



Tuberculosis System Overview in Georgia

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Abbreviations

BCG	Bacillus Calmette-Guérin (vaccine)
CCM	Country Coordination Mechanism
DOT	Direct observation of treatment
DOTS	Directly observed treatment, short-course
DR-TB	Drug-resistant tuberculosis
DSM	Direct smear microscopy
DS-TB	Drug sensitive tuberculosis
FLD	First Line TB Drugs
GNI	Gross National Income
LFU	Los to Follow-Up
LSS	Laboratory Surveillance Station
LTBI	Latent tuberculosis infection
MDR-TB	Multidrug-resistant TB
MoLHSA	Ministry of Labour, Health and Social Affairs
MSF	Médecins Sans Frontières
NCDC	National Centre for Disease Control and Public Health
NCTLD	National Centre for Tuberculosis and Lung Diseases
NHA	National Health Accounts
NRL	National Reference Laboratory
NSP	National Strategic Plan
NTC	National Tuberculosis Council
NTP	National Tuberculosis Program
PLHIV	People living with HIV
RR-TB	Rifampicin-Resistant Tuberculosis
SLD	Second-line anti-TB drugs
SSA	Social Service Agency
TB	Tuberculosis
TGF	The Global Fund to Fight AIDS, Tuberculosis and Malaria
UHC	Universal Health Coverage
WHO	World Health Organization
XDR-TB	Extensively drug-resistant tuberculosis
ZDL	Zonal Diagnostic Laboratory

General Overview

Georgia is located in the South Caucasus region at the crossroads between Western Asia and Eastern Europe, bordering Armenia, Azerbaijan, Russia and Turkey. Georgia has a multi-ethnic population of 3.73 million people with the majority being Georgian (86.8%), followed by Azeri (6.3%), Armenians (4.5%) and other nations (2.4%). Georgia is divided into nine administrative-territorial units or regions – Samegrelo-Zemosvaneti, Racha-Lechkhumi, Imereti, Guria, Samtskhe-Javakheti, Shida Kartli, Kvemo Kartli, Kakheti and Mtskheta-Mtianeti – the capital city, Tbilisi, the autonomous republics of Adjara and Abkhazia and the autonomous region of South Ossetia. (Now, de facto Abkhazia and South Ossetia are beyond Georgia's jurisdiction.) Therefore, for sampling purposes, only eleven regions are considered, including Adjara and Tbilisi, but excluding Abkhazia and South Ossetia. Georgia is further divided into sixty-four municipalities or districts (excluding noncontrolled areas) and twelve cities.¹ Each region has a regional centre or main city, and each municipality (district) has a district centre which is semi-urban area) and villages (rural area).

Over the last twenty years, Georgia has achieved significant economic growth despite a number of large and long-lasting economic shocks.² The gross domestic product (GDP) per capita rose from PPP\$ 2,590 in 2000 to PPP\$ 9,599 in 2015,³ and the country has moved to the upper-middle income group with an estimated gross national income (GNI) of 4,160 USD in 2015.⁴

Yet, poverty and unemployment remain as Georgia's key economic challenges. Although poverty in Georgia has fallen from 24.6% in 2004 to 20.1% in 2015, it is still high in rural areas (25.3% in 2015).⁵ The GINI coefficient of total consumption expenditures remained at around 0.40 from 2006 to 2015, and according to the National Statistics Office of Georgia, the employment rate among males was higher (67.6%) than the females (52.9%) in 2015.

Health Financing in Georgia

The health finance system in Georgia consists of general taxation, external funding, private insurance schemes and direct out-of-pocket payments (OOP).

According to the National Health Accounts (NHA), Georgia's total health expenditure was 8.5% of its GDP in 2014 while Georgia's public expenditures on health was just 1.6% of its GDP during the same year according to the latest WHO estimates (HFADB). Public allocations on health in Georgia increased during the last few years, reaching 2.7% of its

¹ National Statistics Office of Georgia, <http://www.geostat.ge> (based on the General Population Census in November 2014); not including separated regions of Abkhazia and South Ossetia

² Georgia country snapshot. <http://www.worldbank.org/Georgia>

³ The World Bank, for 2015 (PPP, current international \$) <http://data.worldbank.org/country/georgia>

⁴ The World Bank, for 2015 (Atlas method, current US\$), <http://data.worldbank.org/country/georgia>

⁵ National Statistics Office of Georgia, (share of population under 60% of the median consumption) <http://www.geostat.ge>

GDP in 2016 (rough estimates of authors). Nevertheless, if compared internationally, Georgia's public spending on health remains low – Commonwealth of Independent States (CIS) average = 3.4%, European Union (EU) average = 7.2% in 2014.⁶

The share of health spending in the total Georgian government's expenditure was 5% in 2014 (WHO estimates) and 8.9% in 2016 (authors estimates) – one of the lowest in the region (CIS average = 9.6%, EU average = 15.3% in 2014). In absolute terms, public health expenditure in 2014 was PPP\$ 131 per capita, which is nearly five times lower than the average for other CIS countries (PPP\$ 636 per capita) and twenty times lower than the EU average (PPP\$ 2,711 per capita). Table 1 presents all of this information.

Although the Government of Georgia (GoG) introduced many health financial reforms over the past two decades, high OOP payments remain a key challenge for the government (66% of total health expenditure in 2014 according to the NHA). OOP payments in Georgia are primarily spent on pharmaceuticals, followed by official co-payments, direct formal payments to health facilities and informal payments to health care providers. Outpatient drugs are not subsidized by the Universal Health Coverage (UHC) program in Georgia, but only certain essential drugs for managing common chronic conditions are covered for poor populations each year. (The UHC drug benefit does not include anti-TB medications, which are covered by a separate TB state program). Although public sources of health financing have grown, OOP spending continues to be the main method of funding health in Georgia.

Table 1. Key Demographic, Economic and Health Indicators

	Results	Source of Information
Total population of country	3,720,400	National Statistics office of Georgia, 2016
Distribution of population (rural/urban)	42.79% / 57.21%	National Statistics office of Georgia, 2016
Life expectancy at birth	72.7	National Statistics office of Georgia, 2016
Male	68.3	
Female	77.2	
Infant mortality rate	8.6 per 1000 live birth	NCDC, 2015
Under 5 mortality rate	10.2 per 1000 live birth	NCDC, 2015
Maternal mortality ratio	32.1 per 100,000 live births	NCDC, 2015
Immunization coverage under 1 year (including pneumococcal & rotavirus)	BCG - 92.5% DTP3 - 93.7%	NCDC, 2015

⁶ European Health for all Database (HFA-DB), July 2016 update. <http://data.euro.who.int/hfad/>

Income or wealth inequality (Gini coefficient)	0.42	National Statistics office of Georgia, 2015
Total health expenditure as % of GDP	6%	WHO, HFADB (2014)
	8.5%	National Health Accounts (2014)
Government expenditure as % of GDP	1.6%	WHO, HFADB (2014)
	2.7%	Author's estimates for 2016
Public expenditure on health as % of total government expenditure	5%	WHO, HFADB (2014)
	8.9%	Author's estimates for 2016
Public expenditure on health PPP\$	131 \$	WHO, HFADB (2014)
Out of pocket payments as proportion of total health expenditure	66%	National Health Accounts (2014)

During the last two decades, the GoG initiated several health reforms to move away from the centralized Semashko Model, which was inherited from the Soviet Union. The initial reform in early 1990s included several changes to financing healthcare – separating healthcare financing from provisional functions; removing all health care personnel from the State's payroll and decentralizing the provider network by granting them autonomy and then privatizing them.^{7,8} The next wave of reforms started in 2007, which aimed to increase financial protection for the poor; promote private insurance plans to reduce out-of-pocket payments and increase primarily private infrastructure investments.⁷

In 2013, the newly elected GoG initiated a flagship UHC program to provide basic outpatient, inpatient and emergency services for all uninsured citizens. People not covered by private insurance plans are eligible for this program, which provides a range of general and specialist healthcare services in both outpatient and in-patient settings. Many of the UHC services require some type of co-payment, but exemptions exist for those classified as 'living in poverty,' and reduced prices are available for those over the age of sixty.⁹

There are a number of similar GoG-funded vertical programs, offering specific services that do not require co-payments: primary care for rural populations, psychiatric services, **TB care**, HIV/AIDS care, kidney dialysis and diabetes care.

⁷ Zoidze A, Rukhadze N, Chkhatarashvili K, Gotsadze G. Health Insurance for Poor: Georgia's path to universal coverage. 2012

⁸ Gotsadze G., Zoidze A., Vasadze O. Reform strategies in Georgia and their impact on health care provision in rural areas: evidence from a household survey. SocSciMed. 2005 Feb;60(4):809-21

⁹ The Government of Georgia resolution on Universal health coverage #36, 21 February 2013

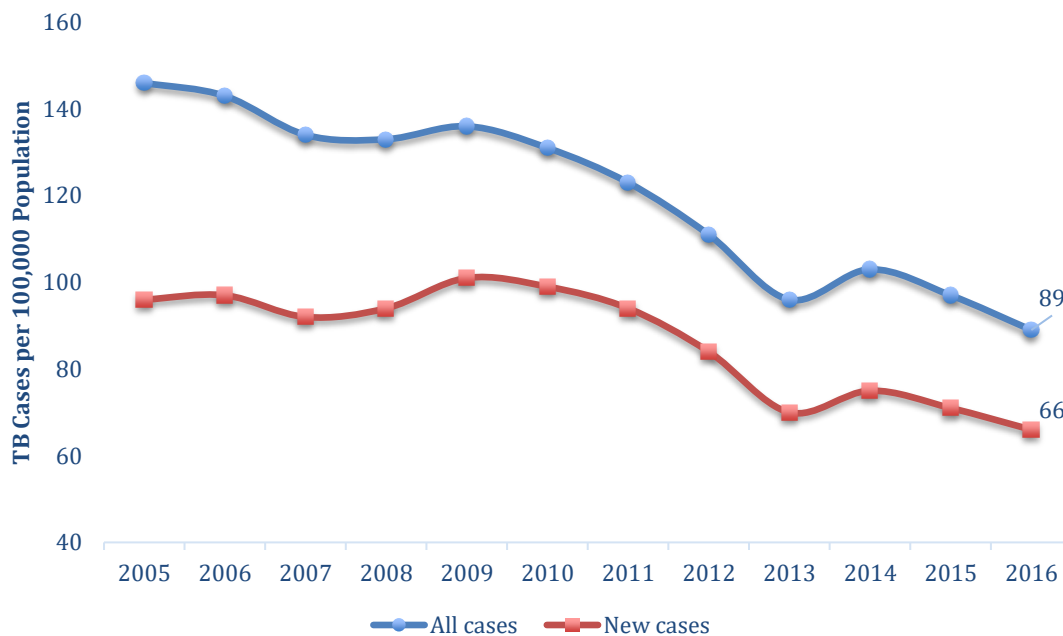
TB Epidemiology

Georgia is one of the priority countries for drug-resistant tuberculosis (DR-TB) in the WHO European Region.¹⁰ The WHO Global TB Report (2016)¹¹ shows that the estimated incidence rate of all forms of TB in Georgia was 99 per 100,000 in 2015, and mortality was 3.9. The proportion of Rifampicin-Resistant/Multidrug-Resistant Tuberculosis (RR/MDR-TB) among new TB cases was 12% and 33% among previously treated TB cases.

Through the introduction of internationally recognized strategies and practices, Georgia has achieved significantly positive results in the fight to reduce TB's national presence. For example, the country has met the MDG 6c and Stop TB Partnership 2015 targets by reducing the TB prevalence and mortality rates by 50% since 1990.

Also, the number of TB cases in Georgia has been decreasing over the past decade, which is shown in the data provided by the National Centre for Tuberculosis and Lung Disease (NCTLD) in Figure 1 and Figure 2.

