



Georgia TB laboratory network assessment and recommendations report

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ACRONYMS

ACF	Active Case Finding
AIDS	Acquired Immune Deficiency Syndrome
AFB	Acid-fast Bacilli
BTEP	Biotechnology Exchange Program
CCM	Country Coordinating Mechanism
CRDF	U.S. Civilian Research & Development Foundation
DOT	Directly Observed Treatment
DOTS	Directly Observed Treatment, Short course
DST	Drug Susceptibility Test
EQA	External Quality Assurance
GDF	Global Drug Facility
GLC	Green Light Committee
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
HIV	Human Immunodeficiency Virus
ICRC	International Committee of the Red Cross
IDP	Internally Displaced Person
KAP	Knowledge, Attitudes and Practices
MDR-TB	Multidrug Resistant Tuberculosis
MOLHSA	Ministry of Labor, Health and Social Affairs
NCDC	National Center for Disease Control
NCTBLD	National Center for Tuberculosis and Lung Disease
NGO	Non-governmental Organization
NIH	National Institutes of Health (USA)
NRL	National Reference Laboratory
NTP	National Tuberculosis Program
PHC	Primary Health Care
SISUF	Social Insurance State United Fund
TB	Tuberculosis
UV	Ultraviolet
WHO	World Health Organization

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EXECUTIVE SUMMARY

Georgia has made significant progress in confronting its epidemic of tuberculosis and multidrug-resistant tuberculosis (MDR-TB). It has also met the Millennium Development Goals in this regard. The World Health Organization (WHO) estimates that the overall TB incidence, mortality and prevalence rates in Georgia have been falling steadily since the year 2000. In order to sustain this success in the context of ongoing fundamental reforms of the health system, Georgia will have to meet and overcome several challenges, including drug resistance, TB in prisons, and the need to maintain and expand its laboratory network to meet increased case findings.

In 2011, the Georgian government initiated fundamental reforms of its health system with a strong emphasis on privatization. Both primary health care as well as hospitals have been privatised. While this is seen as an opportunity for the Georgian private sector, it has also placed limitations on the national TB laboratory network. The NRL and NCDC are centralised and they have lost about 36 TB microscopy centres that have not been retained by the private sector in the privatization process. This was an outcome of an evaluation around the logistics and financial considerations of retaining them.

Privatisation and the accompanying centralisation of diagnostic resources has resulted in arrangements for the transportation of sputum from clinics to the NCDC and NRL being put in place that are not optimal for specimen viability and security. The Georgian Postal Services presently is trialling an alternative system that appears to be more efficient. Trials continue in a few selected centres.

MDR-TB continues to be major issue in Georgia as up to 12% of MDR-TB are new cases and this suggests a high transmission rate within communities. TB cases rates are in decline, but the number of microscopes per unit population is much lower than the WHO recommendation of 1:100 000. Moreover, the number of sputum confirmed cases by microscopy from various regions around Georgia is very high, indicating that patients are referred for diagnosis when they are already infectious and probably have been transmitting the disease.

The current Georgian Laboratory network is well equipped and organised and performs its role in an efficient and effective manner. The NCDC labs are fully integrated and are well equipped and adequately staffed. However, there are issues of motivation and performance that need to be addressed at the private sector clinics which now house the former government TB clinics. The TB specialists' staff there feel disempowered and are not motivated to perform at their previous levels. Private TB clinics receive a fixed fee based on a TB suspect identification basis. However, they are generally not interested in providing diagnostic services beyond sputum collection.

Overall, the impression is that laboratories need strengthening in terms of their organisation as well as a structured EQA. Also, and critically, a review of the

adoption and implementation of new technologies, such as the GeneXpert at regional labs, the utility of Line Probe Assays and the introduction of LED microscopes needs to be undertaken.

Discussions with private sector clinics around the possibility of introducing LED microscopes and GeneXpert technologies in a few selected private sites – in line with the recommendations of this report. Key to this would be to devise creative modalities for the deployment of the technologies in areas beyond TB diagnosis, something the versatility of the GeneXpert makes possible. A successful trial of this proposal would be critical to engaging the private sector and fully integrating them into the health system as a means of improving case detection and diagnosis.

A model has been devised in collaboration with URC Georgia which suggests, based on the incidence in many regions of Georgia, that at least seven (7) new labs need to be installed – in private hospitals – and added to the existing TB screening and diagnostic network. This will mitigate the loss of the previous 36 public health clinics and also increase the number of TB suspect cases to investigate as an aid in early detection. These labs should be directly EQA-supervised by NRL and should ideally be located in regions where most cases are detected. As well, these proposed new labs will require both training as well as EQA from NRL. The initial investment could be funded from donors such as the Global Fund and operating costs can be subsidised for TB diagnosis by Government initially and then recovered via non-TB testing and diagnostic work that utilises the versatility of the GeneXpert.

SUMMARY RECOMMENDATIONS

1. Main Programmatic Issues

1. Privatization

In 2012, Georgia undertook privatization of primary health care, including hospitals and TB services. The context for TB control is thus changing as Georgia is fundamentally reforming its health system. In 2012, TB dispensaries were absorbed into private general medical facilities. Some of the responsibilities for the national TB program have been transferred from the National Center for TB and Lung Diseases (NCTBLD) to National Center for Disease Control and Public Health (NCDC). NCDC partially, along with the NCTBLD, is now responsible for TB surveillance, key parts of the TB laboratory network, and initiating investigation of contacts to TB cases. NCDC took responsibility for TB control including the network of smear microscopy TB laboratories.

This period of reform also has potential pitfalls. There is a lack of clarity in roles and responsibilities of central and regional structures including MoLHSA, NCTBLD, and NCDC. The new players have varying levels of experience and expertise in TB control. National clinical practice guidelines and protocols are currently being updated and have yet to be introduced, and there is no TB monitoring plan to assure accountability of the new TB service providers. In order to reap the benefits of health reform, certain specialized TB functions must be maintained at the national and regional level.

In 2012 a decrease in case notification was observed. However experts agree that this was mainly explained by the large decrease in smear laboratories from 36 to 7 and difficulties with sputum transportation.

2. Diagnostic delays

Under the Expand-TB project launched in Tbilisi and Kutaisi, new rapid TB tests and laboratory methods have been implemented at central and regional reference level to help identify more rapidly MDR-TB cases. However, countrywide typical schedule of sputum transportation on a once-weekly basis causes many delays in TB examination and TB treatment, and more noticeably particularly long delays to obtain molecular tests (HAIN) and culture-DST results that are only available in the 2 reference laboratories mentioned above. The privatization has resulted in an increased centralization of diagnostic testing. However, inefficient sputum transport logistics combined with the difficulty to reach numerous towns and villages in mountainous terrain especially in winter time is resulting in an unequitable access in TB diagnosis, testing results and initiation of treatment. Furthermore, postal service, as a courier for sputum transport, has been introduced in only two regions. Special transport boxes with ice-packs are used to transport the specimens. Lastly, privatization has shifted TB staffing decision to the private facilities that have absorbed the TB dispensaries. This resulted in job cuts in nurses, data collectors, pharmacists, and drivers leading to increased time for receiving diagnostic results and to treatment interruptions because of lack of follow-up.

A further barrier that causes delays in diagnosis and treatment is the fact that In Georgia, only TB doctors can order laboratory testing for TB, so TB diagnosis relies on referral from Primary Health Care (PHC) providers. Referral from PHC providers are not systematically recorded, nor is feedback to the referring doctor.

An assessment by the USAID TB Prevention Project in January to May 2012 in Kakheti and Imereti found that 31% of referrals from PHC providers were confirmed with TB. By contrast, at the national level in 2010-2011, 15-19% of patients with sputum examined were found to be smear-positive. The higher proportion of confirmed cases from PHC referrals suggest that PHC providers are referring only patients with classic signs of TB (such as coughing up blood and lung cavities seen on chest x-ray). This suggests they may be missing patients with less advanced disease, who could be detected and treated earlier to prevent progressive lung destruction and transmission to others.

While the country's laboratory algorithms include testing of all TB patients for MDR-TB, only 52% of previously treated patients and 83% of new culture positive TB cases were tested for isoniazid and rifampin in 2011. Given the levels of MDR-TB are three times higher in previously treated patients than new patients in Georgia, the country has defined previously treated patients at high risk of MDR-TB, along with TB patients who have been in contact with infectious MDR-TB patients. If these patients are smear positive, Georgia's laboratory algorithm means they will have LPA which yields results within a day. If they are smear negative but their sample arrives to the Tbilisi or Kutaisi lab within four days of collection, MGIT testing will be performed which yields first line DST results within one to two weeks. But if they are smear negative and their sample arrives later than four days after specimen collection, solid media takes up to six weeks to determine drug susceptibility results. This long delay is mitigated in Tbilisi by the NRL's use of Xpert MTB/RIF which will yield results within a day. Moreover, 38% of the nation's civilian patients are tested in Kutaisi, so they do not have access to this new technology, which WHO recommends for all patients at high risk of MDR-TB.¹

3. Case Management and default rates

A very high default rate still remains today that can be alleviated by a more patient centred TB case management approach by the NCDC. The National TB strategy is transitioning from a vertical program towards a more integrated TB service delivery model that includes pulmonologists. Increased training, certification activities and implementation of the Practical Approach to Lung (PAL) health should improve access to TB care, early diagnosis and treatment and reduce TB patient defaults.

4. Tracking the Government spend on TB Health Services

If successful, the Georgia model may serve other country programs about how to engage private sector to ensure TB care sustainability. Hospitals have been

privatized countrywide with support from insurance companies. Under the TB privatization agreement, private general medical services are paid by government with fixed salaries for more than 2000 primary health care physicians and nurses. However, health workers rarely comply with evidence-based clinical protocols and quality assurance systems. The private medical centers are not empowered nor feel public health responsibility as all decisions are still taken centrally for them in Tbilisi. Lastly, the TB health infrastructure remains of poor quality. Overall, the value of the government budget spent on TB health services can hardly be tracked by the current outdated health management information system and used for informed decisions.

In addition, the Government will have to find significant alternative sources of funding to replace and sustain that funding presently being supplied by foreign donors such as the Global Fund and other Grantees. The table below summarizes the funding gaps¹.

Table 1: Funding sources and funding gap 2013-2015

Total Budget Required (US\$)	Government contribution	Global Fund contribution	Other Grants contribution	Gap
Fiscal Year 2013				
14 135 666	5 015 417	3 184 734	1 128 425	4 807 091
Fiscal Year 2014				
14 363 431	5 083 171	3 184 733	809 503	5 286 024
Fiscal Year 2015				
14 814 085	5 166 709	3 184 733	720 520	5 742 123

1 Summary of the major findings on constraints to adequate laboratory performance

1.1 Findings and conclusions

POLICY
Georgia is one of the 27 HIGH MDR-TB burden countries, globally. MDR-TB prevalence is very high- 10.9% among New and 31.7% among Previously treated, in 2011.
Only 67% of estimated MDR-TB cases are diagnosed by the program
Strong political commitment from MOLHSA.
Health system reforms are introduced rapidly from 2011.
State funded universal Health program to help free of cost access to services to the people. Geographic access to TB services is ensured through 66 rayon level TB clinics providing outpatient services and 5 specialist TB hospitals. TB Lab diagnosis is provided through newly organised national lab network with about 9 functional TB labs, in all.
Effective policies for decentralization of diagnostic capacity required. Additional diagnostic facilities at peripheral level - in the private sector- with adequate incentivisation needed, in line with needs and taking into account geographical distribution of hospitals and NCDC laboratories
Effective routine surveillance system operational for TB and MDR-TB, in the country, for past few years. The system is paper based, as well as electronic.
Policies for PHC referrals are not fully streamlined, leading to delays in diagnosis and consequently detection of TB at 'advance' stage, and continued transmission.
Programmatic guidelines and trainings for contact tracing, and prompt lab referral needs strengthening- for early diagnosis.
Guidelines for effective and prompt sputum transport are needed.
Policies for Community level TB control: Prompt Referral for diagnosis, treatment initiation and DOTs support need streamlining.
Taking into account roll out of new diagnostics (Xpert MTBRif to peripheral level and MTBDRsl to intermediate level at Kutaisi) and implementation of additional DST at NRL (like PZA, LNZ and other drugs for future MDR/XDRTB treatment, lab specific- long term strategic plan including partnerships coordination (across the health system) required for effective implementation of TB diagnostics.
A good EQA program is in place for smear microscopy covering all current microscopy laboratories (including 2x/year visit by NRL and 4x/year visit by local TB coordinator). Genotypic DST is checked through proficiency testing organized by the NRL. The NRL participates in international EQA proficiency testing for phenotypic and genotypic DST. Yet no EQA guideline and implementation official documents exist. Uniform Lab policy is lacking. Currently no systematic EQA network..

ORGANIZATION (COVERAGE/ RELATIONSHIP WITH NTP)

NTP organisational structure is ambiguous. While NRL is directly under NCTBLD, peripheral TB labs come under NCDC. TB Contact tracing also rests with NCDC.

Health reforms altered the vertical chain of command, but new lines of supervisory accountability have not been specified for TB patient care functions or overall TB program management

NRL (Tbilisi) diagnosed about 49% of smear positive new cases notified by the country for 1 and 2nd Quarter 2013. It performed sputum microscopy for about 47% of TB patients in the country.

Lack of clarity in different partner supported activities- no clear roles and responsibilities

Disproportionate TB treatment and care facilities compared to TB diagnostic facilities: Few Laboratories and microscopy centres vs population and case load especially MDR TB

No TB labs in the private sector, while privatization is key strength of Health system reforms of MoLHSA

Inadequate community level participation for TB diagnosis and care

Organisational structure for lab services and TB program were strengthened, recently, at all levels with specific roles and responsibilities.

Lack of effective coordination for general quality management and in particular lab quality issues between NCDC/NCTALD linked mainly due to lack of key focal point/QA-Manager

HUMAN RESOURCES (INCLUDING TRAINING/SUPERVISION)

National TB reference Lab is adequately resourced and demonstrated proficiency in TB bacteriology with 100% accuracy for Proficiency testing (EQA) for DST conducted by Supranational reference Lab (SRL)-Antwerp. Kutaisi Culture and LPA lab is also adequately for staff (6 bacterioscopists, 2 molecular biologists, 2 bactriologists). Batumi LSS has 2 bacterioscopists. Peripheral labs are sources with one bacterioscopist.

The national lab, Kutaisi regional lab, and Batumi LSS lab cater for more than 75% of the country's smear microscopy-workload. Peripheral labs have sufficient work-loads to maintain proficiency for sputum microscopy. On average, the work-loads range from 8 to 18 smears per day in peripheral labs (variable from lab to lab). NRL has average work-load of over 40 smears per day.

Annual training/refresher training plan is needed, followed with well-resourced activities

NCDC contracts out NRL to provide regular supervision of Lab staff from Higher level to peripheral labs, under the GF supported activities. This is a continuous activity needing adequate resources as well as timely corrective trainings/orientations to lab staff for Quality improvement of TB lab services including culture at regional level : i.e Kutaisi culture lab.

Lack of designated focal point (at all levels) is seen as weakness for Lab quality management, and bio-safety

TECHNICAL SERVICES (STANDARD METHODS/OPERATIONS)

National TB laboratory EQA guidelines (for sputum microscopy, C&DST, molecular diagnostics) need updating given the changes that took place after health reforms

Operational and technical issues facing the labs were not listed, plausible reasons and corrective measures were not undertaken. With very high work-loads of smears in the labs (minimum work-load in any lab was over 2000 smears/year), regular quality improvement steps will enhance accurate case detection, and motivate lab staff to be technically more vigilant.

