



## Early View

Original article

# Applying a Standardised Approach to Strengthen Performances of GeneXpert Networks (ASAP-GxNet) program: lessons learned from Burkina Faso, 2019

Alagna Riccardo, Sawadogo Léon Tinnoga, Tagliani Elisa, Adjima Combarry, Cirillo Daniela Maria

Please cite this article as: Riccardo A, Léon Tinnoga S, Elisa T, *et al.* Applying a Standardised Approach to Strengthen Performances of GeneXpert Networks (ASAP-GxNet) program: lessons learned from Burkina Faso, 2019. *ERJ Open Res* 2020; in press (<https://doi.org/10.1183/23120541.00283-2020>).

This manuscript has recently been accepted for publication in the *ERJ Open Research*. It is published here in its accepted form prior to copyediting and typesetting by our production team. After these production processes are complete and the authors have approved the resulting proofs, the article will move to the latest issue of the ERJOR online.

Copyright ©ERS 2020. This article is open access and distributed under the terms of the Creative Commons Attribution Non-Commercial Licence 4.0.

**Applying a Standardized Approach to Strengthen Performances of GeneXpert Networks (ASAP-GxNet) program: lessons learned from Burkina Faso, 2019**

Alagna Riccardo<sup>1</sup>, Sawadogo Léon Tinnoga<sup>2</sup>, Tagliani Elisa<sup>1</sup>, Adjima Combary<sup>2</sup>, Cirillo Daniela Maria<sup>1</sup>

**Affiliations:**<sup>1</sup> IRCCS San Raffaele Scientific Institute, Milan, Italy; <sup>2</sup> National Tuberculosis Program, Ouagadougou, Burkina Faso

**Corresponding author:** Riccardo Alagna, IRCCS San Raffaele Scientific Institute, Milan, Italy.

Email: [alagna.riccardo@hsr.it](mailto:alagna.riccardo@hsr.it)

## **Introduction**

The World Health Organization (WHO)'s endorsement of Xpert MTB/RIF assay in 2010 represented a significant breakthrough in TB diagnostics [1]. With the unprecedented need to take advantage of new technology and improve TB diagnosis, investment in TB laboratory strengthening, including Xpert MTB/RIF implementation, has also increased. Since 2012, the sales' volume of Xpert MTB/RIF tests have increased dramatically from 1.3 million to nearly 12 million cartridges sold in 2018 solely to the public sector (personal communication). However, massive deployment of Xpert MTB/RIF at thousands of sites has highlighted that, if not implemented with a comprehensive accompanying tools package and within the context of a strengthened health system, diagnostic tests alone could likely fail to meet the expected impact on TB care cascade [2]. Although performing the Xpert assay is relatively simple, the national GeneXpert network's management is complex, and several settings have reported operational and programmatic challenges associated with the assay implementation and routine clinical use [2].

Successful national GeneXpert network requires robust managerial skills able to identify strengths and weaknesses as well as efficiently and proactively respond to the network needs. In this context, national GeneXpert focal points play a crucial role in supporting the national TB programme (NTP) to coordinate efforts and needs, to monitor the implementation of national guidelines, and to guarantee continuity of test services in term of reagents supplies, training, maintenance, quality assurance and supervision [3]. Despite its importance, in some settings, the focal point is not available or has weak managerial skills. This results with several bottlenecks such as delayed procurement and supply of cartridges, lack of regular supervision, inadequate preventive maintenance, and delayed replacement of damaged modules. As a result, many national GeneXpert networks are inefficient underutilized. Although some network assessment

tools and training programs exist, these are not suitable for the broader vision needed to manage a complex network such as the GeneXpert one.

The TB Supranational Reference Laboratory (SRL) of Fondazione Centro San Raffaele of Milan, Italy, and the National TB Program of Burkina Faso, developed the Applying a Standardized Approach to Strengthen Performances of GeneXpert Networks (ASAP-GxNet) program to strengthen local managerial skills and conduct a standardized impact assessment of the network. In this article, we describe the tool kit and the results from pilot implementation in Burkina Faso [2].

### **The ASAP-GxNet competency-based program**

ASAP-GxNet is a paper and online competency-based training program composed of an innovative GeneXpert assessment tool along with a series of short courses and work-based projects to quantitatively improve the network while strengthening managerial capacity of the national GeneXpert focal point.

The program, based on the principles of the Strengthening Laboratory Management Toward Accreditation (SLMTA) training curriculum [4], has been customized to include tools specifically addressing the key elements of the national GeneXpert network. The ASAP-GxNet program lasts for six months and contains two distinct pillars: A standardized assessment tool, and a training program with improvement projects (Figure 1).

