National Tuberculosis Strategy and Operational Plan for Georgia 2013-2015

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NATIONAL TB STRATEGIC PLAN OF GEORGIA 2013-2015

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ACRONYMS

ACSM	Advocacy, Communications, and Social Mobilization
AFB	Acid- Fast Bacilli
AIDS	Acquired Immune Deficiency Syndrome
AOTR	Agreement Officer's Technical Representative
CCM	Country Coordinating Mechanism
DOTS	Directly Observed Treatment Short-course Strategy
DR – TB	Drug Resistant Tuberculosis
DST	Drug Sensitivity Testing
EQA	External Quality Assurance
FDC	Fixed Dose Combination
GEL	Georgian Lari (Currency)
GF	Global Fund to Fight AIDS, TB, and Malaria
GHRN	Georgia Harm Reduction Network
GFMA	Georgia Family Medicine Association
GLC	Green Light Committee
HMIS	Health Management Information System
HIV	Human immunodeficiency virus
HR	Human Resources
IC	Infection Control
KAP	Knowledge, Attitudes, and Practices
LPA	Line Probe Assay
MGIT	Mycobacteria Growth Indicator Tube (liquid media method)
MoCLA	Ministry of Corrections and Legal Advice
MDR – TB	Multidrug-resistant Tuberculosis
M&E	Monitoring and Evaluation
MoS&E	Ministry of Science and Education
MOLHSA	Ministry of Labour, Health and Social Affairs of Georgia
MSF	Médecins Sans Frontières
NCDC	National Center of Disease Control and Public Health
NCTBLD	National Centre for Tuberculosis and Lung Diseases
NGO	Non-governmental Organization
NTP	National Tuberculosis Program

OR	Operational Research
PHC	Primary Health Care
PPM	Public – Private Mix
QA	Quality Assurance
QI	Quality Improvement
RFA	Request for Applications
SLD	Second Line Drugs
TB	Tuberculosis
TPP	USAID Georgia Tuberculosis Prevention Project
TSMU	Tbilisi State Medical University
URC	University Research Co., LLC
USAID	United States Agency for International Development
USD	United States Dollar
WHO	World Health Organization
XDR-TB	Extensively Drug-Resistant Tuberculosis

EXECUTIVE SUMMARY

Georgia has made significant progress in confronting its epidemic of tuberculosis and multidrug-resistant tuberculosis (MDR-TB). The World Health Organization (WHO) estimates that the overall TB incidence, mortality and prevalence rates in Georgia have been falling steadily since the year 2000. To sustain this success in the context of ongoing fundamental reforms of the health system, this Plan addresses the main challenges Georgia faces, including drug resistance, TB in prisons, and the need for the commitment of domestic resources to sustain the effort when donor funding decreases.

Multidrug resistance (MDR) greatly complicates Georgia's TB epidemic, since this type of TB requires nearly two years of treatment with more toxic, more expensive and less effective medicines. MDR-TB spreads like ordinary TB, from person to person through the air. Georgia is one of the 27 countries with the highest burden of MDR-TB in the world.

Georgia has implemented new laboratory technology for rapid detection of TB and drug resistance, allowing Georgia to identify 63% of the estimated MDR-TB cases among notifications in 2011. However, this suggests that more than one third of the MDR-TB cases did not have access to MDR-TB treatment, and can serve as sources of infection to others. Once MDR-TB is detected, Georgia has succeeded in providing access to appropriate treatment, but the country has not yet achieved treatment success goals. Over one third of the MDR-TB patients who start treatment are later lost to follow up, and can also serve as sources of infection for others. As a result of a large "reservoir" of infectious MDR-TB patients, more than one in ten new TB patients has MDR-TB. These patients were never treated for TB before; they became infected by breathing MDR-TB bacteria from an infectious MDR-TB patient. MDR-TB in these new TB patients is a warning sign that MDR-TB is spreading in the community.

As a result of active TB screening efforts in the penitentiary system, more than one in five TB cases notified nationwide in 2011 was in prison inmates. But there is also evidence that ongoing transmission is contributing to this large burden of disease. Intensified efforts are needed to more promptly and thoroughly identify and treat cases of TB to prevent transmission in prisons and upon release.

The country's progress in controlling TB has required a major investment from the government and donors. Currently, a number of essential TB control functions (capacity building, HSS, procurement and management of health products and equipment for diagnosis, anti-TB and second line treatment side effect medicines, central and regional supervision of TB service points, TB&HIV services, incentives and enablers for DOT) are largely or completely dependent on the Global Fund project, which ends in 2015 as does the United States Agency for International

Development (USAID) TB Prevention Project. This makes 2013-2015 a critical window to determine which investments have brought the most value for money, and to determine how they can be sustained with domestic resources. This plan aims to define and budget for essential TB control functions, so Georgia can protect its investment in TB control. Failure to carry out essential TB control functions would risk increasing TB spread, at much greater financial and human costs.

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

Integrating TB services into ambulatory care has the potential to improve detection of patients with TB signs or symptoms, who can then be evaluated for TB.

Integration of TB surveillance, contact tracing, and laboratory into a larger public health system, if adequately managed and implemented, has the potential to provide more coordinated care for patients, and improved efficiency and sustainability of TB services. New players can bring new resources to contribute to TB control. The *National Health Care Strategy* includes other initiatives that would greatly advance TB control: permit requirements for health facilities, accreditation for doctors and nurses, emphasis on evidence-based guidelines, creation of a unified health information system and population health reports, improved access to quality medicines, support of patients' rights, and prevention of nosocomial infections.

This period of reform also has potential pitfalls. There is a lack of clarity in roles and responsibilities of central and regional structures including MoLHSA, NCTBLD, and NCDC. The new players have varying levels of experience and expertise in TB control. National clinical practice guidelines and protocols are currently being updates and have yet to be introduced, and there is no TB monitoring plan to assure accountability of the new TB service providers. In order to reap the benefits of health reform, certain specialized TB functions must be maintained at the national and regional level. These include assessment and oversight of TB program performance, supervision and assurance of quality of care and service coverage, policy development, and clinical and laboratory expertise. This plan seeks to address these challenges in order to mitigate the potential pitfalls of health reform.

The goal of this plan is to stop the spread of TB in Georgia and reduce the TB burden by sustaining universal coverage of quality diagnosis and treatment of all TB patients, including those with M/XDR-TB. To achieve this aim, the plan sets the outcome targets of improved detection and treatment of TB and MDR-TB. Achieving these targets will require actions listed under the plan's seven strategic areas and 17 strategic objectives. This plan—which represents the consensus of key stakeholders—can be used to advocate for the resources and policy changes necessary for implementation.

PART A. INTRODUCTION

The Georgian government has initiated fundamental reforms of its health system. Both primary health care (PHC) and hospitals have been privatized, and insurance coverage has expanded. The governance and management structures of the National TB program have also changed. The responsibility of leading the National TB program has been partially transferred from the National Center for TB and Lung diseases to various national institutions with varying degree of experience and expertise in TB response.

In Georgia, the Country Coordinating Mechanism (CCM) for TB, HIV/AIDS and Malaria is the high level body to oversee the implementation of the county's TB control program. Advised by the Ministry of Labor, Health and Social Affairs (MoLHSA), the CCM decided to develop this National TB Strategy and Action Plan for 2013-2015. The purpose is to guide the complex transition from a vertical towards an integrated TB service delivery model, and the new involvement of multiple parties responsible for various components of the National TB response. This strategy aims to serve as a road map for national and international stakeholders in planning and implementing specific activities aimed at reducing the TB burden in the context of Georgia's health reform.

Georgia has strong political commitment to protecting its population from TB. The *National Health Care Strategy*[2] commits MoLHSA to adhere to the strategic plan for TB control, and aims to reduce the TB prevalence by 25% in 2016 compared to 2005. Georgia endorsed the *Roadmap to Prevent and Combat Drug-Resistant Tuberculosis: The Consolidated Action Plan to Prevent and Combat M/XDR-TB in the WHO European Region, 2011–2015* .[6] In a September 2011 in Baku, Georgia committed to harmonize its national health strategy with the *Consolidated Action Plan.*

This plan is guided by the following principles from *Georgia National Health Care Strategy, 2011-15*:[2]

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

METHODS

The TB Strategy Working Group has been established under the auspices of the Country Coordinating Mechanism to lead national efforts to develop this TB strategy and Action Plan. The core team of the group is composed of the director of National

Center for TB and Lung Diseases; Director of Global Fund Projects Implementation Center, Director of Global Fund TB Program and Chief of Party of USAID Georgia TB Prevention Project. This group was extended to include representatives of the national and international institutions involved in TB programs, governance, planning and implementation.

This strategy is designed to fit within the country's *National Health Care Strategy*2, and comprehensively cover all aspects of TB control. To produce the plan, the following documents and strategies were reviewed, and all relevant elements incorporated:

Georgia

- *National Health Care Strategy, 2011-2015*
- *National HIV/AIDS Strategic Plan for 2011-2016*
- *Georgia Health Management Information System Strategy "Healthy Georgia, Connected to You", MoLHSA 2011*
- *A 5 year MDR expansion plan: MDR-TB prevention and management in Georgia (2010-2015)*
- *National Strategy for Advocacy, Communication and Social Mobilization in Tuberculosis Control, 2011-2013*
- *National Infection Control plan, draft 2010*
- *Performance Framework for grant number GEO-T-GPIC from the Global Fund to Fight AIDS, TB and Malaria*
- *USAID TB Prevention Project (TPP) Strategic Approach 2011-2015 and Year 2 Work Plan (2012-13)*

WHO

- *Roadmap to Prevent and Combat Drug-Resistant Tuberculosis: The Consolidated Action Plan to Prevent and Combat M/XDR-TB in the WHO European Region, 2011–2015*
- *The Global Plan to Stop TB: 2011-2015*

Findings and recommendations from the 2012 missions by the Green Light Committee[1] and the Global Drug Facility[17] were also incorporated, as were assessments prepared by local consultants for this planning effort.

This plan includes impact, outcome and output indicators. Process indicators will be selected for the action plan. Indicators are phrased as results to be achieved. Where ever possible, indicators were selected from those Georgia routinely collects and reports from regional to the national level and to WHO each year. Several indicators are currently collected for the Global Fund project. The 2015 targets included in this draft were set by Georgia[2,3,4,5] or WHO[6,7]. The Monitoring and Evaluation (M&E) Framework in Annex 4, lists the sources for each indicator and targets, as well as Georgia's baseline performance. One of the activities of this plan is to develop a national TB M&E Plan, to spell out how the data will be collected, how often, and who is responsible.

During the planning process, these strategic objectives, indicators, targets and activities were modified with stakeholder input. Targets were assessed in light of the stakeholders' views of what is ambitious enough to meet the needs of the Georgia population, yet feasible to accomplish by 2016. The activities in this plan can guide the selection of specific, more detailed, time-bound actions, each of which will need the commitment of a lead implementing organization. The action plan was costed to inform stakeholders on resources required in the immediate future to meet the targets and intensify advocacy efforts to cover the funding gaps.

TERMINOLOGY:

The core terms used in this strategy, which describe the nature of the problem and the response to it are defined below:

- **Tuberculosis** (TB) encompasses all types of TB, including drug resistant TB.
- **Multi drug resistant Tuberculosis** (MDR-TB) refers to TB bacteria that are resistant to at least isoniazid and rifampin, the two most powerful first line anti-TB drugs.
- **Extensively drug resistant** (XDR) refers to TB bacteria that are resistant to isoniazid, rifampin, and two important second line drugs: a fluoroquinolone and an injectable agent.
- **National TB Program** (NTP) refers to the country-wide response to TB, and includes all the actors in government agencies, the private sector, and civil society that contribute to controlling TB

PART B. GOALS AND TARGETS

Goal: The strategy aims to stop the spread of TB in Georgia and reduce the TB burden including M/XDR-TB.

KEY IMPACT INDICATORS AND TARGETS

By 2015,

- The notified TB incidence will decrease by at least 1% per year
- The estimated TB mortality rate will reduce from 3.7 to 3 per 100000 population
- The prevalence of MDR TB among previously treated TB cases will be less than <12% (Baseline in 2011: 32%)
- The proportion of MDR-TB patients with extensive drug resistance will decrease by at least 2% (Baseline in 2011: 6%)

KEY OUTCOME INDICATORS AND TARGETS FOR TB CASE DETECTION

By 2015,

- the case notification rate will decrease to 102 new and relapse TB cases per 100,000 population (Baseline in 2011: 105 per 100,000)

- the proportion of estimated MDR-TB cases detected will be more than 85% (Baseline in 2011: 63%)

KEY OUTCOME INDICATORS AND TARGETS FOR TB TREATMENT[1]

In the cohort of TB patients starting treatment in 2015,

- > 85% of new smear and/or culture positive TB patients will be successfully treated (Baseline in 2010 cohort: 76.5%)
- > 75% of MDR-TB patients will be successfully treated (Baseline in 2009 cohort: 53.7%)

The National TB Strategy is organized around the logic model presented in table 1. The table outlines seven strategic areas. Strategic Areas 3-7 are "cross cutting," in that they contribute to (or are important for) both TB case detection and treatment.

1. See Part D and Annex 4 for additional indicators and targets for each Strategic Area. Annex 4 also lists the Georgia, WHO or Global Fund source for each indicator and target.

TABLE 1. RESULTS FRAMEWORK (LOGIC MODEL) WITH KEY INDICATORS

(See Part D and Annex 5 for additional indicators and numerical targets)

Strategic Area	Outputs →	Outcomes →	Impact
1. TB diagnosis	Patients with suspected TB have sputum examined TB patients tested for drug resistance* Timely, accurate laboratory testing	TB and MDR-TB cases* notified	Reduced TB mortality Reduced level of M/XDR in TB patients Fewer health workers with TB Reduced level of HIV among TB patients
2. TB treatment	Uninterrupted drug supply Adequate Patient support	All form of TB including DR-TB patients* successfully treated Reduced death, loss to follow-up, treatment failure*	
3. Governance, financing, monitoring	Sufficient government funding to TB budget	*(Contribute to rest of outcomes in this column)*	
4. Human resources	TB service points with good performance during performance review visits		
5. Infection control (IC)	Facilities with TB IC plan implemented		
6. Empower TB patients and communities	TB patients provided TB advice and support by trained community members		
7. TB/HIV collaboration	TB patients with known HIV status Clients screened for TB	HIV+ TB cases detected Improved TB treatment outcomes for HIV+ TB patients	

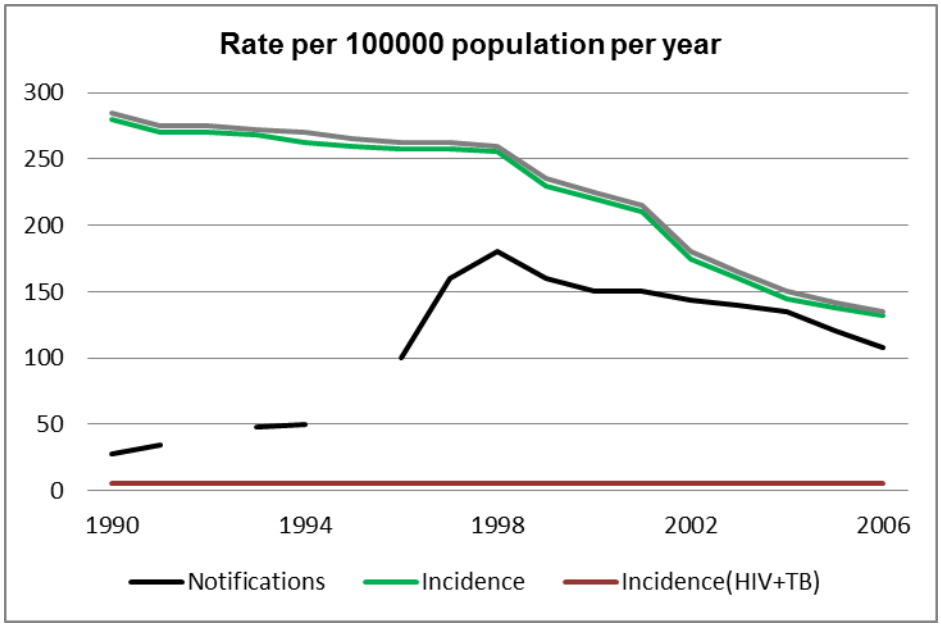
Note: *These indicators should be analyzed for new and previously treated, civil and prison, MDR and other patterns of drug resistance, children and adults, men and women, and by region of Georgia.

PART C. TB SITUATION ANALYSIS

Estimates of TB prevalence : WHO estimates that 6,900 Georgians (0.159% of the population) were living with TB in 2011. Georgia has met the Millennium Development Goal 6 (to reverse the incidence of TB) and the Stop TB partnership 2015 targets to reduce the prevalence and mortality by 50% compared to 1990. Moreover, Georgia has met its 2016 target to reduce the TB prevalence rate by 25% compared to 2005. Estimated TB prevalence rate has decreased from 304 cases per 100,000 in 2005 to 159 TB cases per 100,000 in 2011. However, the country's estimated prevalence rate remains nearly three times higher than that of the WHO European region.[8]

National trends in TB case notifications: The number of notified TB cases (new and relapse cases) per 100,000 population increased greatly in the late 1990s (dark black line in Figure 1). This was followed by a decline in the estimated incidence rate (light line with uncertainty intervals shaded in Figure 1). By 2011, Georgia was successful in detecting 84% of the estimated 5,400 TB cases that arose that year. However, this means that 16% of the country's TB patients (nearly 900) were not detected and therefore could not access treatment. This puts them at risk for dying of TB, and their communities at risk for continued spread of TB.