High work-load peripheral microscopy labs are not yet installed with LED FM microscopes. Improvement in sensitivity and motivation of technician in terms of new technology makes led an excellent option despite additional training and quality assurance requirements.

PROCUREMENT (EQUIPMENT/ SUPPLIES)

Procurement and management of equipment and supplies is very good, and adequate storage space is available at NRL/NTP.

Although Comprehensive annual equipment maintenance contracts not in place, the overall centralised management of procurement (equipment/supplies) is satisfactory.

At present, most of the equipment and consumables (for LPA, GeneXpert, liquid culture MGIT 960 etc.,) are provided by the partners.

QUALITY ASSURANCE OF SERVICES

Severe constraints- no systematic approach undertaken/updated in line with Govt.'s health reforms measures

At present no quality management system exists

Need a focal point for quality assurance, at each level of laboratory services.

A national level quality manager- focal point- is needed to bring in coordination between different MOLHSA divisions, and keeping specific requirements of TB lab services.

1.2 Summary recommendations

Sl.No.	Recommendations
Specific Laboratory recommendations	
R1	Extend the access to new diagnostics at all levels of service delivery. It is proposed that seven (7) private hospitals and one (1) public hospital in the

Sl.No.	Recommendations
	most affected regional areas be equipped with GeneXpert and LED and Fluorescent microscopy technology in order to screen and diagnose early onset TB. This allows effective decentralisation of lab services/ and equitable work-distribution/ and early diagnosis of TB, and prompt treatment initiation/ help 'cuts-down' transmission of TB.
R2	Objectively reassess strategic plan for GeneXpert technology implementation based on set criteria. Allow redistribution of some of the planned GX systems from Govt. to Private sector, with appropriate policy on incentivisation to encourage reach and timely access to rapid technologies
R3	Develop and implement guidelines for effective and prompt sputum transport to C&DST labs, and prompt result feed-back
R4	Develop and implement National EQA guideline: include routine on-site supervision, and Proficiency testing. MOLHSA to adequately resource the EQA activities
R5	NRL to provide effective leadership for Lab policy guidelines, and QA system in the country- rather than get immersed in routine patient-care
R6	Urgently assess and develop a Laboratory HR policy in line with MOLHSA HR policies- and advocate for adequately qualified/trained Laboratory technical staff.
R7	NTRL to develop annual training/refresher training plan, MOLHSA/Partners provide adequate resources to conduct quality trainings
R8	Institute system for regular supervision of Lab staff from higher level- based on redrafted EQA guidelines. At Kutaisi lab close on-site supervision is warranted to improve quality of culture on a continuous basis.
R9	NRL may consider orientation/quality improvement work-shops for the Lab staff to retain the higher levels of motivations. Updating the skills as well as technical-know-how of the lab staff (some of who were formally trained long years-back) will help high motivations/ quality improvements.
R11	Develop and resource a sustainability plan for equipment maintenance, and lab reagents and commodities. At present, most of the equipment and consumables are provided by the partners- e.g., LPA, GeneXpert, MGIT 960 etc.,
General Recommendations (NTP/Health services)	
R12	Streamline policies for PHC referrals to cut-short delays in diagnosis and to curtail continued TB transmission in communities. Strengthen M&E at all levels.
R13	Develop effective mechanisms to coordinate the Partner support- based on the National strategic plan.

Sl.No.	Recommendations
R14	Conduct coordination meetings between NCDC/ZSS/LSS tiers for addressing gaps and quality improvement- technical as well as operational issues.
R15	Establish focal point at NCTBLD/NCDC for (a) Lab QA management (b) Lab reagent/consumables/equipment management for forecasting and logistics. Position a coordinator between various MOLHSA and Private Hospitals, facilities. Adequately resource this activity- with partnerships

2 Chapter 1: INTRODUCTION

2.1 Country Background

Georgia is a country in the Caucasus region of Eurasia. Located at the crossroads of Western Asia and Eastern Europe, it is bounded to the west by the Black Sea, to the north by Russia, to the south by Turkey and Armenia, and to the southeast by Azerbaijan. The capital of Georgia is Tbilisi. Georgia covers a territory of 69,700 square kilometres (26,911 sq mi), and its population is almost 5 million. Georgia is a unitary, semi-presidential republic, with the government elected through a representative democracy.

Georgia has made significant progress in confronting its epidemic of tuberculosis and multidrug-resistant tuberculosis (MDR-TB) since late nineteenth. The World Health Organization (WHO) estimates that the overall TB incidence, mortality and prevalence rates in Georgia have been falling steadily since the year 2000². To sustain this success in the context of ongoing fundamental reforms of the health system, this Plan addresses the main challenges Georgia faces, including drug resistance, TB in prisons, and the need for the commitment of domestic resources to sustain the effort when donor funding decreases.

The context for TB control is changing as Georgia is fundamentally reforming its health system. The majority of both primary health care facilities and hospitals have been privatized, and coverage with state funded health programs has expanded.³

In 2012, most TB dispensaries were absorbed into private general medical facilities. Some of the responsibilities for the national TB program have been transferred from the National Center for TB and Lung Diseases (NCTBLD) to the National Center for Disease Control and Public Health (NCDC), and currently both centers are partially responsible for TB surveillance, key parts of the TB laboratory network, and the of initiation of TB contact investigations. The different levels of expertise and experience of the current players in TB control and the lack of clarity in the roles and responsibilities of these players cause challenges to and weaknesses in the TB control system, including e.g. delay in sputum transportation to laboratories. Intensive consultations are ongoing to overcome these problems and strengthen TB control at all levels. Further to these health system and

institutional reforms, the national clinical practice guidelines and protocols need to be finalized and introduced, as well as a TB monitoring plan to assure accountability of the new TB service providers.

One of the major challenges remains MDR-TB and TB/HIV co-infection. TB and HIV control activities are not very well integrated. Analysis of the 2009 cohort of MDR-TB patients showed a high default rate. Georgia has implemented diagnostics for rapid detection of TB and drug resistance, enabling Georgia to identify 63% of the estimated MDR-TB cases among notified TB cases in 2011. However, this suggests that about one third of the MDR-TB cases were not detected and, hence, continues to transmit this drug resistant form of disease. Currently a number of essential TB control functions are largely depending on The Global Fund project and the United States Agency for International Development (USAID) TB Prevention Project, which both end in 2015, after which country has to sustain TB control through domestic resources.¹

Georgia has strong political commitment to protecting its population from TB. The National Health Care Strategy commits MoLHSA to adhere to the strategic plan for TB control, and aims to reduce the TB prevalence by 25% in 2016 compared to 2005. In order to guide the complex transition from a vertical towards an integrated TB service delivery model CCM/MoLHSA developed and adopted the National TB Strategy for 2013-2015.² The strategy aims to serve as a road map for national and international stakeholders in planning and implementing specific activities for reducing the TB burden in the context of Georgia's health reform. It is guided by the following principles¹

- Equal access to health services
- Patient-focused
- Affordable and efficient
- Public-private partnerships and competition
- Transparency and public involvement
- Adequacy of resources
- Intersectoral approach.

The national TB strategy and all parties in the new Georgian health system recognize the need to strengthen DOT (Directly Observed Treatment) of TB cases with anti-TB and Multi-Drug Resistance (MDR) -TB drugs throughout the country. Key components of the DOTS strategy are diagnosis and treatment monitoring by sputum smear microscopy. As DOTS is expanded to cover increasing portions of the population TB laboratory networks must be reinforced to meet these needs and with the ability to provide high quality and reliable laboratory services.

2.2 Scope of this Project

2.2.1 Purpose of this assignment:

Purpose of this assignment is to make recommendations for the development a TB laboratory network strengthening plan for Georgia. The plan should be based on assessment of current lab capacity and its functional characteristics (including

staffing level, reviewing proficiency in performing conventional and new WHO endorsed technologies, availability of quality assurance measures, biosafety.

3 Chapter 2: TB LABORATORY NETWORK ASSESSMENT IN GEORGIA

3.1 Introduction

The laboratory is an essential part of the diagnosis, treatment, prevention, and control of TB. Delays in laboratory confirmation of TB and reporting of drug-susceptibility results can lead to delays in initiation of therapy, prolonged infectiousness, inappropriate therapy, and missed opportunities to prevent transmission.⁴

In the early 1990s, such delays contributed to the resurgence of TB and the emergence of multidrug-resistant TB (MDR TB) in Georgia. In response to the very real threat and high incidence of MDR TB, this project aims ultimately to strengthen TB testing laboratories in Georgia and places emphasis on providing prompt and reliable laboratory results.

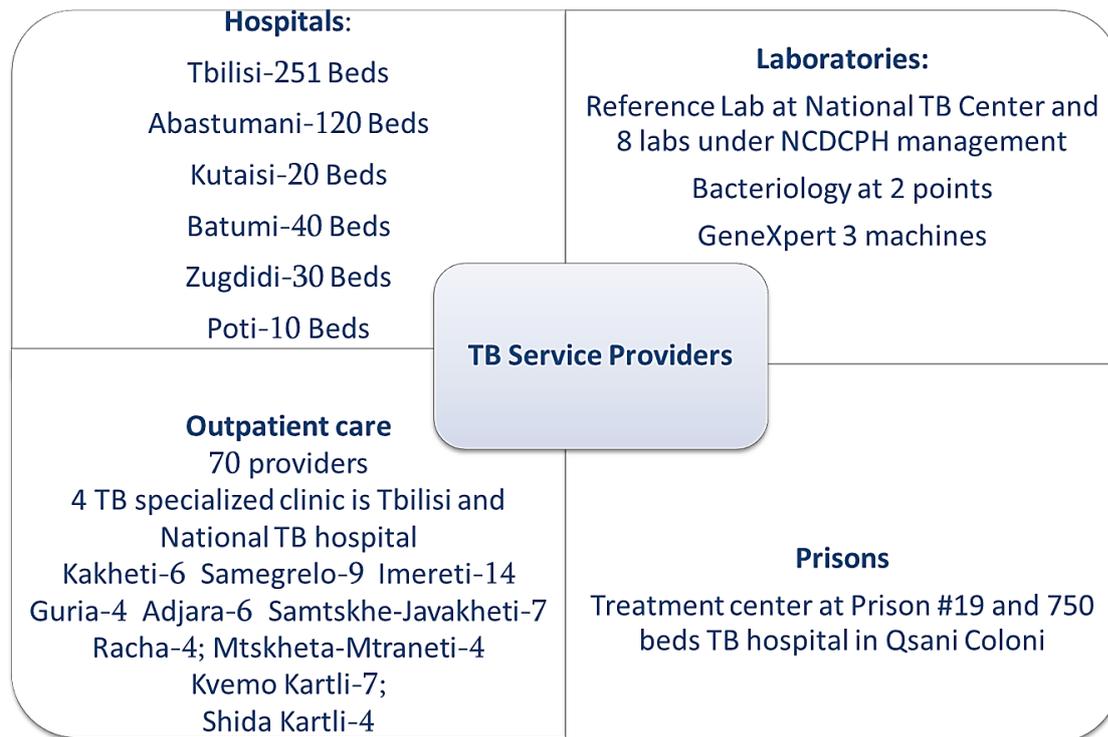
3.2 Organization of TB Laboratory Services in Georgia

Until December 2011, TB care had been provided as a vertical programme in Georgia. The programme was headed by the NCTBLD in Tbilisi. There were TB clinical and monitoring specialists working in each region through TB dispensaries. There were also TB “cabinets” located under the jurisdiction of TB dispensaries, and there were “DOTS Spots” throughout urban regions. All labs had been run by the NCTBLD until December 2011.

There are 5 civilian hospitals with 400 beds for TB care:

- 1 in Tbilisi (NCTBLD):- the national reference TB hospital
- One each in Abastumani, Batumi, Kutaisi and Zugdidi. – Some of these are general Infectious Diseases Hospitals with beds dedicated to TB care (e.g. Batumi). (See figure 1 for a complete listing of TB treatment facilities throughout Georgia).

Figure 1.: Listing of TB treatment and diagnostic facilities throughout Georgia

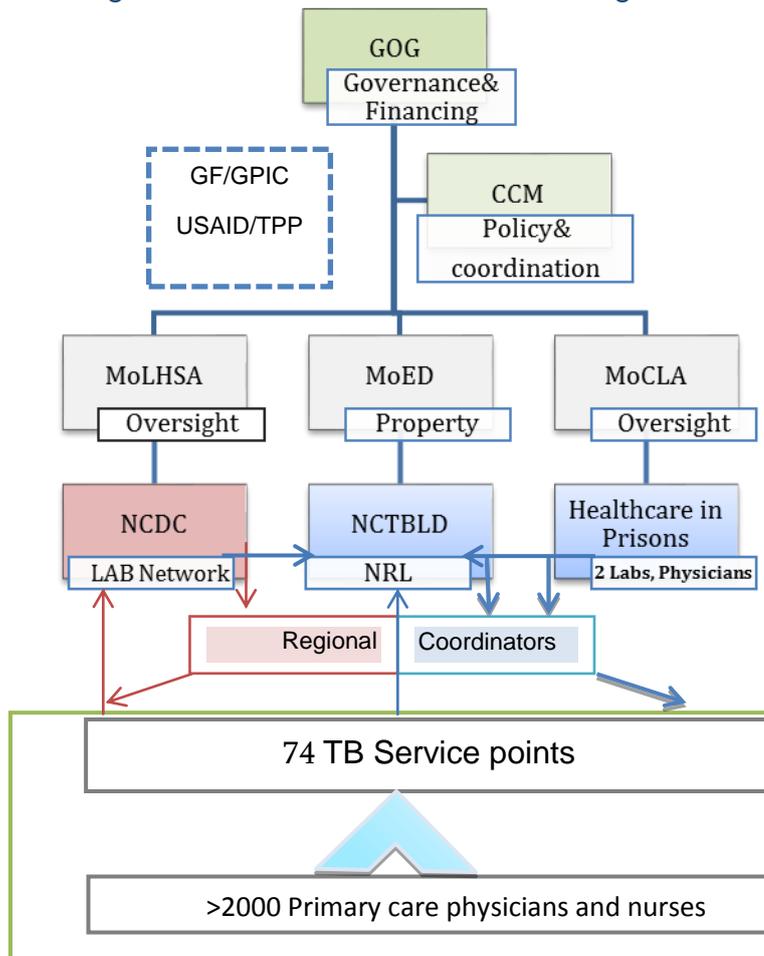


The Ksani prison hospital is a new facility. Prison reform and a general amnesty decreased the number of prisoners from around 24000 to about 7000 in 14 prisons. This release included many TB patients with the result that the hospital is now under-utilised with 30% bed utilization rate in 2013. The prison TB programme is fully integrated into the National TB programme including reporting, monitoring, training, patient education.

In remote regions, TB care can be provided by village doctors and nurses with supervision from the NCTBLD and local TB cabinets. Access to primary care and TB specialised services are fully covered by the state within Universal Health Coverage and TB State Programs. Therefore there is no financial barrier that may prevent Georgian citizens to seek medical care for TB.

Georgia's recently re-organized laboratory network consists of the National Reference Laboratory (NRL) in the capital, a regional laboratory in Kutaisi, eight peripheral smear microscopy laboratories in the civilian sector and two in the prison system (Figures 1 and 2). The NCTBLD is responsible for the NRL and the prison laboratories, while the NCDC is responsible for the regional and civilian peripheral laboratories, as well as collection of specimens from 65 local TB service points and transporting samples to peripheral laboratories for smear microscopy, and to Kutaisi and NRL for culture and drug susceptibility testing (DST). Figure 2 below shows this new arrangement.

Figure 2. Organization of TB Treatment and Diagnostic Services



For the last decade, a total of 150 new hospitals and primary health care service centres were built throughout the country. Besides providing in-patient care, these service centres house primary care physicians and nurses and offer a range of clinical sub-specialities. They also have X-ray facilities and clinical laboratories.

