Final

National Strategy for Tuberculosis Control in Georgia 2019-2022

Contents

Acronyms

ACF	Active case finding
ACSM	Advocacy, communication and social mobilization
ADRs	Adverse drug reactions
AIDS	Acquired immune deficiency syndrome
ART	Anti-retroviral therapy
BCG	Bacillus Calmette-Guérin (vaccine)
CCM	Country Coordination Mechanism
CPT	Cotrimoxazole-preventive therapy
DCT	Diagnostic counseling and testing
DOT	Direct observation of treatment
DOTS	Directly observed treatment, short-course
DRS	Drug resistance survey
DR-TB	Drug-resistant tuberculosis
DSM	Direct smear microscopy
DST	Drug susceptibility testing
EQA	External quality assurance
EU	European Union
FIND	Foundation for Innovative Diagnostics
FLDs	First-line anti-TB drugs
GEL	Georgian Lari
GLC	Green Light Committee
GNI	Gross National Income
GoG	Government of Georgia
GTSF	Global Tuberculosis Strategy and Framework
HIV	Human immune deficiency virus
ICRC	International Committee of the Red Cross
IDACIRC	Infectious Diseases, AIDS and Clinical Immunology Research Center
IGRA	Interferon-gamma release assays
ISO	International Organization for Standardization
KAP	Knowledge, attitude and practices
KfW	Kreditanstalt für Wiederaufbau (the German Development Bank)
LED	Light-emitting diode
LPA	Line probe assays
LSS	Laboratory Surveillance Station
LTBI	Latent tuberculosis infection
M. Tb	Mycobacterium tuberculosis
MDR-TB	Multidrug-resistant TB
MGIT	Mycobacterium growth indication tube
MoC	Ministry of Corrections
MoIDP&LHSA	Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia

MSF	Médecins Sans Frontières
MSM	Men having sex with men
NAP	National AIDS Program
NCDCPH	National Center for Disease Control and Public Health
NCTLD	National Center for Tuberculosis and Lung Diseases
NGO	Non-governmental organization
NHA	National Health Accounts
NRL	National Reference Laboratory
NSP	National Strategic Plan
NTC	National Tuberculosis Council
NTP	National Tuberculosis Program
PAL	Practical Approach to Lung Health
PDR-TB	Polydrug-resistant TB
PHC	Primary health care
PLHIV	People living with HIV
PWID	People who inject drugs
QMS	Quality Management System
SARMA	State Agency for Regulation of Medical Activities
SLDs	Second-line anti-TB drugs
SRL	Supranational Reference Laboratory
SSA	Social Service Agency
SWs	Sex workers
TB	Tuberculosis
TGF	The Global Fund to Fight AIDS, Tuberculosis and Malaria
TPP	Tuberculosis Prevention Project
TST	Tuberculin skin test
TWG	Technical Working Group
UHC	Universal Health Coverage
UN	United Nations
UNAIDS	Joint United Nations Program on HIV/AIDS
UNICEF	United Nations Children's Fund
URC	University Research Company
USAID	United States Agency for International Development
USD	United States dollar
WHO	World Health Organization
XDR-TB	Extensively drug-resistant tuberculosis
ZDL	Zonal Diagnostic Laboratory

Introduction

Tuberculosis (TB) remains an important public health problem in Georgia. Despite significant progress in the implementation of TB control interventions during the last decade, the country faces a number of important challenges that require further intensified and streamlined efforts to effectively control the epidemic by securing universal access to prevention, diagnosis and treatment of all forms of the disease, and ensuring effective integration and management of TB control interventions within the overall health system framework.

The Government of Georgia is committed to increasingly allocate financial and other resources for effective TB control. National TB Control interventions are currently guided by the National TB Strategy for 2016-2020. Based on a mid-term review of 2016 data, the revised strategy defined targets and priorities for the National TB Response for the 2019-2022 period. In order to clearly illustrate progress towards the End TB Strategy targets the strategy includes 2015 estimated TB incidence (99 per 100000) and mortality (5 per 100000) as a baseline for impact and selected outcome indicators. The costed action plan was developed for this four-year implementation period.

The Strategy development was coordinated by the Georgia Country Coordinating Mechanism (CCM)[1] for TB, HIV/AIDS and Malaria. Stakeholders involved included the Parliamentary Committee for Health and Social Issues, Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia , Ministry of Corrections[2], National Center for Disease Control and Public Health (NCDC&PH), Research Practice Center for Infectious Diseases, AIDS and Clinical Immunology, National Center for Tuberculosis and Lung Diseases, Representatives from United States Agency for International Development (USAID), United Nations (UN) Populations Fund, non-governmental organizations (NGOs) working in the TB field, representatives from the most affected communities, and TB patients. The Policy and Advocacy Advisory Committee (PAAC) established under the auspices of CCM, which unites representatives of all the above mentioned partners, was used as a platform for national dialogue and ongoing consultations. Thus, the present Plan represents the outcome of the cooperation of all country stakeholders and international experts participating in TB control who have provided technical assistance to the country to ensure compliance of proposed interventions with international standards and best practices. The Government is grateful to the Global Fund to Fight Aids, Tuberculosis and Malaria and USAID[3] for provision of technical assistance in the development of this Plan.

1. Situational Analysis

1.1 Analysis of the legislative framework

The legal framework for TB control in Georgia is composed of a set of laws and regulations which stipulate the right of Georgian citizens to receive quality medical services in a non-discriminatory environment where all basic human rights, freedoms and guarantees are protected. The Constitution of Georgia and the following laws guide the National TB Response and clearly define the government's commitment in the fight against TB:

1. Georgian Law on Public Health
2. Law of Georgia on Health Care
3. Law of Georgia on Medical Activities
4. Law of Georgia on Patient's Rights

1 CCM ordinance is adopted by #220 decree of Georgian Government from June 18, 2012

[2] Ministry of Corrections is being integrated with the Ministry of Justice

3 The National TB Strategy for 2016-2020 was developed with USAID support in 2015

5. Law of Georgia on Tuberculosis Control

The Georgian Law on Public Health defines the responsibility of the Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia to guide development and implementation of the National Strategy for Tuberculosis Prevention and Control.

In December of 2015, the Law of Georgia on Tuberculosis Control was enacted. The law defines basic principles of TB control and state obligations to provide continuous access to diagnosis and treatment. Responsibilities of patients are also emphasized, as compliance with prescribed treatment regimens is critical for public health purposes.

According to the Law of Georgia on State Budget, the amount of funding for the TB State Program is determined annually for the diagnostic and treatment services provided to high risk groups and people confirmed with TB.

The European Union (EU)-Georgia Association Agreement requires the country to improve control of communicable diseases, including TB. In order to fulfill these requirements, the Government of Georgia (GoG) will make additional efforts to strengthen the TB epidemiological surveillance system. Antimicrobial resistance is a global threat, and GoG will consider its prevention as high priority.

1.2 Alignment with the United Nations Sustainable Development Goals

The third goal of the UN Sustainable Development Strategy to "ensure healthy lives and promote well-being for all at all ages" underscores the necessity of universal access to health care services and decreasing the incidence and associated burden of priority diseases, including TB.

Providing universal access to health services has been a top priority for the Government. In the context of the anticipated transition from donor funding, this plan will guide the government actions towards sustainable financing of TB services for improved access and coverage. Health systems will be strengthened and innovative tools and solutions introduced to improve efficiency of the system and make it patient-centered in order to comprehensively meet diverse healthcare needs across the TB care continuum from prevention to cure. This plan, through effective and evidence-based interventions will enable the country to make substantial progress towards SDGs, including 90% reduction in new TB cases and 80% reduction in mortality by 2030 compared to 2015.[4]

1.3 The burden of TB in Georgia

General information. At the beginning of 2015, the population of Georgia was 3.73 million[5], with 57.4% of the total population residing in urban areas[6]. According to the World Bank, the country's economy registered an average 5.5% annual growth during the last five years; the estimated gross national income (GNI) was USD 3,560 per capita in 2013, while about 15% of the population live below national poverty line[7].

TB estimates and notifications. Despite significant progress achieved in recent years, the burden of TB, especially its drug-resistant forms, remains high in Georgia. According to the World Health Organization (WHO), the latest estimated TB incidence was 92 per 100,000 population (for 2016[8]), which is substantially higher than average for the WHO European Region 32.6 per 100,000 population. The estimated 2016 mortality rate was 4.8 per 100,000 population (excluding TB/HIV cases).

4. The United Nations Sustainable Development Goals (SDGs) include ending the TB epidemic by 2030 under Goal 3.
5. Excluding separated regions of Abkhazia and South Ossetia
6. *National Statistics Office of Georgia*, http://www.geostat.ge (data accessed in May 2018)
7. *World Bank*, for 2013 (Atlas method, current USD), http://data.worldbank.org/country/georgia
8. *Global Tuberculosis Report 2017*, WHO, http://www.who.int/tb/publications/global_report/en/

According to the National TB Program (NTP) notifications data, a total of 3,330 TB cases, all forms, were registered in the country in 2016 (including in the penitentiary sector), for a rate of 89.2 per 100,000 population. Out of these, 2,983 were new and relapse cases comprising incidence rate of 80.1 per 100,000. During the last five years, the absolute number of TB cases has decreased substantially[9]. Between 2012 and 2016, the total number of TB notifications decreased by 33% and the number of new cases decreased by 35% (Table 1).

Table 1. TB notifications in Georgia by case category, 2012-2016[10]

Category	*2012*	*2013*	*2014*	*2015*	*2016*
New and relapse cases (incident):	***3,942***	***3434***	***3200***	***3152***	***2983***
• ***Pulmonary, bacteriologically confirmed***	***2318***	***2109***	***2103***	***2072***	***1998***
• ***Pulmonary, clinically diagnosed***	***677***	***584***	***393***	***411***	***373***
• ***Extra pulmonary (bacteriologically confirmed, clinically diagnosed)***	***947***	***741***	***704***	***669***	***612***
Retreatment cases, (pulmonary or extra pulmonary, bacteriologically confirmed or clinically diagnosed)	***1032***	***885***	***650***	***459***	***347***
All TB cases:	***4,974***	***4,319***	***3,850***	***3,611***	***3,330***

Among new and relapse TB cases registered, almost 70% are males (male/female ratio: 2.0). The disease affects mainly the young and the most economically productive part of the population: more than half of the incident TB cases occur among individuals aged 15-44 years (2016).

Drug-resistant TB. The high burden of anti-TB drug resistance is the key challenge for the NTP and the main obstacle for effective TB control in the country. WHO estimated that 460 patients with multidrug-resistant TB (MDR-TB[11]) needed treatment in 2016[12]. The first nationwide representative Drug Resistance Survey (DRS), conducted in 2005-2006, revealed MDR-TB prevalence of 6.8% among new smear positive cases and 27.4% among previously treated cases[13]. In 2013, routine drug susceptibility testing (DST) by the National Reference Laboratory found MDR-TB present in 11.2% of new cases and in 38.1% of previously treated cases. The final data for 2016 show MDR prevalence of 11.2% and 38.4% in new and previously treated cases, respectively. Among all cases with DST results, MDR-TB was found in 16.6% of them. The first-line resistance profile for 2010-2016 is presented in Table 2 below.

Table 2. Pattern of resistance to first-line anti-TB drugs in new and previously treated culture-positive cases, 2010-2016[14]

Year	**New cases**						**Previously treated cases**					
	Cases with DST results	***Resistance profile, %***					**Cases with DST results**	***Resistance profile, %***				
		Sensitive to all FLDs	*H+ resistance*	*R+ resistance*	*MDR-TB*	*Other patterns*		*Sensitive to all FLDs*	*H+ resistance*	*R+ resistance*	*MDR-TB*	*Other patterns*
2010	**1,988**	44.6	13.7	0.4	9.5	31.9	**567**	33.3	13.6	0.5	31.4	21.2
2011	**2,197**	52.5	12.8	1.0	10.9	22.7	**675**	35.6	12.3	1.3	31.7	19.1
2012	**1,931**	59.5	13.4	0.6	9.2	17.3	**541**	42.0	10.7	0.6	31.2	15.5

9. Note: Starting from 2006 Georgia has reached and over-reached the old WHO case detection target of 75% and that used to be high as 100% an even more (i.e. 105% in some years). For 2016, if using the WHO estimates for new and relapse cases based on the country profile data, the case detection is 83%.
10. National Center for Tuberculosis and Lung Diseases (NCTLD), 2017
11. MDR-TB is defined as resistance to isoniazid (H) and rifampicin (R), the most potent anti-TB drugs, with or without resistance to other first-line drugs.
12.WHO Tuberculosis Country Profiles, http://www.who.int/tb/country/data/profiles/en/
13. Lomtadze N. et al. *Prevalence and risk factors for Multidrug-Resistant Tuberculosis in the Republic of Georgia: A Population Based Study.* Int J Tuberc Lung Dis. 2009 January; 13(1): 68–73.
14. *NCTLD / National Reference Laboratory (NRL)*

2013	**1,629**	58.9	11.7	0.4	11.2	17.8	**527**	38.3	9.9	0.0	38.1	13.7
2014	**1,482**	57.7	12.3	0.2	11.6	18.2	**503**	38.0	9.5	1.4	39.2	11.9
2015	**1,447**	58.5	10.5	0.7	11.6	18.7	**479**	36.5	10.6	0.8	38.8	13.2
2016	**1,383**	60.2	11.9	0.7	10.3	16.9	**401**	40.6	7.5	1.2	38.4	12.2

About one-third of all laboratory-confirmed MDR cases also have resistance to second-line anti-TB drugs (SLDs) – fluoroquinolones or injectable agents, and between 6-7% of MDR patients have extensively drug-resistant TB (XDR-TB)[15].

Childhood TB. In 2016, 187 TB cases, all forms, were registered in children aged 0-18 years, (21 TB cases per 100,000 children), 30 of which were form 0-4 age group. 16 (8%) out of them had RR-TB, 2 of which belong to 0-4 age group. The absolute number of childhood TB cases almost halved within the last seven years, (with 255 cases registered in 2010). The proportion of pediatric TB cases during the last decade has also decreased from 6.2% in 2005 to 3.66% of all TB cases in 2016. Eleven (11) pediatric TB meningitis cases occurred in 2014-2016, while no such cases were registered during 2013.

TB in prisons. Improved infection control and a substantial decrease in the number of detainees contributed to a dramatic drop of TB cases in prisons. In 2016, the absolute number of TB cases in prisons was 84, three times lower than it was in 2013.

In 2011-2016, the number of new cases decreased from 800 to 42. TB notification rates for all TB cases have decreased from 4,860 to 900, and for new cases it decreased from 3,320 to 50 per 100,000 prisoners. However, TB notification rates in the penitentiary system are much higher than in the civilian sector (7 times higher for new cases and 10 times higher for all cases).

In 2013-2016, there were no lethal cases among TB patients in prisons, compared to 50 deaths in 2011 and 21 in 2012. MDR-TB prevalence remains high and requires attention. In 2013, MDR-TB accounted for 7.7% of new culture-positive cases and for 40.8% of retreatment cases; in 2016, it was 9.1% and 55.2% respectively.

HIV-associated TB. Based on SPECTRUM estimates (2018) there are 10500 individuals of all ages living with HIV in Georgia with an HIV prevalence rate of 0.5% in adult population aged 15-49 years. Since 1989 country has been actively monitoring the epidemic and has reached significant achievements, but HIV/AIDS remains as important public health issue. According the National AIDS center, reported number of people leaving with HIV/AIDS for 14 May 2018 is 7012. Majority of infected are males (5248), within the age group of 29 - 40.

HIV largely remains concentrated among key vulnerable populations: men having sex with men (MSM), people who inject drugs (PWID), and sex workers (SWs). MSM have the highest rates of recent HIV infections; HIV prevalence in this risk group has increased from 7% in 2010 to 20.5% in 2015[16]. According to latest estimates, the number of PWID in Georgia is 52,000, and HIV prevalence ranges from 0.4% to 9.1% among different PWID groups. [17] HIV prevalence among pregnant women and blood donors (0.04% in both sub-populations) is lower than in the general population. Co-infection with hepatitis C virus (HCV) is common; HCV antibodies are detected in up to half of the registered people living with HIV (PLHIV) in Georgia.

The proportion of TB patients with known HIV status increased from 62% in 2013 to 97%[18] in 2016 (2886/2983). HIV prevalence among TB patients remains low compared to other countries in the region; during the last five years, it varied between 1.7-2% among TB cases, all forms, tested for HIV. In the group of MDR patients, however, TB-HIV co-infection is more frequent: 5.3% of MDR-TB cases were HIV-positive in 2012-2013.

15. XDR-TB is defined as MDR-TB with resistance to a fluoroquinolone and to a second-line injectable drug.
16 http://www.unaids.org/en/regionscountries/countries/georgia
17 Population Size Estimation of People Who Inject Drugs in Seven Cities of Georgia, 2016-2017, Bemoni Public Union(BPU); Curatio International Foundation (CIF)
18 WHO Global TB Report 2017 (page 242)

Conversely, TB is frequent among HIV-infected individuals. During 2011-2013, 1,440 newly diagnosed PLHIV were screened for TB, and active disease was found in 252 cases (17.5%). TB is the leading cause of mortality among PLHIV, accounting for 21% of the total number of deaths in this population group (1998-2012 cohorts)[19].

1.4 Organization of National TB Program

The implementation of the internationally recommended TB control strategy based on Directly Observed Treatment, Short course (DOTS) in Georgia started in 1995, and countrywide DOTS coverage was achieved in 1999, including in the penitentiary sector.

Since 2016 TB control interventions in Georgia have been guided by the *National Tuberculosis Strategy and Operational Plan for Georgia 2016-2020*. This update remains fully in line with the 2016-2020 strategy framework but defines priority interventions for an additional 2-year period. The Strategy will be implemented by various governmental and nongovernmental organizations as outlined below.

The Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia (MoIDP&LHSA) bears the overall government responsibility for public health issues in the country, including TB control. It undertakes this function in close interaction with other relevant state entities and collaborates with NGOs and international partners in the planning, implementation, monitoring and evaluation of TB control activities.

The Georgian Country Coordinating Mechanism (CCM) for TB, HIV/AIDS and Malaria is the high-level body entrusted to facilitate horizontal links and participatory governance of disease control programs. The CCM includes representatives from different governmental entities, external development assistance agencies, as well as civil society organizations. A specific important function of the CCM is to oversee the implementation of the support from the Global Fund to Fight AIDS, Tuberculosis and Malaria (TGF).

TB control services in Georgia have undergone substantial changes over the last decade and are provided by both public and private health care institutions. TB laboratories have been downsized and integrated into the network of public health laboratories under the management of the National Center for Disease Control and Public Health (NCDCPH). Currently, these include six regional Laboratory Surveillance Stations (LSSs) in Akhaltsikhe, Gori, Ozurgeti, Poti, Telavi and Zugdidi and two Zonal Diagnostic Laboratories (ZDLs) in Batumi and Kutaisi. The entire network is supervised by the National TB Reference Laboratory (NRL) at the National Center for Tuberculosis and Lung Diseases (NCTLD) in Tbilisi.

Otherwise, TB care delivery in Georgia is integrated into the provision of general health care services, which have been reorganized and restructured through privatization since 2012. TB services are provided by specialized TB units as well as by primary health care (PHC) units. There are a total of 69 outpatient specialized TB units at the district and regional level, which are organizationally part of private health care provider institutions. In addition, six specialized TB inpatient facilities function in the civilian sector in Tbilisi (NCTLD), Kutaisi, Batumi, Zugdidi, Abastumani and Poti, with a total capacity of 466 beds (out of which 170 beds are intended for treatment of M/XDR-TB cases). There are about 870 staff in the specialized TB service, including 184 TB doctors, 379 nurses and 25 laboratory personnel.

In Georgia, TB detection is mainly done through passive case finding. PHC providers are responsible for identifying TB suspects and referring them to specialized TB service units for diagnosis. Diagnosis of TB is established by direct sputum smear microscopy and Xpert MTB/RIF, supported by X-ray in cases with negative microscopy/Xpert results and confirmed by culture. Sputum specimen transportation is organized from district TB units to the LSSs, and from LSSs to ZDL Kutaisi or NRL. Kutaisi laboratory is a regional center for Western Georgia and provides culturing on liquid and solid media and sensitivity testing using new molecular methods such as line probe assay to the first and second line drugs. Conventional DST on solid and liquid cultures is currently performed at the NRL only. The NRL performs the full range of TB laboratory investigations and is responsible for laboratory quality assurance country-wide and performs

19. Chkhartishvili N. el Al. Mortality and Causes of Death Among HIV-Infected Individuals in the Country of Georgia: 1989–2012, AIDS Res Hum Retroviruses. 2014 Jun 1; 30(6): 560–566.doi: 10.1089/aid.2013.0219

sensitivity testing for third line drugs. Xpert MTB/RIF diagnostic technology has been widely implemented in the country since 2013, contributing to faster detection of resistant forms of TB. Currently, 38 Xpert MTB/Rif instruments are operational in the country, including in the penitentiary system.

Case classification and definition of treatment category are done in the specialized TB service units. Treatment regimens are administered according to WHO recommendations. Uninterrupted supply of quality anti-TB drugs is ensured country-wide. Until 2014 procurement of TB drugs was completely carried out with the financial support from the Global Fund. From 2015, the government is procuring first line TB medications and has been gradually increasing its financing for second line drugs. In order to assure the quality of drugs there are established procedures for port clearance, storage, distribution to service delivery sites, stock monitoring and replenishment that are in compliance with international requirements.

One third (30%) of TB patients (all forms) are hospitalized during the intensive phase of treatment; the majority of those hospitalized have MDR-TB. Eighty percent (80%) of patients with this form of TB start their treatment in inpatient care. During out-patient treatment, follow-up of patients and drug dispensing are carried out by district TB units and village PHC facilities. Ensuring DOT is the goal for all TB patients; monetary incentives are provided to the patients to increase adherence to treatment with Global Fund support and government contribution.

The country uses a standardized TB recording and reporting system, which has been upgraded to include the latest WHO recommendations and additional country needs. Individualized recording and reporting is incorporated into the national electronic TB database. This strategy places particular emphasis on implementation of the integrated TB electronic database, which is one of the major intervention areas.

The Ministry of Corrections (MoC), through its Medical Department, is responsible for TB control activities in the penitentiary system. Case detection in the penitentiaries combines passive case finding and active case finding (at entry and regular screening). TB treatment in prisons is provided at the TB Prison Hospital in Ksani (Shida-Kartli region) and at the Central Prison Hospital in Gldani (Tbilisi). These institutions also have TB laboratories performing microscopy and Xpert MTB/RIF.

Systematic TB/HIV collaborative activities between the NTP and the National AIDS Program (NAP) were initiated in 2005 and are continued through joint programming and technical consultations, adjusting of guidelines and case management protocols, and collaboration and coordination of activities related to the provision of HIV counselling and testing for TB patients, screening for active TB among PLHIV, administration of antiretroviral therapy (ART) in patients with TB/HIV co-infection, data exchange and integration of monitoring/reporting systems, as well as through alignment and coordination of interventions among high-risk groups, including those implemented with Global Fund support.

Over the last decade, significant progress has been made countrywide in treatment outcomes of drug-sensitive TB cases. The treatment success rate of all TB cases increased from 62.5% in 2004 to 82.1% in 2015, and the proportion of patients interrupting treatment during the same period has decreased from 16.3% to 9.3% (among new AFB-positive cases, treatment interruption fell from 12.7% to 6.5%)[20]. The full treatment results of the 2015 cohort of new AFB-positive cases are as follows: treatment success – 83.1%, default – 6.5%, failure – 4.6%, death – 4.3%, transfer out – 0%, not evaluated – 1.4%.

To manage drug-resistant TB, Georgia conducts routine drug resistance surveillance as a continuation of the first nation-wide representative Drug Resistance Survey, which was carried out in 2005-2006. The DST data for the last seven years are presented in table 2 above. Although lower than in other countries in the region, the burden anti-TB drug resistance is high and this represents a key challenge for effective TB control in the country.

