results
- Project supplies needs to ensure sufficient supply of CBNAAT reagents to support IRL network as CBNAAT testing increases

Site Visit C. Delhi and Noida

Team: Anh Innes (Team Lead), Amy Piatek, Sundari Mase, Rohit Sarin, Urvashi Singh, M. Hanif, Jyoti Jaju, Shanoo Mishra

Key Findings

- Staffing/HR
  - Dedicated and motivated staff at all levels, ready and willing to take on strengthening diagnostic network to reach NSP goals
  - HR challenges –vacant positions
  - Staff training needed, e.g. STLS, LT, biosafety
- Supervision:
  - On-site evaluations were mostly conducted according to RNTCP guidelines; reports normally not kept on site
  - KPIs are regularly collected and reported as per RNTCP guidelines
- Diagnostic algorithm: discordant results (smear versus CBNAAT) inconsistently handled
- Procurement: Supply chain management for diagnostics generally working well
- DMCs with low volume of smear microscopy
- Specimen transportation not being done: patients or family members transporting specimens
- Sub-optimal biosafety practices in some sites at DMC and PHI level (e.g. waste management)
- Health care worker screening not standardized
- Data management challenges
  - Data security, confidentiality (e.g. use of WhatsApp), connectivity
- Private sector
  - Some examples of sensitization of private sector practitioners but limited engagement

Recommendations

- Improve efficiencies of diagnostic network
  - Consider specimen transportation to decrease burden on patients
  - Assess microscopy volume at DMCs
- Improve data management
  - Address data security and confidentiality
  - Automate referral tracking to ensure no patients lost in the pathway
- Biosafety and infection control
  - Improve waste management and infection control capacity and infrastructure
  - Standardize health care worker screening
- Training and supervision:
  - Evaluate training needs and adjust strategy: increase refresher trainings, etc.
  - Keep reports for supervisory visits on site to facilitate learning

Site Visit D: Maharashtra

Team: Martina Casenghi (Team Lead), Sarabjit Chadha, Sunil D Khaparde, Camilla Rodrigues, Nerges Mistry, Ameeta Joshi, Amit Koregaonkar

Key Findings (Mumbai)

- Diagnostic Network well laid out
- Functional C&DST labs and referral structure
- Sample transportation well organized
- Functional integration of academics and private laboratories
- Inadequate supervision by NRL and IRL
- Lower level facilities (DMC and CBNAAT) sites characterized by:
  - Poor availability of well trained and proficient personnel
  - Inadequate infection control and biosafety measures (including waste management)
  - Registers and records poorly maintained (lack of sample referral log, incomplete registers)
  - Challenging to monitor implementation of diagnostic algorithm. Follow-up for smear-negative patients does not always follow algorithm
  - Weak processes for transmission of results from the laboratory to the facilities, clinicians and to patients
  - Uncertainty as to whether EQA is accurately implemented because of a high consistency of 100% scores
  - Data management primarily paper-based
  - Data routinely collected but not analyzed to improve quality and performance
  - Patient confidentiality and data security not ensured (i.e., use of WhatsApp)

Key Findings (NAGPUR)

- Challenges observed in Mumbai also observed in Nagpur
- Structure of TB diagnostic network not clearly communicated to all lower level facilities
- Referral linkages unclear for some sites
- Weak referral system in place - Courier system not implemented, sample transportation relies heavily on "human couriers" (*i.e.*, attendants, patients, staff)
- IRL facing serious infrastructure limitations (such as lack of generator) and technical challenges (high rate of contamination)
- IRL heavily reliant on FIND supported staff
- Weak implementation of diagnostic algorithms (inconsistent access to CBNAAT for HIV+ patients; outdated DST panels)
- Procurement gaps: GX cartridges stock-outs in May 2017

Recommendations

- Laboratory capacity needs to be scaled up to accommodate the implementation of the new diagnostic algorithm
- Clearly communicate the referral process and test availability to all facilities in the network
- Implement use of electronic solutions and simultaneous communication of results to patients and clinicians
- Address infrastructure, technical and HR issues observed at IRL Nagpur
- Verify quality of EQA implementation
- Expand scope of supervisory visits beyond technical aspects to include review of performance indicators, record keeping, etc.
- Revise training programs and include on the job-training, regular competency assessment, regular mentorship and supervision
- Implementation of sample referral log, transport log. Update and optimize registers to reflect currently recommended algorithm (Xpert column; CXR column)
- Implement data analysis and regular M&E to identify gaps
- Biosafety and waste management should be assessed as part of supervisory visits
- Regular health examination of all contractual laboratory staff