TB care will now occur within these primary care facilities. The previous physical TB care structure of regional TB dispensaries, cabinets and “DOTS Spots” have now all been physically integrated into these general care medical facilities. Under this model, the 5 TB care hospitals mentioned earlier will remain open and provide in-patient care for all patients with known or suspected TB needing in-patient services. This includes a growing number of patients with drug-resistant TB.

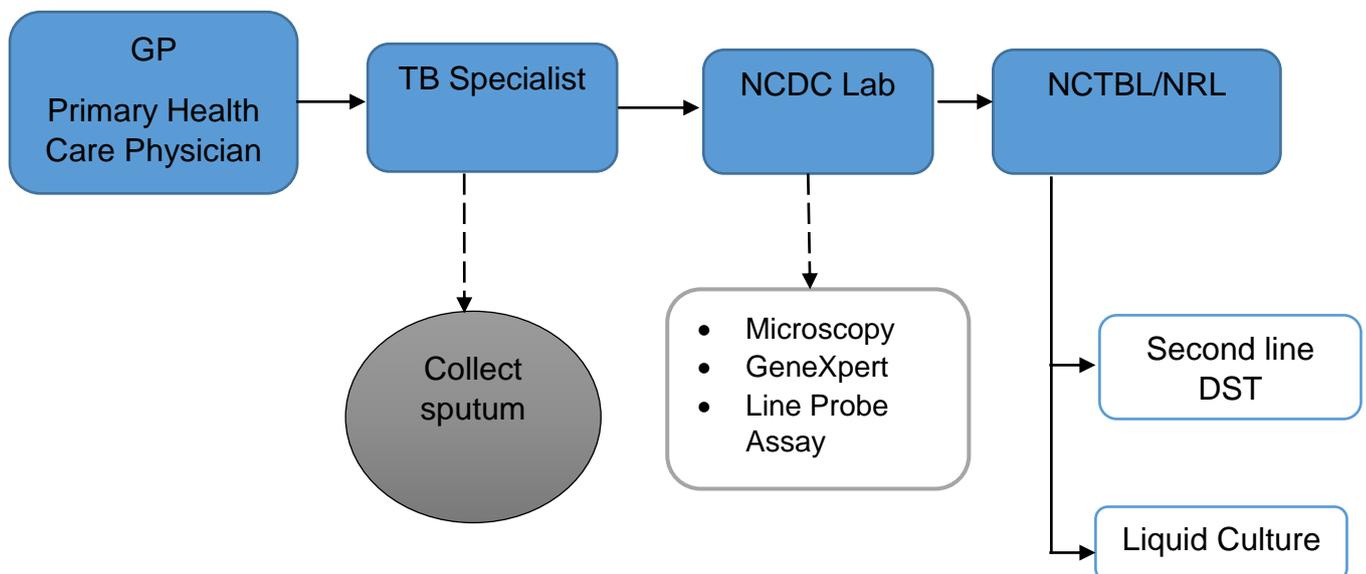
In sum, there are now multiple public and private stakeholders tasked with TB control in Georgia. These include:

- NCTBLD
- NCDCPH with the Global Fund Project Implementation Unit
- NGOs
- The private clinic owners and investors

The NCTBL/NRL reference lab in Tbilisi remains the referral lab for the country. Other lab services are now being managed by the NCDCPH. This has been done by moving previous local hospital based TB microscopy services to the network of 10 NCDCPH labs throughout the country. These labs are responsible for collecting sputum (and other specimens) from the general medical service centres, transporting this sputum to the NCDCPH labs, and performing smear microscopy on them.

Cultures and full DST is done by the NRL in Tbilisi, including **GeneXpert molecular testing**. TB cultures plus Hain molecular testing is done in Kutaisi. The NCDCPH is responsible for sample flow, including returning results to the general medical facilities. The NCTBLD also assists with the transport of specimens and results. The NCDCPH labs are well-equipped and have proficiency testing provided through a quality monitoring programme of the Centres for Disease Control (CDC, USA). See figure 3 for patient flow within the TB screening system.

Figure 3: Patient flow within the TB screening system



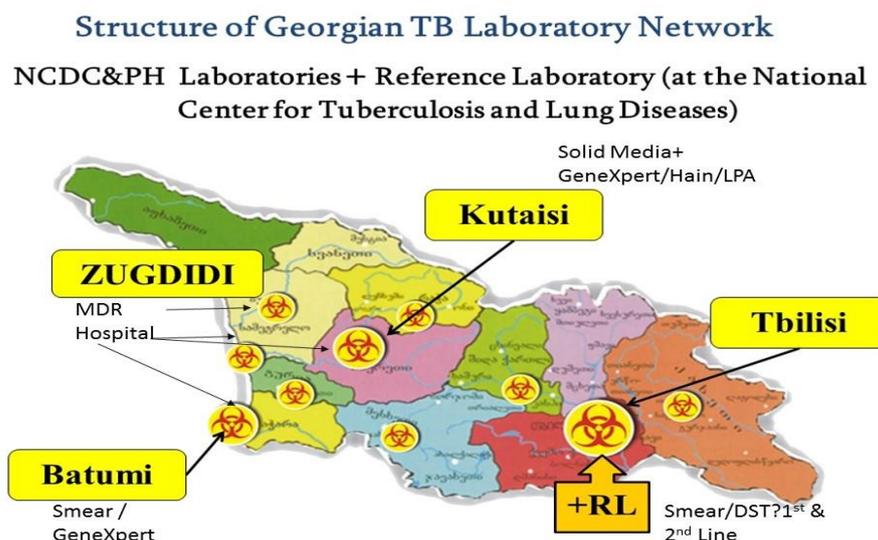
3.3 TB testing resources in Georgia

Georgia successfully implemented routine culture in 2006, then liquid media (MGIT) methods in 2008 and line probe assay (LPA, Hain) in 2010. LPA allows drug resistance to be detected in one and MGIT in about fourteen days, rather than the 42 days or more it takes when solid media alone is used. Georgia has achieved what WHO considers complete routine drug resistance surveillance.¹

According to the country's diagnostic algorithms, specimens received in Kutaisi or Tbilisi within four days of specimen collection can be analysed using MGIT. In 2011, following the reorganization of laboratory network, about 35% of specimens either arrived too late or experienced other problems that made liquid media testing not possible. In June 2012, the GDF and GLC missions reported that the time to receive diagnostic results has increased.⁵ It is partially determined by formal procedures that should be followed by laboratory staff during transferring the

documented test results to the treatment points. According to these procedures, lab results should be sent as a hard copy or electronically. Figure 4 below shows the present relative disposition of TB testing resources throughout Georgia.

Figure 4: Disposition of TB testing Resources throughout Georgia



By way of example, GeneXpert was introduced to two regional centres in Adjara and Imereti in late 2013. The table 2 below presents results for the first five months of operation and shows an encouraging uptake of the technology.

Table 2: GeneXpert Throughput in 1st 5 months of operation at 2 sites

ADJARA GeneXpert: 2014						
	January	February	March	April	May	Total
TB (+)	2	5	11	6	13	37
TB (-)	20	32	34	24	57	167
No Result	0	4	0	0	1	5
Total Results	22	41	45	30	71	209
Average monthly workload per lab staff	11	20.5	22.5	15	35.5	20.9
Average daily workload per lab staff	0.52	0.98	1.07	0.71	1.69	1.00
IMERETI GeneXpert: 2014						
	January	February	March	April	May	Total
TB (+)	5	17	12	14	14	62
TB (-)	36	60	63	75	65	299
No Result	0	1	0	0	0	1
Total Results	41	78	75	89	79	262
Average monthly workload per lab staff	6.8	13	12.5	14.8	13.2	60.3
Average daily workload per lab staff	0.33	0.65	0.6	0.7	1	2.90

With donor support, the country has implemented new technologies successfully. The recommendations made herein will expand and strengthen the laboratory network now and after 2015 when donor support is anticipated to decrease.

3.4 TB Facts

Georgia is among 27 countries with high MDR TB burden. According to the WHO Global TB Report 2013, the TB prevalence in Georgia is 158 per 100,000 population and the incidence is 116 per 100,000. The treatment success rate for TB in new smear and culture positive cases is 76% and no more than 50% among MDR TB cases. In 2013 a total of 4206 patients were registered for treatment in the National Tuberculosis Programme (NTP)⁶. Of these, 3081 were new cases and 1125 were previously treated patients (see Figure 4). See tables 4 and 5 for incidence and prevalence rates and trends in case notification.

Figure 5: All Registered TB cases in Georgia (absolute numbers) 1999-2013

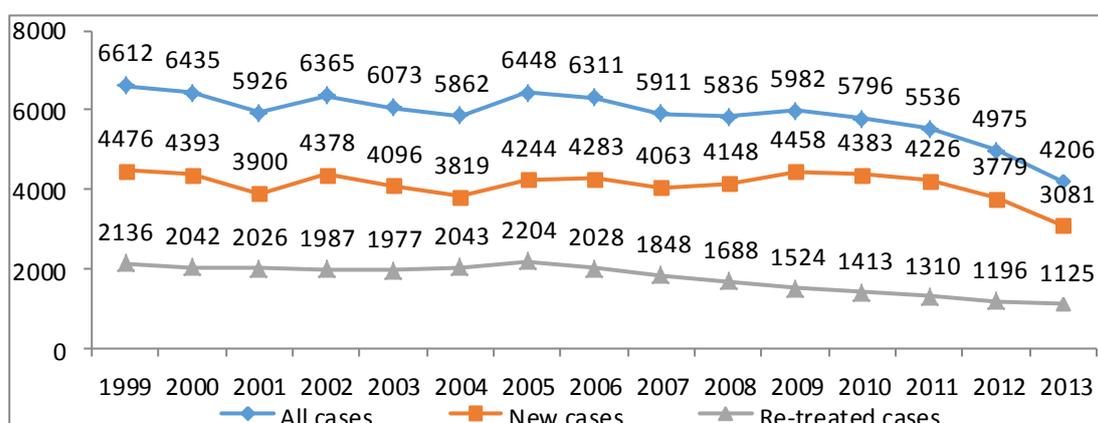


Table 3: Incidence, prevalence and mortality rates 2008-2012.

Year	Incidence	Prevalence	Mortality
2008	94.3	132.7	4.2 (vital registration)
2009	101.1	135.6	3.4(vital registration)
2010	98.5	130.2	2 (vital registration)
2011	94.3	123.5	3.5 (vital registration)
2012	84.2	110.9	3.9 (vital registration)

3.5 Case Findings and Programme Performance Data

Table 4: TB case notification (2009-2012)

Case notifications ⁵	2009		2010		2011		2012	
	#	%	#	%	#	%	#	%
New Cases								
Smear positive	2056	46.1	2140	48.8	2026	48	1651	43.6

Smear negative	1057	23.7	1033	23.6	1094	25.9	1141	30.1
Smear unknown	62	1.4	55	1.2	47	1.1	47	1.2
Extra pulmonary TB	1283	28.8	1155	26.4	1056	25	950	25
Other	0	0	0	0	0	0	0	0
Total new	4458	100	4383	100	4223	100	3789	100
Retreatment cases								
Relapse	275	18.1	291	20.7	324	24.7	164	13.5
Treatment after failure	91	6	63	4.5	60	4.6	105	8.6
Treatment after default	184	12.1	162	11.5	125	9.5	122	9.8
Other	968	63.8	893	63.4	801	61.1	805	68.1
Total retreatment	1518	100	1409	100	1310	100	1196	100

Figure 6 and table 5 show regional distribution of TB cases, indicating concentration of cases in large cities e.g. Tbilisi, Zugdidi, Batumi and Kutaisi.

Figure 6: Suspected and Confirmed TB Cases by Region

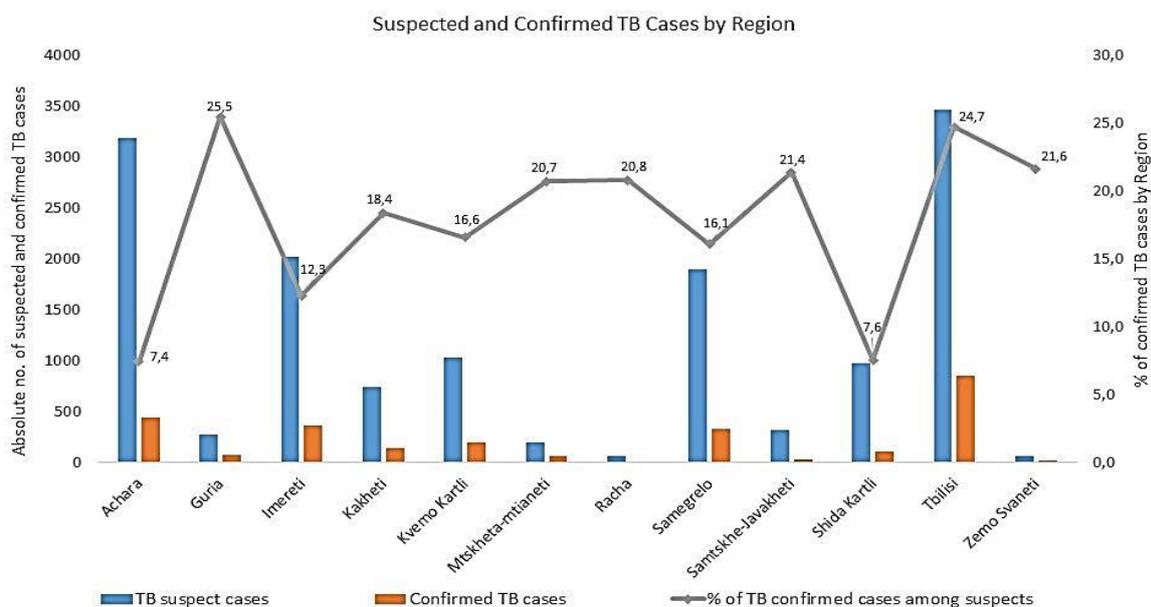


Table 5: TB suspect and confirmed cases by Region

Region	TB suspect cases	Confirmed TB cases	% of TB confirmed cases among suspects
--------	------------------	--------------------	--

Adjara	3184	446	7,4
Guria	274	74	25,5
Imereti	2023	363	12,3
Kakheti	746	148	18,4
Kvemo Kartli	1028	201	16,6
Mtskheta-mtianeti	202	62	20,7
Racha	66	13	20,8
Samegrelo	1899	329	16,1
Samtskhe-Javakheti	325	34	21,4
Shida Kartli	975	112	7,6
Tbilisi	3461	856	24,7
Zemo Svaneti	65	17	21,6

The table 5 confirms that TB confirmed cases by microscopy are very high in some regions, well above the expected 10%. This implies that patients seek care, are referred and diagnosed by microscopy when they are already sputum-positive.

Table 6: Case Findings – reporting period 2012

TB case category	All cases	% All	Children 0-4	Children 5-14	% Children
New cases	3778	75.9	69	146	100
Smear+ve Pulmonary TB	1648	33.1	0	9	4.2
Smear – Pulmonary TB	1186	23.8	7	12	8.8
Extra-pulmonary TB	944	19	62	125	87
Previously treated Smear + PTB cases	630	12.7	0	0	0
Relapse	161	3.2	0	0	0
Treatment after interruption (Defaulters)	87	1.7	0	0	0
Treatment after failure	102	2	0	0	0
Other cases	846	17	0	0	0
Total	4974	100	69	146	100

As showed on figure 4 above, in 2009 a total of 5982 cases were registered, dropping to 4206 in 2013. Retreatment cases dropped from 1524 to 1125 in the same period. However, 68% (805 patients) were registered as other treatment cases. These are patients who had known previous anti-TB treatment status. Of these, 363 were Culture-positive; 441 were Culture –negative/not done/unknown. This large number (68%) bears further investigation.