A baseline assessment using the standardized tool is conducted at the beginning of the program to identify the strengths and weaknesses of the network. The baseline score is used to identify key priority areas to be addressed during the training curriculum. The training program is then conducted in a series of three workshops, one every eight weeks, with improvement projects carried out by the national GeneXpert focal point in the time frame between workshops. An

external mentor supports the national GeneXpert focal point along the entire programme. The primary duties of the external mentor are to conduct an objective evaluation of the national GeneXpert network, to train the national GeneXpert focal point, and to guide him/her on the improvement projects.

At the end of six months program, a final assessment (exit) using the same standardized tool is conducted, and the difference between baseline and exit scores provide a quantitative measure of the impact of the ASAP-GxNet program.

#### *Standardized assessment tool*

The standardized assessment tool enables the National GeneXpert focal point in collaboration with the NTP to evaluate the GeneXpert network functionality. The assessment tool was developed using a ASLM/APHL LABNET scorecard based approach [5]. It also incorporates critical elements described in the “Practical guide to implementing a quality assurance system for Xpert MTB/RIF testing” [6] and includes various checklists and questionnaires developed by the Global Laboratory Initiatives (GLI) [7].

The tool allows to assess three main “Areas”: a) GeneXpert Network capacities, b) GeneXpert quality indicators, and c) Managerial capacities (Table 1). Each “Area” includes a set of “Core capacities” each comprising a number of specific “Components” that are assessed by a series of questions (one hundred seven questions in total) (Figure 2A). Points are assigned to each “Component” based on the compliance with international recommendations, with each question totaling a maximum of 3 Points.

Each “Component” is then highlighted with a specific color based on the total number of points accumulated, to facilitate the visual identification of the areas that need strengthening (Figure 2B).

In addition to the color-code visualization of the “Components”, a final “Score” based on the total

number of points is provided to determine the network “Star rating” – from ‘0 stars’ (0-27 points, <20%) to ‘4 stars’ (109-135 points, 80-100%) (Table 1). The assessment tool is distributed to the national or international relevant parties beforehand and completed within two days with the external mentor from SRL Milan.

### *Training program and Improvements projects*

The training program aims to improve the national GeneXpert focal point capacity in coordinating and accomplishing multiple managerial tasks [8]. The curriculum was developed taking into consideration the key elements of the GII Training Package “Diagnostic network strengthening and Xpert MTB/RIF (Ultra) implementation” [8]. Based on the principle of “learning by doing”, fifteen theoretical sessions are combined with simulations and hands-on practical exercises. Along the six-month course, three five-day workshops are organized approximately every 8 weeks, covering the ten “Core capacities”. For each workshop, four days are dedicated to the analysis and strengthening of two to three “Core capacities”, while the fifth day is dedicated to developing or updating the related sections of the country GeneXpert operational plan.

In addition to the training curriculum, 15 practical activities are used to allow national GeneXpert focal point to acquire the new learning concepts and use the ASAP-GxNet tools.

. During the training period, improvement projects are carried out by the national GeneXpert focal point to enhance his/her managerial capacity and accountability. A total of thirty-eight improvement projects can be carried out depending on the specific “Core capacities” covered during the workshops and based on gaps identified during the initial network assessment.

### *Costs associated to the program*

The ASAP-GxNet program is available free-of-charge for any country interested in improving the managerial skills of the national GeneXpert focal point and aiming at optimizing the use of the available resources to address the gaps of the GeneXpert network through an evidence-based decision-making process. Access to ASAP-GxNet toolkit is possible through registration to the ASAP-GxNet online application. The online tool aims at guiding Users on the utilization of the ASAP-GxNet and to keep record of the performance and improvements during the program. It is important to note that the implementation of the ASAP-GxNet program requires the support of an external mentor with extensive experience in TB laboratory strengthening. Therefore, the main costs are related to technical assistance/mentorship.

### **Methods**

#### *Pilot implementation of the ASAP-GxNet program in Burkina Faso*

The Xpert MTB/RIF assay (Cepheid, Sunnyvale CA) was first introduced in Burkina Faso in June 2013 with the placement of one 4-module GeneXpert machine (GX4) at the TB National Reference Laboratory (NRL). Subsequently, in October 2016, two additional GX4 instruments were installed at two regional laboratories. By the end of 2016, the GeneXpert network was expanded with additional twelve GX4 machines resulting in a total of 15 instruments covering all regions in the country.