Site Visit E: Uttar Pradesh

Team Agra: Heidi Albert (Team Lead), Christiaan Mulder, Avi Bansal, Himanshu Jha
Team Lucknow: C. N. Paramasivan (Team Lead), Kenneth Castro, Jyoti Arora, Yogesh Patel

Key findings

- Dedicated and motivated staff at all levels
- Supply chain management for diagnostics generally working well
- Good infrastructure and practices at both IRLs; IRL Lucknow in preparation for NABL accreditation
- CBNAAT is not being fully utilized for key populations (PLHIV, paediatrics and EPTB)
- Under-utilization of CBNAAT at some sites (DMCs) and over-utilization at others, leading to delay in turnaround time (IRLs)
- Gap in referral of CBNAAT RIF resistant patients for SL DST
- Gaps in district coverage of SL DST
- Limited collaborations with private sector labs or clinicians
- Effective linkages between labs, patients, clinicians & programme were not always present
- Inadequate infrastructure and biosafety practices in some sites at DMC and PHI level (e.g. waste management, HCW screening)
- HR challenges – staff not regularly paid, vacant positions, staff turnover, insufficient staff for EQA, need for training
- Non-availability of funds at some sites
- OSE and RBRC conducted according to RNTCP guidelines at district level, although gaps in coverage (not all participating laboratories received a supervisory visit at least once a year); however, no errors identified by RBRC under IRL Agra and repeated recommendations remain to be implemented
- KPIs are regularly collected and reported to higher level
- Data management – data security, confidentiality, gaps and delays in Nikshay entry and predominantly paper-based system, many systems used for sending reports
- Incomplete coverage of supportive supervision by IRLs
- Delays experienced in extended DST reporting, SL-LPA PT and lack of OSE visits by NRL
- NRL needs to build internal capacity to take on supervision of 8 existing C/DST labs and 3 new labs utilizing committed funds
- NRL lacks data management unit to support state functions and infrastructure for LPA testing is pending
- The reports of patients for C&DST are inordinately delayed at times.

Recommendations

- Implement out-sourcing of waste management, screening of staff, PPE and improved infection control in facilities
- Resolve outstanding HR challenges with responsible authorities
- Review and strengthen RBRC implementation, deploy electronic data systems
- Emphasize analysis of KPI, RBRC and OSE data and use for corrective action; retrain supervisory staff
- The NRL needs to be in a pro-active role in ensuring laboratory services in its assigned states which are adequate, efficacious and quality assured.
- Sensitize public and private sector clinicians on availability of CBNAAT and key populations eligible for testing
- Ensure adequate testing capacity according to testing demand
- Establish procedures and monitor referral for SL DST
- The NRL should maintain respectable timelines in reporting of results on patients investigations
- Consider alternative mechanisms to engage private sector and develop evidence-based guidelines on district level activities for PPM and monitoring
- Conduct sensitization of clinicians in public and private sector
- Support NRL to build internal capacity for supervisory role, consider mentoring plan or twinning with another NRL
- Leverage Nikshay and planned connectivity of CBNAAT for improved programme management; ensure sufficient, trained staff for data analysis and use. Provide guidelines and training of data security and confidentiality

Site Visit F: Odisha

Team: Thomas Shinnick (Team Lead), Chris Macek, Imran Syed, Dasarathi Das, Shailaja Humnabadkar, Amit Sahu