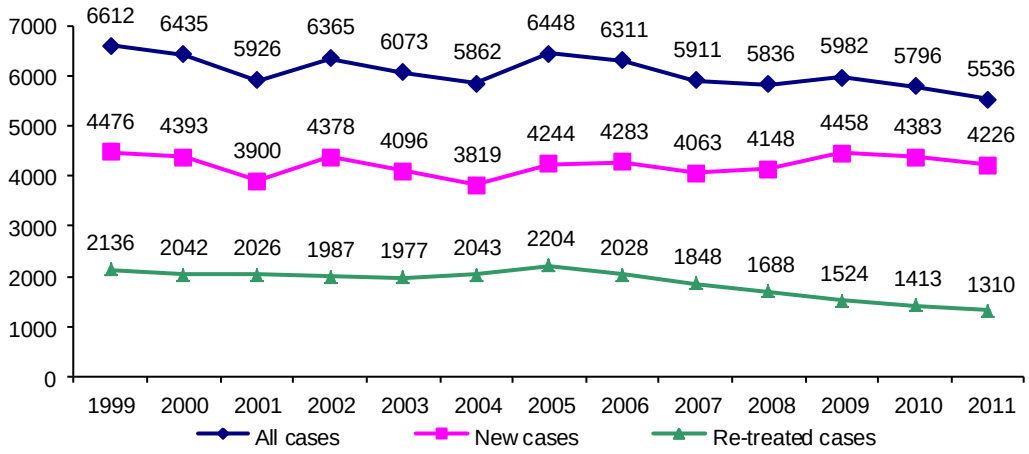
FIGURE 1.TB NOTIFICATION RATE AND ESTIMATED INCIDENCE RATES, 1990-2011, GEORGIA



From 2009 to 2011, the notification rate of new and relapse cases fell slightly from 108 to 105 per 100,000[9]. In 2011, the absolute number of all TB cases was 5% lower than the prior year (Figure 2, NCTBLD). It doesn't appear this is due to diminished TB case finding efforts; nationally the number of patients with sputum examined for TB diagnosis increased 3% from 13 069 to 13 410.While new TB case notifications fell 7%, the number of previously treated TB cases dropped by 14%. This downward

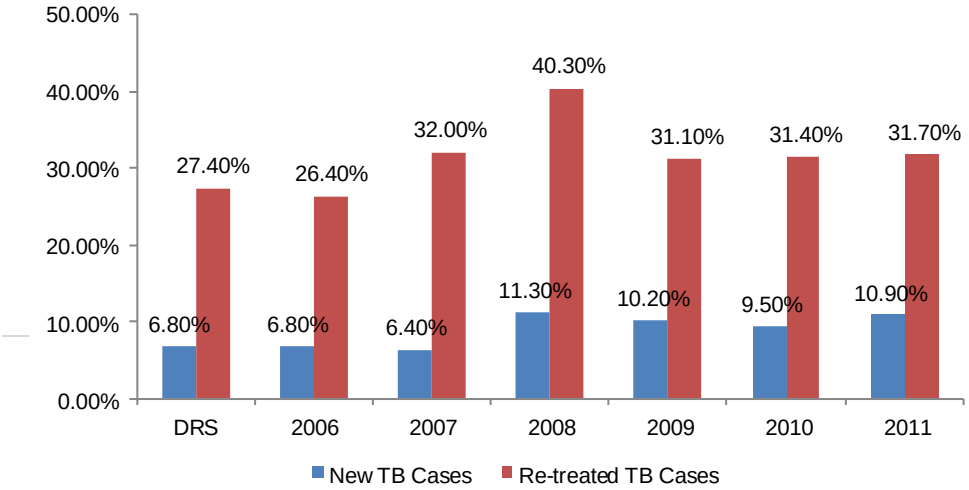
trend masks one group of previously treated patients (relapses) whose numbers increased 18% from 2009 to 2011. All other subgroups of retreatment patients (failure, default and other) had decreasing numbers of notifications. One of the possible reasons that contributed to increased number of relapses are attributed to declining number of "other" TB cases which itself is a result of more precise reporting &reporting. (18% decrease of "other "cases since 2009) (Determining the proportion of relapse patients with MDR-TB is one of the questions for further investigation in Annex 3.).

FIGURE 2. ALL REGISTERED TB CASES, GEORGIA 1999-2011 (ABSOLUTE NUMBERS)



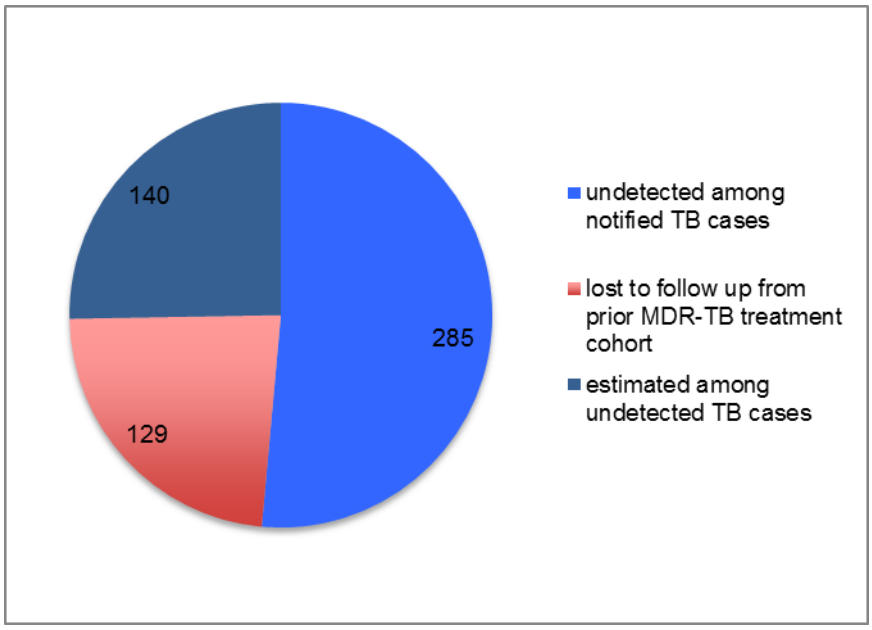
Drug resistance: In 2011, 31.7% of previously treated culture positive TB patients had multidrug resistance.8 That year, 10.9% of new culture positive pulmonary TB patients had multidrug resistance, slightly higher than the 9.5% in 2010, but similar to the 10-11% in 2008 and 2009 *(Figure 3).* These patients never had TB treatment before; they became infected by breathing MDR-TB bacteria from an infectious MDR-TB patient. MDR-TB in a new TB patient is a warning sign that MDR-TB is spreading in the community. Georgia must have a substantial "reservoir" of MDR-TB patients serving as sources of infection for these patients who were never treated for TB in the past. The size and composition is estimated below, in order to determine what interventions are needed to cure the MDR-TB patients in this reservoir, and stop the spread of MDR-TB to others.

FIGURE 3. MDR-TB AS A % OF NEW AND PREVIOUSLY TREATED PULMONARY TB CASES, 2006-11



If drug resistance testing were performed for all the new pulmonary and all the previously treated patients notified in 2011, WHO8 estimates that Georgia would find 760 MDR-TB cases.[2] In 2011, the National Reference Laboratory confirmed 475 MDR-TB cases, or 63% of the estimated 760 occurring that year among TB notifications.8 This suggests that the remaining 37% (285 MDR-TB cases) were not detected, not appropriately treated, and remain at high risk of death. It also means that over one third of the MDR-TB cases among the country's notifications are likely to remain infectious and spread MDR-TB to others. They form one segment of the reservoir of infectious MDR-TB patients *(Figure 4).* Another segment is the 129 MDR-TB patients who began MDR-TB treatment in the last cohort (2009) but were lost to follow up, had no outcome evaluated, or whose treatment failed. Finally, there are likely to be another 140 cases of MDR-TB among the 900 patients whose TB cases was not detected.[3] Activities to find and cure each segment are discussed in Strategic Objectives 1.4 and 2.2 below.

FIGURE 4. UNCURED MDR-TB CASES



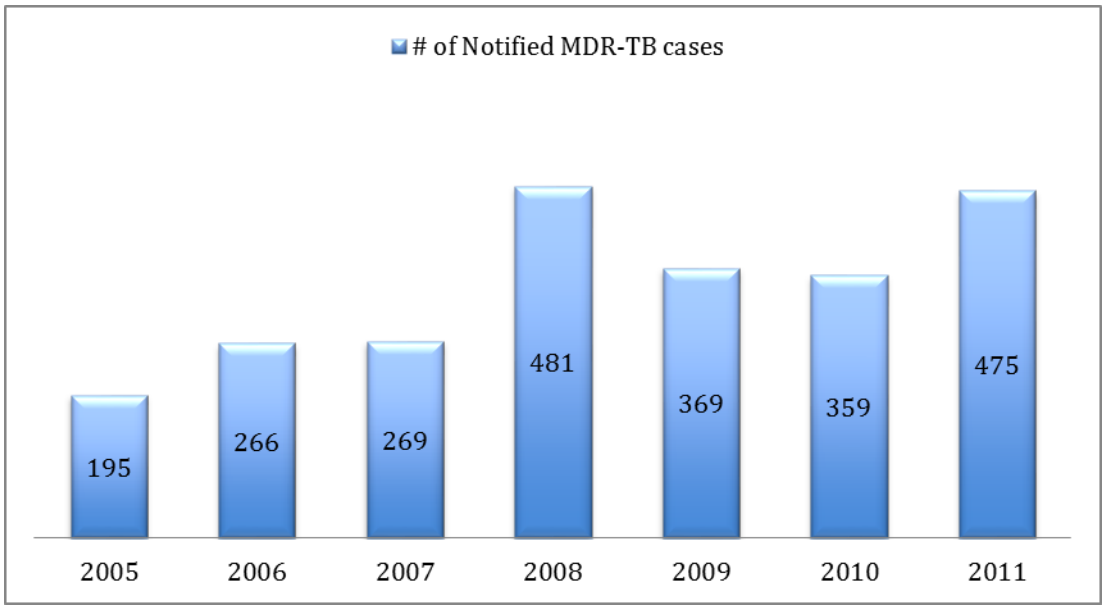
The absolute numbers and notification rates of confirmed MDR-TB cases have risen from 2005 to 2011, corresponding to increasing MDR-TB testing as the country implemented routine drug susceptibility testing for all patients in 2008 (*Figure 5).* It will be useful to determine the treatment history of the MDR-TB cases to see if the increase is also associated with retrieval of MDR-TB patients who were lost to follow

2. WHO multiplies 11% by the 3167 notified new pulmonary cases to estimate that there were 340 (uncertainty range 300-390) MDR-TB cases among the country's new pulmonary cases notified in 2011. Similarly, WHO multiplies the 32% by the 1310 retreatment notifications to estimate that there were 420 (uncertainty range 370-460) MDR-TB cases among the country's previously treated notifications in 2011.

3. 16% of tested TB cases in 2011 were MDR-TB1. 16% of 900 = 140

up in prior years and then were found and brought back into care. In the 2009 cohort, only 3% of the patients had returned after being lost to follow-up.[1]

FIGURE 5. # OF NOTIFIED MDR-TB CASES, GEORGIA, 2005-2011



In 2011, 440 of the 475 confirmed MDR TB patients were tested for resistance to a fluoroquinolone and a second-line injectable agent; 28 (6%) were found to have extensively drug resistant TB.[10]

In Georgia, 12-13% of new and previously treated pulmonary TB cases were found to have isoniazid resistance in 2011.[1] Inadequate treatment can generate MDR-TB if these patients acquire resistance to rifampin.[11]

Children: In 2011, 206 children under the age of 15 were reported with TB[9], and comprised 4% of the country's total TB cases. The TB case notification rate for this age group has fallen markedly from 88.8 per 100,000 in 1998 to 27.1 per 100,000 in 2011 *(NCTBLD).* Similarly the number of cases of TB meningitis has fallen from 28 in year 2003, to 2 to 3 per year from 2009-2011. This form of TB is particularly devastating as it has a high risk of death or chronic neurologic disability.

Regions of Georgia. In 2011, Tbilisi reported 27% of the country's civilian TB cases, followed by Samegrelo and Adjara which each reported 10% (NCTBLD). Adjara had the highest TB case notification rate (141 per 100,000), followed by Tbilisi (126 per 100,000), Samegrelo (111 per 100,000), and Mtskheta- Mtianeti (101 per 100,000).

HIV associated TB: see Strategic Area 7.

Prison inmates: see Strategic Objective 1.3.

PART D. STRATEGIC AREAS AND OBJECTIVES, TARGETS, ACTIVITIES

This plan is divided into seven Strategic Areas. The first area-detecting TB and drug resistant TB- is critical so patients can be appropriately treated, and do not die from TB; effective treatment also halts the spread of TB in the community. The second Strategic Area is universal coverage of TB treatment and care. Strategic Areas 3 through 7 all contribute to (or are important for) diagnosing and appropriately treating TB patients; they are the necessary "foundation" for these first two essential TB control functions. MDR-TB diagnosis and treatment, as well as TB care in prisons are integrated throughout the strategic areas.

Each Strategic Area begins with a rationale, followed by targets (compared with baseline), a summary of Georgia's progress and remaining gaps, then proposed activities.

STRATEGIC AREA 1: UNIVERSAL COVERAGE OF HIGH QUALITY TB DIAGNOSTIC SERVICES

This plan focuses TB detection efforts on three groups of patients expected to have a significant yield of TB cases: those attending primary care facilities (Strategic Objective 1.1), close contacts of infectious TB patients (1.2), and prison inmates (1.3).[4] TB diagnosis depends on a fully functional laboratory network (1.4) for bacteriologic confirmation and detection of drug resistance.

OUTCOME INDICATOR AND TARGET

By 2015,

- the case notification rate will decrease to 102 new and relapse TB cases per 100,000 population (Baseline in 2011: 105 per 100,000)

1.1. MAXIMIZE INTEGRATION OF TB SERVICES INTO GENERAL HEALTH FACILITIES AS AN OPPORTUNITY TO IDENTIFY AND DIAGNOSE PATIENTS WITH TB SYMPTOMS

RATIONALE

Respiratory complaints prompt a significant proportion (5 to 30%) of visits to primary health care services by people over age 5 in low and middle-income countries with a low prevalence of HIV infection.[12,13] The proportion of these patients with TB depends on the TB prevalence in the community, but can be significant. (Detection of TB in inpatients of general hospitals is discussed under Strategic Area 5.)

[4] See also intensified TB case finding in people living with HIV in Strategic Area 7 below.

OUTPUT INDICATORS AND TARGETS

In 2015,

- 20% increase in patients with suspected TB referred from primary health care (PHC) (Baseline <10% in 2012)

PROGRESS AND REMAINING GAPS

Before health insurance was established, Georgians had low utilization of health care services due to large out-of-pocket expenditures for health care.2 By improving access to primary care, health reform has the potential to facilitate more timely and thorough TB case detection. In Georgia, only TB doctors can order laboratory testing for TB, so TB diagnosis relies on referral from PHC providers. Referral from PHC providers are not systematically recorded, nor is feedback to the referring doctor. Barriers and factors that facilitate identification of suspected cases of TB and referrals from PHC providers have not been fully explored. It is unclear if PHC providers delay referral until after obtaining other tests such as chest x-ray examinations or prescribing trials of non-TB antibiotics.

An assessment by the USAID TB Prevention Project in January to May 2012 in Kakheti and Imereti found that 31% of referrals from PHC providers were confirmed with TB. By contrast, at the national level in 2010-2011, 15-19% of patients with sputum examined were found to be smear-positive.[5] The higher proportion of confirmed cases from PHC referrals suggest that PHC providers are referring only patients with classic signs of TB (such as coughing up blood and lung cavities seen on chest x-ray). This suggests they may be missing patients with less advanced disease, who could be detected and treated earlier to prevent progressive lung destruction and transmission to others.

(Other barriers to care, such as stigma and out-of-pocket payments, are discussed in Strategic Areas 3 and 6).

ACTIVITIES

a. Conduct operational research to determine barriers and factors that facilitate referrals in primary care settings
b. Develop standard operating procedures (SOP) for PHC providers for TB diagnosis and referrals. This should include
    - TB recording and reporting to monitor key steps in the identification and referral process: registration as a suspected case of TB, referred to TB specialist, reporting of laboratory results. (See also Strategic Objective 3.3)

[5] National Center for Tuberculosis and Lung Diseases Database

- Modifying TB case report to collect referral source (per WHO recommendations)[14]

c. Introduce standard TB case detection module and job aids in all pre- and in-service training curricula for general practitioners

1.2. ENSURE EARLY DETECTION OF TB CASES, ESPECIALLY IN CHILDREN, THROUGH PROMPT AND THOROUGH INVESTIGATION OF CONTACTS TO INFECTIOUS TB CASES

RATIONALE

Contacts are individuals who have breathed the same air as infectious cases of TB. A systematic review on household contact investigations in high TB incidence settings found that an average of 4.5% of contacts had active TB disease.[15]

Rapid evaluation of contacts can find these additional TB cases in time to prevent them from dying of TB or spreading to others. The most infectious TB patients are those who are smear positive and not on effective treatment, and the highest priority contacts to evaluate are those with prolonged and close contact (i.e. such as in a household, prison cell, or hospital ward), children under age 5, people living with HIV, and those in contact to MDR-TB cases.

