



National Strategic Plan for Tuberculosis Control in Georgia 2016-2020

Tbilisi, 2015

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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
FIND	Foundation for Innovative Diagnostics
FLDs	First-line anti-TB drugs
GEL	Georgian Lari
GLC	Green Light Committee
GNI	Gross National Income
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
MoLHSA	Ministry of Labor, Health and Social Affairs
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
UNAIDS	Joint United Nations Program on HIV/AIDS
UNICEF	United Nations Children's Fund
URC	University Research Corporation
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

1. 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. Currently, the interventions are guided by the *National Tuberculosis Strategy and Operational Plan for Georgia 2013-2015*. Besides the fact that the timeline for this Strategy expires at the end of this year, a number of important developments took place in the international policies, guidance and technologies in TB field recently, especially concerning programmatic management of drug-resistant TB, which, similar to other countries in the region, is an acute problem for Georgia.

This National Strategic Plan (NSP) aims to further align the national TB response with the latest international evidence, strategic policies and programmatic guidance. The NSP covers a five-year period 2016-2020; the programmatic interventions as well as financial figures are presented in detail for the first three years of implementation (2016-2018).

The Ministry of Labor, Health and Social Affairs of Georgia took the lead in the NSP development, with important technical inputs provided by the key national stakeholders and in close cooperation with other ministries and government agencies, as well as with the international organizations providing support to TB control in the country. The Government is grateful to the United States' Agency for International Development for provision of technical assistance in the development of this Plan.

The document is structured as follows. First, an overview of TB epidemiological situation in the country is presented with the main indicators and time trends. Second, the key features and main achievements of the National TB Program are described, followed by the identification of the key challenges that are addressed by this Plan.

Third, the Plan presents the overall Goal, targets and Objectives of TB control in the country for the next five years. Fourth, Strategic Interventions are described in detail by each Objective. While keeping the strategic focus for the entire five-year period covered by the Plan, the emphasis in this document is placed on the implementation process during the first three years (2016-2018).

Fifth, the roles and responsibilities of the national stakeholders in the implementation of the Plan are discussed, together with the expected inputs from international partners and identified needs in technical assistance. Sixth, the financial aspects are presented, including the estimate of the overall financing needs in TB control for the first three years of implementation and the forecasts of domestic and external funding for this period and identification of the funding gaps and key considerations for financial sustainability and takeover by the Government. Finally, the main indicators for monitoring the implementation are proposed, which will form the monitoring and evaluation framework for the NSP.

2. The burden of tuberculosis in Georgia

General information. At the beginning of 2015, the population of Georgia was 3.73 million¹, with 57.4% of the total population residing in urban areas². 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 line³.

TB estimates and notifications. Tuberculosis re-emerged as an important public health threat after the breakdown of the Soviet Union, and its burden remains high in Georgia. According to WHO, the latest estimated TB incidence was 116 per 100,000 population (for 2013⁴), which is the fourth highest level among 53 countries of the WHO European Region. The estimated 2013 mortality rate was 7.0 per 100,000 population (excluding TB/HIV cases).

According to the NTP notifications data, a total of 3,850 TB cases, all forms, were registered in the country in 2014 (including penitentiary sector), or 103.3 per 100,000 population; out of these, 2,807 were new cases (75.3 per 100,000). During the last three years, a trend of substantial decrease in the absolute number of TB cases is documented; between 2012 and 2014, the total number of TB notifications decreased by 22.6% and the number of new cases – by 25.7%. On the other hand, an alarming feature is that the proportion of previously treated case among all notified, increased from 24.0% in 2012 to 27.1% in 2014 (Table 1).

Table 1. TB notifications in Georgia by case category, 2012-2014⁵

Category	2012	2013	2014
New cases:	3,779	3,133	2,807
• Pulmonary smear positive	1,649	1,334	1,142
• Pulmonary smear negative / unknown	1,186	1,078	1,004
• Extrapulmonary	944	721	661
Retreatment cases:	1,196	1,187	1,043
• Pulmonary smear positive	631	579	474
• Pulmonary smear negative / unknown	441	513	474
• Extrapulmonary	124	95	95
All TB cases:	4,975	4,320	3,850

Among new TB cases registered, almost 70% are males (male / female ratio 2.24). The disease affects mainly young and the most economically productive part of the population: almost two-thirds of all new TB cases are aged between 15 years and 44 years.

Drug-resistant TB. The high burden of anti-TB drug resistance is the key challenge for the national TB program and the main obstacle for effective TB control in the country. WHO estimated that 710 patients with multidrug-resistant TB (MDR-TB⁶) needed treatment in 2013⁷. 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 cases⁸. In 2013, drug susceptibility testing (DST) by the National Reference Laboratory found MDR-TB already in 11.2% of new cases and in 38.1% of previously treated cases. The final data for 2014 show MDR prevalence of 11.6% and 39.2% in new and previously treated cases, respectively (among all cases with DST results, MDR-TB was found in 18.6% of them). The first-line resistance profile for the last five years is presented in the table below.

¹ Excluding separated regions of Abkhazia and South Ossetia

² National Statistics Office of Georgia, <http://www.geostat.ge> (data based on the General Population Census in November 2014)

³ World Bank, for 2013 (Atlas method, current USD), <http://data.worldbank.org/country/georgia>

⁴ Global Tuberculosis Report 2014, WHO, http://www.who.int/tb/publications/global_report/en/

⁵ National Center for Tuberculosis and Lung Diseases (NCTLD), 2015

⁶ 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.

⁷ WHO Tuberculosis Country Profiles, <http://www.who.int/tb/country/data/profiles/en/>

⁸ 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.

Table 2. Pattern of resistance to first-line anti-TB drugs in new and previously treated culture-positive cases, 2010-2014⁹

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
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

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-TB¹⁰).

Childhood TB. In 2014, 129 TB cases, all forms, were registered in children aged 0-14 years (26 pulmonary TB cases and 103 extrapulmonary cases), constituting 19.9 TB cases per 100,000 of childhood population. The absolute number of childhood TB cases almost halved within the last seven years, having decreased from 255 in 2010. The proportion of pediatric TB cases during the last decade has also decreased from 6.2% in 2005 to 3.4% of all TB cases in 2014. At the same time, 5 pediatric TB meningitis cases occurred in 2014, while no such cases were registered during 2013.

TB in prisons. The average annual number of detainees in the penitentiary system of Georgia (all facilities including pre-trial detention centers) was about 10,370 persons in 2014, down from 24,100 in 2011 (2.3 fold decrease). TB remains an important health problem in prisons, although the absolute number of TB cases, all forms, in the system decreased from 1,172 in 2011 to just 145 in 2014.

Between the same years, the number of new cases decreased from 800 to 66. Respectively, between the same years 2011-2014, TB notification rates have decreased from 4,860 to 1,400 per 100,000 of prison population (all cases) and from 3,320 to 640 per 100,000 (new cases). However, TB notification rates in the penitentiary system are much higher than and exceed the levels in the civilian sector 8.5 times (for new cases) to over 30 times (for all cases).

In 2013-2014, there were no lethal cases among TB patients in prisons, compared to 50 deaths in 2011 and 21 – in 2012. MDR-TB prevalence in 2013 accounted for 9.2% of new culture-positive cases and for 53.1% of retreatment cases; in 2014 (preliminary data), it was 7.7% and 40.8%, respectively.

HIV-associated TB. UNAIDS estimates that at the end of 2013, about 6,400 persons, all ages, lived with HIV in Georgia (range 5,000-8,000), with HIV prevalence rate of 0.3% in adult population aged 15-49 years. Since detecting the first HIV case in 1989, the annual rate of new HIV infections in Georgia has been increasing steadily and reached 10.9 per 100,000 in 2013. As of the end of 2014, a total of 4,695 individuals were diagnosed with HIV in the country. In 2014, 564 new HIV infections were detected (compared to 490 in 2013 and 526 in 2012).

Although the infection is mainly found among males, the proportion of women affected by HIV is on rise and reached 31% in 2014. HIV largely remains concentrated among key affected 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 13% in 2012. The estimated number of PWID in Georgia is 45,000, and HIV prevalence ranges between 0.4% to 9.1% among different PWID groups. In prisons, a significant decrease in HIV prevalence is documented (from 1.4% among inmates in 2008 to 0.35% in 2012). HIV prevalence among pregnant women and blood donors

⁹ NCTLD / National Reference Laboratory (NRL).

¹⁰ XDR-TB is defined as MDR-TB with resistance to a fluoroquinolone and to a second-line injectable drug.

(0.04% in both sub-populations) is lower than that in general population. Co-infection with hepatitis C virus (HCV) is common; HCV antibodies are detected in up to half of the registered PLHIV in Georgia.

Proportion of TB patients with known HIV status is rather low and was 62% in 2013 (2,698 patients out of 4,320 in total were tested for HIV¹¹). HIV prevalence among TB patients is low compared to other countries in the region; during the last five years, it varied between 1.7-2.3% 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.

On the other hand, 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, currently accounting for 21% of the total number of deaths in this population group.

¹¹ *Global TB Report 2014*, WHO

3. Achievements and challenges in tuberculosis control

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

TB control interventions are guided by the *National Tuberculosis Strategy and Operational Plan for Georgia 2013-2015*. The Strategy's goal is to stop the spread of TB in Georgia and reduce its burden including that of M/XDR-TB, with the impact of reduced TB mortality, reduced level of M/XDR and HIV in TB patients, and fewer health workers with TB. The interventions are organized around seven Strategic Areas: 1) TB diagnosis; 2) TB treatment; 3) Governance, financing, monitoring; 4) Human resources; 5) Infection control; 6) Empowering TB patients and communities; and 7) TB/HIV collaboration.

Georgia has assumed strong political commitment to protecting its population from TB. The Ministry of Labor, Health and Social Affairs (MoLHSA) 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 non-governmental organizations 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 the civil society. 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 in 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 in the 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 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 the 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.

Passive case finding is the main method of TB detection. PHC providers are responsible for identification of TB suspects 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 specimens' 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 for culturing, while DST 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. The novel Xpert MTB/RIF diagnostic technology was introduced in 2013 and is being expanded; currently, 17 instruments are operational in the country, including 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. Procurement of TB drugs is currently carried out with the financial support from the Global Fund. There are established procedures for port clearance, storage, distribution to service delivery sites, stocks monitoring and replenishment.

The majority of infectious TB patients are hospitalized during intensive phase of treatment. During outpatient treatment, follow-up of patients and drug dispensing are carried out by TB units and PHC facilities.

Ensuring direct observation of treatment (DOT) is the goal for all TB patients; monetary incentives are provided to the patients to increase adherence to treatment with the Global Fund support and government contribution.

The country uses the standardized TB recording and reporting system, which has been upgraded to include the latest WHO recommendations and additional country needs. Since 2006, individualized recording and reporting is in place and is incorporated in the national electronic TB database.

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 National TB Program 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 the Global Fund support.

Over the last decade, significant progress has been achieved countrywide in treatment outcomes of sensitive TB cases. The treatment success rate of all TB cases increased from 62.5% in 2004 cohort to 78.0% in 2013 cohort, and the proportion of patients interrupting treatment during the same period has decreased from 16.3% to 10.7% (among new AFB-positive cases – from 12.7% to 7.5%)¹². The full treatment results of the 2013 cohort of new AFB-positive cases are the following: treatment success – 81.5%, default – 7.5%, failure – 3.7%, death – 3.5%, transfer out – 0.5%, not evaluated – 3.3%.