Key Findings

- The program actively reaches out to private practitioners to get samples submitted and patients reported
- Dedicated and motivated staff at all levels and all staff are well aware of the new diagnostic algorithm
- Test turnaround times were excellent; rapid reporting via email
- Moving towards universal DST for all smear-positive patients and considering CBNAAT for all clinically diagnosed patients
- Laboratories report patients to DTO who follows up to ensure initiation of treatment
- OSE and RBRC were conducted according to RNTCP guidelines
- Procurement system for diagnostics generally working well
- Waste disposal according to national guidelines
- Efficient specimen transport via "human carriers'
- Staffing levels are inadequate – need additional staff for supervisory activities
- Additional funding is needed at the NRL and IRL
- Supervisory visits from IRL are infrequent – once every 2 to 3 years. IRL visited 6 of 21 DTCs this year
- Nikshay is rarely used and there is no electronic LIMS
- Many Xpert instruments are underutilized (<50 per month), a few are over-subscribed (30 samples a day). Typically, only 12 or 16 samples can be tested per day.
- Currently very few smear-negative, 'high suspicion; presumptive TB pts are tested with CBNAAT
- Specimen carriers are minimally trained in safety issues; triple packaging is not always used, especially if distance is short
- Pick up is scheduled for once a week at DMCs - turnaround times from detecting a patient to getting the results may be up to 7 to 9 days

Recommendations

- Provide sufficient funding and staff for supervisory visits. Prioritize supervisory activities
- Optimize placement of instruments and specimen transport systems
- Expand testing to all priority groups – AFB smear-negative, high suspicion of TB
- Increase specimen pick up to twice a week if funding permits
- Ensure that all staff involved in specimen transport well trained
- Ensure that all samples are properly packaged
- Ensure use of Nikshay for all patient registration and lab results
- Deploy diagnostics connectivity to CBNAAT instruments
- Develop clear guidelines on data security and backup; training and SOP on confidentiality

Site Visit G: Assam and West Bengal

Team: Daniel Orozco (Team lead), Manoj Toshniwal, Prabha Desikan, Nishant Kumar, Lalit Mehandru

Key findings (Assam)

- Dedicated and motivated staff at all levels, ready and willing to take on strengthening diagnostic network to reach NSP goals
- Good lab infrastructure at IRL, DMC and CBNAAT sites
- KPIs are regularly collected and reported as per RNTCP guidelines
- Some private labs are identified but program needs to include them in the system
- IRL is partially functioning, only CBNAAT testing currently performed
- Being a Bedaquiline testing site, continued funding to avoid interruption is needed
- Challenges with hard to reach communities: river islands, harsh geography, long distances, tribal areas
- High risk of flooding in Assam. No contingency plan available
- Staff training needed: Data and lab management
- No formal health screening for staff, but access to medical care if needed
- Salary structure is a challenge for retention, Staff is paid different depending on the source of their salary (FIND/Government/Program)
- Delays in salaries for lab staff (happening regularly over last year)
- Staff are uncertain of their job security as it is not clear if funding is continued

Recommendations (Assam)

- Urgently allocate funding for IRL Guwahati to restart its routine operations beyond CBNAAT
- Develop contingency plan to keep facilities operating or referral to other testing sites in case of flooding
- Improving staff retention through timely salary payments, motivation through trainings and continued mentorship
- EQA: In-depth review of RBRC programme, simplify Training: Lab and clinical training to be strengthened and scaled up (specially for lower levels)
- Create hubs of excellence as a pilot in one region (e.g. decrease number of DMCs, improve referral to hubs with increased CBNAAT capacity)
- Scale up work through mobile clinics for hard to reach communities
- Innovation for improving referral (i.e. pilot use of drones for specimen referral)

Key findings (West Bengal)

- Dedicated and motivated staff at all levels
- Great work to serve all the population, in spite of the very high workload. Staff (lab and managers) very motivated. Few vacancies remain to be filled at IRL
- KPIs are regularly collected and reported as per RNTCP guidelines
- 2 private labs and several NGO sector labs participating in the TB network of labs
- Infrastructure at sites visited seemed limited, overcrowded, difficult for infection control
- Improvements needed on biosafety across sites (IRL, CBNAAT, DMCs)
- High volume of data collected in forms and registers limiting workforce capacity
- Challenges with hard to reach communities: long distances, tribal areas
- No formal health screening for staff, but access to medical care if needed
- No consistent system for service/maintenance of equipment: Microscopes by Union, Culture/DST equipment by FIND, Other equipment by Program

Recommendations (West Bengal)

