

Review of financial sustainability of tuberculosis activities in Georgia

19-20 June 2017 Mission Report

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Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

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Abbreviations

CCM Country Coordinating Mechanism

CSO civil society organization

GFATM Global Fund to fight AIDS, Tuberculosis and Malaria

GoG Government of Georgia

LSHTM London School of Hygiene and Tropical Medicine

MDR-TB multidrug-resistant tuberculosis

MSF Médecins Sans Frontières

M/XDR-TB multidrug and extensively drug-resistant tuberculosis

MoLHSA Ministry of Labour, Health and Social Affairs

NCDCPH National Center for Disease Control and Public Health

NCTBLD National Center for Tuberculosis and Lung Diseases

NSP National Strategic Plan

NTP National Tuberculosis Programme

TB tuberculosis

TSP transition and sustainability plan

XDR-TB extensively drug-resistant tuberculosis

Executive summary

The WHO Regional Office for Europe is supporting six Eastern Partnership countries to document their preparedness to transition from donor- to domestically-funded antituberculosis (anti-TB) activities. As part of this work, two consultants travelled to Georgia for WHO's first in-country discussions for this project on 19–20 June 2017. The discussions focused on successes and challenges related to sustainability; triggers and enablers for transition; gaps in transition-related financial, human resource and programmatic data; and the country's existing transition and sustainability plan (TSP). Findings are outlined below.

The Government of Georgia (GoG) has demonstrated its commitment to population health and well-being, but its ability to finance the full range of anti-TB activities might be undermined by its slow economic growth in recent years and increased external debt (15.1 billion Lari in 30 June 2016).

From a policy and legislative perspective, the Parliament of Georgia has endorsed both the Law on Tuberculosis Control ¹ and the NSP on TB, but still needs to endorse the externally produced TSP for TB and HIV/AIDS programmes. Clinical guidelines for TB prevention and treatment are currently being updated; they were last updated in 2015.

Georgia's fiscal situation poses the greatest risk to sustainable financing for TB activities. Despite this, the health budget increased by more than 2.5 times during 2012–2016, and other key health financing indicators also demonstrate strong political will and commitment to health. However, the total TB funding gap for 2016–2018 is approximately US\$ 11.4 million. The most important gaps are in providing treatment and adherence support to TB patients to multidrug and extensively drugresistant TB (M/XDR-TB) patients.

Georgia's TB programme is run efficiently, with no underutilized service points and an uninterrupted supply of high-quality anti-TB drugs without stock outs. Two brand new facilities have replaced three old outpatient clinics, and another new outpatient clinic is currently being planned.

In general, the switch from Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM) funding to GoG funding for TB activities requires more clarity. A clear statement on the division and allocation of roles and responsibilities following transition is needed, along with a budget for these activities. Further, to avoid losing valuable Country Coordinating Mechanism (CCM) staffers and their associated institutional memory following transition, the CCM could be integrated into a broader, more flexible and adaptable coordinating body that oversees all primary

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¹ Law on Tuberculosis Control; (https://matsne.gov.ge/en/document/view/3104252)

health care. Higher salaries are required to reduce loss of staff to the private sector following transition and to incentivize young medical students to pursue a career in TB – the average age of the TB workforce is 58 years.

Access to clinical investigations and treatment for TB patients is hindered by a shortfall in public provider capacity. This is further complicated by the fact that private clinics – which make up more than 80% of medical service providers – avoid their responsibility to provide services and care to TB patients. Access-related issues are worse in regional areas.

GoG has already fulfilled most of the co-financing requirements, should immediately commence work on a plan to take over 50% of the financial responsibility for procuring laboratory supplies and 75% of the financial responsibility for procuring second- and third-line anti-TB drugs by the end of 2018.

Georgia could benefit from technical assistance to create a more granular overall budgeting process; for supervision, monitoring and surveillance; and to strengthen drug management and storage at the district level. The country would also benefit from continued maintenance support for medical equipment and health information systems, and continued access to the GFATM procurement platform following transition. GoG does not have a minimum quality requirement in place and the country's population size is too small to influence market dynamics. This could lead to the procurement of low-cost, low-quality anti-TB drugs and thus hinder programme success.

Overall, Georgia lacks capacity to fill vital financing gaps for its operational components. Therefore, it is critically important for development partners to recognize the risks that these less-obvious but critical gaps pose to achieving programme objectives.