Regarding the management of drug-resistant TB, Georgia conducts routine drug resistance surveillance as continuation of the first nation-wide representative Drug Resistance Survey, which was carried out in 2005-2006. The DST data for the last five years are presented in Section 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 2006, 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 that time until May 2015, over 4,300 patients were enrolled in second-line TB treatment. At 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 the application of newly developed anti-TB drugs such as Bedaquiline, the use of which will be expanded to all patients in need starting June 2015 through the global donation program supported by the manufacturer and the United States' Government / USAID.

At the same time, the treatment results of M/XDR patients are worrisome and represent the major concern for the national program. Totally for completed M/XDR-TB treatment cohorts for the last five years (2008-2012), only 51.2% of patients were successfully treated, 8.4% died, 4.9% failed treatment, 28.6% defaulted and 7.3% of cases were not evaluated at the end of treatment. The very high rates of treatment interruption are attributed not only to the difficulties by patients 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.

Main achievements of the National TB Program

The following are considered as the main achievements of the National TB Program in Georgia since the

¹² The rates are presented according to the revised WHO classification of TB treatment outcomes (2013)

start of DOTS implementation:

- The Georgian national TB program has achieved remarkable successes in the uptake and implementation of contemporary international strategies and guidance in TB control. All of the main components of the Stop TB strategy are in place and the country is continuously developing and upgrading and developing its practices in order to align to the emerging challenges of TB epidemic and approaches to ensure an effective national TB response.
- Visible improvements have been documented during the recent years in relation to TB burden, proven by the decreasing number of TB cases and TB rates, including the decreasing TB cases in children. The prevalence of drug-resistant forms of TB has been consistently contained at levels that are substantially lower compared to 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 that of newly developed drugs is being scaled up.
- As a key indicator of the positive developments in the national TB control program, treatment outcome of sensitive TB cases are improving including the steady decrease in the proportion of patient lost to follow-up.
- TB control in the penitentiary system is fully integrated in the overall national TB program. The effectiveness of TB control measures in prisons is proven by the decreasing incidence of active TB, as well by the improvement in treatment results, consistent with the overall trend in the country.
- Georgia is considered as a regional leader in aligning its TB care delivery system to the epidemiologic challenges and international best practices. In particular, this refers to the implementation of a predominantly outpatient TB case management, with reduced frequency and duration of hospitalization as a result of optimized and downsized TB hospitals' capacity.
- The country has been effectively implementing external funding support (from the Global Fund and other partners), reliant on the effective and professional collaboration and coordination with the international agencies, as well as across the national stakeholders.

Key challenges for TB control

Despite the important positive developments achieved in TB control, mentioned above, 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.
- 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 lately 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 most-at-risk population groups.
- TB control interventions need to be effectively integrated in all developments affecting the overall health system's organization and management as a priority public health function of the Government

in view of its priority objective of ensuring a universal health coverage system. Besides strengthening the governance and management of the national TB program 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 (first of all, 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.

4. Goal, Targets, Principles and Objectives

Goal

The overall **Goal** of TB control in Georgia is *to decrease the burden of tuberculosis 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 up-to-date international TB strategies, including the global targets in the draft *Post-2015 Global Tuberculosis Strategy and Framework*. The targets are set by the end of the five-year period covered by the Plan, compared to 2014 levels.

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

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

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 ensure the meeting targets, the 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 non-state actors;
- 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*, *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 environment and systems for effective TB control.

5. 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 during the recent 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 ensure universal access to drug susceptibility testing by rapid methods¹³.

Rapid scale-up of new technologies requires the revision of the existing policies and practices and a reconfiguration of the TB diagnostic network. The draft *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 the 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 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 the 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 tuberculosis.

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 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 (smear microscopy, Xpert MTB/RIF, culture in solid and liquid media, 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, 17 instruments are operational in the country, including the penitentiary system.
- Uninterrupted supply of laboratory consumables is ensured for all laboratory diagnostic methods, primarily through TGF.
- Specimen transportation system is functional since 2005 and currently delivers sputum from all peripheral TB units to LSSs, ZDL and NRL; and culture from ZDL to NRL.
- 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 will be completed in 2015).
- 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.

¹³ *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)

Challenges and Gaps

- While the numbers and rates of notified TB cases have substantially decreased in Georgia over the last three years, the effectiveness of TB case detection is of important concern and should therefore be reinforced to ensure testing of all TB suspects, investigation of contacts of patients with active TB, and rapid and full investigation of all detected TB cases for drug resistance.
- TB case detection activities at peripheral level are insufficient. The overall number of suspects tested (number of suspects tested per 1 active TB case, all forms: 4.2 in 2012, 4.0 in 2013 and 4.7 in 2014) is low compared to the levels recommended by WHO (up to 10 suspects per TB case); significantly lower rates are documented in many areas: 25% of all districts report 3 or less suspects tested per 1 TB case. Despite the improvements in the level of contacts' investigations over the last three years, it still remains insufficient; in 2014, on average 3.0 contacts per 1 smear positive TB case were screened (2.5 in 2013 and 2.3 in 2012).
- Despite recent delivery of Xpert MTB/RIF instruments (to LSSs and prisons), its coverage as initial, point-of-care diagnostic method remains insufficient; therefore, further rollout of this technology to peripheral level facilities is required.
- Sputum transportation is not effective in many instances, which leads to increased turnaround time in sample processing, delays in diagnosis and the resulting delays in the initiation of correct treatment.
- While the country achieved the overall high coverage with culture and DST investigations, the use of rapid techniques on liquid media is insufficient (currently, they are performed in less than 40% of cases) and therefore needs to be scaled up.
- Full DST is at the moment performed only at the NRL, which is insufficient given the increasing needs and geographic access issues. Regionalization of DST for Western Georgia (at ZDL Kutaisi) should therefore be considered.
- Systematic screening of PLHIV for TB needs strengthening, especially at peripheral level. In addition, diagnostic counselling and testing for HIV among TB patients is insufficient: despite some improvement during the last three years, HIV test results are available for only about two-thirds of TB patients.
- In view of the need to implement up-to-date internationally recommended diagnostic strategies, the existing national guidance and operational procedures for laboratories require update in order to accommodate for new technologies and diagnostic algorithms.
- 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.

Expected Results

It is expected that full and successful implementation of the interventions under this Objective will ensure that by 2020, 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 needs in 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 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 the patient's resistance status and without delays.

- Appropriate services are in place for contacts' investigations and screening / diagnosis in special groups (children, prisoners, PLHIV), including X-ray diagnostics.

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 support to rollout of rapid molecular testing at district level; implementation of WHO-recommended diagnostics in reference laboratories; improving contacts' investigation, screening and active case finding; and support to the routine operations of the laboratory service.

1.1 Rollout of Xpert MTB/RIF technology

According to the latest international standards and having been endorsed by WHO as a strong recommendation to the national programs, patients at risk for drug resistance should have rapid molecular Xpert MTB/RIF test performed as the initial diagnostic investigation for TB.¹⁴ This recommendation fully applies to Georgia as the country with high drug resistance burden. 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 test is sensitive and specific, and is very valuable in patients who are smear-negative by microscopy. A combination of microscopy and Xpert substantially increases the diagnostic yield. In addition to identifying *M. Tuberculosis*, Xpert detects resistance to Rifampicin, which is a close proxy of MDR-TB in Georgian settings.

The key obvious advantage of Xpert MTB/RIF is the rapidity with which an answer can be obtained – in less than two hours, and its simplicity and adaptability for use in peripheral laboratories. This allows the health care provider to take measures for proper isolation of identified TB cases, separation patients according to the resistance status and, initiated appropriate treatment without delays. The cost-effectiveness of Xpert MTB/RIF has been proven including in countries and settings similar to those in Georgia.

Xpert MTB/RIF is effective in and recommended for use in children, who are smear-negative in the majority of cases and therefore are difficult to diagnose by microscopy. Its application is also recommended in detecting TB in extra-pulmonary specimens. Xpert MTB/RIF investigations are an integral part of the revised national diagnostic algorithm, which foresees clear sequence of actions and relation with other tests (microscopy, culture and DST, as well as radiography).

Persons living with HIV (PLHIV) are highly vulnerable to developing TB if infected and, thus, should be carefully evaluated for the presence of active TB disease. Transmission of drug-resistant strains of *M. Tb* is common in PLHIV as a susceptible population having immunocompromised conditions. PLHIV are also the high priority for evaluation for TB among persons in contact with patients who have infectious TB.

Based on the evidence WHO recommended that Xpert MTB/RIF assay should be used, rather than conventional microscopy, as the initial diagnostic test in individuals presumed to have HIV-associated TB. It is especially relevant taking into account the high prevalence of MDR-TB in Georgia and the fact that the majority of TB/HIV cases are sputum smear negative by DSM.

The use of Xpert does not eliminate the need of culture and DST by other methods, as it is mandatory to obtain the full resistance profile of the patient, to enable the administration of a correct treatment regimen. However, this technology is seen to be an important factor triggering important structural and functional changes in the entire system of TB care delivery, in particular, in terms of regionalization / decentralization of diagnosis and case management and expanding outpatient treatment of TB cases (including MDR-TB cases) in line with WHO recommendations.

For the next five-year period, the annual countrywide needs in Xpert MTB/RIF investigations have been

¹⁴ *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)

estimated at between 29,000 – 31,300 tests per year. This estimate is based on the forecasted TB burden and the assumption that up to 8 Xpert tests are needed to detect one active TB case, as well as it takes into consideration the service settings and different adjustment factors such as repetition and test error rates. As of June 2015, a total of 17 Xpert MTB/RIF instruments are functional in Georgia; however, the current quantity of performed investigations covers just about half of the total country needs.

During the coming two years, it is foreseen to roll out Xpert MTB/RIF technology to district level. While, in order to ensure appropriate population coverage and perform the necessary number of investigations of TB suspects, a total of up to 54 instruments are needed countrywide (these calculations took account of the size of population served in each territory, minimum workload thresholds, distances and transportation options in regard to possibilities for referring the patients to the neighboring facilities), the first-stage rollout will include procurement of 18 additional instruments with the Global Fund support in 2016 (thus reaching the total number of 35 machines, which will serve the diagnostic needs on a ‘point-of-care’ basis). Xpert testing needs in the remaining areas will also be covered through specimen transportation from peripheral units to the LSSs (on ‘referral’ basis).

In the penitentiary system, Xpert testing will continue in the Prison TB Hospital in Ksani (Shida Kartli region) and in the Central Prison Hospital in Gldani (Tbilisi). These two facilities are already equipped with Xpert instruments, which were supplied by the Global Fund project in early 2015.

The Plan also foresees the use of Xpert MTB/RIF technology for testing of individuals suspected for TB among PLHIV. In order to bring services closer to the patients and avoid diagnostic delays, including those due to stigma, one Xpert instrument will function at the Infectious Diseases, AIDS and Clinical Immunology Research Center (IDACIRC) in Tbilisi, which has substantial number of PLHIV under supervision. In other areas, sputum specimens will be collected in PLHIV and referred for testing to Xpert sites in TB units, which are located, in most cases, in the same premises as offices of infectious disease specialists. The use of Xpert MTB/RIF in PLHIV will be included in the revised TB and HIV guidelines and reflected in the overall national TB diagnostic algorithm. Further bacteriological confirmation with rapid culture and DST will be performed in Xpert-positive cases, to define the full resistance profile and adjust the treatment scheme as necessary.