- Top priority: improve biosafety across sites, implement guidelines
- Improve infection control in some overcrowded facilities (Ventilation)
- Streamline reporting and recording to decrease workload by lab and clinical staff
- Need consistent implementation of service/maintenance agreements for core equipment, and phasing-out/ and disposing obsolete equipment
- Scale up work through mobile clinics for hard to reach communities
- Improving staff retention through timely salary payments, motivation through trainings and continued mentorship
- EQA: In-depth review of RBRC programme, simplify
- Training: Lab and clinical training to be strengthened and scaled up (specially for lower levels)

Annex 6. Summaries of Consultations

Consultation with Clinicians

Summary of Discussion

- Private sector is often the first entry point for patients with presumptive TB. Thus, it is critical to engage private practitioners and highlight the importance of laboratory-based diagnosis
- In general, there is an over-reliance on CXR by private practitioners
  - CXR can be a useful screening test or aid to diagnosis and it is useful to have it included as one of the initial steps in the diagnostic algorithm;
  - However, it is important to follow-up CXR with laboratory-based testing
- Some pilots have been done to link private practitioners with the TB diagnostic network, but much more needs to be done. Challenges include:
  - Sensitization and training of private practitioners on importance of laboratory-based diagnosis and RNCTP recommended diagnostic tests and algorithm
  - Strengthening the mechanisms for notification
- From a clinicians perspective, an ideal TB diagnostic network would include a sensitive POC TB diagnostic test (more sensitive than SSM)
  - CBNAAT replacing microscopy is perceived to be a challenge because of the cost, number of machines required, and maintenance
- While most TB patients can be managed based on CBNAAT and LPA results, there are some high risk patients for whom it is key to have access to phenotypic C&DST because of
  - Sensitivity of molecular tests for drug resistance is slightly lower than phenotypic C&DST (thus some resistant cases might be missed by LPA)
  - Need for extended DST that is not available through molecular tests
- Often DMCs do not function optimally. Some DMCs are characterized by low workload which makes difficult to maintain proficiency
- The possibility to reduce the frequency of DMCs (*i.e.*, from 1/100,000 population to 1/200,000 population) and to establish sample collection points was raised for consideration. However the following limitations were highlighted during the discussion:
  - A strong and efficient sample referral and sample transportation network is key in order for this structure to be functional and effective. Otherwise the risk is to decrease access to laboratory services
  - India is moving towards a public health diagnostic network and DMCs will serve different disease areas (i.e., Malaria, TB, etc.). Thus, structure and workload of current DMC network and facilities needs to be considered in light of this upcoming changes

Recommendations

- One strategy to consider is to increase access to CBNAAT testing for private sector. This can increase the likelihood of proper and accurate diagnosis. Consider mechanisms to subsidize costs to improve access of the private sector to CBNAAT
- Consider electronic solutions to strengthen linkages within the diagnostic network and linkages to care
- Reduction of DMC sites or transformation of current DMCs in sputum collection corners needs to take in strong consideration the two issues highlighted above to avoid possible negative consequences to access to healthcare services
- To improve bacteriological confirmation of TB
  - Need to implement monitoring and supervision to ensure clinicians to use and follow recommended diagnostic algorithm
  - Need to improve and train clinicians on patients selection criteria to more effectively identify patients for whom is critical to pursue lab-based diagnosis
  - Need to provide training to both patients and health care provider on diagnostic tests and importance of laboratory- based diagnosis

Consultation with Patient Advocates

Participants: Blessina Kumar; Hari Shankar Singh, The Delhi Network of Positive People (DNP+); Asha, The Delhi Network of Positive People (DNP+) and team members (Martina Casenghi, Marteen van Cleef, and Kenneth Castro)

Summary of Discussion

- Time to TB diagnosis is the biggest challenge perceived by patients. In one study (Kumar *et al*), the time to TB diagnosis ranged from 3 months up to 2 years
  - The main reasons for the long delays in diagnosis include that private practitioners often have a low suspicion of TB and TB tests are rarely prescribed as part of first round of investigation
- Once TB diagnosis is confirmed, linkage to care generally works
- In Delhi, HIV positive patients do have good access to Xpert as initial test and Xpert results are generally available after 3 days (DNP+ experience)
- Communication between laboratory personnel and patients is poor
- HCWs working on TB services in the public sector lack the skills and time to do proper patients counselling in contrary to HIV staff).