Figure 1. TB Cases per 100,000 Population, 2005-2016

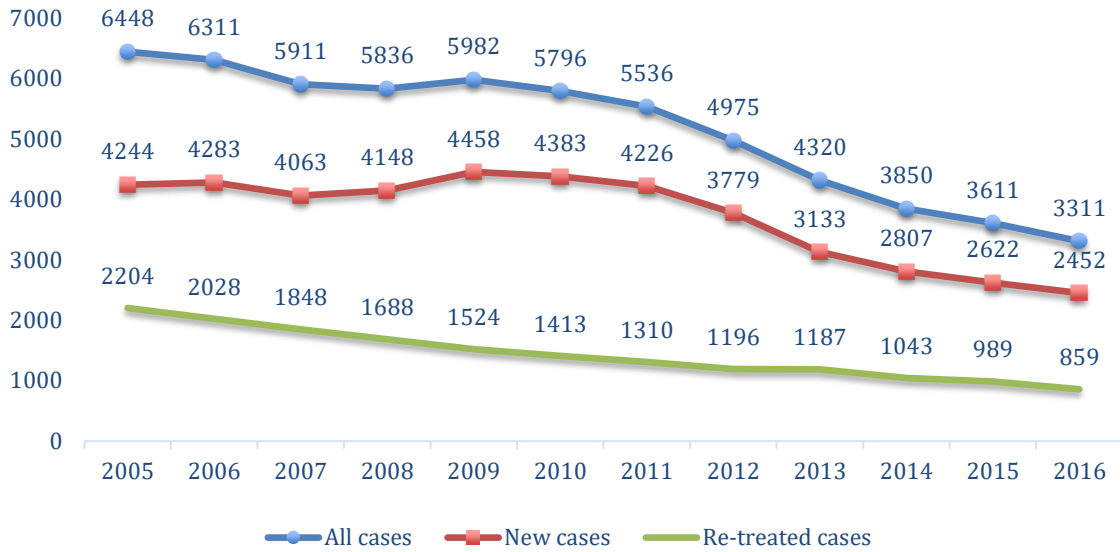


Source: NCTLD, 2017

¹⁰ Tuberculosis country brief, 2016. World Health Organization; Regional office for Europe, 2016

¹¹ Global tuberculosis report 2016. Geneva: World Health Organization; 2016

Figure 2. Notified TB Cases in Absolute Numbers, 2005-2016

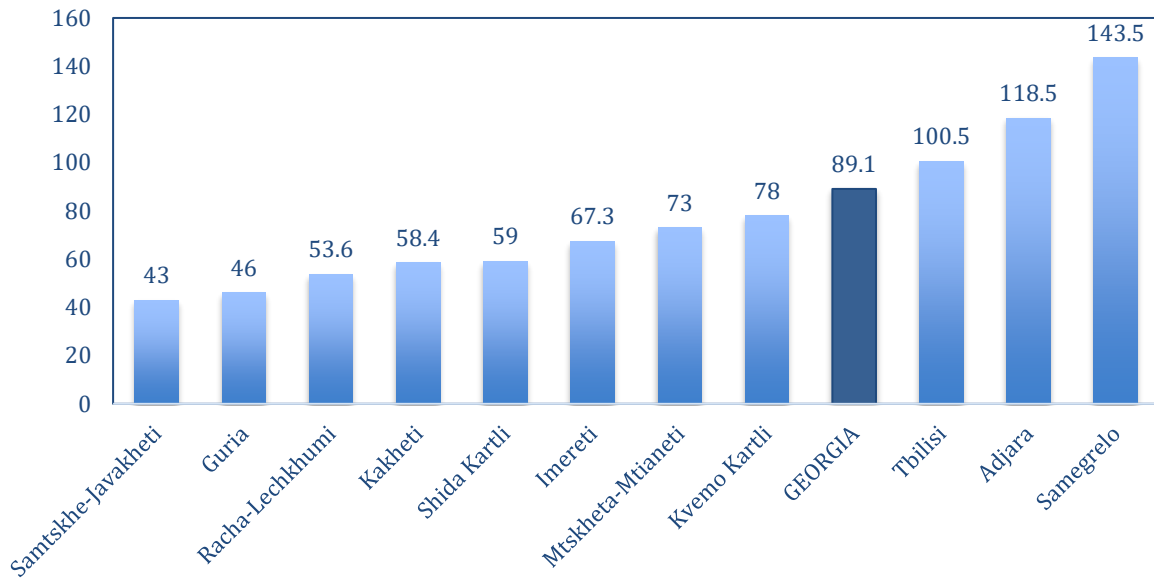


Source: NCTLD, 2017

According to the 2016 NCTLD statistical data shown in

Figure 3, the Samegrelo region has the highest TB prevalence in Georgia (143.5 per 100,000 population), followed by the Adjara region (118.5 per 100,000 population) and then Tbilisi (100.5 per 100,000 population). These three regions are highly populated areas, where almost half of the population of Georgia reside.

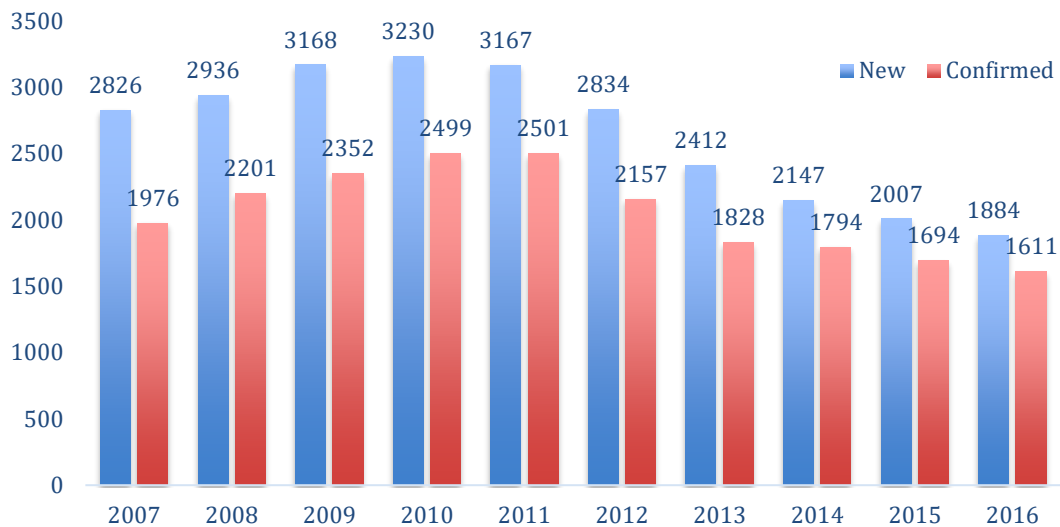
Figure 3. All Case Notification Rates in Regions within Georgia



Source: NCTLD, 2017

Pulmonary TB had the highest proportion among the different types of TB cases in 2016, reaching 85% (Figure 4).

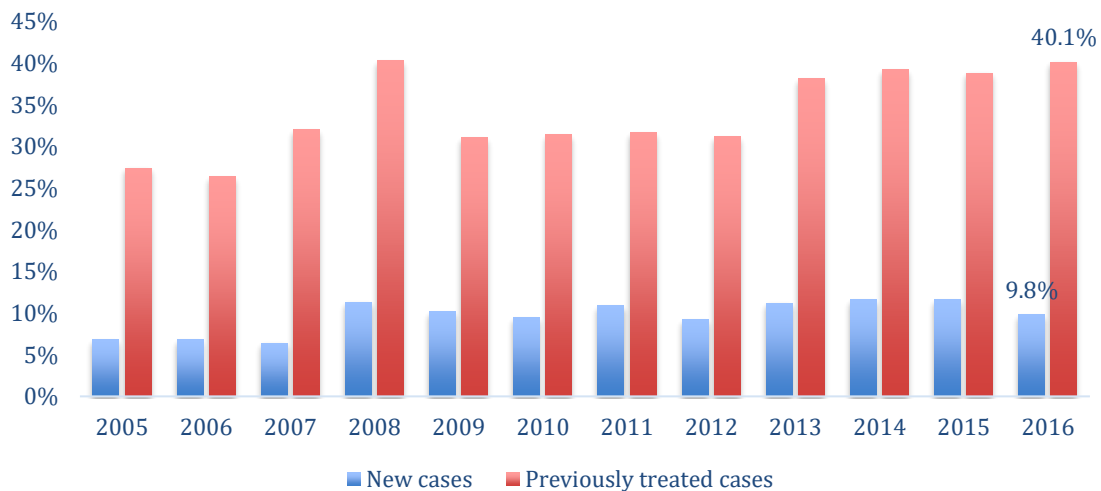
Figure 4. New Pulmonary and Bacteriologically Confirmed TB Cases among Them, 2007-2016



Source: NCTLD, 2017

Fortunately, Georgia is no longer categorized with the group of countries that have a high burden of DR-TB. But as of 2016, the DR-TB prevalence rate is still high among new and previously treated TB cases (Figure 5).

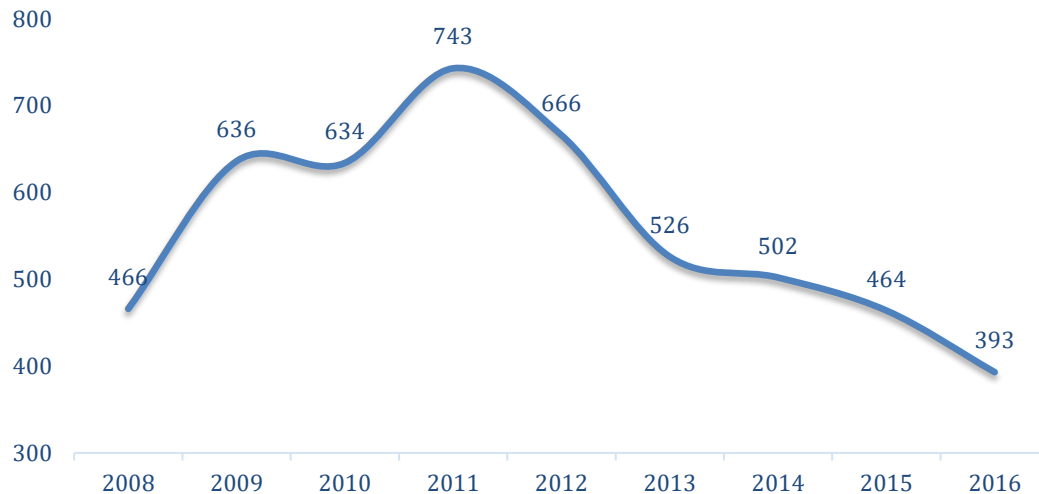
Figure 5. DR-TB Prevalence in Georgia, 2005-2016 (Pulmonary Cases)



Source: NCTLD, 2017

As displayed below, the number of patients taking DR-TB treatment is decreasing each year (Figure 6).

Figure 6. TB cases Enrolled in 2nd Line Treatment (Absolute Numbers)



Source: NCTLD, 2017

Leadership and Governance

Georgia is a democratic state with a republican form of government.

In October 2010, Georgia adopted a new Constitution, which changed the country's governmental system from a presidential state model to a mixed parliamentary-presidential model. Consequently, the powers of the Prime Minister and Parliament increased while the president's decreased.

The administrative system of Georgia and its autonomous regions (excluding Adjara) include the following branches of authority:

- Parliament – legislative power. The Parliament Committee for Health Care and Social Issues is responsible for legislation as well as the supervision of the executive body (the Ministry of Labour, Health and Social Affairs).
- President and Prime Minister – executive power. The president and prime minister split executive power. The president is the head of state while the prime minister is the head of government, being responsible before Parliament.
- The government of the autonomous Republic of Adjara is comprised of the chairperson of the government and ministries (including MoLHSA). The highest legislative body is the Adjara Supreme Council.

General Policy Making System in Georgia

The Parliament of Georgia is the highest legislative body responsible for defining the main political directions of Georgia's health and social sectors. The Parliament approves the State Budget Law, which details the annual budget allocation for state programs. The Parliamentary Committee on Health Care and Social Issues, which is comprised of seventeen members and headed by the Committee Chair, has law-making and government oversight authorities.

The Cabinet of Ministers is headed by the Prime Minister and acts as an executive council mandated to implement state policies. The Prime Minister approves of any government resolutions – or technical regulations – that involve implementing annual state programs. The Ministry of Health, Labour and Social Affairs (MoLHSA) is responsible for policy and regulation development within the health and social sectors. MoLHSA manages the enforcement of state health programs. The technical regulations' specific state health programs define the necessary medical interventions and rules for provider reimbursement within the boundaries of the state health programs.

The Ministry of Finance (MoF) fulfils two main functions – leading the annual budget preparation process and routinely overseeing state budget spending to ensure compliance with the predefined plans and laws.

The Social Service Agency (SSA) is the main health service purchasing body under the MoLHSA. The SSA administers service purchases in accordance with state health programs by contracting suppliers and paying for services according to government-defined rules.