In addition to 17 Xpert machines available (4 at NRL, ZDLs and LSSs and 2 in prisons), 18 instruments will be procured. The number and location of Xpert instruments by sector and region, and the planned quantities of tests for the first three years of NSP implementation are presented in the table below. Additional details per site are included in an annex to this Plan.

Table 3. Xpert MTB/RIF instruments by region / sector and planned number of tests for years 2016-2018

<i>Region / sector</i>	<i>No. of instruments</i>	<i>Location</i>	<i>Number of Xpert tests</i>			
			<i>Year 1 (2016)</i>	<i>Year 2 (2017)</i>	<i>Year 3 (2018)</i>	<i>Total 3 years</i>
Mtskheta-Mtianeti	1	Mtskheta	0	125	677	802
Kakheti	3	Telavi (LSS), Gurjaani, Lagodekhi	890	1,951	2,186	5,027
Shida Kartli	1	Gori (LSS)	1,436	1,750	1,794	4,979
Kvemo Kartli	3	Rustavi, Gardabani, Marneuli	0	1,501	2,164	3,665
Imereti ¹⁵	6	Kutaisi (ZDL), Kutaisi (TB), Sachkhere, Samtredia, Tskhaltubo, Zestaponi	3,551	3,769	4,343	11,663
Guria	1	Ozurgeti (LSS)	609	893	975	2,477
Samegrelo and Zemo Svaneti	3	Zugdidi (LSS), Poti (LSS), Senaki	2,264	2,797	3,019	8,080
Samtskhe-Javakheti	2	Akhaltikhe (LSS), Akhalqalaqi	661	918	1,242	2,822
Adjara	4	Batumi (ZDL), Batumi (TB),	3,104	3,218	3,197	9,519

¹⁵ ZDL Kutaisi will serve the needs of Racha-Lechkhumi and Kvemo Svaneti region (specimens’ referral from TB units in Ambrolauri, Lentekhi, Oni and Tsageri)

Khelvachauri, Kobuleti						
Tbilisi city	4	Tbilisi TB Dispensaries No. 1, 2, 3 and 5	0	877	2,916	3,792
NRL	4	Tbilisi (NCTLD)	6,768	5,941	4,738	17,447
Penitentiary system	2	Prison TB Hospital Ksani, Central Prison Hospital Tbilisi / Gldani	1,500	1,500	1,425	4,425
HIV/AIDS service	1	Tbilisi (IDACIRC)	250	425	500	1,175
Total	35		21,032	25,665	29,176	75,873

The Plan stipulates phased introduction and rollout of Xpert, with appropriate planning and capacity development prior to and during implementation. The supply of Xpert instruments and tests will be accompanied by a set of preparatory and supervisory activities. NCDCPH and NCTLD / NRL will assist the Medical Department of MoC and the National AIDS Program in implementing the technology in prisons and HIV/AIDS service through training of staff, joint monitoring visits, coordination meetings and other relevant activities. Proper maintenance of Xpert equipment will be ensured through the countrywide servicing program.

The main activities under this Intervention include:

- *National consultants* will be employed to work on preparing the design and action plan for Xpert MTB/RIF rollout, conduct training of local providers, facilitate and supervise implementation in each of the country regions.
- *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 district level, TB specialists and laboratory personnel.
- *Procurement of Xpert MTB/RIF instruments, other equipment and supplies (cartridges)* for TB facilities in the civilian sector, penitentiary system and AIDS Centers. Eighteen instruments (mainly 2-module machines) will be procured from the manufacturer¹⁶ in 2016. Further expansion of this technology as ‘point-of-care’ method at district level will be considered by the NTP on the basis of early rollout experience.
- *Other equipment for Xpert MTB/RIF testing sites* includes IT equipment (computers and printers) and uninterrupted power supply (UPS) stations.
- *Procurement of supplies (cartridges) for Xpert MTB/RIF tests.* With the planned pace of rollout of this technology, it is foreseen that the coverage of needs will increase from about 50% in 2015 to 67% in 2016, 82% in 2017, and full countrywide coverage (i.e. covering over 95% of needs) will be ensured starting early 2018.
- *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.
- *Supervision / monitoring of Xpert MTB/RIF implementation* at district level TB units and penitentiary facilities will be carried out by NCTLD and NCDCPH with assistance from the national consultants. A monitoring system will be established to assess the progress and quality and enable for appropriate corrective actions on the way of implementation.
- *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 the next steps.

¹⁶ Xpert® MTB/RIF instruments and tests (cartridges) are produced by Cepheid Corp. Sunnyvale, California, USA. At the moment, it is the only rapid molecular technology approved by WHO for initial use in diagnosing TB.

1.2 TB diagnostic investigations at regional and national level

A new strategy for the development of the network of TB diagnostic services in Georgia will be developed by the end of 2015. This strategy will incorporate the latest international evidence and guidance for TB case detection and diagnosis. It will be complemented by the operational plan containing provisions for relevant organizational arrangements in the system, responsibilities of providers at different levels, staffing plan and detailed budget, activity levels and performance standards, and requirements for quality assurance.

Passive case finding through examination of symptomatic individuals 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 4 below.

Table 4. Planned structure of the TB diagnostic network in Georgia

Level	Institutions	Range of investigations to be performed	Other responsibilities
I. Basic TB management unit (BMU) level	23 BMUs: <ul style="list-style-type: none"> • 20 district / town level TB units¹⁷ • 2 penitentiary facilities: Ksani (No. 19) and Tbilisi / Gldani (No. 18) • AIDS Center Tbilisi (IDACIRC) 	<ul style="list-style-type: none"> • Xpert MTB/RIF 	
II. Regional level	6 Laboratory Surveillance Stations (LSSs): Akhaltsikhe, Gori, Ozurgeti, Poti, Telavi, Zugdidi; and 1 Zonal Diagnostic Laboratory (ZDL) in Batumi	<ul style="list-style-type: none"> • Xpert MTB/RIF • DSM 	<ul style="list-style-type: none"> • Specimen referral in respective regions
III. Sub-national level	Zonal Diagnostic Laboratory (ZDL) in Kutaisi	<ul style="list-style-type: none"> • Xpert MTB/RIF • DSM • Culture • DST to FLDs • DST to SLDs 	<ul style="list-style-type: none"> • Specimen referral in Western Georgia
IV. National level	National Reference Laboratory (NRL) in Tbilisi	<ul style="list-style-type: none"> • Xpert MTB/RIF • DSM • Culture • DST to FLDs • DST to SLDs • Genotyping and other advanced methods 	<ul style="list-style-type: none"> • Specimen referral in Eastern Georgia • Supervision • Quality assurance • Training • EQA with SRL • Research

Direct smear microscopy (DSM) investigations remain an important method for diagnosis TB among suspects and for treatment monitoring. While Xpert MTB/RIF test is expected to ultimately replace DSM as the initial diagnostic test in high DR-TB settings, maintaining microscopy testing in Georgia is justified by the relative simplicity of the technique, its suitability at regional level in terms of infrastructure requirements and availability of trained staff. In addition, microscopy is required for treatment monitoring purposes. Importantly, although the country plans to rapidly roll out Xpert, sufficient and sustainable financing for this technology (for testing and maintenance) is yet to be secured. 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.

At the same time, the renewed diagnostic strategy will include 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

¹⁷ See details in Table 3 above.

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 time 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.

The new strategy for the development of the TB laboratory network will include provisions for further regionalization of TB diagnosis. In particular, capacities for DST to first-line and second line TB drugs in liquid media will be developed at the ZDL Kutaisi, which will serve all needs of Western Georgia. It is planned that by the end of 2017, this laboratory will be fully functional in this regard, with an appropriate quality assurance system in place.

The NRL in Tbilisi and ZDL Kutaisi will perform the entire spectrum of investigations for TB, including direct smear microscopy, Xpert MTB/RIF, automated MGIT technology for rapid isolation of strains in liquid culture and accelerated DST, automated line probe essays (LPA) technology for rapid identification of M. Tuberculosis and detection of H/R resistance, and DST to second-line TB drugs.

The current WHO policy recommends the implementation of liquid culture systems as a part of the country's comprehensive plan for laboratory capacity strengthening that addresses issues such as biosafety, training, maintenance of infrastructure, and reporting of results. The planned developments aim at expanding the use of rapid methods with gradual phasing out culturing on solid media. Traditional culture methods using solid media (such as Lowenstein-Jensen and Ogawa) are less technology-intensive; however, the time to identify growth is significantly longer than in liquid media systems such as the MGIT system. In addition, liquid cultures are more sensitive than solid media cultures and are therefore considered as the gold standard reference method. Solid media culturing will be performed only at the NRL and will be limited to archiving strains and other research purposes.

The use of LPA method is recommended in culture isolates and direct testing of smear-positive sputum specimens. Direct use of LPA on smear-negative clinical specimens is not recommended at present, and culture is still required for such specimens. 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.

It is expected that effective regionalization of TB laboratory diagnosis will lead to substantial improvement of bacteriological confirmation of TB in children and will therefore enable the TB care providers to use treatment regimens that are tailored to resistance profile thus ensuring better outcomes of children with active TB.

The capacities of the National Reference Laboratory will be further developed to enable it as a cutting-edge reference center for TB bacteriology, capable to meet the entire range of national needs and to successfully engage in the highest-level international collaboration in the field. The refurbishment of the new NRL building will be finalized and the laboratory will become fully functional at the new premises by the end of 2015.

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 that on validation and field testing of new diagnostic 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:

- *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.
- *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.
- *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 penitentiary system) in 2016-2020 is about 210,000 tests; however the annual quantities will decrease from about 60,000 in 2016 to less than 32,000 in 2020 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 the next two years, so that in 2017, about 90% of all microscopy tests will be performed using LED technique).
- *Equipment for reference TB laboratories.* Necessary major and minor laboratory equipment and supplies will be provided for ZDL Kutaisi and NRL.
- *Laboratory supplies for MGIT and LPA investigations.* Procurement of consumables and reagents for culturing and DST covers diagnostic and treatment monitoring needs at the NRL and ZDL Kutaisi. It is foreseen to meet at least 90% of the countrywide needs in liquid culture by the end of 2017 and secure full coverage afterwards. The calculations are based on the epidemiological forecast and the planned level of expansion of rapid testing, and take account of the forthcoming changes in the diagnostic algorithm.
- *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 specialized laboratory equipment, as well as maintenance of biosafety equipment and ventilation systems at the NRL and ZDL Kutaisi.
- *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).
- *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 LSSs' 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.
- *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 Contacts' investigation, screening and active case finding for TB among high-risk groups including people living with HIV

It is estimated that the burden of undetected tuberculosis is substantial in Georgia, especially in high-risk groups. Significant delays in diagnosing TB and initiating the appropriate treatment are likely in people with limitations in access to health services. Systematic screening for active TB disease among risk groups them 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 rapidly¹⁸. 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 or/and 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 should ensure that persons in close contact with TB patients are evaluated and managed in line with international recommendations¹⁹. 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.

The Plan stipulates strengthening of contact investigation activities in Georgia during the next five years. A mandatory contact screening protocol will be developed to guide the process of contacts' investigation. The highest priority contacts for evaluation are: 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 may be performed for all other index cases with pulmonary TB.