Recommendations

- Laboratory personnel should be trained to manage communication with patients
- Counselling of TB patients is very important to attract patients and keep them in the diagnostic and treatment pathway. Training is counselling should be emphasized

Consultation with Partners

Summary of consultation meeting with partners:

- Presence of the diagnostic network across the country with roll out of the rapid diagnostics is one of the biggest strength in the program. Availability of mix of technologies in the C&DST laboratories is benefitting the patients.
- Program through FIND has successfully coordinated with support of external donors for establishment of ~46 C&DST laboratories in previous project and additional 15 laboratories in ongoing project, provision of the equipment, laboratory consumables for Liquid C&DST and LPA, human resource (~360) in these laboratories and other support. The laboratory capacity has been enhanced with provisions of additional GT blots, MGIT machines (~26). FIND is facilitating for NABL accreditation in addition to program certifications. Implementation of the Laboratory information management system will reduce paper based reporting and its linkage with Nikshaya / eNikshaya will enhance reporting promptness benefitting the provider and patient. Next grant envisaged upgrading and establishing additional 20 laboratories in addition to sustenance support to existing 61 laboratories for laboratory consumables, AMC, HR with a component of transitioning the support.
- Simultaneous implementation of ambitious scale up and transition strategy for sustenance of the diagnostic network is a big challenge. Transition might impact scale up and hence to be planned in cautious manner. A detailed and phase wise transition plan is required. Well performing laboratories with adequate capacity needs to be prioritized for transition and then other laboratories can be adequately prepared for transition. Procurement of the proprietary items to get transitioned initially and other laboratory consumables and AMC of non-proprietary items / equipment can be done later.
- National level training for laboratory biosafety was conducted and continuity of such activity with handholding and repeated monitoring visits can enable to keep the laboratory staff in bio-safe environment and preventing acquiring infections among laboratory staff.
- Program has expanded the reach of GeneXpert through the support from external donor funding and needs to now focus on further expanding it and consolidating the gains with continuity of the support from the domestic budgets.
- Program is fully integrated with the general health system. All the Community Health Centres hospitals are expected to be DMC with CXR facility. This can further be re-emphasized for extended support with NHM.
- Health system strengthening initiatives are required for infrastructure development and availability of the chest X-ray to accommodate 28 million presumptive TB patients. NHM investments with state level interventions can further improve the access for diagnostics.
- Bedaquiline has been introduced by program under Conditional Access Program and has been timely supported by diagnostic network ensuring availability of the SLDST through the LPA and LC laboratories from the program and partners supported for the Pharmacovigilance, provision of ECG machines and facilitating treatment initiation.

- Increase in the laboratory workload with extended DST and expansion of the SLDST needs to be supported with provision of additional equipment to augment the capacity and need based human resource to manage the additional workload. Increasing the number of laboratories will also improve access as well as release the lab capacity for accommodating the 2nd line and extended DST for the existing laboratories.
- C&DST laboratory maintenance and proper functioning of equipment and AHU remains a challenge. Hard to reach areas like north-east states (e.g. Guwahati) poses additional challenge. Power fluctuations affecting the sensitive equipment result in requirement of spare parts and frequent repairs. All these cause breakdown of the services of the laboratory. Adequate AMC support and plan for substituting the laboratory services with linking to other functional laboratory with additional capacity or to private laboratory was suggested as one of the solution. Network of the bio-medical engineers at regional / state level can help to face such challenges adequately.
- Bio-medical waste management: laboratories are expected to follow the detailed guidelines available under the program, but needs to be operationalized and monitored adequately.
- C&DST laboratories are being provided human resource through the GF project with FIND as sub-recipient of Central TB Division. Transition of the HR has been proposed from the next upcoming project from 1st Jan 2018. This transition might pose risk of losing the trained and skilled laboratory personnel in all these laboratories and this might adversely affect the diagnostic network. The partners expressed this big risk, which might affect the laboratory services and pose losses to the gains achieved in PMDT. Program expressed the need of continuity of these laboratories HR and is in discussions with the Ministry for retention of the laboratory HR.
- Partners are working in community mobilization through the volunteers for mapping of the high risk population, service need of the presumptive TB patients and coordinating to improve the access to diagnostics. Challenges in access were expressed specially for the rural areas, sputum / specimen transportation, equipment maintenance, laboratory supplies, cartridge supplies and availability of the HR in the laboratories. Challenges were expressed on low use of quality diagnostics in the private sector. Adequate support is required for the existing projects to be transitioned to the program to continue and expand the gains achieved by the project. Access needs to be targeted through the PPM initiatives, field staff coordination for specimen transport and extending the project periods by the donors.
- Advocacy and projects for improving the utilization of the quality rapid diagnostics by the program have demonstrated that the CBNAAT laboratory capacity is getting stretched. Cartridges supplies have been adequately managed by the program/project, but access (in time) has remained a problem not only for the public sector but also for the private sector. Additional support for associated functions e.g. printing of the reports, other lab supplies needs to be provided. Local solutions need to be explored to resolve these critical issues.