In 2017, a national GeneXpert focal point was identified and a national Xpert MTB/RIF Operational Plan for the years 2018-2022 was developed and adopted by the National TB Control Program. According to the national TB diagnostic algorithm the Xpert MTB/RIF assay was used as the initial diagnostic test for children, people living with HIV (PLHIV), high-risk MDR-TB patients, prisoners, and miners.

The implementation of the ASAP-GxNet program in Burkina Faso started in March 2019 and ended in December 2019. At that time, the national GeneXpert focal point had little experience in overseeing the GeneXpert network, as no similar programs existed at national level to strengthen the laboratory managerial capacities of the GeneXpert focal point. The program started with the initial assessment (i.e. baseline assessment) of the GeneXpert network. The assessment lasted a total of two-days and was conducted by a mentor from the SRL of Milan.

On the first day, the auditor reviewed the national policies, as well as the national strategies and procedures pertaining to the ten “Core capacities” of the GeneXpert network and identified the main areas for improvement and gaps to be addressed based on the above described scoring system. On the second day, the auditor presented the results of the baseline assessment to the NRL/NTP staff and in conjunction with the country counterpart, developed an action plan for the ASAP-GxNet training program implementation.

A customized training program was thus developed to address the specific areas for improvement identified by the baseline assessment. A total of ten improvement projects were selected to close the identified gaps.

All three workshops were delivered by the same external mentor that conducted the baseline assessment, and that supervised the improvement projects. Due to the country’s unstable security conditions, few deviations from the standard six months ASAP-GxNet program had to be applied. Firstly, part the training was conducted Burkina Faso and part in Milan, Italy, in the presence of the country national GeneXpert focal point. Secondly, the five days-workshops were conducted with a 12 weeks interval, instead of 8 weeks, with the program lasting a total of nine months, instead of six. And lastly, the final (i.e. exit) network assessment was conducted in remote by the same external mentor that implemented the program with the support of the national GeneXpert focal point.

The external mentor reviewed the results of the final assessment, and the overall impact of the ASAP-GxNet program was discussed with the National TB Program with the official presentation of the results to the national TB laboratory network in December 2019.

### *Ethical aspects*

Ethics approval was not sought as implementation of ASAP-GxNet, was conducted as part of a standard of care and routine public health investigation and response, which did not require formal ethics review in Burkina Faso and in Italy.

### **Results**

Upon completion of the ASAP-GxNet program, all the three “Areas” showed a significant improvement, from an overall baseline score of 74/135 points (55%), corresponding to a two stars rating, to 103/135 points (76%), corresponding to a three stars rating at exit, representing a 21% overall point increase from baseline to exit. In particular, significant improvements were observed in nine out of ten “Core capacities”, with the only exception of the “Quality assurance” capacity which remained unvaried (Figure 3A). At the baseline assessment the average percentage points for all core capacities was 48% with “Governance”, “Coverage”, “Maintenance”, “Supply chain management” and “Management” above 50%. As a results of improvements projects and training (Table 2), different grades of progress have been observed at the exit assessment (Figure 3). Three “Core capacities” showed an improvement ranging between 34% to 41%,”Quality indicators” (from 2/12 points (17%) to 7/12 points (58%)), “Data management” (from 4/9 points (44%) to 7/9 points (78%)), and “Workforce” (from 2/6 (33%) points to 4/6 points (67%)). Three “Core capacities” showed an improvement ranging between 20% to 23%, “Installation roadmap” (from 4/9 points (44%) to 6/9 points (67%)), “Supply chain management”(from 9/15 points (60%) to 12/15 points (80%)), and “Network management” (from 31/45 points (69%) to 41/45 points

(91%). Three “Core capacities” showed an improvement ranging between 11% to 13%, “Governance” (from 9/15 points (60%) to 11/15 points (73%)), “Coverage” (from 5/9 points (56%) to 6/9 points (67%)), and *Maintenance* (from 6/9 points (67%) to 7/9 points (78%)).

## **Discussion**

The present report is a descriptive study based on a pilot implementation of a new approach to strengthen the national GeneXpert network. The implementation of the ASAP-GxNet program resulted in an improved management of the national GeneXpert network with 21% points increase from start to the end of the program within a nine months timeframe. This result was achieved by means of a combination of training activities, targeted improvement projects and high commitment of national GeneXpert focal point. The experience in Burkina Faso demonstrates that despite its complexity, the national GeneXpert network can be efficiently strengthened by using a structured approach that addresses challenges of various network key components.