Programmatic management of MDR-TB in the country started with Médecins Sans Frontières (MSF) France support to treatment of DR-TB patients in Abkhazia since 1998. In November 2005, MSF expanded the project to Samegrelo region. The Georgian TB program started expanding countrywide access to MDR-treatment according to international standards in November 2006, based on the application to the WHO's Green Light Committee (GLC) for access to quality second-line drugs at concessionary prices. Since November 2006 through the end of 2016, about 5,000 patients were enrolled in second-line TB treatment. At

20.The rates are presented according to the revised WHO classification of TB treatment outcomes (2016)

the moment, with the support of international partners, the country ensures universal access to diagnosis and treatment of all forms of TB including treatment of extensively-resistant forms of the disease ('pre-XDR' and XDR-TB) with Bedaquiline, Delamanide, as well as with shortened treatment regimens. From June 2015 all patients have access to new generation medications through the global donation program supported by the manufacturer and USAID.

1.5 Main achievements of the National TB Program

The following are considered as the main achievements of the NTP in Georgia since the start of DOTS implementation:

- The NTP has achieved remarkable success in the uptake and implementation of contemporary international strategies and guidance in TB control. By the end of 2015 the country achieved all main components of the "Stop TB" strategy. From 2016 strategic priorities were aligned to the new "End TB" strategy. The country is continuously upgrading and developing its practices and approaches in order to align to the emerging challenges of the TB epidemic and to ensure an effective national TB response.
- Visible improvements have been documented during recent years in relation to reducing the burden of TB, as evidenced by the decreasing number of TB cases and TB rates, including the decreasing number of TB cases in children. The prevalence of drug-resistant forms of TB has been consistently contained at levels that are substantially lower than other countries in the region.
- Universal access is ensured to diagnosis and treatment of all forms of TB including M/XDR-TB. The use of novel rapid diagnostic methods for TB and DR-TB, as well as the use of newly-developed drugs is being scaled up.
- As a key indicator of the positive developments in the national TB control program, treatment outcomes of drug-sensitive TB cases are improving, including a steady decrease in the proportion of patient lost to follow-up.
- TB control in the penitentiary system is fully integrated into the overall national TB program. Consistent with the overall trend in the country, there has been a decreased incidence of active TB as well as improved treatment results among the prison population.
- Georgia is considered a regional leader in aligning its TB care delivery system to the epidemiologic challenges and international best practices, including implementation of a predominantly outpatient TB case management, with reduced frequency and duration of hospitalization as a result of optimized and downsized TB hospital capacity.
- The country has been effectively implementing external funding support (from the Global Fund and other partners), as a result of its effective and professional collaboration and coordination with national and international stakeholders.

1.6 Key challenges for TB control

Despite these important positive developments achieved in TB control, Georgia continues to face a number of serious challenges, which need to be addressed and are further reflected in this Plan.

- TB remains an important public health issue in the country, and the overall TB epidemiological situation continues to be worrisome, first and foremost due to the high burden of drug-resistant TB, which threatens to reverse the recent positive trends and further increase the overall economic and social burden of the disease. At the same time, the treatment results of M/XDR patients are worrisome and represent the major concern for the national program. From 2008-2014, only 49% of M/XDR-TB patients were successfully treated: 5% died, 4.9% failed treatment, 29% defaulted and 8% of cases were not evaluated at the end of treatment. The very high rates of treatment interruption are attributed not only to the difficulties patients face to complete the lengthy (up to 2 years) course of therapy due to social and economic circumstances, but also to insufficient adherence support and medical complications of treatment related to comorbid conditions and adverse drug reactions caused by second-line TB drugs, and failures of health care providers to manage these complications

effectively .While there is a decreasing trend in TB notifications during the last three years, primary attention should be accorded to ensure an effective system for TB case detection/diagnosis, which should address the issue of undiagnosed and/or belatedly diagnosed TB, and provide for rapid detection of drug resistance.

- Poor outcomes of treatment of M/XDR-TB cases is a big issue, which needs to be addressed through implementing the novel treatment approaches reliant on the revised treatment regimens (including scaling up the use of new drugs) but also on strengthening the application of patient-centered approaches with appropriate patient support, which is not limited to provision of incentives but covers a broader set of adherence determinants.
- The burden and impact of TB/HIV co-infection in the country is underestimated and needs to be properly addressed through a set of strengthened collaborative activities between the two national programs, including more active involvement of civil society, especially in addressing the needs of the most-at-risk population groups.
- As the Government continues to work toward ensuring universal health coverage, TB control interventions need to be effectively integrated into wider health sector developments. Besides strengthening the governance and management of the NTP and adjusting financing and allocation arrangements, proper attention should be given to the development of required human and infrastructural resources for providing essential TB services to the entire population.
- Georgia is currently heavily dependent on external support (primarily from the Global Fund) in financing key TB control activities, including procurement of drugs and laboratory equipment and supplies and adherence support, as well as in supporting essential NTP functions such as training and supervision. In view of the fact that external funding support is decreasing with time, there is a stringent need to ensure a substantial and rapid increase in the Government financing of these components, especially those related to complex and costly DR-TB management interventions.

A more detailed description of problems and gaps is presented under each NSP Objective below.

2. Goal, Targets, Principles and Objectives

Goal

The overall ***Goal*** of TB control in Georgia is ***to decrease the burden of TB and its impact over the overall social and economic development in the country, by ensuring universal access to timely and quality diagnosis and treatment of all forms of TB, which will decrease illness and deaths and prevent further development of drug resistance.***

Targets

The ***targets*** reflect the intended progress in the improvement of key TB impact and outcome indicators. These targets have been set in accordance to the national strategic development initiatives and are in line with the Global End TB Strategy targets and the action plan for the WHO European Region 2016–2020. The targets are set by the end of the four-year period covered by the Plan, compared to 2015 levels.

The targets of TB control in Georgia include, by year 2022:

1. Estimated TB mortality rate is reduced by at least 35%; (2015 Baseline estimated mortality 5 per 100000)
2. Estimated TB incidence rate is reduced by at least 20%;(2015 estimated incidence 99:100000
3. The proportion of MDR-TB is less than 12% among new cases and less than 35% among previously-treated cases;
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.

Principles

Attaining the overarching national Goal for TB control will improve the population's health and will contribute to the overall socio-economic development and wellbeing of the people of Georgia. In order to meet these targets, NSP implementation will rely on the following ***principles***:

- Country ownership and increased political commitment to effective TB control;
- Alignment with the overall national development policies and health sector strategies and plans;
- Multisectoral cooperation among governmental partners and involvement of Civil Society Organizations and Patients Groups.
- Protection and promotion of human rights, ethics and equity;
- Compliance with the up-to-date international evidence-based strategies and guidance (*Post-2015 Global TB Strategy and Framework, The End TB Strategy, International Standards for Tuberculosis Care*, and the latest WHO guidelines and tools).

Objectives

The priority 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 environments and systems for effective TB control.

3. Components of the National Strategic Plan

This section presents the Strategic Interventions by Objective.

Objective 1. To provide universal access to early and quality diagnosis of all forms of TB including M/XDR-TB

Rationale

Early and accurate diagnosis is critical to effective TB control. Dramatic progress in advancing TB diagnostic technologies has been achieved globally over the past decade. For countries with high DR-TB burden, including Georgia, WHO recommends rolling out new rapid diagnostic techniques, which allow for timely confirmation of TB, detection of drug resistance and initiation of correct treatment regimen, thus decreasing the risk of further amplification of resistance. In 2011, all Member States of the WHO European Region committed themselves to ensuring universal access to drug susceptibility testing by rapid methods[21]. The updated roadmap for 2016-2020 further acknowledged a vital role of new rapid molecular tests in rapid identification and control of drug resistant TB.[22]

Rapid scale-up of new technologies requires the revision of the existing policies and practices and a reconfiguration of the TB diagnostic network. The *Post-2015 Global Tuberculosis Strategy Framework* (GTSF), approved by the World Health Assembly in May 2014, pays significant attention to TB case detection and diagnosis. In particular, it notes that health services miss many TB patients or identify them after long delays and at advanced stages of the disease. Detection of MDR-TB is an important challenge: globally, it is estimated that only about one-fourth of MDR cases are diagnosed. There is a need to overcome the health system barriers that prevent the rapid expansion of programmatic management of DR-TB

21.*Roadmap to prevent and combat drug-resistant tuberculosis. The Consolidated Action Plan to Prevent Multidrug- and Extensively Drug-Resistant Tuberculosis in the WHO European Region, 2011-2015* (WHO, 2011)
22 Roadmap to implement the tuberculosis action plan for the WHO European Region 2016–2020. Towards ending tuberculosis and multidrug-resistant tuberculosis (WHO, 2016)

including limitations in case detection and full and rapid testing for drug resistance.

One of the main GTSF components is devoted to TB diagnosis and calls upon countries to embrace new strategies and technologies for improving early detection of TB cases, detect and confirm all cases with DR-TB, roll out new diagnostics, and implement systematic screening for TB among selected high-risk groups. Special attention should be paid to diagnosis of HIV-associated TB.

Achievements to Date

- The TB laboratory network has been continuously improved and reconfigured in Georgia over the last decade to comply with the emerging challenges of the TB epidemic, international strategies and guidance, as well as with the national health system development priorities.
- TB laboratories perform the full range of diagnostic investigations for TB and DR-TB, including smear microscopy, Xpert MTB/RIF, culture in solid and liquid media, and DST to first-line and second-line TB drugs by automated MGIT and LPA methods. The novel Xpert MTB/RIF diagnostic technology was introduced and expanded; currently, 38 instruments are operational in the country, including in the penitentiary system. Rapid molecular diagnostics is available at a majority of TB service delivery units at the district level. Xpert is used as a point of care diagnostic test for all presumptive TB cases. This is followed by full investigation of the drug resistance profile in all confirmed cases. Uninterrupted supply of laboratory consumables is ensured for all laboratory diagnostic methods with TGF support. From 2017, state financing covers reagents and laboratory consumables for bacterioscopy and culture on solid media.
- The specimen transportation system has been significantly improved in recent years. As of 2016, Georgian post delivers specimens daily as needed, supporting rapid detection and timely patient enrollment in effective treatment.
- The country has achieved good coverage with bacterial culture and DST. As a result of the improved specimen transportation system, the use of liquid media for rapid diagnostics almost doubled (from 40% in 2014 to 80% by the end of 2016)[23]. The capacity of LPA testing to detect sensitivity to second-line medications has been developed in Kutaisi Zonal Diagnostic Laboratory since 2016.
- The National Reference Laboratory (NRL) at NCTLD is fully functional and conducts continuous EQA for DST with the Supranational Reference Laboratory in Antwerp (Belgium), as well as quality assurance, supervision and capacity building for lower-level laboratories in the country. The NRL physical infrastructure is being upgraded (the new building was completed in 2017).
- Along with the implementation of modern international diagnostic strategies, the current system of management and operational procedures of laboratories was updated and is in compliance with new diagnostic algorithms endorsed by the MoIDP&LHSA in 2018.
- The country has been successfully collaborating with international partners in the area of case detection and diagnosis. Through this collaboration, the country received important support in terms of infrastructure improvement, provision of equipment and supplies, technical assistance, capacity building and quality assurance.

Challenges and Gaps

- WHO recommends active TB case finding to maximize TB detection. The number of presumptive cases to find 1 TB case significantly improved in recent years in Georgia (the overall number of presumptive cases tested per 1 active TB case, all forms: 4.2 in 2012, 4.0 in 2013 and 7.9 in 2016). Despite improvement, this remains low. In terms of contact investigations, in 2016, on average there were 4.6 contacts per 1 smear positive TB case screened (compared to 3 in 2014) demonstrating the need of more active intervention.
- Systematic screening of PLHIV for TB remains a challenge. Diagnostic counseling and testing for HIV among TB patients does not exceed 70%. It is important to integrate TB screening in

23. Data from National Center for Tuberculosis and Lung Diseases

HIV/AIDS and Hepatitis C programs, especially at primary health care level.

- Additional efforts are required to build capacity of staff in the specialized TB service as well as in primary health care; the latter should be reinforced to intensify TB case finding among symptomatic persons, contact tracing and improving referral practices.

Strategic Interventions

Four Strategic Interventions have been identified for this component, which cover priority activities to support the achievement of the Plan's objectives related to diagnosis. These include: 1) support to rollout of rapid molecular testing at district level; 2) implementation of WHO-recommended diagnostics in reference laboratories; 3) improving contacts' investigation, screening and active case finding by primary care providers and CSOs; and 4) support to the routine operations of the laboratory service.

1.1 Rollout of Xpert MTB/RIF technology

According to the latest international standards, patients at risk for drug resistance should have rapid molecular Xpert MTB/RIF test performed as the initial diagnostic investigation for TB.[24] This recommendation fully applies to Georgia as a country with a high burden of drug resistance. Therefore, the rollout of Xpert MTB/RIF technology at the lowest service delivery level (district/municipality), where TB diagnosis is established, is one of the mainstays of the new TB laboratory strategy that is being developed.

Xpert MTB/RIF technology can be also implemented in peripheral laboratories. Detailed recommendations on use of Xpert MTB/RIF technology for all ages and pulmonary and extrapulmonary forms of TB are outlined in the National TB Guidelines approved by MoIDP&LHSA..

Since 2016, the NTP has been using Xpert MTB/RIF testing for initial diagnoses of all cases of HIV-associated TB. According to the TB diagnostic algorithm, Xpert-positive cases are followed with rapid culture, bacteriological confirmation, and DST to determine the complete resistance profile and ensure initiation of effective treatment.

According to an assessment conducted in 2015, a total of 54 machines are required to ensure optimal access to Xpert MTB/RIF technologies countrywide (these calculations took into account of the size of population served in each territory, minimum workload thresholds, distances and transportation options for referring the patients to neighboring facilities). Georgia started implementation of a GeneXpert roll out plan in 2017. By April 2018, there were 38 Xpert MTB/RIF devices installed in selected locations and the number of tests conducted entirely covered the needs of the country. A total of 18,520 tests were performed in 2016 and 22,062 tests were performed in 2017. As part of the FAST strategy rollout at the district level, this number will increase by an additional 9000 tests in 2018. For rapid identification of Rifampicin resistance among HIV infected individuals, one Xpert MTB/RIF has been installed in 2017 at JSC Infectious Disease, AIDS and Clinical Immunology Scientific-practical center inTbilisi. Since 2015, Xpert MTB/RIF systems have been functional in Ksani and Gldani hospitals of the penitentiary system.

Procurement of GeneXpert instruments in accordance with the National Strategy of 2016-2020 will be completed by the end of 2018. Starting from 2019, the NCDC&PH and Referral Laboratory will coordinate phased rollout of Xpert technologies nationwide. Implementation support will include health care workers capacity building, provision of cartridges, calibration/technical services and ongoing supervision for quality assurance. These measures will be implemented systematically by the NTP, in collaboration with the NAP, for both the civil and penitentiary sectors.

The main activities under this Intervention include:

1.1.1. *National consultants* will be employed to support Xpert MTB/RIF rollout, conduct training of local providers, facilitate and supervise implementation in each of the country regions.

1.1.2. *Training of staff in Xpert MTB/RIF*. Appropriate training on practical issues related to Xpert rollout will be provided for staff involved in Xpert rollout including health care managers at the

24 *Automated real-time nucleic acid amplification technology for rapid and simultaneous detection of tuberculosis and rifampicin resistance: Xpert MTB/RIF assay for the diagnosis of pulmonary and extrapulmonary TB in adults and children: policy update* (WHO, October 2013)

district level, TB specialists and laboratory personnel. Refresher trainings are planned once every two years.

1.1.3. *Procurement of Xpert MTB/RIF instruments, other equipment and supplies (cartridges)*. By 2016 Georgia had achieved 87% coverage of targets groups with Xpert testing as primary diagnostic tool. During the strategy implementation period, coverage should approach 100%.

1.1.4. *Maintenance and servicing of Xpert MTB/RIF instruments*. The coverage of costs of calibration, regular checkups and maintenance, replacement of modules and other repairs by an authorized service provider, will be ensured as the mandatory requirement for successful and uninterrupted implementation of the novel technology.

1.1.5. *Supervision / monitoring of Xpert MTB/RIF*. NCDCPH with assistance from the national consultants and in collaboration with NCTLD will continue supervision and monitoring of Xpert MTB/RIF implementation at district level TB units and penitentiary facilities. A monitoring and evaluation component of *Xpert MTB/RIF* will be gradually integrated in NTP monitoring and evaluation framework.

1.1.6. *Workshops and coordination meetings on Xpert MTB/RIF rollout*. Regular coordination meetings and workshops will take place with participation of providers from Xpert testing sites, NTP and local health care managers, in order to exchange implementation experiences, monitor progress and plan next steps.

1.2 TB diagnostic investigations at regional and national level

The network of TB diagnostic services in Georgia is being developed in line with the latest international recommendations. According to the Laboratory Network Development Plan the NRL in Tbilisi and Zonal Diagnostic Laboratory in Kutaisi perform entire spectrum of TB tests, including the direct smear microscopy, Xpert MTB/RIF, automated mycobacterial growth indication tube (MGIT) technology for rapid isolation of strains in liquid culture and accelerated DST, automated genetic LPA technology for rapid identification of *M. tuberculosis* and detection isoniazid/rifampicin resistance, as well as sensitivity testing for second-line drugs.

According to WHO recommendations, the priority of the NTP is the development of culturing techniques on liquid media (e.g. MGIT system).

Since 2017, NTP culture testing has been carried out in full capacity, and sensitivity tests for the first and second line drugs have been performed on liquid media (MGIT). Culture test on solid media (except for research purposes) is carried out in accordance with MGIT guidelines and also to assess contradictory results of TB laboratory tests.

The use of LPA (MTB-DR plus) method is recommended for direct testing of culture isolates and smear-positive sputum specimens. As of now the direct use of LPA (MTB-DR plus) method is not recommended on smear-negative samples. The use of LPA MTBDRsl method is recommended for direct testing of culture isolates, smear-positive and smear-negative sputum samples. In this case, culturing of specimens is mandatory. The above laboratory methods at the reference level (ZDL Kutaisi and NRL) will be applied in strict conformity to the revised diagnostic algorithm, which will be implemented to support the new laboratory network strategy.

Passive case finding through examination of symptomatic individuals who present at medical institutions will remain the main method for TB detection. Active case finding (ACF) will be performed in special population groups (described below under Intervention 1.3). It is planned that, by the middle of the period covered by this Plan, TB diagnosis in Georgia will be established by 32 units at four levels; the details on the institutions per level, type of investigations and other responsibilities within the network are given in Table 3 below.

Table 3: Planned structure of the TB diagnostic network in Georgia

Level	*Institutions*	*Range of investigations to be performed*	*Other responsibilities*
I. Basic TB management	23 BMUs:	• Xpert MTB/RIF	

unit (BMU) level	• 20 district / town level TB units[25] • 2 penitentiary facilities: Ksani (No. 19) and Tbilisi / Gldani (No. 18) • AIDS Center Tbilisi (IDACIRC)	• Direct smear microscopy at penitentiary facilities	
II. Regional level	6 Laboratory Surveillance Stations (LSSs): Akhaltsikhe, Gori, Ozurgeti, Poti, Telavi, Zugdidi; and 1 Zonal Diagnostic Laboratory (ZDL) in Batumi	• Xpert MTB/RIF • DSM	• Specimen referral in respective regions
III. Sub-national level	Zonal Diagnostic Laboratory (ZDL) in Kutaisi	• Xpert MTB/RIF • DSM • Culture • LPA DST to FLDs • LPA DST to SLDs	• Specimen referral in Western Georgia
IV. National level	National Reference Laboratory (NRL) in Tbilisi	• Xpert MTB/RIF • DSM • Culture • DST to FLDs • DST to SLDs • Genotyping and other advanced methods	• Specimen referral in Eastern Georgia • Supervision • Quality assurance • Training • EQA with SRL • Research

According to diagnostic algorithm updated in 2018, direct smear microscopy (DSM) investigation remains an important method for diagnosing TB among suspects and for treatment monitoring. The Xpert MTB/RIF test has finally replaced DSM as the initial diagnostic test. Currently, microscopy is required for treatment monitoring purposes and in Xpert positive patients to determine bacterial load. Therefore, the regional level laboratories (LSSs) will continue to perform DSM in combination with Xpert MTB/RIF testing, in accordance to the revised diagnostic algorithm.

The revised diagnostic strategy includes a comprehensive needs assessment for Xpert and DSM investigations and specimen transportation for each region, based on the population coverage, workload, distances and transportation options, etc. Based on this detailed assessment, the LSSs will be further strengthened in terms of staff capacities.

According to the latest international evidence, same-day DSM is as accurate as testing smears over 2 days. In a diagnostic evaluation for TB, taking into account the expanded testing with Xpert MTB/RIF and based on the ongoing pilot study, the country will gradually shift to examining one smear specimen by microscopy. Fluorescence microscopy is on average 10% more sensitive than conventional light microscopy, and it is associated with improved efficiency. Georgia therefore aims at shifting its laboratories to fluorescence microscopy by the middle of the next program period. Relevant training of laboratory staff in fluorescence microscopy will be provided.

Capacity of the NRL will be further developed to enable it to function as a cutting-edge reference center for TB bacteriology, capable of meeting the entire range of national needs and successfully engaging in the highest-level international collaboration in the field. The NRL will strengthen its quality control and quality assurance function for all TB laboratories in the country. It will continue cooperation with WHO and the Supranational Reference Laboratory (SRL) in Antwerp, Belgium, on external quality assurance (EQA) for WHO-recommended diagnostics. In addition, a set of measures will be implemented to strengthen the quality management system (QMS) at the NRL, including its international accreditation according to ISO-15189 standard.

The NRL will also introduce advanced diagnostic techniques based on genotyping methods, and will actively participate in international research, including research on validation and field testing of new diagnostic

[25] See details in Table 3 above.

techniques. It is aimed that the Georgian NRL itself will join the WHO's network of Supranational Reference Laboratories in 2019. For the above purposes, this Plan stipulates hiring additional staff and training, as well as investments in the relevant technologies at the NRL.

The main activities under this Intervention include:

1.2.1. *Equipment for microscopy laboratories (LSSs).* Light emitting diode (LED) fluorescence microscopes with performance characteristics superior to conventional microscopes, which have been endorsed by WHO, will be procured for all TB laboratories in the network, replacing the older light microscopes. In addition, laboratory furniture will be procured as needed.

1.2.2. *Support to specimen transportation system*. Routine system for transportation of sputum (from district level TB service units without Xpert MTB/RIF to Xpert sites in other districts and LSSs (including DSM), and from LSSs – to ZDL Kutaisi and NRL for culturing and DST) will be supported. However, its format will be revisited in view of the planned reconfiguration of the diagnostic network, as rolling out Xpert MTB/RIF at peripheral level will reduce the need for transporting sputum to LSSs. In turn, extending rapid culture and DST at ZDL Kutaisi will reduce the needs for transportation from Western Georgia to the NRL.

1.2.3. *(1.2.3-1.2.6.) Laboratory supplies for microscopy investigations.* Procurement of consumables and reagents for DSM will cover both diagnostic and treatment monitoring microscopy tests at all levels. The total estimated amount of DSM tests to be performed countrywide (including in the penitentiary system) in 2019-2022 is about 210,000 tests; however the annual quantities will decrease from about 60,000 in 2016 to less than 32,000 in 2022 due to rolling out diagnostic Xpert MTB/RIF tests and reducing the number of smears per investigation. It is envisaged that fluorescent LED microscopy will replace conventional DSM during this strategy cycle, so that in 2020, over 90% of all microscopy tests will be performed using LED technique).

1.2.7. *Laboratory supplies for MGIT, LPA and other investigations.* Procurement of consumables and reagents for culturing and DST covers diagnostic and treatment monitoring needs at the NRL and ZDL Kutaisi. This plan targets meeting 90% of the countrywide need for liquid culture by the end of 2019 and achieving 100% coverage by 2020. These calculations are based on the epidemiological forecast and the planned level of expansion of rapid testing, and take into account the forthcoming changes in the diagnostic algorithm.