INDICATORS AND TARGETS

In 2015,

- >90% of close contacts of smear-positive TB cases will be screened for TB
- 5% of TB cases identified among contacts

(calculate for total, under age 5, and for prison inmates)

(National baseline is unknown)

PROGRESS AND REMAINING GAPS

In the past, TB specialists encouraged TB patients to bring their families to the dispensary for evaluation as contacts, but data have not been compiled and used to assess and improve the yield of contact investigations. Since 2011, NCDC has been assigned responsibility to initiate contact investigations. As NCDC epidemiologists began to make visits to patients' homes, a USAID TPP assessment in six regions from January to May 2012 found that 6% of the investigated contacts were confirmed to have TB. The new regulation mandating reporting of TB cases to NCDC within 24 hours should facilitate more rapid contact investigations, which is especially important for pediatric TB. However, current approach prioritizes cases based on the infectiousness of the index patient and therefore contacts of smear negative and/or extra pulmonary TB cases are neglected.. If active TB is excluded, Georgia guidelines recommend isoniazid to prevent TB in children under age 5 who have

been in contact with infectious drug susceptible TB patients, immune compromised individuals, and those with a new tuberculin skin test conversion.

Georgia's TB guidelines currently recommend investigation of contacts of MDR-TB cases, and pediatric MDR-TB cases were found via this means. At the time of the GLC mission in June 2012, 20 children were receiving MDR-TB treatment, including six children under the age of 5.

ACTIVITIES

a. Develop programmatic guidelines, SOP and an implementation plan (including training) for effective contact tracing of TB and MDR-TB patients by all relevant institutions.
b. Build capacity of NCDPH epidemiologists to trace contacts for early TB case detection among family members.
c. Implement regulation to support prompt notification of confirmed cases of TB within 24 hours by all providers to the National Center for Disease Control and Public Health. Assess its impact.
d. Introduce and implement expanded guidelines on isoniazid preventive therapy.

1.3. ENSURE TIMELY DETECTION OF ALL CASES OF TB IN PRISON INMATES

RATIONALE

Strong TB program in prisons are necessary to find and treat TB patients, and prevent TB from spreading within the penitentiary system and into the community.

INDICATORS AND TARGETS

In 2015,

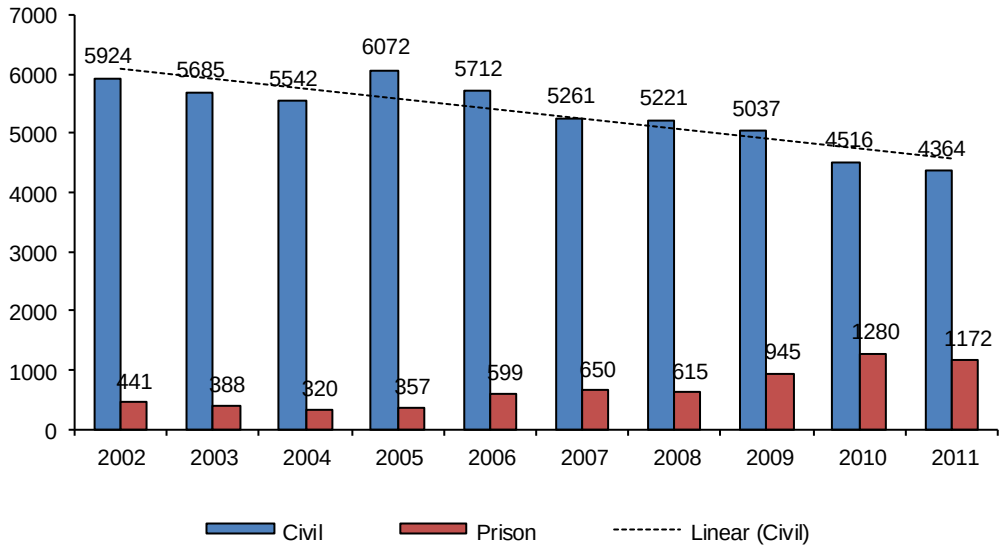
- 100% of prisoners will undergo TB screening on entry (Baseline in January to December 2011: 16,971 (98.4%))

PROGRESS AND REMAINING GAPS

In 2011, 21% of the nation's TB cases were reported from prisons. Symptoms screening upon entry was instituted in 2004, with follow up chest x-ray, clinical evaluation, and sputum testing. The number of TB cases reported from prisons has risen steeply since 2008 (*Figure 6)*, coinciding with implementation of repeated mass screening in 2010. In addition, the prison population rose from 4,000 in 2004 to 25,000 in 2010. Another contributing factor to the rise in prison cases is likely to be ongoing transmission in the penitentiary system. Evidence for this is the higher

proportion of cases among contacts (13/1000) compared to cases found by entry or mass screening (2.6-3.5/1000) (see Table 2, NCTBLD Database).

Figure 6. Number of TB cases in Civilian vs. Penitentiary system, Georgia, 2002-2011



A comparison of screening methods undertaken in selected prisons May 2011 to March 2012 shows active case finding methods (screening on entry, repeated mass screening and contact screening) together found two thirds of the cases.

TABLE 2. TB CASE DETECTION IN INMATES IN SELECTED PRISONS, MAY 2011 THROUGH MARCH 2012 (11 MONTHS) (Source: NCTBLD database)

Type of screening	N. of persons evaluated	N. of confirmed TB cases	TB cases detected per 1000 prisoners screened
Entry	12173	32	2.6
Repeated mass	55405	195	3.5
Contact	2002	26	13.0

ACTIVITIES

a. Conduct operational research to evaluate performance (accuracy and predictive value) of the active TB screening algorithm. Compare cost-effectiveness of the different screening programs to guide policy decisions
b. Introduce standard operating procedures and guidelines for prison health facilities to support implementation effective screening programs
c. Support capacity building of medical personnel within the penitentiary system to improve early TB detection

1.4. ENSURE THAT HIGH QUALITY LABORATORY TESTING SUPPORTS THE RAPID, ACCURATE DIAGNOSIS OF TB AND DRUG RESISTANT TB

RATIONALE

Time matters in TB diagnosis. Prompt detection of TB and drug resistant TB allows appropriate treatment in time to prevent progressive lung destruction and continued spread to others.

OUTCOME INDICATOR AND TARGET

In 2015,

- > 85% of MDR-TB cases will be detected (of estimated among notified TB cases). (Baseline in 2011: 63%)

OUTPUT INDICATORS AND TARGETS FOR TB CASE FINDING

By 2015,

- 80 % of pulmonary cases are confirmed by culture (Baseline in 2011: 63%)
- 100% of TB patients will have a sputum culture performed at diagnosis via automated MGIT on liquid media (Baseline in 2011: 95%)

OUTPUT INDICATORS AND TARGETS FOR M/XDR-TB CASE FINDING

By 2015:

- Close to 100% of previously treated TB patients have MDR-TB testing at the start of retreatment (Baseline in 2011: 52%)
- Close to 100% of new TB patients have MDR-TB testing at the start of treatment (Baseline in 2011: 83%)
- Close to 100% of MDR-TB patients have second line drug susceptibility testing (Baseline in 2011: 93%)

OUTPUT INDICATORS AND TARGETS FOR EXTERNAL QUALITY ASSURANCE (EQA) OF LABORATORY NETWORK

By 2015:

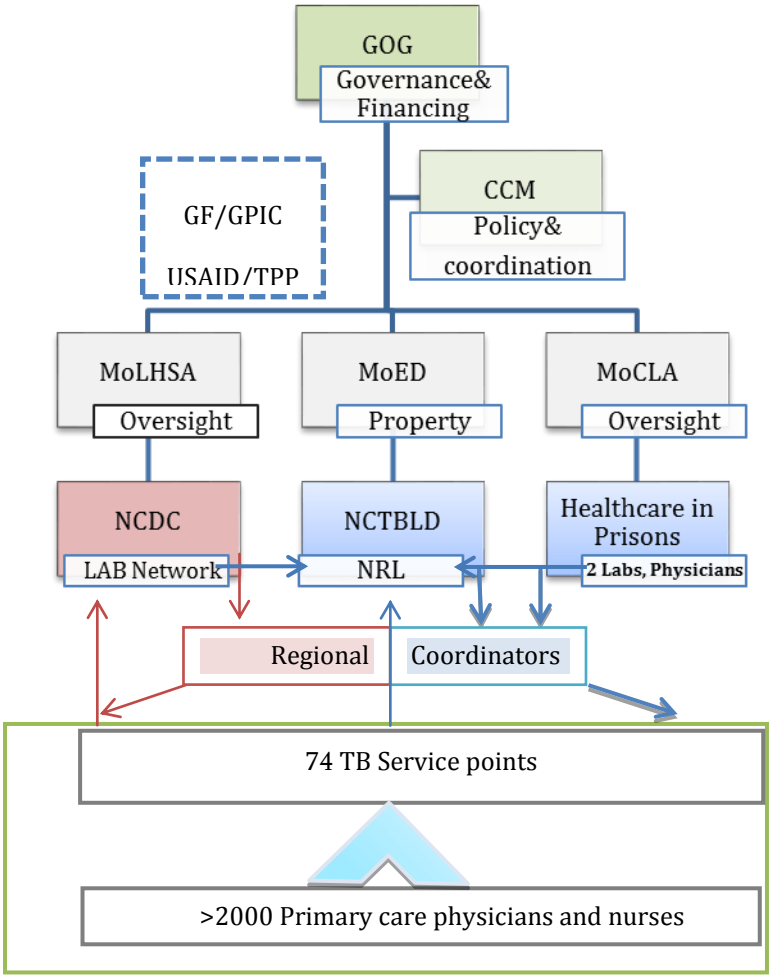
- 100% of smear microscopy laboratories undergo EQA
  - 100% will have acceptable performance
- 100% of culture laboratories will undergo EQA
  - 100% will have acceptable performance
- 100% of DST laboratories will undergo EQA
  - 100% will achieve $\geq$ 95% proficiency for isoniazid and rifampin

(Baseline in 2011 for 29 smear microscopy, 2 culture and 1 DST labs: 100% had EQA, and 100% had acceptable performance. Note: *the baseline reflects performance for the laboratory services until the reorganization in 2012. Baseline for the current organizational setup has yet to be defined*)

PROGRESS AND REMAINING GAPS

Georgia's recently re-organized laboratory network consists of the National Reference Laboratory (NRL) in the capital, a regional laboratory in Kutaisi, eight peripheral smear microscopy laboratories in the civilian sector and two in the prison system (Figure 6). The NCTBLD is responsible for the NRL and the prison laboratories, while the NCDC is responsible for the regional and civilian peripheral laboratories, as well as collection of specimens from 65 local TB service points and transporting samples to peripheral laboratories for smear microscopy, and to Kutaisi and NRL for culture and drug susceptibility testing (DST).

FIGURE 6. ORGANIZATION OF SERVICES



Georgia successfully implemented routine culture in 2006, then liquid media (MGIT) methods in 2008 and line probe assay (LPA, Hain) in 2010. LPA allow drug resistance to be detected in one and MGIT in about fourteen days, rather than the 42

days or more it takes when solid media alone is used. Georgia has achieved what WHO considers complete routine drug resistance surveillance.[6]

According to the country's diagnostic algorithms, specimens received in Kutaisi or Tbilisi within four days of specimen collection can be analyzed using MGIT. In 2011, following the reorganization of laboratory network, about 35% of specimens either arrived too late or other problems made liquid media testing not possible.[16]

In June 2012, the GDF[17] and GLC1 missions reported that the time to receive diagnostic results has increased. It is partially determined by formal procedures that should be followed by laboratory staff during transferring the documented test results to the treatment points. According to these procedures, lab results should be sent as a hard copy or electronically.

In Georgia, culture positive cases among pulmonary TB patients have increased from 66% to 71% in 2009-11, respectively. However, it would be useful to determine why pulmonary cases have negative or unknown culture results, especially if they are smear positive. Reasons may include delays in specimen transport leading to non-viable organisms, laboratory methods problems (such as overly harsh decontamination), or recording errors.

With donor support, the country has implemented new technologies successfully, but no plan is available for strengthening and sustaining the laboratory network for the immediate future or after 2015 when donor support is anticipated to decrease. A laboratory strengthening plan will need to take into account best value for money for TB laboratory services in order to decide which technologies to sustain or introduce, at what levels of the health system they should be deployed, what algorithms are used, and which groups of patients are prioritized.[18,19]

While the country's laboratory algorithms include testing of all TB patients for MDR-TB, only 52% of previously treated patients and 83% of new culture positive TB cases were tested for isoniazid and rifampin in 2011.[7]

Given the levels of MDR-TB are three times higher in previously treated patients than new patients in Georgia, the country has defined previously treated patients at high risk of MDR-TB, along with TB patients who have been in contact with infectious MDR-TB patients. If these patients are smear positive, Georgia's laboratory algorithm means they will have LPA which yields results within a day. If they are smear negative but their sample arrives to the Tbilisi or Kutaisi lab within four days of

[6] $\geq$ 50% of notified pulmonary cases are culture positive, DST results for isoniazid and rifampin are available for >75% of culture positive cases, and EQA for DST results show at least 95% accuracy for H, R.

[7] Georgia has been only analyzing and reporting data on MDR-TB testing in culture positive pulmonary TB patients. In 2011, 145 culture positive new or retreatment extra-pulmonary TB patients presumably had DST done and should be included in the country's drug resistance surveillance. According to the country's laboratory algorithms, an additional 245 smear positive pulmonary patients without culture results were tested using the line probe assay, and thus should have MDR test results available and reported as well (even though susceptibility testing to other first line agents is not possible).

collection, MGIT testing will be performed which yields first line DST results within one to two weeks. But if they are smear negative and their sample arrives later than four days after specimen collection, solid media takes up to six weeks to determine drug susceptibility results. This long delay is mitigated in Tbilisi by the NRL's use of Xpert MTB/RIF which will yield results within a day. Moreover, 38% of the nation's civilian patients are tested in Kutaisi, so they do not have access to this new technology, which WHO recommends for all patients at high risk of MDR-TB.[20,21]

ACTIVITIES

a. Develop TB laboratory network strengthening plan to address quality, turnaround times, selection of patients and algorithms, biosafety, deployment of new technology, specimen transport, EQA, human resources, supervision, information system, reagents and consumables, equipment maintenance[18,19]
b. Maintain uninterrupted provision of diagnostic services through sustainable financing
c. Support continuous capacity building of lab personnel

STRATEGIC AREA 2: UNIVERSAL COVERAGE OF HIGH QUALITY TB TREATMENT AND CARE

RATIONALE

To receive the benefit of treatment, patients must have access not only to starting effective medicines, but also to cure. Effective treatment prevents TB deaths and continued spread to others.

2.1. IMPROVE TB TREATMENT OUTCOMES BY PROVIDING PATIENT-CENTERED SUPPORT.

Note: for community-based DOT and support, see Strategic Area 6

OUTCOME INDICATORS AND TARGETS

In the 2015 cohort of new smear and/or culture positive cases:

- >85% will be successfully treated (Baseline, 2010 cohort: 76%)[8]
- <5% will be lost to follow up, transferred or not evaluated (Baseline, 2010 cohort: 10.4%)

In the 2015 cohort of previously treated patients,

[8] In the WHO 2012 report, the size of this cohort is greater than notified since the cohort includes all culture positive TB cases, not just smear positive pulmonary TB cases.

- > 70% successfully treated (Baseline, 2010 cohort: 61%)
- < 10 % of previously treated TB patients who are lost to follow, transferred or not evaluated (Baseline, 2010 cohort: 15%)

PROGRESS AND REMAINING GAPS

Georgia uses a standard, WHO-recommended regimen for new and previously treated patients, which is adjusted based on DST results. Approximately 12-13% of new and previously treated patients have isoniazid resistance (with rifampin susceptibility). These patients are treated according to WHO recommendations with a 9 month regimen,.[11]

Directly observed therapy in Georgia is predominately clinic-based, provided by TB or primary care nurses at private district or rayon level health facilities, or nurses at the village level. Upon occasion, providers may arrange home-based DOT if patients are unable or unwilling to come to clinic. Two third of TB patients receive food vouchers supported by the Global Fund.[4]

The Georgia hospital master plan decreased the number of TB beds, but no cost savings were redirected to strengthening ambulatory care. Currently, hospitalization is still the norm. The average length of hospitalization for new smear positive TB patients is approximately 25 days, 10 days for new smear negative or extra-pulmonary TB cases, and 75 days for MDR-TB patients. The Ministry of Economics oversees state hospitals, which include 243 hospital beds dedicated to drug susceptible TB, and 159 for MDR-TB, and 20 for palliative care. In addition, the penitentiary system has recently developed new infrastructure for TB infected prison inmates.

Georgia reports patients whose treatment has failed as a separate category from patients who transfer to MDR-TB treatment (whereas WHO lumps them together as "failed"). Approximately 10% of new and 8% of all TB cases in the 2010 cohort transfer to MDR-TB treatment because DST results were received after first line treatment began *(NCTBLD*).