The active engagement of the national GeneXpert focal point was crucial to efficiently translate knowledge acquired during the training and improvement projects to real laboratory implementation. The National GeneXpert focal point was also essential in ensuring National TB Program manager buy-in and commitment to rapidly adapt and implement ASAP-GxNet tools. The external mentor ensured that the improvement projects were focused on major weaknesses and achievable in the short-term. This approach not only created ownership on improvement results among the NTP team, but also allowed to strengthen leadership and management skills at the national focal point. For example, most of the improvement projects focused on adapting and implementing tools for overseeing the overall network as well as for developing a sound pluriannual national Xpert MTB/RIF (Ultra) operational plan to facilitate future planning and implementation.

The main programmatic challenges encountered during the implementation of ASAP-GxNet related to few specific “Core capacities” that required long-term commitment as well as the provision of dedicated funding to support their full implementation and continuation over time. For instance, the “Quality assurance” core capacity required the implementation of an external quality assurance program, which included the provision of a proficiency panel testing. While different options currently exist [6], the enrollment in a proficiency program through an external provider is hampered by the country's lack of sufficient and dedicated funding. On the other hand, in-country preparation of the panels requires extensive planning and technical capacity to initiate the program. The “Governance” core capacity pertains aspects related to the national laboratory strategic plan, national diagnostic algorithm and specimen referral system, all activities that require long-term plan and alignment with national TB program funding cycle to ensure improvement. The “Coverage” core capacity aims at evaluating current and future diagnostic needs and assessing the integration of GeneXpert platform into diagnostic services other than TB. This requires a complex feasibility study and a robust collaborative environment among different disease programs to enable effective integration and utilization of these devices [9-11].

Additional challenges affecting the implementation of the program related to the numerous tasks and duties of national GeneXpert focal point, who over the course of the program, was also appointed as Head of National TB Reference Laboratory thus limiting the amount of time that could be devoted to improvement projects and implementation roadmap.

## **Conclusion**

Strengthening capacities to manage the national GeneXpert network and to identify service weaknesses is crucial to ensure the delivery of high-quality services and continuity of care for patients. Lessons learned from early implementation suggests that ASAP-GxNet program has the

potential to improve the management of complex network in a relatively short timeframe and to raise awareness at country level on the importance of developing the skills and capacity to manage a diagnostic network efficiently. Alignment of ASAP-GxNet implementation with the Global Fund grant cycle may significantly improve the capacity to implement those activities that require dedicated funding. In this context, the selection of improvement projects is critical to ensure that activities are feasible with available resources. Although the experience in Burkina Faso demonstrates that the ASAP-GxNet program has the potential to improve capacity to deliver continuous provision of quality diagnostic services, multiple cycles of the program need to be carried out to result in a sustained long-term impact.

## **Acknowledgements**

ASAP-GxNet is supported by the Stop TB Partnership's TB REACH initiative and is funded by the Government of Canada and the Bill & Melinda Gates Foundation.

The authors are grateful to the National Tuberculosis Programme Team of Burkina Faso and Dr. Virginia Quaresima from IRCSS San Raffaele Scientific Institute.

**Figure 1: ASAPGxNet implementation process**

**Table 1. Areas, Core capacities and Components evaluated by the standardized assessment tool.**

GeneXpert network “Star rating”: ‘0 stars’ (0-27 points, <20%); ‘1 star’ (28-54 points, 20-40%); ‘2 stars’ (55-81 points, 40-60%); ‘3 stars’ (82-108 points, 60-80%); ‘4 stars’ (109-135 points, 80-100%).

**Figure 2: Standardized assessment tool structure and color-code visualization of core capacities results**

A) Structure of standardized assessment tool with questions defining components and core capacities B) Black “0 point”, Red “1 point”, Yellow “2 points”, Green “3 points”.

**Figure 3: Performance of various core capacities, as measured by the ASAP-GxNet assessment tool from baseline to exit audit.**

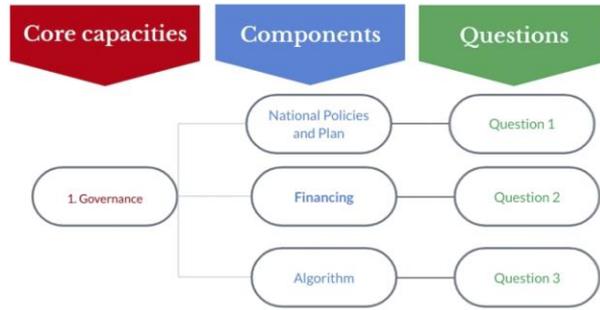
**Table 2: Selection of questions with improved results from baseline to exit assessment and related actions**