1.2.8. *Equipment for reference TB laboratories.* Necessary major and minor laboratory equipment and supplies will be provided for ZDL Kutaisi and NRL.

1.2.9. *Maintenance/servicing of laboratory equipment and ventilation systems*. NCDCPH and NCTLD will secure proper support to maintenance, repairs, spare parts and other servicing needs for all spec*ialized laboratory equipment, as well as maintenance of biosafety equip*ment and ventilation systems at the NRL and ZDL Kutaisi.

1.2.10. *Environmental and individual infection control measures*. Environmental (upper-level ultraviolet germicidal ventilation devices) and individual (N95 / FF2 respirators) measures will be provided for proper infection control and preventing staff at high risk of infection at the NRL and ZDL Kutaisi).

1.2.11. And 1.2.12. *Capacity building of laboratory staff* will be given due priority at the stage of implementation of new techniques and approaches to TB diagnosis. Training of LSS and ZDL Kutaisi personnel will be carried out by the NRL and will cover fluorescence microscopy and culturing/DST, standard operating procedures and quality management, biosafety, data management and other relevant aspects. In addition, staff from the NRL will attend training in advanced diagnostic techniques and quality assurance at the SRL Antwerp.

1.2.13.-1.2.16. *Strengthening NRL quality management system/support to ISO accreditation.* These activities include external technical assistance and auditing of the NRL by an external auditor, international and local training of NRL staff in QMS and aligning the NRL operational procedures and documentation with ISO-15189 standard.

1.3 Contact investigation, screening and active case finding for TB among high-risk groups including people living with HIV

The burden of undetected TB is substantial in Georgia, especially in high-risk groups. Significant delays in diagnosing TB and initiating the appropriate treatment are likely in people with limited access to health services. Systematic screening for active TB disease among risk groups improves early case detection.

The primary objective of screening is to ensure that active TB is detected early and treatment is initiated promptly, with the ultimate aim of reducing the risk of poor treatment outcomes, the adverse social and economic consequences of TB, as well as helping to reduce TB transmission. Systematic screening implies identification of people with suspected active TB, in a predetermined target group, using tests, examinations or other procedures that can be applied rapidly[26]. Such screening is provider-initiated and targets people who do not seek health care because of the lack or neglect of symptoms, barriers to accessing care or for other reasons. Among those whose screening is positive, the diagnosis needs to be confirmed by bacteriological tests and additional clinical assessments.

Based on the latest international evidence and guidance, the following five groups have been identified for systematic screening for active TB in Georgia:

1. Household contacts and other close contacts of patients with active TB;
2. People living with HIV;
3. Persons detained in penitentiary institutions;
4. People with selected medical conditions that constitute risk factors for TB, who seek health care for other reasons;
5. Other subpopulations with estimated high levels of undetected TB and/or limited access to health care services.

Household contacts and other close contacts of patients with active TB. One of the international standards for TB care requires that all providers ensure that persons in close contact with TB patients are evaluated and managed in line with international recommendations[27]. A contact is any person who has been exposed to a person with infectious TB ('index case'). Contacts are divided into two groups, household and non-household. Contact investigation is an important activity to find persons with previously undetected TB and persons who are candidates for treatment of latent TB infection (LTBI). Inability to conduct contact investigations results in missed opportunities to prevent additional cases of TB, especially among children.

In order to strengthen contact investigation activities, the NTP will systematically update a mandatory contact screening protocol. The highest priority groups considered for evaluation will be: persons with symptoms suggestive of TB; children aged <5 years; contacts with immunocompromised states, particularly HIV infection; and contacts of patients with M/XDR-TB. In addition, contact investigation for household contacts and close contacts will continue to be performed for all other index cases with pulmonary TB (introduced in 2017).

HIV counseling and testing will be offered to household contacts of patients who are HIV-infected, as well as to all contacts who have symptoms compatible with active TB. Contacts among children or PLHIV, in whom the clinical evaluation has not detected active TB, should be treated for presumed LTBI. Children should also undergo a nutrition screening and assessment as part of the investigation. If malnutrition is identified, it should be managed according to WHO recommendations[28].

People living with HIV. It is important to ensure that TB is diagnosed early in this risk group, which has a high likelihood of having undetected TB and a high risk of poor health outcomes in the absence of early diagnosis and treatment. Screening for active TB should therefore be undertaken each time when an HIV-infected individual visits a health care facility.

For intensified TB case-finding in PLHIV, WHO[29] recommends the use of a special clinical symptom-based algorithm, which is augmented by chest radiography. PLHIV whose screening test is positive should have an Xpert MTB/RIF test as a primary diagnostic test (see Intervention 1.1 above). PLHIV who do not report

[26] *Systematic screening for active tuberculosis: principles and recommendations* (WHO, 2013)
[27] *International Standards for Tuberculosis Care, Edition 3* (TB CARE I, 2014)
[28] *Guideline: nutritional care and support for patients with tuberculosis* (WHO, 2013)
[29] *Guidelines for intensified tuberculosis case-finding and isoniazid preventive therapy for people living with HIV in resource-constrained settings* (WHO, 2011)

symptoms of active TB disease (current cough, fever, weight loss or night sweats) should be offered treatment for presumed LTBI. Preventive treatment will be conducted in close collaboration and coordination between National TB and HIV programs.

Persons detained in penitentiary institutions. Screening for active TB will be performed in all persons detained in criminal justice facilities during the investigation, in those awaiting trial and in those who have been sentenced. Prison staff are also eligible for systematic TB screening.

The practices of active TB case finding in the Georgian penitentiary system will be further aligned to the international requirements. The program will include mandatory screening when a person enters a detention facility, followed by screening at least once a year while detained, and an exit screening for people leaving detention. In addition, contacts will be investigated whenever a new case is detected.

Prisoners who have symptoms suggestive of TB will undergo TB testing according to the national diagnostic algorithm, with Xpert MTB/RIF as the initial diagnostic test. HIV counselling and testing will be offered to all detainees screened for TB. The screening program in prisons will be combined with screening for other diseases and health promotion activities targeting this group.

People with selected medical conditions that constitute risk factors for TB, who seek health care for other reasons. Screening for active TB disease will be undertaken among people who have risk factors to TB, in addition to passive case finding. The medical groups are prioritized based on their risk of TB, the risk of poor treatment outcomes if diagnosis is delayed and the size of the group in the Georgian settings. The following medical conditions will be considered for TB screening: underweight persons; diabetes mellitus; chronic renal failure or hemodialysis; pregnancy; alcohol dependence; intravenous drug use; tobacco smoking; advanced age; previously treated TB. In addition, the medical providers may consider patients with other medical problems such as gastrectomy, malignancies, immunosuppressive disorders, solid organ transplantation and other conditions requiring immunomodulatory therapies.

The above risk groups should be targeted within the clinic where they are managed. As a common rule, TB screening should be offered if it has not been done during the previous 12 months; however, a different interval may be applied depending on the group. People identified as TB suspects but not confirmed with active disease should be informed about the importance of seeking medical care if TB symptoms continue or re-emerge.

Screening people with diabetes for TB should be combined with reciprocal screening for diabetes in people with TB[30]; similar reciprocation should be applied in regard to smokers and people with chronic obstructive pulmonary disease[31], persons with alcohol use disorders or other drug-use disorders, which can be also combined with HIV screening in drug users[32]. The management of health care institutions should offer screening for active TB to their staff and combine it with other appropriate infection control interventions[33].

Other defined subpopulations with high levels of undetected TB and/or limited access to health care services. The NTP will identify the needs of TB screening in specific geographically defined subpopulations with presumed high levels of undetected TB, as well as other subpopulations which have limitations in accessing appropriate medical services, such as homeless people, people living in remote mountainous areas, migrants and other vulnerable groups.

While the key features of screening other categories above are applicable, systematic TB screening in this group has considerable requirements for human resources and other associated costs and will therefore be targeted and appropriately prioritized within the national program. Community screening is performed by inviting people to a health care facility, door to door visits or systematic screening in shelters and other specific locations. It is envisaged to facilitate the involvement of NGOs in early TB case detection among risk groups in community settings (see Intervention 3.2 below).

During the strategy implementation period active screening programs will be gradually expanded to ensure

30.*Collaborative framework for care and control of tuberculosis and diabetes* (WHO, 2011)
31.*Practical approach to lung health (PAL): a primary health care strategy for the integrated management of respiratory conditions in people of five years of age and over* (WHO, 2005)
32.*Policy guidelines for collaborative TB and HIV services for injecting and other drug users: an integrated approach* (WHO, 2008)
33.*WHO policy on TB infection control in health-care facilities, congregate settings and households* (WHO, 2009)

coverage of new groups. The program will be implemented in close cooperation and coordination between MoIDP&LHSA, MoC and private health care providers. Systematic TB screening will be integrated in the overall national screening program, which is coordinated by NCDCPH. Appropriate financing will be allocated to systematic TB screening interventions from the state budget.

The main activities under this Intervention include:

1.3.1. *Development of national TB screening guidelines*. A separate comprehensive guidance and protocols for systematic TB screening among risk groups, complementary to the national TB guidelines, will be developed by a working group and national consultants.

1.3.2. *Training of health care providers on TB screening*. MoIDP&LHSA through NCDCPH and NCTLD will organize training on systematic TB screening for managers and medical staff from health care institutions involved in provision of TB services including primary care providers and other related services.

1.3.3. *Medical supplies for TB screening.* Procurement of radiography and HIV testing supplies for TB screening among risk groups (Xpert MTB/RIF, microscopy and other laboratory supplies for testing of identified TB suspects are included under Interventions 1.1, 1.2 and 1.4).

1.3.4. *Motivation of health care providers*. Performance-related payments will be included in the payment schemes for health care provider institutions to motivate them for improving early case detection through intensified TB screening of risk groups. Performance-related payments for primary care providers will be elaborated and tested to support provider initiated TB screening and testing at primary care level. Along with other preventive activities, TB screening will be introduced in the quality improvement scheme for providers. The contracts with providers will foresee positive incentives for attaining the performance indicators (starting 2018 and expanding in 2019).

1.4 Support to operations of the laboratory network

This Intervention includes routine support to the operations of the laboratory service facilities as required for ensuring their effective functionality in line with the NTP priorities for the next program period and the revised TB diagnostic strategy.

The main activities under this Intervention include:

1.4.1. *Human resources.* Includes remuneration of staff at LSSs and reference laboratories, with appropriate provisions for additional staffing at ZDL Kutaisi and NRL, to accommodate for the increasing workload, and increase in salary levels according to the Government plans.

1.4.2. *Facility costs.* Includes covering various operational costs at LSSs and reference laboratories.

Expected Results under Objective 1

It is expected that full and successful implementation of the interventions under this Objective will ensure that by 2022, Georgia will guarantee universal access to early and reliable diagnosis of all forms of TB, including:

- TB diagnostic strategies and practices are updated and implemented according to the international standards;
- Rapid molecular tests (Xpert MTB/RIF) are performed as the initial diagnostic investigation for TB at the peripheral (district) level, and the entire country population is covered;
- There is full coverage of DST to first-line and second-line TB drugs by rapid techniques;
- The NRL and zonal reference laboratories are fully operational and perform the full range of necessary tests on regionalized basis;
- TB laboratory network is quality assured at all levels, and effective referrals and coordination are in place between district-level TB units and laboratories at the regional, zonal and national level;

- Reliable links are established between TB diagnostic and treatment units, which provide for administration of appropriate treatment regimen according to patient resistance status and without delays.
- Appropriate services are in place for contact investigations and screening/diagnosis in special groups (children, prisoners, PLHIV), including X-ray diagnostics.

Objective 2. To provide universal access to quality treatment of all forms of TB including M/XDR-TB with appropriate patient support

Rationale

Effective treatment of TB restores the health of the patient, interrupts the spread of the infection in the community and, importantly, prevents the development of drug resistance. Therefore, treatment for TB is not only a matter of individual health but is also an important public health responsibility.

Inadequate treatment is among the main causes for the emergence of M/XDR-TB. WHO emphasizes that national TB programs must implement contemporary case management strategies and standards for achieving national targets and preventing further spread of drug resistance. The Post-2015 Global TB Strategy calls for ensuring universal access to quality treatment for all TB patients, including those with M/XDR-TB. For Georgia, as well as for other countries in the region, tackling the spread of M/XDR-TB is critical to overall TB control. Increased priority should be given to the revision of the TB existing service delivery model by improving the quality of services, further expanding outpatient case management (including that for M/XDR patients) and implementation of patient-centered approaches in TB care.

There are several new anti-TB medicines coming to the market that will help improving the management of M/XDR cases; however, their use requires strong systems for patient monitoring, adherence support, drug management and pharmacovigilance, in order to ensure the best patient outcomes and prevent development of resistance to new drugs. Management of HIV-associated TB, preventive TB treatment, and management of comorbidities influencing patient outcomes also need to be given an increased attention.

Achievements to Date

- WHO-recommended DOTS strategy has been successfully implemented throughout Georgia, in both the civil and penitentiary sectors.
- Uninterrupted supply of quality-assured first-line and second-line anti-TB drugs has been ensured with the Global Fund support, and a reliable system of TB drug management has been established.
- During the last decade, TB service staff and select PHC providers have been trained and retrained in TB treatment and case management.
- Substantial improvements have been attained in treatment outcomes for drug-sensitive TB cases, due to, among other factors, strengthened DOT and provision of adherence support.
- The country provides universal access to treatment of MDR-TB cases, including within the penitentiary system.
- Georgia is among world pioneers in routine application of newly developed anti-TB drugs (such as Bedaquiline) in treatment of M/XDR cases. In May 2018, MoIDP&LHSA approved the National TB Management Guidelines aligned to the latest WHO recommendation on shorter treatment regimens and new anti-TB drugs. The implementation of the new guideline should contribute to improved treatment outcomes.
- In order to ensure safe and effective use of new and repurposed TB drugs, Georgia has been implementing an active drug safety monitoring model that has been operationalized by the National Center for Tuberculosis and Lung Diseases. Ministerial decree as of May 17th 2016 defined aDSM related responsibilities. All clinical and laboratory tests recommended for aDSM purposes have been included in the State TB program since 2016. Adherence support services have been improved through introducing counselors and engaging TB patients groups in peer support and health education. These activities are currently funded by the Global Fund.

Challenges and Gaps

- While similar to internationally reported averages, the treatment success rate for MDR-TB cases is low (about 50%) and is far below the regionally set target of 75% (for 2015).

- A high level of treatment interruption is the main contributor to unfavorable treatment outcomes in MDR patients, due to poor adherence and high frequency of adverse drug reactions, which are not properly managed.
- In 2016, 80% of patients with MDR started treatment at the hospital and stayed there for at least 2 months (average length of stay 61 days). This can partially be explained by the continued insufficiency of outpatient MDR TB treatment.
- Current practices of preventive treatment for latent TB infection are insufficient and need to be scaled up in risk groups, with particular attention to children, contacts of TB cases, and PLHIV. For this purpose, integration and collaboration between specialized TB services, public health services and HIV services requires substantial strengthening.

Strategic Interventions

Under this Objective, six Strategic Interventions are proposed to improve access to and quality of TB treatment. They include: 1) ensuring uninterrupted supply of quality anti-TB drugs and effective drug management; 2) provision of appropriate patient support for adherence to treatment; 3) ensuring proper treatment monitoring, management of adverse drug reactions and comorbidities; 4) improving infection control; 5) preventive treatment and vaccination against TB; and 6) support to the operations of TB treatment institutions.

2.1 Supply of anti-TB drugs and drug management system

Securing an uninterrupted supply of drugs for treatment of all forms of TB, including drug-resistant TB, is a crucial task for the NTP. The country needs to make a substantial effort in ensuring sufficient and sustainable supply of quality anti-TB drugs over the coming years, given the increasing complexity and cost of drug regimens for treatment of patients with advanced resistance and, at the same time, the decreasing level of external support. This Intervention comprises activities aimed at maintaining universal access to TB treatment according to the needs, by ensuring availability of TB drugs in sufficient quantities for each category of TB cases, assuring appropriate quality of medicines, and enabling effective drug management systems.

The estimated need for anti-TB drugs for the four years covered by this Plan was developed on the basis of epidemiological forecasts that accounted for several factors: the trends in case notifications; the expected improvements in case detection in the coming years due to planned rollout of rapid diagnostic techniques; the proportions of case categories (new and retreatment cases, bacteriologically confirmed and clinically diagnosed cases), and the prevalence of drug resistant cases by category.

The results of forecasts for 2019-2022 are presented in Table 4. The estimates include both civilian and penitentiary sectors. It is assumed that the annual number of cases will further decline in 2019-2022. Less than 3,000 cases are expected in 2022, closer to 2,500. At the same time, the improved case detection strategies and quality of laboratory diagnosis will contribute to higher rates of bacteriological confirmation of TB.

Table 4. Forecasted number of TB cases in Georgia by category, 2019-2022 (based on 2014-2016 trends)

Case category	2014	2015	2016	2017	2018	2019	2020	2021	2022
Incident TB cases (new and relapse)	**3 200**	**3 152**	**2 983**	**2 714**	**2 596**	**2 506**	**2 417**	**2 343**	**2 282**
• Pulmonary, bacteriologically confirmed	2103	2072	1998	1818	1739	1678	1619	1569	1529
• Pulmonary, clinically diagnosed	393	411	373	339	325	313	302	293	285
• Extrapulmonary (bacteriologically confirmed, clinically diagnosed)	704	669	612	557	533	514	496	481	468

Retreatment cases, (pulmonary or extrapulmonary, bacteriologically confirmed or clinically diagnosed)	**650**	**459**	**347**	**335**	**305**	**278**	**269**	**260**	**254**
Total TB cases	**3 850**	**3 611**	**3 330**	**3 049**	**2 901**	**2 784**	**2 685**	**2 603**	**2 536**

Table 5 presents the estimated countrywide need for TB treatment (including within the penitentiary sector) by treatment category. This estimate takes into account the planned increase in coverage by rapid culturing and DST, the forecasted prevalence of drug resistance, as well as the target enrolment rates by category.

Table 5. Estimated number of TB cases to be enrolled in treatment in Georgia by treatment category, 2019-2022 (Based on baseline 2015 and 2016 data and epidemiologic trends)

Treatment category	***2015-Baseline***	***2016***	***2019***	***2020***	***2021***	***2022***	***Total (2019-2022)***
First-line treatment	3,002	2,770	2,296	2,212	2,142	2,084	8,734
PDR-TB treatment	147	131	94	84	80	77	335
MDR-TB treatment, total	454	423	386	380	373	366	1,505
• *MDR-TB without resistance to SLDs*	316	293	233	228	224	220	905
• *MDR-TB, 'pre-XDR'*	111	103	127	127	124	121	499
• *MDR-TB, XDR*	27	27	26	25	25	25	101
Total TB cases	3,611	3,324	2,776	2,676	2,595	2,527	10,574

Over the next four years (2019-2022), total of 10,574 TB cases, all forms, will need anti-TB treatment in Georgia. Out of these, about 1505 cases are expected to have advanced drug resistance (M/XDR-TB) and will thus require second-line and third-line TB drugs.

To ensure universal access to TB treatment in the country, the Plan aims at securing an uninterrupted supply of all drugs, which are necessary to manage all types of TB cases as estimated above. The objective of TB drug procurement is to purchase quality drugs from reliable suppliers at the best possible prices. The paramount requirement for procurement is to assure quality of medicines, whether they are procured through external channels or nationally.

TB treatment regimens will be administered in line with the latest WHO guidance, in special that for treatment of drug-resistant TB cases[34]. In order to accommodate for the new guidance, the National TB Guidelines have been updated accordingly.

Standard WHO-recommended MDR regimens, for a total treatment duration of 20 months in most instances (out of which, on average 8 months intensive phase that includes an injectable agent), will be administered in patients without resistance to second-line agents, which currently account for about two-thirds of all laboratory-confirmed MDR-TB cases. In cases with resistance to SLDs (‘pre-XDR’ and XDR-TB), the treatment will be extended to 24 months on average. Newly developed anti-TB drugs(Bedaquiline and Delamanid)will be used in M/XDR treatment in accordance to WHO guidance[35,36].

34.Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis (WHO, 2014)
35.The use of bedaquiline in the treatment of multidrug-resistant tuberculosis. Interim policy guidance (WHO, 2013)
36.The use of delamanid in the treatment of multidrug-resistant tuberculosis. Interim policy guidance (WHO, 2014)

In 2015-2018, first within an operational research context (STREAM trial, EndTB Project and TB Alliance trial) and later through programmatic use, NTP launched the use of modified shorter treatment schemes. Such regimens are applied in MDR-TB cases without resistance to SLDs and will last 9-12 months. The NTP will actively utilize shortened regimens in all appropriate cases in accordance with the National Recommendations of Clinical Practice (Guideline).[37] Active collaboration and technical assistance from international partners, including WHO and the Green Light Committee will be continued to ensure safe and effective use of new schemes.

For application of shorter MDR regimens, the NTP will ensure that relevant WHO requirements are met in this regard, namely: treatment is approved by the ethics review committee ahead of patient enrolment; treatment is delivered under operational research conditions following international standards to assess the safety and effectiveness of the regimen; and an independent board monitors the implementation and reports to WHO. Technical assistance will be sought from the international partners, and appropriate capacity building activities will be conducted, prior the use of shorter MDR regimens.

The Government of Georgia is committed to ensure an uninterrupted supply of anti-TB drugs for treatment of patients with all forms of TB. The Government will allocate additional financial resources to the NTP, which will be sufficient to ensure effective takeover from the Global Fund. First-line drugs are already fully covered by the state budget. Public funding for second and third-line drugs will gradually increase and will reach 100% by 2022. International funding (i.e. Global Fund) will still be required for procurement of drugs for DR-TB treatment during the first three years covered by this Plan. In order to purchase drugs of assured quality, the country will make use of the global procurement mechanisms, such as the Global Drug Facility (GDF), which supply drugs from WHO-prequalified manufacturers.

To ensure effective drug supply, a set of measures are necessary to strengthen the supply chain and all components of drug management, including drug selection, quantification, appropriate procurement methods, supplier selection and qualification, quality assurance, monitoring and supervision. MoIDP&LHSA will be responsible for managing supply of anti-TB drugs from all sources in terms of clearing deliveries at the port, storage and distribution to the regions. The NTP will be responsible for stock management at the central level, ensuring rational use at treatment sites, recording and reporting. The Plan stipulates the need of further management support to ensure a well-functioning TB drug procurement system.

Special emphasis will be placed on improving the pharmacovigilance system for anti-TB drugs, as part of the overall pharmacovigilance system in the country. This necessitates implementation of routine practices for spontaneous reporting on adverse drug reactions (ADRs) by all health care institutions involved in the management of TB cases. Adequate pharmacovigilance, in particular that of newly developed second-line medicines, will allow not only for effective post-marketing surveillance, but will also strengthen NTP capacity to improve the management of ADRs at peripheral service level, thus reducing the risks of treatment interruption and failure because of these reactions.

In collaboration with WHO's International Drug Monitoring Program[38], MoIDP&LHSA will scale up the application of active pharmacovigilance methods in the TB program. Active drug safety monitoring (aDSM) will be implemented by all TB service units treating patient with new anti-TB drugs (Bedaquiline and Delamanid).

The main activities under this Intervention include:

2.1.1. -2.1.5. Procurement of anti-TB drugs. TB drugs will be procured for all categories of TB cases: drug-sensitive TB cases, PDR-TB and MDR-TB that include 'pre-XDR' and XDR cases. Procurement will be done in quantities sufficient to cover all needs (see Table 6 above for estimated breakdown by treatment categories) and avoid waiting lists among patients with advanced resistance. The treatment schemes will comply with WHO recommendations, which will be reflected in the new national TB guidelines and further adapted for gradual implementation of modified MDR regimens. Special priority in procurement will be given to the supply of fixed-dose combinations and pediatric formulations of drugs. The NTP will use newly developed second-line drugs (e.g. Bedaquiline and Delamanid) in MDR treatment regimens (in particular, for treating 'pre-XDR' and XDR cases), and

37. As of May 2018, Approved by MoLHSA
38.Implemented by the Uppsala Monitoring Center (UMC) in Sweden

will strengthen the key functions and processes in the TB drug management system for this purpose.