- Active Case Finding initiatives are being implemented in 300 districts by the project through a partner. Utilization of the rapid diagnostic test through the program in such initiative has remained a challenge in spite of exponential increase of its use. Lot of opportunity cost invested in volunteers and specimen transportation does not get transmitted into gains if rapid diagnostics are not offered due to challenges in the policy interpretation and implementation, and non-availability of lab HR to accommodate additional workload. Monitoring of the policy implementation and upfront testing with rapid diagnostics for all TB risk groups can help in achieving the NSP targets.
- Program is advising 2 sputum smear microscopy, and use of CBNAAT for ACF have not been rolled out. The policy is being implemented in phase wise manner for operational reasons. The existing 628 machines remain insufficient to manage the load and based on preliminary analysis there will be requirement of 1400 machines. GF supported 500 machines in current year and additional 250 machines next year will augment the capacity to manage the workload. Review will be undertaken to roll out the plan. Simultaneously forty-five mobile vans with CBNAAT (GeneXpert) are in process of rolling out by end of the year.
- Amalgamation and aligning the policy on the use of the rapid diagnostics in public sector and private sector is required. Private sector intent to offer CBNAAT for all presumptive TB patients whereas it is a challenge to accommodate all the presumptive TB patients for this test in existing diagnostic network capacity. Program promotes universal DST for all diagnosed TB cases and for presumptive TB cases who are at risk.
- Advocacy is required for engaging the private sector laboratories, which are not yet the part of the program. Proactive involvement of the State National Health Mission can further enhance the reach of the network with involvement of the private sector laboratory linkages with program.
- Issue of laboratories offering non-WHO recommended tests for TB needs to be dealt with awareness among clinicians for prescribing appropriate tests for TB.
- Private sector involvement attempted since last two decades has not getting translated to value addition. More attempts of synergy and amalgamation are required and an effective interface can be a booster to link it.
- The IPAQT project has performed around 200,000 tests. Engagement through the IPAQT laboratories can augment the capacity. Providers are interested and uptake of the CBNAAT in private sector has increased. Sensitization programs to improve awareness on available technologies for quality diagnosis to the providers can further improve the uptake. The demand has been increasing, especially in tier-2 cities with engagement of smaller laboratories. The linkages with IPAQT platform can improve availability of the test for quality diagnosis and can suffice the demand to some extent but will not suffice the program needs.
- Projects are targeting the private sector behavior change for use of quality diagnostics, augmented with the community engagement to link the eligible patients to the laboratories and specimen transportation. This fills the program gaps. Challenge remains for the use of the private sector CBNAAT due to cost. This can be mitigated with provision of the cartridges through the program to reduce the costs in private sector.
- Quality assurance protocol for the GeneXpert / CBNAAT has been planned through the TB Reach Wave 5 project. The EQA mechanisms for the private sector laboratories are being explored through the stakeholder workshop.