Despite significant concerns about loss to follow up of inmates upon release, the 2010 cohort of new smear positive prison cases shows that only 4.2% were lost to follow-up, transferred, or not evaluated, compared to 10.4% among civilian cases *(NCTBLD).*

ACTIVITIES

a. Introduce and implement evidence-based TB treatment guidelines to standardize DOT and ensure provider adherence to DOT;
b. Develop standard operating procedures for TB case management, specifying supporting roles for DOT, responsibilities and structure for quality DOT and addressing patient adherence and follow up when patients are lost;

c. Develop capacity of community based organizations and social support personnel such as village nurses, social workers, community volunteers etc. to provide community-based DOT and improve patient adherence;
d. Ensure sustainability of available mechanisms and introduce effective models to improve treatment adherence (this could include cover DOT transportation costs for patients, and expanding the provision of food parcels);
e. Conduct operational research to analyze the cost of expanding patient support for ambulatory treatment and the potential benefits (which may include less loss to follow up if patients are treated closer to home, less nosocomial transmission);
f. Support dissemination of capacity building, quality improvement and educational interventions in the penitentiary system to improve quality of DOT in prisons:
    - Train prison staff (including nurses) on patient-centered approaches, patient education, communication skills and providing psychological support
    - Introduce TB care quality improvement tools
    - Providing inmates with necessary information about basic IC measures and TB treatment options

2.2. IMPROVE CARE FOR MDR-TB PATIENTS

OUTCOME INDICATORS AND TARGETS

In the 2015 cohort of MDR-TB cases

- 75% will be successfully treated (Baseline, 2009 cohort: 53.7%)
- <5% will be lost to follow up, not evaluated, or transferred (Baseline, 2009 cohort: 31%)
- < 10% will die (Baseline, 2009 cohort: 8%)
- < 10% will have treatment failure (Baseline, 2009 cohort: 6%)
- 75% will be smear and culture negative at 6 months after treatment initiation (interim outcome) (Baseline not available)

OUTPUT INDICATORS AND TARGET

Among MDR-TB cases confirmed in 2015,

- 100% will begin treatment with MDR-TB regimens. (Baseline, 2011: unknown)[9]
- 80% will receive incentives (Baseline in 2011: 67%)

9. 612 laboratory confirmed MDR-TB patients began MDR-TB treatment in 2011.*(4)* Since some were confirmed in prior years, this number is larger than the 465 Georgia confirmed in 2011. The WHO annual data collection form doesn't ask what proportion of the 465 began treatment.

PROGRESS AND REMAINING GAPS

Georgia's first MDR-TB cohort began treatment in 2008. The number of MDR-TB patients started on MDR-TB treatment in 2011 exceeded the numbers confirmed that year because 125 were empirically treated, and 137 were confirmed in prior years.[10]

Georgia achieved universal access to MDR-TB treatment in 2009. However, a treatment completion rate is not high and nearly one third of the 2009 cohort was lost to follow up, not evaluated, or transferred with no final outcome obtained.1 The country uses WHO reporting forms except that interim outcomes (at 6 months) are not routinely collected, so the timing of loss to follow up, death or failure is unknown. The Global Fund project supports food vouchers for treatment adherence and transportation reimbursement, for all patients but due to low treatment compliance, only two third of the MDR-TB patients receive food voucher while transportation cost is provided for all patients. The extent to which patients' social, psychological or economic needs are systematically assessed and addressed is unknown. Barriers to treatment adherence by MDR-TB patients have not been fully explored.

The GLC mission1 in June 2012 found that nurses in prisons have insufficient support and time for administering MDR-TB medicines. This results in patient refusals, treatment interruption and substandard therapy. The GLC mission raised the concern that substandard regimens administered in prison increase the risk of acquired drug resistance generating XDR-TB.

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

ACTIVITIES

a. Conduct operational research to Identify underlying reasons for loss to follow up among MDR-TB patients and determine to what extent a fully ambulatory model could increase adherence.
b. Implement cohort analysis for interim outcomes on a quarterly basis, for use in case and program management, and as a tool to rapidly detect and resolve problems. Improve MDR-TB recording system to be able to provide interim outcomes (sputum culture conversion, death, loss to follow up).
c. Develop system for palliative care for incurable M/XDR-TB patients
d. Develop and implement SOPs for the administration of TB medicines in the penitentiary system, to ensure proper number of drugs are regularly taken and side effects are promptly detected and managed.
e. Improve prison TB recording according to second line drug (SLD) treatment start date, and use registry data to analyze interim and final outcomes.
f. Organize annual mission of international experts to review the care and treatment program for MDR-TB.

2.3. ENSURE AN UNINTERRUPTED SUPPLY OF QUALITY ASSURED FIRST AND SECOND LINE DRUGS

OUTPUT INDICATOR AND TARGET

In 2015,

- No stock outs of first line drugs at central or peripheral levels (Baseline 2011: no)
- No stock outs of second line drugs at central or peripheral levels (Baseline 2011: no)

PROGRESS AND REMAINING GAPS

The drug management system has been centrally managed from the National TB Center using quality-assured first and second line drugs procured from the Global Drug Facility. TB drugs have been distributed by the NCTBLD through its central storage at the Central TB hospital in Tbilisi, and regional storages at TB facilities. In 2011, there were no stock-outs (except during the global shortage of two second-line drugs, which were replaced with alternatives so there were no interruptions in treatment).

This well-functioning system faces two possible sources of disruption.[17] First, funding for the entire drug supply is from the Global Fund project, and there is no national plan for medicines procurement after 2015 when the Global Fund project ends. (Even once local funding is secured, the GDF medicines are not registered in the country, and there are basically no quality assured TB medicines on the local market.)

The second—and more immediate—challenge is privatization being carried out without clear definitions of responsibility for the distribution of TB medicines. Private hospitals normally manage their drug supply through local pharmacies and small regional wholesalers. The June 2012 GDF mission expressed concern that the MOH is considering a plan to shift the responsibility for drug management from the NCTBLD to NCDC which currently has neither the experience nor the infrastructure.[17] The mission found that general hospitals are eliminating the positions of regional TB pharmacists responsible for stock management and reporting. As a result, data entry into national electronic TB register had already slowed down to the point where it had become challenging to collect TB medicines pipeline data needed for accurate management of the drug supply. Citing the uncertainty due to the privatization, central pharmacy at NCTBLD had stopped conducting supervisions.

In Georgia, first line TB drugs are available in private pharmacies without a prescription.[10, 22] A 2012 KAP study conducted by the TPP revealed that 14% of former prisoners had received self-treatment with anti-TB medications, namely with Streptomycin (10.7%), Rifampicin (1.7%) and Isoniazid (0.8%).[23]

Pediatric formulations are provided by GDF grant, and 100% of TB patients are treated with fixed dose combination (FDCs) formulations.[10]

ACTIVITIES

a. Develop a detailed plan listing the roles and responsibilities for all aspects of drug procurement and management, and a monitoring plan in the context of the ongoing health reform
b. Along with Health Strategy improvements in drug supply, introduce regulation to prohibit sale of all antibiotics (including TB medicines) without a prescription
c. Coordinate an in-depth market and pharmaceutical sector assessment to inform TB procurement and supply chain management strategy after 2015 when GF support ends. Assess the availability of public and private capacity and options for supplying quality-assured TB medicines with the government funding (or other than GF funding) – legal and regulatory basis, medicines registration, selection, procurement regulations and practices.
d. Develop SOPs for drug management, including TB and ancillary medicines supply, supervision, data management by private facilities, to avoid stock outs and expired drugs. This should be done using current paper-based system (not waiting for an electronic system to be developed and implemented).
e. Organize annual mission of the Green Light Committee experts

2.4. IMPROVE QUALITY OF TB CARE IN THE CONTEXT OF HEALTH REFORM

PROGRESS AND REMAINING GAPS

As a result of privatization, 65 TB service delivery points were established within private health facilities in 2011, and mandated to ensure uninterrupted provision of TB services. These facilities are part of five private health networks which operate in one or more of the country's 11 regions.

A MoLHSA/USAID TPP survey in May 2012 found that some dispensaries have not actually been moved, but remain in old facilities despite lack of adequate working conditions. Others have been co-located in general medical facilities, but are not functionally integrated. Few TB doctors have access to a computer or the internet. Many primary care practitioners (PCPs) consider TB service delivery beyond their competencies and are reluctant to actively collaborate with TB staff. There is also reluctance on the part of the TB doctors to re-locate to private health facilities.

The move towards integrated TB service delivery model is bringing new players to TB control with varying levels of experience and expertise in this field. There is a lack of clarity in roles and responsibilities of central and regional structures including MoLHSA, NCDC, NCTBLD, regional coordinators.

The GF project has supported supervision by NCTBLD at each level, but funds have not been identified to sustain this after 2015. Furthermore, supervision is not

sufficient for ensuring high quality TB care. TB services have the opportunity to adopt the broader health system's process oriented quality improvement methods. Continuous improvement of health service quality is among the National Health sector reform priorities.[2] All National stakeholders with some responsibilities in TB diagnosis, prevention and treatment should develop a common agenda for setting and maintaining high quality TB care standards. Indicators in this plan provide a minimum set of quality measures.

Geographic access is an issue where lack of transportation or long distances make clinic-based DOT difficult for patients. A KAP survey conducted by the USAID TB Prevention Project in summer 2012 found that 44% of patients must travel one to three hours to access TB services.[23] It's much easier to access primary care facilities and two third of patients can do so within 30 minutes. The May 2012 MoLHSA/USAID TPP survey found that TB doctors are only available once a week or two weeks per month in four sites.

There is no financial access barrier to specialized TB services. TB services remain free of charge to patients as long as they are provided by TB doctors and nurses. Patients can freely access TB services by referral from a primary health care (PHC) provider. However, patients who do not have insurance and are not beneficiaries of the village health care program should pay out-of-pocket to see the primary care provider, who then will decide if referral is necessary.

People living below the poverty line receive state subsidized vouchers to purchase insurance. In September 2012, the Government of Georgia extended insurance coverage to include children under six years of age, students, and people over 65 years of age. An estimated half the population is now enrolled in the State funded insurance scheme. The rest of the population is responsible for buying their own insurance or paying out-of-pocket for health services.

INDICATORS AND TARGETS

By 2015,

- 100% of health facilities involved in TB care have TB care protocols elaborated
- >50% of health facilities providing TB care conduct TB clinical audits annually

(Baseline unknown)

ACTIVITIES

a. Strengthen institutional capacity of private health care providers for TB care provision through continuous performance evaluation and professional feedback
b. Develop internal quality improvement systems for TB services in general medical facilities, to include local protocols based on National TB Guidelines and quality standards, job aids, training, audits, satisfaction

surveys of TB service clients[24] Consider monetary or other incentives to providers (certificates of merit, etc).

c. Evaluate current accountability and contracting mechanisms between the payer (the State) and the private providers to ensure quality. Elaborate simple reporting system in line with the NTP reporting requirements (see also Strategic Areas 3.2 and 3.3)
d. In line with the Georgia *National Health Care Strategy,* include TB quality of care measures and minimum requirements in accreditation of private health facilities

STRATEGIC AREA 3. EFFECTIVE GOVERNANCE, ADEQUATE FINANCING AND MONITORING OF GEORGIA'S TB RESPONSE

RATIONALE

Stewardship is one of the critical building blocks of any health system, and requires management, oversight, policy guidance, collaboration, regulation, and accountability.[25]

3.1. STRENGTHEN GOVERNANCE AND COORDINATION OF GEORGIA'S TB RESPONSE

PROGRESS AND REMAINING GAPS

MoLHSA oversees implementation of the State TB Management Program and is responsible for ensuring adequate access to and quality of TB services. National Center for Tuberculosis and Lung Diseases is considered the center for clinical excellence and the leading agency responsible for setting and implementing TB care quality standards. In addition to clinical functions, and its central unit was recognized by a 2009 Ministerial decree as the leading entity of the National TB Program. Recent reforms aimed at improving efficiency of the system resulted in the transfer of the part of TB surveillance role to the NCDCPH. NCDCPH epidemiologists trace contacts of smear positive patients and organize their timely referral for diagnosis and treatment. NCTBLD remains responsible for reporting on TB related statistics at national and international levels.

Until 2012, 11 regional coordinators reported directly to the NCTBLD, and also served as directors of stand-alone TB dispensaries and supervisors of TB staff in their region. They have played key roles in supervision, laboratory oversight, surveillance, and drug management. Now part of their non-clinical time is supported by the NCTBLD and part by the NCDC. The regional coordinators find it difficult to effectively respond to the dual-role related administrative and reporting requirements, and report that lack clear understanding of the ongoing processes in terms of the TB program implementation and their specific functions.

Private general hospitals/outpatient clinics which became part of TB service delivery network early 2012 are responsible to meet the State TB management program

requirements: maintain a full time TB team composed of a physician and a nurse, ensure unlimited access to all diagnostic services accept sputum microscopy and culture. The program does not require them to play any role in adherence support, supervising implementation of DOT by primary care providers and TB reporting/recording quality assurance.

MoLHSA, jointly with the Medical Division of the Penitentiary Department of the Ministry of Corrections and Legal Advice (MoCLA) bears the full responsibility for TB control activities in prisons, per a 2010 joint decree.

While integration of TB dispensaries is slated to occur in Tbilisi, there is not yet a detailed plan for division of responsibilities and lines of authority among the general medical facilities, NTBC, NCDC.

ACTIVITIES

a. Revise and redefine roles and responsibilities of national and regional structures in planning, implementing and monitoring the country's TB program in the context of the ongoing reforms.
b. Introduce effective mechanisms to improve coordination between MoCLA and MOLHSA in controlling TB within the prisons, and continuity of TB care upon release
c. Provide technical support to strengthen management capacity of MOLHSA, NCDCPH, NCTBLD and other structures involved in the National TB response. Facilitate effective operational planning of NTP interventions.
d. Conduct operational research to identify barriers and motivators for private providers to provide TB services

3.2. ACHIEVE SUSTAINABLE FINANCING OF THE COUNTRY'S TB RESPONSE BY MAXIMIZING THE USE OF EXISTING RESOURCES AND MOBILIZING ADDITIONAL RESOURCES, AND INCREASING DOMESTIC FUNDING.

INDICATORS AND TARGETS

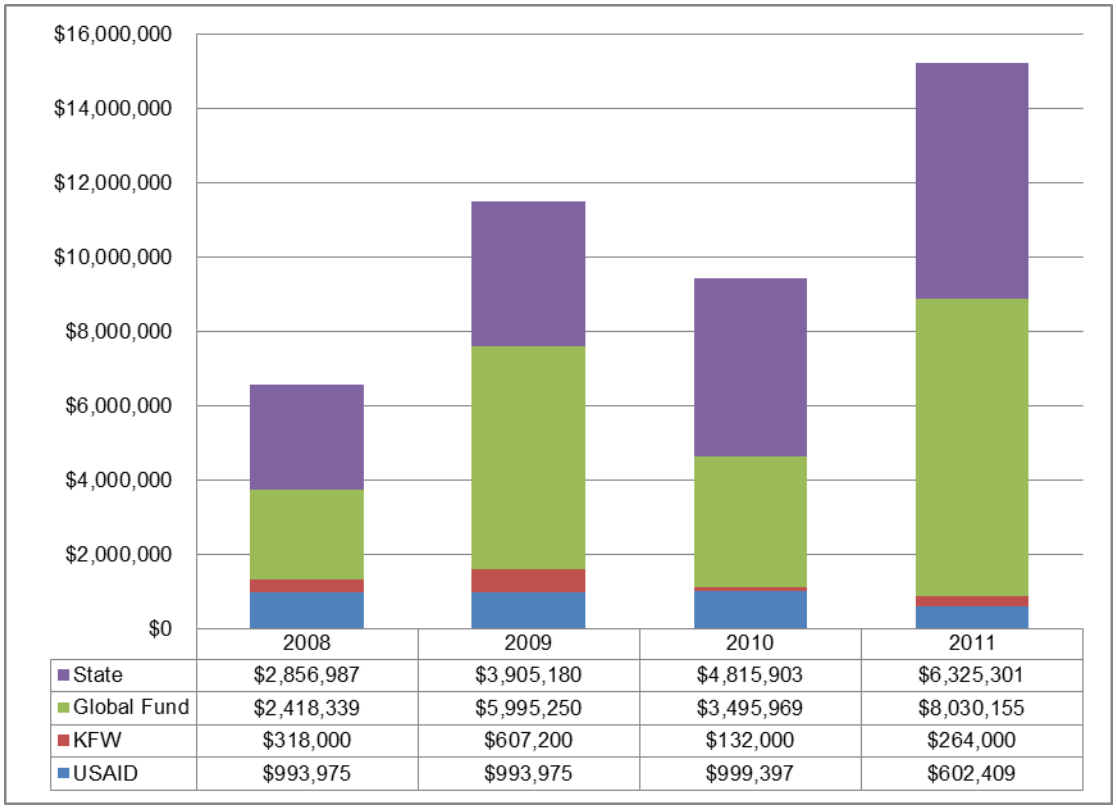
By 2015,

- the gap in financing of core elements of TB control will be reduced
- ≥ 70% of total annual TB funding needs are financed by domestic sources (Baseline in 2011: 41%)

PROGRESS AND REMAINING GAPS

As shown on figure 7, the Government's contribution to TB budget in 2011 doubled since 2008, but slightly decreased in 2012. In 2011, the State's 10.5 million GEL comprised 65% of the total TB budget (See figure 7).