2.1.6. *Supply management* activities will be conducted to provide for appropriate coverage of delivery costs, storage/stock management and distribution to the regions and TB treatment delivery sites.

2.1.7. *External technical assistance* will be provided to MoIDP&LHSA/State Agency for Regulation of Medical Activities (SARMA) and the NTP in priority problems related to strengthening the national drug management system in view of decentralization of TB care delivery and application of modified treatment regimens for M/XDR-TB. Specific support will be sought for the implementation of active pharmacovigilance methods in line with the contemporary international practices and requirements for the use of new anti-TB drugs.

2.1.8. *National consultants* will support the NTP in the area of TB drug management including provision of training for TB care providers, monitoring of stocks, supervision of drug utilization, recording and reporting within the upgraded national TB information system, and pharmacovigilance.

2.1.9. *-2.1.10. Capacity building in drug management* will be achieved through international and local training of the NTP management staff and TB service staff, to enable effective implementation of the drug management requirements, with special attention to the application of new anti-TB drugs and management of ADRs.

2.1.11. *In-country quality assurance of TB drugs.* In line with the international requirements, the MoIDP&LHSA through SARMA will ensure a functional system for in-country quality control of supplied anti-TB medicines by certified laboratories.

2.1.12. *Clinical supervision* of the implementation of new drugs and treatment regimens for M/XDR-TB will be supported by the regular visits of the 'mobile MDR-TB consilium' to peripheral TB units, in continuation of the successful practice launched in 2015 within the ongoing TGF project.

2.2 Patient support to improve adherence to TB treatment

The outcomes of TB treatment depend on patient adherence to the prescribed regimen. Adherence support is therefore a key component of the TB program. It is especially relevant for patients with M/XDR-TB, who need to undergo lengthy (up to two years) treatment, have daily visits to health facilities and often suffer from serious adverse effects caused by TB medicines. In addition, various social and economic factors often prevent patients from completing treatment, such as the need to resume work to maintain family income.

A patient-centered approach to TB treatment is instrumental for promoting adherence to the therapy, improve quality of life and relieve suffering. Ensuring proper adherence to the regimen implies DOT, where a treatment supporter closely supervises the intake of TB medicines by the patient. With DOT, ADRs and other complications can be recognized quickly and managed appropriately. Needs for additional social support can also be promptly identified. Individualized patient-centered approaches for ensuring adherence include a flexible mix of health facility- and community-based DOT.

Treatment support is a cornerstone of the best practices for TB management. In Georgia, at present adherence support to TB patients is mainly provided through the Global Fund project; the Government covers a portion of the cash incentives for MDR-TB patients. This Plans calls for sustaining these practices beyond TGF support and further expanding them though implementation of effective patient-centered approaches, which will have impact on adherence and treatment outcomes.

Expansion of quality outpatient TB treatment, including for drug-resistant cases, is a priority NTP task for the next program period and represents an important step towards implementation of patient-centered care. However, to be successful, it requires comprehensive patient support measures to motivate the patients to accept and adhere to this model, including provision of incentives and enablers to the patients, psychosocial support, enablers for health care workers (including PHC staff) and innovative approaches such as 'Video-observed treatment' (VOT) using mobile telephone technologies.

To ensure sustainable takeover from external donors, the Government will encourage an increasing participation of NGOs and community establishments in the field. The NSP aims at developing mechanisms for financial and programmatic takeover by the Government. It is planned that by the end of 2018, the required set of patient support activities will be covered by domestic resources.

The main activities under this Intervention include:

2.2.1. And 2.2.2. Incentives and enablers for TB patients. It is aimed to provide incentives to all TB patients on treatment, regardless of the form of disease and treatment regimen, as the key means for strengthening adherence. Based on the ongoing experience, it is planned to continue the practice of monetary incentives to patients in most cases, under strict observation of compliance. Enablers (such as reimbursement of transportation expenses), as well as additional patient support measures (e.g. nutritional supplements) will be considered depending on the individual patient's medical and social conditions and service delivery context.

2.2.3. And 2.2.4. ***Enablers for health care staff***. As some TB patients will need to be visited at home by a health worker for drug dispensing and follow-up, additional enablers to caregivers (PHC nurses) will be provided in the form of reimbursement of local transport costs for home visits. Additionally, MoIDP&LHSA will explore the options for the establishment of performance payments to the staff of the specialized TB service and PHC service in relation to TB care (primarily, linked to adherence and successful completion of treatment, in special for full outpatient treatment of M/XDR-TB cases), and integration of these payments into provider payment schemes.

2.2.5. And 2.2.6. ***Psychological and social support to TB patients***. In appropriate settings, patient support teams, which may include psychologists, social workers and peer-supporters (e.g. former TB patients, family members) will be established. A similar intervention was initiated in 2017 with Global Fund support. These groups provide information, education and psychosocial support to motivate TB patients to complete treatment and address potential risk factors for interruption of the prescribed regimen, with special attention to M/XDR-TB cases and individuals from socially disadvantaged and high-risk groups.

2.2.7. Mobile technologies for adherence support. Demonstration projects will be carried out in defined settings, which will use mobile telephone technologies for strengthening adherence to TB treatment – through consultations, reminders (for drug taking and scheduled visit to specialists), verification of intake, provision of incentives to compliant patients, etc. For this purpose, the NTP will work on mobilizing additional resources through the collaboration international partners as well as with the providers of mobile telephone services in Georgia.

2.3 Treatment monitoring, management of adverse drug reactions and comorbidities

Close monitoring of patients throughout their anti-TB treatment is essential as it allows providers to evaluate the bacteriological and clinical responses and to adjust treatment strategies as necessary, thus providing for better patient outcomes. Bacteriological monitoring includes sputum smear microscopy, culture and DST; these methods will be applied in line with the latest WHO standards for each treatment category, including the targeted use of Xpert MTB/RIF in sensitive and poly-resistant TB (PDR-TB) cases and monthly cultures during the whole duration of M/XDR-TB treatment. Bacteriological monitoring provides for timely detection of acquired drug resistance and for relevant adjustment of the treatment regimen.

Comprehensive clinical monitoring of patients during anti-TB treatment requires performing of a range of laboratory and other diagnostic investigations, which are necessary, inter alia, to properly detect and manage adverse effects of TB medications. Radiographic investigation (e.g Chest X-ray) is a useful adjunct in assessing response to treatment, although it is not a substitute for microbiologic evaluation. In patients with extrapulmonary TB and in children, clinical evaluations are often the only available means of assessing the response to treatment.

ADRs are common when administering anti-TB medicines, especially those used for treatment of drug-resistant TB cases. ADRs may lead to very serious and even life-threatening complications and are important contributors to unfavorable treatment results. NTP will further strengthen the system for early recognition and proper management of ADRs as an important prerequisite for improving the effectiveness of DR-TB treatment, especially taking into account its decentralization and the increasing use of new anti-TB agents.

The Government will continuously ensure availability of all necessary clinical laboratory tests and other investigations for diagnosing undesired effects of TB drugs, as well as pharmaceuticals to treat ADR-induced morbidities, in accordance with the international evidence and guidance. These tests and drugs will be provided free of charge to all TB patients, regardless the form of disease or setting where the cases are

managed.

Clinical monitoring is also important to diagnose and treat complications related to various comorbidities. In addition to the severity of TB disease, a number of other factors can affect the response to and outcome of treatment, including concomitant illnesses and psychosocial issues. Addressing co-morbid conditions commonly associated with TB decreases treatment interruption, prevents drug resistance, and decreases treatment failures and deaths. This Plan emphasizes the need to reinforce the thorough assessment for co-morbid conditions and other factors that could affect TB treatment response, and provision of appropriate medical services to manage these conditions for ensuring an optimal outcome for each patient. Particular attention will be paid to diseases and conditions known to affect treatment outcome, including HIV, other immunosuppressive disorders, diabetes mellitus, chronic obstructive pulmonary disease (COPD), malnutrition, alcohol and other substance abuse, and tobacco smoking.

TB is strongly associated with HIV infection. In Georgia, active TB is found in over 16% of individuals newly diagnosed with HIV, and is the leading cause of death among PLHIV (21.3% overall since the onset of HIV registration in 1989). HIV infection increases the likelihood of progression from infection with *M. Tb* to active TB disease. Although HIV prevalence in the general population of Georgia is low, HIV-infected individuals are always at high risk of TB.

Intensified TB case finding among PLHIV is described under Objective 1. Diagnostic HIV counseling and testing (DCT) will be performed in all TB patients in Georgia at the start of their TB treatment. Special attention will be given to risk groups with higher prevalence of HIV, such as injecting drug users. The NTP will integrate provider-initiated DCT in the routine protocol for the management of TB patients. Rapid serologic HIV tests will be supplied to all inpatient and outpatient medical facilities providing TB treatment, and will be administered by TB service staff. The National AIDS Program (NAP) will be responsible for confirmation of cases detected as HIV-positive at TB units. In cooperation with NAP, the NTP will ensure that rapid tests for Hepatitis B and Hepatitis C are offered to TB patients simultaneously with DCT for HIV. Integrated screening programs for HIV hepatitis C and TB will continue to ensure timely detection and proper management of these diseases. Access to antiretroviral therapy (ART) will be ensured for all co-infected patients. In line with the latest international standard[39], in TB/HIV patients who have profound immunosuppression, ART will be initiated within two weeks of beginning TB treatment. For all other TB patients co-infected with HIV, ART should be initiated not later than within two months after the start of TB treatment. All TB/HIV patients should receive ART as early as possible as it results in substantial reduction in mortality and AIDS-related morbidity, and improves survival and quality of life of HIV-infected persons. The Plan aims at ensuring universal access to ART for the patients with HIV-associated TB (not less than 90% since the first year of implementation), and it is estimated that about 468 TB/HIV patients will require treatment with antiretroviral drugs during 2019-2022 (Table 6).

Table 6. Estimated HIV prevalence among TB cases, ART enrolment rates and number of TB/HIV patients to receive ART in Georgia, 2019-2022.

	2019	***2020***	***2021***	***2022***	***Total 4 years***
Total estimated number of TB cases	2,784	2,685	2,603	2,536	10,608
Estimated HIV prevalence among all TB cases, %	4.27%	4.53%	4.80%	5.07%	
Estimated number of TB/HIV cases	119	122	125	129	494
ART enrolment rate among TB/HIV cases	94%	95%	95%	95%	
Number of TB/HIV patients on ART	112	115	119	122	468

The composition of TB treatment regimens does not differ between HIV-positive and HIV-negative patients

[39] *International Standards for Tuberculosis Care, Edition 3* (TB CARE I, 2014)

as they must be designed in accordance to the patient's TB drug resistance profile (see Intervention 2.1 above). However, a number of important issues associated with concomitant therapy for TB and HIV infection are to be considered, including overlapping drug toxicity profiles, drug-drug interactions and potential problems with adherence to multiple medications. Therefore, co-infected patients should be closely monitored to identify ADRs. All patients with TB and HIV infection should also receive Cotrimoxazole preventive therapy (CPT) for prevention of opportunistic infections.

Proper management of TB/HIV co-infection requires effective communication and interaction between TB services and HIV/AIDS services. For this purpose, the NTP and NAP will further collaborate for developing appropriate joint case management protocols and ensuring their implementation by all involved providers. Integration of TB and HIV services has been shown to result in reductions of mortality and higher treatment success rates; it also improves ART enrollment and its early initiation.

Co-management of hepatitis C and TB is becoming an increasingly important issue in Georgia. The National Tuberculosis Program will work to strengthen the treatment monitoring system and ensure selection of optimal regimens to improve clinical outcomes of patients with TB and hepatitis C.

Because of its high and increasing prevalence in Georgia, diabetes mellitus in relation to TB is a particular concern. Diabetes triples the risk of developing TB and increases the severity of the disease. Conversely, TB can worsen blood glucose control in persons with diabetes. Therefore, TB patients with diabetes require careful clinical management to ensure that optimal care is provided for both diseases. TB patients should be screened for diabetes at the start of their treatment; management of diabetes in patients with TB should be provided in full accordance with the up-to-date clinical standards[40]. It is estimated that diabetes care will be required in up to 1,047 TB patients during the strategy implementation period 2019-2022 (262 cases annually).

Macronutritional deficiencies are both causes and consequences of TB. All TB patients should have a nutritional assessment at the beginning of and during treatment; and nutritional care should be provided according to the international recommendations[41].

Other diseases and treatments, for example immunosuppressive therapies by corticosteroids and tumor necrosis factor (TNF) alpha-inhibitors, increase the risk of TB and may alter the clinical features of the disease. Physicians in the general health service need to be aware of the increased risk of TB and be alert for symptoms that may indicate the presence of TB disease in such patients, and isoniazid preventive treatment should be considered if active TB is excluded. These aspects will be covered in the TB Screening Guideline and Protocols that are under development and will be finalized by the end of 2018. The guideline recommendations will be incorporated into training programs of primary care and other relevant providers in general health settings.

The main activities under this Intervention include:

2.3.1. *Laboratory supplies for bacteriological tests for treatment monitoring.* Supplies for direct smear microscopy, cultures and DST will be procured in quantities necessary for monitoring treatment progress in all patient groups. Note: these quantities are included in the total number of laboratory tests presented in Intervention 1.

2.3.2. *Clinical tests for patient monitoring.* Appropriate clinical investigations (blood chemistry and other clinical laboratory tests, radiography and other investigations) will be ensured for clinical assessment of TB patients on treatment and recognition and management of ADRs of anti-TB drugs (in particular, second-line drugs). Clinical testing will be performed in accordance to the national TB treatment guidelines, aligned with WHO recommendations.

2.3.3. *Rapid HIV tests for TB institutions*. In order to facilitate timely detection and ensure quality treatment of HIV-associated TB, rapid HIV testing assays will be provided for diagnostic counseling and testing of TB patients for HIV. Rapid tests for Hepatitis B and C will be provided in parallel. Note: procurement of confirmatory HIV tests (ELISA, Western Blot) is included under the National Strategic Plan for HIV/AIDS.

[40] *Collaborative framework for care and control of tuberculosis and diabetes* (WHO, 2011)
[41] *Guideline: Nutritional care and support for patients with tuberculosis* (WHO, 2013)

2.3.4. *Training in HIV counselling and testing* will be offered to TB service staff at outpatient TB service delivery units and primary care, with special emphasis on pre and post-test counseling techniques, for positive and negative results and also on the WHO-proposed diagnostic approach and the use of rapid HIV test at the point of care.

2.3.5. *Training in TB and diabetes management* will be provided for TB service staff and endocrinologists in the regions. Several groups already received this training with Global Fund support. The trainings will continue to increase the coverage of relevant providers.

2.3.6. *Pharmaceuticals for management of adverse drug reactions and comorbidities.* Drugs for management of ADRs arising from anti-TB drugs will be procured for inpatient and outpatient TB treatment sites according to the WHO-recommended list and taking into account the expected type and frequency of side effects of the new drugs, which will be increasingly used in M/XDR treatment schemes. Necessary quantities of insulin, oral anti-diabetic medications and other drugs for management of other common concomitant diseases will also be supplied to TB service facilities. Note: procurement of drugs for ART and CPT and tests for monitoring ART therapy will remain the responsibility of the National AIDS Program and is therefore included in the National HIV Strategy.

2.4 TB infection control in health care facilities

High rates of MDR-TB in new patients in Georgia are an indication that MDR organisms are spreading in the community. Transmission of drug-resistant strains is much more likely in health care facilities (especially hospitals) and congregate settings such as prisons. Proper TB infection control and prevention of nosocomial transmission of TB to patients and household members, as well as to medical personnel, are important tasks of the NTP, especially in view of the need to improve the scope and quality of programmatic management of drug-resistant TB.

The systemic measures for TB infection control are integrated within the planned reconfiguration of the TB care delivery system. Careful screening of suspects and early identification of patients with TB are of key importance. Diagnostic delays will be minimized by using rapid molecular tests (including rapid DST) and by carrying out diagnostic investigations in parallel rather than in sequence. Rapid diagnosis of TB and DR-TB and determination of resistance profile allow for early initiation of correct treatment regimen according to the patient's resistance profile, which has proven to substantially reduce infectiousness.

The Georgian NTP will continue avoiding unnecessary and prolonged hospitalizations of TB patients as these escalate the risk of nosocomial transmission of strains and amplification of resistance. Emphasis is therefore placed on further prioritizing full (from day one) outpatient TB case management, including for DR-TB cases. Inpatient TB treatment will be carried out following clear, strictly defined criteria for admission, duration of hospital stay and discharge, which were approved by MoIDP&LHSA in May 2018.

The implementation of the above strategies will further reduce the risk of TB transmission and is seen as a key requirement for controlling the burden of anti-TB drug resistance.

The international TB care standards include the requirement that each health care facility engaged in TB treatment should implement an appropriate TB infection control plan to minimize possible transmission of *M. Tb* to patients and health personnel. This Intervention includes activities aimed at strengthening management capacities of health care institutions at all levels for effective implementation of all three categories of TB infection control measures: administrative controls, environmental controls, and individual protection measures.

- *Administrative controls* include: triage and separation of TB suspects from other patients in outpatient general health service facilities; physical separation of patient flows through sections of inpatient TB facilities (i.e. potentially infectious patients from non-infectious patients, M/XDR-TB patients from patients with sensitive forms of TB); movement of patients within wards based on treatment progress and bacteriological and clinical improvement (e.g. avoiding placing newly admitted patients in the same room with patients who have been hospitalized for several weeks); separation of TB patients with HIV infection from other TB patients; patient education activities regarding cough etiquette and other measures; provision of appropriate information on TB to health workers and offering them access to regular screening for TB.
- *Environmental controls.* Systematic use of natural ventilation in outpatient and inpatient TB service

facilities is given priority. Mechanical negative pressure ventilation will be further used in special areas of reference laboratories. The application of mechanical ventilation in specialized TB hospitals is not advised because of its ineffectiveness in large areas and, in addition, due to difficulties in maintenance and high costs. Additionally, upper level ultraviolet germicidal irradiation (UVGI) devices should be properly placed in patient wards, procedure rooms and other areas with risk of TB transmission.

- *Individual protection measures* include: use of disposable particulate respirators (of certified N95 or FFP2 standards) by health care providers in areas with high risk of TB transmission; systematic use of surgical masks for coughing patients in all facilities.

The main activities under this Intervention include:

2.4.1. *National consultants* in infection control will support MoIDP&LHSA and NCDCPH in the revision and update of the national standards and action plan for TB infection control, taking into account up-to-date international requirements and the planned reconfiguration in the functioning of TB services. They will also assist in the development of infection control plans at institutional level (for inpatient and outpatient facilities), training for staff, and supervision of implementation in respective areas.

2.4.2. *Environmental infection control measures.* Upper-room ultraviolet germicidal irradiation (UVGI) devices will be supplied and installed in defined high-risk areas for infection in TB service facilities.

2.4.3. *Individual infection control measures*. With government and Global Fund funding, individual protection measures (N95 / FFP2 particulate respirators) will be provided for TB service staff at high risk of infection in the TB treatment institutions, as well as masks for patients (particularly patients with MDR-TB) to reduce the risk of nosocomial transmission of TB strains from infectious persons.

2.5 Preventive treatment and vaccination against TB

Prevention of TB has been identified as an area which requires significant improvement within the Georgian TB program. This Plan aims at improving preventive TB treatment in identified risk groups and maintaining universal coverage of vaccination against TB. Preventive activities will be implemented in accordance to the up-to-date international recommendations, laid down in the *Post-2015 Global Tuberculosis Strategy Framework* and related technical guidance[42,43].

Latent tuberculosis infection (LTBI) is a state of persistent immune response to stimulation by *M. Tb* without evidence of clinically manifested active TB. The infected persons have no symptoms of TB disease and are not infectious, but they are at risk for developing active TB disease. This can be averted by preventive treatment. The most recent analysis of evidence, undertaken by WHO, has shown that administration of LTBI treatment does not increase the risk of drug resistance. Nevertheless, scaling up preventive treatment must be accompanied by a comprehensive systematic screening for active TB disease (see Intervention 1.3 above), as well as by the effective national TB drug resistance surveillance system.

Population-wide mass LTBI testing and treatment is not feasible due to imperfect tests, potential side effects, and high costs. Therefore, preventive treatment should be administered in population groups in which the risk of progression to active disease significantly exceeds that for the general population. On the basis of the latest evidence and risk-benefit considerations, the following seven groups have been identified for systematic testing and treatment of LTBI in Georgia:

1. People living with HIV
2. Child and adult contacts of pulmonary TB cases
3. Persons detained in correctional facilities (prisoners)
4. Patients with the following diseases or treatment conditions: silicosis, renal dialysis, treatment with anti-tumor necrosis factor (TNF) inhibitors, and preparation for organ or hematologic transplantation

[42] *International Standards for Tuberculosis Care, Edition 3* (TB CARE I, 2014)
[43] *Guidelines on the management of latent tuberculosis infection* (WHO, 2015)

5. People who inject drugs (PWID)
6. Health care workers
7. Immigrants from high TB burden countries

Screening for symptoms among PLHIV is crucial for identifying both active TB cases and persons who should receive preventive therapy. PLHIV who do not have active TB disease at screening, should receive testing for LTBI and, if positive, preventive treatment. The combined use of ART and LTBI therapy significantly reduces the incidence of TB in PLHIV.

Children (particularly those under the age of five years) are a vulnerable group because of the high likelihood of progressing from latent infection to active TB; they are also more likely to develop disseminated and serious forms of TB disease such as meningitis. For these reasons, testing and treatment for LTBI is indicated in children who are contacts of TB cases, with special attention to children under five years of age.

Mantoux tuberculin skin test (TST) will be used to detect LTBI in individuals belonging to the above risk groups. LTBI screening health care providers using interferon-gamma release assays (IGRA) is planned from 2019.

The NTP will continue to use the common preventive treatment regimen (Isoniazid for at least 6 months); however the care providers may consider using shorter WHO-recommended regimens for LTBI (Isoniazid plus Rifampicin or Rifampicin alone for 3-4 months) because of tolerance or adherence considerations. At the moment, effective evidence-based preventive treatment for contacts of MDR-TB cases is not available. Therefore, emphasis will be placed on thorough clinical assessment of these contacts and their consequent monitoring for the development of active TB disease for the period of at least two years.

MoIDP&LHSA will place special emphasis on reinforcing TB prevention as an essential component of the national TB control program, including its coverage in the universal health care program and allocation of dedicated financial resources. To be effective, LTBI management requires a comprehensive package of activities that includes: identifying and testing eligible individuals; delivering treatment under clinical supervision, ensuring proper adherence and management of adverse events, and establishing monitoring and evaluation of the process. Specialized TB service units will bear the overall responsibility for conducting preventive TB treatment. This will be accomplished in close cooperation with other providers, involved in provision of medical and other services to the abovementioned groups at risk, including public health services under NCDCPH (for investigation of contacts), National AIDS Program (for PLHIV and PWID through outreach harm reduction activities) and penitentiary services (for prisoners).

During the first two years (in 2019 and 2020) of the NSP implementation, the NTP will update the existing guidance to accommodate for the expanded scope of TB preventive work and will conduct necessary capacity building activities. Relevant provisions will be incorporated into the national TB information system to ensure effective monitoring and evaluation of preventive interventions, including development of specific recording and reporting tools, standardized indicators and data capturing mechanisms to inform decision making for program implementation.

The Bacillus Calmette-Guérin (BCG) vaccination prevents disseminated TB disease, including meningitis and miliary TB, which are associated with high mortality in infants and young children. At the same time, the impact of BCG vaccination on transmission of *M.Tb* is limited as it does not prevent primary infection or reactivation of latent pulmonary infection, which is the principal source of bacillary spread in the community. Repeated BCG vaccination (re-vaccination) in children and BCG vaccination of adults have no proven benefits and therefore will not be performed.