Also of concern, was the decrease in smear positive case detection of 2026 in 2011 to 1651 in 2012. This concern is based around the fact that the number of smear microscopy labs decreased from 36 to 10 in that year as well as problems with transportation of samples to the testing labs. Family doctors and GPs are not allowed to send patients for sputum examination directly to a lab. Only patients

who have TB symptoms and who have been screened by a TB examiner are eligible for sputum collection and for the sending of the sputum to the NCDC lab.

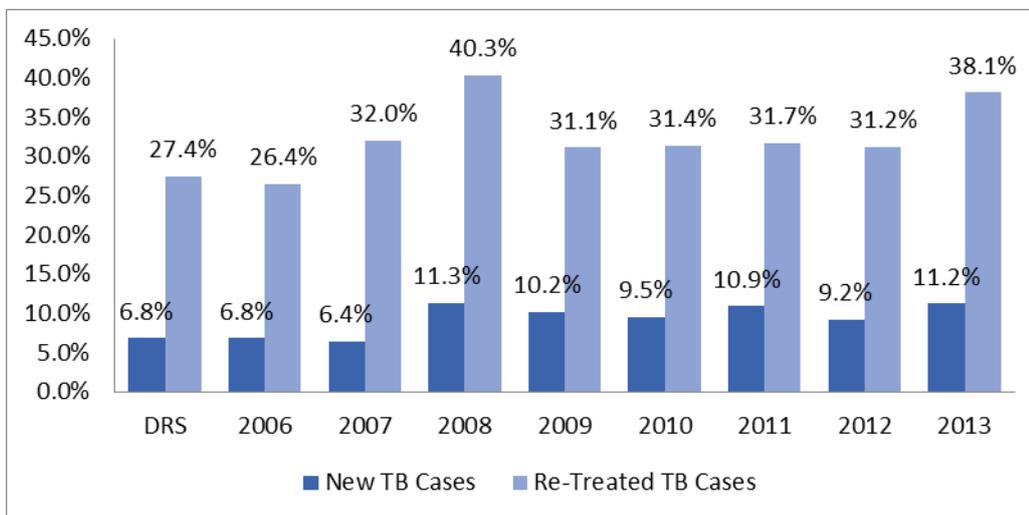
As well, TB in prisons is of concern. While active TB screening using a symptoms questionnaire was introduced recently, in an effort to improve case detection, there is no X-Ray equipment within prisons. 20% (1:5) of cases notified nationwide in 2011 was for prison inmates – effectively 1172 cases were reported in the prison system (21% of all reported cases) for 2011 and dropping down to 208 in 2013 (5%).

This drop off mirrors the national drop off rate and coincides with the period when the healthcare system was privatised. Read against the high number of suspected sputum-positive cases being reported regionally, it suggests that there is a disconnect between screening and diagnosis as TB-suspected cases are on the increase but TB cases themselves are in decline.

3.6 MDR-TB and HIV Co-infection

One of the major challenges remains MDR-TB and TB/HIV co-infection. TB and HIV control activities are not very well integrated. Analysis of the 2009-2013 cohorts of MDR-TB patients showed a high default rate (26-8 to 29.7%) . Georgia has implemented diagnostics for rapid detection of TB and drug resistance, enabling Georgia to identify 63% of the estimated MDR - TB cases among notified TB cases in 2011. See figure 6. ⁶

Figure 7: New and re-treated TB cases in Georgia



Georgia’s first MDR-TB cohort began treatment in 2008. The number of MDR-TB patients started on MDR-TB treatment in 2011 exceeded the numbers confirmed that year because 125 were empirically treated, and 137 were confirmed in prior years.

Georgia achieved universal access to MDR-TB treatment in 2009. However, a treatment completion rate is not high and nearly one third of the 2009 cohort was

lost to follow up, not evaluated, or transferred with no final outcome obtained. The country uses WHO reporting forms except that interim outcomes (at 6 months) are not routinely collected, so the timing of loss to follow up, death or failure is unknown.

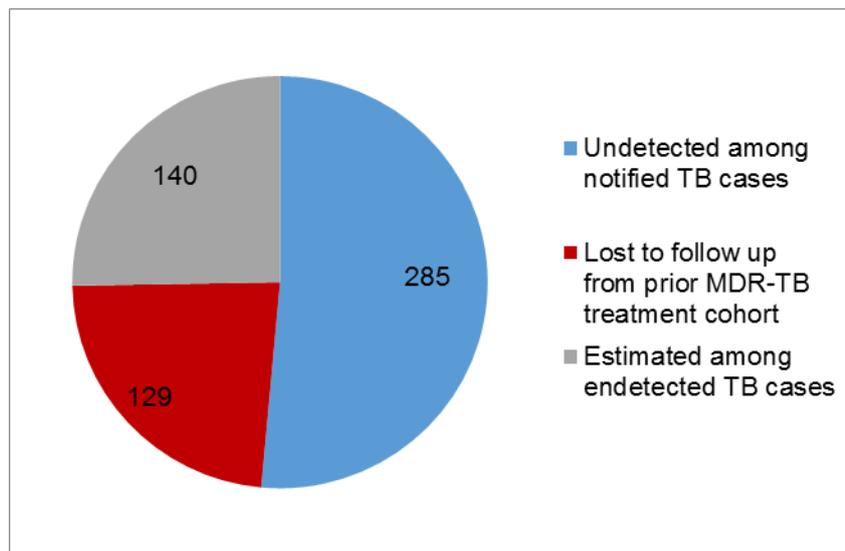
The Global Fund project supports patient incentives for treatment adherence and transportation reimbursement. However, the extent to which patients' social, psychological or economic needs are systematically assessed and addressed is unknown. Barriers to treatment adherence by MDR-TB patients have not been fully explored.

The GLC mission in June 2012 found that nurses in prisons have insufficient support and time for administering MDR-TB medicines. This results in patient refusals, treatment interruption and substandard therapy. The GLC mission raised the concern that substandard regimens administered in prison increase the risk of acquired drug resistance generating XDR-TB.⁵

While there is no waiting list for MDR-TB treatment, the one central consilium has a heavy workload. The GLC Mission was concerned that this is leading to delays in treatment initiation, and insufficient time for regular case discussions that would improve case management, drug management and program monitoring.⁵

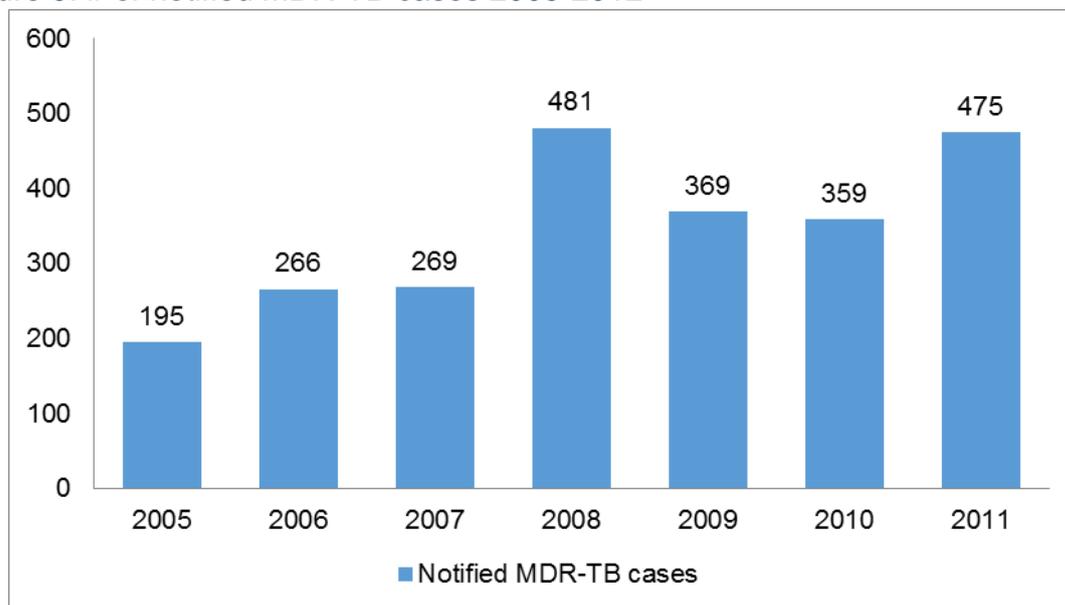
If drug resistance testing were performed for all the new pulmonary and all the previously treated patients notified in 2011, WHO estimates that Georgia would find 760 MDR-TB cases.⁽⁸⁾ In 2011, the National Reference Laboratory confirmed 475 MDR-TB cases, or 63% of the estimated 760 occurring that year among TB notifications. This suggests that the remaining 37% (285 MDR-TB cases) were not detected, not appropriately treated, and remain at high risk of death. It also means that over one third of the MDR-TB cases among the country's notifications are likely to remain infectious and spread MDR-TB to others. They form one segment of the reservoir of infectious MDR-TB patients (*Figure 7*). Another segment is the 129 MDR-TB patients who began MDR-TB treatment in the last cohort (2009) but were lost to follow up, had no outcome evaluated, or whose treatment failed. Finally, there are likely to be another 140 cases of MDR-TB among the 900 patients whose TB cases was not detected.¹

Figure 8: Uncured MDR-TB cases



The absolute numbers and notification rates of confirmed MDR-TB cases have risen from 2005 to 2011, corresponding to increasing MDR-TB testing as the country implemented routine drug susceptibility testing for all patients in 2008 (Figure 9: # of notified MDR-TB cases 2005-2011)

Figure 9: # of notified MDR-TB cases 2005-2012



In 2011, 440 of the 475 confirmed MDR TB patients were tested for resistance to a fluoroquinolone and a second-line injectable agent; 28 (6%) were found to have extensively drug resistant TB.

In Georgia, 12-13% of new and previously treated pulmonary TB cases were found to have isoniazid resistance in 2011. Inadequate treatment can generate MDR-TB if these patients acquire resistance to rifampin.

Children: In 2011, 206 children under the age of 15 were reported with TB, and comprised 4% of the country's total TB cases. The TB case notification rate for this age group has fallen markedly from 88.8 per 100,000 in 1998 to 27.1 per 100,000 in 2011 (*NCTBLD*). Similarly the number of cases of TB meningitis has fallen from 28 in year 2003, to 2 to 3 per year from 2009-2011. This form of TB is particularly devastating as it has a high risk of death or chronic neurologic disability.

3.7 The Laboratory Network Assessment Tool

This assignment⁷ employs a Laboratory Network Assessment Tool in order to develop TB laboratory network strengthening plan for Georgia. The plan will be based on an assessment of current lab capacity and their functional characteristics. These include:

- staffing levels
- reviewing proficiency in performing conventional and new WHO endorsed technologies
- availability of quality assurance measures
- biosafety

3.7.1 Outcomes of the assessment

The assessment will:

- provide information in a standardized way on the health laboratory administrative organization and environment
- provide a snapshot of a representative sample of laboratories at various levels
- identify strengths and weaknesses of the health laboratory system
- raise awareness on the laboratories' performance at country level
- provide objective data to national decision -makers for planning and implementing laboratory capacity strengthening activities

3.7.2 The assessment method

To fully assess the laboratory system, two sorts of areas need to be addressed: strategic organization and support at the national level from the government (e.g. defining policies and regulatory framework), and specific technical capacities at the laboratories level. Therefore, the following assessment protocol is based on two complementary phases:

1. Assessment of the structure, organization and regulations of the national laboratory system(s) through collection of data at central level (and intermediate/peripheral level if time and resources allow and/or if health authorities are decentralized) using interviews or meetings.

2. Assessment of a limited number of laboratories that are representative of the national laboratory system and its organizational structure. It is recommended to assess laboratories from different entities or networks, operating under different status and funding mechanisms (public and private sector, hospital and academic sector, faith-based facilities, military facilities) and from each level of the health care delivery system (primary, secondary and tertiary, if any) and administrative organization.⁸

3.7.3 Results and outcomes of the Laboratory Network Assessment

Two regional laboratories at Adjara and Imereti were assessed as representative of the national laboratory system and its organizational structure. The tools described in Appendix 2 were used as the main instrument for data gathering.

I. Basic information on the country to be assessed

1. The name of country: **Georgia**
2. Population: **4,487,200 (2013 est.)** Rural population = **about 47% of total Population**
3. NTP manager & head of the National TB Reference laboratory (NTRL) or equivalents:

	NTRL head or equivalent	NTP head or equivalent
Name	Dr Rusudan Aspindzelashvili	
Address	50 Maruashvili Str Tbilisi	
Telephone	+99532 2309991	
Fax	+995 32 291 0251	
Email	asporusiko@yahoo.com	

4. TB patients notified in the previous year: **2013**

Pulmonary tuberculosis			Smear-Negative/ unknown	Extra-Pulmonary TB	Total
Smear-positive					
New	Retreatment	Total			
1334	1187	2521	1078	721	4320

If national level data is not available, it can be replaced with regional or local data with clear description of the source.

Notification of TB cases- Regional distribution- 2013

#	Region	Pulmonary TB								Extrapulmonary TB		Total number			Population
		All registered Cases				New cases				All registered	New cases	All registered cases	New cases	Re-treated cases	
		AFB(+)	AFB(-)	AFB(NA)	Total	AFB(+)	AFB(-)	AFB(NA)	Total						
1	Tbilisi	641	425	27	1093	444	315	25	784	272	239	1365	1023	342	1173200
2	Mtskheta-Mtianeti	46	20	0	66	38	13	0	51	24	20	90	71	19	108900
3	Kakheti	129	57	2	188	82	47	2	131	58	53	246	184	62	405000
4	Shida Kartli	98	81	1	180	72	57	1	130	47	41	227	171	56	313700
5	Kvemo Kartli	174	125	1	300	124	85	1	210	76	65	376	275	101	512100
6	Imereti	193	155	2	350	140	112	1	253	115	102	465	355	110	703600
7	Guria	47	58	1	106	39	43	1	83	21	19	127	102	25	139000
8	Samegrelo	221	190	2	413	159	126	2	287	81	73	494	360	134	476600
9	Samckhe-Javakheti	29	51	1	81	17	29	0	46	13	13	94	59	35	213600
10	Adjara	222	277	5	504	162	176	5	343	79	73	583	416	167	395400
11	Racha-Lechkhumi	17	5	0	22	12	3	0	15	3	3	25	18	7	46100
12	prisons	96	105	0	201	45	34	0	79	27	20	228	99	129	9800
	Total	1913	1549	42	3504	1334	1040	38	2412	816	721	4320	3133	1187	4487200

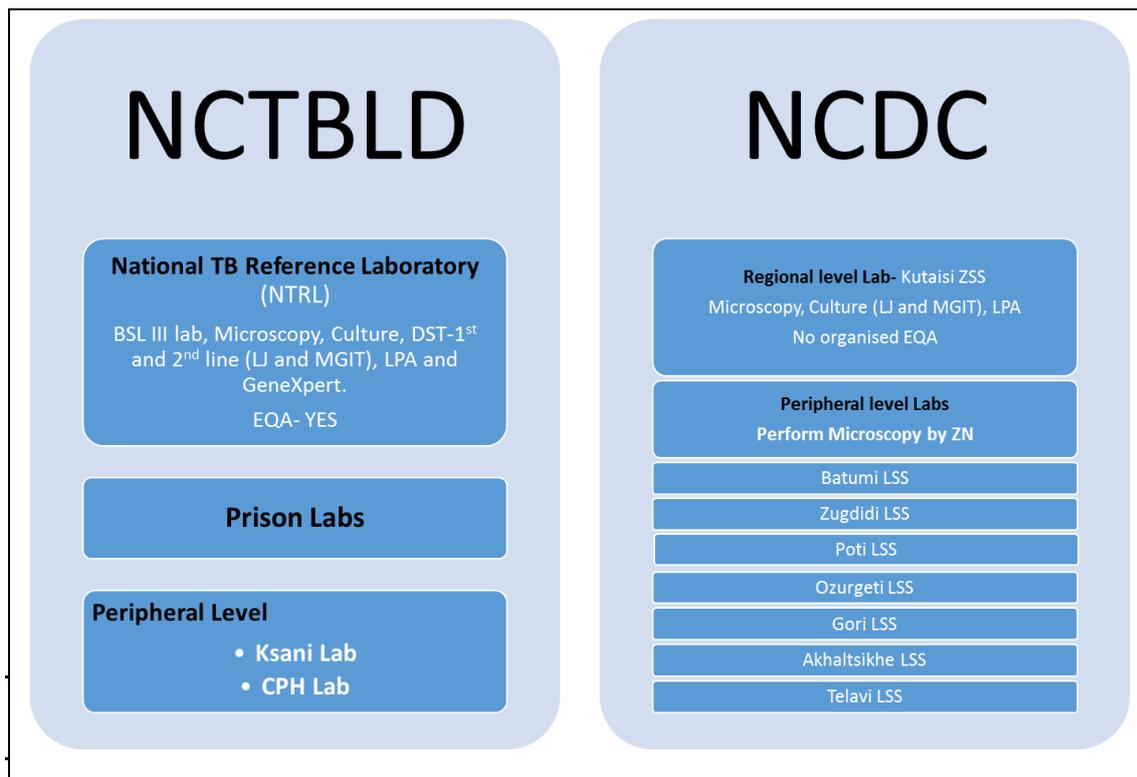
2. Structural and functional profile of the laboratory network for the NTP

TB laboratory services should be organized taking into account accessibility to the entire population and provision of all the necessary services for efficient TB case-management. The NTP of some countries has a built-in or fully integrated laboratory network, while in other countries TB laboratory services are integrated into the general health system or provided by completely independent organizations at some or all levels. When the laboratory network is independent from the NTP, coordination must be established to ensure functional integration of the network into NTP to provide comprehensive TB case-management.