FIGURE 7. TB FUNDING SOURCES IN GEORGIA, 2008-2011



	2008	2009	2010	2011
State	$2,856,987	$3,905,180	$4,815,903	$6,325,301
Global Fund	$2,418,339	$5,995,250	$3,495,969	$8,030,155
KFW	$318,000	$607,200	$132,000	$264,000
USAID	$993,975	$993,975	$999,397	$602,409

Sources: *MoLHSA, National Health Accounts, GPIC*

MoLHSA pays a fixed cost per patient diagnosed and treated for TB, depending on the complexity of the patient service. Depending on whether the private networks perceive these rates as adequate compensation, the networks will have an incentive to provide TB services.

ACTIVITIES

a. Develop a plan for self sufficiency of the Georgian Government to continue free access to TB services after the Global Fund project is completed in 2015
b. Analyze TB control operational costs (including sufficient staffing, monitoring and evaluation activities, drugs and new diagnostics) and present a proposal to the Ministry of Finance for increased domestic financing
c. Advocate to establish a line item in the domestic budget for the procurement of first and second line drugs through the GDF to ensure provision of quality drugs are low cost

d. Identify and evaluate options for redirection of existing domestic TB resources for more cost effective investment.
e. Analyze options for inclusion of TB diagnostic and treatment services in the country's basic health package and essential drugs covered by the national health insurance scheme

3.3. COLLECT, ANALYZE AND USE MONITORING, EVALUATION AND SURVEILLANCE DATA TO UNDERSTAND TB EPIDEMIOLOGY AND IMPROVE TB PROGRAM PERFORMANCE.

RATIONALE

Well-designed health management information systems (HMIS) are critical for effective program monitoring, and evidence-based policy making. The TB program also needs a system for communicating clinical information for patient management (culture and DST results), as well as for managing the program (TB drug management, budgeting and reimbursement, supervision, monitoring implementation of this plan. Emergence of new players with varying levels of TB experience, and the central role of for-profit medical facilities make the need for effective monitoring even more acute.

PROGRESS AND REMAINING GAPS

TB recording and reporting is largely paper based. The web-based TB system in use (SAFE/MEDES) requires external consultants to make any modification. Existing software does not comply with the country's new e-Health strategy. The country's HMIS strategy provides an opportunity to improve TB clinical and program management, but currently lacks any detail on the unique needs of a TB management information system.[26]

INDICATORS AND TARGETS

By 2015

- 100% reporting units submitting timely reports according to national guidelines (Baseline: 100% in 2011).

ACTIVITIES

a. Analyze the current TB information system, and develop recommendations for improvement.
b. Develop an M&E plan for Georgia's TB response, harmonized with the national Health Strategy, National HIV strategy, GF project, and WHO recommendations and data collection forms.[10,27]
c. Support the development and implementation of a TB module within HMIS that serves the needs of the TB program including patient support revisions to

enable monitoring of program performance, evaluate the implementation of this Strategic Plan, further policy development. (See reference 28.)

d. Conduct a national TB program review jointly by a Georgian and international team

STRATEGIC AREA 4: HUMAN RESOURCES AVAILABLE AT EACH LEVEL WITH THE PROFESSIONAL COMPETENCE AND SUPPORT TO MEET GEORGIA'S TB RESPONSE PLAN'S TARGETS

RATIONALE

TB control depends on health workers who are well trained, motivated, supported, sufficient in numbers, and appropriately distributed geographically and by type of service.[29]

PROGRESS AND REMAINING GAPS

The *National Health Care Strategy* describes steps to remedy the nursing shortage and improve the qualifications of health personnel, including enhancing doctors' certification tools, establishing a nurse certification program, and accrediting post graduate training programs. The TB specialty has now been combined with pulmonology, which is expected to broaden the expertise of practitioners and make the profession more attractive to younger doctors. Family physicians have taken a short term residencies to enhance their TB care skills. The *National Health Care Strategy* also calls for the development and implementation and regular update of evidence-based practice guidelines, and a clinical audit system to encourage a systematic evaluation of the quality of care.

Georgia currently faces several challenges in assuring appropriate human resources for TB control. First, health reform has altered the vertical chain of command, but new lines of supervisory accountability have not been specified for TB patient care functions or overall TB program management. The training needs for new health care personnel (such as primary care providers) and new agencies providing TB control services (such as NCDC) have not been fully assessed or met. Privatization means that the decisions on TB staffing are now the responsibility of private facilities that have absorbed TB dispensaries. The GDF mission in June 2012 was informed of cuts in nurses, data collectors, pharmacists, and drivers. Brief interviews with TB dispensaries and analysis of TB forms suggest that the time for receiving the diagnostic results generally increased, and there had been an increase in treatment interruptions because of lack of staff for DOT and follow-up.[17]

For development of laboratory staff, see Strategic Area 1. For NGO's see Strategic Area 6

The *National Health Care Strategy* calls for the regulation of the penitentiary health care system using public sector norms and regulations, including training prison medical staff.

4.1. ENSURE HUMAN RESOURCES ARE AVAILABLE TO PERFORM ESSENTIAL TB FUNCTIONS AT NATIONAL, REGIONAL AND DISTRICT LEVELS TO MEET PATIENT CARE AND TB PROGRAM PERFORMANCE TARGETS

INDICATORS AND TARGETS

By 2015,

- 95% of TB service delivery points provide excellent/good performance during performance review visits (Baseline unknown)
- 95% of penitentiary facilities with appropriate practices for TB detection and DOT as documented during performance review visits (Baseline unknown)

ACTIVITIES

a. As part of the country's human resource development plan, conduct a task analysis for each TB control function, by level of the health system and category of health worker. Consider new tasks (such as contact investigation by NCDC, as well as ongoing tasks).
b. Define needed number, distribution and cadre of staff to conduct the tasks identified; compare to current staffing pattern. Consider which tasks can be shifted to less specialized personnel, and when cross training primary health care staff is appropriate (such as in low burden rayons or at the village level).
c. Train primary care physicians and nurses in TB early detection and follow up
d. Define competencies for all levels of TB service providers, and develop a training plan in coordination with professional associations and other groups that provide training
e. Train and certify TB specialists as pulmonologists to be able to provide services such as Practical Approach to Lung (PAL) health[13] in order to improve patient access to diagnosis and treatment of all pulmonary conditions, and provide career opportunities to the TB specialists.
f. Strengthen capacity of private health care sector (network managers, hospital managers and clinicians, PHC facility managers and clinicians) to ensure access to quality TB diagnosis and treatment.
g. Train all prison staff (doctors, nurses and security staff) on TB, MDR-TB and how to prevent TB transmission

STRATEGIC AREA 5. PREVENT TB TRANSMISSION IN HEALTH FACILITIES AND PRISONS

RATIONALE

Critical infection control measures are to rapidly diagnose TB and MDR-TB, and treat patients so they are no longer infectious (see Strategic Area 1). For TB infection control, priority should be given to settings where TB is drug resistant, exposed people are especially vulnerable to developing disease if infected or dying if

they develop TB (such as people living with HIV), exposure is of longer duration (such as hospitals or any setting with diagnostic delays), control measures are lacking, or a large number of people are exposed.

5.1. STRATEGIC OBJECTIVE: MINIMIZE THE RISK OF TB TRANSMISSION IN HEALTH CARE SETTINGS AND PRISONS THROUGH ADEQUATE IC MEASURES

IMPACT INDICATOR AND TARGET.

By 2015:

- By 2015, the ratio of TB notification rates (health care workers versus general population) will be ≤1 (Baseline unknown)

OUTPUT INDICATOR AND TARGET.

By 2015,

- 80% of State TB hospitals, HIV care sites, private general medical hospitals and clinics, and prisons with facility-specific infection control plans in line with national standard operating procedures, based on facility-specific risk assessments (Baseline unknown).

PROGRESS AND REMAINING GAPS

Georgia's TB infection control regulatory framework consists of one Minister's Decree issued in 2010 which includes only two requirements: separate entries for TB services in general health care facilities, and mechanical ventilation and negative pressure in staff rooms providing TB services and waiting areas with TB patients. There is National TB Infection control working group including representatives from NCTBLD, NCDC, penitentiary sector and partner organizations, but it has not been approved officially. A National Plan for TB-IC developed in 2010 has no budget, thus implementation process has been very slow.

With the support of the State budget as well as donor and partner organizations, Georgia has improved TB infection control in the following facilities: central TB hospital in 2008, MDR-TB department in 2012, National Reference Laboratory, and the TB colony in Ksani prison.

A TB risk assessment in the regional facilities was conducted jointly by MoLHSA and USAID/TPP early 2012. The assessment found that facilities lack SOP for cough monitoring or triage/separation of infectious patients. Mechanical ventilation and upper room ultraviolet germicidal irradiation lamps are not available at all TB treatment sites. The Global Fund project supports procurement of surgical masks for infectious TB patients and certified respirators for health care workers providing TB services. Fit testing for staff wearing respirators is available only at the NCTBLD hospital.

Nosocomial TB transmission is not just a concern in TB facilities. Whenever the diagnosis of TB is delayed in a patient admitted to a general hospital or attending a general medical clinic, there is the risk of spread to staff and other patients. Cough etiquette is not commonly practiced, and procedures are not uniformly in place for promptly identifying, separating, and triaging people with TB symptoms to receive services quickly so their time in the health facility is minimized.

Nosocomial transmission is also of great concern in settings serving immunocompromised patients. The National HIV/AIDS center is not designed to mitigate the risk of nosocomial TB transmission.3

The State budget covers annual health worker TB examinations but these are not mandatory, and there is no central registry for health care worker TB surveillance data. Penitentiary workers do not have routine TB screening. There are no national level indicators and no monitoring checklist for TB infection control.

The *National Health Strategy* calls for the development of modern infection control standards for medical facilities in the prison and civilian sectors, to be included in facility accreditation requirements.

ACTIVITIES

a. Review and revise IC control regulations and standards to be consistent with WHO recommendations to prevent nosocomial TB transmission in health facilities
b. Develop a Standard Operational Manual for TB infection control for health facilities and prisons, to include standards, indicators, and a monitoring checklist
c. Introduce regular mandatory TB screening for all health care and prison workers.
d. Assess and upgrade physical infrastructure to permit safe TB service delivery at all facilities providing TB care
e. Review and upgrade national standards for respiratory protection, to include a comprehensive program with training, fit testing, procuring, distributing and maintaining sufficient quantities of approved respirators.

STRATEGIC AREA 6: EMPOWER TB PATIENTS AND COMMUNITIES

RATIONALE.

ACSM refers to advocacy, communication and social mobilization. Advocacy works to keep governments strongly committed to TB control efforts and to influence decision-makers to increase resources invested in TB control.[22] Advocacy is discussed in Strategic Objective 3.2.) Communication aims to raise awareness, improve knowledge and influence positive changes in attitudes and practices among specific groups. Social mobilization is the process of building alliances and engaging communities to bring visibility and a sense of urgency to TB and to stimulate demand for TB services.[22]

INDICATOR AND TARGET

By 2015,

- 50% of patients will be provided DOT by trained community members (Baseline unknown).

PROGRESS AND REMAINING GAPS

Social mobilization efforts have included trainings for journalists, annual World TB Day activities, concerts, sports events and the recruitment of famous people as a national "TB ambassador." For TB communication, the NCTBLD and partners have developed print media targeting TB patients and various risk groups, video, television and radio segments, and materials and training for health care providers. The national ACSM has not been fully implemented.[22]

Georgia still utilizes initial hospitalization for most TB patients, while WHO recommends mainly ambulatory models even for MDR-TB patients. A key component of ambulatory care is community involvement, but there are few NGOs involved in TB control, and weak capacity of community based organizations to provide TB advice and support patients and their families.

Involving communities can also reduce stigma, which remains high in Georgia. A KAP survey conducted in 2012 by the USAID TPP found that all but 37% of university students and teachers would try to hide their illness from others.

6.1. ESTABLISH COMMUNITY-BASED DOT TO SUPPORT SUCCESSFUL TREATMENT

ACTIVITIES

a. Support local NGOs in assisting patients to adhere and complete TB treatment through small grants programs aimed at improving demand for and quality of TB services
b. Establish community-based TB support service (to supplement the current clinic-based DOT for patients who are reluctant or unable to come to clinic) by utilizing community and faith-based organizations, and task-shifting to trained community members with supervision by health services.
c. Provide trainings for volunteer treatment supporters on adherence counseling and interpersonal communication.
d. Engage the National Service Probation and the Penitentiary Department to implement a treatment continuation program for newly-released prisoners. Enlist NGO partners already working in the penitentiary system to monitor and facilitate follow-up and communication between the penitentiary and civilian services.
e. Assess and improve materials for TB patients and family members on treatment adherence.

6.2. REDUCE TB RELATED STIGMA THROUGH COMMUNICATION AND SOCIAL MOBILIZATION

ACTIVITIES

a. Provide technical assistance and small grants to local NGOs and faith based organization for improving TB awareness and fighting TB stigma by means such as concerts, shows, sport activities, and annual World TB Day
b. Assess and improve materials for prison inmates and staff on timely detection of TB symptoms and how to access and complete treatment.
c. Evaluate the knowledge, attitudes and practices of key target groups
d. Consistent with the WHO guidance on ethics of tuberculosis prevention, care and control[30], adopt the TB Patients' Charter in the relevant Georgian legislation.

STRATEGIC AREA 7. ENHANCE TB/HIV COLLABORATION TO REDUCE THE BURDEN OF TB IN PEOPLE LIVING WITH HIV AND THE BURDEN OF HIV IN TB PATIENTS

RATIONALE

TB and HIV programs should collaborate to deliver integrated services to address the interface of the TB and HIV epidemics.[31] (See also infection control in Strategic Area 7)

IMPACT INDICATOR AND TARGET

By 2015:

- Less than 2% TB patients will be HIV-positive (Baseline in 2011: 2% of TB patients with known HIV status)

7.1. REDUCE THE BURDEN OF HIV IN TB PATIENTS BY PERFORMING HIV TESTING FOR ALL TB CASES, AND IMPROVING SURVIVAL AMONG HIV-POSITIVE TB PATIENTS

OUTCOME INDICATOR AND TARGET

- In the 2015 cohort of HIV-positive TB patients, 60% will be successfully treated (Baseline in the 2010 cohort of new patients: 40%)

OUTPUT INDICATOR AND TARGET

By 2015:

- 90% of notified TB cases tested for HIV (Baseline in 2011: 66%)
- >95% of HIV-positive TB patients receive antiretroviral therapy (ART)(Baseline in 2011: 76%)

- Close to 100% of HIV+ patients receiving co-trimoxazole (Baseline in 2011: 56%)

PROGRESS AND REMAINING GAPS

The proportion of TB patients with known HIV status has increased from 10% in 2005 to 45% in 2011. In 2011, 2% of the TB patients with known HIV status were HIV-positive.

WHO estimates that the incidence rate of HIV-positive TB has been rising in Georgia from 2009 to 2011 although it remains below Europe's rate.[9] The National AIDS program found there were 78 people living with HIV in 2011 who began TB treatment, whereas the TB data system recorded 50.[10]

WHO recommends that all TB patients living with HIV have rapid testing for MDR-TB.[32] Georgia's laboratory algorithm includes line probe assay for all smear positive patients, as well as liquid and solid media. The national HIV care center in Tbilisi conducts Xpert MTB/RIF testing which can yield results even in smear negative patients. Yet Georgia reported that only about half of its 50 HIV-positive TB patients notified in 2011 had testing for MDR-TB.[10]This is of great concern given the possibility of rapid, highly fatal outbreaks among people living with HIV.

In the 2010 cohort of 35 new and previously treated HIV-positive patients, 15 (43%) had been previously treated, compared to just over one quarter of the country's TB cases as a whole. Among the 20 new HIV-positive TB patients, only 40% were successfully treated; 25% failed treatment or were transferred to MDR-TB treatment (Table 3). The treatment outcomes for the 15 previously treated HIV-positive TB patients were substantially worse: 73% failed treatment or transferred to MDR-TB treatment.

TABLE 3. OUTCOMES FOR HIV-POSITIVE TB PATIENTS WHO STARTED TB TREATMENT IN 2010

	registered	treat success	died	failed*	defaulted	not evaluated
all new (#)	20	8	4	5	1	2
(%)		40%	20%	25%	5%	10%
retreatment (#)	15	2	1	11	1	0
(%)		13%	7%	73%	7%	0%

Source: reference 10

ACTIVITIES

a. Offer diagnostic counseling and testing to all TB patients at the start of TB treatment
b. Determine reasons for the high proportion of previously treated patients and the poor treatment outcomes for HIV-positive TB patients

c. Ensure rapid tests for drug resistance are performed when TB is suspected, and TB treatment regimens promptly modified to ensure effective TB treatment.
d. Ensure timely initiation (according to the EB guidelines) of antiretroviral therapy in TB patients.
e. Assess barriers to timely ART initiation and opportunities for improved access
f. Support HIV-positive TB patients to adhere to ART via measures such as home-based adherence monitoring
g. Provide technical support to the TB and HIV programs to strengthen mechanisms for collaboration and information exchange

7.2. REDUCE THE TB BURDEN IN HIV-POSITIVE PEOPLE AND IDUS

INDICATORS AND TARGETS

By 2015,

- 100% of people living with HIV enrolled in HIV care are screened for TB (Baseline in 2011: 387, or 100%)
- #/% starting isoniazid preventive therapy, once active TB disease is excluded (Baseline in 2011: 61, or 16% of total number of people living with HIV enrolled in care)

PROGRESS AND REMAINING GAPS

Currently IDU screening is supported by the GF grant, which is implemented by the local NGOs contracted out by NCTBLD. In 2011, 424 new HIV infections were detected and over 90% were linked to HIV clinical care. That year, Georgia had an estimated 5000 people living with HIV, of whom 3033 were registered. Heterosexual transmission has replaced intravenous drug use as the major transmission mode. [33] There has been an extensive cooperation between the National HIV and TB programs that resulted in a joint TB/HIV strategy and clinical guidelines for managing TB and HIV co-infection. However, the joint efforts need to be strengthened and continued to address those major public health concerns effectively.