Overview of key recommendations

Area	Action	Timeline	Responsible Agency
Financing and planning	Advocate for GoG endorsement of the TSP led by the Curatio International Foundation	Q4 2017	Curatio International Foundation and the Ministry of Labour, Health and Social Affairs (MoLHSA) of Georgia

Update guidelines (M/XDR-TB clinical guidelines to address the implementation of shorter multidrug-resistant TB (MDR-TB) regimens and palliative care guidance) to reflect the current best standards of care	Before the end of Q1 2018	Center for Tuberculosis and Lung Diseases (NCTBLD)
Provide technical assistance to departments in need to ensure that health budgets can be planned and maintained at the necessary level of detail	Technical assistance requirements should be defined by Q1 2018 and integrated in 2018	WHO Regional Office for Europe
Form an advocacy coalition to communicate the enormous implications of the President Decree on the Minimum Wage ² to the Parliament of Georgia	Formation by Q1 2018 and submission to the Parliament by the end of Q1 2018	GFATM, WHO Regional Office for Europe, Médecins Sans Frontières (MSF), Curatio International Foundation and civil society organizations (CSOs)
Formal documentation of clear and fair stipulated roles and responsibilities for stock management and distribution and for budgeting	Engagement by the end of Q4 2017; agreement by the end of	GFATM and relevant GoG staffers

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 $^{^2\,}President\ of\ Georgia\ Decree\ on\ Minimum\ Wage;\ https://www.matsne.gov.ge/ka/document/view/99592$

		Q1 2018	
	Explicitly acknowledge and plan to address non-finance-related gaps	Engagement by the end of Q4 2017; plan of action by the end of Q1 2018	GFATM, MSF, WHO
	Take over 50% of financial responsibility for procuring laboratory supplies and 75% of second- and third-line anti-TB drugs by the end of 2018	Action plan for takeover by Q1 2018	GoG
	Advocate for a plan or budget to support better salaries for CCM staffers following GFATM withdrawal	Policy brief delivered by the end of Q1 2018	MoLHSA
	Deliver a case study highlighting the negative impact of the Law of Georgia on Public Procurement ³	Q1 2018	MoLHSA
Supervision, monitoring and surveillance	Ensure that supervisory visits continue after GFATM withdrawal – add this to the National Strategic Plan (NSP) for TB	Q1 2018	GFATM, WHO, MSF and GoG
	Monitor and evaluate GFATM's plan to support the expansion and upgrade of the current e-TB database	Ongoing; first review by the end of Q1 2018 and half-yearly reviews thereafter	GoG
Medicines procurement	Formally agree to ensure that GoG does not lose access to the GFATM's procurement	Engagement should begin in Q1 2018 and be	GFATM, WHO Regional Office for

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³ https://matsne.gov.ge/en/document/view/31252

	platform after the transition	agreed by mid-2018	Europe
	Assist GoG in developing a minimum quality requirement for drugs in Georgia via the WHO prequalification of medicines programme	Engagement should begin in Q1 2018 and be agreed by mid-2018	GFATM and WHO
Quality, safety and standards	Put in place a maintenance and updating mechanism for equipment (health information systems, gene expert machines, vehicles, etc.)	Mechanism defined by mid-2018 and shared prior to the final transition	GFATM
Service delivery and linking with other interventions/health system strengthening	Address the Private Provider Agreement (due to expire in 2018) to prevent private providers from abandoning TB service delivery	Q1 2018	All relevant GoG departments; Multiple cross- sectoral stakeholders
	Continue the programme of increasing staff remuneration	Ongoing	GoG
	Make full use of purchasing/negotiating power, along with regulatory and licensing mechanisms, to ensure that private service providers deliver TB services	Ongoing	GoG
Evidence-based TB policy and practice	Monitor the results-based financing pilot being implemented by the Curatio International Foundation and the London School of Hygiene and Tropical Medicine (LSHTM) to see whether supply-side incentives are	Immediately contact the Curatio International Foundation to establish a date to discuss	GoG

	cost-effective and affordable	findings	
Communications	Provide resource mobilization	By the end of	WHO,
and advocacy	and advocacy training to assist with proactive CSO participation in TB policy- making	2018	GFTAM

Q1: first quarter; Q4: fourth quarter.

Overview

On 19–20 June 2017, two WHO consultants visited Tbilisi, Georgia to assess the financial sustainability of TB activities in the country and its readiness to transition from a donor-financed to a government-financed programme. This document provides an overview of this mission and the resulting findings.

Scope and purpose of technical assistance mission

Under the framework of a United States Agency for International Development Regional Platform project, the WHO Regional Office for Europe is supporting the six Member States within the Eastern Partnership4 to document their preparedness to transition to government-financed programmes and the financial sustainability of their TB activities in light of reduced support from GFATM and other donors. The project will review the sustainability of donor-financed TB activities, analyse the challenges and potential consequences of the transition, and suggest actions to mitigate challenges and maximize opportunities in the six Eastern Partnership countries. Georgia was the first Eastern Partnership country visited during this project.