Georgia will continue to adhere to WHO recommendations on vaccination against TB[44,45]. Until new and more effective vaccines become available, a single dose of BCG vaccine will be given to all infants as soon as possible after birth. The exceptions are infants who are known to be HIV-infected and infants with unknown HIV status who are born to HIV-infected mothers. In cases where infants have been exposed to TB shortly after birth, BCG vaccination should be delayed until completion of prophylactic isoniazid treatment.

44.*BCG vaccine* (WHO Weekly epidemiological record No. 4, 2004, 79, p. 27-38)
45.*Revised BCG vaccination guidelines for infants at risk for HIV infection* (WHO Weekly epidemiological record No. 21, 2007, 82, p. 193-196)

The main activities under this Intervention include:

2.5.1. *Development of national LTBI management guidelines.* Based on the latest international recommendations, the NTP will develop the national guidance on LTBI testing and preventive treatment, to be carried out in identified risk groups.

2.5.2. *Training on LTBI management will be provided for health care providers from specialized TB services in the ci*vilian and penitentiary sector, as well as for the staff from public health services and HIV services.

2.5.3. *Diagnostic tests for LTBI.* TST (Mantoux) tests will be procured centrally for testing for latent TB infection in defined risk groups. IGRA (interferon-gamma release assay) tests will be procured for targeted testing of health care workers at risk starting mid-2019.

2.5.4. *Drugs for TB preventive treatment.* Isoniazid (and Rifampicin for selected use) will be procured in necessary quantities for the scaled up implementation of preventive LTBI treatment in risk groups.

2.5.5. *Procurement of BCG vaccines.* Centralized procurement of BCG vaccines will be carried out using the state budget funds. The vaccines will be procured from WHO-prequalified manufacturers using the global pooled procurement mechanism (through UNICEF Supply Division), in order to ensure high quality of products and concessionary prices.

2.6 Support to operations of TB treatment institutions

This Intervention includes routine support to the operations of TB service institutions, as well as relevant investments as required for ensuring their effective functionality in line with the NTP priorities for the next program period. The plan for investments in TB service infrastructure will be developed within the next year.

While prioritization of outpatient case management is a clear priority, infrastructure rehabilitation will be required in selected inpatient TB facilities to ensure appropriate conditions for patients who need hospitalization and improved infection control conditions with proper separation of patient flows according to their infectiousness and resistance status. It is also envisaged to establish a facility for palliative care, which will accommodate patients who have failed all available treatment alternatives and will need symptomatic treatment and nursing/social care.

Adequate infrastructure will be created at currently operational TB treatment facility for patients with confirmed TB who will undergo involuntary treatment/isolation according to the Georgia TB Control Law adopted in 2015.[46].

The main activities under this Intervention include:

2.6.1. *Physical infrastructure strengthening:* In 2016-2018, infrastructure of two outpatient facilities have been developed in Tbilisi with Global Fund support. In order to improve the quality of TB hospital services, during the strategy timeframe, infrastructure of the National Center for Tuberculosis and Lung Diseases will be improved to ensure compliance with international standards of TB treatment (including surgery). *Medical equipment for TB service institutions.* Following a needs and inventory assessment, outdated medical equipment will be replaced by new equipment at public TB inpatient facilities.

2.6.2. *Human resources at TB treatment institutions.* Remuneration of staff in inpatient and outpatient TB institutions (including the newly established palliative care facility), with planned increase in salary levels according to the Government plans.

2.6.3. *Facility costs at TB treatment institutions.* Coverage of utilities and other costs in inpatient and outpatient TB institutions (including the newly established palliative care facility).

Expected Results

Implementation of the interventions under this Objective aims at ensuring, by 2022, universal access to high-quality treatment of all forms of TB, including M/XDR-TB, in Georgia:

[46] The law on Tuberculosis Control, Paragraph 14

- TB treatment and case management strategies and standards, in particular those for management of drug-resistant TB and HIV-associated TB, are upgraded and implemented according to the up-to-date international recommendations;
- All diagnosed TB patients, including those with advanced drug-resistant forms of the disease, are provided with appropriate treatment, which is based on resistance status and initiated without delays;
- Uninterrupted supply of quality assured anti-TB drugs (first-line, second-line and third-line drugs), and appropriate systems for drug management are in place, including procurement, storage and distribution, stock management, recording and reporting, management of adverse drugs reactions and pharmacovigilance;
- An effective model for TB care delivery model is implemented, which employs patient-centered approaches and is based primarily on outpatient management of TB cases, including those with M/XDR-TB;
- Appropriate adherence support (cash and non-cash incentives, enablers and other means) and treatment of co-morbid conditions are provided to all TB patients in need, to ensure compliance to treatment and best patient outcomes;
- Proper conditions and measures for TB infection control are secured in all inpatient and outpatient TB treatment sites;
- Testing for and preventive treatment of latent TB infection is provided to all individuals in need from defined risk groups according to international and national recommendations for LTBI.

Objective 3. To enable supportive environments and systems for effective TB control

Rationale

Addressing broader social and economic determinants will ultimately have a decisive impact on the burden of TB. TB care and prevention will continue to benefit from general economic growth, poverty alleviation, enhanced social protection and reduced inequalities. In this regard, the *End TB Strategy* calls on countries to pursue 'health-in-all' policies through applying multisectoral and multidisciplinary approaches to improving health, which will greatly facilitate effective TB control.

At the same time, GTSF emphasizes the need to create supportive environments and specific systems to ensure the attainment of goals and targets of the national TB strategic plans. This requires, first of all, a well-resourced, organized and coordinated health system. TB services are an integral part of the national health system, and sustainable success in TB control needs, therefore, proper alignment within the overall reform processes and strengthening the core health system functions. Appropriate monitoring and evaluation systems need to be in place to assess the progress of TB interventions, which should include all relevant health system aspects.

Implementation of universal health coverage (UHC) policies is presented as one of the key GTSF components. In December 2014, the Government of Georgia approved the *Georgian Healthcare System State Concept*[47], which supports the health-in-all approaches and has UHC as the mainstay for the health system development in the country until 2020. The Concept presents TB control as one of its priorities and calls for improving quality of TB services.

Besides the health system, the role of communities and non-state actors is of high value in implementing patient-centered approaches and addressing the needs of population groups at risk. GTSF calls for building strong and sustainable coalitions for fighting TB that include all stakeholders. Civil society organizations have specific competencies which should be used by the national program, such as reaching out to vulnerable populations, mobilizing communities, channeling information and framing effective service delivery models.

[47] Government of Georgia, Decree No. 724, 26 December 2014, 'On Approval of Georgian Healthcare System State Concept 2014-2020: Universal Healthcare and Quality Management for Protection of Patient Rights'

TB control strategies and service delivery have to explicitly account for human rights, ethics and equity. TB care and prevention often pose ethical dilemmas, and the NTP needs to address them with due respect to relevant ethical values and globally recognized principles. TB-related research is another component of the supportive environment, which should generate reliable evidence for decision making at all levels.

Achievements to Date

The increasing commitment of the Government of Georgia to effective TB control is proven by increasing levels of TB expenditures, including its goal of taking over a large share of the financing from the Global Fund.

- The Concept for health care development adopted by the Government of Georgia in December 2014 appropriately prioritizes TB control interventions and their integration into the overall process of transformation of the health system.
- The Georgian Country Coordination Mechanism (CCM) guides and oversees the country efforts in diseases' control implemented with the Global Fund support, as well as cooperation between different governmental agencies and partnerships with NGOs.
- Traditionally, there has been close and constructive collaboration among the national stakeholders involved in TB control, including the penitentiary system and HIV/AIDS program. The NTP management and coordination arrangements at the central level were strengthened by the establishment of the National TB Council (NTC) in November 2014.
- Over the last decade, Georgia has benefitted from intensive and productive cooperation with external partners in the area of TB control: WHO, German Government (GIZ/KfW/GOPA), United States Government/USAID, ICRC, MSF, EXPAND-TB/FIND, and others. The country has successfully implemented the Global Fund TB grants from Rounds 4, 6 and 10 as well as a grant under the Global Fund new funding model.
- Continuous professional development of medical personnel participating in TB service has been supported through state and donor financing. System capabilities are also continuously strengthened for implementation of innovative methods of treatment and diagnosis.
- Involvement of civil society organizations in TB control has been substantial since 2012. The USAID Georgia TB Prevention Project has supported many community-based initiatives aimed at TB awareness raising, treatment adherence support, and TB case detection among high risk groups. These activities will be further expanded to enhance patient-centeredness and achieve better treatment outcomes.
- The Georgian NTP actively participates in international clinical research projects on TB.

Challenges and Gaps

- The major challenge that NTP faces during this strategy implementation period is maintaining universal access to quality TB prevention, diagnosis, treatment and care services in the context of an anticipated reduction of donor funding.
- In the context of anticipated transition from the Global Fund to state financing, improving efficiency of the system becomes of particular importance. This can be achieved by optimizing the TB service delivery network and strengthening mechanisms for continuous quality improvement.
- The use of hospital capacities compared to other countries in Eastern Europe and Central Asia is relatively low in Georgia, but the average length of stay for MDR-TB is 86 days and widely ranges from 45 to 127 (2016 data). This can be explained by the absence of uniform hospitalization criteria. The new National TB Control Guidelines based on WHO recommendations was enacted in May 2018, and includes already defined hospitalization and discharge criteria. However, for the full execution of these criteria it is also important to revisit payment mechanisms for hospital services to avoid unjustified hospitalization and prolonged stay.
- Strengthening public-private partnership in Georgia remains crucial for maintaining and expanding access to TB service. Payment mechanisms for private providers should be refined to insure their

stable and long-term engagement in TB service delivery.

- The low reimbursement of physicians and nurses is a major systemic challenge that affects health workers motivation. The challenge is further exaggerated by the fact that a majority (69.8%) of physicians within the State TB Control Program are pre-retirement or retirement age and the influx from the new cadre of physicians is low. [48]
- The role of primary care providers in TB detection and management has yet to be improved. Capacity building of primary care providers is needed constantly to ensure active case finding and quality DOT administration at ambulatory level.
- Efforts are required to support implementation of the TB Control Law enacted by the parliament of Georgia in 2015. During the upcoming strategy cycle, particular emphasis will be placed on enactment of the provisions of the new law supporting TB treatment adherence, protecting patients' rights to have unlimited access to high quality service, roles and responsibilities of private facilities as well as public health services in contact investigation, treatment adherence support etc.
- TB-related operational research needs to be intensified to address the functions of the health system in relation to TB control and performance of services (such as financial burden on households in relation to TB care, problems in accessing services, delays on the patient's pathways, hospital performance, and service-related risk factors for M/XDR-TB).

Strategic Interventions

Under this Objective, four Strategic Interventions are proposed to create the supportive environments and systems for effective implementation of diagnostic and treatment interventions described above. They include: 1)strengthening key functions and processes in the health care system for TB control; 2) supervision, monitoring and evaluation of the NTP; 3) supporting advocacy, communication, and social mobilization (ACSM) and engagement of civil society; and 4) research on priority issues of TB control.

3.1 Strengthening core health system functions for TB control

In line with the principles and priorities of the Georgian Healthcare System State Concept 2014-2020, the Government will ensure that the needs of TB control are properly integrated into the planned health system transformation process. For this purpose, a set of actions will be undertaken for strengthening the main health system functions in this regard: governance and management, financing and allocation, resource development, and service delivery.

Governance and management

According to the WHO guidelines[49], a national TB control program should embrace the following structures: a central NTP unit (including the national TB reference laboratory); regional coordination units for TB control (including regional laboratories); and health service delivery points (including inpatient facilities and outpatient units, integrated into general health services). Effective governance, program management, and coordination between stakeholders and implementers are essential to the success of TB control interventions.

During the next four-year period covered by the NSP, MoIDP&LHSA will apply specific measures to strengthen the governance and management arrangements of the national program. The NSP outlines two priority areas for improving the NTP governance and management for 2019-2022: 1) strengthening the NTP governance arrangements at the central level; and 2) ensuring harmonization of key legislation and regulations in line with NSP priorities.

A functional NTP central unit is a key requirement for effective implementation of complex TB control interventions. To ensure effective program management and coordination, the arrangements instituted in late 2014[50] will be operationalized and further developed. The National TB Council (NTC) will act in the capacity of the central coordination body for the NTP. The NTC will oversee the implementation of this

48 Rapid assessment of human resources for TB in Georgia, April 2017, Andrei Mosneaga, Consultant, USAID
49*Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis* (WHO, 2014)
50 MoLHSA Order No. 01-282/ო from 11 November 2014 *'On the establishment of the Central Coordination Body for TB Control, the National TB Council, and endorsement of its bylaw'*

NSP, carry out strategic and operational planning of key activities, support mobilization of required resources for TB control, and facilitate the mainstreaming of legislation, regulations and standards in line with best international practices. The NTC will be responsible for monitoring and evaluating the progress towards achieving the objectives and targets of the national TB response.

The NTC appoints the National TB Coordinator to be in charge of practical tasks related to NTC operations and all other program implementation issues.

A primary task for the NTC and the National TB Coordinator is to ensure effective cooperation between the four key entities for TB control at the central level: the Country Coordination Mechanism (CCM), the Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia (MoIDP&LHSA), the National Center for Disease Control and Public Health (NCDCPH) and the National Center for Tuberculosis and Lung Diseases (NCTLD), as well as to promote appropriate involvement and coordination of other ministries and governmental agencies, private providers of medical services, other non-state actors and international partners.

The NTC will accord special attention to proper integration of TB control interventions in the civilian and penitentiary sectors, as well as to strengthening the collaboration between TB services and HIV services. For this purpose, the NTC will ensure the effective involvement of the Ministry of Corrections and Legal Advice (MCLA) and the National HIV/AIDS Program (NAP). The functions and responsibilities of key national stakeholder organizations are described in detail in Section 4 below and reflected in the NSP Action Plan.

The NSP envisions that the role of NCDCPH in the NTP will further increase over the four-year implementation period. This specifically relates to TB surveillance, diagnosis and program monitoring and evaluation, with the aim of integration within the overall disease surveillance function undertaken by NCDCPH. For this purpose, NCDCPH and NCTLD will develop and implement practical mechanisms for ensuring that the National TB Reference Laboratory (organizationally part of NCTLD) will carry out its central-level methodological and supervisory role in close interaction with NCDCPH network of public health laboratories (ZDLs and LSSs). In addition, NCTLD's activities related to TB recording and reporting and supervision will be supported by NCDCPH in order to ensure compliance and coordination within the overall disease surveillance program. Necessary provisions will be introduced in the relevant normative acts to upgrade the NCDCPH statute, staffing schedule and financing, in order to enable the Center to effectively manage the increasing scope and complexity of work.

TB-related provisions will be integrated in the regulations related to universal health coverage and other acts regulating service provision, with special attention to enabling the private health care providers for executing the expected functions in TB control and, on the other hand, to ensuring appropriate oversight and monitoring by the State. Besides system-wide regulations, specific TB guidelines and service protocols will be also upgraded as indicated above.

Special emphasis is placed on strengthening the collaboration between the NTP and the National HIV/AIDS Program. Both National Strategic Plans for TB and HIV have been developed in close coordination between the two programs, to ensure appropriate inclusion of collaborative activities as recommended by WHO and UNAIDS, such as interventions to reduce TB burden in HIV-infected prisoners ('the Three I's for HIV/TB'[51]) and administration of ART in patients with HIV-associated TB (see more details under Objectives 1 and 2). National TB and HIV guidelines will be revised accordingly, and all TB/HIV interventions will be implemented in close coordination between the NTP and NAP, including integration of information systems.

An important challenge for the NTP is enabling effective program management at the sub-national (regional and district) level, given the need to decentralize TB case management, including promoting full outpatient treatment of TB patients. During the next program period, MoIDP&LHSA and NTC will undertake appropriate measures to ensure that reliable program management is in place in the regions, and it is sustained and further developed beyond Global Fund support. In order to ensure effective coordination of TB service delivery in the regions, MoIDP&LHSA will secure appropriate funding support for TB coordinators and additional staff at regional level for supervision, data management support and other tasks in all country

[51] *WHO policy on collaborative TB/HIV activities: guidelines for national programmes and other stakeholders* (WHO, 2012)

regions, as well as, in collaboration with MCLA, in the penitentiary system.

Financing and allocation

The Government of Georgia is committed to secure the increasing and sustainable financing of all essential TB control interventions, outlined in this Plan. The four-year period covered by the NSP is crucial for the national TB response in terms of effective financial takeover from the Global Fund and other external donors.

The MoIDP&LHSA and NTC will carry out appropriate advocacy activities within the Government to secure sufficient level of TB-related expenditures and reliable allocation mechanisms at all levels of health care. Within the ongoing process of transition to UHC system, MoIDP&LHSA will make sure that TB control interventions are properly included in this coverage, taking into account the importance of TB control as a key public health responsibility and the financial vulnerability of clients as the majority of TB patients are at risk of catastrophic expenditures if required to pay a substantial share of costs directly out-of-pocket.

Therefore, diagnostic and treatment interventions for all forms of TB (including M/XDR-TB), as well as adherence support to patients, TB preventive activities and NTP supportive measures (training, supervision, information system, etc.) will be covered under the state budget financing in accordance to the scheme that will be designed and applied by the Government in the coming years. It is stipulated that the package of TB services will increase stepwise and will include all essential needs by the end of NSP period (2022).The details on financing levels for TB control interventions (with overall funding needs' estimate, anticipated level of funding and funding gaps) are presented in Section 5.

The increasing level of Government financial contributions should be complemented by effective and efficient allocation and provider payment mechanisms, which will provide that the funds reach the real patient needs. For this purpose, the methods of payment for TB-related services will be revised by MoIDP&LHSA and the Social Service Agency (SSA) in 2019, and introduced country-wide. The scheme for allocation of state funds will contain appropriate provisions for budget equilibration and subsidies, to ensure sufficient funding for regions and areas with higher disease burden or/and access-to-service issues (e.g. estimated high level of undetected cases). Regarding provider payment mechanisms, the changes will be tailored to each TB care setting: hospitals, specialized outpatient TB services, as well as PHCs (including performance payments to PHC providers for TB-related work, such as contacts' screening, LTBI testing and preventive treatment). [52]

The redesign of provider payment schemes will take into account relevant international experience.

Inpatient TB care payment will be revised by moving from bed-day payments to per case payments (e.g. having two different case payments: DS TB and DR TB) and as mentioned earlier even higher priority should be given in enforcing implementation of admission and discharge criteria. Alternatively sifting selected hospitals to global budget based payment can also be considered. For primary care providers performance related payment schemes piloted and expanded countrywide in 2019.

Human resources

From 2015-2017, MoIDP&LHSA has successfully implemented the professional integration of phthisiatry in the field of pulmonology. As a result, the full spectrum of TB competencies was included in the residency programs of the phthisiatry-pulmonology specialty. In 2017, a short-term residency program was launched targeted at borderline specialties to have them retrained into phthisiatry-pulmonology. This short-term residency program that is recognized by MoIDP&LHSA and implemented by the faculty of Tbilisi State Medical University will be offered to interested eligible physicians of borderline specialties. This is an immediate solution to human resource shortages for the NTP in selected areas.

Additionally, to ensure compliance with the latest international recommendations, undergraduate and postgraduate medical education curricula will be regularly updated. Short-term training courses for continuous update of TB related skills and competencies will be offered to TB specialists, primary care

[52] Triin Habicht, Technical assistance for development of sustainable financing models for TB control in Georgia, January 11, 2017, TB-REP

providers and public health workers.

Special attention will be paid to improving staff motivation and retention in TB services. MoIDP&LHSA will assure that remuneration of staff working in TB services is increased substantially from the current low level, and becomes comparable (or advantageous) compared to other medical specialties. For this purpose, MoIDP&LHSA will secure relevant provisions in the service contracts with private health care providers. The increased level of remuneration of TB service staff (for both doctors and nurses) is foreseen in the NSP financial needs estimates and budget forecasts.

Service delivery

A key focus of this strategy is to support patient-centered TB care model development in Georgia. The following will be undertaken to achieve progress in this direction:

- MoIDP&LHSA and other partners will support the implementation of TB management guidelines launched in 2018. This guideline details hospitalization criteria and also defines the principles for organizing TB services at the outpatient level, including the role of community-based organizations and former patients in peer education and adherence to TB and DR TB treatment.
- MoIDP&LHSA and NCDCPH will work on improving referrals, coordination and other aspects of integration between the levels of care (inpatient care, outpatient specialized care, PHC) and services (such as, TB service and HIV service);
- Strengthening quality control and quality assurance in TB diagnostic, curative and preventive services at all levels will be priority intervention to be implemented through collaborative efforts of MoIDP&LHSA, NCTBLH, NCDCPH, TB and Primary Care professional associations and CSOs
- Diversification of TB care provision aiming at better meeting patients' needs through application of patient-centered approaches, involvement of communities and non-state actors in adherence support and psychosocial adaptation, and covering special needs such as symptomatic treatment and palliative care. MoIDP&LHSA will assess the effectiveness of adherence support programs implemented by CSOs and elaborate financing mechanisms for their continuous engagement within the National TB Program.

The NTP relies on further strengthening public-private partnerships in the delivery of TB-related services to the population. While TB control is an important public health function and the responsibilities for steering, oversight and monitoring and evaluation (M&E) lie with the State and will be exercised by NTC and MoIDP&LHSA, private health care providers will remain responsible for the provision of the most of TB diagnostic, curative and preventive services to the population. These services will be provided in close cooperation with relevant public institutions such as NCDCPH and NCTLD.

Over the next program period, a number of measures are planned to facilitate the provision of TB services by private providers. To uphold universal access to essential TB care in all areas of the country, the tasks and responsibilities of private providers will be formalized in annual service contracts with MoIDP&LHSA/SSA. These agreements will stipulate in detail the scope and volume of services to be provided. The payment conditions will be clearly articulated in the contracts, according to the payments methods (see above under financing and allocation). Additionally, the modes of cooperation, related to referrals and other processes, between private medical centers and public institutions (NCDCPH territorial units and laboratories, public hospitals) will be elaborated. The NTP will undertake continuous capacity building of medical staff, quality assurance and program monitoring and evaluation through different means described above (guidelines, training, supervision, etc.).

During the Plan timeframe, the NTP will further prioritize outpatient model of TB care delivery, including treatment of M/XDR-TB cases in ambulatory conditions starting day one.

For this purpose, all programmatic and financial instruments outlined above will take special account of the need to expand outpatient case management and improve its quality. Appropriate provisions will be included in the guidelines, provider payment schemes, diagnostic approaches at peripheral service level (including the use of Xpert MTB/RIF technology), drug management system including pharmacovigilance and management of ADRs, supervision and recording and reporting system.

Taking into account re-emphasis on primary health care level, articulated in the Georgia health care

development Concept, contemporary approaches for TB prevention, care and control will be further integrated into PHC training curricula, regulations and payment schemes (including motivation and performance payments to PHC providers for successful management of outpatient TB cases).

It is anticipated that implementation of the above measures will allow for expanding quality outpatient treatment, so that by the end of 2022, 75% of all drug-sensitive and PDR-TB and 40% of M/XDR-TB cases will be treated without hospitalization. In addition, by the end of 2022, the average length of stay will be reduced by at least 50% in drug-sensitive and PDR cases, as well as in MDR cases. Delivery of TB services close to the patients' place of residence and in a community environment is a key component of patient-centered care, which will contribute to better patient outcomes and improvements in the overall health system performance.

The NTP will ensure that the TB care delivery system in Georgia is fully capable to address specific aspects of TB treatment, such as treatment of TB in children, extrapulmonary TB and application of surgery. Management of such cases will continue to be carried out in respective departments of the National Center for Tuberculosis and Lung Diseases in Tbilisi, which will receive additional support in terms of staff, infrastructure and technology. The national TB pediatric guidelines will be updated in 2019 to include the most recent evidence for management of pediatric TB cases, including those with drug-resistant forms of disease.

