



ASSESSMENT OF TB DIAGNOSTIC NETWORKS: A NEW TOOL

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TB Diagnostic Network Assessment Tool

Why do we need such a tool? How did we get here?

How can we prioritize network strengthening interventions that will make a difference?

When/why did the shift to thinking about “diagnostic” networks start?

Very soon after first introduction of Xpert into a few high burden countries:

The initial attitude around implementation from high-level policy/strategic experts and other stakeholders downplayed potential complexities:

- “Once policy reform is done, implementation of the Xpert technology does not require major TA effort or cost.”
- “...current experience suggests that no more than 20% of the initial implementation cost (including hardware, software, staff cost, specimen referral, contingencies), should be sufficient to address the TA needs.”
- “Xpert is so simple that I could teach my mother in one day to run the test.”
- “All we need to do is get the instruments in country – it will be easy for countries to introduce and scale-up”.
- “We’re buying instruments but have no budget for TA – can we use your partners if there are any problems?”

Why the shift?

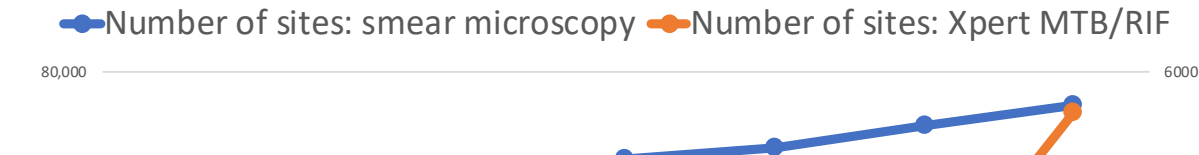
Several studies show that Xpert is not the magic bullet...

- Theron Lancet 2014: Conclusion: “However, the benefits (of Xpert testing) did not translate into lower tuberculosis-related morbidity, partly because of high levels of empirical-evidence-based treatment in smear-negative patients.”
- Churchyard Lancet Global Health, 2015: Conclusion: “Xpert did not reduce mortality at 6 months compared with sputum microscopy. Improving outcomes in drug-sensitive tuberculosis programmes might require not only better diagnostic tests but also better linkage to care.”

Initial testing algorithms restricting to “high risk” populations resulting in slow uptake, low utilization of instruments

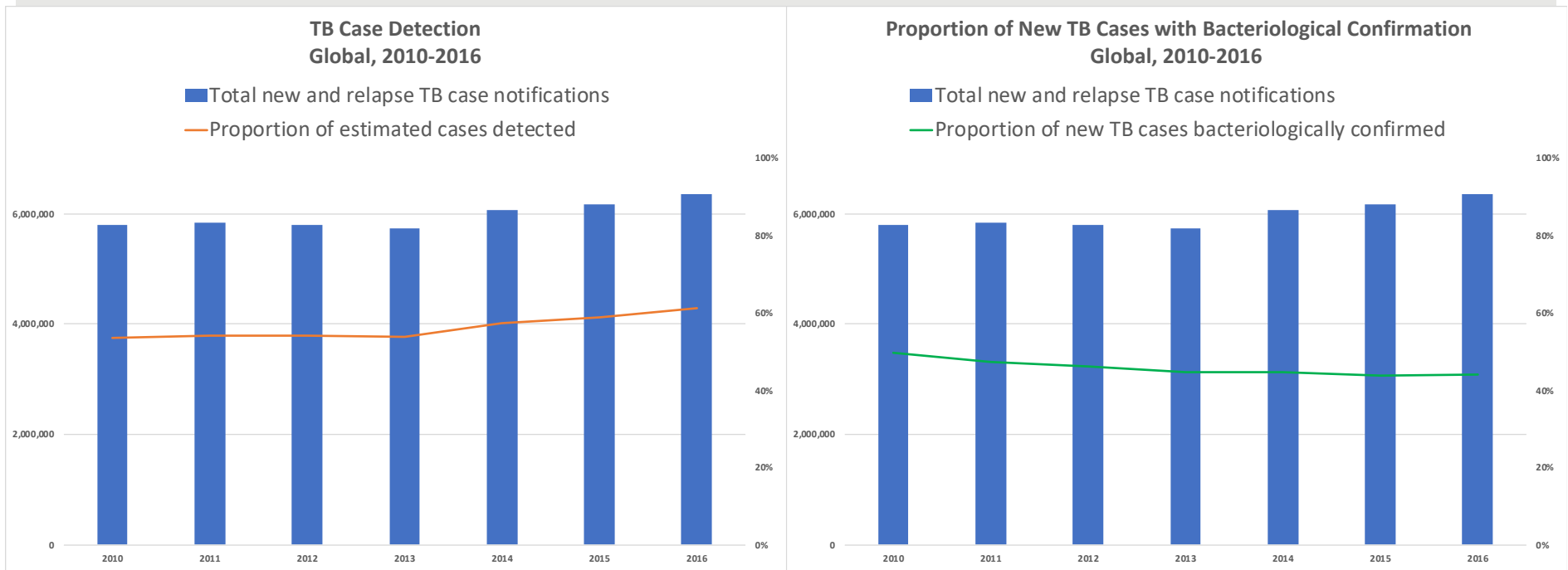
Seeing “unimpressive” results – EXCEPT in the time to diagnosing DR-TB