The mission objectives were to:

- discuss sustainability successes and challenges to date with relevant stakeholders;
- explore the triggers and enablers for transition;
- identify the gaps in key transition-related financial, human resource and programmatic data; and
- support the review and subsequent development of tailored strategic plans in countries where these are currently lacking, and review and provide expert opinion on existing ones.

Consultants are grateful to the WHO Regional Office for Europe's joint TB, HIV and viral hepatitis programme for driving the preparations for the technical mission; Marijan Ivanuša, WHO Representative of the WHO Country Office in Georgia, for providing overall support during the mission; and Nino Mamulashvili, for being available to participate in most of the meetings. Special thanks are given to Dr Zaza Avaliani, Director of NCTBLD, for mobilizing his staff and organizing meetings with the MoLHSA of Georgia.

⁴ Eastern Partnership countries comprise Armenia, Azerbaijan, Belarus, Georgia, the Republic of Moldova and Ukraine

Mission report

Socioeconomic and geopolitical context in Georgia

Georgia ranks 70th in the United Nations Development Programme's Human Development Index and has a population of approximately 3.7 million, of which 52% live in urban areas.5 The health status of the population deteriorated owing to a serious decline in socioeconomic conditions in the 1990s; compared with western countries, health indicators remain unfavourable.

After the war between the Russian Federation and Georgia in August 2008, the Russian Federation occupied the Georgian regions of Abkhazia and South Ossetia – amounting to approximately 20% of Georgia's internationally recognized territory. Occupation of these regions continues, presenting serious challenges that extend to population health, impacting on TB prevention, diagnosis, treatment and management. Nevertheless, Georgia remains a solid example of post-Soviet democracy and stability, and is firmly committed to Euro-Atlantic integration.

Georgia's gross domestic product per capita has gradually increased over the last decade. It reached upper-middle-income status in 2015, when the gross domestic product per capita grew to US\$ 3743 (from US\$ 1763 in 2006).6 The Georgian Government has demonstrated its commitment to population health and well-being, but its ability to finance the full range of TB activities might be undermined by the slow economic growth of recent years and increase in external debt (15.1 billion Lari as of June 30, 2016).

Policy and strategies pertaining to TB

The Georgian Government decree No. 724, dated 26 December 2014, on the 2014–2020 State Concept of the Health Care System of Georgia, defines TB as a priority among communicable diseases, along with HIV and hepatitis C.

The Parliament of Georgia endorsed the Law on Tuberculosis Control (dated 11 December 2016), based on WHO-recommended principles for TB control. This implies a political will to meet the obligations of the state in the area of TB control, including respect for and protection of the rights of individuals, society and patients.

Georgia developed a five-year NSP for TB for the 2016–2020 period that aims to align the national TB response with the latest international evidence, strategic policies and programmatic guidance. It is consistent with the End TB Strategy⁷ and

⁵ Human development reports: Georgia. New York: United Nations Development Programme; 2017 (http://hdr.undp.org/en/countries/profiles/GEO, accessed 6 July 2017).

⁶ GeoStat. Tbilisi: National Statistics Office of Georgia; 2017 (http://www.geostat.ge/, , accessed 6 July 2017).

WHO End TB Strategy; (http://www.who.int/tb/strategy/End_TB_Strategy.pdf?ua=1)

the TB action plan for the WHO European Region 2016–2020⁸. The NSP includes programmatic interventions and detailed financial figures for the first three years of implementation (2016–2018). The MoLHSA of Georgia took the lead in developing NSP, with important technical input provided by key national stakeholders. NSP for TB is endorsed by GoG.

With the support of GFATM, Curatio International Foundation consultants drafted a TSP for TB and HIV/AIDS programmes. The TSP was designed using a transparent and participatory process, with close involvement of all major stakeholders including the CCM, MoLHSA, National Center for Disease Control and Public Health (NCDCPH) and TB and HIV service providers, along with CSOs and patient groups. The Curatio International Foundation's TSP was drafted by Curatio consultants contracted under the GFATM Program, however, the development process went through PAAC, chaired by the Deputy Minister and was endorsed and cleared by the CCM, although it has not yet been endorsed by the government.

The NCTBLD is the main governmental TB institution, and is tasked with providing care for TB, M/XDR-TB, and extrapulmonary and paediatric TB patients. It is also the only facility providing surgical intervention for TB patients in need. NCTBLD is responsible for and leads the development of clinical guidelines and practices. Clinical guidelines for TB prevention and treatment are available, although some need to be updated; for example M/XDR-TB clinical guidelines, guidelines addressing the implementation of shorter MDR-TB regimens and palliative care guidance.

Financing and planning

GoG has made strenuous efforts to improve access to health care and eliminate health disparities among the general population. The GoG health budget increased by more than 250% during 2012–2016. The share of government spending on health as a percentage of general government expenditure is increasing, as is the share of government spending on health as a percentage of total health expenditure. The introduction of universal health care in Georgia provides evidence for GoG's political commitment to, and planning for, improvement in population health.