(1) **Structural profile (public sector):** please write the number of health facilities in the table below

Level of the service	No. of functional facilities	No. doing AFB-microscopy
Central	1 (NCTBLD)	1 (NCTBLD)
Intermediate	1 (NCDC)	1 (NCDC)
Peripheral	8 (NCDC)	8 (NCDC)
Total number	9	9

Figure 10. Structural profile of TB laboratory network



TB Diagnostic Labs: Akhaltsikhe LSS; Batumi LSS; Foti LSS; Gori LSS; *Kutaisi ZDL*; Ozurgeti LSS; **Tbilisi NRL**; Telavi LSS; Zugdidi LSS. **Prisons:** Ksani Prison TB hospital, and CPH

Please describe the relationship of every level of laboratory with the NTP, according to the classification system described here below:

A= TB laboratory system fully integrated structurally (defined as budget, staff, and organization) and functionally (defined as operational) into the NTP

B= TB laboratory system separated structurally but functionally integrated through recording/reporting mechanisms, supervision & QA

C= TB laboratory system separated structurally from the NTP but reporting to the NTP with supervision & QA of laboratory services undertaken by another agency (describe the over-all system in which TB laboratory system is placed)

D= Other relationship – describe

D description:

Georgia's has a reorganised laboratory network consisting of the National Reference Laboratory (NRL) in the capital, a regional laboratory in Kutaisi, eight peripheral smear microscopy laboratories in the civilian sector and two in the prison system. The NCTBLD is responsible for the NRL and the prison laboratories, while the NCDC is responsible for the regional and civilian peripheral laboratories, as well as collection of specimens from 65 local TB service points and transporting samples to peripheral laboratories for smear microscopy, and to Kutaisi and NRL for culture and drug susceptibility testing (DST). In 2011, 21% of the nation's TB cases were reported from prisons. Subsequent to the Health reform in 2012, erstwhile TB dispensaries in the

rayon's were integrated into private general medical facilities. However, the TB service in Tbilisi, and TB hospitals in the country were not privatized.

Are there problems with coverage for AFB-microscopy, even if only in some areas:

- **over-decentralisation?**

TB treatment facilities are disproportionate to TB diagnostic labs

- **poor accessibility?**

1. *Sub-optimal sputum/specimen transport network leading to extended delays in testing sputum and result feed-back. Post office based, or transport vehicle are used for specimen referral. Sometimes, long distances from the PHC to labs were noticed as reason for long Turnaround times for test results.*
2. *In Georgia, only TB doctors can order laboratory testing for TB, so TB diagnosis relies on referral from PHC providers. Delayed referral from PHC providers to TB doctors is identified as the prime reason for very high TB positivity (up to 31%) in PHC specimens.*

Please describe possible existence, role and level of integration of specialised TB services (for TB diagnosis besides treatment):

- *TB hospitals exist.*

Including National level TB referral hospital (NCTBLD), there are 5 TB hospitals. Two prisons have TB hospital services. About 6 hospitals provide care for patients on M/XDR treatment.

- *TB outpatient clinics: Several TB outpatient clinics exist.*

**Is there a problem of referral / transfer of diagnosed patients from these facilities?
Is there a special hospital or wards for MDR-TB? If yes, describe the hospitalization policy for MDR-TB.**

MDR-TB is mainly managed from NCTBLD, at Tbilisi (Hospital and TB BSL 3 laboratory).

Is there already an important involvement of the private sector in TB (lab) diagnosis?

Primary care and hospitals are privatised as a result of reforms of health systems. However, TB diagnostic labs are managed still under the Government. There is a great scope for involvement of private diagnostics facilities in the country for TB control- both for early TB diagnosis and prompt treatment initiation. This is can be achieved by introduction of rapid and fully automated molecular MDR-TB diagnostics.

(2) Functional profile (public sector)

Please specify availability (level, number or names of institutions if few) and use of other bacteriological methods:

- **Culture** : 2 labs- NCTBLD and Kutaisi ZDL- both by LJ solid media and MGIT liquid

media systems

- **DST:** 2 labs as mentioned above for culture; use both LJ and MGIT methods for First and second line DST
- **Fluorescence microscopy:** Not utilized for case detection
- **molecular diagnosis of drug resistance:** Line Probe assay (LPA)- (1 Lab- Kutaisi ZDL) and GeneXpert (at 3 sites, presently- plans to extend)

(3) NTP Laboratory Guidelines

a) Is there a national TB laboratory manual? (please attach)

-YES (at NTRL level and distributed to periphery laboratories)

b) What are the NTP guidelines standard procedures for smear microscopy?

- **Smear preparation:** **Direct smear** / ~~concentrated smear~~ / both
- **Stains:** **Ziehl-Neelsen carbol-fuchsin** / ~~Kinyoun carbol fuchsin~~ / fluorescence
- Where are the staining solutions prepared? ~~Peripheral laboratories/ Intermediate laboratories/~~ **Central laboratory**
- Do those laboratories have equipment and supplies essential for preparation of stains?

YES, adequate

c) What are the NTP guidelines for the use of culture: for diagnosis of smear-negative TB? Only as first step for DST? describe the indications in case a policy exists

- Media and culture system used?
- Decontamination technique used?
- How are samples neutralised? If repeated washing is performed, are centrifuges sufficiently powerful (3000 g, not just RPM)?
- Is incubation properly done (temperature, time)?

Standard methods used for both LJ and MGIT methods, as per international requirements. Specimens are decontaminated prior to Culture. According to the country's diagnostic algorithms, specimens received within four days of specimen collection, at the two culture labs (Kutaisi or Tbilisi-NCTBLD), are tested using MGIT. Beyond 4 days of date of collection of sputum, they are tested by LJ solid media. About 35% of specimens either arrived too late or other problems make liquid media testing not possible.

Flow of patients: Nurses collect sputum for presumptive TB individuals, and screening by a questionnaire. Only TB doctor can sent sputum for examination. Specimens are transported with cars to 8 NCDC laboratories for smear as well for other examination according doctor prescription. Sputum specimens are collected by a nurse. Samples for molecular testing are sent to NRL from 3 LSS only. Others send specimens to Kutaisi. Samples are batched- testing twice a week. Results are usually provided, the next day of testing. NCDC send specimens to Tbilisi for culture, molecular examination, DST, as per TB doctor's request. Thus, this referral system is not optimal causing extended delays at all levels, and 'late' diagnosis of TB and MDR-TB.

NSP 2013-15, targets to scale-up the bacterial culture with 100% coverage to TB as well as MDR presumptive patients. Recent GLC-GDF mission recommended reassessment of number of TB diagnostic labs in the country - and to increase them to cut-short the patient and laboratory turn-around-times.

Country's laboratory policy recommends testing of all TB patients for MDR-TB. However, only 52% of previously treated patients and 83% of new culture positive TB cases were

tested for isoniazid and rifampin in the year 2011. Currently though DST is done for all cultures (new or previously treated) according to the degree of growth.

d) What are the NTP guidelines for use of DST, by type (slow culture-based methods; rapid culture-based methods; genetic methods)? In case a national policy exists, describe the indications for each group of methods (for diagnosis of MDR-TB / for resistance surveillance (DRS); define the drugs targeted by method and by objective (MDR-TB diagnosis / DRS)

- Standard DST method(s) used: system for genetic testing? Method and medium culture-based (specify for each if more than one)?
- Technical details culture-based DST:
 - Drug concentrations (taking into account potency?); drugs used (origin, expiry, correct storage); antibiotic powder supply problems? Give medium inspissation details if applicable.
 - Inoculum preparation: standardisation system; dilutions used for inoculation; are loops or pipettes used?
 - Reading and interpretation
- Technical details genetic DST:
 - How are samples for genetic DST transported to the laboratory?
 - Which measures are taken to prevent and detect cross-contamination? DNA extraction method used?

Country's laboratory policy recommend testing of all TB patients for MDR-TB. However, only 52% of previously treated patients and 83% of new culture positive TB cases were tested for isoniazid and rifampin in the year 2011. Routine surveillance system for MDR-TB has been effectively implemented in the country.

All previously treated TB patients, Contacts of MDR-TB patients under for smear, C&DST tests. LPA is used if the patient is smear positive. MGIT is used if smear negative and sample is obtained within 4 days of sputum collection. LJ is used if the sample collection date is more than 4 days. One third of samples that arrive in C&DST labs are not processed due to delays.

LPA- Hain's test- is used as per standard procedures , local developed protocols and as per manufacturer's instructions. 'Amplicon contamination' is avoided by taking adequate precautions in laboratory facility-design.

GeneXpert is recently introduced at limited sites.

3. Method and system for implementation of quality assurance

- (1) Are there NTP guidelines (or protocol) for quality assurance of smear microscopy? Please attach.

Yes: There are guidelines for quality assurance of smear microscopy. But Lab network needs improvements- on quality assurance particularly for culture in peripheral laboratory in the present system.

- (2) Describe measures of internal quality control for smear microscopy at each level. (Specimen reception/handling; stains/staining; equipment function, etc.) ;
Quality assurance system for smear microscopy has been operational since 2004. There

are clear guidelines and operational forms for smear microscopy quality assurance

Results of quality control visits by NRL are sent to NCDC responsible officer. The data exchange format is available in Georgian.

- *Peripheral: IQC measures generally followed,*
- *Intermediate: IQC measures generally followed,*
- *Central: Standard SOPs are followed as per the International guideline material*

Method and system of external quality assessment (EQA) of smear microscopy:

- *In 2012-2013 sputum microscopy quality control was undertaken at all 11 microscopy labs. This has been reported to WHO for the global report*

- Which methods are in use? For which level of laboratories / techniques?
(and qualitative) is considered as 100% error
 - How are slides kept? Presence of identification number & absence of results on slides?
 - How many slides (positives / negatives / scanty) are sampled per microscopy unit per year? How is random sampling done, and by whom?
 - Is there a coordinator for rechecking at intermediate level? How is first level blinded rechecking assured?
 - Is the second control on discordants done? By whom? Blinding? Is restaining being used? At which level?
 - Does results analysis include a check on validity of the controls? Are minimum performance targets clearly defined?
 - Is there a different system for rechecking of fluorescence microscopy? In the affirmative, please describe. Also specify in case no rechecking of fluorescence microscopy is done.
 - *Quality control for fluorescence microscopy is conducted with the same method as for Ziehl-Neelsen.*
 - *Guidelines are available for details. 1 error (significant and qualitative) is considered as 100% error*

(3) Results of smear microscopy EQA.

EQA results are available in Georgian and can be obtained from NRL on request.

a) Slide rechecking

- no. of labs covered by rechecking; or approximate percentage of total microscopy labs covered (then also describe regularity)
- no. of positive, scanty and negative smears rechecked in total for all labs (most recent report; please specify the year)
- no. of labs with HFP (high false positives) detected
- no. of labs with excessive FN (false negative) detected
- corrective action taken?
- numbers and error %: high false positive / positives rechecked; all false negative (high plus low) / all negatives rechecked

b) Panel testing- *Not performed since 2010*

- Describe type and constitution of panels used: manufactured for the purpose or

from routine? Stained as well as unstained smears? Number of strong positives / scanty / negative smears, and total in the panel?

- How are manufactured lots validated? Are tests taken during a supervision visit or unsupervised?
- Number of rounds done last year? Number of microscopy units covered?
- How are results analysed? How is feed-back and corrective action organised?
- Please give results of these rounds as detailed as possible

(5) Supervisory visits (last year) . *Supervisory visits are conducted regularly according to the predefined plan. Regional supervision is conducted 4 times per year. In addition to that, regional coordinators conduct 44 visits annually to peripheral laboratories. (11 labsX4 quarters). Central supervision takes place twice per year. 16 visits of central supervision are conducted to 8 labs twice per year. This is supported by the Global Fund project.*

Direction of supervision		No. of visits	
		Planned	Done
Intermediate to periphery	By laboratory person	-	-
	By non-laboratory person	44	44
Central to periphery		16	16
Central to intermediate		2	2

(6) Is supervisory visit (on-site evaluation) carried out with a check-list? If so, attach it. If not, what points are checked during supervisory visit?

Supervisory visits are conducted regularly according to the predefined plan. Regional supervision is conducted 4 times per year. In addition to that, regional coordinators conduct 44 visits annually to peripheral laboratories. (11 labsX4 quarters). Central supervision takes place twice per year. 16 visits of central supervision are conducted to 8 labs twice per year. This is supported by the Global Fund project.

(7) Describe the mechanism for feedback of the results of EQA or onsite supervision, from intermediate / national level

The supervision visit is reported and signed by responsible staff. Copy of the supervision report stays at lab and the original is kept by a supervisor. A supervisor check if recommendations of previous visit are met.

(8) Are there mechanisms to ensure that corrective actions (QI) are taken and sustained after the feedback?

The supervision visit is reported and signed by responsible staff. Copy of the supervision report stays at lab and the original is kept by a supervisor. A supervisor checks if recommendations of previous visit are met.

(9) If culture examination is routinely performed, describe how QC and EQA for culture examination are implemented in brief. Also quote per cent fully contaminated and per cent negatives from smear-positive specimens of untreated cases (new and relapse)

as per most recent data (specify year / quarter) at the NRL.

NRL and Kutaisi regional lab perform culture on solid and liquid media. NRL EQA measures are adequate.

(10) Describe how QC and/or EQA for DST are implemented, per method used.