The role of surgery in TB treatment is being re-evaluated, especially in view of its importance in the management of M/XDR-TB cases. In line with the latest evidence and guidance[53], NCTLD will work on expanding the application of surgery for pulmonary TB according to specific criteria and indications, including localized cavitary forms with continuous excretion of mycobacteria, and for treatment of M/XDR-TB cases in circumstances when complicated clinical conditions and limited therapeutic options (i.e. extensive resistance to TB drugs) will likely lead to treatment failure and death. In such conditions, radical surgical interventions, performed in combination with comprehensive preoperative and postoperative care and appropriate chemotherapy, render for improved treatment results. It is aimed that the surgical activity in pulmonary M/XDR-TB cases will increase during the next five years and contribute to improved patient outcomes in this group of patients.

Covering special patient needs includes provision of palliative care in those patients who have failed all available TB treatment alternatives and require symptomatic treatment and nursing/social care. For this purpose, it is planned to establish a palliative care facility in the country, following the detailed assessment of needs and identification of additional resources for infrastructure, staff and operational support. The work will continue to upgrade TB service delivery infrastructure to ensure quality delivery of services. Additional investments in premises and medical equipment will be undertaken based on the in-depth needs assessment.

Legal and ethical issues in TB control

Observing the key ethical principles and values, such as social justice and equity, solidarity, pursuing common good, reciprocity, subsidiarity, participation, transparency and accountability is essential for adequate TB control. In line with WHO guidance[54], the actions in the area of TB ethics and legal aspects in Georgia during the next five years will address all of the key dimensions, namely the Government's obligation to provide access to TB services; information, counseling and consent; supporting adherence to TB treatment; the link between the availability of drug susceptibility testing and access to M/XDR-TB treatment; health care workers' rights and obligations; involuntary isolation and detention; and TB-related research.

According to WHO recommendations, the Law of Georgia on TB Control underlines the Government's commitment to provide access to the TB prevention, diagnostic (investigations) and management services (including palliative care of a person suffering from tuberculosis), as well as financial access to anti-TB medications. For public health interests, the law allows the involuntary isolation of a patient with communicable form of tuberculosis, as an extreme measure, when all means of compulsory investigations and voluntary involvement of patient in the treatment process has been exhausted and without the use of involuntary isolation measures spread of infections cannot be avoided. To protect public and individual

[53] *The role of surgery in the treatment of pulmonary TB and multidrug- and extensively drug-resistant TB* (WHO/EURO, 2014)
[54] *Ethics guidance for the implementation of the End TB Strategy (WHO, 2017)*

interests, and the right to make informed decision regarding individual's health, MoHLSA with Georgian TB Coalition will work on development and implementation of ethical standards for TB control according to WHO recommendations. The NTP will also ensure adequate involvement of legal and ethical issues in clinical practice recommendations and training programs.

The main activities under this Intervention include:

3.1.1. *External technical assistance* will be sought in priority areas related to strengthening the health system's functions for TB control, in particular in revising financing and provider payment mechanisms, human resources planning and medical education, improving TB service delivery with expanding outpatient case management, and strengthening the links to health services' performance in the national TB information system.

3.1.2. *National consultants* will be engaged in practical work on revision/update of the relevant legislative and regulatory documents for improving the health services' performance for effective TB control, including support to symptomatic treatment / palliative care. Lack of the well functional palliative care model is a major weakness of the NTP in Georgia. This program proposes to support elaboration and implementation of palliative care policy and evidence-based practice model in Georgia through external and local technical assistance, high level workshops, study tours for NTP officials to countries in which the TB palliative care model is well established. This activity will include local and international technical assistance, training, high level meetings, and a possible study tour for high level officials.

3.1.3. *International training* and support to attendance of key international TB events abroad (conferences, high-level meetings and consultations) will be provided for NTC and MoIDP&LHSA staff, NTP coordinators and leading TB specialists from both the civilian and penitentiary sectors.

3.1.4. *Training of health care managers* from private provider organizations will be conducted to facilitate the implementation of new approaches and changes for effective TB care delivery. *Management capacity building* for the NTP will be supported by training of staff of NTP entities at the central and regional level. The training program will focus on managerial aspects to support the planned reorganization of TB service delivery with emphasis on coordination of services across different levels of care, expanding quality treatment in ambulatory conditions and implementation of patient-centered approaches.

3.1.5. *Short-term and professional training programs for physicians in borderline specialties.* Building competencies of non-TB specialists in TB detection is important precondition for early case detection and timely referral. Georgian Association for Physiatrists and Pulmonologists. This training will build on experience of USAID TB Prevention Project, use already available training resources *and* target additional 400 physicians over the 2.5 year period. *Professional training programs for physicians in borderline specialties*: In order to address current and anticipated human resource shortage a three-month short term residency program placement will be offered to eligible physician in selected areas. Forty doctors will be retrained and certified in Phtisiatry-Pulmonology by 2022.

3.1.6. *Training in TB management for epidemiologists*: Training programs for epidemiologists will be organized in various aspects of TB detection and management. Epidemiologists at public health centers play a key role in contact tracing. It is planned to expand their role to achieve greater involvement in adherence support. The strategy intends to continuously support capacity building of epidemiologist and organize refresher training courses once every two years on the most important aspects of TB case management in line with their responsibilities.

3.1.7. *Training and performance appraisal of PHC personnel:* During the strategy period performance appraisal and on-site mentoring will be provided to 500 primary care teams which have not received this support since 2016. In order to ensure greater coverage and regular interaction with training materials for health care workers, The NFP proposes to develop web-based learning courses on various aspects of TB diagnostics and MDR TB management. The availability of computer-based training will create a good opportunity for many Georgian physicians to improve TB related competencies. Two electronic modules will be developed with the Global Fund support in 2019-

2022. In addition, NTP will continue using ECHO model for supporting peripheral service delivery points in clinical decision making and improving quality of services they deliver.

3.1.8. *National consultants* will assist in the organization of policy dialogue and technical discussions among key stakeholders, introducing amendments to the existing laws and development of new legislation and regulations.

3.1.9. *Training in legal/ethical issues* will be organized in view of the amended legal framework, for managers of health care institutions and other relevant medical and non-medical personnel.

3.1.10. *Support implementation of performance based financing scheme for primary care providers:* performance based payment will be tested in a smaller scale and recommendations will be prepared for is further roll out on evaluation of this intervention.

3.2 Supervision, monitoring and evaluation of the National TB Program

Program supervision, monitoring and evaluation is an essential public health function, and is an integral part of the national program's governance and management setup. While supportive NTP supervision will be maintained as a key instrument for oversight and implementation support, its scope and tasks will be further expanded in the process of taking over from the Global Fund, taking into account the national TB control priorities.

Supervision will cover all aspects related to implementation of TB control interventions outlined by this Plan at the regional, district and institutional levels: case detection, diagnostic activities and laboratory support (with separate supervision of rollout of molecular diagnostics at peripheral service level, see Intervention 1.1); screening for active TB among contacts and other risk groups; treatment/case management; patient adherence support and defaulter tracking activities; drug management including pharmacovigilance and management of ADRs; management of comorbidities; LTBI testing and preventive treatment; TB/HIV related activities; and recording and reporting.

It is planned to continue the current setup for NTP supervision: central supervision visits by NCTLD staff to the regions two times a year, and regional supervision visits to districts within the regions on a quarterly basis. For effectiveness and relevancy of supervision, the checklists and format of reports will be updated to accommodate for NSP requirements and new interventions, ensure delivery of evidence for service improvement decisions at the spot, and provide for effective data analyses and evidence generation for decision making at the national level. Importantly, supervisors will pay increasing attention to service performance through addressing such aspects as delays in diagnosis, referral issues, delays between diagnosis and treatment initiation, etc.

The national TB information system will be further strengthened. All components of the patient-oriented electronic system (developed with the USAID support in 2016) will be fully activated, which will create real-time data collection and analysis. The MoHLSA and the National TB Control Council will mobilize resources for technical and administrative support for an integrated electronic module.

The main activities under this Intervention include:

3.2.1. to 3.2.3. Support to NTP supervision. Field monitoring and supervision of program implementation will be further strengthened. Central supervision visits will be conducted to the country regions twice a year, and regional supervision visits to districts within regions on a quarterly basis.

4. *NTP program coordination meetings* will be held at the central level with participation of NTP staff from the regions, to discuss the supervision findings, identify key problems at sites and plan for corrective measures and the next steps.

3.2.5. to 3.2.7. Upgrade and maintenance of the national electronic TB database. Technical services by local consultants will be provided in necessary software upgrades and maintenance of the national electronic TB database. Recording & Reporting forms and related guideline will be printed and disseminated regularly.

3.2.8. *Comprehensive TB program reviews* are conducted by the WHO Regional Office for Europe, in cooperation with other partners, and cover all areas of TB control in the country. It is planned to have the next NTP review mission to Georgia in late 2019.

3.2.9. Operational support to implementation of Global Fund programs: The strategy envisions continued operations of Global Fund programs principle recipient in Georgia. Adequate managerial and administrative support will be provided to GF PR to ensure effective administration of available resources.

3.2.10. Cars for public health centers and regional NTP staff. Transportation means are essential for the National Tuberculosis Program to ensure safe and timely distribution of drugs and medical supplies and sputum delivery to the laboratory facilities. Substitution of existing cars with the new in Tbilisi and regions was implemented in 2017-2018 with Global Fund support. Purchase of additional cars will be considered based on needs.

3.3 Civil society engagement, advocacy, communication and social mobilization (ACSM) for TB control

The improvements in TB service delivery require the reinforcement of patient-centered care, which is particularly relevant for the management of drug-resistant TB and for ensuring access to essential interventions for the disadvantaged and at-risk population segments. The Government of Georgia recognizes the need for strengthening the partnerships with the civil society establishments and the involvement of non-state actors as a key prerequisite for the success of the nationwide TB response.

The Plan stipulates increased collaboration between the public health services and non-state actors in different aspects of TB control including ACSM for enhanced population knowledge and awareness of TB and reducing TB-related stigma, patient support and follow up for improving adherence to TB treatment, and addressing the needs of vulnerable and high-risk population groups. In this context, NGOs' participation in TB control in Georgia needs further development. This Intervention aims at implementing patient-centered approaches through fostering the local NGOs' involvement in TB care. The key component is support to NGO projects, which will assist in implementing innovative models for ensuring adherence to TB treatment, tailored to the specific local conditions and to the needs of individual patients. The NGO projects are expected to employ a number of common interventions, such as multidisciplinary teams for comprehensive approach to the patient and improved coordination with relevant public and private services; social accompaniment for beneficiaries at high risk of defaulting; and promotion of patient rights and equal access to essential services.

During the strategy cycle, NTP will further support implementation of already piloted successful models (e.g. community based adherence support program for DR TB patients by peers and multidisciplinary team, engagement of Georgia Orthodox Church in TB detection and adherence support, engagement of schools in TB education, media advocacy, etc).

Special attention will be paid to facilitating access to TB prevention, diagnosis and care for hard-to-reach groups at high risk, such as prisoners and ex-prisoners, PLHIV, people who inject drugs (PWID) and other risk groups. In these groups but also overall, respect and promotion of TB patients' rights and medical ethics in TB care should be given priority, in line with the provisions of the international Patient Charter in Tuberculosis Care (PCTC)[55]. In this regard, the NTP will encourage the involvement of NGOs that have experience working with the above population segments, including that in delivering HIV prevention and harm reduction services.

Establishment of the Georgia TB Coalition in 2017 should be considered as an important step towards strengthening the platform of civil society organizations and a predictor for their active involvement in the National TB Response. The Coalition comprises of more than 20 NGOs and operates as a single platform for TB detection, prevention and treatment advocacy. Its main function is to ensure adequate reflection of needs of vulnerable groups and TB patients into strategies, programs and specific interventions. In close collaboration with other governmental and non-governmental actors the TB coalition will continue extensive ACSM efforts aimed at reducing TB related stigma, stimulating positive health seeking behavior and achieving sustainable access to quality TB services for all in need.

The main activities under this Intervention include:

[55] *Patients' Charter for Tuberculosis Care* (World Care Council, 2006)

3.3.1. *Support to Georgian Tuberculosis Coalition*. The Partnership comprises representatives of civil society organizations, which are active in the field of health (including organizations currently providing HIV prevention, care and support services) and/or in working with vulnerable population groups and promoting human and patient rights to access to health and social care. In collaboration with governmental structures and private health care providers, the Partnership will streamline advocacy efforts for effective TB control, develop and promote initiatives aimed at inclusion of people affected by the diseases in decision making related to TB care, and assist in implementing practical tools for involving non-state actors in provision of adherence support and social adaptation services for TB patients as well as the groups at high risk.

NGO projects. It is envisaged that the NGO projects will target in two main areas: 1) implementation of innovative approaches in adherence support for TB patients at community level; and 2) support to case detection, case management and prevention among hard-to-reach population groups at risk (prisoners and ex-prisoners, PLHIV and PWID).

3.3.2. *NGO projects for innovative approaches in adherence support* will aim at supporting patients within the community environment during ambulatory treatment, with special attention to DR-TB cases. This will be addressed through intensified psychological support, involving families, church and community actors, information/education, following up on referrals and using motivation schemes tailored to individual patient needs.

3.3.3. *NGO projects for case detection, case management and prevention* among population groups at risk will implement intensified and innovative interventions aimed at improving care-seeking behavior, attendance for diagnosis and compliance to treatment in prisoners and ex-prisoners, PLHIV and PWID. Special emphasis will be placed on strengthening the referrals between different levels of services (including the links between penitentiary and civilian services) social accompaniment, psychological support, involving local public authorities and community leaders, information/education and other means.

3.3.4. National NGO workshops on TB control, civil society involvement and community response will be organized, in order to provide a forum for discussing and analyzing the results of the implementation of NGO projects, identifying the potential for further involvement of civil society beyond the Global Fund and other external support through partnerships with public authorities and private sector, and to share innovative experiences.

3.3.5. *A TB knowledge, attitude and practice (KAP) study* will be undertaken in 2021 in different target groups to determine objectives for changing behaviors and advocacy / communication needs, with particular emphasis on M/XDR-TB issues. Survey results will indicate directions for priority actions by the NTP and other partners.

3.3.6. *Production of TB informational and educational materials.* Different types of printed and audiovisual materials will be developed and distributed in health care settings and special settings (e.g. penitentiary facilities) and during various ACSM events.

3.3.7. *Training and briefings for mass-media* will also be organized with the aim of improving quality of TB-related information to the population, strengthening advocacy and increasing awareness of decision makers, with special emphasis on the planned changes in TB care delivery.

3.3.8. *ACSM activities during the World TB Days.* Various ACSM activities, including the organization of a nation-wide conference for TB professionals, will be conducted on and around the World TB Day (24 March), following the topics that are proposed by WHO for each year's campaign.

3.4 Research in priority areas of TB control

The use of reliable evidence facilitates proper decision making for improved performance of the national TB control program. Well-designed and targeted operational research is a valuable tool for generating such evidence, especially when implementation of innovative and/or system-wide actions is required. This Intervention aims at further developing the national capacities and building experience in modern and robust TB-related research.

The NSP stipulates support to two types of research activities: 1) clinical research, including participation in

the international medical research/clinical trials; and 2) operational research in priority aspects related to implementation of TB control interventions in Georgia.

The NTP, through the National Center for Tuberculosis and Lung Diseases as the leading national institution for TB expertise and clinical excellence, will work on further developing the links with the international partners and intensify resource mobilization efforts for conducting clinical research related to TB diagnosis and clinical management.

Operational research is planned in three main areas: 1) impact of new strategies and technologies for management of drug-resistant TB; 2) changes in effectiveness and efficiency of health services provision due to structural and functional reconfiguration in TB care delivery model; and 3) influence of innovative community-based patient-centered interventions over TB patients' outcomes, social and economic recovery and beneficiaries' satisfaction. The findings of these studies will assist the MoIDP&LHSA and other national partners in evidence-based decision making in the key components of TB control, covered by this Plan.

The main activities under this Intervention include:

3.4.1. *Clinical research studies* will be conducted in cooperation with the international partners (WHO, International Union Against Tuberculosis and Lung Disease, and others including TB Alliance the new *end TB* project implemented by MSF and Partners in Health). These include participation in clinical trials for new drugs (such as STREAM study mentioned under Intervention 2.1 above) and diagnostic technologies and research related to risk factors and co-morbid conditions.

3.4.2. *Operational research studies* will be conducted in priority areas for TB control in the country. The scope of research will be defined depending on the funding available (including external support) and implementation capacities.

Expected Results

*Implementa*tion of the interventions under this Objective aims at ensuring, by 2022 that appropriate environments and systems are in place to effectively provide for universal access to high quality patient-centered TB control interventions in Georgia, including:

- The National TB Program has effective management capacities at the central and regional level and undertakes the required range of functions, with appropriate financial coverage by the state;
- The state financing of TB control interventions is sufficient to cover the needs, and the takeover from external donors is completed;
- The regulations and norms for the health care services support the implementation of the integrated patient-centered model of TB care delivery, which is reliant on outpatient case management with proper PHC involvement, demonstrates improved performance of TB institutions, and ensures appropriate quality of services;
- The system for TB recording and reporting, monitoring and evaluation is upgraded in line with the international requirements and national health system's needs, and provides reliable evidence for decision-making;
- Civil society role in TB control is increased through increased involvement in innovative community-based interventions, which are increasingly sustained by domestic funding;
- The national legal framework in relation to TB is expanded and harmonized with the international law, and provides for proper realization of the obligations by the State, and rights and responsibilities of patients and health care providers.
- Findings of operational and clinical research studies available and used for decision making

4. Implementation Responsibilities

The scope of work required to achieve the NSP goal and targets calls for effective governance, coordination

and implementation arrangements. A key principle for the Plan realization is the promotion of participatory and multisectoral approach to the program planning, implementation, monitoring and evaluation. In line with global and regional guidance, the Plan foresees full engagement of different government agencies, non-state actors as well as international partners in this process.

National partnerships

This document provides a basis for legislative and normative acts, operational plans, technical guidelines and other relevant documentation to follow, which will form a sound implementation framework delineating explicit roles and responsibilities of the involved partners and facilitating effective multisectoral and multidisciplinary actions. The implementation of the Strategic Interventions presented above will build on the successful practices and will aim at creating new and strengthening the existing partnerships for effective TB control.

- The ***National TB Council (NTC)*** is the coordination body for the national TB program at the central level; it will oversee the NSP implementation, carry out strategic and operational planning, engage in mobilization of additional domestic and external resources for TB control, and facilitate the mainstreaming of legislation, regulations and standards in the field. The NTC will monitor and evaluate the progress towards achieving the NSP objectives and targets, and will be in charge of other practical tasks related to the NSP implementation.
- The ***Country Coordination Mechanism (CCM) for HIV/AIDS, Tuberculosis and Malaria*** will continue to facilitate horizontal links and participatory governance of TB control program, through active participation of the governmental partners (MoIDP&LHSA, other ministries and governmental bodies), external development assistance agencies as well as the civil society, while continuing to undertake a special function to obtain additional support from the Global Fund and oversee its implementation.
- The ***Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia (MoIDP&LHSA)*** will undertake the overall state leadership and governance for the NSP implementation, strategic planning, development of relevant legislation and regulations, human resource policies, advocacy and resource mobilization for TB control. A key task for both the NTC and MoIDP&LHSA is ensuring effective cooperation and coordination between the key government agencies for TB control at the central level: the National Center for Disease Control and Public Health (NCDCPH) and the National Center for Tuberculosis and Lung Diseases (NCTLD), as well promoting appropriate involvement of other ministries and governmental agencies, private providers of medical services, other non-state actors and international partners.
- The ***National Center for Disease Control and Public Health (NCDCPH)***, a legal entity under public law (LEPL) accountable to MoIDP&LHSA, will further increase its involvement in TB control, in particular in the areas of TB surveillance, management of the public health laboratories' network providing diagnosis of TB, and program monitoring and evaluation. NCDCPH will continue to serve as the Principal Recipient for the Global Fund grants, including the forthcoming new TB grant in 2019-2022.
- The ***National Center for Tuberculosis and Lung Diseases (NCTLD)*** is a central-level public institution and the national excellence center for TB clinical management. Besides providing treatment of TB cases, NCTLD will continue to carry out its methodological and supervisory functions for specialized TB services countrywide, which involve development of guidelines and protocols, capacity building of medical personnel, and monitoring of quality of services including field supervision and routine recording and reporting on TB. The National TB Reference Laboratory (currently part of NCTLD) will undertake its functions in TB diagnosis in close interaction with NCDCPH laboratory network.
- The ***Ministry of Corrections (MoC)*** is responsible for the implementation of TB control interventions in the penitentiary system and will ensure their full integration and coordination within the overall national program. Under NTC stewardship, MCLA and MoIDP&LHSA will further develop their collaboration in TB control that will include joint planning of interventions and development of regulations providing for further strengthening the collaboration between the civilian and penitentiary health care services.

- ***The Infectious Diseases, AIDS and Clinical Immunology Research Center (IDACIRC)***, in its capacity of the central unit for the National HIV/AIDS Program (NAP), will closely cooperate with the NTP to ensure effective implementation of activities aimed at improving the management of HIV-associated TB, which have been included in both TB and HIV National Strategic Plans. Special emphasis will be placed on the coordinated revision of national TB and HIV guidelines, integration of information systems and enabling conditions for appropriate integration of TB and HIV services at the central, regional and district levels.
- The ***Ministries of Economy and Sustainable Development, Finance, Education and Science, Regional Development and Infrastructure*** and other central and local government bodies will support MoIDP&LHSA in legal matters, ensuring prioritized and appropriate financing of health care interventions including those for TB control, institutional development, TB-related informational and educational activities and other relevant issues. During the next NSP period, the NTC, CCM and MoIDP&LHSA will place priority emphasis on advocacy activities with the governmental partners, aiming at enabling an effective and coordinated multisectoral response to TB epidemic.
- Implementation of priority activities, outlined in the Plan, relies on the close involvement of the ***medical education institutions***, which are expected to play an important role in generating scientific evidence, graduate education and continuous capacity development of the health care staff. ***National TB Coalition*** serves as a platform for fostering the involvement of different non-state actors (including civil society organizations, associations of patients and health professionals) in TB control activities in the country. The Plan is reliant on the increasing participation of ***non-governmental organizations*** in TB control activities, specifically in those aimed at promoting patient-centered care and addressing the needs of vulnerable and high-risk population groups.

External support

Financial and programmatic support from international donors and development assistance partners has been instrumental in the area of TB control in Georgia. While the Government is committed to increasingly allocate financial, human and other resources for strengthening TB control interventions, the country will still be in need of external support in the field of TB control during the coming years. The NSP therefore relies on further streamlining the external assistance to meet its objectives and targets. The key international partners include:

- ***The Global Fund to Fight AIDS, Tuberculosis and Malaria (TGF)***. The ongoing TB project (grant GEO-T-NCDC) under New Funding Model will be completed in 2019. The National Center for Disease Control and Public Health is the Principal Recipient of the grant funds. In August 2018, the CCM will apply for a follow-up grant within TGF's New Funding Model (NFM). The NFM application will cover 2019 –2022 period and will include interventions, for which domestic financing are not sufficient and also capacity building to improve efficiency of TB measures and assure its sustainability.
- ***The United States' Agency for International Development (USAID)***. Over the last decade, USAID has been a key partner to the Government in strengthening the TB control program in the country. Further support in the provision of strategic guidance and technical assistan***ce by a Tuberculosis Advisor to MoIDP&LHSA and NCDCPH from USAID is expected. In addition***, Georgia will still have access to the technical assistance within Bedaquiline donation program which USAID implements in collaboration with Stop TB Partnership (at least during the first year of the Strategy implementation).
- ***The World Health Organization (WHO)*** through its Regional Office for Europe and Country Office in Georgia will continue to be the key partner of the national program in all priority developments and initiatives related to TB control in the country. In particular, WHO is expected to carr*y* out monitoring and evaluation of the NSP implementation.
- ***Other external partners***. To ensure achievement of the national TB control goal and targets, the NTC, CCM and MoIDP&LHSA will undertake further resource mobilization efforts with other potential external partners to ensure appropriate coverage of priority interventions, especially those related to M/XDR-TB diagnosis and treatment, health system strengthening and TB-related research.