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 recommendations²⁰.

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, WHO²¹ 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 symptoms of active TB disease (current cough, fever, weight loss or night sweats) should be offered treatment for presumed LTBI.

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.

¹⁸ *Systematic screening for active tuberculosis: principles and recommendations* (WHO, 2013)

¹⁹ *International Standards for Tuberculosis Care, Edition 3* (TB CARE I, 2014)

²⁰ *Guideline: nutritional care and support for patients with tuberculosis* (WHO, 2013)

²¹ *Guidelines for intensified tuberculosis case-finding and isoniazid preventive therapy for people living with HIV in resource-constrained settings* (WHO, 2011)

The practices of active TB case finding in the Georgian penitentiary system will be further aligned to the international requirements. The program will always include 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 should 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 should 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 TB²²; similar reciprocation should be applied in regard to smokers and people with chronic obstructive pulmonary disease²³, persons with alcohol use disorders or other drug-use disorders, which can be also combined with HIV screening in drug users²⁴. The management of health care institutions should offer screening for active TB to their staff and combine it with other appropriate infection control interventions²⁵.

Other defined subpopulations with high levels of undetected TB or / and 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 non-governmental organizations in early TB case detection among risk groups in community settings (see Intervention 3.2 below).

This Plan stipulates that the upgraded and expanded program for systematic TB screening will be fully operational by early 2018. For this purpose, a number of preparatory measures and capacity strengthening activities will be carried out in 2016-2017. The program will be implemented in close cooperation and coordination between MoLHSA, MoC and private health care providers. Systematic TB screening will be integrated in the overall national screening program, which is coordinated by NCD/CPH. Appropriate financing will be allocated to systematic TB screening interventions from the state budget.

The main activities under this Intervention include:

²² Collaborative framework for care and control of tuberculosis and diabetes (WHO, 2011)

²³ 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)

²⁴ Policy guidelines for collaborative TB and HIV services for injecting and other drug users: an integrated approach (WHO, 2008)

²⁵ WHO policy on TB infection control in health-care facilities, congregate settings and households (WHO, 2009)

- *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.
- *Training of health care providers on TB screening.* MoLHSA 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 and other related services.
- *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).
- *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. 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).

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:

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

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 the national TB programs must implement contemporary case management strategies and standards for achieving the 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 having M/XDR-TB. For Georgia, as well as for other countries in the region, this represents the paramount necessity for putting TB under control overall. In this regard, an increasing 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 require 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. In addition, such components of the national TB response as management of HIV-associated TB, preventive TB treatment and management of comorbidities influencing patient outcomes, need to be given an increased attention.

Achievements to Date

- Being among the first countries in the region to introduce DOTS, Georgia has successfully implemented this strategy throughout the country, including penitentiary system.
- Uninterrupted supply of quality-assured first-line and second-line anti-TB drugs is ensured with the Global Fund support, with a reliable system for TB drugs' management.
- During the last decade, TB service staff and part of PHC providers have been trained and retrained in TB treatment and case management.
- Substantial improvements have been attained in treatment outcomes for sensitive TB cases, due to, among other factors, strengthened direct observation of treatment and provision of adherence support.
- The country provides universal access to treatment of MDR-TB cases, including 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.

Challenges and Gaps

- While similar to internationally reported average, treatment success rate for MDR-TB cases is low (about 50%) and is far below the regionally set target of 75% (for 2015).
- 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.
- The national TB guidelines need to be aligned to with the up-to-date international standards for treatment and case management, especially for drug-resistant TB, and continuously updated afterwards.
- On the threshold of the expanded use of new TB drugs and modified MDR treatment regimens, the country needs to strengthen all components of drug management, including management of adverse drug reactions and establishment of a system for active pharmacovigilance for new drugs.

- 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.

Expected Results

Implementation of the interventions under this Objective aims at ensuring, by 2020, universal access to high-quality treatment of all forms of TB, including M/XDR-TB, in Georgia:

- 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 (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.

Strategic Interventions

Under this Objective, five Strategic Interventions are proposed, which all aim at improving access to and quality of TB treatment. They include ensuring uninterrupted supply of quality anti-TB drugs and effective drug management; provision of appropriate patient support for adherence to treatment; ensuring proper treatment monitoring, management of adverse drug reactions and comorbidities; improving infection control; and support to the operations of TB treatment institutions.

2.1 Supply of anti-TB drugs and drug management system

Securing uninterrupted supply of drugs for treatment of all forms of TB, including drug-resistant TB, is a crucial task for the National TB Program. 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 aiming 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 the effective drug management system.

The estimate of country needs in anti-TB drugs for the five 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 2016-2020 are presented in Table 5. The estimates include both civilian and penitentiary sectors. It is assumed that the annual number of cases will be stable during years 2015-2017

(about 3,800 TB cases, all forms). For the following three years, it is expected that the annual notifications will gradually decrease and will be under 3,600 in 2020. 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 5. Forecasted number of TB cases in Georgia by category, 2016-2020

Case category	2016	2017	2018	2019	2020	Total 5 years
New pulmonary SS(+)	1,192	1,212	1,226	1,221	1,209	6,060
New pulmonary SS(-)	981	955	926	903	874	4,639
New extrapulmonary	636	628	615	601	586	3,066
Sub-total, new cases	2,809	2,795	2,767	2,725	2,669	13,765
Retreatment pulmonary SS(+)	506	512	514	506	495	2,533
Retreatment pulmonary SS(-)	427	410	392	376	356	1,961
Retreatment extrapulmonary	91	88	83	80	78	420
Sub-total, retreatment cases	1,024	1,010	989	962	929	4,914
Total TB cases	3,833	3,805	3,756	3,687	3,598	18,679

The following table presents the estimated countrywide needs in TB treatment (including penitentiary sector) by treatment category. This estimate took account of 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 6. Estimated number of TB cases to be enrolled in treatment in Georgia by treatment category, 2016-2020

Treatment category	2016	2017	2018	2019	2020	Total 5 years
First-line treatment	3,146	3,112	3,059	2,994	2,914	15,225
PDR-TB treatment	175	172	168	162	153	830
MDR-TB treatment, total	500	510	516	518	518	2,562
• MDR-TB without resistance to SLDs	344	343	342	340	336	1,705
• MDR-TB, 'pre-XDR'	124	131	136	138	140	669
• MDR-TB, XDR	32	36	38	40	42	188
Other treatment and palliative care	11	11	12	14	13	61
Total TB cases	3,833	3,805	3,756	3,687	3,598	18,679

Over the next five years 2016-2020, about 18,680 TB cases, all forms, will need anti-TB treatment in Georgia. Out of these, about 2,560 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 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 cases²⁶; 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

²⁶ Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis (WHO, 2014)

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^{27,28}.

At the same time, the Georgian NTP will introduce modified, shortened MDR-TB regimens starting with the enrolment in the clinical trials and operations research starting 2015, within the framework of *STREAM* study, *endTB* project (supported by MSF in the country) and *TB Alliance* study²⁹, with the following expansion under programmatic conditions. Such regimens will be applied in MDR-TB cases without resistance to SLDs and will last 9-12 months³⁰. This takes account of the growing evidence on the effectiveness and safety of shorter MDR treatment. These regimens are better tolerated by patients and are less costly than the standard 20-month treatment regimen. Under close patient observation and meeting the requirements of operational research conditions, the NTP plans to enroll the increasing number of cases in shorter MDR treatment regimens, so that about half of MDR-TB patients (without resistance to SLDs) will be enrolled under shorter treatment schemes at the end of 2017.

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 short MDR regimens.

The Government of Georgia is committed to ensure uninterrupted supply of anti-TB drugs for treatment of patients with all forms of TB. The Government will allocate additional financial resources to the National TB Program, which will be sufficient to ensure effective takeover from the Global Fund during the first two years of the NSP: first-line drugs – 100% from the state budget starting 2016, and second-line drugs – 35% in 2017 and at 75% in 2018. External funding (through the Global Fund) will still be required for procurement of drugs for DR-TB treatment during the first two 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: drugs' selection, quantification, appropriate procurement methods, supplier selection and qualification, quality assurance, monitoring and supervision. MoLHSA will be responsible for managing supply of anti-TB drugs from all sources in terms of clearing deliveries in 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 at improving the pharmacovigilance system for anti-TB drugs, as part of the overall pharmacovigilance system in the country. It implies implementation of routine practices for spontaneous reporting on 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 the NTP capacities to improve the management of adverse drug reactions 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 Program³¹, MoLHSA will scale up the application of active pharmacovigilance methods in the TB program, such as targeted reporting and cohort

²⁷ *The use of bedaquiline in the treatment of multidrug-resistant tuberculosis. Interim policy guidance* (WHO, 2013)

²⁸ *The use of delamanid in the treatment of multidrug-resistant tuberculosis. Interim policy guidance* (WHO, 2014)

²⁹ Status at the time of submission of the Concept Note: 1) *STREAM* study: the site assessment performed (June 2015); study protocol shared; anticipated enrolment 25 eligible subjects per year. 2) *endTB* project (clinical trial component): study protocol shared; anticipated enrolment 75 eligible subjects per year. 3) *TB Alliance* study: trial initialization.

³⁰ Based on 'Bangladesh' regimen, reported to give high, relapse-free cure rate in MDR-TB patients (consisting of a minimum of 4 months of Km-Cfz-Gfx-E-H-Z-Pto, prolonged if necessary until conversion was achieved, followed by 5 months of Gfx-E-Z-Cfz)

³¹ Implemented by the Uppsala Monitoring Center (UMC) in Sweden

event monitoring. In particular, these methods will be applied for post-marketing surveillance of the new anti-TB drugs (Bedaquiline and Delamanid) using the standardized approach and protocols, which will be required to be implemented by all TB service units.

The main activities under this Intervention include:

- *Procurement of anti-TB drugs.* TB drugs will be procured for all categories of TB cases: 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 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 will strengthen the key functions and processes in the TB drug management system for this purpose.

- *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.
- *External technical assistance* will be provided to MoLHSA / 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. With USAID funding support through Management Sciences for Health (MSH), starting June 2015, MoLHSA supports the application of active pharmacovigilance methods in the TB program, such as cohort event monitoring (CEM). CEM will be applied for post-marketing surveillance of the new anti-TB drugs (Bedaquiline and Delamanid) using the standardized approach and protocols, which will be implemented by all TB service units.
- *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.
- *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.
- *In-country quality assurance of TB drugs.* In line with the international requirements, the MoLHSA through the State Agency for Regulation of Medical Activities (SARMA) will ensure a functional system for in-country quality control of supplied anti-TB medicines by certified laboratories.
- *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 the patients’ adherence to the 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 for maintaining 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 direct observation of treatment (DOT), when 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, along with identification of the needs for additional social support. 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 part of cash incentives for MDR-TB patients. This Plans calls for sustaining these practices beyond TGF support and further expanding them through implementation of effective patient-centered approaches, which will have impact on adherence and treatment outcomes.

Expansion of quality outpatient TB treatment, including that 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 'remote DOT' using mobile telephony technologies.

Aiming at successful takeover from the external donors and sustainability, the Government will encourage an increasing participation of non-governmental organizations 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 the domestic resources.