The Medical Service Regulation Agency (MSRA) is responsible for issuing licenses and permits for health care providers and facilities as well as certificates for medical professionals. In addition, the agency is mandated to investigate patients' complaints regarding the quality of medical services.

The National Centre for Disease Control and Public Health (NCDC) is responsible for planning and overseeing public health activities in Georgia, providing technical guidance, monitoring and supervision, surveillance and national level reporting. The NCDC acts as a Principal Recipient (PR) of The Global Fund-supported (TGF) programs in Georgia, including the TB grant.

Local municipal governments acquire limited responsibilities for health promotion, healthy lifestyle formation and some measures for disease prevention. They have established the Public Health Centre (PHC), which is staffed with epidemiologists, statistician and other personnel. The salaries and operational expenses for these staff members are covered by the local municipality budget. (Epidemiologists' roles are described under the section, "TB Outpatient Care.")

The autonomous republic of Adjara enjoys the same benefits and other health programmes as the state of Georgia. The Adjarian government can also implement additional

programmes for its local population. Residents of Abkhazia and South Ossetia can benefit from the state health programmes in their territories under the control of the Georgian Government.

TB Legal Framework

The initiative, Georgia Healthcare System Concept (GHSC) 2014-2020: Universal Healthcare and Quality Management for the Protection of Patient Rights, identifies ten goals that target all health system building blocks. These targets include surveillance, diagnostic and quality assurance as well as prevention and management measures of important communicable diseases that allow the integration of TB services into the general health care system while strengthening supervision.

Two important TB laws were passed in 2016 – the new Tuberculosis Law and the National Strategic Plan for TB Control in Georgia for 2016–2020 (NTP). The former mandates

Goal, Targets and Objectives of the NTP:

Goal

The overall **goal** of TB control in Georgia is to decrease the burden of tuberculosis and its impact on the overall social and economic development in the country. By ensuring universal access to timely and quality diagnosis as well as treatment of all forms of TB, there can be a decrease in the number of TB-related illnesses and deaths as well as further prevention of the development of drug-resistant TB.

Targets

The **targets** reflect the intended progress of key TB impact and outcome indicators. These targets have been set in accordance with the national strategic development initiatives, and they are in line with up-to-date international TB strategies, including the aims stated in *Post-2015 Global Tuberculosis Strategy and Framework*. The targets were set at the end of the five-year period covered by the Plan, having been compared to the 2014 levels.

The **targets** of TB control in Georgia by the year, 2020:

1. TB mortality rate is reduced by at least 25%
2. TB incidence rate is reduced by at least 15%
3. The proportion of MDR-TB among new cases is under 15% and among previously treated TB cases – under 40%
4. Universal access to diagnosis and treatment of all forms of TB, including M/XDR-TB, is ensured so that
 - At least 90% of estimated MDR-TB cases are diagnosed and
 - At least 75% of all notified MDR-TB cases are successfully treated

Objectives

The key interventions and activities included in this Plan are organized around three main **objectives:**

1. To provide universal access to early and quality diagnosis of all forms of TB, including M/XDR-TB
2. To provide universal access to quality treatment of all forms of TB including M/XDR-TB with appropriate patient support
3. To enable supportive environment and systems for effective TB control

involuntary isolation of infected individuals. If a patient refuses treatment, a court order will enforce his/her quarantine. Below are the goals, targets and objectives of the NTP.¹²

TB Care Governance and Management

MoLHSA is the highest body in governance that manages TB activities in Georgia. On the other hand, the Georgian Country Coordinating Mechanism for TB, HIV/AIDS and malaria (CCM)¹³ is a high-level government body that facilitates horizontal links and participatory governance of disease control programs. The CCM includes representatives from different governmental entities, external development assistance agencies and civil society. One important function of the CCM is to oversee the implementation of The Global Fund grant.

The National Centre of Tuberculosis and Lung Disease (NCTLD) and National Centre for Disease Control and Public Health (NCDC) are two leading institutions focused on TB control in Georgia. The NCTLD is the national centre of excellence for TB clinical management, and it is responsible for supervising the capacity building of other specialized TB services' medical personnel as well as monitoring the quality of field supervision and routine TB recording and reporting.

The NCDC is responsible for disease surveillance, laboratory network and national statistics. The NCDC currently and will continue to serve as the Principal Recipient (PR) for the new TB grant under The Global Fund's New Funding Model.

Both institutions administer and implement the *TB State Program* and *TGF supported Tuberculosis project*.

However, public-private partnership remains a challenge for managing TB activities. Both public and private healthcare providers are contracted and financed by the SSA for a full range of TB services. This agreement between the government and private sector on delivering TB services will expire in 2018. Due to low interest in retaining TB services from the private sector, there is a risk of discontinuing TB service deliveries for affected populations unless urgent measures are taken. This issue is further discussed in the 'Contracting and Payment Mechanism' section.

Service Provision

Health services in Georgia are organised as general primary care, specialized outpatient care, secondary care and public health/laboratory services.

¹² CCM Georgia. 2015. National Strategic Plan for Tuberculosis Control in Georgia 2016-2020

¹³ Only 5 cases of Malaria were registered in Georgia in 2015, among which 3 were imported cases.

General Primary Care Service Provision

Service provision underwent significant structural and financial reorganizations due to the waves of healthcare reform. The Semashko Model inherited from the Soviet Union was characterized by a centralized delivery system based on territorial networks of primary healthcare facilities in district centres –known as policlinics – with rural ambulatories and Feldsher-Midwifery Points (FAPs) at the lowest level. All of these services were operational subunits of the district hospital, which managed all health finances for the district.

In 1997, policlinics became free-standing independent legal entities with the responsibilities of managing and contracting all PHC and outpatient specialized services. Most facilities were under state ownership, but they were privatized after the 2007 healthcare reform. Currently, most health providers are private for-profits (owned by holdings that operate a number of health facilities throughout the country¹⁴ or separately standing private facilities) with a few public providers remaining. Primary Care Centres are located in municipal centres (semi-urban areas) as well as regional centres and major cities (urban areas). In rural areas, doctors are individual entrepreneurs responsible for their PHC budgets, and the SSA contracts them directly.

At present, general PHC services are provided by 367 primary care centres (policlinics or policlinic-ambulatory unions), thirty-six independent rural ambulatories and 1270 rural doctors (individual entrepreneurs).

Specialised Service Provision

TB diagnosis and treatment are provided free of charge to all citizens of Georgia.

TB services are provided through general primary care, specialised outpatient care, specialised secondary care and public health/laboratory services, which are further elaborated below and in Table 2.

- General Primary Care Service Providers – PHCs are in urban areas (major cities and regional centres), semi-urban areas (district centres) and rural ambulatories.
- Specialized Outpatient Care – TB outpatient units (former TB dispensaries) exist in every urban and semi-urban area. In most places, they are structurally integrated in PHCs. In other words, TB specialists – doctors and nurses – are contracted by Primary Care Centres to perform their duties as part of the TB state program. There are sixty-eight TB units in all among which, four are in Tbilisi.
- Specialized Secondary Care – TB inpatient departments are located in Tbilisi and three TB regional centres (Adjara, Samegrelo and Samtskhe-Javakheti regions).

¹⁴ Medical Corporation EVEX is a holding with the largest chain of hospital and outpatient services countrywide, currently represented with 76 inpatient clinics in 6 regions of Georgia

- Public Health Centres – PHCs are in every municipal and regional centres as well as major cities. In total, there are sixty-four PHCs. (The role of PHCs is described under the section “Public Health Services.”)
- Laboratory Services – These are integrated into regional and municipal PHCs. In Tbilisi, a reference laboratory is located at the NCTLD. The laboratory network consists of seven Laboratory Surveillance Stations (LSS) located in regional centres, two Zonal Diagnostic Laboratories (ZDL) in Adjara and Imereti which serve different regions and the Reference Laboratory in Tbilisi.

TB services are provided primarily through the *TB state program* and *TGF funded grant*. Besides this, the *UHC* and *Rural Doctor state programs* provide some services for TB care. Other donors (MSF, USAID) also participate in some activities related to TB care.

The TB State Program is a vertical program funded by the MoLHSA budget that covers TB diagnostics; TB drugs (100% first-line drugs, 25% second-line drugs); drugs for adverse reactions to TB treatment; salaries for TB specialists (phthysiatrists) and TB nurses; hospitalization and infrastructure costs and incentives for MDR patients (twenty months for 300 patients).

The Global Fund grant supports second-line TB drugs, a portion of lab supplies and incentives for drug-resistant (DR) and drug sensitive (DS) patients. Other donors (MSF, USAID) fund new drugs for multidrug/extensively drug-resistant tuberculosis M/XDR-TB patients; incentives for M/XDR-TB; transportation costs for additional visits to the Direct Observation Treatment (DOT) centre and supplements to DOT nurses to implement DOT under new treatment regimen.

Table 2. TB Care Services by Source of Financing

Services	Type of Service Provider HR	Type of Service Provider Facility	UHC Program	Rural Doctor State Program	Local Municipal.	TB State Program	TGF TB Grant	MSF TB Grant	USAID Donation
Presumptive case identification	Family doctor	PHC urban, semi-urban, Rural ambulatory	X	X					
Presumptive case Diagnostics	Phthysiatrist	TB unit				X			
Sputum collection and referral to regional lab	DOT nurse	TB unit				X			
Lab diagnostics (Microscopy, Xpert Culturing)	Lab specialist	Public Health Lab; NCTLD; PHC centres with G/Xpert				X	X		
Establishment of regimen for DS-TB patients	Phthysiatrist	TB unit				X			
Establishment of regimen for DR-TB patients	Phthysiatrist	NCTLD				X			
DOT of DS-TB patients (urban/semi-urban areas)	DOT nurse	TB unit				X			
DOT of DS-TB patients (rural/semi-urban areas)¹⁵	nurse	Rural ambulatory		X					
DOT of DR-TB patients (urban/semi-urban areas)	DOT nurse	TB unit				X	X		
DOT of DR-TB patients (rural/semi-urban areas)	nurse	Rural ambulatory		X			X		
DOT of DR-TB patients with new drugs (urban/ semi-urban areas)	DOT nurse	TB unit				X	X	X	
Drugs for DS-TB DOT (FLD)						X			
Drugs for DR-TB DOT (SLD)						X	X		
Drugs for M/XDR-TB DOT (new drugs)								X	X
Drugs for adverse reactions to TB drugs						X			X
Follow-up of TB patients	Phthysiatrist	TB unit				X			

¹⁵ Difference across the rows in this table for the same service is between providers and facilities.

Adverse drug reaction management	Phthysiatrist	TB unit	X		
Adverse drug reaction management	Other specialists	NCTLD	X		
TB hospital care		NCTLD and 3 regional TB centres	X		
Coordination of TB activities in the region	TB coordinator		X	X	
Supervision of DOT process (drug & incentives monitoring)	TB supervisor		X	X	
Adherence counselling of TB patients	Adherence consultant	NCTLD and 9 regional TB centres		X	X
TB contacts tracing, LFU patients tracing	Epidemiologist		X		
Incentives for DS-TB patients				X	
Incentives for DR-TB patients			X	X	X
Transportation voucher for DR-TB patients				X	X

TB Diagnosis

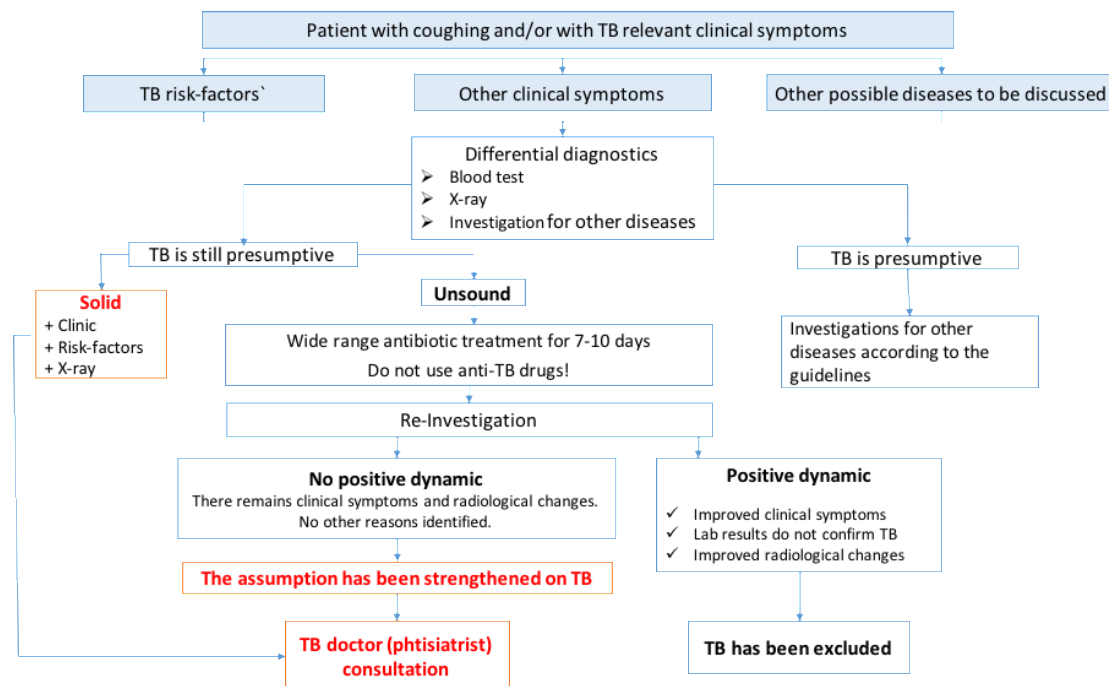
TB cases are identified via passive or active case findings. Presumptive TB cases include patients who present TB symptoms; have been in contact with a TB patient or have a family history of TB. Passive case finding is the main method of TB detection.