## References

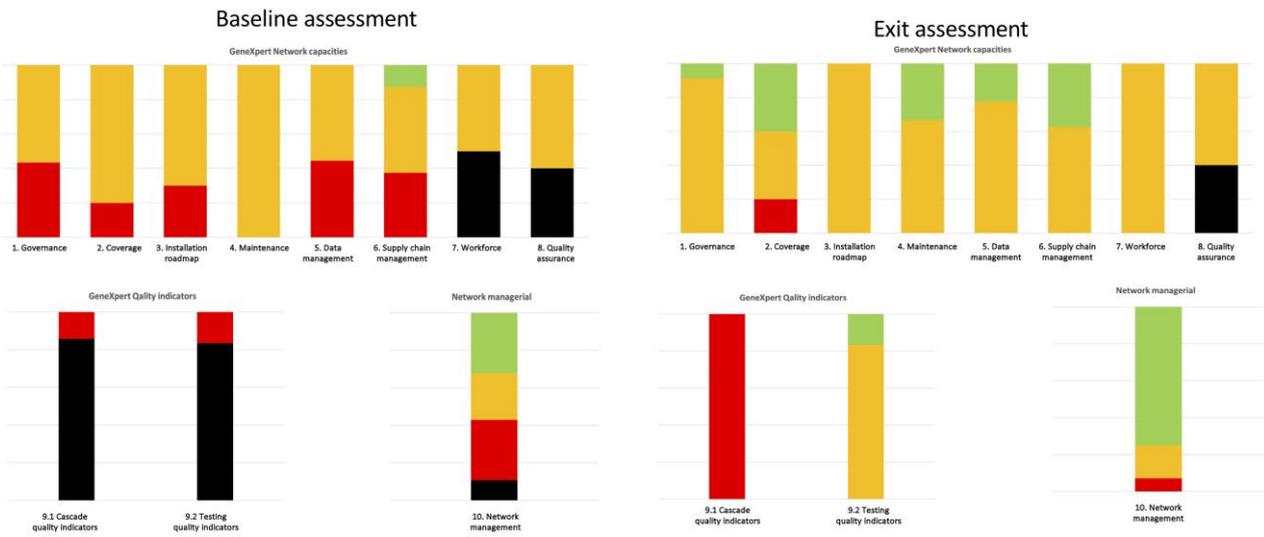
1. World Health Organization. Policy statement: automated real-time nucleic acid amplification technology for rapid and simultaneous detection of tuberculosis and rifampicin resistance: Xpert MTB/RIF. Policy statement. Geneva, World Health Organization, 2011.
2. Albert H, Nathavitharana RR, Isaacs C, Pai M, Denkinger CM, Boehme CC. Development, roll-out and impact of Xpert MTB/RIF for tuberculosis: what lessons have we learnt and how can we do better? *Eur Respir J* 2016; 48(2): 516-525.
3. Alagna R, Sawadogo TL, Combarry A, Diande S, Cirillo DM. ASAP-GxNet project in Burkina Faso: fulfil country capacity gaps to ensure efficient utilisation of GeneXpert instruments in tuberculosis care and cascade. *ERJ Open Res* 2019; 5(1).
4. Yao K, Maruta T, Luman ET, Nkengasong JN. The SLMTA programme: Transforming the laboratory landscape in developing countries. *Afr J Lab Med* 2014; 3(3).
5. Ondoa P, Datema T, Keita-Sow MS, Ndiokubwayo JB, Isadore J, Oskam L, Nkengasong J, Lewis K. A new matrix for scoring the functionality of national laboratory networks in Africa: introducing the LABNET scorecard. *Afr J Lab Med* 2016; 5(3): 498.
6. Practical Guide to Implementing a Quality Assurance System for Xpert MTB/RIF testing - Global Laboratory Initiatives <http://www.stoptb.org/wg/gli/xpertqguide.asp>.
7. Xpert MTB/RIF Training Package - Global Laboratory Initiatives <http://www.stoptb.org/wg/gli/trainingpackages.asp>.
8. GLI Training Package: Diagnostic network strengthening and Xpert MTB/RIF (Ultra) implementation [http://www.stoptb.org/wg/gli/TrainingPackage\\_XPERT\\_MTB\\_RIF\\_Ultra.asp](http://www.stoptb.org/wg/gli/TrainingPackage_XPERT_MTB_RIF_Ultra.asp).
9. Ndlovu Z, Fajardo E, Mbofana E, Maparo T, Garone D, Metcalf C, Bygrave H, Kao K, Zinyowera S. Multidisease testing for HIV and TB using the GeneXpert platform: A feasibility study in rural Zimbabwe. *PLoS One* 2018; 13(3): e0193577.
10. Bassett IV, Forman LS, Govere S, Thulare H, Frank SC, Mhlongo B, Losina E. Test and Treat TB: a pilot trial of GeneXpert MTB/RIF screening on a mobile HIV testing unit in South Africa. *BMC Infect Dis* 2019; 19(1): 110.
11. Nash M, Ramapuram J, Kaiya R, Huddart S, Pai M, Baliga S. Use of the GeneXpert tuberculosis system for HIV viral load testing in India. *Lancet Glob Health* 2017; 5(8): e754-e755.