The main activities under this Intervention include:

- *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.
- *Enablers for health care staff.* As part of 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, MoLHSA 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 in the provider payment schemes.
- *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 for provision of 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 at-risk groups.
- *Mobile technologies for adherence support.* Demonstration projects will be carried out in defined settings, which will use mobile telephony technologies for strengthening adherence to TB treatment – through consultations, reminders (for drug taking and scheduled visit to specialists), verification of intake, provision of bonuses 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 telephony 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 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 implies 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. Chest radiograph (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.

Adverse drug reactions (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. The system for early recognition and proper management of ADRs will be strengthened by the NTP 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 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 to 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. The Government will take over this program component from the Global Fund in 2016.

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: HIV, other immunosuppressive disorders, diabetes mellitus, chronic obstructive pulmonary disease (COPD), malnutrition, alcohol and other substance abuse, and tobacco smoking.

Tuberculosis 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 above. On the other hand, 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.

Access to antiretroviral therapy (ART) will be ensured for all co-infected patients. In line with the latest international standard³², in TB/HIV patients who have profound immunosuppression³³, 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 690 TB/HIV patients will require treatment with antiretroviral drugs during 2016-2020 (Table 7).

³² *International Standards for Tuberculosis Care, Edition 3* (TB CARE I, 2014)

³³ CD4 count <50 cells/mm³

Table 7. Estimated HIV prevalence among TB cases, ART enrolment rates and number of TB/HIV patients to receive ART in Georgia, 2016-2020

	2016	2017	2018	2019	2020	Total 5 years
Total estimated number of TB cases	3,833	3,805	3,756	3,687	3,598	18,679
Estimated HIV prevalence among all TB cases, %	3.3%	3.6%	4.0%	4.3%	4.5%	
Estimated number of TB/HIV cases	126	139	150	158	163	735
ART enrolment rate among TB/HIV cases	90.2%	92.4%	93.7%	94.2%	95.0%	
Number of TB/HIV patients on ART	113	128	140	149	155	686

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

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 standards³⁴. It is estimated that diabetes care will be required in up to 1,700 TB patients during the next five years 2016-2020 (310-360 cases annually).

Macro- and micronutritional 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 recommendations³⁵. Additional nutritional support should be considered for patients who do not have the financial means to meet their nutritional needs during TB treatment.

Other diseases and treatments, for example immunosuppressive therapies by corticosteroids and tumor necrosis factor (TNF) alpha-inhibitors, increase the risk of tuberculosis 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 (see Intervention 2.5 below).

The main activities under this Intervention include:

- *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.
- *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

³⁴ Collaborative framework for care and control of tuberculosis and diabetes (WHO, 2011)

³⁵ Guideline: Nutritional care and support for patients with tuberculosis (WHO, 2013)

particular, second-line drugs). Clinical testing will be performed in accordance to the national TB treatment guidelines, aligned with WHO recommendations.

- *Rapid HIV tests for TB institutions.* In order to facilitate timely detection and, further, 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.
- *Training in HIV counselling and testing* will be offered to TB service staff, with special emphasis on the WHO-proposed diagnostic approach and the use of rapid HIV test at the point of care.
- *Training in TB and diabetes management* will be provided for TB service staff and endocrinologists in the regions, based on the TB / diabetes guidelines that are currently elaborated with USAID / URC project support.
- *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 HIV Plan.

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 national TB program, 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 lead to a consequent major reduction in 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 that of DR-TB cases. Inpatient TB treatment will be carried out following clear, strictly defined criteria for admission, duration of hospital stay and discharge. 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 that aim 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:

- *National consultants* in infection control will support MoLHSA and NCDCPH in the revision and update of the national standards and action plan for TB infection control, taking account of 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.
- *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.
- *Individual infection control measures.* 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 (in special, MDR cases) 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^{36,37}.

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 are not feasible due to imperfect tests, potential side effects and the high cost. 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 benefit-risk 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)

³⁶ *International Standards for Tuberculosis Care, Edition 3 (TB CARE I, 2014)*

³⁷ *Guidelines on the management of latent tuberculosis infection (WHO, 2015)*

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

Screening for symptoms among persons with HIV infection 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. The increased use of another test based on interferon-gamma release assays (IGRA) will be considered by the end of the period covered by this Plan, upon the mid-term evaluation of progress in the implementation of preventive treatment activities and subject to availability of funds.

The NTP will continue to use the common preventive treatment regimen (Isoniazid for at least 6 months); however the care providers may decide use 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.

MoLHSA 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 NCD/CPH (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 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 in the national TB information system for ensuring 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^{38,39}. 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

³⁸ *BCG vaccine* (WHO Weekly epidemiological record No. 4, 2004, 79, p. 27-38)

³⁹ *Revised BCG vaccination guidelines for infants at risk for HIV infection* (WHO Weekly epidemiological record No. 21, 2007, 82, p. 193-196)

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.

The main activities under this Intervention include:

- *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.
- *Training on LTBI management* will be provided for health care providers from specialized TB services in the civilian and penitentiary sector, as well as for the staff from public health services and HIV services.
- *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-2017.
- *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.
- *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 the patients who need hospitalization, for improving 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.

The main activities under this Intervention include:

- *Renovation / refurbishment of TB service institutions.* The Government will allocate funding for infrastructure rehabilitation of TB inpatient facilities and selected outpatient institutions, to improve patient conditions and infection control. This will include establishment of the new palliative care facility by end-2017. All investments will be based on a comprehensive needs' assessment taking into account the revised model of care and optimization of inpatient TB services.
- *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.
- *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.
- *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).

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

Rationale

Addressing broader social and economic determinants will ultimately have a decisive impact over the burden of tuberculosis. TB care and prevention will continue to benefit from general economic growth, poverty alleviation, enhanced social protection and reducing inequalities. In this regard, *Post-2015 Global Tuberculosis Strategy Framework* (GTSF) calls the 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*⁴⁰, which supports the health-in-all approaches and has UHC as the mainstay for the health system development in the country for the period until 2020. On the other hand, 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 competences 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.

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 the measures to take over from the Global Fund.
- The recently adopted Concept for health care development appropriately prioritizes TB control interventions and their integration in 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 non-governmental organizations.
- Traditionally, there has been close and constructive collaboration among the national stakeholders involved in TB control, including 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.

⁴⁰ 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'

- Prisons are an integral part of the national TB program, in terms of integration with diagnostic services in the civilian sector, procurement of drugs, adherence support, training, supervision, recording and reporting system and other activities.
- Regular NTP supervision visits from the central and regional levels are carried out with TGF project support. Georgia uses a comprehensive individualized electronic TB information system, which has been upgraded to accommodate for the most up-to-date WHO recommendations and to use the new software platform.
- TB diagnosis and treatment are part of the ‘essential package’ of services which are provided free of charge to the patients. The costs of services are covered by the state budget through the TB program and by the Global Fund project.
- Staff capacity building / training program is in place and covers TB doctors and nurses and TB laboratory personnel, as PHC providers.
- Georgia has been promoting contemporary approaches in TB care delivery including optimization of laboratory network, reduction of hospital capacities and promotion of outpatient TB case management.
- Average length of stay for TB treatment in hospitals has markedly decreased and is significantly lower when compared to other countries in the region (the same applies to the number / rate of TB beds). It has a positive impact over DR-TB rates as well as efficiency in the use of resources in the health system.
- The Georgian NTP actively participates in the international clinical research projects on TB.

Challenges and Gaps

- There is a lack of institutionalized and functional central NTP management unit. There is a lack of capacity at the central level for effective coordination of involved institutions. The mechanism for regional coordination of TB activities is tied to the Global Fund program and the roles of local public administrations is unclear. Strengthening the regional implementation and coordination arrangements is required given the advantages of decentralized TB service delivery, in particular in terms of further expanding outpatient management of TB cases.
- The NTP heavily relies on external funding, primarily that from the Global Fund, in TB diagnosis (laboratory equipment and consumables, as well as specimen transportation system, supervision and capacity building of laboratory staff). At the moment, anti-TB drugs are also provided fully under TGF support, as well as the major part of patient incentives. In view of decreasing TGF support over the next program period, the Government must ensure effective programmatic and financial takeover of these essential and costly components of the national TB program.
- Despite the planned increases, the overall level of state funding of TB interventions is insufficient, and a substantial gap in the coverage of needs is estimated for the next five years. Major efforts are required to uphold the Government’s financial commitments in TB control taking into account the high DR-TB burden and the need to sustain complex interventions related to new diagnostics, treatment regimens and patient support.
- Provider payment mechanisms for TB services are suboptimal and, at large, do not stimulate improvements in quality of care and efficiency.
- The expected increases in scope and load of work of specialized TB service units at peripheral level, in view of decentralization of diagnosis and case management with appropriate patient support, would require relevant increases in staffing levels. The current levels of remuneration of TB staff are low, which leads to demotivation in work and discontent in terms of performing new tasks and career development perspectives at large.
- Primary health care providers are insufficiently involved in TB case detection and case management. The current setup and regulation of services have insufficient provisions for PHC involvement in TB control activities and do not stimulate effective referrals and other collaboration with specialized TB services.

- Strong efforts are required to strengthen ambulatory TB care (especially for M/XDR patients), which includes updating regulations, capacity building for both TB service and PHC providers, close monitoring and supervision, as well as systemic changes in the system e.g. revision of financial flows and mechanisms across the levels of care.
- The TB recording and reporting system requires further upgrading in view of recent developments, such as the implementation of new diagnostics, new drugs and pharmacovigilance, and the needs to establish the links to monitoring performance of health care services.
- Overall, the involvement of civil society and community establishments in TB control is weak. There are no functional mechanisms for the Government to support (and pay for) non-state actors' involvement, which needs to be considered as an important prerequisite for implementation of patient-centered approaches (in terms of informational and educational activities, adherence support, outreach work with groups at risk, etc.).
- The legal framework for TB requires strengthening to address the ethical issues related to TB prevention, care and control. These include the role and obligations of private providers and patients' rights and responsibilities, e.g. in terms of adherence to treatment.
- 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).

Expected Results

Implementation of the interventions under this Objective aims at ensuring, by 2020, that appropriate environment 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.

Strategic Interventions

Under this Objective, four Strategic Interventions are proposed, which aim at creating the supportive environment and systems for effective implementation of diagnostic and treatment interventions described above. They include strengthening key functions and processes in the health care system for TB control; supervision, monitoring and evaluation of the national TB program; supporting ACSM and engagement of civil society, addressing legal and ethical issues related to TB, and 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 in 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 guidelines⁴¹, 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 five-year period covered by the NSP, MoLHSA 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 2016-2020: strengthening the NTP governance arrangements at the central level; and 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 2014⁴² will be operationalized and further developed. The National TB Council (NTC) will act in the capacity of the central coordination body for the national TB program. The NTC will oversee the implementation of this 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 Labor, Health and Social Affairs (MoLHSA), 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 6 below and reflected in the NSP Action Plan.

The NSP envisions that the role of NCDCPH in the national TB program will further increase over the next five years. 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 manage effectively the increasing scope and complexity of work.

During the first two years of NSP implementation, MoLHSA will lead a comprehensive revision of the key

⁴¹ *Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis* (WHO, 2014)

⁴² MoLHSA Order No. 01-282/ᄁ from 11 November 2014 'On the establishment of the Central Coordination Body for TB Control, the National TB Council, and endorsement of its bylaw'

legislation and regulations, in order to align them with the NSP priorities and enable effective implementation of the planned interventions. Besides the new law on tuberculosis which will be adopted in 2015, specific amendments will be made to other laws of Georgia and bylaws regulating public health. 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'⁴³) 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 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, MoLHSA 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 the Global Fund support. In order to ensure effective coordination of TB service delivery in the regions, MoLHSA 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 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 five-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 MoLHSA 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, MoLHSA 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 (2020). 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 7.