Diagnosis is based on physical examination, laboratory results, chest X-ray, prior treatment and/or previous history of TB.

A patient with TB-like symptoms at the PHC level is identified by a family doctor and put on empirical treatment for about two weeks (using a broad-spectrum antibiotic) according to the presumptive TB case management guidelines. If the treatment does not work, then the patient is referred to a phthysiatrist at a TB unit (either integrated into the PHC or is a separately standing dispensary). Patient could also self-refer to the phthysiatrist.

Figure 7 presents a diagram of this diagnosis process

Figure 7. TB Diagnostic Algorithm at PHCs



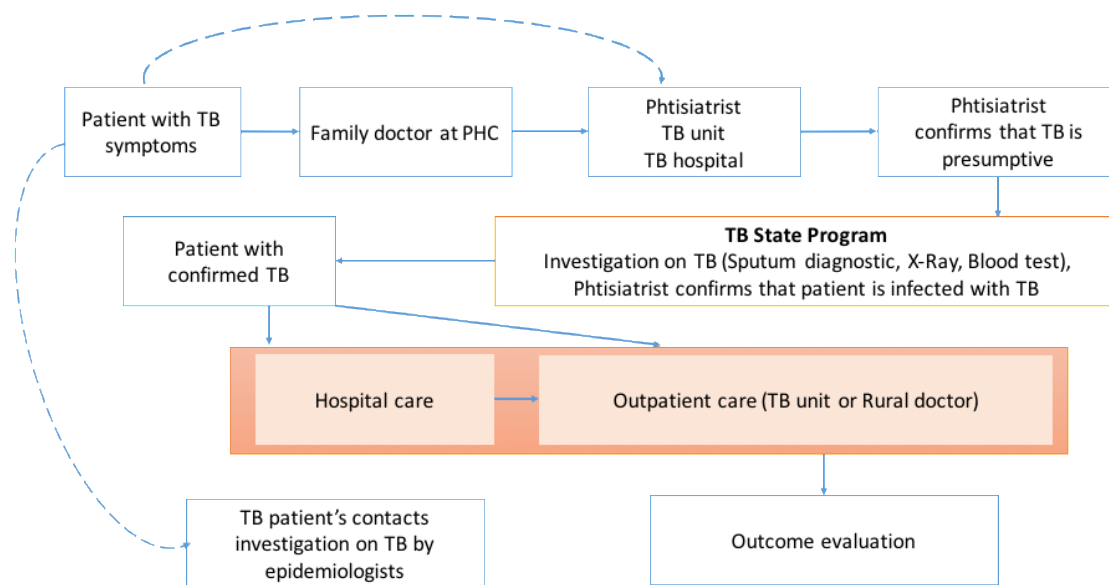
The TB specialist continues the diagnosis process to confirm or reject the TB case. The diagnosis is established by a direct sputum smear microscopy and Xpert MTB/RIF, which is supported by X-ray. The TB sputum specimen for diagnosis is taken by a DOT nurse and sent to the LSS by a courier service. (For more information about this service method, please see “Laboratory Service.”) The results from these rapid diagnostic techniques are then confirmed by culture.

After the patient is diagnosed with TB, s/he is enrolled in a TB program and starts treatment with anti-TB drugs. In general, sputum positive patient treatment starts at the NCTLD hospital, and sputum conversion treatment continues afterwards in the

outpatient setting as depicted in Figure 8. (Details of outpatient and inpatient TB care are described in the following sections.)

Unfortunately, general practitioners in some clinics are not very active in referring possible TB patients to specialists. Only 18% of presumptive TB cases were referred by PHC in 2015 partly because of poor recognition of TB patients.¹⁶ In some cases, as mentioned above patients with TB symptoms directly self-refer to specialized TB services at TB units instead of PHCs.

Figure 8. Patient Flow in the System



TB Outpatient Care

In 1995, Georgia implemented DOT strategies and started providing universal access to TB treatment within ten years. Access to drug-resistant TB treatment has been ensured since 2009 largely through The Global Fund's support.¹⁷ Joint efforts to control TB in Georgia have resulted in significant improvement in TB diagnosis and treatment:

- **In rural settings**, a family nurse is responsible for implementing DOT for DS or DR patients located in the respective coverage area within the *Rural Doctor state program's* frame. A TB doctor from a TB unit defines the treatment plan for patients.
 - For DS patients, DOT is implemented five times a week or every two or three days. (In some cases, it is done once a week if the village does not have a local nurse, who must then visit the village purposefully for direct observation.) Medication is then given to the patient for self-administration. This variation of practice is agreed upon between the TB doctor and supervisor, who controls DOT implementation.

¹⁶ USAID Georgia. Tuberculosis prevention project in Georgia. Final report 2011-2016, 2016

¹⁷ Extensive review of tuberculosis control, prevention and care in Georgia, mission report, 6-14 November, WHO regional office for Europe, 2014

- For DR patients, DOT is administered six days a week (including Saturday), but only direct observation is allowed for DR patients. If the patient cannot come to the facility, the nurse takes the medication to the patient's home although such type of service is not reimbursed by any source.
- Nurses receive a regular salary from the state Rural Doctor program as well as additional monthly supplements for DOT implementation on Saturdays from TGF grant. (More information about this is discussed in the "TB Service Contracting" section.) On average, 450 rural family nurses are involved in DOT administration throughout Georgia. The nurses change according to their patients' conditions from the treatment scheme. There are about one or two patients under a rural family nurse's care. Prior to inclusion in the DOT process, nurses are instructed and included in the monitoring process by a supervisor from a regional level TB unit. TB drugs in rural facilities are distributed by supervisors.
- **In urban (large cities or regional centres) and semi-urban (municipal) areas,** DOT is implemented by TB units in the frame of the *TB state program*. TB units are staffed with phthisiatrists and TB or DOT nurses. The number of personnel varies depending on the population size under the coverage area.
- Historically, TB units (also called TB dispensaries) were separately standing public facilities within one vertical TB system. A number of TB dispensaries existed in large cities, and each dispensary served a district population. Since 2012, the majority of TB units have been structurally integrated into primary care centres, but some state-owned TB units are still functional in the regions. After several reorganizations, the number of TB units in Tbilisi decreased from twelve to four. All four facilities are state-owned, and one is within the NCTLD. There are sixty-eight TB units in total operating throughout Georgia, including five in Tbilisi. Two new TB units opened in Tbilisi during Fall of 2017. The main purpose of these new TB units is to overcome geographical barriers for certain patients living in Tbilisi. These units have been built with the financial support of the Global Fund, allowing patients who are currently receiving care at the NCTLD to be redistributed among these units.
- Phthisiatrists are responsible for diagnosis, case classification, treatment regimen establishment (for DS patients), case management of all TB cases and TB drugs adverse reaction management in the coverage area. The treatment regimen for MDR patients is established by the medical consilium at the NCTLD. In most cases, DR patients are hospitalized for several months and are followed up by a phthisiatrist after discharge. Salaries are paid from the state TB program.
- DOT of DS and DR patients is a direct responsibility of DOT nurses.
 - For DS patients – DOT is implemented five times a week or every second working day.
 - For DR patients – DOT is implemented six days a week, including Saturday. DR-TB patient must strictly visit the TB unit, where DOT is administered. Salaries are covered from the state TB program. Additional supplements for DOT nurses and rural nurses for DOT administered on Saturdays are provided by TGF grant. For M/XDR-TB patients under a new treatment plan, DOT is implemented seven days a week, twice each day. Additional

supplements for Sunday and second DOT during a day is provided by the MSF grant.

- Specificity of DOT implementation in Tbilisi – Following the reduction of the number of TB units in Tbilisi, some modifications of DOT were allowed with regard to DS-TB patients. A TB nurse and a DS-TB patient agree to meet in the city (outside of the TB unit) three times a week, where the nurse gives the patient his/her medication. There is no direct observation of the treatment. Such a patient is assigned to a certain TB unit, where the patients records are maintained. There is no mechanism to proof if this schedule (three times a week) is followed. There is no additional travel reimbursement for the nurse. ,
- In Tbilisi, DOT is also delivered to patients by mobile DOT. These ambulance-type vehicles are staffed by a DOT nurse and driver from NCTLD . This new approach of DOT implementation is financially supported by the Global Fund, and thirty-six patients are currently receiving treatment with this type of service.
- The Global Fund also supports the Video Directly Observed Treatment (VDOT) smartphone application for twenty-six DR-TB patients in Tbilisi. The following criteria are considered when determining whether VDOT is suitable for each patient:
 1. The patient has successfully completed the initial weeks of in-person DOT with close to 100% adherence
 2. The patient is not experiencing major side effects
 3. The patient is willing to accept and follow VDOT procedures
 4. The patient can accurately identify and swallow his/her own medication independently
 5. The patient speaks a language that can be accommodated by a VDOT personnel, who can provide consistent care for the patient.Smartphones are provided by The Global Fund, and nine patients have successfully completed treatment using VDOT.

- A TB coordinator and TB supervisor are assigned to a regional level TB unit. The TB coordinator is responsible for overall TB activities in the region, and s/he is supported by a TB supervisor, who is responsible for drug distribution across TB units, rural ambulatories, DOT monitoring and patients incentives management.
- One human resources challenge is aging TB specialists and nurses. Most nurses in Georgia are female with the median age being 49 years-old and 31% in pre-retirement and retirement ages (>55 years). The median age of a TB doctor in Georgia is 58 years in the regions and 55 in Tbilisi. Due to low financial motivation and risky activity, the next generations of doctors are not willing to work in the field of TB. In fact, eight out of sixty-eight TB units have their designated phthysiatrist, and sometimes one phthysiatrist serves several TB units. This problem will intensify in the future because of low renewal of human resources.

TB Hospital Care

TB hospital care is provided by four specialized TB inpatient facilities operating throughout Georgia – Tbilisi, Batumi, Zugdidi and Abastumani. In total they have a maximum capacity of 440 beds of which, 174 beds are used for treating M/XDR-TB cases. DS symptomatic patients are usually hospitalized if they are diagnosed with compatible imagery that is confirmed through a sputum smear; culture (for respiratory forms of TB) or morphological and/or bacteriological evidence from samples adequate to the extra pulmonary forms. Home treatment is possible if there is a shortage of inpatient beds and proper conditions exist at the patient’s place of stay.

According to the guidelines, DR patients’ treatment starts with hospitalization. The average duration of stay in the hospital is about two months. For smear negative and extra pulmonary cases, the average stay is ten days while twenty-five days is typical for smear positive cases and seventy-five days for MDR-TB cases.¹⁷ Some patients may have social reasons for longer stays, or they may have complications with organizing outpatient treatment (DOT is twice a day or six times per week). Patients enrolled in a new treatment regimen must visit the TB unit twice a day. After conversion, DR patients are discharged from the hospital. Once released, the patient will continue treatment at a TB unit or with a rural family nurse. Bacteriological monitoring of DR patients is done monthly until conversion and then quarterly by repeating Drug Susceptible Testing.