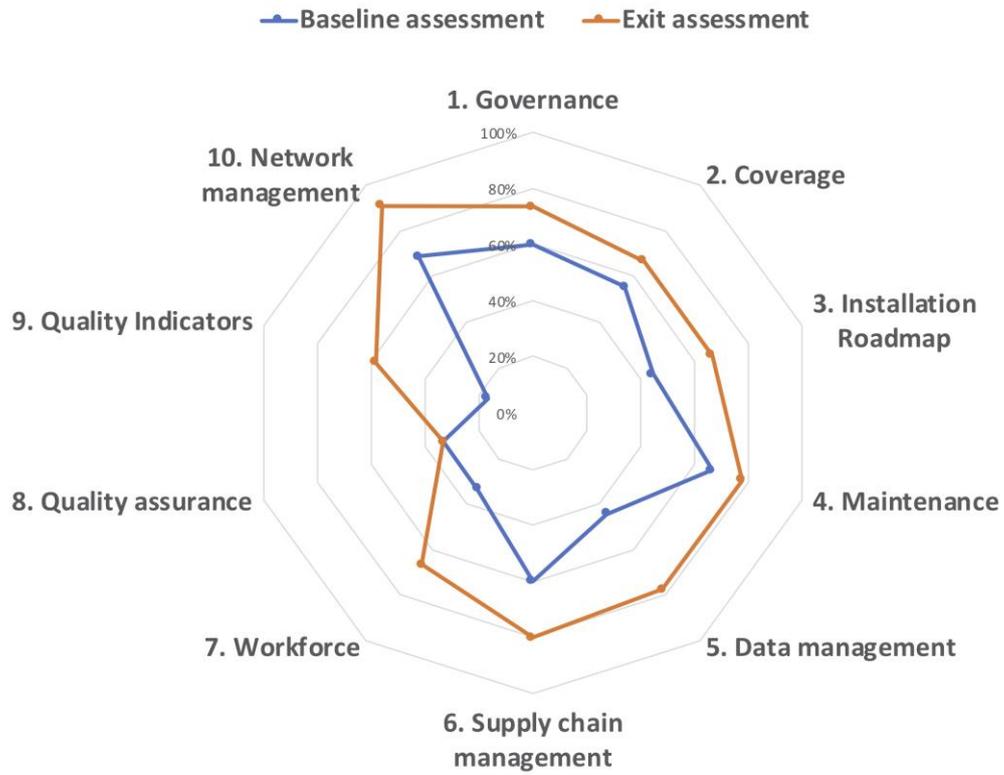


A



B





Area	Core capacities	Components	Points
<u>GeneXpert network capacity</u>	<b>1. Governance</b>	Governance; National Policies and Plan Financing; Algorithm; Specimen Referral System	15
	<b>2. Coverage</b>	GeneXpert integration; Current GeneXpert coverage; Future GeneXpert coverage	9
	<b>3. Installation Roadmap</b>	Pre-installation ; Installation, Post-installation	9
	<b>4. Maintenance</b>	Warranty; Calibration, Service interruption	9
	<b>5. Data management</b>	Sample data management, Data analysis, Reporting	9
	<b>6. Supply chain management</b>	Forecast, Procurement, Distribution, Stock management, Service interruption	15
	<b>7. Workforce</b>	Network management, Training	6
	<b>8. Quality assurance</b>	Quality assurance, External quality assurance	6
<u>GeneXpert quality indicators</u>	<b>9. Quality Indicators</b>	Diagnostic cascade quality indicators, Performance quality indicators	12
<u>Managerial capacity</u>	<b>10. Management</b>	National Policies and Plan, Algorithm, Financing, Coverage, Pre-installation, Installation, Post-installation, Warranty Calibration, Data management, Forecast, Procurement, Stock management, Training, Quality	45
<b>Total score</b>			135