NRL is linked with SNRL at Antwerp, for Proficiency testing

Laboratory performance and workload analysis

(1) Smear microscopy done last year: 2013- Country

Result	Ziehl-Neelsen			Fluorescence microscopy		
	Number of smears examined			Number of smears examined		
	Diagnosis	Follow-up	Total*	Diagnosis	Follow-up	Total
Positive	2506 (10%)	306 (1.6%)	2812	321 (4.0%)	865 (26.6%)	1186
Negative	21517	18278	39795	7585	2381	9966
Scanty	-	-	-			
Total	24023	18584	42607	7906	3246	11152

* Category- no sputum done/unknown also included.

(2) Cultures done last year:

NRL	Year								
Microscopy result	Culture results				Culture results				Grand Total
	Not on treatment (new and relapse only)				Treatment follow-up / started treatment				
	Pos	Neg.	Con.	Total	Pos.	Neg	Con.	Total	
Positive	1168	59	42	1269	876	320	74	1270	2539
Negative	500	3274	200	3974	468	4016	344	4828	8802
Scanty	-	-	-	-	-	-	-	-	-
Total	1668	3333	242	5243	1344	4336	418	6098	11341
Intermediary level	Number of labs included / total doing culture								
Microscopy result	Culture results				Culture results				Grand Total
	Not on treatment (new and relapse only)				Treatment follow-up / started treatment				
	Pos	Neg.	Con.	Total	Pos.	Neg	Con.	Total	
Positive									
Negative									
Scanty									
Total									

(3) DST performed last year: 2013

Level	Slow culture-based		Rapid culture-based		Rapid genetic	
	No. done	MDR detected	No. done	MDR detected	No. done	MDR detected
National	2266	513	1054	176	4343	619
Intermediate	-	-	-	-	-	-
Total						

(4) Workload of laboratory workers at different levels last year: 2013

	Averages	Central	Intermediate	Peripheral
Smear	Number staff per lab	13	6 Lab Techs (Kutaisi regional)	1 Lab Tech
microscopy	No. of smears / year / staff	35153/2013/10 smears/year	~2500 smears/staff	Range: 2500-4100
Culture	Number staff per lab	3	2 techs (Kutaisi)	
	No. of cultures / year / staff	11341/2013/3	~1650 tests/staff	
DST	Number staff per lab	5		
	No. of DST / year / staff	4496/2013/5		

Smear work load of Labs* (April 2013-March 2014,Source:NCDC/Social Service Agency):

Lab	Total Smears
<i>Foti LSS</i>	2420
<i>Zugdidi LSS</i>	3846
<i>AkhaltshikheLSS</i>	2352
<i>GoriLSS</i>	3455
<i>TelaviLSS</i>	2541
<i>Batumi LSS</i>	8847
<i>Ozurgeti LSS</i>	1485
<i>Kutaisi ZDL</i>	13343
Total	38289

*Tbilisi-NRL data not included

Culture and LPA work-load of Kutaisi regional Lab (Jan-May 2014, for 5 months):

Test	Number of tests
TB cultures (Solid and Liquid)	1499
LPA	552

NRL (NCTBLD Lab) work Load: Number of tests performed (in 2011 and 2012):

Test	Year 2011	Year 2012
BACTEC MGIT Culture	5570	6625
LJ Culture	10195	14248
DST MGIT	1541	1413
DST LJ 1st Line	3340	2707
DST LJ 2nd Line	1558	1268
LPA	3875	2980
GeneXpert (Xpert MTB/RIF)	602	1047

Safety

- Microscopy laboratories Disinfectant(s) in use? *NRL uses 0,1 % Chloramine solution, Antiseptica Combi Surface 1% Solution. This is described in detail in SOPs for microscopy.*
- Disposal of used sputum containers, sticks, other contaminated materials? Cleaning work place, how often? With what? Described in SOP
- Use of hand basin? YES
- Proper use of lab coats, gloves, etc.? YES
- If safety cabinets are used: what is policy on installation? Type: local manufacture? Certified at factory? Properly maintained?

Safety cabinets exist in each lab. 2 x Class II/TypeB, 1 x Class II/TypeA certified by manufacturer, installed in October 2013 by EXPAND TB safety consultants. Safety cabinets are certified by EXPAND TB as well.

(1) Culture and drug susceptibility laboratory

Laboratory layout designed to control the airflow? Negative pressure maintained?
 Use of centrifuges and their specification: aerosol containment?
 Use and maintenance of safety cabinet(s)?

NRL is TB level 3 lab- and performs techniques as per the international requirements.

(2) Is emphasis during training on safe laboratory practices correct? (transmission via air and not skin; untreated patient far more dangerous than his sputum; relatively low danger of smearing technique)

Yes, this is done in line with WHO recommendations.

*There is a need for basic training at LSS level in TB **laboratory lab work including Good Lab Practises, and bio-safety.***

(3) Regular health check-up of laboratory workers

Chest X-ray and sputum examination? If yes, how often?

Yes, laboratory workers have regular check-up at NCTBLD annually. Their medical charts are also kept at TB center.

-
Any documented laboratory infection during last 3 years?

No, there has not been any laboratory infection documented during last 3 years.

-
Systematic documentation in this regard need to be verified.

Human resource development

(1) Is there a NTP training plan (describe and attach a copy).
USAID TB Prevention Project in FY2014 plans to provide refresher training for 34 laboratory technicians in microscopy and 13 of lab staff in GeneXpert. However, there is no long term plan to address regular capacity building needs.

Until 2013 regular lab training were supported by GF, Training plan is attached. Last training for lab technicians was conducted in May 2013.

(2) Give details of AFB-microscopy staff training.

- Who provides the training?
- Where is it conducted?
How often is it conducted?
- How long is the training: theoretical part / practical part? What is the curriculum (attach)?
- Are there training facilities and what equipment are used?
- Describe the training materials available e.g. laboratory manual? Training modules?

Training is provided by NRL. It is performed at National Centre for Tuberculosis and Lung Diseases (NRL premises). The 3-day training includes both theoretical and practical parts. Curriculum is available in Georgian. Training manual is based on WHO recommendations and is updated regularly.

(3) Approximate proportion of laboratory workers receiving refresher training each year.

Presently, the training/refresher trainings are getting formulated. In 2014 refresher training will be provided for 60% of staff (depends on availability of funding).

(4) How many staff were trained overseas the last two years _____ (where, for how long, how funded)? Are they still involved in TB laboratory work?

Four of NRL staff received 4 days training in LED microscopy in Azerbaijan in FY 2014

(5) Describe the number and level of educational institutions for licensed laboratory workers. Can school-leavers do TB work independently: AFB-smears? Culture? DST?

NRL is a sole provider for this type of trainings. There is 3 day training curricula available.

(6) Approximate number of technicians newly licensed in a year.

In 2013 1 lab technician was newly licensed from Batumi LSS, 2 from Kutaisi and 1

from Zugdidi.

- (7) Describe turnover rates of laboratory staff at central, intermediate and peripheral levels.

29 Peripheral TB labs under government were closed. About 8-10 Labs are now functional- under entirely new set of administration, integrated within general laboratory services. One TB technician per labs is recruited Staff drainage is not observed at any level.

- (8) Is there a register of laboratory staff with training and experience in TB diagnosis?
Yes, NRL keeps this registry.

- (9) Describe the unmet resource requirements for human resources development at central, intermediate and peripheral levels.

Procurement and distribution of supplies and equipment

- (1) Is there a plan for the procurement and distribution of supplies (laboratory reagents, consumables etc.) and equipment (microscopes, incubators, safety hoods etc.)? If available, please attach.

YES

- (2) Do NTP or Reference Laboratory expert(s) take part in the procurement system? For estimates of requirements? For choice of good quality materials?

YES

- (3) Describe the system for procurement and distribution at national and regional levels, including:

- At which level are funds made available for procurement? **CENTRAL**
- Who is responsible for estimated requirements at various levels? **NRL-NCDC**
- Who is making final decisions on quantities and suppliers? **NRL**
- What is the storage and distribution system up to the periphery?

Is the budget for procurement and distribution of supplies and equipment of the last 2 years sufficient? Consider central, intermediate and peripheral levels separately (attach)?

GLOBAL FUND PROCUREMENT and FIND (EXPAND-TB)

- (4) Describe the system of recording and reporting for the status of supplies and equipment within the laboratory system. Is a standard used (if available, please attach)? *Yes standard is used*

- (5) Have there been interruptions in laboratory work at central, intermediate and peripheral levels due to shortages of supplies and equipment? **VERY RARE**

- (6) Are buffer stocks of supplies and equipment kept? Please describe the system and give an indication of size of buffer stocks at different levels.

*At peripheral (first) and intermediate (second level) buffer stocks are for 1 to 4 months.
At a central level for at least 9 months.*

- (7) Describe the maintenance system for equipment including availability of spare parts (especially bulbs & objectives) for microscopes.

Maintenance of equipment has been mentioned repeatedly, even though NRL

Equipment is controlled daily. Service once in 6 months, if problem occurs immediately

(8) What is the average lifespan of microscopes? What are the major causes of malfunction?

Average life span 10 years. Major causes of malfunction are light damage and objective lenses damage

Procurement and Distribution: Problems mentioned

3.8 Data management

(1) Are a standard TB microscopy request form and TB microscopy register book in use? (If yes, please attach both). Do the form and registry book conform to WHO/IUATLD format?

The request form is as per WHO/IUATLD guidance

(2) Is there a culture/DST request form and registry book conform to WHO/IUATLD recommended format?

Culture and DST request form, and Lab register as per the WHO/IUATLD recommendations

(3) On average, how long does it take for the laboratory report to be produced after the clinic has sent the patient or specimen to the laboratory (turnaround time): for smear microscopy; for culture; for DST? What is the average delay for the patients to be put on treatment?

Microscopy results are available in 2 to 4 -6 days, culture in 7-60 days, DST in 28 days

(4) How often are laboratories required to report on their performance (monthly, quarterly, 6-monthly or annually) and to which authorities do they send their reports? Are there standard reporting forms (if yes, please attach)?

Peripheral Labs report to NCDC. Delays in reporting are noticed. About 6 months delay in full lab data set compilation. NRL submits monthly report to the Global Fund project implementation unit, to EXPAND TB on a quarterly basis and to WHO annually for Global TB Reporting

(5) Is feedback on laboratory reporting, supervision and/or EQA data given regularly after proper analysis? If yes, how and from which level?

With the reorganisation of the services going on for past two years- EQA for sputum microscopy is functional according to the national guideline . (12)

A copy of the Assessment Tool used in this study is available in Appendix 2.

2. Recommendations

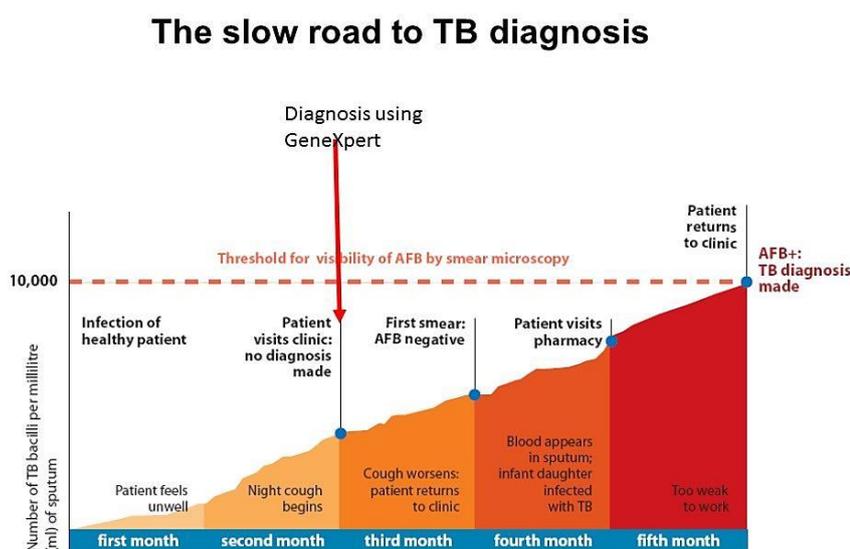
2.1 An innovative strategic funding/service model

The budget required for the implementation of the National TB Strategy is insufficient compared with the available resources. (See Table 1: Funding sources and funding gap 2013-2015).

Either or both an increased funding or new income streams will be required to improve the motivation of private health care providers to implement infectious control measures up to the level of international standards. Today a fixed cost per patient diagnosed and treated for TB is paid by government which varies on the complexity of the patient service. These rates may or not be perceived as adequate compensation and in most cases are not considered a sufficient incentive to provide quality TB services. Private laboratories have the duty to ensure unlimited access to all diagnostic services except sputum microscopy and culture which are considered low-margin ancillary tests. It's time to evaluate the current levels of accountability of the private sector and the contracting mechanisms between the payer (government) and the private providers to ensure quality, access and proper TB infection control.

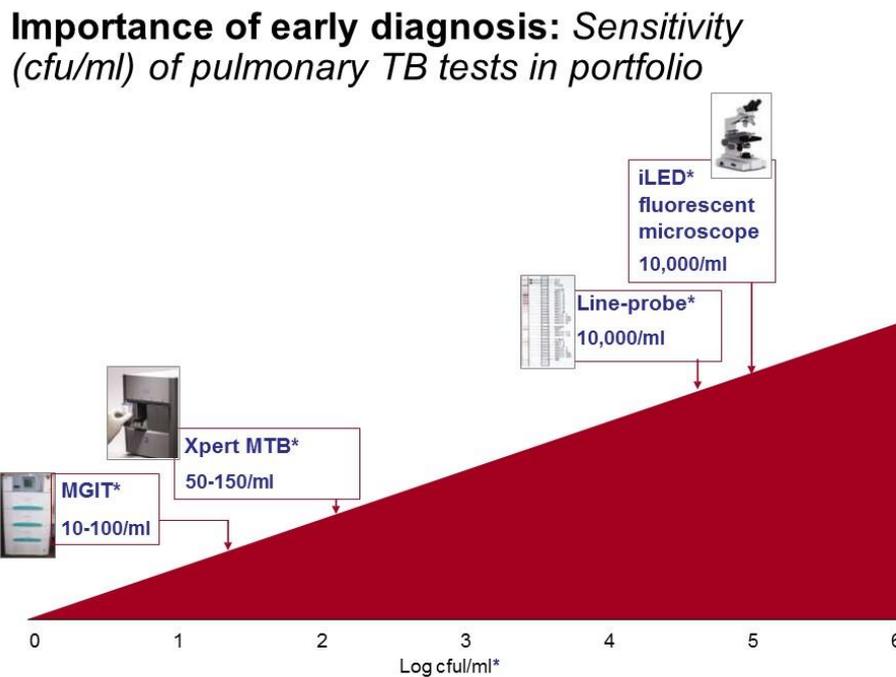
One of the key issues facing public health officials in the Georgia NTP is to shorten the time taken to diagnose and begin treatment for TB. Current delays centre around the transport system used to get samples to testing labs expeditiously and with the samples still viable. Also, there are not enough facilities and not enough equipment to do first line screening via questionnaires, X-ray and microscopy. The figure 11 illustrates the passage of the infection and the time missed in not using a rapid diagnostic tool.

Figure 11: Slow road to TB diagnosis – Diagnosis period shortened with GeneXpert



New rapid laboratory technologies are allowing Georgia to identify more rapidly MDR-TB cases. These technologies are presently only available at a national level. This means that there could be delays of up to 2 weeks or more until results are available and treatment is initiated. The importance of early diagnosis not only brings benefits to patients but there is concomitant economic savings to be had as well. Classic smear techniques require $\geq 10\,000/\text{ml}$ bacteria to be present for identification and diagnosis. Technology such as the GeneXpert require at a minimum only $50\text{-}150/\text{ml}$. Figure 12 shows the sensitivity of pulmonary TB tests.