Treatment regimens are administered according to the WHO’s recommendations¹⁸:

- DS-TB treatment lasts six months (including a two month intensive phase treatment).
- MDR-TB treatment lasts twenty months, and XDR-TB treatment duration is twenty-four months.

Programmatic use of the new drug, Bedaquiline (Bdq) began in August of 2015 through USAID donations and with the support of Médecins Sans Frontières (MSF). Shortly afterwards, Georgia gained access to Delamanid (Dlm) program.

Throughout Georgia, there are 145 TB specialists working in the outpatient and inpatient levels.

Laboratory Services

Diagnosis of TB is established by direct sputum smear microscopy and Xpert MTB/RIF, which is first confirmed by X-ray and then by culture for cases with negative microscopy/Xpert results. Sputum specimen transportation is organized by courier service from district TB units to the regional LSS. The National Reference Laboratory (NRL) performs a full range of TB laboratory investigations, and it is responsible for laboratory quality assurance countrywide. The novel Xpert MTB/RIF diagnostic technology was introduced in 2013 and is being expanded. Currently, nineteen machines operate in Georgia – four at the NRL in the NCTLD, ZDLs and LSSs under the NCDC as well as two in prisons.

¹⁸ WHO, Treatment of tuberculosis: guidelines – 4th ed. WHO/HTM/TB/2009.420

The GoG plans to roll out Xpert MTB/RIF technology at the district level and install Xpert machines in select PHCs. Nineteen machines will be installed in different regions out of which, fourteen will be installed in private healthcare facilities, where TB services are integrated. These selected facilities belong to EVEX medical corporation or Geo Hospitals group, which is the second biggest chain of medical facilities. The distribution of Gene-Xpert machines is considered to motivate private providers to retain TB services as they can be used for other diagnostic purposes.

In the last two years, the sputum collection and transportation system have improved. Since 2014, the sputum samples have been sent through the Georgian postal system, which is a mode of transportation used in all regions of Georgia.

The most expensive laboratory activities in Georgia are covered by TGF grant. The funds provided by the government for TB diagnostic activities cover a small portion of lab needs and should gradually increase from 2016-2020 according to the Transition Plan. There are currently twenty-five laboratory specialists working throughout Georgia.

Public Health Services

Epidemiologists are responsible for TB and LFU patients' contact tracings. Epidemiologists are staffed at municipal public health centres established and financed by local municipalities. In addition, PHCs are contracted by the NCDC (under *the Surveillance state program*) to provide additional public health duties, including those related to TB. Epidemiologists are informed about the LFU patients from regional TB coordinators, and their duty is to visit these patients at their homes to convince them to return to treatment.

There are no separate operational funds for visiting the patients' homes. It is meant to be covered by local municipalities, but the funding is scarce and not sufficient. Consequently, epidemiologists try to reach patients through the phone. But these two ways of contact are not always effective because of inaccurate addresses and phone numbers provided by LFU patients.

TB/HIV Services

Georgia is a low HIV prevalence country. The estimated adult HIV prevalence in Georgia is 0.4%, but with an increasing trend of new infections.¹⁹ Since the onset of the epidemic, 6204 new HIV infections were registered. Most affected individuals are within the age group of 29–40 years-old. From 2015–2016, about 700 new infections were registered – the highest amount recorded in Georgia. The HIV epidemic is largely concentrated among key populations: men having sex with men (MSM) and people who inject drugs (PWID). In 2015, the HIV prevalence was 21.7% (95% CI 17.1% - 26.8%) and 2.2% (95% CI 1.53% - 2.99%) among MSM and PWID respectively.

Georgia is one of the first countries in the Central and Eastern Europe (CEE)/CIS regions to have achieved and maintained universal access to Antiretroviral Treatment (ART). By April 20, 2017, a total of 6,311 HIV/AIDS cases were registered in the Infectious

¹⁹ UNAIDS. <http://www.unaids.org/en/regionscountries/countries/georgia/>

Diseases, AIDS & Clinical Immunology Research Centre, including 4,698 (74.4%) men and 1,613 (25.6%) women with the majority of the patients within the 29-40 years of age range. 3,507 patients developed AIDS (55.6%), and 1,279 patients died (20.3%). 3,786 patients are on ART.

HIV/TB co-infection. Based on the National Policy, all adults and children enrolled in HIV care should be covered with TB symptom screening. The country reports 100% coverage of People Living with HIV (PLHIV) screening for TB. For HIV-hospitalized patients, sputum is collected by a nurse and sent to a TB facility for further investigation. Ambulatory HIV-infected patients with presumptive TB are referred to a TB-specialised facility for further investigation. TB is frequent among HIV-infected individuals, and it is the leading cause of mortality among PLHIV (21%).

Based on the National Guidelines on management of TB & HIV co-infection, HIV testing should be offered to all TB patients at the time of TB treatment initiation. Testing for HIV is done with rapid tests, but the proportion of TB patients tested for HIV was 70% in 2015²⁰ and 85% in 2016.²¹ Testing for HIV among TB patients in tuberculosis services has improved over the years, yet these services still need to be better organized, especially at the peripheral service delivery level. According to the NCTLD, the main reason of no full coverage of HIV testing is refusal from parents to test their children. (In 2016, 5.6% of all registered TB cases were children between 0-17 years of age.)

Georgia has four main AIDS centres, but the National AIDS Centre in Tbilisi is the only place where final confirmation of HIV infection is performed (through blotting). According to the Centre, PLHIV do not have access to quick diagnosis and adequate professional counselling because of low experience among peripheral TB staff.

Overall, HIV prevalence among TB patients in Georgia is low compared to other countries in the CIS, indicating insufficient detection of HIV infection among TB patients. In 2015, about seventy to eighty cases of TB/HIV coinfections were diagnosed.

Table 3. TB/HIV Co-infection (%)

	2010	2011	2012	2013	2014	2015	2016 prel. data
TB/HIV co-infection (%)	1.9	2.0	2.2	2.1	2.2	3.1	2.7

DOT for PLHIV is provided in the same way as for other TB patients.

TB Patient Support

Incentives for patients. Until 2013, material support for patients to ensure adherence to proper treatment included food vouchers and financial incentives for transportation. These were given to drug susceptible and M/XDR TB patients. For a year and a half, this support was interrupted, and monetary incentives were introduced instead for TB

²⁰ Green Light Committee for the WHO European Region monitoring mission in Georgia, February 2017

²¹ Personal communication with NCTLD specialist

patients in June of 2014. For DS patients, the incentives were given for uninterrupted treatment with TGF financial support (overall, 160 GEL or 64 USD net rate).

The DOT regimen for DR-TB patients requires six visits per week. The TB state program provides 100 GEL or 40 USD (net rate) for DR patients on a monthly basis for uninterrupted treatment during a maximum period of twenty months. The TB state program for 2007 included incentives for 300 DR patients, and the rest of the DR-TB patients' financial incentives were covered by TGF grant. For XDR-TB patients whose treatments are longer than twenty months (typically twenty-four months), their incentives for the additional four months are paid from the MSF grant.

Furthermore, DR patients receive transportation costs that are estimated on an individual basis and should cover daily transportation to the facility. The patient gets an average of 1–4 GEL (0.40 – 1.60 USD) per day. In the case of M/XDR-TB patients who are on a new treatment scheme, they receive additional transportation costs to visit the TB unit every evening and Sunday, which is supported by MSF.

Financing and Contracting

TB Expenditures and Funding Gap

Government expenditure on TB control increased gradually from 10.9 million GEL in 2012 to 20.0 million GEL in 2016 (Table 4). Data on OOP expenditures by the NHA from 2012-2014 demonstrated a slight decrease in share (from 6.3% to 5%), but stability in absolute terms that comprised 1.4 million GEL.

Table 4. Total Expenditures on TB Control by Financing Scheme (GEL), 2012-2014

	2012	2013	2014	2015	2016
Government spending	10,916,438	14,532,049	15,855,729	15,292,900	20,917,000
External funding	9,196,993	11,069,433	10,720,171		
OOP	1,352,698	1,385,163	1,412,866		
Total	21,466,129	26,986,645	27,988,766		

Source: 2012-2014 (NHA); 2015-2016 (Budget execution)

The breakdown of external funding by agency shows that The Global Fund is a major contributor for TB control (

Table 5). Regarding the nature of assistance, the NHA data show that over half of the external TB-related support in 2014 (52.7%) went to the supply of medical goods (i.e. TB drugs and other medical consumables), followed by various support classified under health system governance, administration and financing (25.5%).

Table 5. External Funding on TB Control by Agency (GEL), 2012-2014

	2012	2013	2014
Global Fund	7,787,539	8,445,864.31	7,655,257.66
USAID	576,637	1,762,799.99	1,514,727.25

WHO	19,816	18,500.00	17,200.00
MSF	813,001	842,269.15	1,532,985.61
Total	9,196,993	11,069,433	10,720,171

Out-of-pocket payments for TB control are made on curative care only with higher share on outpatient care than inpatient care (Table 6). The NHA does not provide details on OOP expenditures. However, based on the qualitative study on barriers to adherence, we could imply that OOPs are primarily spent on medications used for managing TB drugs adverse reactions as well as transportation costs related to traveling from different regions to Tbilisi for specialist services at the NCTLD .

Table 6. Out-of-Pocket Payment on TB Control by Function (GEL, % of total), 2012-2014

	2012		2013		2014	
Inpatient curative care	460,804	34.10%	647,630	46.80%	556,997	39.40%
Outpatient curative care	891,895	65.90%	737,533	53.20%	855,869	60.60%
Total OOP	1,352,698		1,385,163		1,412,866	

Source: NHA

Fulfillment of the NSP objectives will require major investments from the government and donors. The GoG intends to increase financing of TB control from public sources, which is demonstrated by the approved state programs budget for 2017 and the TB program budget projections for the next three years reflected in the Midterm Expenditure Framework (Table 7).

Table 7. Government Allocation on TB Control (GEL), 2017-2020

	2017	2018	2019	2020
Government allocations	15,400,000	15,500,000	18,000,000	19,000,000

Source: 2017 approved TB State Program budget; 2018-2020 MTEF projections

The Global Fund, the major contributor in external funding, will support Georgia during the next three years and will gradually phase out.

Table 8. TFG-Approved Budget for TB Control (USD), 2017-2019

	2017	2018	2019
TGF approved budget	5,689,000.00	3,812,000.00	2,624,000.00

The NSP for 2016-2018²² provides estimations for the funding gap based on total needs, expected domestic financing and external funding estimates (

Table 9). Despite the government's increasing financial commitment and anticipated external funding support, the estimated funding gap remains significant given the requirements for increasing access to diagnosis and treatment of TB patients (including

²² CCM Georgia. 2015. National Strategic Plan for Tuberculosis Control in Georgia 2016-2020