Core Capacity	Baseline points	Exit points	Components	Question	Baseline answer	Exit answer	Actions
1. Governance	9/15 (60%)	11/15 (91%)	Financing	Is there any instrument to estimate costs related to instrument purchase and implementation?	No tool available	Tool available and used. Budget aligned with operational plan	- Training on the use of ASAP-GxNet financing tool
				Are costs for cartridges procurement estimated?	Detailed cost estimation is available but not aligned with operational plan	Detailed cost estimation is available and aligned with operational plan	- Training on cartridges quantification
			Algorithm	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?	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 and all persons being evaluated for TB.	- Improvements not dependent by ASAP-GxNet. - Following network analysis country planned to move to universal use of Xpert MTB/RIF in 2020
			Specimen Referral System	Is there national TB specimen referral and transportation strategy?	There is a TB specimen referral and transportation strategy approved	There is an integrated specimen referral and transportation strategy approved	- Improvements not dependent by ASAP-GxNet. - Country planned to move to integrated specimen referral system
2. Coverage	5/9 (56%)	6/9 (67%)	Current GeneXpert Coverage	Is an evidence-based method used to estimate the future needs of GeneXpert instruments?	Estimation is based on detailed evidences	Estimation is based on detailed evidences. Revised every year (or when needed)	- Improvement projects on "development of a document for identification of network needs" - Training on the use of "ASAP-GxNet assumption tool"
3. Installation roadmap	4/9 (44%)	6/9 (67%)	Pre-installation	Is the selection of new GeneXpert sites based on standardized criteria?	New sites are selected by geographical reasons only	A documented list of criteria, including geographical, epidemiological and infrastructural information, is described in the Xpert implementation plan and used to select new sites	- Improvement projects on "development of a document for identification of network needs" and - Training on the use of ASAP-GxNet matrix needs tool
				Is a standardized checklist available and used to evaluate the site prior installation?	A standardized checklist is available and used but not detailed	A standardized checklist is available and used to evaluate the site prior installation. In line with FIND checklist template	- Improvement project to revise and update national document
			Installation	Is a standardized checklist available and used to evaluate the instrument installation?	A standardized checklist is available and used but not detailed	A standardized checklist is available and used to evaluate the site prior installation. In line with FIND checklist template	- Improvement project to revise and update national document
			Post-installation	Is a standardized checklist available and used to evaluate GeneXpert sites?	A standardized checklist is available and used but not detailed	A standardized checklist is available and used to evaluate the site. In line	- Improvement project to revise and update national document

						with FIND checklist template	
<b>4. Maintenance</b>	<b>6/9 (67%)</b>	<b>7/9 (78%)</b>	<b>Warranty</b>	Is there a mechanism in place to monitor GeneXpert instrument repairs at testing sites?	Yes, but the current mechanism is not functional	Yes, but it functions well only at some testing sites	- Improvement project on implementation of Xpert tracking tool
			<b>Calibration</b>	Are all GX instruments calibrated every year?	Some GX instruments are calibrated every year with delay	All GX instruments are calibrated in due time	- Improvement project on implementation of Xpert tracking tool - Training on calibration plan and strategy
			<b>Service interruption</b>	Is a back-up plan (including SOPs) available in case of service interruption due to equipment failure for handling specimens during these times, identification of referral laboratory for testing, and referral procedures?	Only ad hoc back-up plan takes place during equipment failure.	Back-up plan (including SOPs) is available but not applied for handling specimens during service interruption due to equipment failure	- Improvement project to develop a back-up plan for all Gx sites
<b>5. Data management</b>	<b>4/9 (44%)</b>	<b>7/9 (78%)</b>	<b>Sample data management</b>	Is there any connectivity system for Xpert MTB/RIF-(ULTRA) testing in place?	No connectivity system available	Connectivity system is in place, but it only partially covers the network	- Improvement project to select connectivity system supplier. - Connectivity system implementation on-going
			<b>Data analysis</b>	Are there adequately trained personnel, software and/or tool that receives laboratory data from all levels, analyzes the data and generates reports?	There are personnel trained but not adequate software or tools to analyze and report Xpert MTB/RIF-(ULTRA) data	There are personnel trained, adequate software or tools to analyze data. Complete reports are generated on regular basis	- Improvement project to implement ASAP-GxNet quarterly report data collection - Training through the ASAP-GxNet program
				Are statistical data collected, analyzed, and used for decision making purposes and shared within NTP?	Only few Xpert MTB/RIF-(ULTRA) indicators are collected and analyzed	A comprehensive list of Xpert MTB/RIF-(ULTRA) indicators are collected and analyzed and effectively used for decision making purposes	- Improvement project to implement quality indicators - Training quality indicators
			<b>Reporting</b>	Is there an electronic system that enables reporting of diagnostic data to local and national program?	Electronic reporting for GeneXpert network improvement purposes is functional in reference laboratories only.	Electronic reporting for GeneXpert network improvement purposes is functional at all levels and analyzed for a limited range of purposes.	- Improvement project to implement ASAP-GxNet quarterly report data collection
<b>6. Supply chain management</b>	<b>9/15 (60%)</b>	<b>12/15 (80%)</b>	<b>Forecast</b>	Is forecast of Xpert MTB/RIF-(ULTRA) needs done based on past and projected consumption?	No system and methodology are used	Past and projected consumption is used to forecast Xpert MTB/RIF-(ULTRA) needs. Forecasts are revised on a year basis	- Training on cartridges forecast
			<b>Service interruption</b>	Have testing facilities provided uninterrupted GeneXpert testing services, with no disruption due to cartridges stock outs (or since last assessment)?	Some testing facilities (more than half of total number) have faced at least one instance in the last year of testing service interruption	Some testing facilities (less than half of total number) have faced at least one instance in the last year of testing service interruption	- Not dependent by ASAP-GxNet training - Improvement projects to develop a backup plan for GeneXpert machines troubleshooting