Number of Sites with Smear Microscopy or Xpert MTB/RIF



- UNITAID EXPAND TB Project (2009-2013) - \$87m to increase MDR-TB detection capacity in 27 countries
- South Africa national policy for upfront Xpert testing for all patients (2011), with other countries slowing following
- Introduction of Xpert MTB/RIF with demonstration and scale-up supported by many external donors (2011 -)
- Xpert MTB/RIF cartridge “buy down” (2012)
- Number of WHO policies and GLI implementation guidance around diagnostics- with uptake by countries
- Increased Global Fund grants supporting MDR-TB diagnosis and treatment





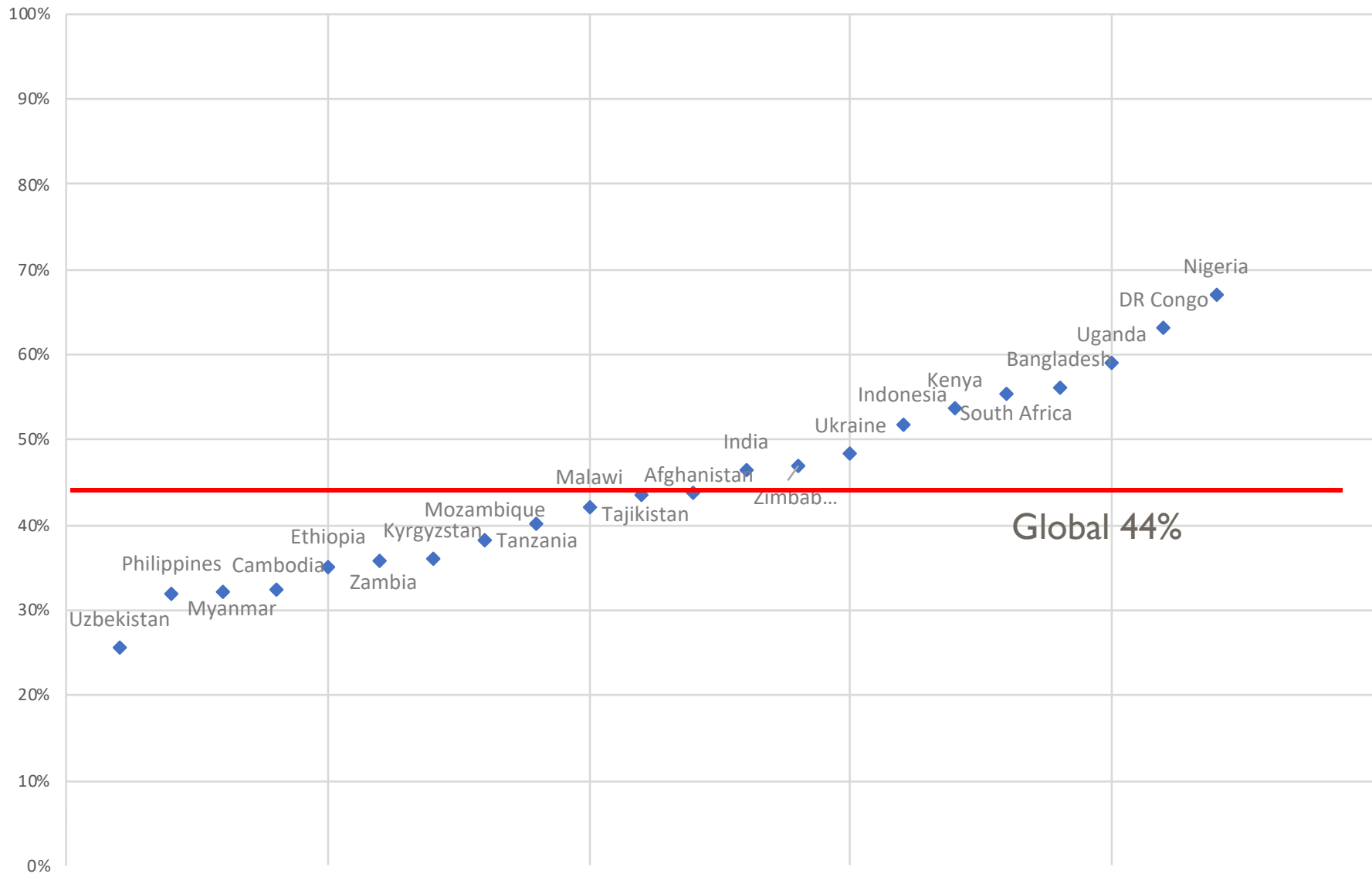
2010– 2016

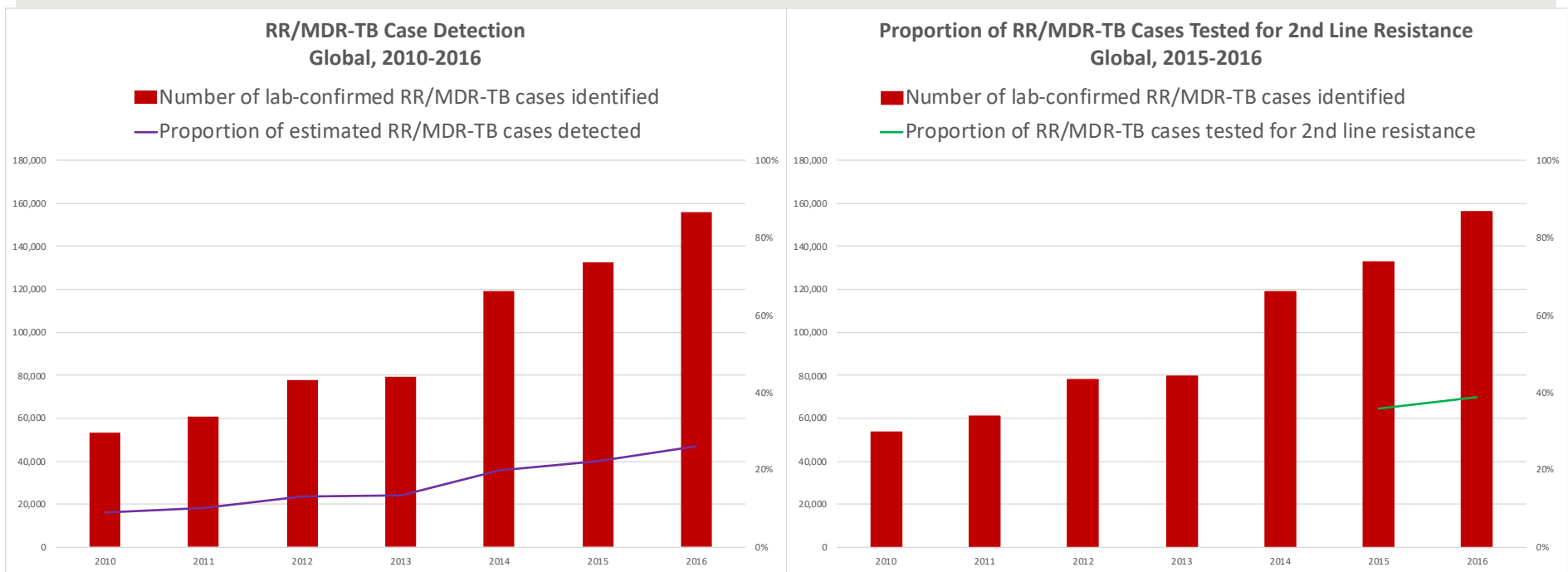
- Overall detection of new TB cases increased from 5.8 m to 6.4 m
- Proportion of estimated TB cases detected increased from 53% to 61%