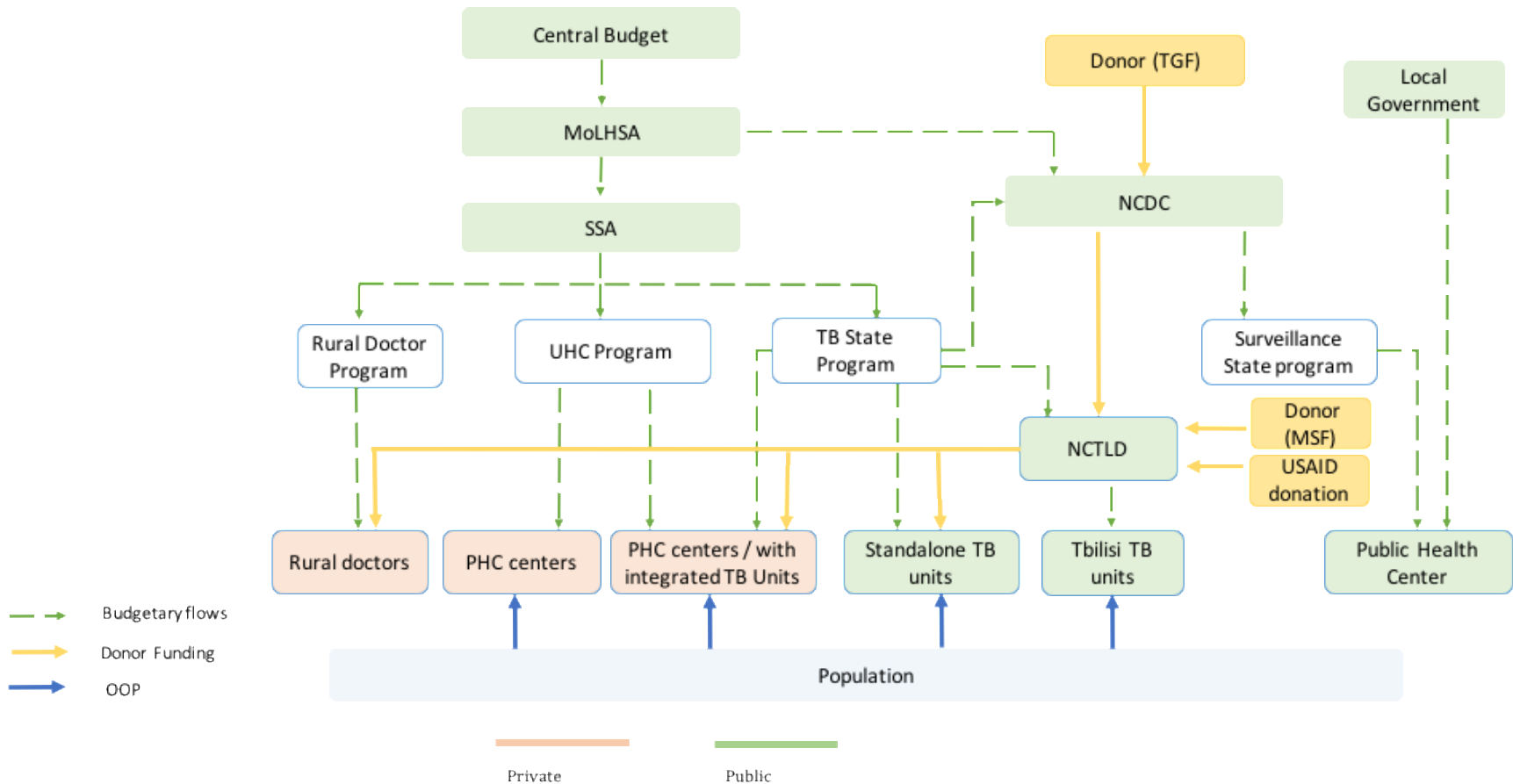
M/XDR-TB) in addition to implementing patient-centred approaches as well as community and civil society involvement. The total funding gap from 2016-2018 is estimated to be about 11.2 million USD, which constitutes a 20% deficit of the total needs of 55.9 million USD in the same period. The most important gaps are faced by the supply of anti-TB drugs for treating M/XDR-TB cases and the provision of adherence support for patients.

Table 9. Funding Gap in USD for 2016-2018

Objective	Total funding needs	Government funding	External funding	Funding gap
Provide universal access to early and quality diagnosis of all forms of TB including M/XDR-TB	10,779,226	3,647,860	4,413,339	2,718,026
Provide universal access to quality treatment of all forms of TB including M/XDR-TB with appropriate patient support	31,252,490	19,099,690	7,041,515	5,101,760
Enable supportive environment and systems for effective TB control	11,946,571	334,840	9,922,088	1,689,643
Annual cost increase adjustment	1,872,256	203,980	0	1,677,800
TOTAL	55,850,543	23,286,370	21,376,942	11,187,229

TB Financial Flow

TB services are financed through the state budget – mainly from the TB state program as well as Rural Doctor state program, UHC and Surveillance state program – Donors funds and OOP expenditures.



TB Service Contracting and Payment Mechanisms

As mentioned above, the SSA contracts service public or private providers for services under the state's TB, Rural Doctors and UHC programs. *The Surveillance state program* providers (municipal PHCs) are contracted by the NCDC, and services under *TGF grant* are provided through contracts from the NCDC to NCTLD. MSF directly contracts the NCTLD for M/XDR-TB patients' new drug treatments.

Outpatient Level

The Rural Doctor state program is financed through a global-budget financing model. The program sets the salary for rural doctors at 650 GEL (260 USD)²³ and 455 GEL (182 USD) for nurses. Rural doctors do not participate in any activities related to TB care except for TB presumptive case identification and referral to TB specialised services. On the other hand, rural nurses are responsible for DOT of DS and DR patients in the catchment area. Apart from a monthly salary, nurses receive an additional fixed 40 GEL (16 USD) on a monthly basis for implementing DOT for DR patients on Saturdays. (This fixed monthly amount given to nurses is not linked to the number of DR-TB patients.) This supplement income is paid from TGF grant, which flows through the NCDC to the NCTLD. (The NCTLD is TGF grant sub-recipient).

The UHC program service providers are funded at a fixed rate per capita for PHC services. Their monthly budget is formed according to the catchment population size. Family doctors and nurses are contracted by the PHC manager and reimbursed at fixed monthly salaries. The UHC program does not define the salary base for family doctors and nurses. The average salary for family doctors working in urban PHCs is 1000 GEL (400 USD) with somewhat lower salaries in the regions. There is no additional funding linked to their performances.

The provider payment mechanism for specialised outpatient services at TB units – either integrated at PHCs or separately standing – is based on a fee-for-service method. The TB State program establishes tariffs for outpatient services (see Table 11). The facilities are reimbursed on a monthly basis according to provided services. Phthysiatrists and DOT nurses are contracted by the Health facility management.

The *TB state program* defines monthly based salaries, which are 360 GEL (144 USD) for doctors and 280 GEL (112 USD) for nurses. Based on this information, it is possible for TB doctors to have salaries three times lower than family doctors in PHCs and two times lower than rural doctors. Managers can freely upgrade their staff's salaries, but this practice shows that doctors and nurses usually receive a minimal monthly base. The Tbilisi NCTLD staff receives a higher salary than their colleagues in the regions and even in Tbilisi TB units that are subcontracted by the NCTLD. Just like the rural level nurses implementing DOT, the

²³ The salaries and supplements are shown in gross rates that are subject to 20% taxation

TB unit nurses receive an additional 40 GEL (16 USD) for DR patients' DOT on Saturdays. Nurses enrolled in new treatment under the MSF grant receive additional financial supplements to fulfill DOT during evening hours and on Sundays. The amount is 56 GEL (22.4 USD) per week or 224 GEL per month (89 USD). In general, monthly remunerations of phthysiatrists are 2.5 times lower than the average nominal salary²⁴ and even lower than the salary of a primary healthcare nurse.

Service providers – the majority of which are private – should be motivated to have a high number of patients every month as their monthly reimbursement from the state program is tied to their performances. However, the health personnel itself does not have financial motivation with this regard because their salaries are fixed regardless of their performances or the number of patients they treat. Facilities that have a few number of TB patients under treatment have difficulty in maintaining TB services because there is no financial profit and in some cases, they can hardly reimburse their phthysiatrists and nurses.

For the providers that have a network of PHC, service providers (e.g. corporation EVEX) can pool funds and reallocate resources. Nevertheless, health care providers have no interest in keeping TB services that are a threat to the uninterrupted delivery of TB care. Currently, private service providers are tied to an agreement with the GoG to provide TB services, but this agreement will expire in 2018.

Table 10. Salaries and Supplements of Personnel Involved in TB Care by Source in GEL

Type of service provider	Type of service provider	UHC Program	Rural Doctor State Program	Local municipality	TB State Program	TGF TB grant	MSF TB grant
HR	facility						
Family doctor	PHC centre urban, semi-urban	1000					
Rural Doctor	Rural ambulatory		650				
Rural nurse	Rural ambulatory		455			40	
Phthysiatrist	TB unit				360		
DOT nurse	TB unit				280	40 (for DR DOT)	224 (for new treat)

²⁴ The National Statistics Office of Georgia, average nominal monthly salary of hired employees, 2015

Phthysiatrist*	NCTLD (outpatient dep)	900	
Phthysiatrist	TB units in Tbilisi	670	
Lab specialist	Public Health Lab; NCTLD; PHC centres with G/Xpert	900	
TB coordinator		240	700
TB supervisor		500	
Epidemiologist		550	

Phthysiatrists involved in clinical trials receive additional salaries ranged from 280 USD to 560 USD per month.

Table 11. TB Outpatient Service Tariffs in GEL (TB State Program for 2017)

N	TYPE OF OUTPATIENT SERVICE	COST (GEL)
1	Presumptive pulmonary TB case/contacts diagnostics (service cost per case)	
1.1	Adult/Medical Personnel	44
1.2	Child (<18)	50
2	Presumptive non-pulmonary TB case/contacts diagnostics (service cost per case)	
2.1	Tuberculous Pleurisy	140
2.2	Osteoarticular TB	110
2.3	Urogenital TB	76
2.4	Female genital TB	118
2.5	Peripheral lymph node TB	92
2.6	Abdominal TB	70
3	Outpatient care (monthly voucher)	
3.1	DS-TB	50
3.2	DR-TB (intensive phase)	158
3.3	DR-TB (continuation phase)	84
3.4	MDR-TB with new drugs (intensive phase)	279
3.5	MDR-TB with new drugs (continuation phase)	155
3.6	Latent TB	26

Hospital Level

Two payment methods are used for hospital services reimbursements. When a patient is hospitalised for therapeutic (non-surgical) care, the services are paid per diem. When surgical intervention is required, payment is done through fee-for-service. The tariffs are established by the TB state program (**Table 12**).

Table 12. TB Inpatient Service Tariffs in GEL (TB State Program for 2017)

	TYPE OF INPATIENT SERVICE	COST (GEL)
4	Surgery	
4.1	Pulmonary TB (Pneumectomy)	2575
4.2	Abdominal surgery	1210
4.3	Surgery for osteoarticular TB	3930
4.4	Surgery for urinary tract TB	2080
4.5	Minimally invasive Thoracic surgery	1455
4.6	Lymph nodes surgery	1165
4.7	Surgery for male genital system TB	745
5	Inpatient care	
5.1	DS-TB (Tbilisi)	92
5.2	DR-TB (Tbilisi)	129
5.3	TB Meningitis (Tbilisi)	121
5.4	DS-DR TB (Regions)	45
5.5	Difficult diagnostic case (limited inpatient days- max 4 days)	224
6	Sputum diagnostics with Gene-Xpert	10

Sputum diagnostics with Gene-Xpert are reimbursed from the TB state program for 10 GEL. Test systems are provided through TGF grant.

TB drugs are financed from public and donor sources. Under the TB state program, all first-line drugs and 25% of second-line drugs (SLD) will be procured in 2017 with a gradual increase of government contribution as well as 100% drug procurement from the public sources in 2020. The Global Fund and MSF grants cover most SLD needs at the present. An uninterrupted supply of quality TB drugs is ensured countrywide, and drug procurement is implemented by the NCDC. Procured drugs are delivered to the NCTLD, which distributes them to the regional, district and rural levels. Drugs for managing anti-TB treatment adverse reactions are financed through *the TB state program*. The MSF also contributes in purchasing drugs for adverse reactions for patients who cannot afford them based on the phthysiatrists' requests through a special form usually for patients living in regions.

TB Information System

Georgia uses a comprehensive individualized electronic information system (E-Health) that incorporates TB module. The new platform was endorsed by the GoG in April of 2015, and it was installed at all peripheral TB service delivery sites, providing access for TB doctors. The module was updated to accommodate the most up-to-date WHO recommendations and to use the new software platform. All indicators and data collection tools have been aligned with the latest WHO standards. Diagnostic/laboratory data, including Xpert MTB/RIF data,

will be integrated with the rest of the database. The E-Health TB module is not currently functional.

Another TB HIS currently operates in Georgia (in both paper and electronic forms). The electronic system works at the regional and central levels (NCTLD). Phthysiatrists at the district level notify the regional level about TB cases through paper-based forms sent on a weekly basis. Quarterly, regional coordinators collect the main paper registries (TB-03) from district facilities and electronically validate data entered from individual forms (TB-10/12) by checking them with TB-03. The database managers at the NCTLD are responsible for validating and processing the entire dataset. Moreover, they oversee the coordination of the reporting entities and control whether the case notification (TB-10/12, hospital admission forms, HIV data, DST results, etc.) is done in a timely manner. The database has a separate module with a predefined standard reporting tool that can generate report forms for local and national purposes as well as spreadsheets with raw data for non-standard analyses and processing data tables. The TB HIS electronic database also can generate indicators for WHO reporting.

Monitoring and Supervision

According to the National Tuberculosis Strategy and Operational Plan, TB control in Georgia is supposed to be monitored via a set of fifty-five indicators. A vast majority of the indicators are adopted from the WHO regional M/XDR response plan, and the supervisory visits are covered by TGF funding and the TB state program.