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 MoLHSA and the Social Service Agency (SSA) in 2016, piloted in 2017 and introduced country-wide in 2018. 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 tailor each TB care setting: hospitals, specialized outpatient TB services, as well as PHC

⁴³ WHO policy on collaborative TB/HIV activities: guidelines for national programmes and other stakeholders (WHO, 2012)

(including performance payments to PHC providers for TB-related work, such as contacts' screening, LTBI testing and preventive treatment).

The redesign of provider payment schemes will be done taking into account the international experience. The potential advantages of each modification will be carefully weighed against the risks of distorting the providers' practices and creating 'perverse incentives', which may result in either overuse of services (such as, excessive referrals for testing for active TB) or, on the contrary, in under-provision of services and suboptimal quality of care (such as, clinically unjustified refusals in hospitalization or preterm discharges from the hospital in order to obtain savings).

Human resources

As part of the human resource development policy and long-term plan for the health sector, stipulated by the health system development Concept, MoLHSA and NTP will carry out an inventory and needs' assessment for human resources in the specialized TB service, taking into account the distribution by specialty (physicians, nurses, laboratory personnel), setting of care (hospitals, outpatient facilities) and region, as well as the age distribution and the required level of staffing in mid- and longer-term perspective. Based on this assessment, a human resources plan for TB service will be elaborated and integrated in the overall health system manpower development plan (by end-2016).

Integration of pulmonology and phthisiatry specialties in the medical education system will be completed; starting academic year 2017, the graduated students will engage in residency specialization which will combine the current curricula for TB doctors and pulmonologists. It is expected that such merging will allow for applying a more comprehensive, integrated approach to pulmonary illness (in line with WHO's Practical Approach to Lung Health, PAL), as well as for bridging the anticipated gaps in filling the positions of TB specialists, especially at district level. The quotas for pulmonologists in the annual requests by the state to the medical universities will increase accordingly, to accommodate for the needs of TB care.

In addition, the graduate and postgraduate medical education curricula for TB will be updated, to embrace the modern notions and developments in relation to TB pathogenesis, epidemiology, diagnosis and treatment, as well as priority aspects for individual case management, prevention and public health.

Special attention will be paid to improving staff motivation and retention policies in TB services. MoLHSA 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, MoLHSA 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

MoLHSA and other involved governmental partners will make sure that the planned changes will be implemented in line with the following main principles and directions for development of TB service provision during the next program period:

- Priority development of outpatient TB case management, including cases with M/XDR-TB;
- Rationalization of approaches to hospitalization of patients with TB, based on the contemporary evidence that includes the risks of nosocomial transmission of DR-TB and infection control requirements;
- 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;
- 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.

The Georgian national TB program 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 M&E lie with the State and will be exercised by NTC and MoLHSA, 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 MoLHSA / 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.).

MoLHSA will complete a comprehensive assessment of TB hospitals' capacities including the needs estimates for medium term (until 2020). While this assessment is yet ongoing, it has become evident that the overall number of TB hospitals beds in Georgia does not need to be increased (on the contrary, for example, TB beds' capacity in the penitentiary system is highly excessive and should be downsized and/or used for other purposes). It is concluded on the basis of the latest epidemiological trends and forecasts revealing a decrease in the total annual numbers of TB cases (see Table 5 above). The planned implementation of contemporary approaches in TB case management prioritizing outpatient treatment (including management of M/XDR-TB cases in ambulatory settings starting day one) should further result in the decreased frequency of hospitalizations and reductions in the length of hospital stays in all categories of TB patients.

The current hospitalization practices will be reviewed and clear criteria will be developed in terms of indications for hospitalization, duration of hospital stay and discharge. The hospital admissions should be based exclusively on clinical needs of the patients, and not on epidemiological or social factors. These criteria will be an integral part of the new national TB guidelines, and their implementation will be closely monitored by the NTP through supervision and other relevant means. The reduction in the rate of hospitalizations and ALOS will significantly improve the program performance and outcomes, first of all by diminishing the risks of nosocomial transmission of TB strains in hospitals thus halting the spread and amplification of drug resistance. In addition, this will increase efficiency in the use of public financial resources.

During the next five years covered by this Plan, 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 recent 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 end-2017, 50% of all drug-sensitive and PDR-TB and 20% of M/XDR-TB cases are treated without hospitalization. By the end of 2020, these rates will increase to 70% and 40%, respectively. In addition, it is aimed to decrease, by end-2020, the average length of stay by at least 30% in sensitive and PDR cases, and by at least 50% - in MDR cases. Delivery of TB services close to the patients' place of residence and 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 guidelines have been updated to include the most recent evidence for management of pediatric TB cases, including those with drug-resistant forms of disease^{44,45}.

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 guidance⁴⁶, 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.

Strengthening quality management systems is one of the mainstays of the ongoing transformation of the Georgian health care system. In line with this requirement, this Plan emphasizes the need to ensure effective quality control and quality assurance for TB diagnostic, curative and preventive services at all levels. This will be achieved through: development and implementation of guidelines and protocols in accordance to up-to-date international recommendations; training / capacity building of medical staff; the use of appropriate medical technologies for TB diagnosis and treatment (including Xpert MTB/RIF and other WHO-recommended diagnostics); implementation of new anti-TB drugs and treatment regimens; supportive supervision by the NTP; elaboration of specific indicators related to quality of care, their regular monitoring and integration in the TB information system; provision of financial incentives to health care providers related to quality of care and patient outcomes; carrying out targeted client satisfaction surveys, and other appropriate means.

Integration of TB and HIV services will be promoted as it is necessary for proper control of TB/HIV co-infection. The NTP and the National AIDS Program will work with private providers of medical services in the territories to make sure that the full range of TB/HIV collaborative interventions, stipulated in this Plan under Objectives 1 and 2, are effectively implemented and monitored. The current setup of health centers at district level, where both TB and HIV services are under one organizational and management structure, provides good opportunities for further integration and effective collaboration.

Comprehensive patient-centered approaches also call for diversification of TB care delivery models to account for specific needs of the patients and their families. This includes involvement of community and other non-state actors through provision of adherence support and adaptation (see Intervention 3.2 below).

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 by end-2017, following the detailed assessment of needs and identification of additional resources for infrastructure, staff and operational support. During the first two years of NSP period, technical assistance will be provided in this area and palliative care guidelines and regulations will be developed and enacted, and additional support will be provided for infrastructure, human resources and other related costs. The palliative care facility for TB will be included in the state health care infrastructure development plan, stipulated by the Concept.

Legal and ethical issues in TB control

TB prevention, care and control comprise a complex set of interventions that raise important ethical and policy issues, which need to be adequately addressed. These concerns have been accentuated by the problem

⁴⁴ *Guidance for national tuberculosis programmes on the management of tuberculosis in children – 2nd edition* (WHO, 2014)

⁴⁵ *Management of Multidrug-Resistant Tuberculosis in Children: A Field Guide – Second Edition* (Sentinel Project, 2015)

⁴⁶ *The role of surgery in the treatment of pulmonary TB and multidrug- and extensively drug-resistant TB* (WHO/EURO, 2014)

of M/XDR-TB, which is especially difficult to detect and treat. Therefore, this Plan emphasizes the need to ensure that a robust legal framework is in place in Georgia to provide for execution of effective TB control as an essential public health function of the State, based on securing full and equal access to TB services for the entire population, reducing stigma and discrimination and ensuring observation of rights and responsibilities of the patients.

A comprehensive TB program should be able to protect individuals and communities through the proper treatment of infected individuals and the prevention of new infections. This calls for observing the key ethical principles and values, such as social justice and equity, solidarity, pursuing common good, reciprocity, subsidiarity, participation, transparency and accountability. In line with WHO guidance⁴⁷, 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.

The Government of Georgia will fully uphold its obligation to provide universal access to TB services as grounded in its duty to fulfil the human right to health. This implies a duty to ensure the appropriate quality of care, which extends to TB treatment as well as to diagnostic methods. Thus, the Government is committed to regulate the provision of TB services to ensure that they are consistent with internationally accepted quality standards. MoLHSA and NTC will take the initiative in the process of harmonizing the legislation of Georgia and relevant bylaws in line with the international standards for patient rights and TB ethics. It is expected that the new Law on Tuberculosis will be adopted by the Parliament in 2015. Further, appropriate amendments will be introduced to other laws and bylaws which have relevance to public health and, in particular, TB control.

Important specific legislative aspects that will be addressed during the NSP period include delineation of responsibilities of private health care providers for provision of TB services including the overall accountability to MoLHSA and other public bodies, obligations and functions related to reporting and organization of services for meeting the needs of the population served. On the other hand, a framework for the patients' rights and responsibilities in TB care will be established, with special provisions for outpatient case management. The NTP will also ensure that legal and ethical issues are properly included in the guidelines and training programs.

One special issue in TB ethics relates to involuntary isolation and detention of patients with contagious TB disease. In general, TB treatment is provided on a voluntary basis, with the patient's informed consent and cooperation. Engaging the patient in decisions about treatment shows respect, promotes autonomy, and improves the likelihood of adherence. Non-adherence is in most cases the direct result of failure to appropriately engage the patient in the treatment process. The emphasis will therefore be continuously placed on ensuring universal access to diagnosis and treatment of all forms of TB, including M/XDR-TB, and strengthening different measures for patient support as part of the overall patient-centered approach to TB care in the country.

At the same time, there are infrequent occurrences of TB patients unwilling to undergo treatment. If a patient willfully refuses treatment and, as a result, represent a threat to the community in terms of spreading TB and M/XDR-TB, then limiting that individual's human rights may be necessary to protect the wider public. In these cases, the interests of other members of the community may justify efforts to isolate the patient involuntarily, which could be considered legitimate under international human rights law. It should be emphasized that involuntary isolation and detention will be limited to specific and strict criteria and used only as a very last resort. Isolation or detention of TB cases will therefore be applied to exceptional circumstances, when an individual is known to be contagious, refuses treatment, and all reasonable measures to ensure adherence have been attempted and proven unsuccessful.

The main activities under this Intervention include:

- *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

⁴⁷ *Guidance on ethics of tuberculosis prevention, care and control* (WHO, 2010)

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.