Figure 12: Importance of early diagnosis



Current health reform will have to transition to more ambulatory TB treatment under the care of the private health care providers, GPs and village nurses in a more patient-centred approach for case management. Presently, private health care facilities are not allowed to perform these services; only a state TB health professional can.

The newly established TB Private Sector has the opportunity now to shift more tests and tasks towards highly efficient and profitable molecular diagnostics. The cornerstone of such tests should be the Gene Xpert system and the associated Xpert range of assays. Besides critical infectious diseases like TB, the Xpert range of assays includes associated infections, oncology, genetics, immune-compromised and women's health and STD diseases. With this system, single platform the same basic cartridge works with all tests and the GeneXpert Systems. This unique platform design easily allows increase in testing capacity. Last, with time-to-result in about an hour including sample preparation time provides maximum medical value. Georgian TB laboratories have a unique opportunity to

turn into last generation molecular diagnostics laboratories, and increase their value proposition in:

- Increasing access to molecular diagnostics services for the population
- Increasing the demand for molecular diagnostics tests
- Generating a sustainable revenue

There is a situation in regional Georgia where increasingly high rates of MDR-TB are being seen. (See Figure 15; Regional Case Notification 2009-2013) for more background. This current period wherein the National Strategic Plan for 2013-2015 is being rolled out represents an opportunity to trial a different and potentially more profitable model of public-private partnership and which could hold the promise of bringing the situation depicted in Figure 15: Regional Case Notification 2009-2013 under control.

2.2 A model for managing an increased regional TB suspect case load

As efforts to improve and increase case findings proceed, there will be an increased work load for TB microscopy labs. Findings in the form of the increased regional TB suspects (see Figure 5: Regional Case Notification) suggest that this has become a priority that need to be dealt with earlier rather than later since to leave its resolution unattended means that the downstream TB health care system will take a perhaps unnecessary strain that might be avoided now.

The model makes two assumptions:

1. The number of patients with presumptive TB with sputum tested increases
2. Number of TB contacts increases with intensified contact tracing by NCDC epidemiologists

The figure that follows (Figure 13: Summary of Model to manage additional TB Sputum Smears) sets out a summarised (top-level) view of the workings of the model.

Figure 13: Summary of Model to manage additional TB sputum smears

	Assumptions	Proportion of detected patients	
		Baseline %	Target %
Assumption 1	Number of patients with presumptive TB with sputum tested increases	16.5	10
		Baseline in absolute Numbers	Target in absolute numbers
		14258	26600
Assumption 2	Number of TB contacts tested increases with intensified contact tracing by NCDC epidemiologists	Baseline %	Target %
		5%	2.5
		Baseline in absolute Numbers	Target in absolute numbers
		4509	9080
	Additional smear microscopies to be conducted for diagnosing patients with presumptive TB symptoms and contacts	42,844.00	
Assumption 3	Number of smear tests for monitoring remains unchanged	50,807	50,807.00
	Additional smear microscopy to be conducted for monitoring # of Additional smear tests performed	-	
		42,844.00	
	Microscopy Staff need at current workload (1 technician/20 smears per day)	17	
	Microscopy Staff need at increased workload (1 technician/20 smears per day)	25	

Note: Assumption is made that the number of smears for monitoring will increase as a result of improved compliance and improved case finding.

	Number of population per TB labs	Number of microscopes	Population per microscope
Akhalsikhe LSS	214,000.00	1	214,000
Batumi LSS	395,000.00	2	197,500
Foti LSS	48,000.00	1	48,000
Gori LSS	183,600.00	1	183,600
Kutaisi ZDL	749,000.00	6	124,833
Ozurgeti LSS	138,800.00	1	138,800
Tbilisi NRL	1,797,000.00	13	138,231
Telavi LSS	404,000.00	1	404,000
Zugdidi LSS	430,500.00	1	430,500

There are at least two methods that could be used to manage the additional 42 844 smear tests that would need to be performed.

- Option1: Increase the number of lab technicians at existing facilities in order to accommodate the anticipated increase in workload. (Presently set at 20 smears per technician.)
- Option 2: Install additional labs at selected sites in the most affected high-incidence regions/ areas. (See Table 15: Regional Case Notification)

Implementation of Option 2 would begin to address (and ultimately resolve) two (2) issues raised in this report.

Firstly, any new labs installed should be in high-incidence areas/regions. This would, with other measures such as improved community awareness around TB screening, improved case finding and early diagnosis. Secondly, it would allow private sector hospitals to become TB screening and diagnostic centres and they would ultimately replace the “lost 36 TB labs” that existed before privatization. Thirdly, with the new Labs inside the regions and communities they serve, the potential for samples and specimens to be lost and be delayed in transit would be minimised. This would not remove the other current problem of samples and specimens being damaged in transit.

A worksheet containing the base data for the model is attached in Appendix 1.

It is proposed that seven (7) private hospitals and one (1) public hospital in the most affected regional areas be equipped with GeneXpert and LED and Fluorescent microscopy technology in order to screen and diagnose early onset TB. The following figure shows the proposed sites.

Table 7: Proposed sites for private TB labs

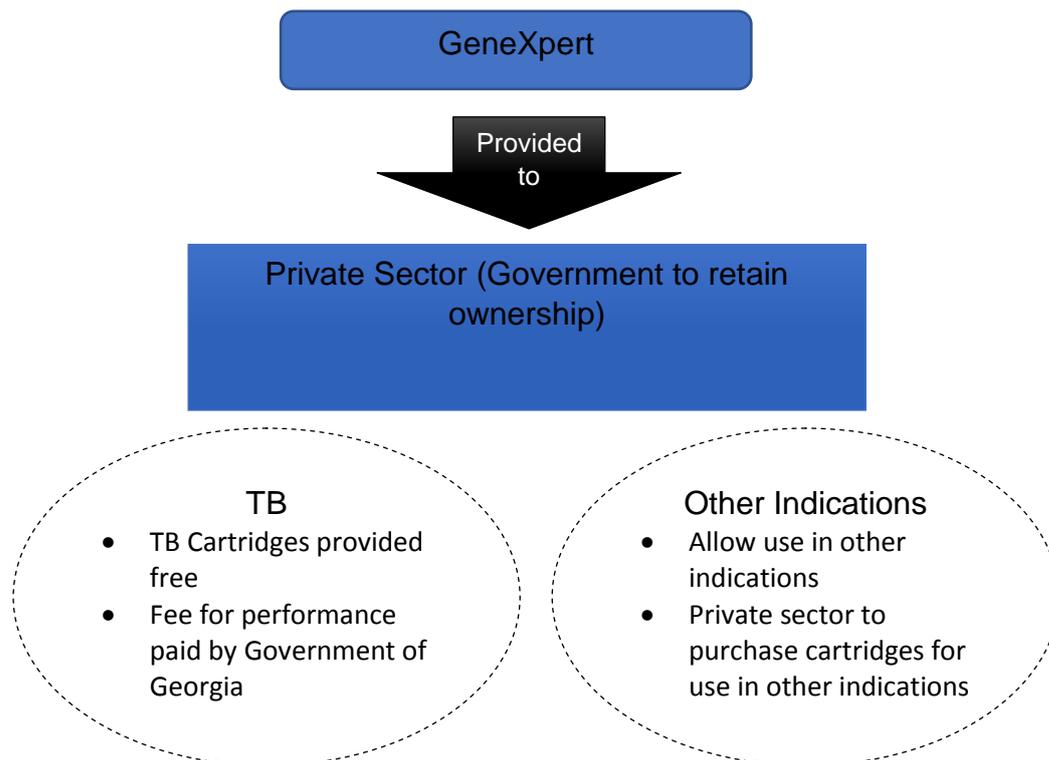
Kakheti	Gurjaani	Private
Imereti	Kutaisi & Sachkhere	Private
Samegrelo	Zugdidi	Private
Adjara	Batumi	Private
Kvemo Kartii	Rustavi & Marneuli	Private
Imereti	Kutaisi	Public

Government, through the Global Fund, would facilitate these acquisitions and the equipment itself would remain the property of government. With the support of Expand TB and the Global Fund, Regional algorithms may need to be developed to adjust for variable logistic characteristics from region to region and to guarantee equitable access to Xpert testing.

As well, government would acquire and provide the necessary reagents and cartridges free. Further, government would continue to pay the present fee of US\$25 per test plus a nominal fee per test performed with GeneXpert.

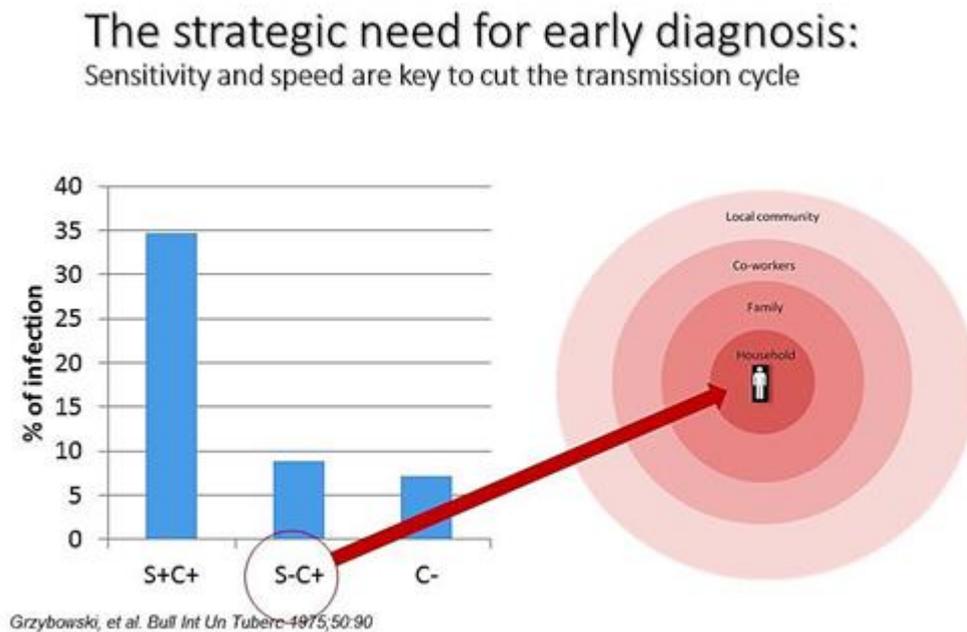
This model, as recommended, would have Xpert instrument provided for free to private TB labs under conditions of service to the government and conditional payments in return. One of these conditions will be to reintroduce widely sputum LED smear microscopy for treatment monitoring and follow-up. See figure 14.

Figure 14: Government provides GeneXpert to private sector



Some barriers that limit free access to TB screening should be overcome. After proper training and education, general practitioners and not only TB doctors should be allowed to send for sputum examination directly to the NCDC smear laboratories. This may result in an increased TB work load that can ensure a sufficient diagnosis load for other ailments generating stable revenues (Figure 15).

Figure 15: Need for early diagnosis



For this model to be effective the government has to evolve the payment mechanism from input-oriented (budgets per hospital bed, per staff, per laboratory infrastructure) to outcome-oriented (per case/service-based payment).

Fees paid to TB private laboratories should include:

1. Type of services, favouring most cost effective services in priority
2. Contracting terms for reaching certain volumes/work load of certain services (e.g. per case smear microscopy payments)

Figure 16: Sites of proposed new TB screening labs



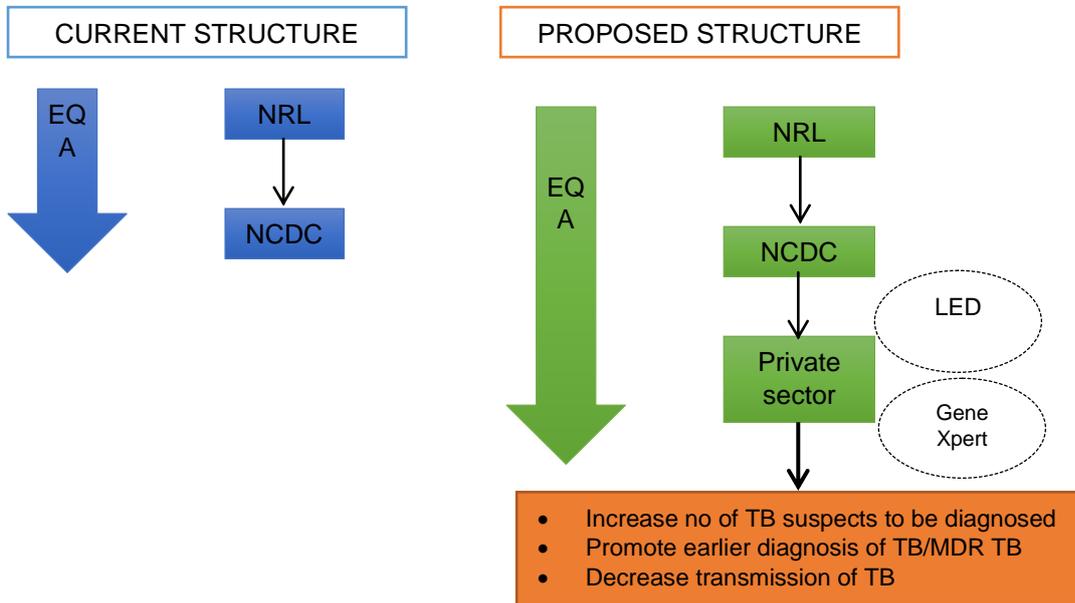
3. Performance measurements linked to bonus rewards upon reaching quality improvement indicators to be evaluated independently according to international EQA methods.

This will allow government purchasing of health services to move from passive to strategic. The MoLHSA may not anymore allocate scarce and valuable budget resources in agreement with historical pre-set norms and should be the main actor to influence service provider outputs. As a result, the financial risk will also gradually move to the providers. To ensure minimal provider revenues but alleviate financial risks, the government may include floor for expenditures as well as spending ceilings.

A few pre-requisite steps to the above recommendations will need to be in place:

1. Ensure standardized laboratory protocols are properly described in national guidelines
2. Ensure that laboratory outputs can and will be measured efficiently
3. Ensure that the MoLHSA has clear expected health gains and has identified the essential laboratory services to be delivered
4. Ensure that any programmatic and logistic bottleneck has been cleared to effectively allow the coverage and the scale up of the proposed model.

Figure 17: Proposed new Lab structure incorporating private labs



For private hospitals this proposed model represents an opportunity that opens the door to greater range of diagnostic capability, given the diverse testing menu of the GeneXpert System. (See figure 18 below)⁹

Figure 18: GeneXpert Clinical Test Menu.