- Issues of pre-treatment evaluation and other ancillary tests for case holding and case management was raised and mechanisms needs to be explored for the same.
- The policy of use of rapid diagnostics is not at the same level of implementation across the country; differential implementation is required in different parts of the country. The differential approaches are required to reach the National Strategic Plan targets. State specific understanding of the NSP and resources is required and CTD can lead this to make State specific operational plans. This can enable to reach the NSP targets. Partners working in various states can provide crucial inputs (state specific) based on the local issues and can help to mitigate the challenges faced in the states.
- The ambitious NSP can be implemented through the different partners in public sector as well as private sector. Partner's collaboration is excellent, but few gaps required to be filled. Continuous dialogue for good collaboration is required as some of the policies are not fully conversant by partners.
- NSP is aspirational plan but not yet fully implemented. Plan is being implemented as the resources are available; Program has plan to have incentives in place to cover wage loss, nutrition and other expenses incurred to mitigate catastrophic costs; once approval is there, all patients will get the incentive. Innovations can be shared from local experience and provide guidance to the program for scale up of specific solutions in other geography where it is needed.
- CTD's plan to reach the last patient irrespective of private or public sector requires augmenting and meeting the diagnostic needs supplemented with adequate resources. Policy landscape and state specific operational plans need to be considered as implementation capacity varies across the country.

Consultation with NRLs

Summary of Discussion

- Systems, algorithms, protocol and guidelines for program TB diagnostic network with tired structure are in place by and large. However there are gaps in implementation due to challenges with human resource, limited trainings & monitoring and funding.
- There is an urgent need to relook and strengthen External Quality Assurance mechanism for the TB diagnostics at all level starting from microcopy to rapid molecular test and culture & drug-susceptibility testing.
- New diagnostic algorithm has been well discussed with numerous bodies/ personnel and is appropriately designed for efficient implementation.
- TB Diagnostic network need to focus on patient centered care and comprehensive patient care cascade.
- Lack of community/ patient awareness of free public sector diagnostic services (even among the educated portion of the population) and stigma (impacts prevention and diagnostic identification of patients) are the key barriers for access to TB diagnostics.
- Decentralized diagnostics are essential for patient access to care - incorporation of technologies, as Truenat in diagnostic algorithm should facilitate access to rapid TB diagnostics.
- HR vacancies and timely availability of funds are the key constraints for adequate provision of services and supervision for quality assurance.
- Assessment of NRL capacity is required in order to determine the number of NRLs needed to optimally support the network.
- Program should develop a plan for establishment of new NRLs and IRLs and their linkages.
- There should be a plan with allocated resources to strengthen NRLs capacity before considering establishment of new NRLs.
- Lessons learned from recent NRL establishment (2 new labs) should be taken into consideration to inform any future efforts for designating existing lab/s as NRL.
- Coordination among NRLs and NRL/IRL needs strengthening (frequency, types of communication, etc.)
- NRL supervision of IRLs is recommendation-based, while IRLs report to, and are regulated by respective states. National level laboratory tiered structure is not empowered to support/ enforce recommendations between supervisory levels.
- Mechanism for private sector engagement is currently not explicitly defined; generating awareness, building trust, developing co-ownerships and direct/indirect incentives appear to be the cornerstone of any strategy.
- NRLs can potentially contribute in engagement of private sector laboratories.
- Quality assurance of TB diagnostics is equally essential for private sector laboratories.
- There is a urgent requirement for staff need assessment based on volume of tests (current and projected) required to be taken care by a facility and such staff planning required to be appropriately supported with resources.

- NRLs are concerned about biosafety both at NRLs and at lower levels of the network. Biosafety checklist used during the supervisory visits, but practical implementation/ follow-up of gaps is challenging due to lack of administrative authority over IRLs. HCW biosafety challenges are greater and could be the focus (more than labs).
- Engagement of corporate sector to help supplement resources should be considered as an option.
- State-level procurement of laboratory reagent & chemicals will be very challenging without NRL oversight.

Recommendations

- Timely availability of funds and resources to NRLs and IRLs is extremely critical and required to be ensured for effective implementation of policies and guidelines.
- Vacancies should be filled as soon as possible to address HR constraints to ensure regular supervision.
- Administrative challenges for implementation of recommendations of supervisory visits required to be addressed.
- Operational plan for NRLs in view of NSP should be developed which should include resource allocated coordination mechanisms between and within tiered lab network and respective administrative bodies.
- Currently available NRLs and IRLs should be strengthened before proceeding for establishment of other NRLs/IRLs.
- Staff retention plan for HR working in labs including insurance to be formulated.
- Mechanism need to be established for getting patient feedback from end-user perspective
- NRL should prepare and follow the annual plan for supervisory visits and follow-up.

Ministry of Health and Family Welfare
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