Technical assistance

Despite substantial progress in capacity development during the last decade, the Georgian NTP remains in need of technical support in the implementation of TB control interventions, especially in view of the recent changes in the international policies, guidance and technologies, which are to be implemented to achieve universal access to needed services, in particular those related to diagnosis, treatment and care for drug-resistant forms of TB.

This Plan outlined the needs in technical support, which will be provided in three main formats. *External technical assistance* will be carried out by international experts and will be procured through competitive bidding or sought from the external partner agencies according to their mandate and field of expertise. *Technical Working Groups (TWGs)* will be established in selected areas of TB control to develop appropriate legislative and regulatory frameworks and guidance, which will enable the implementation of the international standards of TB care in the country, as well as will assist in streamlining the health system and other national processes. A number of *national consultants* will be employed to undertake specific technical tasks and to assist in facilitating and overseeing implementation.

Table 7 below summarizes the technical assistance activities included in the Plan, by Intervention and type of support.

Table 7. Technical assistance activities (external consultancies, technical working groups and national consultants) for 2019-2022, by NSP Strategic Intervention

No.	*Intervention*	*External technical assistance*	*Technical Working Groups*	*National consultants*
1.1	Rollout of Xpert MTB/RIF technology			X
1.2	TB diagnostic investigations at regional and national level	X		X
1.3	Contacts' investigation, screening and active case finding for TB among high-risk groups including people living with HIV		X	X
1.4	Technical Assistance in preparation for the ISO 15189 for the NCTLD National Mycobacteriological Reference Laboratory that includes needs assessment, and the action plan that NCTLD will follow to reach the requirements of the ISO 15189.This exercise will include in country and remote work.	X		X
2.1	Supply of anti-TB drugs and drug management system	X		X
2.2	Patient support to improve adherence to TB treatment		X	X
2.3	Treatment monitoring, management of adverse drug reactions and comorbidities			X
2.4	TB infection control in health care facilities			X
2.5	Preventive treatment and vaccination against TB			X
3.1	Strengthening core health system functions for TB control	X	X	X
3.2	Advocacy, communication, social mobilization (ACSM) and civil society engagement for TB control			X
3.3	Addressing legal and ethical issues in TB control		X	X

5. Financing of TB Control Interventions

This section summarizes the estimates of the Government funding of TB control activities, contribution of external partners as well as the estimates of the total TB program needs and the funding gap for implementation of priority TB control interventions, outlined above in the document. The actual expenditures are presented for the last five years (2012-2016), while detailed estimates were made for the 2019-2022 period.

Government funding

The National Health Accounts (NHA) of Georgia estimate that the total health expenditures (from all sources) were GEL 2.79 billion (about USD 1.4 billion) in 2016. Out of these, despite decline trend (66.9% in 2013 to 56.9% in 2016) direct out-of-pocket payments by patients / households represented the largest share, followed by the state budget (38%), private health insurance (6%), other domestic sources (2.4%) and external aid (1.1%).

Regarding the total state expenditures in the health sector, there has been a considerable and steady increase in the government health funding during the last years; between 2012 and 2016, this level increased from GEL 450.3 million to GEL 1.06 billion (2.3 fold increase).

Table 8 shows that the total expenditures directly related to tuberculosis control in Georgia (from all sources) increased from 21.4 million GEL in 2012 to 29.9 million GEL in 2016 (39%). State financing increased from 10.9 million GEL in 2012 to 13.68 million GEL in 2016 (51% of the total TB control expenditures). During the period from 2012 to 2016, the amount of out-of-pocket payments was halved and its share of expenditures decreased to less than one-third of 2012 levels.

Table 8. Total expenditures on TB control in Georgia by source, 2012-2016, GEL

Source of funding	*Total Expenditure on TB Control, GEL*					*Share in total Expenditure*				
	2012	*2013*	*2014*	**2015**	**2016**	*2012*	*2013*	*2014*	**2015**	**2016**
Government spending	10,916,438	14,532,049	15,855,729	13,912,649	15,210,272	51%	54%	57%	58%	51%
External funding	9,196,993	11,069,433	10,720,171	9,110,401.9	14,126,455	43%	41%	38%	38%	47%
Out-of-pocket payments	1,352,698	1,385,163	1,412,866	874,120	630,902	6%	5%	5%	4%	2%
Total	**21,466,129**	**26,986,645**	**27,988,766**	23,897,171	29,967,630	100%	100%	100%	100%	100%

The government expenditure on TB-related services per one TB case (all forms) increased from GEL 2,194 in 2012 to GEL 4,569 in 2016 (in USD equivalents, from USD 1,329 to USD 1942.6[56]). Table 9 presents the structure of the government TB spending by function/budget category. The highest share of funds is spent on curative services; within this category, expenditures on inpatient curative care still prevail over those on outpatient care. By item, the highest share of funds is spent on staff salaries, followed by indirect costs, food for inpatients, and laboratory and diagnostic services.

Table 9. Government expenditures on TB control in Georgia by function, 2012-2016, GEL

	Function / category	*2012*	*2013*	*2014*	*2015*	*2016*
1	*Curative care*	*7,950,144*	*9,734,125*	*8,986,948*	*10,962,725*	*12,798,987*
1.1	*Inpatient curative care*	*5,066,755*	*5,840,470*	*5,673,707*	*8,229,175*	*9,792,633*
1.1.1	*Staff salaries*	*1,657,298*	*1,700,463*	*1,521,718*	*2,133,942.00*	*2,539,369.00*
1.1.2	*Ancillary drugs and supplies*	*245,325*	*288,539*	*296,720*	*349,615.00*	*416,038.00*
1.1.3	*Laboratory and diagnostic services*	*463,476*	*725,121*	*702,143*	*733,246.00*	*872,555.00*
1.1.4	*Psycho-social rehabilitation*			*4,172*		
1.1.5	*Food for patients*	*604,930*	*391,636*	*305,384*	*523,457.00*	*622,908.00*
1.1.6	*Indirect costs*	*1,423,563*	*1,642,955*	*1,878,165*	*3,776,879.00*	*4,494,447.00*
1.1.7	*Unspecified expenses*	*672,163*	*1,091,756*	*965,405*		

56 Average annual exchange rates (National Bank of Georgia, www.nbg.gov.ge), GEL for USD 1: 2012 – 1.651, 2013 – 1.663, 2014 – 1.766. 2015-2.2841; 2016-2.3498; 2017-2.4988

					712,036.00	*847,316.00*
1.3	*Outpatient curative care*	*2,883,389*	*3,893,655*	*3,313,241*	*2,733,550.00*	*3,006,354.00*
1.3.1	*Rural PHC providers (rural doctors DOT)*	*102,000*	*112,800*	*148,800*	*142,620.00*	*136,809.00*
1.3.3	*Outpatient specialist care (includes urban PHC providers DOT)*	*2,781,389*	*3,780,855*	*3,164,441*	*2,590,930.00*	*2,869,545.00*
1.3.3.2	*Laboratory diagnostic services*	*1,198,284*	*1,763,951*	*1,678,611*	*1,033,995.00*	*1,190,238.00*
1.3.3.4	*Ancillary drugs and supplies*	*133,488*	*56,635*	*12,054*	*12,631.00*	*13,624.00*
1.3.3.5	*Staff salaries*	*913,904*	*1,191,128*	*1,184,302*	*1,240,977.00*	*1,338,515.00*
1.3.3.6	*Indirect costs*	*535,713*	*769,141*	*289,474*	*303,327.00*	*327,168.00*
5	*Medical Goods*	*136,601*	*216,607*	*241,633*	*379,200.00*	*392,561.00*
6	*Preventive care*	*0*	*60,466*	*36,353*	*372,153.00*	*489,353.00*
6.4	*Healthy condition monitoring programmes*		*60,466*	*36,353*	*36,353.00*	*36,353.00*
6.9.	*Other not classified*				*335,800.00*	*453,000.00*
7	*Governance and health system financing administration*			*142,184*	*171,000*	
8	*Capital investments*	*2,829,694*	*4,520,851*	*6,448,611*	*498,200*	*1,529,371*
	Total	*10,916,439*	*14,532,049*	*15,855,729*	*13,912,649*	*15,210,272*

Similar to calculations of the TB control financial needs (see Table 11 below), the figures for the state budget expenditure do not account for a part of expenditures at the general health service institutions, that may be apportioned for TB-related activities at specialized outpatient facilities and rural PHC units. This contribution may add up to 13% on top of the figures for outpatient public expenditures for TB control above (for 2016, about GEL 500,000 or about USD 204086).

External funding

External financial support to TB control in Georgia has been substantial and has importantly contributed to the strengthening of the NTP. Over the last five years, however, the number of externally supported programs and projects and the size of external funding contributions to TB control have decreased. The main international partners in the area of TB control are the Global Fund to Fight AIDS, Tuberculosis and Malaria (TGF), the United States' Government/USAID, WHO and Médecins Sans Frontières (MSF) France. Table 10 gives the breakdown of TB-related funding support by these agencies for 2012-2016.

Table 10. External funding contributions to TB control in Georgia, by agency, 2012-2016, USD

Agency	*2012*	*2013*	*2014*	*2015*	*2016*
The Global Fund to Fight AIDS, Tuberculosis and Malaria (TGF)	$4,716,862	$5,078,692	$5,210,719	$1,568,939	$2,924,564
United States Agency for International Development (USAID)	$349,265	$1,060,012	$857,716	$921,238	$571,606
World Health Organization (WHO)	$12,002	$11,124	$9,740	$657	$851
Médecins Sans Frontières (MSF)	$492,429	$506,476	$868,055	$1,429,081	$2,299,994
Total	*$5,570,558*	*$6,656,304*	*$6,946,230*	*$3,919,915*	*$5,797,015*

The share of direct external contributions, within the total estimated allocations to TB control in the country, has decreased from 47% in 2012 to 38% in 2015, with subsequent increase to 47% in 2016. This can be explained by MSF contribution that is currently being declined with anticipated phase out in 2018. Currently, the Global Fund is the main external source of funding, accounting for 58% of overall international funding support in the field of TB control in 2012-2016. Regarding the nature of assistance, according to NHA data, over half of the external TB-related support in 2016 (56%) went to the supply of medical goods (TB drugs and other medical consumables), followed by various support classified under health system governance, administration and financing (28%).

Funding needs estimate

For the purposes of this strategic planning document, financial needs estimates were performed for each of the Strategic Interventions, presented above per Objective, for the entire four years covered by the Plan (2019-2022). The total estimated need of funding for TB control for this period is about USD 47.2 million. The table below presents the breakdown of the estimated needs by Objective and Intervention.

Table 10. Estimate of financial needs for implementation of TB control activities in Georgia for 4 years 2019-2022, by NSP Objective and Strategic Intervention, USD

No.	*Objective / Strategic Intervention*	*2019*	*2020*	*2021*	*2022*	*Total 2019-2022*
1	**To provide universal access to early and quality diagnosis of all forms of TB including M/XDR-TB**	**2,622,369**	**2,636,191**	**2,689,193**	**2,716,557**	**10,664,311**
1.1	Rollout of Xpert MTB/RIF technology	464,424	464,424	464,424	464,424	**1,857,695**
1.2	TB diagnostic investigations at regional and national level	558,331	526,842	515,067	494,675	**2,094,915**
1.3	Contacts' investigation, screening and active case finding for TB among high-risk groups including people living with HIV	80,000	80,000	97,200	95,000	**352,200**
1.4	Support to operations of the laboratory network	1,519,614	1,564,926	1,612,502	1,662,458	**6,359,501**
2	To provide universal access to quality treatment of all forms of TB including M/XDR-TB with appropriate patient support	**7,211,344**	**6,669,293**	**6,652,436**	**6,587,102**	**27,120,176**
2.1	Supply of anti-TB drugs and drug management system	1,157,424	1,140,783	1,117,825	1,095,583	**4,511,615**
2.2	Patient support to improve adherence to TB treatment	967,405	952,763	938,983	926,448	**3,785,599**
2.3	Treatment monitoring, management of adverse drug reactions and comorbidities	219,621	209,580	208,036	199,310	**836,548**
2.4	TB infection control in health care facilities	24,672	24,672	24,672	24,672	**98,688**
2.5	Preventive treatment and vaccination against TB	142,984	128,455	149,882	128,051	**549,371**
2.6	Support to operations of TB treatment institutions (outpatient and inpatient)	4,699,239	4,213,039	4,213,039	4,213,039	**17,338,354**
3	To enable supportive environment and systems for effective TB control	**2,080,047**	**1,760,623**	**1,836,923**	**1,576,010**	**7,253,603**
3.1	Strengthening core health system functions for TB control	808,562	563,713	542,713	349,100	**2,264,088**
3.2	Supervision, monitoring and evaluation of the National TB Program	591,760	494,460	591,760	494,460	**2,172,440**
3.3	Advocacy, communication, social mobilization (ACSM) and civil society engagement for TB control	459,725	482,450	482,450	512,450	**1,937,075**
3.4	Research on priority issues of TB control	220,000	220,000	220,000	220,000	**880,000**
4	**Annual cost increase adjustment**	595,688	553,305	558,928	543,983	**2,251,904**
	TOTAL	**12,509,449**	**11,619,413**	**11,737,480**	**11,423,653**	**47,289,994**

NOTE. The estimate covers the costs of TB service and specific TB interventions, but does not include costs of general health services, that may be apportioned for TB (such as, share of PHC providers' work dedicated to TB-related activities).

The above estimates were made on the basis of programmatic needs assessments, which were performed for each Intervention and took into account the epidemiological situation (including, for example, expected number of TB cases to be treated and prevalence of drug resistance for each case category), planned increases in the coverage with the Intervention, and service capacities.

The unit costs were used based on the current prices (national and international); in addition, a provision for annual cost increases (about 5% on average taking into account the domestic price inflation and trends in international prices) was included in the calculation compared to 2019 as baseline.

The average annual needs for TB control (not including PHC costs) in 2019-2022 are estimated at 11.8 million USD. This is estimated at 3.38 USD per year per capita of the total country population. This is less than 2016-2018 expenditures (17.8 million USD) due to the positive trend of the TB epidemic and the decrease of medication costs. In 2016-2018 substantial investments were made to strengthen lab and outpatient TB service delivery infrastructure (procurement of GeneXpert, mobile units, equipment for NCTBLD etc). Therefore, investment costs envisioned by this strategy are minimal.

Based on the estimates of total needs, expected domestic financing and external funding for TB control interventions (through the ongoing and forthcoming Global Fund project and contributions by other external partners), the funding gap for the period covered by this Plan (2019-2022) was estimated. These estimates are presented in Table 12 below.

Table 12. Estimated total funding needs, Government funding, external funding and funding gap for implementation of TB control activities in Georgia, total for 2019-2022, by NSP Objective, USD

No.	*Objective*	*Total funding needs*	*Government funding*	*External funding*	*Funding gap*
1	To provide universal access to early and quality diagnosis of all forms of TB including M/XDR-TB	10,664,311	6,718,670	2,620,453	1,325,188
2	To provide universal access to quality treatment of all forms of TB including M/XDR-TB with appropriate patient support	27,120,176	21,866,560	1,840,533	3,413,083
3	To enable supportive environment and systems for effective TB control	7,253,603	903,160	5,134,932	1,215,511
4	Annual cost increase adjustment	2,251,904	1,474,420	38,721	297,689
	TOTAL	47,289,994	30,962,810	10,075,713	6,251,472

Despite the increasing Government financial commitments and sizeable anticipated external funding support during the strategy implementation period, the estimated funding gap remains significant, given the requirements for decisive scale up in access to diagnosis and treatment of (including M/XDR-TB), implementation of ample patient-centered approaches including adherence support, introducing provider incentives based on their performance and increased coverage of risk groups with involvement of the communities and civil society.

The total funding gap for years 2019-2022 is estimated at about USD 6.2 million, which constitutes a 13% deficit of the total needs of USD 47.28 million for the same period. The gap is mainly explained by the need for strengthening outpatient TB service delivery network through increasing financial motivation of health care workers and private facility owners, as well as supporting operationalization of performance based incentives schemes initially on a small scale. The decision on further scale up of the performance based financing model through domestic funding will be made based on the evaluation of the pilot. The detailed calculations for estimating financial needs, breakdown of funding by source and Objective/Intervention and other details are provided in a separate annex to this document.

Sustainability and takeover

Public Health is one of the priorities declared by the GoG. This is reflected in the governmental documents and supported by 2.5-time increased state healthcare budget for the years 2012-2016. The share of the healthcare expenses in the total public expenditures and the total amount of healthcare spending are increasing. Implementation of the Universal Healthcare Program and C Hepatitis Elimination Program and approval of the National HIV/AIDS and TB Strategic Plans are only some of those many activities that demonstrate the GoG commitment towards improving health status of population.
In order to address complex challenges to effective TB response, GoG will increase funding allocations to TB program to maintain access to quality services and drugs. Particular consideration will be given to maintaining engagement of Civil Society Organizations and Patients groups in TB service delivery. The role of CSOs in TB adherence support has been defined by the National TB Control Guideline (Adopted in 2018 by MoIDP&LHSA), work will continue for integration of CSOs' activities into the State TB program through viable financing mechanisms (Strategic Intervention 3.3) .
Average age, geographical distribution and lack of motivation of people working in the field of TB put the sustainability of the TB program at a significant risk. Incomplete institutionalization and integration of donor financed training programs in the formal education system is also a problem.[57] This strategy intends to address human resources related gaps through strategic intervention 3.1. MoIDP&LHSA will work on developing a continuous professional development policy which will also address professional development needs of health care workers engaged in TB service delivery, including CSOs.
Strengthening TB health management information systems is a critical precondition for long term sustainability of the program. This area will be addressed through strategic intervention 3.2.
Improving quality of TB services by making the system more patient-centered is one of the major interventions of this strategy. Building a patient-centered TB care model will require effective collaboration between public and private health care providers delivering TB services in Georgia. Although many private hospitals successfully adopted TB care standards in their respective settings and made substantial investment for developing safe and effective clinical environment for TB teams; there is still a potential risk that some of them will not continue participation into the State TB Program, if reimbursement level is not adequate. MoIDP&LHSA in collaboration with all TB stakeholders has been working on introducing mechanisms for strengthening public-private partnership in TB control. This strategy envisions intensive work on elaborating effective financing model and introducing incentivizing service contracts to ensure sustainable participation of private providers in TB service delivery.
Strengthening governance, improving a system for supply chain management and building patient-centered TB service delivery model are all key considerations towards sustainability of the National TB response, which are addressed in this strategy.

During the last decade, implementation of key programmatic interventions in TB control in Georgia has been fully or predominantly reliant on external funding (first of all, the Global Fund, which has been covering most important and most expensive expenditures, such as procurement of TB drugs, laboratory consumables and patient support).

Taking into account the fact that the amount of available TGF financial resources will be decreasing during the period covered by this Plan, the Government of Georgia is committed to increase the level of domestic funding in order to bridge the gaps and gradually take over the funding of priority TB control interventions. Transition preparedness assessment conducted in 2017 revealed major risks to sustainable delivery of TB services during the transitional period and thereafter. Therefore, this strategy through relevant interventions intends to address these areas.

The Strategy sets a clear timeline and transition schedule for gradual takeover of currently donor supported activities. In this regard, the following key interventions will be given priority consideration in terms of taking over external funding or increasing the current level of government expenditure:

- *Salaries of staff and facility expenditures in TB service institutions*. The Government will continue to uphold the operations of the public health laboratories' network, which provide bacteriological diagnosis of TB (under NCDCPH management). Using the funding of the NTP and/or under the

57. Georgia TB and HIV Programs Transition Plan, Adopted by CCM in 2017

Universal Health Care scheme, it is planned to increase the level of staff remuneration according to the relevant Government policies. The Government will continue covering the facility expenses of the health care provider institutions providing TB care and will increase the payments for relevant budget lines as required.

Timeframe: continuous

- *Renovation and refurbishment of inpatient TB treatment facilities*. The Government will allocate, as well as advocate for with the management of private medical provider networks, additional financing for renovation of TB inpatient and outpatient facilities, which are in need of infrastructure rehabilitation (including relocation from current premises). This includes establishment of the palliative care facility for patients who failed all available treatment options.

  Timeframe: 2019-2022

- *Microscopy and conventional culture investigations (consumables, reagents)* was in 2016. Government will provide continuous funding to ensure access to quality TB diagnoses.

  Timeframe: continuous

- *Clinical investigations for TB patients on treatment and medicines for management of adverse drug reactions of anti-TB drugs* will be continued to be funded by the government.

  Timeframe: continuous

- *Individual infection control protection for staff and patients*. Respirators for staff at increased risk of infection working in TB and inpatient TB treatment sites, including prisons, as well masks for TB inpatients, will be continued to be procured from domestic sources.

  Timeframe: continuous

- *First-line anti-TB drugs* will be continued to be funded by the government. The system for TB drugs' procurement and supply management will be further strengthened.

  Timeframe: continuous

- *MGIT and LPA laboratory investigations (consumables, reagents, maintenance of equipment and other costs)*. The Government will gradually engage in the procurement of supplies during the second half of the Plan.

  Timeframe: 2016-2022 (50% takeover by end- of 2019, 75% by end of 2020, 100% by end of 2022).

- *M/XDR-TB Patient adherence support (incentives, enablers)*. The Government will assure for provision of adherence support as a key component of the patient-centered TB case management, thus taking over from TGF project, which currently covers the most of this support.

  Timeframe: 2016-2020 (75% takeover by end of 2018, 100% by end of 2020).

- *Second-line and third-line TB drugs*. The Government is committed to engage in own procurement of drugs for treatment of M/XDR cases and to scale it up during the NSP period, in order to ensure the financial sustainability of the program in view of decreasing external support.

  Timeframe: 2016-2022 (75% takeover by end of 2019, 80% takeover by end of 2020, 100% by end of 2022).

6. Potential risks associated with the Strategy implementation

As gradual reduction of donor funding is anticipated during the strategy implementation period, there are some risks that available government resources may not be sufficient to fully cover the program needs and eliminate the funding gap that is largely caused by the estimated recommended salary level of health care workers within the NTP as well as growing facility costs. This strategy considers a set of interventions aimed at mitigating this risk that includes intensive advocacy, and improving system's efficiency by strengthening

outpatient TB care delivery and building capacity of primary care providers for early detection of TB and treatment follow up.

7. Indicators for monitoring implementation

Implementation of this strategy (2019-2022) will be regularly monitored against 7 impact and outcome indicators and 10 output indicators to illustrate coverage with TB services.

National Center for Disease Control and Public Health will coordinate the strategy monitoring and evaluation processes and will prepare reports in line with the global reporting requirements. Implementing partners including the Global Fund supported project will contribute towards M&E efforts through data quality assurance and evaluation studies when appropriate.

M&E indicators and targets are presented in Annex 1.