ACTIVITIES

Activities include:

a. Strengthen capacity of the Georgia Harm Reduction Network to ensure early recognition of TB by social workers and counselors working with IDUs
b. Routinely detect and treat latent TB infection in people living with HIV

8. IMPLEMENTATION OF THE NATIONAL TB STRATEGY FOR 2013-2015

The National Tb Strategy will be implemented through close collaboration between all stakeholders. The implementation will be coordinated by the NTP central unit as identified by MoLHSA. The detailed plan of activities including targets and the implementation timeline is presented in annex 6. MoLHSA and the NTP central unit will mobilize local and international technical assistance to guide the implementation and promote evidence-based decision making and planning. The technical assistance plan is allocated in annex 5.

8.1. NECESSARY FINANCIAL RESOURCES

WHO stop TB planning and budgeting tool was used to estimate necessary financial resources and assess funding gap to be covered for a full scale implementation. Default values provided by WHO were applied for calculating costs of treatment, diagnostics, infectious control measures, office equipment, personnel and use of general health services. Country-specific unit costs were applied for per diems, transportation costs and local and international TA. The number of potential beneficiaries is determined according to the epidemiological trend and is as follows (Table 4):

TABLE 4: ESTIMATED NUMBER OF POTENTIAL BENEFICIARIES

Potential Beneficiaries	2013	2014	2015
Estimated number of new TB patients	4,832	4,966	5,105
Estimated number of prisoners to be screening for TB	15000	15000	15000
Estimated number of health care workers to be screened	350	400	500
Estimated number of contacts to be investigated	4000	4000	4000
Estimated number of VCT and PMTCT clients testing positive	134	145	155
Estimated number of MDR and XDR patients that require incentives	532	589	646

Total estimated need for the three-year period amounts to US $**43,313,182**.

For financial gap analyses the budget required for implementation of the National TB Strategy for 2013-2015 was compared with the available resources. The TGF round 10 Georgia grant, if continued successfully will allow for maintaining universal access to TB diagnosis and treatment services. USAID TPP will provide its input in human resource development and health systems strengthening. The state budget will cover operational costs related to TB service delivery and support NTP management entities. Increased funding will be required to improve motivation of private health care providers and introduce stringent infectious control measures at general hospitals providing TB care. Table 5 outlines potential funding sources, which is based on the historical budget and the list of activities currently financed within the

State, GF and USAID programs. Significant advocacy will be required to mobilize needed financial resources and to fill the existing gap.

TABLE 5. SUMMARY OF FUNDING SOURCES AND FUNDING GAPS PER ACTIVITY

Fiscal Year	**2013**	Expected Funding			
	Budget Required	Government	Global Fund	Other Grants	Gap
Improving diagnosis	677,922	254,864	303,600	43,558	75,900
Patient support	1,018,598	-	649,295	269,032	100,271
First-line drugs procurement and management	296,096	-	234,001	-	62,096
M&E	193,220.00	-	30,366	132,488	30,366
Program management and supervision	173,492	-	60,331	52,436	60,725
HRD: Staff	3,523,951	1,598,410	110,688	-	1,814,853
HRD: International technical assistance	235,321	-	32,936	189,412	12,973
HRD: Training	283,224	-	76,160	150,000	57,064
Collaborative TB/HIV activities	179,746	-	8,872	-	170,874
MDR-TB: Second-line drugs	3,484,954	-	1,647,573	-	1,837,381
High risk groups	145,480	145,480	-	-	-
Infection control	747,500	-	30,912	148,000	568,588
Involving all care providers: PPM/ISTC	51,403	-	-	51,403	-
Community involvement	23,596	-	-	23,596	-
Operational research	84,500	-	-	68,500	16,000
General use of Health Services	3,016,663	3,016,663	-	-	-
Total Budget	**14,135,666**	**5,015,417**	**3,184,734**	**1,128,425**	**4,807,091**
Fiscal Year	2014	Expected Funding			
	Budget Required	Government	Global Fund	Other Grants	Gap
Improving diagnosis	686,578	272,586	303,600	34,492	75,900

Patient support	854,574	-	649,295	163,832	41,447
First-line drugs procurement and management	304,368	-	234,001	-	70,368
M&E	166,426	-	30,366	26,426	109,634
Program management and supervision	173,492	-	60,331	52,436	60,725
HRD: Staff	3,622,398	1,598,410	110,688	-	1,913,300
HRD: International technical assistance	240,000	-	32,936	150,000	57,064
HRD: Training	256,766	-	76,160	93,680	86,925
Collaborative TB/HIV activities	188,534	-	8,872	-	179,662
MDR-TB :Second-line drugs	3,852,877	-	1,647,573	-	2,205,304
High risk groups	136,600	136,600	-	-	-
Infection control	747,500	-	30,912	148,000	568,588
Involving all care providers: PPM/ISTC	48,382	-	-	48,382	-
Community involvement	24,255	-	-	24,255	-
Operational research	68,000	-	-	68,000	-
General use of health services	3,075,575	3,075,575	-	-	-
Total Budget	**14,363,431**	**5,083,171**	**3,184,733**	**809,503**	**5,286,024**
Fiscal Year	**2015**	**Expected Funding**			
	Budget Required	Government	Global Fund	Other Grants	Gap
Improving diagnosis	704,795	290,803	303,600	34,492	75,900
Patient support	872,584	-	649,295	205,912	17,377
First-line drugs procurement and management	312,871	-	234,001	-	78,871
M&E	14,476	-	30,366	14,476	-30,366
Program management and supervision	173,492	-	60,331	52,436	60,725
HRD: Staff	3,723,596	1,598,410	110,688	-	2,014,498
HRD: International technical assistance	240,000	-	32,936	150,000	57,064
HRD: Training	305,103	-	76,160	109,626	119,317
Collaborative TB/HIV activities	199,793	-	8,872	-	190,921
MDR-TB: Second-line drugs	4,220,801	-	1,647,573	-	2,573,228

High risk groups	149,080	149,080	-	-	-
Infection control	619,500	-	30,912	20,000	568,588
Involving all care providers: PPM/ISTC	43,646	-	-	43,646	-
Community involvement	24,933	-	-	24,933	-
Operational research	81,000	-	-	65,000	16,000
General use of health services	3,128,416	3,128,416	-	-	-
Total Budget	**14,814,085**	**5,166,709**	**3,184,733**	**720,520**	**5,742,123**

ANNEX 1. RELATIONSHIP TO OTHER GEORGIA AND INTERNATIONAL PLANS AND STRATEGIES

	Georgia			International	
Strategic areas of this plan	**Health Strategy**	**TPP**	**GF**	**WHO Stop TB Strategy****	**EURO Roadmap**
1. Universal access to high quality TB diagnostic services	2.4, 4.2	1.1-1.3	2	1B. 2B. MDR 2C. Contacts	
2. Universal access to high quality TB care and patient support	1.4, 2.4	2.4	3, 4	1C. 1D. Drug 2B. MDR 5. Community engagement	
3. Effective governance, coordination, financing of the national TB program	1.2, 1.3, 1.6, 2.1, 2.5, 4.1, 4.4, 5	1.3 2.1-2.3	1 6	1A, 1E 4. Engage all providers 5. Advocacy 6. Operational research	
4. Human resources development, supervision	2.2, 2.3	2.5	1	3A	
5. Infection control	4.2	3		3B	
6. Empower communities	3	1.4-1.5		5. Communication and social mobilization	
7. HIV	4.4*	2.4	5	2A	

*See also Strategic Priorities 2.2 and 3.1 of the *Georgia National HIV/AIDS Strategic Plan for 2011-2016*

***MDR-TB (2B) and prison (2C) are integrated throughout the plan*

ANNEX 2 MAPPING OF NATIONAL/REGIONAL ROLES IN CARRYING OUT ESSENTIAL NATIONAL AND REGIONAL TB CONTROL FUNCTIONS

Annex 2a. Mapping of National/Regional roles in carrying out essential national and regional TB control functions (as of October 2012)

TB control function	MoLHSA	MCLA	NCTBLD	NCDC	TB Service providers	Other
1. Diagnosis of TB						
Contact investigation			**X (as TB services provider)**	**X**	**X**	
Entry and mass screening		In prisons	In prisons			
Diagnosis in clinics		**X (through its physicians)**	**X**		**X**	
Laboratory*						
Lab network strengthening, develop SOP, training			NRL			
EQA of 8 peripheral labs performing smear microscopy			NRL			
Operation of the 8 peripheral labs				X		
Operation of 2 prison smear microscopy labs		X				
EQA of regional lab's culture performance			NRL			
EQA of NRL						SRL
Transportation of samples				X		
Transportation of samples in prisons			X			
Reporting results to TB Specialists			X	X		
Consumables and reagents			X	X		
2. Successful treatment						
DOT provision		X	X		X	
Monitor DOT (through DOT supervisors)			X	X (as per state program)		
Patient support			X		X	
Drug management*						
Forecasting			X			
Procurement			**X**			GPIC GDF
Quality monitoring	National Drug Regulatory Authority					
Storage						
Distribution of drugs			X		X	
Supervision			X			
Quality of Clinical care						
Inpatient care of complex TB cases			X			All TB hospitals
Clinical TB guidelines, SOPs for implementation	Guidelines accreditation		X			Professional associations

TB control function	MoLHSA	MCLA	NCTBLD	NCDC	TB Service providers	Other
	board					
Prison hospitals and clinics		X	X			
Consilium for drug resistant cases			**X**			
3. Governance, finance, monitoring						
National						
Adequate central TB management capacity for policy, planning, budgeting*	X	X				
A specific senior staff member is designated to be accountable for TB control nationwide*	Ministerial decree		X Decree #372/o			
Sufficient operational budget line item to carry out management functions*	x	x				
Results-based operational plan to implement Stop TB Strategy, supported by committed resources*	x	x				CCM
Reimburse on fee-for-service basis	x					SSA
Regional coordination			X	X		
Prison: NCTBLD and MCLA jointly bear the full responsibility[10]	X	X	X			
Supervision and monitoring of TB services		X	X			
Procurement of TB drugs, and drugs for treatment of side effects		X	X			GF
Clinical care		X	X			
Surveillance, M&E						
TB performance indicators are used in country's HMIS*						
Complete paper forms			X	X	X	
Enter data					X	
Clean, analyze, disseminate data			X	X		
Use data to improve program performance	X	X	X	X		
Reporting to WHO			X			
Make improvements to M&E system	X	X				
Drug resistance surveillance			NRL			
4. Human resources						
Performance supervision*						
of Regional TB coordinators			X	X		

10. Joint decree of MoLHSA and MoCLA, 2010

TB control function	MoLHSA	MCLA	NCTBLD	NCDC	TB Service providers	Other
of TB specialists in general health facilities					Facility management	
of village doctors identifying and referring patients with TB symptoms, providing DOT					Facility management and TB teams	
5. Infection control						
Physical infrastructure in hospitals	x					
IC planning, implementation in hospitals	x				Private facility managers	
IC planning, implementation in prisons		X	X			
6. Empower TB patients and communities						
ACSM activities	x	x	x	x	x	NGO's
7. HIV						
ART initiation and monitoring in TB patients	x		x			AIDS center

Notes:

(a) Numbers correspond to plan Strategic Areas

(b) * These functions are those emphasized by WHO in: Contributing to health system strengthening. Guiding principles for national TB programs. 2008 http://www.who.int/tb/publications/2008/en/index.htm

Annex 2b. Role map at local level (following path of the patient) as of Oct 2012

Patient pathway	PHC	TB specialist	Other
Identify patients with TB symptoms	x		
Referral to TB specialist	x		
Request sputum examination		TB doctor	
Sputum collection (including instructions to patient)		TB nurse	
Provider-initiated HIV testing		x	HIV test in NCDC labs
Report bacteriology results to TB specialist			NCDC lab NRL
Select initial regimen		TB doctor	If MDR: consilium
DOT 6 days/ week at health facility		TB nurse* or PHC nurse	
DOT at patient's home		TB nurse or PHC nurse	
TB case management: assess and address patients' social, psychological, economic needs			
Adherence counseling		TB teams	
Identify contacts			NCDC epidemiologist
Place tuberculin skin test		NCTBLD nurse	NCDC epidemiologist
Further management and treatment of contacts		x	
Follow up if TB treatment interruptions; retrieve lost patients		x	
Follow up sputum exams		x	
Medical exams twice a month while on TB treatment;		x	
Identify and manage side effects to TB medicines	x	x	
Treat concomitant conditions (diabetes, HIV)	x		3 HIV centers in country

*or Village doctors (Family practice doctors) in rural ambulatory clinics

ANNEX 3. ISSUES FOR FURTHER EVALUATION (OR OPERATIONAL RESEARCH)

Strategic Area 1

1. Determine key barriers to TB case detection in primary care settings
2. Determine levels of MDR in subgroups of retreatment patients starting retreatment (relapse, return after default, treatment failure)
3. Evaluate performance of active screening methods in prisons. Assess attrition and delays in the patient initiated pathway in prisons
4. Assess turnaround times from collection of specimen to reporting results to clinician and TB doctor
5. Determine reasons why some pulmonary TB patients are culture negative
6. Analyze all available drug resistance results (including from extrapulmonary cases)

Strategic Area 2

1. Identify underlying reasons for loss to follow up among MDR-TB patients
2. Determine size and characteristics of uncured MDR-TB patients

3. Identify factors that influence acquiring and amplification of DR during in-patient treatment and effectiveness of infection control measures in TB hospitals

Strategic Area 3.

1. Interview TB patients and providers (PHC and TB specialists) about accessibility of TB services and barriers they may face in the general medical facilities.
2. Conduct operational research to identify barriers and motivators for private providers to provide TB services;

Strategic Area 4. Conduct task analysis; assess current staffing in both the civilian and penitentiary systems

Strategic Area 5.

1. Conduct and compile risk assessments of high priority facilities
2. Assess effectiveness of infection control measures in TB hospitals

Strategic Area 6. Evaluate KAP of key populations

Strategic Area 7

1. Evaluate reasons for the high proportion of retreatment patients among HIV-positive TB patients, and reasons for poor treatment outcomes

2. What are barriers to ART initiation and adherence in TB patients living with HIV
3. Do home based support and/or integrated HIV and TB services improve outcomes

ANNEX 4. MONITORING AND EVALUATION FRAMEWORK

Notes:

- Yes/No indicators from *(6)* are not in this framework; instead they are listed as activities in body of plan unless already accomplished
- all applicable impact, outcome and output targets from Georgia are included. If no Georgia target available, this strategy uses published WHO targets *(6, 7)*.
- Process indicators are developed for the action plan
- A number of these indicators should be analyzed for new and previously treated TB patients, civilian and prison, MDR and other patterns of drug resistance, children and adults, men and women, and by region of Georgia.
- Data source for all indicators is the National TB program data base at National Center for TB and Lung Diseases.