BUT

- Proportion of new TB cases bacteriologically confirmed decreased from 50% to 44%

PROPORTION OF NEW TB CASES BACTERIOLOGICALLY CONFIRMED 2016

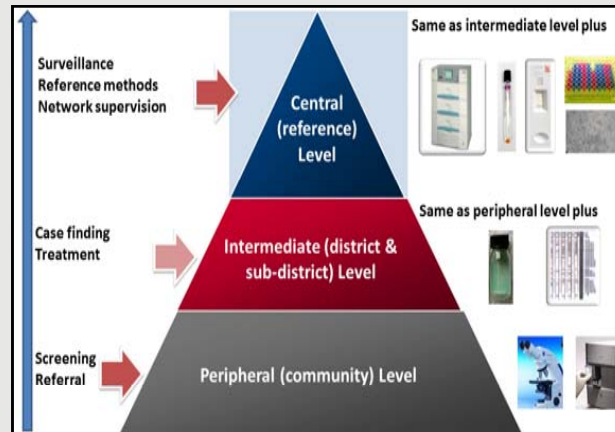




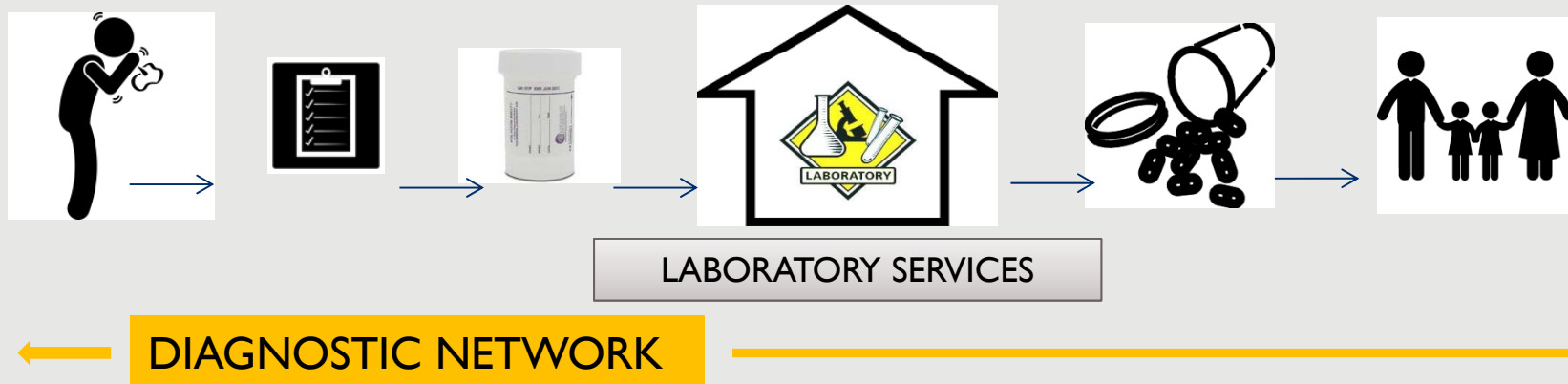
2010– 2016

- Overall detection of RR/MDR-TB cases increased from 53k to 156k
- Proportion of estimated TB cases detected increased from 9% to 26%
- Proportion of RR/MDR-TB cases tested for 2nd line resistance remains slightly below 40%

Transitioning from “tiered” laboratory services...



...to a comprehensive, person-centered diagnostic cascade



How did we define the diagnostic cascade, determine which components are critical?

Learning from introduction of Xpert in countries:

- Xperts were scattered around a country without an informed plan
- Data on placement, performance or clinical management was non-existent or very difficult to obtain
 - What was the time from sputum collection to test, test to result and result to treatment initiation?
 - Were modules failing? Were instruments working optimally? How were countries forecasting?
- Clinicians and non-laboratory staff were not included in trainings or sensitized; private providers and labs were not included and had no access
- There were no quality or proficiency plans around testing
- Instruments were not POC and sometimes not even “near” POC
 - ”Xpert” is not a case-finding strategy
 - No specimen transport or referral system planned or in place
- The “promise” of “fast followers” went unrealized

Assessment tool - background

There are many tools available to evaluate individual components of a laboratory system or diagnostic network; however, no one comprehensive tool available to assess complex TB diagnostic networks