Regular field supervision and monitoring visits are organized across the country. The system of M&E in Georgia includes three levels of supervision on the district, regional and national levels. Supervisory visits from the national to district levels are done regularly by a team of specialists using standard checklists. Supervisory visits from regions to each of the district TB units are performed by each regional TB coordinator on a quarterly basis as well as the national supervision team twice per year. Thus, every TB unit is supervised by the national supervision team every six months. During the supervision visits, registration forms, patients' medical records and the balancing of medications are checked and evaluated on the reported data's consistency to the actual situation. During site visits, the following are checked: presumptive TB cases registration forms and treated TB patients' registration forms. These forms provide information on how many patients are on treatment; how many of them are new patients; how many of them have a history of previous treatment; how many patients have pulmonary and non-pulmonary forms of TB; how many patients have bacteriologically confirmed diagnoses; how many of them are clinically diagnosed; how many patients have been tested for HIV and how many of them are on ART.

Afterwards, the TB patients' medical cards are checked to evaluate how accurately the patients' treatment outcomes are registered in this form. TB regional coordinators are staff of the NCTLD, and they also work in the TB units of the regions. In total, there are ten regional coordinators (nine in the regions and one in Tbilisi). In two cases, the TB coordinators also act as TB doctors (phthysiatrists) in their catchment area, and they are paid from the TB state program for their duties. Regional coordinators are responsible for collecting the data from TB units under their coverage areas according to the M&E forms and reporting them to the NCTLD M&E department every month.

There are four M&E forms – clinical management, data management, infection control and laboratory and drug management. (The forms are described in detail in the TB HIS inventory). The forms are used to provide feedback and recommendations, and a copy of the form is retained at the facility to enable its follow-up.

The M&E department at the NCTLD operates a special Excel database, where all information delivered through the M&E forms is entered and analysed. Information from this database is credible and used to verify the main TB database, which also operates at the NCTLD.

The Global Fund TB Grant Support

In June of 2015, Georgia applied for the TB Concept Note to TGF New Funding Model (NFM) window, which was approved by The Global Fund. The NFM Project Objective 4 (Intervention 4.3. 'To improve financing mechanisms to support the integration and increase in coverage, effectiveness and quality of the TB and HIV/AIDS services') articulates the introduction of the Results Based Financing (RBF) mechanism for improving utilization and quality of TB services. Below is the citation from the proposal that outlines the RBF introductory activities:

"TGF support is sought for external and local technical assistance in exploring the feasibility, designing and piloting of performance-based service delivery contracts with health care providers, Pay For Performance (P4P) schemes for outpatient service providers, and implementation of the new provider payment mechanism for inpatient TB services. The feasibility assessment and the design of the P4P schemes in Georgia will have to address (but not limited to) the following issues:

- What motivates and deters people from seeking care;
- Which incentive schemes will best motivate providers in private and public systems (through wide consultations with TB specialists and PHC personnel);
- The timelines and dynamics for projected changes in healthcare and TB financing;
- The cost-effectiveness of existing and potential private-public models — including which models and funding mechanisms are best suited for the Georgia

context and NSP goals of TB control and which have the potential to reach scale and be sustained;

- How the public purchaser and the private provider organizations can best work together, including the more frequent use of results-based financing.

The P4P pilot results will be also be evaluated about P4P's possible impact on performances and sustainability in the field of TB and on other services where no similar incentive scheme is applied. It should be noted that all planned changes in financing, allocation and service delivery in relation to TB care should be in line with the overall processes in the health care system. Currently the Government and the Ministry of Labour, Health and Social Affairs (MoLHSA) of Georgia are in the process of defining the directions and mechanisms for the health system's development over the medium-term period, which includes the priority financing of the Primary Health Care (PHC) services and exploring the P4P mechanisms for chronic diseases management. It was therefore decided to carry out the most of the above mentioned NFM activities under Intervention 4.3 of the grant implementation (between July 2017 – June 2018), as it is expected that by that time the overall mechanisms and schemes are expected to be in place. Technical assistance through TGF will be required to adjust them for the specifics of TB services, especially in terms of targeting the planned changes in TB care delivery model with prioritization of the integration of the TB services at PHC level and outpatient TB case management including that of M/XDR-TB cases.”

In June of 2017, the Global Fund implemented a one year pilot project in five major Georgian cities – Tbilisi, Rustavi, Batumi, Zugdidi and Kutaisi – aimed at promoting civil society's participation to reduce LFU rates among DR-TB patients. A team consisting of a psychologist, social worker and peer worker reached out to the 250 DR-TB patients enrolled in this program.

At the end of 2017, a new call was announced about the smartphone application, VDOT. Thirty-seven patients, who have used VDOT, showed that they preferred taking their medication between 19:00 – 21:00. Two nurses served these patients, but as the number of patients enrolled in this treatment plan increases, two nurses will not be able to serve them all. The Global Fund has set a ten-month period deadline so that by the end of 2018, VDOT will be the leading phone application assisting TB patients.

The Global Fund is also sponsoring a TB awareness project among Orthodox and Islamic religious leaders, who will deliver TB awareness messages to their congregations during Sunday services. A TB media campaign designed to raise TB awareness among the general public is also financed by the Global Fund.

Lastly, The Global Fund is developing a training series for phthysiatrists to improve their knowledge on HIV counselling and testing; for endocrinologists to increase their understanding about TB–diabetes comorbidities management and for PHC doctors to increase TB detection rate.

Civil Society Sector Role

In Georgia, the NGO division for TB is less developed than the HIV sector. TB-focused NGOs are relatively new, and their capacity is quite weak in terms of internal administration as well as program and financial management. In addition, they are exclusively dependent on donor-funded programs. Most of them have gained experience in TB-related activities, including ACSM, training, active case finding among hard-to-reach high-risk groups and operational research thanks to the USAID Georgia Tuberculosis Prevention Project (TPP) implemented from September 2011 to December 2015.

The mapping of the CSO sector involved in TB activities was done in 2016. This process identified that in total, seventeen local NGOs are currently active with TB work in Georgia. Two particularly exciting groups that have emerged since 2014 are Patient Union and the TB Georgian Coalition.

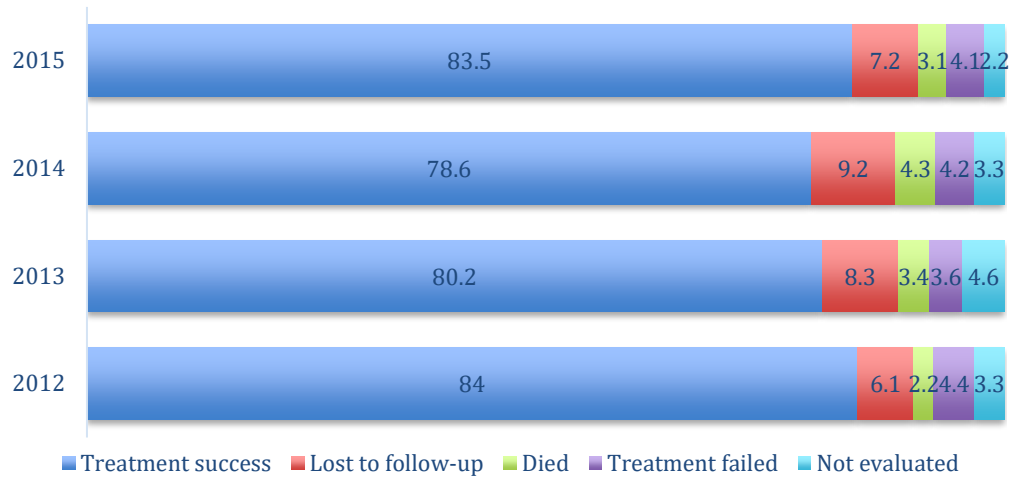
1. **In 2014, a new community based organization – Patient Union** – was officially registered, which united current and former TB patients motivated to engage in the fight against TB in Georgia. However, the capacity of Patient Union remains extremely limited with no history of receiving any funds from financial sources. Despite this, Patient Union is involved in TB community mobilization and advocacy work on a voluntary basis. Patient Union is a member of the Country Coordination Mechanism (CCM) to represent TB constituencies.
2. Shortly after the Patient Union was founded, a decision was made to establish **TB Georgian Coalition (TBGC)** – an informal, voluntary and membership-based forum of CSOs engaged in TB work. Currently, the TBGC unites eighteen member organizations. However, only a few of these organizations are actually engaged in TB work with the majority focusing on HIV. Integrating TB into their work at the single organizational and Coalition levels will require more resources.

Program Performance

Performance Indicators

Treatment outcomes are satisfactory for DS-TB patients (Figure 9).

Figure 9. DS-TB Treatment Outcome (%), 2012-2015 Cohorts

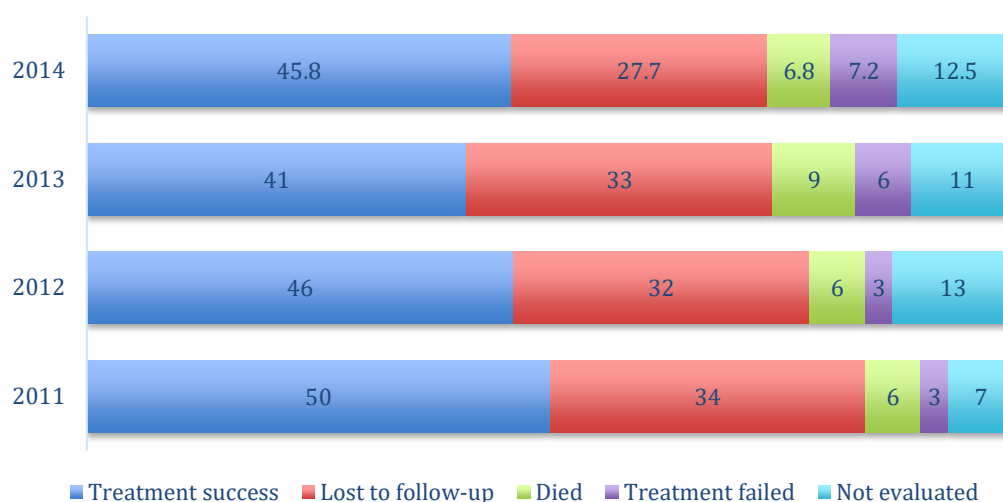


Source: NCTLD, 2017

Despite universal access to TB care services and social support, late diagnoses and a high number of LFU patients remain problematic, especially among M/XDR-TB patients. The trend over the last several years shows that a third of DR-TB patients stopped treatment (Figure 10).

A study on 133 LFU patients from the 2014 DR-TB cohort (462 patients) showed that the median duration of treatment from initiation to termination was 192 days or about six months

Figure 10. DR-TB Treatment Outcomes (%), 2011-2014 Cohorts



As the number of DR-TB patients with poor treatment outcomes has increased, additional resistance to SLDs (XDR-TB) has been observed. XDR-TB comprised almost 16% of all MDR-TB cases in 2014. The share of patients with XDR-TB among repeatedly treated MDR-TB cases has increased in recent years, which is of great concern.

Of the new MDR-TB cases in 2015, 23.8% had resistance to fluoroquinolones (Fq); 36.6% to second-line injectables and 9.1% to both groups of drugs. In the same year, the proportion of repeatedly treated MDR-TB cases with resistance to Fq was 47.8%; 39.6% to second-line injectables and 25.8% to XDR-TB. Despite this, it is important to highlight that about 40–45% of all MDR-TB strains tested were susceptible to both Fq and second-line injectables (Table 13). This is particularly relevant since the NTP intends to introduce the WHO-recommended nine-month regimen.²⁵

As of 31 December 2016, 294 patients are enrolled in treatment plans with new TB drugs.

Table 13. Treatment Outcomes of Patients Receiving Bdq/Dlm, July 2014 –December 2016

TOTAL NUMBER OF ENROLLED PATIENTS:	294
PATIENTS ON BDQ	231
PATIENTS ON DLM	63
STILL ON TREATMENT	210
PATIENTS WHO HAVE AN OUTCOME:	84
CURED	35 (42%)
COMPLETED	6 (7%)
LFU	22 (26%)
DIED	15 (18%)
FAILURE/REFUSED TREATMENT	3 (3.5%)
NOT EVALUATED (LEFT THE COUNTRY)	3 (3.5%)

²⁵ Green Light Committee for the WHO European Region monitoring mission in Georgia, February 2017

Currently, Tbilisi patients, who do not adhere to their treatment, are visited by psychologists and social workers. However, this service is lacking in the areas outside of Tbilisi. To address the high LFU rate, the NCTLD hired outreach nurses and adherence consultants to work in all ten regions, including Tbilisi.