	Indicators	**Baseline**	**Year (source)**	**2015 Target**	**EURO *(5)***	**Reference for source of indicator or target**
	Key Impact and Outcome Indicators					
1.	estimated TB mortality rate	3.7 per 100,000	2011 (8)	3 per 100,000		*5*
2.	% of previously treated TB patients with multidrug resistance	32%	2011 (8)	12%	3.4.5	6
3.	% of MDR-TB cases with extensive drug resistance (XDR)	6%	2011 (4)	decrease	3.4.6	6
	1. TB case detection					
4.	notification rate of new and relapse TB cases	105 per 100,000	2011 *(9)*	102 per 100,000		**Error! Bookmark not defined.**11
5.	**TB case detection in general medical facilities**					
6.	# patients with suspected TB referred from primary care providers	unknown		20% increase		*5*
7.	# of suspected TB cases with sputum examined	13 410	2011			*(34)*
8.	% of smear positive among suspected cases with sputum examined	2 148	2011			*(5, 34)*
	TB case detection in contacts[11]					
9.	# of TB cases identified among contacts	104	2011			*10*
10.	# of contacts of smear-positive TB cases screened for TB	3 475	2011			*10*
	TB case detection in prisoners					
11.	# of TB cases notified from prisons	1 172	2011 (NCTBLD)			

11. Analyze for all ages, under 5 years of age, and for prison inmates

	Indicators	Baseline	Year (source)	2015 Target	EURO *(5)*	Reference for source of indicator or target
12.	#, % of prisoners screened for TB at entry	8 446 (97%)	July-Dec 2011 *(16)*	97%		5
	Detection of drug resistance					
13.	MDR-TB cases detected as % of those estimated among TB notifications	63%	2011 *(8)*	85%	3.4.2	6, 7, Outcome
14.	% of previously treated patients with first line DST at the start of retreatment	52%	2011 *(8)*	100%	2.1.8	*(6, 7, 16)*
15.	% of new patients with first line DST at start of treatment	83%	2011 *(8)*	100%	2.1.7	*(6, 7, 16)*
16.	% of MDR-TB patients with SLD susceptibility testing	93%	2011 *(10)*	100%	2.1.9	*(6)*
	Laboratory					
17.	# of smear microscopy laboratories for which EQA was carried out, % of all labs performing smear microscopy	29 (100%)	2011 *(10)*	100%		7
18.	#, % of smear microscopy units for which EQA was carried out, that demonstrated acceptable performance	29 (100%)	2011 *(10)*			
19.	# of culture labs for which EQA was carried out, % of all labs performing culture	2 (100%)	2011 *(10)*			
20.	#, % of culture labs for which EQA was carried out, that demonstrated acceptable performance	2 (100%)	2011 *(10)*			
21.	DST labs with EQA according to international standards	1 (100%)	2011 *(10)*	100%	2.1.1	6
22.	% of DST labs achieve $\geq$ 95% proficiency for isoniazid and rifampicin (via EQA)	100%	2011 *(10)*	100%	2.1.2	6
23.	#, % of TB patients with a sputum culture performed at diagnosis via automated MGIT on liquid media	2 834 (65%)	July-Dec 2011 *(16)*	90%	2.1.3	*(16)* marker for receipt in lab within 4 days of specimen collection
24.	% of pulmonary cases that are culture positive	71%	2011 *(10)*	increase	2.1.5	*(10)*
	2. Treatment					
25.	% of new smear and/or culture positive pulmonary TB patients successfully treated	76%	2010 *(9)*	85%	1.4.2	*(4)*
26.	% of new TB patients lost to follow-up, transferred or not evaluated	10.4%	2010 *(9)*		1.2.1	6
27.	% of previously treated TB patients successfully treated	61%	2010 *(9)*	increase	1.4.3	6
28.	#, % TB patients on first line TB treatment receiving food vouchers at least once in the reporting period	3 071 (56%)	July-Dec 2011 *(16)*	75%		*(16)*
29.	% of MDR-TB patients	53%	2009 *(1)*	75%	3.4.8	6 Outcome

	Indicators	Baseline	Year (source)	2015 Target	EURO *(5)*	Reference for source of indicator or target
	successfully treated					
30.	% of MDR-TB patients dying during treatment	8%	2009 *(1)*	< 10%	3.4.9	6
31.	% of MDR-TB patients whose treatment fails	6%	2009 *(1)*	< 10%	3.4.10	6
32.	% of MDR-TB patients lost to follow up, transferred out, not evaluated	31%	2009 *(1)*	< 5%	3.4.11	6
33.	Interim treatment success of MDR-TB patients[12]	not available		75%	No	*(6, 16)*
34.	% of confirmed MDR-TB cases starting MDR treatment in programs following international guidelines	unknown		100%	3.4.7	*(6, 7, 16)*
35.	treatment success rate among prisoners with new lab confirmed pulmonary TB	84%	2010 (NCTBLD)	85%	7.2.3	Need to validate
36.	# of MDR-TB patients receiving incentives	300 (42%)	July-Dec 2011 *(16)*	80%		*(16)*
37.	stock-outs of first or second line drugs	no	2011 *(10)*	no		*(10)*
38.	# health facilities with TB care protocols	unknown		100%		
39.	# health facilities conducted TB clinical audits			50%		
	3. Governance					
40.	gap in financing of core elements of TB control	unknown		decrease	1.3.1	6
41.	% of total annual funding needs financed by domestic sources	41%	2011 (NCTBLD)	≥ 70%		7
42.	Reporting units submitting timely reports according to national guidelines	100%		100%		
	4. Human resources					
43.	% of TB service delivery points that provide excellent/good performance during performance evaluation visits	unknown	July-Dec 2011 *(16)*	95%		*(16)*
44.	% of penitentiary facilities with appropriate practices for TB detection and DOT as documented during performance evaluation visits	unknown	July-Dec 2011 *(16)*	95%		*(16)*
	5. Infection control					
45.	ratio of TB notification rates in health care workers versus general population	unknown		≤1	4.1.1	6 Impact

[12] # smear and culture negative at 6 months after treatment start, as proportion of all who started

	Indicators	Baseline	Year (source)	2015 Target	EURO *(5)*	Reference for source of indicator or target
46.	# facilities with infection control plans based on risk assessment	unknown		100%	4.2.1	
	6. Empower people with TB and their communities					
47.	# of TB patients provided DOT by trained community members	unknown				
48.	# of small grants implemented by NGOs			10		*5*
	7. HIV/TB					
49.	% of TB patients who are HIV-positive	2%	2011 *(8)*	decrease	7.1.3	6 Impact
50.	% of notified TB cases tested for HIV	46%	2011 *(8)*	100%	7.1.1	GF
51.	% of HIV+ TB patients receiving antiretroviral therapy	76%	2011 *(8)*	> 95%	7.1.4	See *(3)* target # 3.1.4.2
52.	% of HIV+ TB patients receiving cotrimoxazole	56%	2011 *(8)*	100%	7.1.5	7
53.	% with treatment success among HIV+ new TB cases	40%	2010 *(10)*	increase	7.1.7	7
54.	# intravenous drug users screened for TB	1 230	July-Dec 2011 *(16)*	1750		*(16)*
55.	#, % people living with HIV attending HIV care services who were screened for TB at the last visit	387 (100%)	2011 *(8, 33)*	100%		7
56.	#, % people living with HIV starting isoniazid preventive therapy	61(16%)	2011 *(8,33)*	70%		7

ANNEX 5: TECHNICAL ASSISTANCE PLAN

Area for TA	International TA	Local TA	Potential Funding Source
Develop standard operating procedures (SOP) for PHC providers for TB diagnosis and referrals.		2013	USAID TPP
Introduce standard TB case detection and care module in all pre- and in-service training curricula for general practitioners		2013-2015	USAID TPP
Develop programmatic guidelines, SOP and an implementation plan (including training) for effective contact tracing of TB and MDR-TB patients by all relevant institutions.		2013	USAID TPP
Introduce standard operating procedures and guidelines for prison health facilities to support implementation of effective screening programs		2013-2014	TBD
Develop or revise TB laboratory network strengthening plan to address quality, turnaround times, selection of patients and algorithms, biosafety, deployment of new technology, specimen transport, EQA, human resources, supervision, information system, reagents and consumables, equipment maintenance	2013-2014	2013-2014	TBD
Develop standard operating procedures for TB case management, specifying supporting roles for DOT, responsibilities and structure for quality DOT and addressing patient adherence and follow up when patients are lost		2013-2014	USAID/TPP
Develop system for palliative care for incurable M/XDR-TB patients	2013		TBD
Develop and implement SOPs for the administration of TB medicines in the penitentiary system, to ensure proper number of drugs are regularly taken and side effects are promptly detected and managed.		2013-2014	TBD
Develop a detailed plan listing the roles and responsibilities for all aspects of drug procurement and management, and a monitoring plan in the context of the ongoing health reform	2013		TBD
Conduct an in-depth market and pharmaceutical sector assessment to inform TB procurement and supply chain management strategy after 2015 when GF support ends	2014		TBD
Develop SOPs for drug management to avoid stock outs and expired drugs.		2014	TBD
Evaluate current accountability and contracting mechanisms between the payer (the State) and the private providers to ensure quality.	2013		TBD
Provide technical support to strengthen management capacity of MOLHSA, NCDCPH	2013-2015	2013-2015	USAID/TPP Other

and other structures involved in the National TB response. Facilitate effective operational planning of NTP interventions			
Develop a plan for self sufficiency of the Georgian Government to continue free access to TB services after the Global Fund project is completed in 2015	2014	2014	TBD
Analyze TB control operational costs (including drugs and new diagnostics) and present a proposal to the Ministry of Finance for increased domestic financing	2013-2014		TBD
Analyze options for inclusion of TB diagnostic and treatment services in the country's basic health package and essential drugs covered by the national health insurance scheme	2014	2014	TBD
Analyze the current TB information system, and develop recommendations for improvement.		2013	USAID/TPP
Develop an M&E plan for Georgia's TB response, harmonized with the national Health Strategy, National HIV strategy, GF project, and WHO recommendations and data collection forms		2013	USAID/TPP
As part of the country's human resource development plan, conduct a task analysis for each TB control function, by level of the health system and category of health worker.	2014	2014	USAID/TPP
Define needed number, distribution and cadre of staff to conduct the tasks identified; compare to current staffing pattern. Consider which tasks can be shifted to less specialized personnel, and when cross training primary health care staff is appropriate (such as in low burden rayons or at the village level)		2014	USAID/TPP
Define competencies for all levels of TB service providers, and develop a training plan in coordination with professional associations and other groups that provide training		2014	USAID/TPP
Annual mission for laboratory network	2013; 2014; 2015		TBD
Annual GLC mission	2013; 2014; 2015		TBD
Annual mission for MDR-TB	2013; 2014; 2015		TBD

ANNEX 6: TB NATIONAL ACTION PLAN 2013-2015

	TB Action Plan 2013-2015	Indicators	Baseline (2011)	2013	2014	2015	2015 Target	Responsible agency	Stakeholders	Funding Source		
										STATE	GLOBAL FUND (Potential)	USAID
SA1	**Universal coverage of high quality TB diagnostic services**	The case notification rate	105 per 100,000				102 per 100,000					
		% of previously treated TB cases will have multidrug resistance.	32%				<12					
		the proportion of MDR-TB patients with extensive drug resistance will decrease by	6%				at least 2%					
SO1.1.	**Maximize integration of TB services into general health facilities as an opportunity to identify and diagnose patients with TB symptoms**	Increase in patients with suspected TB referred from primary health care (PHC)	<10%				20%					
		TB cases detected	TBD				50%					

		among referrals from general medical facilities										
1.1.	Conduct operational research to determine barriers and factors that facilitate referrals in primary care settings	Research Conducted	N/A		Yes			Local/International NGOs or Research institutions	MoLHSA/NCDCPH/NCTBLD			TPP
1.2.	Develop standard operating procedures (SOP) for PHC providers for TB diagnosis and referrals	SOP Developed	N/A	Yes				GFMA/TBLDSA	MoLHSA/NCDCPH/NCTBLD/Private HSO			TPP
1.3.	Introduce standard TB case detection and care module in all pre- and in-service training curricula for general practitioners	Modules developed	N/A		Yes		Yes	GFMA/TBLDSA	MoLHSA/NCDCPH/NCTBLD			TPP
SO 1.2	**Ensure early detection of TB cases, especially in children, through prompt and thorough investigation of contacts to infectious TB cases**	% of close contacts of smear-positive TB cases will be screened for TB	TBD				>90%					
		% of TB cases identified among contacts	TBD				5%					
2.1.	Develop programmatic guidelines, SOP and an implementation plan (including training) for effective contact tracing of TB and MDR-TB patients by all relevant institutions.	Programmatic guidelines and SOP for contact tracing developed		Yes				NCDCPH	MoLHSA/NCTBLD	State		
2.2.	Build capacity of NCDPH epidemiologists to trace contacts for early TB case detection among family members	# of epidemiologists trained		Yes				NCDCPH	MoLHSA			TPP

2.3.	Implement regulation to support prompt notification of confirmed cases of TB within 24 hours by all providers to the National Center for Disease Control and Public Health. Assess its impact.	Assessment report available		Yes				NCDCPH	MoLHSA/NCTBLD	State		
2.4.	Introduce and implement expanded guidelines on isoniazid preventive therapy	IPT guidelines available and implementation evaluated		Yes	Yes	Yes		NCDCPH	MoLHSA/NCTBLD/Private HSOs	State	TBP	TPP
SO1.3	**Ensure timely detection of all cases of TB in prison inmates**	% of prisoners will undergo TB screening on entry	97%				>97%					
3.1.	Conduct operational research to evaluate performance (accuracy and predictive value) of the active TB screening algorithm. Compare cost-effectiveness of the different screening programs to guide policy decisions	Research Conducted		Yes			Yes	Local or international NGOs or Research institutions	MoCLA/MoLHSA/NCDCPH/NCTBLD	TBD		
3.2.	Introduce standard operating procedures and guidelines for prison health facilities to support implementation of effective screening programs	Screening guidelines introduces in prisons					Yes	MoCLA/MoLHSA/NCDCPH/NCTBLD		TBD		
3.3.	Support capacity building of medical personnel within the penitentiary system to improve early TB detection	# of medical personnel trained on TB detection		TBD	TBD	TBD		MoCLA/MoLHSA/NCDCPH/NCTBLD		TBD		
SO1.4	**Ensure that high quality laboratory testing supports the rapid, accurate diagnosis of TB and drug resistant TB**	% of MDR-TB cases will be detected (of estimated among notified TB cases)	63%				>85%					

4.1.	Develop or revise TB laboratory network strengthening plan to address quality, turnaround times, selection of patients and algorithms, biosafety, deployment of new technology, specimen transport, EQA, human resources, supervision, information system, reagents and consumables, equipment maintenance	Laboratory Network Master Plan Developed		Yes			Yes	MoLHSA/NCDCPH/NCTBLD	Local and International NGOs	TBD		
4.2.	Maintain uninterrupted provision of diagnostic services through sustainable financing	% of pulmonary cases are confirmed by culture	71%				80%	MoLHSA/NCDCPH/NCTBLD	Local and International NGOs	State	TBP	
		% of TB patients will have a sputum culture performed at diagnosis via automated MGIT on liquid media	95%				100%	MoLHSA/NCDCPH/NCTBLD	Local and International NGOs	State	TBP	
4.3.	Support continuous capacity building of lab personnel	# of lab personnel take refresher training annually		20	20	20	60	MoLHSA/NCDCPH/NCTBLD	Local and International NGOs		TBP	TPP
SA2	**Universal coverage of high quality TB treatment and care**	Treatment success rate										
SO2.1	**Improve TB treatment outcomes by providing patient-centered support.**	New smear or culture positive cases	76%				85%					
		Retreatment cases	61%				>70%					
2.1.1.	Introduce and implement evidence-based TB treatment guidelines to standardize DOT and ensure provider	TB Guideline introduced and performance data		100		100	100 Biennially	Professional Associations	MoLHSA/NCDCPH/NCTBLD		TBP	TPP

	adherence to DOT	available, # of TB specialists trained on updated guideline										
2.1.2.	Develop standard operating procedures for TB case management, specifying supporting roles for DOT, responsibilities and structure for quality DOT and addressing patient adherence and follow up when patients are lost	SOP Developed			Yes			MoLHSA/ NCDCPH/NCTBLD	Donors/International NGOs			TPP
2.1.3.	Develop capacity of community based organizations and social support personnel such as village nurses, social workers, community volunteers etc. to provide community-based DOT and improve patient adherence	# of individuals trained in community-based TB care		100	100	100	300	Local NGOs	MoLHSA/NCDCPH/NCTBLD		TBP	TPP
2.1.4.	Introduce effective mechanisms to improve treatment adherence (this could include cover DOT transportation costs for patients, and expanding the provision of food parcels);	% of MDR patients receiving incentives for good adherence	42%				80%	MoLHSA/NCDCPH/NCTBLD	Donors/International NGOs		TBP	
2.1.5.	Conduct operational research to analyze the cost of expanding patient support for ambulatory treatment and the potential benefits (which may include less loss to follow up if patients are treated closer to home, less nosocomial transmission);	Research Conducted			Yes		Yes	MoLHSA/NCDCPH/NCTBLD	Donors/International NGOs			TPP

2.1.6	Support dissemination of capacity building, quality improvement and educational interventions in the penitentiary system to improve quality of DOT in prisons	# of educational materials disseminated in prisons; # of workshops attended by staff of the penitentiary system together with the civilian health system staff		10000 leaflets 4 Workshops	10000 leaflets 4 Workshops	10000 leaflets 4 Workshops	30000leaflets; 12 Workshops	MoLHSA/ NCDCPH/NCTBLD	Donors/International NGOs	State	TBP	TPP
SO2.2.	**Improve care for MDR-TB patients**	Treatment success rate	53%				75%					
2.2.1.	Conduct operational research to Identify underlying reasons for loss to follow up among MDR-TB patients and determine to what extent a fully ambulatory model could increase adherence.	Research Conducted	NA	Yes				MoLHSA/NCDCPH/NCTBLD	Donors/International NGOs			TPP
2.2.2.	Implement cohort analysis for interim outcomes on a quarterly basis, for use in case and program management, and as a tool to rapidly detect and resolve problems. Improve MDR-TB recording system to be able to provide interim outcomes (sputum culture conversion, death, loss to follow up)	Report available	NA	Yes	Yes	Yes	Yes	MoLHSA/NCDCPH/NCTBLD	Local and International NGOS	State		TPP
2.2.3	Develop system for palliative care for incurable M/XDR-TB patients	% of TB patients in need receive palliative care (breakdown by care in hospice/care at home)	TBD		Yes		TBD after baseline	MoLHSA/NCTBLD	Local and International NGOS	State	TBP	

2.2.4.	Develop and implement SOPs for the administration of TB medicines in the penitentiary system, to ensure proper number of drugs are regularly taken and side effects are promptly detected and managed.	SOP developed	NA	Yes			Yes	MoCLA/MoLHSA	NCTBLD	State	TBP	
2.2.5.	Improve prison TB recording according to second line drug (SLD) treatment start date, and use registry data to analyze interim and final outcomes	TA provided to improve TB recording in the penitentiary system	NA	Yes			Yes	MoCLA/MoLHSA	NCTBLD	State	TBP	
2.2.6.	Organize annual mission of international experts to review the care and treatment program for MDR-TB	Mission report available	NA	Yes	Yes	Yes	Yes	MoLHSA	NCTBLD			
SO2.3.	Ensure an uninterrupted supply of quality assured first and second line drugs	No stock outs of first line drugs at central or peripheral levels	No				No					
		No stock outs of second line drugs at central or peripheral	Yes				No					
2.3.1	Develop a detailed plan listing the roles and responsibilities for all aspects of drug procurement and management, and a monitoring plan in the context of the ongoing health reform	Plan developed and endorsed by the GoG	NA	Yes			Yes	MoLHSA/NCDCPH/NCTBLD	Local and International NGOS		TBP	
2.3.2.	Along with Health Strategy improvements in drug supply, introduce regulation to prohibit sale of all antibiotics (including TB medicines) without a prescription	Regulations introduced	NA		Yes		Yes	MoLHSA/NCDCPH/NCTBLD	Local and International NGOS	State		