- To meet this need, a tool was developed that incorporates the approach of the ASLM/APHL LABNET scorecard and the laboratory core capacity described in the International Health Regulations with TB-specific components from GLI and other internationally-recommended guidance.

The tool was:

- Influenced by checklists and questionnaires that were adapted or newly developed for use in a Nigeria TB Diagnostic Network Assessment in March 2016
- Further refined during a recent assessment of India's TB diagnostic network (November 2017)

What the tool is:	What the tool is not:
<ul style="list-style-type: none"> ✓ Will 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 	<ul style="list-style-type: none"> ✗ A way to impose new algorithms, policies, recommendations onto countries blindly
<ul style="list-style-type: none"> ✓ Structured to use semi-quantitative scoring to identify the “capability” stage of various aspects of the network 	<ul style="list-style-type: none"> ✗ A way to find fault or blame within a country's network or program
<ul style="list-style-type: none"> ✓ A means to help identify areas for improvement 	<ul style="list-style-type: none"> ✗ A scorecard to compare networks among different programs
<ul style="list-style-type: none"> ✓ Usable to monitor performance of national TB diagnostic networks and systems over time 	<ul style="list-style-type: none"> ✗ A way to provide a list of non-specific recommendations
<ul style="list-style-type: none"> ✓ Country-led and owned 	<ul style="list-style-type: none"> ✗ A means to conduct routine supervision at various levels or assess individual facility-level services ✗ Meant to be used <u>only</u> for large, international assessments