The adherence department was recently formed as a new structural unit at the NCTLD. This department consists of a chairperson, two psychologists and two social workers in Tbilisi; nine adherence consultants in regions (one per region) and a database manager. Medical background is not mandatory for this position. Also, an adherence consultant can be nurse, psychologist, doctor, social worker or person with an educational background and relevant skills for this position. A selected candidate should be reliable, supportive, sociable and have the ability to convince non-adherent patients to not interrupt treatment. The major responsibilities of this position include education and counselling, psycho-social support, follow-up and registration of treatment side effects in a specially elaborated database. An adherence consultant's target audiences are TB patients (DS- as well as DR-TB patients) and their families. The adherence consultant closely communicates with his/her patients and is fully aware of the details of the patients' treatment plans. This model is still under development and not all responsibilities of this department are currently in place. For example, the side effects monitoring database has not yet been elaborated.

The adherence consultant receives a fixed salary of 500 GEL (gross) per month. The personnel salaries are funded by The Global Fund, and there is ongoing negotiation between the NCTLD and MSF to cover operational costs.

Adherence to Treatment

In 2016, the Curatio International Foundation conducted a qualitative study to investigate factors that enhance or hinder treatment adherence among sixty DR-TB patients – those who were successfully treated; those currently on treatment but having difficulty to adhere to treatment and LFU patients. Key stakeholders and service providers were also interviewed. The findings are grouped into structural, social, personal and health system factors according to the study's conceptual framework.

Structural Factors

Employment and treatment. Some conflict exists between the Labour Code and TB treatment regimen. Employed patients' working hours and difficulty in obtaining sick leave for treatment do not allow them to comply with the treatment regimen. In addition to this, some patients do not disclose their disease to their employers because of stigma or fear of losing their jobs. Therefore, it is difficult for such patients to combine their work and treatment regimens, and they are forced to abandon treatment.

On the other hand, communication with colleagues and going to work helps patients overcome negative side effects of treatment and/or bad reactions to the treatment. Due to

financial problems, patients with low economic statuses face difficulties with taking additional tests and purchasing medications for managing side effects. The side-effect problems are discussed in more detail below in the section dedicated to healthcare.

Monetary incentives. The incentive system works well among patients, especially for patients with low economic statuses because it provides them a certain source of income.

Support from family and friends. Lack of attention from family and friends negatively affects adherence to treatment. When a family member is actively involved in the treatment process and supervises the patient's visits, the patient is more responsible for his/her health and his/her family.

Peer influence. Exchanging information about difficulties overcome by other patients has a positive impact on adhering to treatment. Most patients said that their decision to continue receiving medicine was a result of the negative consequences of abandoning treatment, which they saw in other patients.

Stigma. Due to stigma, patients conceal information about their illness and avoid communicating with other people since they are afraid that their attitudes toward them will change. Stigma was mentioned by recalcitrant and defaulting patients as well as those who successfully completed TB treatment. Only 15% of patients mentioned this issue, but it has never been named as the main reason for abandoning treatment.

Personal Factors

Awareness about the illness. Deficit information was revealed among defaulting and recalcitrant patients. One-fourth of these patients stated that they missed visits to the DOT centre or stopped treatment altogether because their tuberculosis symptoms disappeared, or they felt much better. There were also some cases when patients abandoned their treatment and then resumed it once their health started to deteriorate.

Motivation. Patients who had successfully completed TB treatment stated that one of their main sources of motivation was the need to take care of family members in addition to their own health.

Health System Factors

Free treatment. The opportunity to receive treatment free of charge was viewed as a huge benefit. Providers emphasized the positive steps made in the provision and management of TB services. The majority of physicians spoke about a properly running laboratory system, namely the opportunity to make timely and safe tests; the introduction of a new method of lab diagnostics; the functioning of a well-organized transportation system and the implementation of the Cold Chain principles. In addition, the physicians stressed the need for a system that ensured a continuous supply of medications and the opportunity of working without interruptions.

Decision-making process. Service providers expressed dissatisfaction with their limited involvement in the decision-making process. According to them, different changes were

made in the program without considering their opinions or including them in discussions. As for patient participation, it must be noted that patients did not express such expectations.

Compassionate medical personnel. A majority of the patients stressed many times of the medical personnel's positive role during the long and difficult treatment period. Patients talked about the attentive treatment they received from doctors and nurses. According to these patients, the nurses not only gave them the prescribed medication but also provided moral support. Attentive and compassionate medical personnel significantly influenced patients' behaviour and encouraged them to complete their treatment.

Personnel financial motivation. The research revealed a financial problem related to service providers, namely low remuneration, which is below the average salary level. According to service providers, their only stimulus is professional (intrinsic) motivation. The research also demonstrated that service providers do not have full financial support necessary to perform their obligations within the program. Doctors and nurses must personally cover the costs of communicating with patients, which is not a small share of their monthly salary. At the same time, the examples above show that frequent communication positively influences and stimulates patients during the treatment process.

The same problem was identified amongst epidemiologists. They talked about an overloaded work volume and complained about inadequate financing of their efforts. Epidemiologists are responsible for finding LFU patients via phone calls or transport costs, which are not covered.

LFU patients stated that before the treatment default, medical personnel actively contacted them when they missed visits and asked for their reasons. After the patient defaulted, medical personnel asked questions about the main reason, but then all communication stopped. Once a patient is designated lost to follow-up, medical personnel are no longer obliged to contact them. Patients view this as a lack of attention from medical personnel.

Geographical distribution. Both patients and specialists discussed about the existence of a geographic barrier to service access for the Tbilisi population. Transportation to the DOT centres for patients is a problem because there are only four DOT centres in Tbilisi at present, and their locations are not evenly distributed. Patients living in regions have service access problems in managing side effects. They must often go to Tbilisi to receive these services.

Infrastructure problems. It is important to mention that DOT centres also have infrastructural problems. For example, regional facilities do not have enough space to provide high quality ambulatory services. Even though the condition of integrated facilities has improved, these buildings do not usually meet international standards, like constant natural or artificial ventilation and ultraviolet lighting. Due to the inadequate spaces or poor sanitary conditions of ambulatory facilities, patients share their experiences with each other, which can help them overcome their difficulties.

Difficulties with DOT regimen

According to rural and urban patients, the treatment regimen, which takes place under immediate supervision, is problematic. It is difficult for patients to visit medical facilities everyday over a very long period to take their medicine. This causes the so-called “pill burden” when patients become exhausted from taking many pills for a long period of time. Patients included in the new treatment scheme must visit a medical facility twice a day, which is problematic even though they have transportation vouchers.

Side effects. All LFU patients named side effects as one of the main reasons for interrupting treatment. The Tbilisi population has better access to such services, which are available at the NCTLD. The Centre has hired different specialists, who play an important role in managing side effects. Moreover, Tbilisi patients are better informed and use UHC services for their benefit. In regions, patients either visit narrow profile doctors directly or come to Tbilisi, which is related to additional expenses.

Risks of TB service continuation. The study revealed the existence of service continuity risks. Some problems that put the provision of service by private service providers at risk were identified in the regulations. The situation is exacerbated by a lack of motivation at the institutional and personal levels. It has become evident that the heads of medical facilities show less interest in implementing unprofitable activities, like TB services. Service providers also have low incentives to improve performance indicators since there are no mechanisms linked to results.

A new quantitative study investigating factors for LFU has been implemented by the NCDC and the results will soon be available.

Patient Satisfaction

No information is available on patient satisfaction.

Other Studies

Within the framework of the endTB project, MSF has been supporting an observational study on the programmatic use of new and repurposed drugs, which began in April of 2015. In this study, each patient is closely monitored for his/her response to treatment and potential adverse events. The study is planned to run until the end of 2019 with an opened enrolment period until April of 2017. 300 patients are included.

Georgia is committed to running a clinical trial on new drugs. This trial is supported by UNITAID, and it is implemented by MSF as an essential part of the endTB project. The main objectives of the study are to compare the efficacy of different treatment regimens and assess the frequency of adverse events. This is a randomized clinical investigation of new

shorter regimen. The clinical trial studies five “user-friendly” interventions (each containing one new drug) and one control arm. The study investigates the safety and efficacy of five new treatment regimens. Up to 180 patients will be enrolled in the study, but no additional incentives or supplements will be given to them. Although additional investigations are not covered by the state program, it will be covered by the MSF. One patient was involved in this clinical trial in February of 2017.

There are three clinical trials currently undergoing at the NCTLD (Tbilisi location).

1. One is previously mentioned endTB trial that studies shorter treatment regimen for MDR patients. Four patients are currently involved in this study. This is a three yearlong project, and 180 MDR-TB patients should be involved in total (sixty patients per year). MDR-TB patients living in Tbilisi or in regions close to Tbilisi are suspected to be involved in this study. But if the final cohort does not reach 180 patients, those living in other regions of Georgia might be included in this study.
2. The second study is the STREAM trial (phase 2), which is in the preparation stage. At least twenty-five MDR-TB patients will participate in this study. The STREAM trial evaluates the effectiveness of a six-month MDR-TB treatment and a nine-month all oral regimen. In April of 2017, a community engagement workshop was held in Tbilisi, and the Community Advisory Board (CAB) was established for this trial. Patients from Tbilisi and other areas close to Tbilisi will be involved in this study.
3. The third study which is also in the preparation phase is the NIX-trial. This trial will test a novel regimen that holds the potential of being a shorter, all-oral and affordable treatment for XDR-TB patients. The NIX-TB regimen consists of drugs with minimal resistance, pretomanid, bedaquiline and linezolid. Participants will be treated with the intent of curing for six to nine months. Nix-TB is an open label trial that enables patients to be assessed at regular intervals. At least thirty XDR-TB, pre-XDR-TB or MDR-TB patients previously treated but did not succeed with treatment will be enrolled in this trial. Implementation of this trial started in September of 2017, and it will be financially supported by the TB Alliance.

The STAND-trial has just been completed with two patients' participation. The STAND trial tested PaMZ, a three-drug regimen, which comprised of two candidate drugs that were not yet licensed for use - pretomanid (previously known as PA-824) and moxifloxacin - as well as one already approved TB antibiotic, pyrazinamide. Georgia enrolled in this trial at a late stage and implementation of this trial stopped because the cohort was reached. Between two patients, one interrupted the treatment, but the second successfully completed it. The follow-up phase for this second patient continued until December 2017. This study was also implemented with the financial support of the TB Alliance.

Clinical trials are undergoing at the NCTLD, using its material-technical resources. Phthysiatrists and other specialists at the NCTLD involved in clinical trials (cardiologist, endocrinologist, etc.) receive additional salaries based on separate contracts signed in the project frame. This is a remuneration for the work that is performed within the trial. TB

doctors receive fixed salaries while nurses and other specialists receive financial incentives through a bonus system based on the amount of work done within the trial. A doctor's salary depends on his/her qualifications: a highly qualified personnel's hourly rate is around 70 USD while middle level personnel receive 35 USD per hour. In general, staff can be reimbursed for eight hours of work per month. At present, only two phthysiatrists from the NCTLD are paid from the clinical trials. Patients do not receive any cash incentives for participating in the trials. All tests and investigations related to patients' health condition are performed at the NCTLD.

Data Protection

The law on patients' rights²⁶ regulates medical providers' activities about information confidentiality. The main articles of this law are articulated as follows:

Medical care providers shall be obligated to protect the confidentiality of information held by them about patients both during the patients' lives and after their deaths.

Medical care providers may disclose confidential information if:

- a) The patient agrees
- b) The non-disclosure of information poses a risk to the life and/or health of third persons (whose identities are known)
- c) While using patient information for educational or scientific purposes, the data are represented in such a way that patients cannot be identified
- d) It is provided for in the legislation of Georgia.

The patient may be assumed to have consented when medical care providers reveal confidential information about the patient's health status to other people participating in the medical care.

Medical providers cannot interfere in the patient's family or private life, except when:

- a) Interference is necessary for diagnosing, treating and caring for the patient. In this case, the consent of the patient shall be necessary.
- b) The lives and/or health of the patient's family members are in danger.

²⁶ Law of Georgia on the Rights of Patient. 5 May 2000.
<http://www.healthrights.ge/legislation/national/rights-of-patient/?lang=en>