- *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.
- *International training* and support to attendance of key international TB events abroad (conferences, high-level meetings and consultations) will be provided for NTC and MoLHSA staff, NTP coordinators and leading TB specialists from both civilian and penitentiary sectors.
- *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.
- *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.
- *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.
- *PHC onsite performance appraisal and mentoring.* Engagement of primary care providers is a critical strategy for improving detection and care of tuberculosis (TB). In Georgia, there is a need for greater involvement of family physicians and nurses in TB management to more quickly identify TB cases, support treatment, and successful outcomes. The Government of Georgia, supported by USAID TB Prevention Project implemented various educational interventions from 2012 aimed at building the capacity of primary care providers in TB recognition and treatment. In order to evaluate impact of educational interventions on primary care providers' performance in TB detection and care, a group of appraisers composed of a family physician, a nurse and a TB specialist visited more than 500 family medicine practices in five regions of Georgia. The performance appraisal allows to explore the extent to which the trained providers retain newly acquired competencies and identify factors that have a substantial impact on their daily practice, and determine the way they deliver TB related services. During onsite visits PCPs receive adequate mentoring and support in their usual care settings to reinforce skills acquisition. It is proposed to continue performance appraisal for PCPs and target additional 350 teams trained with USAID TB Project support in 2015. The appraisal beside direct impact on providers competencies will also, help them to identify institutional, environmental, and community factors that influence TB service delivery and to identify and implement effective TB care models in general practice. The USAID project monitoring data showed that during three years nationwide the share of patients referred to TB specialists from PHC services increased by 300%, from average 4% to 16%. Training and performance appraisal have proved to be the most effective strategies as the referral growth rate was especially significant in regions where PHC providers were trained and the training was followed by the performance appraisal further promoting knowledge and skills of family physicians and nurses.
- *e-Learning programs.* 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. Similar course was developed by USAID TB Prevention Project in 2013 available at www.tpp.ge; Three electronic modules will be developed with the GF support in 2016-2018.
- *Elaborate and support implementation of palliative care model* . 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. The Activity will include local and international TA, training, high level meetings, possible study tour for high level officials.

- *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 years period.
- *Training programs for epidemiologists 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. USAID TB Prevention project was providing annual training for a cohort of 110 epidemiologists involved in TB care since 2012. The NFM proposes to continuously support capacity building of epidemiologist and organize refresher training course in 2017 on most important aspects of TB case management in line with their responsibilities.

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 account of 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 level: 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 2 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, supervision will pay an increasing attention to the 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. The new individualized electronic information system (development supported by USAID / URC) was endorsed for use by the Government in April 2015 and will become operational at all peripheral TB service delivery sites by the end of this year. All indicators and data collection tools have been aligned to the latest WHO standards. Diagnostic / laboratory data, including Xpert MTB/RIF data, will be integrated with the rest of the database; data related to TB/HIV collaborative activities, as well as drug management data (including those related to ADRs and pharmacovigilance) will be appropriately included by end-2016. Further, integration of health service performance data (such as hospital activity indicators, data on contacts' investigation and delays in service provision), as well as links to expenditure data, will be completed (by end-2018).

The main activities under this Intervention include:

- *Support to NTP supervision.* Field monitoring and supervision of program implementation will be further supported. 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.

- *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.
- *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.
- *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 2017.
- *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. Most of the vehicles currently operated by NTP are heavily depreciated and often out of order. Frequent repair is needed that requires substantial resources. Therefore, substitution of existing cars with the new is proposed to improve capacity of the program for PSM and sputum transportation. Nine vehicles will be purchased one for each region and one for Tbilisi.

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 becomes of special relevance for the management of drug-resistant TB and, on the other hand, 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 advocacy, communication and social mobilization (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 the 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.

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)⁴⁸. 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.

The Plan aims, in accordance to WHO recommendations, to support a partnership platform for non-state organizations active in the field of TB. This platform will foster, as its primary role, the involvement of different actors (including civil society organizations, associations of patients and health professionals, private sector) in TB control activities in the country. While, in the first half of the NSP period, this component will rely on further support from international partners (including the Global Fund), the Government will facilitate the expansion of successful practices beyond the external support and identify

⁴⁸ *Patients' Charter for Tuberculosis Care* (World Care Council, 2006)

mechanisms and resources for increasing the state contributions in the field.

The value of TB advocacy, communication and social mobilization (ACSM) is well understood by the national TB program; however, the capacities to implement these activities should be further developed. The enhanced ACSM is needed to address the challenge of drug-resistant TB, which requires high-level commitments for allocation of substantial financial resources and strengthening programmatic performance, as well as increasing personal responsibilities of medical professionals and patients.

The recent developments in TB control strategies and technologies call for the adaptation and upgrade of informational and educational activities, implemented within the TB control program. Proper information and education work with TB patients and households is an integral part of the patient-centered TB care, which has high impact on the patient outcomes, especially in conditions of predominantly outpatient TB case management. Comprehensive ACSM approaches imply active involvement of different non-state partners such as civil society organizations, church, patient advocates, peer supporters, mass media and others. The NTP will use the updated information packages and will diversify approaches that are tailored to different audiences.

ACSM activities will be an integral part of the NGO projects. All activities under this component are closely linked to other Interventions under Objectives 1-2, which cover the needs of TB diagnosis, treatment and patient support, as well as they will be used to facilitate the health system performance strengthening efforts described under Intervention 3.1.

The main activities under this Intervention include:

- *Support to the National Stop TB Partnership.* The Partnership will comprise 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: i) implementation of innovative approaches in adherence support for TB patients at community level, and ii) support to case detection, case management and prevention among hard-to-reach population groups at risk: prisoners and ex-prisoners, PLHIV and PWID.
 - 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.
 - 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.
- *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.
- *TB knowledge, attitude and practice (KAP) study* will be undertaken in 2018 in different target groups to determine objectives for changing behaviors and advocacy / communication needs, with

particular emphasis on M/XDR-TB issues. The survey's results will indicate directions for priority actions by the NTP and other partners.

- *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.
- *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.
- *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: i) clinical research, including participation in the international medical research / clinical trials; and ii) 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: i) impact of new strategies and technologies for management of drug-resistant TB; ii) changes in effectiveness and efficiency of health services provision due to structural and functional reconfiguration in TB care delivery model; and iii) 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 MoLHSA 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:

- *Clinical research studies* will be conducted in cooperation with the international partners (WHO, International Union Against Tuberculosis and Lung Disease, and others including the new *endTB* 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.
- *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.

6. 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 (MoLHSA, 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 Labor, Health and Social Affairs (MoLHSA)** 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 MoLHSA 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 MoLHSA, 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 under TGF New Funding Model.
- 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 MoLHSA 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 MoLHSA 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 MoLHSA 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 educational institutions***, which are expected to play an important role in generating scientific evidence, graduate education and continuous capacity development of the health care staff.
- The Plan foresees the establishment and development of the ***National Stop TB Partnership***, which will serve as a platform for fostering the involvement of different non-state actors (including civil society organizations, associations of patients and health professionals, private sector) 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) will be completed in June 2016. The National Center for Disease Control and Public Health is the Principal Recipient of the grant funds. In July 2015, the CCM will apply for a new grant within TGF's New Funding Model (NFM). The NFM application will cover a 2.5-year period between 01 July 2016 – 31 December 2018 and will include priority interventions, for which significant gaps in domestic financing are present, in particular in diagnosis and treatment of DR-TB cases, patient support and interventions addressing population groups at risk.
- ***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. Currently, USAID supports the Tuberculosis Prevention Project (TPP), implemented by University Research Company (URC), supporting the implementation of health system's strengthening strategies for integration of TB service, health care provider capacity building, partnership leveraging with the stakeholders, and behavior change communication. The TPP project will be completed by the end of 2015. In addition, USAID supports the provision of strategic guidance and technical assistance by a Tuberculosis Advisor to MoLHSA and NCDCPH. The Plan relies on continuing technical support by USAID in priority strategic interventions outlined above.
- ***Médecins Sans Frontières (MSF)*** is expected to continue the assistance in clinical management of M/XDR-TB patients, currently provided by the compassionate use program for new anti-TB drugs

and the recently launched global *endTB* project, which includes Georgia as one of 16 project focus countries (including clinical trials' component), and MSF is the implementing partner in the country.

- **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 carry 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 MoLHSA 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.

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

Table 8. Technical assistance activities (external consultancies, technical working groups and national consultants) for 3 years 2016-2018, 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
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

7. 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 three years (2012-2014), while detailed needs' estimates were made for the first three years covered by the Plan (2016-2018). The financial forecast for the remaining two years will be performed at the time of medium-term review of the implementation of the Plan.

Government funding

The estimates for the state budget financing of TB control interventions, as well as for the external contributions, were carried out on the basis of the study report on *Expenditures on Tuberculosis Control in Georgia 2012-2014*, carried out with USAID / URC TPP project support in the beginning of 2015⁴⁹.

The National Health Accounts (NHA) of Georgia estimate that the total health expenditures (from all sources) were GEL 2.19 billion (about USD 1.32 billion) in 2013. Out of these, direct out-of-pocket payments by patients / households represent the largest share (66.9%), followed by the state budget (23.8%), private health insurance (4.6%), other domestic sources (2.4%) and external aid (2.3%). With the expansion of Universal Health Care program in 2014, it is assumed that this breakdown changed substantially, which would be evidenced after the 2014 NHA data become available.

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 2014, this level increased from GEL 426.4 million to GEL 720.8 million (69.1% increase in absolute GEL terms). Respectively, health expenditures as the share of the total state budget expenditure have increased from 6.5% in 2012 to 10.0% in 2014. The Medium-Term Expenditure Framework (Basic Data and Directions 2016-2018) foresees further increases in the government health spending to GEL 904.9 million GEL in 2018. This growth is mostly attributable to the increased expenditures within MoLHSA health programs, in particular due to the expansion of the Universal Health Coverage program, which is planned to grow from GEL 338.5 million in 2014 to GEL 520.0 million in 2018 (by 53.6%).

As shown in the table below, the total level of expenditures for activities directly related to TB control in Georgia (from all sources) increased from GEL 21.5 million in 2012 to GEL 28.0 million in 2014 (by 30.4%), primarily due to the increase in the government TB spending (from GEL 10.9 million in 2012 to GEL 15.9 million in 2014, or by 45.2%). In USD equivalents, based on the National Bank exchange rates, the government TB-related expenditures were about USD 6.61 million in 2012, USD 8.74 million in 2013 and USD 8.98 million in 2014. At the same time, the share of direct out-of-pocket payment for TB-related services is relatively low and has further decreased from 6.3% in 2012 to 5.0% in 2014.

Table 9. Total expenditures on TB control in Georgia by source, 2012-2014, GEL

Source of funding	Abs., GEL			% of total		
	2012	2013	2014	2012	2013	2014
Government spending	10,916,438	14,532,049	15,855,729	50.9	53.8	56.7
External funding	9,196,993	11,069,433	10,720,171	42.8	41.0	38.3
Out-of-pocket payments	1,352,698	1,385,163	1,412,866	6.3	5.1	5.0
Total	21,466,129	26,986,645	27,988,766	100.0	100.0	100.0

The government expenditure on TB-related services per one TB case (all forms) increased from GEL 2,194 in 2012 to GEL 4,130 in 2014 (in USD equivalents, from USD 1,329 to USD 2,339⁵⁰, or by 76.0%). Table 10 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

⁴⁹ *Expenditures on Tuberculosis Control in Georgia 2012-2014* (USAID Georgia / Tuberculosis Prevention Project, March 2015)

⁵⁰ 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.

indirect costs, food for inpatients, and laboratory and diagnostic services.