Annex 1. Monitoring and Evaluation Framework

No.	*Impact and Outcome Indicators*	*2014*	*Baseline 2015*	*2016*	*2019*	*2020*	*2021*	*2022*
1.	Estimated TB notification rate: new cases and relapses, per 100,000	106	99	92	64.6	63.3	62.0	60.8
2.	MDR prevalence among new TB cases	11.6%	11.6	10.2%	<12%	<12%	<12%	<12%
3.	MDR prevalence among previously treated TB cases	39.2%	38.8%	38%	<35%	<35%	<35%	<35%
4.	Estimated TB mortality rate (excluding TB/HIV), per 100,000	5.1	5.0	4.8	4	3.75	3.5	3.225
5.	Treatment success rate, of new and relapse TB cases	79.6% (2013 cohort)	83.1% (2014 cohort)	84% (2015 cohort)	86%	90%	92%	95%
7.	Treatment success rate, laboratory confirmed RR/MDR-TB cases	47.5% (2012 cohort)	42.8% (2013 cohort)	48.9% (2014 cohort)	67%	75%	>75%	>75%
No.	***Output Indicators***	***Baseline (2014)***	***2015***	***Baseline 2016***	***2019***	***2020***	***2021***	***2022***
1.	Percentage of notified new and relapse TB cases tested using a WHO-recommended rapid diagnostic (for example Xpert MTB/RIF) as the initial diagnostic test	32%	64%	83%		>85%		>95%

2.	Coverage of first-line drug susceptibility testing among notified culture-positive TB patients (new and previously treated)	2163/2296 (94%)	2108/2205 (96%)	1982/2027 (98%)	>95%			>95%
3.	Coverage of second-line drug susceptibility testing among notified MDR patients	396/425 (93%)	385/407 (95%)	331/361 (92%)	>95%	>95%	>95%	>95%
4.	Interim results of MDR-TB treatment: percentage of patients with culture conversion at six months of treatment	317/502 (63%)	320/465 (69%)	296/395 (75%)		85%		>90%
5.	Number of contacts of TB patients screened for active TB, per 1 TB case (all forms)	1.2	1.5	1.6		3.5		4
6.	TB notification rate in the penitentiary system: all cases, per 100,000 of average annual prison population	1388	1173	889		<800		<700
7.	Proportion of TB patients with known HIV status (percentage of notified TB cases, all forms, tested for HIV)	68%	88%	96%		95%		>95%
8.	Prevalence of HIV among all TB cases	2.2%	3.1%	2.4%		≤ 4.5%		
9.	Percentage of TB cases, all forms, receiving the entire treatment in outpatient (ambulatory) setting	30%		30% (2014)		65%		70%
10.	Share of out of pocket payments in total TB expenditures	5%	4%	2%		1%		0.5%

Annex 2. Georgia TB NSP 2019-2022 Implementation Plan

No.	*Objective / Intervention / Activity*	*Units*					Total funding needs					
			Year 1 (2019)	*Year 2 (2020)*	*Year 3 (2021)*	*Year 4 (2022)*	*Year 1 (2019)*	*Year 2 (2020)*	*Year 3 (2021)*	*Year 4 (2022)*	***Total 4 years (2019-2022)***	**Funding Sources and anticipated gap**
1	**To provide universal access to early and quality diagnosis of all forms of TB including M/XDR-TB**						**2,622,369**	**2,636,191**	**2,689,193**	**2,716,557**	**10,664,310.9**	**Government funding 63% funding gap 12%**
1.1	**Rollout of Xpert MTB/RIF technology**						**464,424**	**464,424**	**464,424**	**464,424**	**1,857,695**	
1.1.1	National consultants, Xpert MTB/RIF	Consultancy day	24	24	24	24	14,400	14,400	14,400	14,400	**57,600**	
1.1.2	Training of staff in Xpert MTB/RIF	Number of central and regional sessions	7	7	7	7	17,400	17,400	17,400	17,400	**69,600**	
1.1.3	Cartridges for Xpert MTB/RIF tests	Number of cartridges	29,176	29,176	29,176	29,176	328,524	328,524	328,524	328,524	**1,314,095**	
1.1.4	Maintenance and servicing of Xpert MTB/RIF instruments	Number of Active modules	112	112	112	112	84,000	84,000	84,000	84,000	**336,000**	
1.1.5	Supervision / monitoring of Xpert MTB/RIF implementation	Number of peripheral Xpert sites	38	38	38	38	15,200	15,200	15,200	15,200	**60,800**	
1.1.6	Workshops and coordination meetings on Xpert MTB/RIF	Number of coordination workshops	1	1	1	1	4,900	4,900	4,900	4,900	**19,600**	
1.2	**TB diagnostic investigations at regional and national level**						**558,331**	**526,842**	**515,067**	**494,675**	**2,094,915**	
1.2.1	Equipment and furniture for microscopy laboratories						0	0	0	0	**0**	

No.	Objective / Intervention / Activity	Units					Total funding needs					
			Year 1 (2019)	*Year 2 (2020)*	*Year 3 (2021)*	*Year 4 (2022)*	*Year 1 (2019)*	*Year 2 (2020)*	*Year 3 (2021)*	*Year 4 (2022)*	***Total 4 years (2019-2022)***	**Funding Sources and anticipated gap**
1.2.2	Support to specimen transportation system	Annual cost of specimens' transportation	1	1	1	1	50,000	50,000	50,000	50,000	**200,000**	
1.2.3	Laboratory supplies for microscopy investigations	No. of LED tests	24,069	20,203	19,648	19,175	12,034	10,102	9,824	9,588	**41,547**	
1.2.4	Laboratory supplies for LPA investigations	LPA Hain	2,637	2,533	2,459	2,403	29,457	28,326	27,519	26,892	**112,194**	
1.2.5	Laboratory supplies for solid-media culture investigations	Number of tests	7,334	7,162	6,973	6,809	9,534	9,311	9,064	8,852	**36,762**	
1.2.6	Laboratory supplies for MGIT investigations	Total number of tests (Culture, DST 1st line, DST 2nd Line)	17,174	16,733	16,284	15,903	91,838	89,035	86,591	84,576	**352,040**	
1.2.7	Genotyping tests at NRL	Number of tests	783	747	725	707	156,600	149,400	145,000	141,400	**592,400**	
1.2.8	Equipment for reference TB laboratories	Annual cost of minor equipment and supplies for reference labs	1	1	1	1	88,400	88,400	88,400	88,400	**353,600**	
1.2.9	Maintenance / servicing of laboratory equipment and ventilation systems	Annual cost	1	1	1	1	40,000	40,000	40,000	40,000	**160,000**	
1.2.10	Individual infection control measures (respirators) for TB laboratories	No. of respirators	1,584	1,584	1,584	1,584	3,168	3,168	3,168	3,168	**12,672**	
1.2.11	Training of ZDLs and LSSs staff	No. of trainings at central level	2	2	2	2	5,600	5,600	5,600	5,600	**22,400**	

No.	Objective / Intervention / Activity	Units					Total funding needs					
			Year 1 (2019)	*Year 2 (2020)*	*Year 3 (2021)*	*Year 4 (2022)*	*Year 1 (2019)*	*Year 2 (2020)*	*Year 3 (2021)*	*Year 4 (2022)*	***Total 4 years (2019-2022)***	**Funding Sources and anticipated gap**
1.2.12	Training of NRL staff in advanced laboratory techniques abroad	No. of person-events	2	2	2	2	9,800	9,800	9,800	9,800	**39,200**	
1.2.13	External technical assistance, strengthening NRL quality management system / support to ISO accreditation	Number of TA units	2	1	1	1	36,400	18,200	18,200	18,200	**91,000**	
1.2.14	International training, strengthening NRL quality management system / support to ISO accreditation	Number of person events	2	2	2	2	8,200	8,200	8,200	8,200	**32,800**	
1.2.15	Training of staff, strengthening NRL quality management system / support to ISO accreditation	No. of trainings	1	1	1		10,100	10,100	10,100	0	**30,300**	
1.2.16	National consultants, strengthening NRL quality management system / support to ISO accreditation	No. of person-months	12	12	6		7,200	7,200	3,600	0	**18,000**	
1.3	**Contacts' investigation, screening and active case finding for TB among high-risk groups including people living with HIV**						**80,000**	**80,000**	**97,200**	**95,000**	**352,200**	
1.3.1	National consultants, development of national TB screening guidelines	No. of person-months	0	0	12	0	0	0	7,200	0	**7,200**	
1.3.2	Training in TB Screening	Budgeted under objective 3										
1.3.3	Medical supplies for TB screening	Annual cost for the following coverage	80%	80%	90%	95%	48,000	48,000	54,000	57,000	**207,000**	
1.3.4	Motivation payments / performance bonuses to health care providers, related to screening for active TB in risk groups	Coverage, %	80%	80%	90%	95%	32,000	32,000	36,000	38,000	**138,000**	
1.4	**Support to operations of the laboratory network**						**1,519,614**	**1,564,926**	**1,612,502**	**1,662,458**	**6,359,501**	

No.	Objective / Intervention / Activity	Units					Total funding needs					
			Year 1 (2019)	*Year 2 (2020)*	*Year 3 (2021)*	*Year 4 (2022)*	*Year 1 (2019)*	*Year 2 (2020)*	*Year 3 (2021)*	*Year 4 (2022)*	***Total 4 years (2019-2022)***	**Funding Sources and anticipated gap**
1.4.1	Human resources, TB laboratories	Annual Salaries					613,388	613,388	613,388	613,388	**2,453,552**	
1.4.2	Facility costs, TB laboratories	Maintenance					906,226	951,538	999,115	1,049,070	**3,905,949**	
2	**To provide universal access to quality treatment of all forms of TB including M/XDR-TB with appropriate patient support**						**7,211,344**	**6,669,293**	**6,652,436**	**6,587,102**	**27,120,176**	**Government funding 80%, Funding gap 13%**
2.1	**Supply of anti-TB drugs and drug management system**						**1,157,424**	**1,140,783**	**1,117,825**	**1,095,583**	**4,511,615**	
2.1.1	Anti-TB drugs, first line treatment	Number of patients	2,296	2,212	2,142	2,084	81,738	78,747	76,255	74,190	**310,930**	
2.1.2	Anti-TB drugs, PDR treatment	Number of patients	94	84	80	77	27,166	24,276	23,120	22,253	**96,815**	
2.1.3	Anti-TB drugs, MDR treatment (standard regimen)	Number of patients	233	228	224	220	445,030	435,480	427,840	420,200	**1,728,550**	
2.1.4	Anti-TB drugs, MDR treatment (shortened regimen)	Number of patients	26	25	25	25	31,460	30,250	30,250	30,250	**122,210**	
2.1.5	Anti-TB drugs, 'pre-XDR' and XDR treatment	Number of patients	127	127	124	121	494,030	494,030	482,360	470,690	**1,941,110**	
2.1.6	In-country supply management of anti-TB drugs	Annual PSM cost	1	1	1	1	6,000	6,000	6,000	6,000	**24,000**	
2.1.7	External technical assistance in drug management, centralized procurement and pharmacovigilance	Number of TA units	1	1	1	1	15,000	15,000	15,000	15,000	**60,000**	
2.1.8	National consultants, drug management	No. of person-months	12	12	12	12	7,200	7,200	7,200	7,200	**28,800**	
2.1.9	Training in drug management, international	No. of person-events	2	2	2	2	7,200	7,200	7,200	7,200	**28,800**	
2.1.10	Training in drug management, local	No. of trainings at central level	2	2	2	2	7,000	7,000	7,000	7,000	**28,000**	

No.	*Objective / Intervention / Activity*	*Units*					Total funding needs					
			Year 1 (2019)	*Year 2 (2020)*	*Year 3 (2021)*	*Year 4 (2022)*	*Year 1 (2019)*	*Year 2 (2020)*	*Year 3 (2021)*	*Year 4 (2022)*	***Total 4 years (2019-2022)***	**Funding Sources and anticipated gap**
2.1.11	In-country quality assurance of TB drugs	Annual cost	1	1	1	1	20,000	20,000	20,000	20,000	**80,000**	
2.1.12	Clinical supervision of implementation of new drugs and treatment regimens for M/XDR-TB: mobile consilium	Annual cost	1	1	1	1	15,600	15,600	15,600	15,600	**62,400**	
2.2	**Patient support to improve adherence to TB treatment**						**967,405**	**952,763**	**938,983**	**926,448**	**3,785,599**	
2.2.1	Incentives for TB patients	Costs are based on estimated numbers of DS and DR TB patients receiving incentives					500,473	487,750	475,846	465,007	**1,929,076**	
2.2.2	Enablers for TB patients						76,022	74,104	72,227	70,530	**292,883**	
2.2.3	Enablers for health care staff - PHC DOT nurses and fuel	Annual costs	1	1	1	1	80,500	80,500	80,500	80,500	**322,000**	
2.2.4	Administration of monetary incentives	Annual costs	1	1	1	1	26,410	26,410	26,410	26,410	**105,640**	
2.2.5	Incentives for health care staff, related to adherence to TB treatment	Annual costs	1	1	1	1	64,000	64,000	64,000	64,000	**256,000**	
2.2.6	Psychological and social assistance to TB patients	Annual costs	1	1	1	1	160,000	160,000	160,000	160,000	**640,000**	
2.2.7	Mobile technologies for adherence support (demonstration projects)	Annual costs	1	1	1	1	60,000	60,000	60,000	60,000	**240,000**	
2.3	**Treatment monitoring, management of adverse drug reactions and comorbidities**						**219,621**	**209,580**	**208,036**	**199,310**	**836,548**	
2.3.1	Bacteriological tests for TB treatment monitoring. **NOTE: included under Intervention 1.2 above.**						0	0		0	**0**	
2.3.2	Clinical tests for patient monitoring during TB treatment	Costs are based on estimated number of patients and clinical tests					113,540	110,380	107,450	104,860	**436,230**	

No.	Objective / Intervention / Activity	Units					Total funding needs					
			Year 1 (2019)	*Year 2 (2020)*	*Year 3 (2021)*	*Year 4 (2022)*	*Year 1 (2019)*	*Year 2 (2020)*	*Year 3 (2021)*	*Year 4 (2022)*	***Total 4 years (2019-2022)***	**Funding Sources and anticipated gap**
2.3.3	Training of TB service staff in HIV counseling and testing	Number of trainings at central and regional levels	6	3	6	3	14,400	7,200	14,400	7,200	**43,200**	
2.3.4	Rapid HIV tests for TB institutions	Number of tests	2,756	2,806	2,720	2,650	4,961	5,050	4,896	4,770	**19,678**	
2.3.5	ARV drugs and Cotrimoxazole for TB/HIV patients. **NOTE: covered by HIV NSP (and HIV application to TGF).**						0	0	0	0	**0**	
2.3.6	Tests for ART monitoring in TB/HIV patients. **NOTE: covered by HIV NSP (and HIV application to TGF).**						0	0	0	0	**0**	
2.3.7	Training of health care staff in management of TB and diabetes	Number of regional trainings	2	4	2	4	3,200	6,400	3,200	6,400	**19,200**	
2.3.8	Pharmaceuticals for management of ADRs during TB treatment	Number of patients	2,784	2,685	2,603	2,536	83,520	80,550	78,090	76,080	**318,240**	
2.4	**TB infection control in health care facilities**						**24,672**	**24,672**	**24,672**	**24,672**	**98,688**	
2.4.1	National consultants, TB infection control	No. of person-months	12	12	12	12	7,200	7,200	7,200	7,200	**28,800**	
2.4.2	Environmental infection control measures (UVGI devices) for TB treatment institutions	Included in TB treatment institutions costs					0	0	0	0	**0**	

No.	*Objective / Intervention / Activity*	*Units*					Total funding needs					
			Year 1 (2019)	*Year 2 (2020)*	*Year 3 (2021)*	*Year 4 (2022)*	*Year 1 (2019)*	*Year 2 (2020)*	*Year 3 (2021)*	*Year 4 (2022)*	***Total 4 years (2019-2022)***	**Funding Sources and anticipated gap**
2.4.3	Individual infection control measures (respirators) for TB treatment institutions	No. of respirators	8,736	8,736	8,736	8,736	17,472	17,472	17,472	17,472	**69,888**	
2.5	**Preventive treatment and vaccination against TB**						**142,984**	**128,455**	**149,882**	**128,051**	**549,371**	
2.5.1	National consultants, development of national LTBI management guidelines and protocol	No. of person-months	0	0	12	0	0	0	7,200	0	**7,200**	
2.5.2	Training on LTBI diagnosis and preventive treatment for general health care providers	Number of trainings at central and regional levels	6	0	6	0	14,400	0	14,400	0	**28,800**	
2.5.3	Diagnostic tests for LTBI	Total No. of LTBI tests	18,000	18,000	18,000	18,000	34,200	34,200	34,200	34,200	**136,800**	
2.5.4	Drugs for preventive treatment of LTBI	Total No. of LTBI treatments	4,000	4,000	4,000	4,000	77,600	77,600	77,600	77,600	**310,400**	
2.5.5	BCG vaccines	Estimated No. of newborns to be vaccinated	16,784	16,655	16,482	16,251	16,784	16,655	16,482	16,251	**66,171**	
2.6	**Support to operations of TB treatment institutions**						**4,699,239**	**4,213,039**	**4,213,039**	**4,213,039**	**17,338,354**	
2.6.1	Human resources, TB treatment institutions (Outpatient and inpatient)	Annual costs for salaries	1	1	1	1	1,898,439	1,898,439	1,898,439	1,898,439	**7,593,756**	
2.6.2	Investment costs, TB treatment institutions	Supportive equipment for NCTBLD					486,200	0	0	0	**486,200**	

No.	Objective / Intervention / Activity	Units					Total funding needs					
			Year 1 (2019)	*Year 2 (2020)*	*Year 3 (2021)*	*Year 4 (2022)*	*Year 1 (2019)*	*Year 2 (2020)*	*Year 3 (2021)*	*Year 4 (2022)*	***Total 4 years (2019-2022)***	**Funding Sources and anticipated gap**
2.6.3	Facility costs, TB treatment institutions (Outpatient and inpatient)	Annual costs	1	1	1	1	2,314,599	2,314,599	2,314,599	2,314,599	**9,258,398**	
3	**To enable supportive environment and systems for effective TB control**						**2,080,047**	**1,760,623**	**1,836,923**	**1,576,010**	**7,253,603**	**Government funding 12%, External 71% funding gap 17%**
3.1	**Strengthening core health system functions for TB control**						**808,562**	**563,713**	**542,713**	**349,100**	**2,264,088**	
3.1.1	External technical assistance, strengthening health system functions for TB control	Number of TA units	1	1	1	1	18,700	18,700	18,700	18,700	**74,800**	
3.1.2	National consultants, legislation and regulations for improving health services' performance for TB control, including palliative care	No. of person-months	15	15	15	15	9,000	9,000	0	0	**18,000**	
3.1.3	Training and attendance of international TB events abroad	No. of person-events	12	12	12	12	280,849	24,000	24,000	24,000	**352,849**	
3.1.4	Training of health care managers in priority issues of TB control	Number of trainings at central and regional levels	1	1	1	1	5,100	5,100	5,100	5,100	**20,400**	
3.1.5	TB management training of TB service staff: doctors		10	10	10	10	39,200	39,200	39,200	39,200	**156,800**	
3.1.6	TB management training of TB service staff: nurses and epidemiologists		16	16	16	16	44,800	44,800	44,800	44,800	**179,200**	
3.1.7	Training and performance review of PHC providers in TB control		65	65	65	65	194,900	194,900	194,900	194,900	**779,600**	
3.1.8	National consultants, legal framework and TB ethics	No. of person-months	0	20	0	0	0	12,000	0	0	**12,000**	

No.	*Objective / Intervention / Activity*	*Units*					**Total funding needs**					
			Year 1 (2019)	*Year 2 (2020)*	*Year 3 (2021)*	*Year 4 (2022)*	*Year 1 (2019)*	*Year 2 (2020)*	*Year 3 (2021)*	*Year 4 (2022)*	***Total 4 years (2019-2022)***	**Funding Sources and anticipated gap**
3.1.9	Training in TB legal and ethical issues	Number of trainings at central and regional levels	8	8	8	8	22,400	22,400	22,400	22,400	**89,600**	
3.1.10	Support piloting Results Based Financing Scheme	Amount of incentives to selected providers					193,613	193,613	193,613	0	**580,839**	
3.2	**Supervision, monitoring and evaluation of the National TB Program**						**591,760**	**494,460**	**591,760**	**494,460**	**2,172,440**	
3.2.1	Central NTP supervision	No. of central supervision rounds per year	2	2	2	2	25,000	25,000	25,000	25,000	**100,000**	
3.2.2	Regional NTP supervision	No. of regional supervision rounds per year	4	4	4	4	10,000	10,000	10,000	10,000	**40,000**	
3.2.3	NTP supervision in the penitentiary system	No. of regional supervision rounds per year	4	4	4	4	5,480	5,480	5,480	5,480	**21,920**	
3.2.4	NTP program coordination meetings	No. of meetings per year	4	4	4	4	2,200	2,200	2,200	2,200	**8,800**	
3.2.5	National consultants, TB information system	No. of person-months	18	18	18	18	10,800	10,800	10,800	10,800	**43,200**	
3.2.6	IT services, maintenance of national TB database	Annual cost of IT services for TB information system / database	1	1	1	1	20,000	20,000	20,000	20,000	**80,000**	
3.2.7	Printing of TB guidelines, R&R forms and registers	Annual cost of printing (NTP)	1	1	1	1	12,000	12,000	12,000	12,000	**48,000**	

No.	Objective / Intervention / Activity	Units					Total funding needs					
			Year 1 (2019)	*Year 2 (2020)*	*Year 3 (2021)*	*Year 4 (2022)*	*Year 1 (2019)*	*Year 2 (2020)*	*Year 3 (2021)*	*Year 4 (2022)*	***Total 4 years (2019-2022)***	**Funding Sources and anticipated gap**
3.2.8	Human resources support to program supervision, M&E	Human resources costs for project M&E (NCTLD, regional coordinators, prisons and database management)	1	1	1	1	202,700	202,700	202,700	202,700	**810,800**	
3.2.9	WHO reviews of the National TB Program	Cost of WHO review of the national TB program	1	0	1	0	97,300	0	97,300	0	**194,600**	
3.2.10	Management and administration costs of the Global Fund TB project	Annual costs of TGF project management	206,280	206,280	206,280	206,280	206,280	206,280	206,280	206,280	**825,120**	
3.3	**Advocacy, communication, social mobilization (ACSM) and civil society engagement for TB control**						**459,725**	**482,450**	**482,450**	**512,450**	**1,937,075**	
3.3.1	Support to the Georgian TB Coalition	Level of TWG workload per year	1	1	1	1	12,000	12,000	12,000	12,000	**48,000**	
3.3.2	NGO projects for innovative approaches in adherence support	No. of active grants	4	4	4	4	240,000	240,000	240,000	240,000	**960,000**	
3.3.3	NGO projects for case detection, case management and prevention among risk groups	No. of active grants	2	2	2	2	120,000	120,000	120,000	120,000	**480,000**	
3.3.4	National NGO workshops on TB control, civil society involvement and community response	No. of workshops	1	1	1	1	7,000	7,000	7,000	7,000	**28,000**	
3.3.5	TB knowledge, attitude and practice (KAP) studies	No. of KAP studies	0	0	0	1	0	0	0	30,000	**30,000**	
3.3.6	TB informational and educational materials	Estimated annual cost					25,000	25,000	25,000	25,000	**100,000**	
3.3.7	Training and briefings for mass-media on TB	N of trainings at central and regional levels	6	6	6	6	13,000	13,000	13,000	13,000	**52,000**	
3.3.8	ACSM activities during the World TB Days	estimated cost per event					20,000	20,000	20,000	20,000	**80,000**	

No.	Objective / Intervention / Activity	Units					Total funding needs					
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3.3.9	TGF SR management and administration cost for CSO / ACSM component	Annual cost					22,725	45,450	45,450	45,450	**159,075**	
3.4	**Research on priority issues of TB control**						**220,000**	**220,000**	**220,000**	**220,000**	**880,000**	
3.4.1	Clinical research studies	Annual cost	1	1	1	1	100,000	100,000	100,000	100,000	**400,000**	
3.4.2	Operational research studies	Annual cost	1	1	1	1	120,000	120,000	120,000	120,000	**480,000**	
	SUB-TOTAL						**11,913,761**	**11,066,107**	**11,178,552**	**10,879,670**	**45,038,090**	
4	Annual cost increase adjustment						595,688	553,305	558,928	543,983	**2,251,904**	
	TOTAL						**12,509,449**	**11,619,413**	**11,737,480**	**11,423,653**	**47,289,994**	