— TB NETWORK ASSESSMENT TOOL

— THE PROCESS



I – Standards, capacities and components

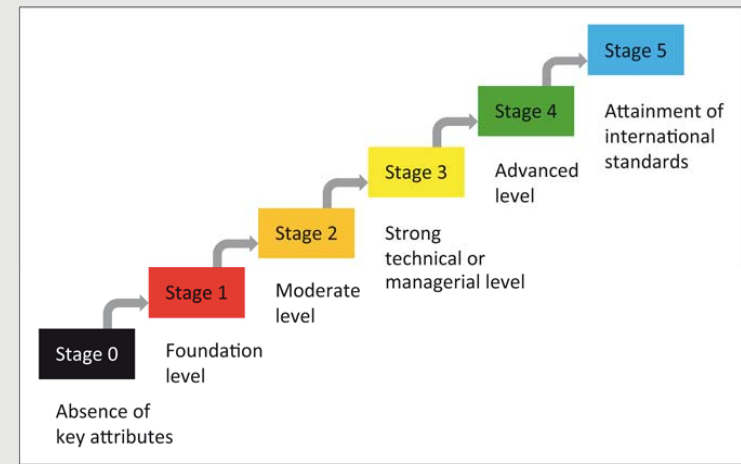
	Standard	Core Capacity	Components
1	The country has a fully endorsed political, legal and regulatory framework in place which supports the achievement of the NSP and that organizes and controls all public and private diagnostic services to support the NSP, with sufficient dedicated funding available.	Political, legal, regulatory and financial framework	<ul style="list-style-type: none"> - 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.	Structure and organization of the diagnostic network	<ul style="list-style-type: none"> - Diagnostic Network - Coordination and management - Programmatic and operational research
3	The national TB diagnostic network provides complete coverage and universal access to TB diagnostic services to the entire population of the country.	Coverage	<ul style="list-style-type: none"> - Diagnostic network coverage - Sample referral system - Linkages - Emergency 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.	Diagnostic algorithm	<ul style="list-style-type: none"> - Algorithms - TB diagnosis - Drug-resistant TB
5	Testing is performed in a manner and in facilities that ensure safety for the staff, the customers, the community and the environment.	Biosafety	<ul style="list-style-type: none"> - Facilities - Biosafety and biosecurity manual - Biosafety systems - Waste management

	Standard	Core Capacity	Components
6	Testing is performed with state-of-the-art and well-maintained equipment and an uninterrupted supply of quality reagents and consumables using standardized testing methods throughout the country.	Equipment and supplies	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - Education and training - Staffing - Human resources development strategy - Competency-based job descriptions
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.	Diagnostics data management	<ul style="list-style-type: none"> - Diagnostics connectivity and remote monitoring - Data collection forms - Reporting - Data analysis and sharing - Surveillance and epidemiology - Security and confidentiality of information
9	High quality diagnostic services producing accurate and reliable results are available throughout the network.	Quality of the diagnostic network	<ul style="list-style-type: none"> - Documents and document control - Quality assurance - Quality management system - Certification and accreditation

2 – Methodology to measure capacities

Questions & Capability Levels

- Standardized questions are used to assess to what degree each component meets the diagnostic network standard
- Attributes of each component are used to define 6 stages/capability levels
- Stages (0–5) measure the progress towards accomplishing a component



Examples of Questions & Capability Levels

Components	Questions	Description of stage					
		0	1	2	3	4	5
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 TB diagnostic algorithms and SOPs are available at all facilities in the public sector, but not current or complete.	Current national TB diagnostic algorithm available, but not at all public facilities.	Current national TB diagnostic algorithm available at all public facilities and some private labs.	Current national TB diagnostic algorithm available at all public and private facilities and regularly reviewed and updated.
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 any TB tests.	Quality indicators and performance measures are routinely monitored for some TB tests at some tiers, but infrequently analyzed.	Quality indicators and performance measures are routinely monitored and evaluated for all TB 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 laboratories. Includes regular review of quality indicators and monitoring systems.
Specimen referral This relates to the coverage of the specimen referral system. Can any laboratory or facility refer any type of approved specimen to the appropriate level for testing or for confirmation according to NTP guidelines?	Are TB specimen referral and transportation systems in place at the local, regional and national levels?	No system in place for transporting specimens between tiers. Only <i>ad hoc</i> 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 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 – Country self-assessment

The country should perform a self-assessment of their capacity in key diagnostic network areas by identifying their capability stage

The self-assessment should be performed by a small technical group including representatives of the national TB program, national TB reference laboratory and intermediate reference laboratories as well as other national level laboratory, program and clinical experts.