2.3.3.	Coordinate an in-depth market and pharmaceutical sector assessment to inform TB procurement and supply chain management strategy after 2015 when GF support ends. Assess the availability of public and private capacity and options for supplying quality-assured TB medicines with the government funding (or other than GF funding) – legal and regulatory basis, medicines registration, selection, procurement regulations and practices.	Assessment conducted and the strategy elaborated	NA		Yes		Yes	MoLHSA/NCDCPH/NCTBLD	Local and International NGOS	State		TPP
2.3.4.	Develop SOPs for drug management to avoid stock outs and expired drugs.	SOPs developed	NA		Yes		Yes	MoLHSA/NCDCPH/NCTBLD	Local and International NGOS		TBP	
2.3.5	Organize annual mission of the Green Light Committee experts	Mission report available	NA	Yes	Yes	Yes	Yes	MoLHSA/NCDCPH/NCTBLD			TBP	
SO2.4	**Improve quality of TB care in the context of health reform**	% of health facilities involved in TB care have TB care protocols elaborated	TBD	70%	80%	90%	100%					
		% of health facilities providing TB care conduct TB clinical audits annually	TBD	25%	35%	50%	50%					
2.4.1.	Strengthen institutional capacity of private health care providers for TB care provision through continuous performance evaluation and professional feedback	Number of PE visits performed	None	300	300	300	900	MoLHSA/NCDCPH/NCTBLD	Local and International NGOS			TPP
2.4.2.	Develop internal quality improvement	#/% of private clinics	None		25%	25%	50%	MoLHSA/NCDCP	Local and			TPP

	systems for TB services in general medical facilities, to include local protocols based on National TB Guidelines and quality standards, job aids, training, audits, satisfaction surveys of TB service clients	accredited in TB care						H/NCTBLD	Internationa l NGOS			
2.4.3.	Evaluate current accountability and contracting mechanisms between the payer (the State) and the private providers to ensure quality.	Evaluation report available	No	Yes			Yes	MoLHSA/NCDCP H/NCTBLD	Local and Internationa l NGOS			TPP
2.4.4.	In line with the Georgia *National Health Care Strategy,* include TB quality of care measures and minimum requirements in accreditation of private health facilities	Accreditation of TB service points initiated	No		Yes		Yes	MoLHSA/NCDCP H/NCTBLD	Local and Internationa l NGOS			TPP
SA 3	**Effective governance, adequate financing and monitoring of Georgia's TB response**											
SO3.1	**Strengthen governance and coordination of Georgia's TB response**											
3.1.1.	Revise and redefine roles and responsibilities of national and regional structures in planning, implementing and monitoring the country's TB program in the context of the ongoing reforms	ToR for the NTP Central coordinating unit revised and endorsed	Ministerial decree as of 2008	Yes			Yes	CCM/MoLHSA/NC DCPH/NCTBLD	Local and Internationa l NGOS	State		TPP
3.1.2.	Introduce effective mechanisms to improve coordination between MoCLA and MOHLSA in controlling TB within the prisons, and continuity of TB care upon release	Statute/decree on coordination issued	NA	Yes			Yes	MoCLA/MoLHSA	Local and Internationa l NGOS	State		

3.1.3.	Provide technical support to strengthen management capacity of MOLHSA, NCDCPH and other structures involved in the National TB response. Facilitate effective operational planning of NTP interventions	# of LTA and ITA days provided	NA	Yes	Yes	Yes	Yes	MoLHSA/NCDCPH/NCTBLD	Local and International NGOS		TBP	TPP
3.1.4.	Conduct operational research to identify barriers and motivators for private providers to provide TB services	Research Conducted	NA	Yes			Yes	MoLHSA/NCDCPH/NCTBLD	Local and International NGOS			TPP
SO.3.2	**Achieve sustainable financing of the country's TB response by maximizing the use of existing resources and mobilizing additional resources, and increasing domestic funding.**	the gap in financing of core elements of TB control					Reduced					
		% of total annual TB funding needs are financed by domestic sources					> 70%					
3.2.1.	Develop a plan for self sufficiency of the Georgian Government to continue free access to TB services after the Global Fund project is completed in 2015	Plan developed	NA		Yes		Yes	CCM/MoLHSA/NCDCPH/NCTBLD	Local and International NGOS			TPP
3.2.2	Analyze TB control operational costs (including drugs and new diagnostics) and present a proposal to the Ministry of Finance for increased domestic financing	Proposal elaborated	NA		Yes		Yes	CCM/MoLHSA/NCDCPH/NCTBLD	Local and International NGOS			TPP

3.2.3.	Advocate to establish a line item in the domestic budget for the procurement of first and second line drugs	# of high level advocacy meetings conducted	NA	2	2	2	6	CCM/MoLHSA/NCDCPH/NCTBLD	Local and International NGOS		TBP	TPP
3.2.4.	Identify and evaluate options for redirection of existing domestic TB resources for more cost effective investment.	Options identified and the report available	NA		Yes		Yes	CCM/MoLHSA/NCDCPH/NCTBLD	Local and International NGOS			TPP
3.2.5.	Analyze options for inclusion of TB diagnostic and treatment services in the country's basic health package and essential drugs covered by the national health insurance scheme	Options identified and the report available	NA		Yes		Yes	CCM/MoLHSA/NCDCPH/NCTBLD	Local and International NGOS			TPP
SO.3.3.	**Collect, analyze and use monitoring, evaluation and surveillance data to understand TB epidemiology and improve TB program performance**	% reporting units submitting timely reports according to national guidelines	**100%**				**100%**					
3.3.1	Analyze the current TB information system, and develop recommendations for improvement.	Evaluation report available		Yes			Yes	CCM/MoLHSA/NCDCPH/NCTBLD	Local and International NGOS			TPP/HSSP
3.3.2	Develop an M&E plan for Georgia's TB response, harmonized with the national Health Strategy, National HIV strategy, GF project, and WHO recommendations and data collection forms	M&E Plan elaborated and endorsed by GoG		Yes			Yes	CCM/MoLHSA/NCDCPH/NCTBLD	Local and International NGOS		GF Project	TPP
3.3.3.	Support the development and implementation of a TB module within HMIS that serves the needs of the TB program including patient support revisions to enable monitoring of	TB Module developed			Yes		Yes	CCM/MoLHSA/NCDCPH/NCTBLD	Local and International NGOS			TPP/HSSP

	program performance, evaluate the implementation of this Strategic Plan, further policy development											
3.3.4.	Conduct a national TB program review jointly by a Georgian and international team	Review conducted			Yes		Yes	CCM/MoLHSA/NCDCPH/NCTBLD	Local and International NGOS	TBD		
SA 4	**Human resources available at each level with the professional competence and support to meet Georgia's TB Response plan's targets**											
SO 4.1.	**Ensure human resources are available to perform essential TB functions at national, regional and district levels to meet patient care and TB program performance targets**	% of TB service delivery points provide excellent/good performance during supervision visits	**65%**				**95%**					
		% of penitentiary facilities with appropriate practices for TB detection and DOT as documented during supervision visits	86%				94%					
4.1.1.	As part of the country's human resource development plan, conduct a task analysis for each TB control function, by level of the health system and category of health worker.	Task analyses conducted		Yes				MoLHSA/NCDCPH/NCTBLD	Local and International NGOS, Universities			TPP

4.1.2.	Define needed number, distribution and cadre of staff to conduct the tasks identified; compare to current staffing pattern.	Job descriptions elaborated		Yes				MoLHSA/NCDCPH/NCTBLD	Local and International NGOS, Universities			TPP
4.1.3.	Training primary care physicians and nurses in TB early detection and follow up	# of Family physicians and nurses trained		400	200	200	800	MoLHSA/NCTBLD	GFMA		TBP	TPP
4.1.4.	Define competencies for all levels of TB service providers, and develop a training plan in coordination with professional associations and other groups that provide training	Competencies defined and endorsed		Yes			Yes	MoLHSA/NCDCPH/NCTBLD	Local and International NGOS, Universities			TPP
4.1.5.	Train and certify TB specialists as pulmonologists to be able to provide services such as Practical Approach to Lung (PAL) health in order to improve patient access to diagnosis and treatment of all pulmonary conditions, and provide career opportunities to the TB specialists.	# of TB specialists certified in pulmonology	TBD	50	50	50	150	MoLHSA/NCDCPH/NCTBLD	Local and International NGOS, Universities			
4.1.6.	Strengthen capacity of private health care sector (network managers, hospital managers and clinicians, PHC facility managers and clinicians) to ensure access to quality TB diagnosis and treatment.	# of workshops organized for managers	4	4	4	4	12 (10 participant per session)	MoLHSA/NCDCPH/NCTBLD	Local and International NGOS, Universities	State	TBP	TPP
4.1.7	Train all prison staff (doctors, nurses and security staff) on TB, MDR-TB and how to prevent TB transmission	# and % of prison staff trained	TBD	TBD	TBD	TBD	TBD after situation analyses	MoLHSA/NCDCPH/NCTBLD	Local and International NGOS, Universities	State	TBP	TPP (TA)
SA 5	**Prevent TB transmission in health facilities and prisons**											

SO5.1	**Minimize the risk of TB transmission in health care settings and prisons through adequate IC measures**	the ratio of TB notification rates (health care workers versus general population)	Unknown				≤1					
5.1.1.	Review and revise regulations and environmental control standards to be consistent with WHO recommendations to prevent nosocomial TB transmission in health facilities	Revised decree issues	NA	Yes			Yes	CCM/MoLHSA/NCDCPH/NCTBLD	Local and International NGOS			TPP
5.1.2.	Develop a Standard Operational Manual for TB infection control for health facilities and prisons, to include standards, indicators, and a monitoring checklist	SOP Developed	NA	Yes			Yes	CCM/MoLHSA/NCDCPH/NCTBLD	Local and International NGOS			TPP
5.1.3.	Introduce regular mandatory TB screening for all health care and prison workers	Screening program launched	NA		Yes		Yes	CCM/MoLHSA/NCDCPH/NCTBLD	Local and International NGOS	State		
5.1.4.	Assess and upgrade physical infrastructure to permit safe TB service delivery at all facilities providing TB care	# of private health facilities with upgraded infrastructure	NA	32	18		50	CCM/MoLHSA/NCDCPH/NCTBLD	Local and International NGOS			TPP
5.1.5.	Review and upgrade national standards for respiratory protection, to include a comprehensive program with training, fit testing, procuring, distributing and maintaining sufficient quantities of approved respirators.	National Standards upgraded	NA	Yes			Yes	CCM/MoLHSA/NCDCPH/NCTBLD	Local and International NGOS	State		TPP
SA6	**Empower TB patients and communities**											

SO 6.1.	**Establish community-based DOT to support successful treatment**	% of patients will be provided DOT by trained community members					50%					
6.1.1.	Support local NGOs in assisting patients to adhere and complete TB treatment through small grants programs aimed at improving demand for and quality of TB services	# of small grants programs implemented by local NGOs	3	4	4	4	15	Local and International NGOS	CCM/MoLHSA/NCDCPH/NCTBLD			TPP
6.1.2.	Establish community-based TB care (to supplement the current clinic-based DOT for patients who are reluctant or unable to come to clinic) by utilizing community and faith-based organizations, and task-shifting to trained community members with supervision by health services	% of TB patients receiving support from trained community members	TBD	25%	30%	50%	50%	Local and International NGOS	CCM/MoLHSA/NCDCPH/NCTBLD			TPP
6.1.3.	Provide trainings for volunteer treatment supporters on adherence counseling and interpersonal communication	# of volunteers trained		60	60	60	180	Local and International NGOS	CCM/MoLHSA/NCDCPH/NCTBLD			TPP
6.1.4.	Engage the National Service Probation and the Penitentiary Department to implement a treatment continuation program for newly-released prisoners. Enlist NGO partners already working in the penitentiary system to monitor and facilitate follow-up and communication between the penitentiary and civilian services.	% of released prisoners enrolled into the NTP within 10 days of discharge	Unknown				80%	CCM/MoLHSA/NCDCPH/NCTBLD	Local and International NGOS	State		
6.1.5.	Assess and improve materials for TB patients and family members on	Materials available		Yes	Yes	Yes	Yes	Local and International	CCM/MoLHSA/NCDCP			TPP

	treatment adherence							NGOS	H/NCTBLD			
SO 6.2.	**Reduce TB related stigma through communication and social mobilization**											
6.2.1.	Provide technical assistance and small grants to local NGOs and faith based organization for improving TB awareness and fighting TB stigma by means such as concerts, shows, sport activities, annual World TB Day and White Flower street actions	# of NGO representatives trained	20	20	20	20	60	Local and International NGOS	CCM/MoLHSA/NCDCPH/NCTBLD			TPP
6.2.2.	Assess and improve materials for prison inmates and staff on timely detection of TB symptoms and how to access and complete treatment.	Materials available		yes			Yes	MCLA/NCTBLD	Local and International NGOs		TBP	
6.2.3.	Evaluate the knowledge, attitudes and practices of key target groups	KAP survey conducted	Sep-12			Yes	Yes	CCM/MoLHSA/NCDCPH/NCTBLD	Local and International NGOS			TPP
6.2.4.	Consistent with the patients' rights section of the National Health Care Strategy, adopt the TB Patients' Charter	TB Patients' Charter Adopted			Yes		Yes	CCM/MoLHSA/NCDCPH/NCTBLD	Local and International NGOS	State		TPP
SA 7	**Enhance TB/HIV collaboration to reduce the burden of TB in people living with HIV and the burden of HIV in TB patients**	Less than _2_% TB patients will be HIV-positive					**2% of TB patients with known HIV status**					
SO7.1.	**Reduce the burden of HIV in TB patients by performing HIV testing for all TB cases, and improving**	In the 2015 cohort of HIV-positive TB patients, 60% will be					**40%**					

	survival among HIV-positive TB patients	successfully treated										
7.1.1.	Offer diagnostic counseling and testing to all TB patients at the start of TB treatment	% of TB patients tested for HIV	66%	75%	80%	90%	90%	MoLHSA/NCDCPH/NCTBLD	Local and International NGOS	State	TBP	
7.1.2.	Ensure rapid tests for drug resistance are performed when TB is suspected in HIV positive individuals, and TB treatment regimens promptly modified to ensure effective TB treatment.	% of HIV-positive TB patients tested for TB and treated according to the national guidelines	TBD				100%	MoLHSA/NCDCPH/NCTBLD	Local and International NGOS	State	TBP	
7.1.3.	Ensure timely initiation (according to the EB guidelines) of antiretroviral therapy in TB patients.	% of TB patients receiving ART according to the National Guidelines	TBD				TBD after baseline	MoLHSA/NCDCPH/NCTBLD	Local and International NGOS	State	TBP	
7.1.4.	Assess barriers to timely ART initiation and opportunities for improved access	Assessment conducted	NA		Yes		Yes	MoLHSA/NCDCPH/NCTBLD	Local and International NGOS	State	TBP	
7.1.5.	Evaluate reasons for the high proportion of retreatment patients among HIV-positive TB patients, and reasons for poor treatment outcomes	Evaluation report available	NA		Yes		Yes	MoLHSA/NCDCPH/NCTBLD	Local and International NGOS	State	TBP	
7.1.6.	Condut OR to evaluate effectiveness of home based support and integrated TB/HIV services	Research Conducted	NA			Yes	Yes	MoLHSA/NCDCPH/NCTBLD	Local and International NGOS	State	TBP	
7.1.7.	Ensure that HIV-positive TB patients are supported to adhere to ART via measures such as home-based adherence monitoring	% of HIV-positive TB patients receiving home-based adherence monitoring	TBD				TBD after baseline	MoLHSA/NCDCPH/NCTBLD	Local and International NGOS	State	TBP	

7.1.8.	Provide technical support to the TB and HIV programs to strengthen mechanisms for collaboration and information exchange	# of days of ITA and # of LTA provided	NA	30	30	30	90	MoLHSA/NCDCPH/NCTBLD	Local and International NGOS	State	TBP	
S.O.7.2	**Reduce the TB burden in HIV-positive people and IDUs**	100% of people living with HIV enrolled in HIV care are screened for TB					**387, or 100%**					
		#/% starting isoniazid preventive therapy, once active TB disease is excluded					**61, or 16% of total number of people living with HIV enrolled in care**					
7.2.1.	Strengthen capacity of the Georgia Harm Reduction Network to ensure early recognition of TB by social workers and counselors working with	# of Social Workers Trained	NA	60			60	MoLHSA/NCDCPH/NCTBLD	Local and International NGOS			TPP
7.2.2.	Routinely detect and treat latent TB infection in people living with HIV	#/% starting isoniazid preventive therapy, once active TB disease is excluded	(Baseline in 2011: 61, or 16% of total number of people living with HIV enrolled in care)	30%	50%	70%	70%	MoLHSA/NCDCPH/NCTBLD	Local and International NGOS	State	TBP	

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