Table 10. Government expenditures on TB control in Georgia by function, 2012-2014, GEL

<i>Function / budget category</i>	2012	2013	2014
HC1 Curative care	7,950,142	9,734,125	8,986,948
<i>HC1.1 Inpatient curative care</i>	5,066,754	5,840,470	5,673,707
HC1.1.1 Staff salaries	1,657,298	1,700,463	1,521,718
HC1.1.2 Ancillary drugs and supplies	245,325	288,539	296,720
HC1.1.3 Laboratory and diagnostic services	463,476	725,121	702,143
HC1.1.4 Psychosocial rehabilitation	-	-	4,172
HC1.1.5 Food for patients	604,930	391,636	305,384
HC1.1.6 Indirect costs	1,423,563	1,642,955	1,878,165
HC1.1.7 Unspecified expenses	672,163	1,091,756	965,405
<i>HC1.3 Outpatient curative care</i>	2,883,389	3,893,655	3,313,241
HC1.3.1 Rural PHC providers (rural doctors DOT)	102,000	112,800	148,800
HC1.3.3 Outpatient specialist care (including urban PHC providers DOT)	2,781,389	3,780,855	3,164,441
<i>HC1.3.3.2 Laboratory diagnostic services</i>	<i>1,198,284</i>	<i>1,763,951</i>	<i>1,678,611</i>
<i>HC1.3.3.4 Ancillary drugs and supplies</i>	<i>133,488</i>	<i>56,635</i>	<i>12,054</i>
<i>HC1.3.3.5 Staff salaries</i>	<i>913,904</i>	<i>1,191,128</i>	<i>1,184,302</i>
<i>HC1.3.3.6 Indirect costs</i>	<i>535,713</i>	<i>769,141</i>	<i>289,474</i>
HC5 Medical goods	136,601	216,607	241,633
HC6 Preventive care	-	60,466	36,353
<i>HC6.4 Health condition monitoring programs</i>	-	60,466	36,353
HC7 Governance, administration and financing	-	-	142,184
HC8 Capital investments	2,829,694	4,520,851	6,448,611
Total	10,916,438	14,532,049	15,855,729

Similar to calculations of the TB control financial needs (see Table 12 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 2014, about GEL 497,000 or about USD 281,000).

External funding

External financial support to TB control in Georgia has been substantial and has importantly contribution to the strengthening of the national TB program. 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. Currently, 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 11 gives the breakdown of TB-related funding support by these agencies for 2012-2014.

Table 11. External funding contributions to TB control in Georgia, by agency, 2012-2014, USD⁵¹

<i>Agency</i>	2012	2013	2014
The Global Fund to Fight AIDS, Tuberculosis and Malaria (TGF)	4,716,862	5,078,692	4,334,800
United States Agency for International Development (USAID)	349,265	1,060,012	857,716
World Health Organization (WHO)	12,002	11,124	9,740
Médecins Sans Frontières (MSF)	492,429	506,476	868,055
Total	5,570,559	6,656,304	6,070,312

⁵¹ It was not possible to obtain information on funding contributions from other agencies such as EXPAND-TB

The share of direct external contributions, within the total estimated allocations to TB control in the country, has decreased from 45.7% in 2012 to 40.3% in 2014. Currently, the Global Fund is the main external source of funding, which has contributed to 77.2% of the overall estimated amount of international funding support in the field of TB control during the last three years (2012-2014). Regarding the nature of assistance, according to NHA data, over half of the external TB-related support in 2014 (52.7%) 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 (25.5%).

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 first three years covered by the Plan (2016-2018). The total estimated need of funding for TB control for this period is about USD 55.05 million. The table below presents the breakdown of the estimated needs by Objective and Intervention.

Table 12. Estimate of financial needs for implementation of TB control activities in Georgia for 3 years 2016-2018, by NSP Objective and Strategic Intervention, USD

No.	Objective / Strategic Intervention	2016	2017	2018	Total 2016-2018
1	To provide universal access to early and quality diagnosis of all forms of TB including M/XDR-TB	3,301,135	4,133,502	3,344,589	10,779,226
1.1	Rollout of Xpert MTB/RIF technology	714,346	425,484	611,624	1,751,453
1.2	TB diagnostic investigations at regional and national level	903,602	1,713,914	687,670	3,305,186
1.3	Contacts' investigation, screening and active case finding for TB among high-risk groups including people living with HIV	1,800	147,200	80,000	229,000
1.4	Support to operations of the laboratory network	1,681,387	1,846,904	1,965,295	5,493,586
2	To provide universal access to quality treatment of all forms of TB including M/XDR-TB with appropriate patient support	9,467,262	10,799,297	10,985,931	31,252,490
2.1	Supply of anti-TB drugs and drug management system	1,682,087	1,644,623	1,597,972	4,924,682
2.2	Patient support to improve adherence to TB treatment	991,775	1,096,394	1,116,943	3,205,111
2.3	Treatment monitoring, management of adverse drug reactions and comorbidities	280,852	300,297	271,496	852,645
2.4	TB infection control in health care facilities	17,472	87,922	44,272	149,666
2.5	Preventive treatment and vaccination against TB	61,939	89,903	137,065	288,908
2.6	Support to operations of TB treatment institutions	6,433,136	7,580,158	7,818,183	21,831,477
3	To enable supportive environment and systems for effective TB control	3,764,771	4,219,690	3,962,110	11,946,571
3.1	Strengthening core health system functions for TB control	106,100	407,500	335,200	848,800
3.2	Supervision, monitoring and evaluation of the National TB Program	704,946	709,740	494,460	1,909,146
3.3	Advocacy, communication, social mobilization (ACSM) and civil society engagement for TB control	333,725	482,450	512,450	1,328,625
3.4	Research on priority issues of TB control	2,620,000	2,620,000	2,620,000	7,860,000
4	Annual cost increase adjustment	0	957,624	914,632	1,872,256
	TOTAL	16,533,168	20,110,113	19,207,262	55,850,543

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' assessment, which were performed for each Intervention and took account of 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 for years 2017 and 2018 compared to 2016 as baseline.

The average annual needs for TB control (not including PHC costs) in 2016-2018 are estimated at USD 18.6 million, or about USD 5.1 per year per capita of the total country population.

Funding gap

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 first three years of the period covered by this Plan (2016-2018) was estimated; it is presented in the table below.

Table 13. Estimated total funding needs, Government funding, external funding and funding gap for implementation of TB control activities in Georgia, total for 3 years 2016-2018, 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	10,779,226	3,647,860	4,413,339	2,718,026
2	To provide universal access to quality treatment of all forms of TB including M/XDR-TB with appropriate patient support	31,252,490	19,099,690	7,041,515	5,101,760
3	To enable supportive environment and systems for effective TB control	11,946,571	334,840	9,922,088	1,689,643
4	Annual cost increase adjustment	1,872,256	203,980	0	1,677,800
	TOTAL	55,850,543	23,286,370	21,376,942	11,187,229

Despite the increasing Government financial commitments and sizeable anticipated external funding support during the next three years, 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 and increased coverage of risk groups with involvement of the communities and civil society.

The total funding gap for years 2016-2018 is estimated at about USD 11.2 million, which constitutes a 20% deficit of the total needs of USD 55.9 million for the same period. The most important gaps are faced by in the supply of anti-TB drugs for treatment of M/XDR-TB cases and in the provision of adherence support to the patients. The detailed calculations for estimating financial needs, breakdown of funding by source and Objective / Intervention and other details are given in a separate annex to this document.

Sustainability and takeover

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 next five-year 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.

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 national TB program and/or under the 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: 2015-2020

- *Microscopy and conventional culture investigations (consumables, reagents)* will be taken over by the Government (currently covered under the Global Fund support).

Timeframe: 2015-2016 (100% takeover by mid-2016).

- *Clinical investigations for TB patients on treatment and medicines for management of adverse drug reactions of anti-TB drugs.* These costs, currently mainly covered by TGF, will be borne by the Government.

Timeframe: 2015-2016 (100% takeover by mid-2016)

- *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 procured from domestic sources.

Timeframe: 2015-2016 (100% takeover by mid-2016)

- *First-line anti-TB drugs.* The Government is committed to establish a reliable system for TB drugs' procurement and supply management, and to allocate sufficient financial resources for this purpose. FLDs will be used in treatment of sensitive TB cases, PDR-TB cases and in isoniazid-preventive therapy (IPT).

Timeframe: 2015-2016 (100% takeover by mid-2016)

- *Xpert MTB/RIF, 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 5-year period covered by the Plan.

Timeframe: 2016-2020 (50% takeover by end-2018, 100% by end-2020).

- *Patient adherence support (incentives, enablers).* The Government will develop mechanisms and identify funding 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 (50% takeover by end-2018, 100% by end-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: 2016-2020 (75% takeover by end-2018, 100% by end-2020).

8. Indicators for monitoring implementation

Proper program monitoring and evaluation is crucial for the success of implementation of the NSP interventions. In order to ensure the achievement of the overarching TB control targets (see Section 4 above) and enable for effective adjustment of activities, a set of indicators was developed to monitor the implementation progress, with the targets set for mid-term and end-term of the period covered by this Plan.

Table 8 below presents the impact and outcome indicators and targets, which are intended for monitoring the overall epidemic trends and patient outcomes.

Table 14. NSP impact and outcome indicators

No.	Indicator	Baseline (2014)	Mid-term target (2018)	End-term target (2020)
1.	TB notification rate: all cases, per 100,000	103.3	100.1	96.1
2.	TB notification rate: new cases and relapses, per 100,000	82.9	81.2	78.3
3.	MDR prevalence among new TB cases	11.6%	< 15%	< 15%
4.	MDR prevalence among previously treated TB cases	39.2%	< 40%	< 40%
5.	TB mortality rate (excluding TB/HIV), per 100,000	6.8	6.0	5.1
6.	Treatment success rate, new smear positive TB cases	81.0%	86%	90%
7.	Treatment success rate, laboratory confirmed MDR-TB cases	47.5%	65%	75%

Key output and coverage indicators and targets (vis-à-vis 2014 baseline) are presented in the following table. These indicators refer to the planned changes in the coverage of priority interventions and improvements in the service performance.

Table 15. Key output and coverage indicators

No.	Indicator	Baseline (2014)	Mid-term target (2018)	End-term target (2020)
1.	Coverage of rapid molecular M. Tb detection and MDR screening (Xpert MTB/RIF) as initial diagnostic test in TB suspects	50%	85%	95%
2.	Coverage of first-line drug susceptibility testing among notified culture-positive TB patients (new and previously treated)	92%	95%	> 95%
3.	Coverage of second-line drug susceptibility testing among notified MDR patients	78%	95%	> 95%
4.	Interim results of MDR-TB treatment: percentage of patients with culture conversion at six months of treatment	72%	80%	85%
5.	Number of contacts of TB patients screened for active TB, per 1 TB case (all forms)	1.3	2.5	3.5
6.	TB notification rate in the penitentiary system: all cases, per 100,000 of average annual prison population	1,400	1,000	> 800
7.	Proportion of TB patients with known HIV status (percentage of notified TB cases, all forms, tested for HIV)	67%	85%	95%
8.	Prevalence of HIV among all TB cases	2.2%	≤ 4.0%	≤ 4.5%
9.	Percentage of TB cases, all forms, receiving the entire treatment in outpatient (ambulatory) setting	30%	45%	65%
10.	Government expenditure for TB control services as percentage of general government expenditure for health care	2.2%	3.5%	≥ 4.0%

Additional output and process indicators will be part of the Monitoring and Evaluation Plan, which will be developed following the endorsement of the NSP. This M&E Plan will present in detail the definitions for all indicators; list of indicators per each NSP Objective and Strategic Intervention; annual (and quarterly, where

relevant) targets for the first implementation period; sources of information, methods for data collection, aggregation and analysis; and definition of responsibilities of implementing institutions by sector and level of care provision.