GeneXpert® System : Clinical CE-IVD Test Menu

			Number of Tests	Catalog Number
Healthcare Associated Infections	Xpert® MRSA	Active MRSA Surveillance Testing In About an Hour	10 120	GXM RSA-100N-10 GXM RSA-120
	Xpert® SA Nasal Complete (formerly known as Xpert MRSA/SA Nasal)	Pre-surgical testing of <i>S. aureus</i> and MRSA In About an Hour	10	GXSACOMP-CE-10
	Xpert® MRSA/SA SSTI	Detect MRSA & SA Skin and Soft Tissue Infections In About an Hour	10	GXM RSA/SA-SSTI-CE
	Xpert® MRSA/SA BC	Detection of MRSA and SA in Positive Blood Culture Bottles In About an Hour	10	GXM RSA/SA-BC-CE-10
	Xpert® C. difficile	Accurate Detection of <i>Clostridium difficile</i> In Less Than One Hour	10	GXC DIFFICILE-CE-10
	Xpert® vanA/vanB	Screening for VRE In Less Than One Hour	10	GXVANA-B-CE-10
Critical Infectious Disease	Xpert® Norovirus	Rapid Detection of Norovirus GI & GII in as Little as 45 Minutes	10	GXNOV-CE-10
	Xpert® Flu	Detection of Flu A and Flu B with 2009 H1N1 Call Out In Just Over One Hour	10	GXFLU-CE-10
	Xpert® EV	Rapid Molecular Diagnostic Testing for Enteroviral Meningitis In 2.5 Hours	10	GXE V-100N-10
	Xpert® MTB/RIF	Two Hour Detection of MTB and Resistance to Rifampicin	10	GXMTB/RIF-10
Sexual Health	Xpert® HPV	High risk HPV DNA screen and 16,18/45 genotyping in less than 60 minutes	10	GXHPV-CE-10
	Xpert® CT/NG	Accurate Detection of <i>Chlamydia trachomatis</i> (CT) and <i>Neisseria gonorrhoeae</i> (NG) in 90 Minutes	10	GXCT/NG-CE-10
	Xpert® CT	Accurate Detection of <i>Chlamydia trachomatis</i> (CT) in 90 Minutes	10	GXCT-CE-10
Oncology/ Genetics	Xpert® GBS	Intrapartum or Antepartum Group B Streptococcus Testing In Just Over 30 Minutes*	10	GXGBS-100N-10
	Xpert® BCR-ABL Monitor	Simplified, Rapid Testing for Improved CML Patient Management in Less than Two Hours	10	BCR-100N-10
	Xpert® FII & FV	30-minute Test for Genetic Risk of Thrombosis	10	GXFIFV-10

* For Positive Results

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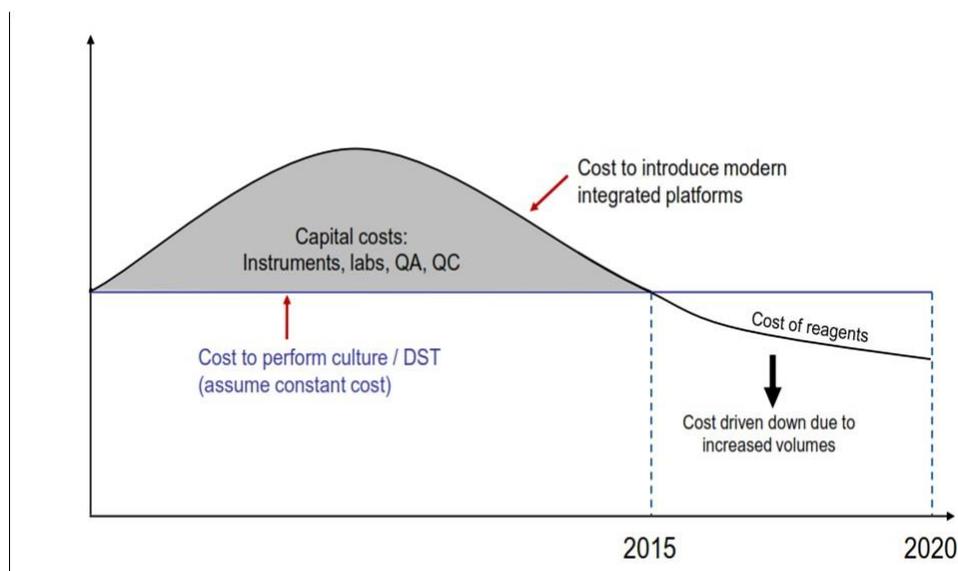
Cepheid. A better way.

Multi disease technology platform	
Existing test cartridges on the GeneXpert platform	
Staphylococcus aureus colonization	Bordetella pertussis
Vancomycin resistance	Bordetella parapertussis
Clostridium difficile	HSV Type 1
MRSA from tissue or blood	HSV Type 2
Group B Streptococcus	RSv Type A
Enteroviral meningitis	RSV Type B
Coagulation disorders	Norovirus GI
Anthrax	Norovirus GII
	Flu A
	Flu B
	Leukemia (BCR-ABL)

This no-cost acquisition of technologies that would add significant value to their operations and their revenue stream also removes for the private hospitals the costs of both acquiring the equipment as well as operating it. Further, should the government decide after several years to withdraw its offer of free consumable supply such as cartridges, then the private operators would have built up operational volumes sufficient to drive down the costs, as the figure below illustrates.

Figure 19: Decreasing cost of new technologies over time

Decreasing cost of new technologies over time.



In sum, there are compelling reasons – from a TB public health standpoint – to make use of the Xpert MTB/RIF to diagnose pulmonary TB and rifampicin resistance in adults and children

- Xpert MTB/RIF should be used rather than conventional microscopy, culture and DST as the initial diagnostic test in adults suspected of having MDR-TB or HIV-associated TB (strong recommendation, high-quality evidence).
- Xpert MTB/RIF should be used rather than conventional microscopy, culture and DST as the initial diagnostic test in children suspected of having MDR-TB or HIV-associated TB (strong recommendation, very low-quality evidence).
- Xpert MTB/RIF may be used rather than conventional microscopy and culture as the initial diagnostic test in all adults suspected of having TB (conditional recommendation acknowledging resource implications, high-quality evidence).
- Xpert MTB/RIF may be used rather than conventional microscopy and culture as the initial diagnostic test in all children suspected of having TB (conditional recommendation acknowledging resource implications, very low-quality evidence).
- Xpert MTB/RIF may be used as a follow-on test to microscopy in adults suspected of having TB who are not at risk of MDR-TB or HIV-associated TB, especially when further testing of smear-negative specimens is necessary (conditional recommendation acknowledging resource implications, high-quality evidence).

Ministries of health and national TB programs should actively obtain information on the adoption of Xpert MTB/RIF by private-sector laboratories and other private health-care providers, seek information about their intended use, and enforce notification of all TB cases detected in the private sector using Xpert MTB/RIF. In settings where private sector providers are widely used by TB patients, these providers should be made aware of the availability of Xpert MTB/RIF, and which groups should have priority for testing using Xpert MTB/RIF; referrals from these providers should be actively monitored. Collaboration among private providers and national TB programmes may be mutually beneficial, allowing private providers to access concessional prices and national TB programmes to ensure that patients detected in the private sector are duly reported and subsequently registered for appropriate treatment.

2.3 Other recommendations

1. Quality management

In Georgia, the development of accurate laboratory diagnosis requires appropriate laboratory quality management systems. Despite laboratory specialists currently developing a national laboratory network that incorporates standard operating procedures and external quality control using national reference laboratories, quality of TB care remains sub-optimal.

The on-going foreign assistance to the Georgian government and to the TB private sector is key to maximize the effectiveness of limited government funds for health. This assistance is also important to ensure privatization initiatives can positively impact access and the quality of services for the target populations afflicted by tuberculosis. External aid is also required to support improvement in overall planning, optimizing budgets and expenditures and improving transparency.

Recommendations:

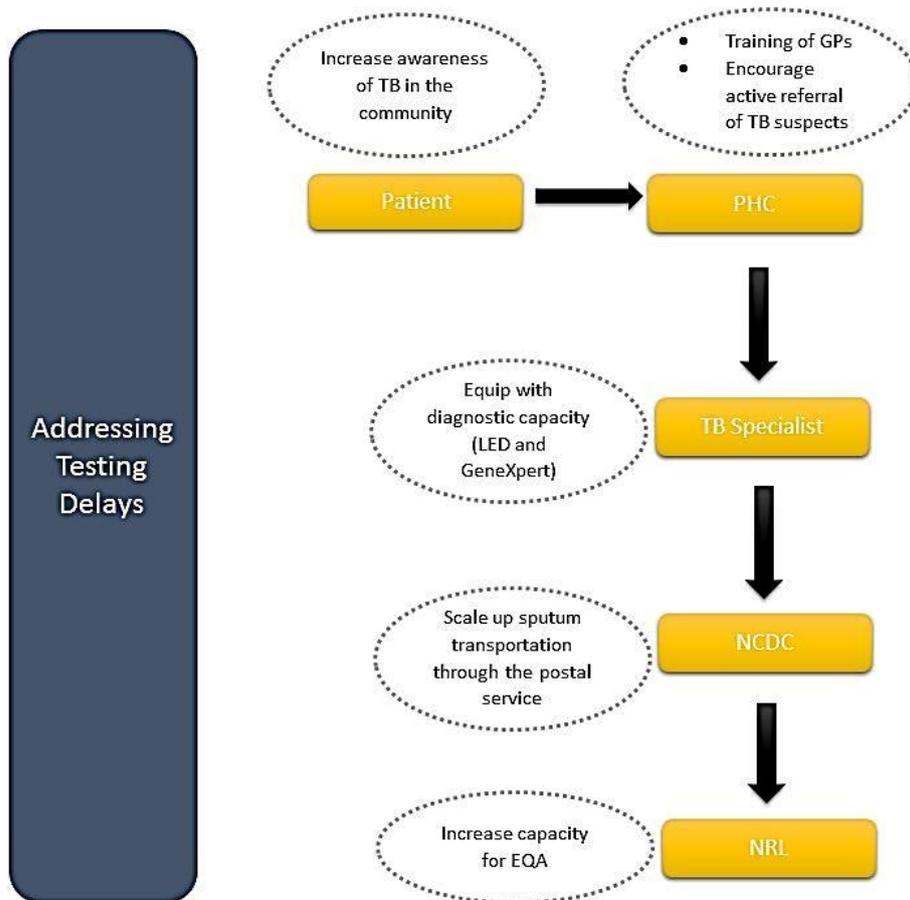
1. *Minimum quality of care requirements should be set for the accreditation of private health facilities in line with the Georgia National Health Care Strategy.*
2. *Improve access to quality TB diagnosis and treatment by strengthening the capacity of the private health care sector to train and educate facility managers and clinicians according to the international standards of TB care (3rd edition, 2014;)¹⁰*
3. *100% of smear microscopy laboratories should undergo external quality assurance and have acceptable performance at or above baseline level of 2011 prior to privatization*

Ensure Global Fund support is sufficient to expand process oriented quality improvement methods as stated in the National Health sector reform priorities

Further, it's recommended that:

1. Both sputum transport and test results delays need to be dramatically reduced. On average, smear microscopy results need to be delivered to the caring physician within 24 hours.
2. Countrywide, coverage of smear microscopy labs should be increased again well over 30.

Figure 20: Addressing testing delays



3. A more integrated patient-centred TB service delivery model has to be developed
4. Minimum quality of care requirements should be set for the accreditation of private health facilities in line with the Georgia National Health Care Strategy.
5. Improve access to quality TB diagnosis and treatment by strengthening the capacity private health care sector to train and educate facility managers and clinicians according to the international standards of TB care.
6. 100% of smear microscopy laboratories should undergo external quality assurance and have acceptable performance at or above baseline level of 2011 prior to privatization
7. Ensure Global Fund support is sufficient to expand process oriented quality improvement methods as stated in the National Health sector reform priorities.

4 Chapter 4: Key steps and milestones for TB laboratory network strengthening in 2015-2018

Based on the laboratory assessment results and key recommendations for strengthening TB laboratory services in Georgia this section outlines steps and milestones to be undertaken for the next five years to optimize access to TB diagnostics and improve quality of care.

The table below outlines key activities to be implemented for strengthening TB laboratory capacity in Georgia during the next three-year period.

Suggested timelines and Implementation of Recommendations	
Year 1	
1	Rationalise GX implementation, location, target groups, and redraft comprehensive EQA national guidelines
2	Start new GX and LED FM labs- in private sector to address- Recommendation 1
3	Trainings to the lab staff- GX, and LED FM; Recording and reporting of Lab work; Performance indicators
4	Redistribute the referral network work-load to ensure optimal utilization of new GX as well as LED FM systems
5	Reinforce EQA components- Microscopy (including LED FM)-Random checking; and GX (Sputum Quality Controls/Error-Invalid reduction)
6	Continue rapid diagnostics for MDR-TB. Continue LPA (ideally LPA work-load goes down with GX introduction, quality improves, prompt MDR Rx starts; and NRL get more time for supervisory role- time for evidence gathering for new interventions; Second line DST strengthens
7	Continue measures for reducing TAT for specimen receipt to within 3 days at NRL/Kutaisi lab
Year 2	
8	Strengthen the HR at Central lab-for National EQA leadership- supervisory visits, quality improvement work-shops etc.,
9	Quality assessment of Labs and quality improvements based on deficiencies
10	Strategize to extend 'Culture' to all TB patients
11	Assess and address gaps in patient delays, systematically, including the policy changes needed
12	Effectively resource the system- plan ahead for partner collaborations
Year 3	
13	Increase awareness at Primary care level for TB and MDR-TB- with a focus on improved diagnostics
14	Encourage pro-active role for GP- first patient contact of TB suspect
15	Cut-short Patient and Health system turnaround times for diagnosis
16	Disseminate the impact of work to all partners and stakeholders

5 Chapter 5: APPENDICES

5.1 Appendix 1: Assessment Tool



TB Laboratory assessment tool_Georgia.pdf

5.2 Appendix 2: Base Data for Model



LaboratoryModellin
g.xlsx

5.3 Appendix 3: List of Stakeholders met with during visit 03 June-11 June 2014.

Date	Name of Organisation	Name of Individual	Title of Individual
3 June 2014	NCTBLD	Rusudan Aspindzelashvili	Head: National Reference Laboratory
	Medison Clinic	Marina Gogildze	Head: TB Department
		Various	Clinic Staff
		Zeza Obgaidze	Director
4 June 2014	NCDC: Imereti Division	Gocha Giorgidze	Head
		Various	Lab Staff
5 June 2014	Global Fund: Project Implementation Unit	Nino Lortkipanidze	Manager
		Nino Lomtadze	Coordinator
		George Kuchukhidze	M&E Specialist
6 June 2014	NCDC	Amiran Gamkrelidze	Director-General
		Irma Khonelide	Deputy Director
		Eka Kavtaradze	Deputy Director
9 June 2014	NCTBLD	Rusudan Aspindzelashvili	Head: National Reference Laboratory
	Ministry of Corrections and Legal Assistance	Natia Landia	Director: Health Department
		Various	Prison Staff
10 June 2014	Telavi Health Centre	Tasiko Nakhutsrishvili	TB Specialist
	NCDC: Kakheti Regional Lab	Maia Gogchuri	Lab Technician
		Tamar Teimurashvili	Epidemiologist
11 June 2014	USAID/Caucasus	Tamar Sirbiladze	Director: Health and Social Development Office
	NCDC	Amiran Gamkrelidze	Director-General

References

1. National Tuberculosis Strategy and operational Plan for Georgia 2013-2105 (January 2013)
2. WHO Global TB Control 2012
http://www.who.int/tb/publications/global_report/en/index.html
3. USAID Tuberculosis Prevention Project: Improving Quality of TB services under the New Service Delivery Mechanism in Georgia; Key Recommendations, February 2012
4. CDC. National action plan to combat multidrug-resistant tuberculosis. MMWR 1992;41(No. RR-11; Cantwell MF, Snider DE, Cauthen GM, Onorato IM.
5. GLC/GDF Europe Mission for monitoring the implementation of the national M/XDR-TB Response Plan in Georgia; 1-5 July 2013 . Vaira Leimane
6. National TB Database at National Center for Tuberculosis and Lung Diseases
7. Terms of Reference for Laboratory Network Assessment – Georgia assignment June-July 2014, USAID Georgia TB Prevention Project
8. World Health Organization: Laboratory Assessment Tool, April 2012, WHO/HSE/GCR/LYO/2012.2
9. Cepheid GeneXpert Product Specification Brochure 2012
10. USAID Tuberculosis Prevention Project: Improving Quality of TB services under the New Service Delivery Mechanism in Georgia; Key Recommendations, February 2012