					due to cartridges stock outs	due cartridges stock outs	
7. Workforce	2/6 (33%)	4/6 (67%)	Network management	Does the National GeneXpert Focal Point have adequate managerial knowledge and skills (plan, organize, lead and control) to oversight the GeneXpert network?	The Focal Point has adequate knowledge of the network but limited capacity to plan, organize different tasks of the network	The Focal Point has adequate knowledge and skills to oversight the network	- Training through the ASAP-GxNet program
				Does the National GeneXpert Focal Point have a list of daily/monthly/annual routine work tasks?	No list of routine work tasks is available	A comprehensive list of daily/monthly/annual routine work tasks is available and performed in due time	- Training through the ASAP-GxNet program
				Does the GeneXpert Focal point use and update the Xpert tracking or similar tool to optimize network management?	No	The Xpert tracking or similar tool is used, data exploited and regularly updated	- Improvement project on implementation of Xpert tracking tool
8. Quality	2/6 (33%)	2/6 (33%)	Quality Assurance	Is a standardized checklist available and used to evaluate GeneXpert sites?	A standardized checklist is available and used but not complete	A standardized checklist is available and used to evaluate the site. In line with FIND checklist template	- Improvement project to revise and update national document
9. Quality indicators	2/12 (17%)	7/12 (58%)	Diagnostic cascade quality indicator	End TB Strategy laboratory target indicator 1	No data available	Data available target not achieved	- Improvement project on implementation of Xpert tracking tool and data collection/analysis tool
				End TB Strategy laboratory target indicator 2		Target achievable in a reasonable time frame	
				End TB Strategy laboratory target indicator 3		Data available target not achieved	
				End TB Strategy Laboratory target indicator 4		Target achievable in a reasonable time frame	
				End TB Strategy laboratory target indicator 7		Data available target not achieved	
				End TB Strategy laboratory target indicator 8		All data available full analysis	
				Data completeness		Media rate below the target. One or more sites with rate above the target	
				Error rate		Media rate below the target. No site with rate above the target	
			Invalid rate	Results reported in 24h in some sites			
			No result rate	Number of tests slightly			
			Specimens with a result reported within 24hrs				
Media of maximum Xpert testing							

				capacity per month		below the maximum Xpert testing capacity (2-3 test per day)	
<b>10. Network Management</b>	<b>31/45 (69%)</b>	<b>41/45 (91%)</b>	<b>National Policies and Plan</b>	Does the GeneXpert Focal point revise the Xpert implementation plan every year?	Not done (due to reasons directly linked or not to GeneXpert Focal Point capacities)	Planned	- Training through the ASAP-GxNet program
			<b>Algorithm</b>	Does the GeneXpert Focal point monitor, through data GeneXpert sites, the adherence of national diagnostic algorithm?		Yes, done and actions are taken for those sites not adherent	
			<b>Installation</b>	Have you developed and/or updated a standardized training (1-day) materials?		Yes done	
			<b>Data Management</b>	Are information from GeneXpert sites routinely updated on Xpert tracking tool?		Yes done	
				Are periodic data from GeneXpert sites routinely collected and analyzed?		Yes done	
<b>Quality</b>	Does the GeneXpert Focal point periodically analyze quality indicators and results for all GeneXpert sites?	Yes done					