4 – Verification of Country Self-Assessment

During the in-country visit, the assessment team reviews and verifies the country's self-assessed stages for each component

Many components can be verified by reviewing documents (e.g., the NSP) provided by the national program

- The Tool contains a list of documents to review for the corresponding questions.

Stages for other questions are assessed during 'verification' visits to national, intermediate and peripheral laboratories, and during interviews with national, intermediate and peripheral program staff

- The Tool contains a list of points to verify for the corresponding questions during the verification visits.
- A standard list of questions to guide the verification process for each core capacity and component is in the Tool.

5 – Determining Capability Stages

No	Questions	0	1	2	3	4	5
Component 4. Algorithm			Overall stage 1				
1	Is a clear national TB diagnostic algorithm available that is responsive to the epidemic, patient-centered, 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.
2	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 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 is regularly updated. ✓
3	Are diagnostic tests ordered according to standard diagnostic algorithms and based on national policy and patient risk factors and history? (patient preference)	No	National TB diagnostic algorithm is followed by some clinicians in the public sector for some patient categories.	National diagnostic algorithm is followed by some public sector clinicians for all patients. ✓	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.	Stage 4 with all public and private sector clinicians.
4	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 updated.

“Weakest Link”:

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.

5 – Determining Capability Stages

Core Capacity 3. Coverage	Component	Stage
Standard: Coverage The national TB diagnostic network provides complete coverage and universal access to TB diagnostic services to the whole population throughout the country. Referral mechanisms exist to rapidly and safely refer specimens upstream to the appropriate level for testing and to provide timely results to enable initiation of appropriate treatment. An efficient diagnostic-clinical interface allows for appropriate diagnostic tests to be ordered and performed and ensures the timely linkage of diagnosed patients to appropriate care and treatment.	Diagnostic network coverage	
	Question 1	4
	Question 2	2
	Question 3	4
	Sample referral system	
	Question 1	3
	Question 2	5
	Question 3	5
	Question 4	2
	Question 5	1
	Linkages	
	Question 1	3
	Question 2	1
	Question 3	4
Emergency preparedness		
Question 1	4	
Total	38	

Progress towards reaching stage 5 (or 100% capability) for all components within a core capacity can be determined:

1. Translate each question's capability stage into 'points'.
2. Add up the points for all of the questions within the core capacity.
3. Calculate the capability percentage as: $[(\text{Total number of points for all questions within a core capacity}) / (\text{total number of questions} \times 5)] \times 100$.
In the example, the percentage is:
 $[38 / (12 \times 5)] \times 100 = 63\%$

6 – Key findings and priority interventions

- A mixed methods approach is used which includes both qualitative and quantitative data.
- Findings from both the site level and national level assessments should inform the team's final findings and recommendations.
- The assessment team will prepare a final report, and submit all documents to the National TB Program.
- There will be a follow-up exercise done together with the NTP/NRL in a timely manner – to ensure that priority interventions have been operationalized – and if not, that proper and specific TA is identified
 - A follow-up staging is ideal to re-prioritize interventions given the rapidly changing landscape and needs of the diagnostic network

Next steps

The “final” version is undergoing review by a subset of GLI core team members, high burden country programs and other technical experts.

- It will eventually be endorsed by GLI available to be used to assess any country’s TB diagnostic network.
- Need to develop an electronic version/tablet friendly for ease of data collection and analysis

Designing a shorter, condensed version of the Tool that will “triage” the capacities during a desk review or by a local partner, or NTP.

- Areas will be prioritized for a more in-depth assessment according to the standard Tool
- For example, if the country or external consultant identifies that the “coverage”, “biosafety” and “quality” capacities are weakest by doing the self-assessment,, then specific technical experts in these three areas can use the tool to assess specific components and verify the capacities

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