Despite these advances, large financial and planning-related gaps remain. The total funding gap for 2016–2018 is approximately US\$ 11.4 million – with the most important gaps in the supply of M/XDR-TB treatments and the provision of adherence support for patients.

It should be noted that Georgia does not have capacity to prepare sub-accounts on spending at disease level. This limits the government's ability to plan budgets

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⁸ Tuberculosis action plan for the WHO European Region 2016–2020; (http://www.euro.who.int/__data/assets/pdf_file/0007/283804/65wd17e_Rev1_TBActionPlan_150588_withCov er.pdf?ua=1)

accordingly; the country would benefit from technical assistance to develop a suitable system.

The country's fiscal situation (which is caused by external factors and not by a lack of commitment or prioritization from GoG) is considered the biggest cause of uncertainty and risk to sustainability for TB activity financing. It is widely accepted that if the economy improved, the TB budget would increase; however, trends show that the economy is shrinking.

Further, the importance of the lack of capacity to fill vital financing gaps for operational components and lack of recognition among development partners of the risks that these less-obvious but critical gaps pose to programme objectives cannot be understated. Gaps related to the key interventions outlined in Georgia's NSP for TB and the actions taken to mitigate them are outlined below.

Staff salaries and facility expenditure in TB services are to be increased in accordance with relevant Government policies; timeline: continuous

Partly achieved. Salaries of TB health care workers have increased in Tbilisi but not at the regional level. It is unlikely the salaries of regional TB health care workers will increase until the President Decree on the Minimum Wage is updated. Currently, private clinics are only required to pay staff around 280 Lari per month (US\$ 117). This disincentivizes young medical students from pursuing a career in the area of TB and thus brings forward the inevitable problems arising from an ageing TB workforce (with an average age of 65 years). 9

Renovation and refurbishment of TB facilities; timeline: 2015–2020

Progress has been made. An inpatient paediatric unit of the NCTBLD has been built, following an investment of 1.3 million Lari. There are currently five outpatient clinics in Tbilisi: one brand new facility was built to replace two old outpatient clinics and another new outpatient clinic is currently under negotiation. The Western Georgia Center of TB and Lung Diseases was partly privatized with investment obligation and is under renovation.

Provision of microscopy and conventional culture assays; timeline: 2015–2016 (with 100% takeover by mid-2016)

This was successfully implemented in October 2016. GoG is procuring and delivering to the all laboratories, including National Reference Lab. Some concerns were raised about roles and responsibilities emerging from the switch

⁹ President Decree N351 on Minimum Wage is generally used for administrative penalties and sanctions as defined by the legislation of Georgia. For example, in case of civil offenses, the court may impose sanctions (payment of minimum wage rate) over the employer. In the public sector, salaries are defined by the Law of Remuneration - the private sector is not dependent on the standards defined by this law.

from GFATM to GoG funding, including a lack of clarity about the staff responsible or budget available for managing and distributing stock.

Clinical investigation of TB patients; timeline: 2015–2016 (with 100% takeover by mid-2016)

This service has been taken over by GoG, although there is a gap in service availability. Georgia's health system does not have the capacity to support access to this service in all regions: this is solely related to capacity issues complicated by programmatic issues. For example, private clinics actively dissuade TB patients from attending their clinics, thus avoiding their responsibility to provide services and care to TB patients. The consequent reduced capacity to execute tasks and responsibilities represents a significant barrier to proper TB management.

It is therefore short-sighted to look at this situation in purely financial-terms. Although funding for TB clinical investigations has indeed been taken over by GoG, providers do not always provide the services.

Individual infection control for TB staff and patients; timeline: 2015–2016 (with 100% takeover by mid-2016)

Budget planning for this activity is complete: GoG has provided funds and an order for procuring quality respirators has already been placed in the electronic bidding system.

Procurement of first-line anti-TB drugs; timeline: 2015–2016 (with 100% takeover by mid-2016)

GoG has successfully taken over procurement of first-line anti-TB drugs.

Procurement for laboratory investigations; timeline: 2016–2020 (50% takeover by the end of 2018 and 100% by the end of 2020)

Work towards this intervention has not yet commenced, but this is not perceived as a problem. It was noted that this intervention does not refer only to consumables but extends to salary and reagents, training etc. A single agency will be responsible for procuring all relevant supplies and services and no bottlenecks or problems are foreseen.

Develop mechanisms to provide adherence support to patients; timeline: 2016–2020 (50% takeover by the end of 2018 and 100% takeover by the end of 2020)

GoG is ahead of schedule on this intervention, having already taken over a major part (if not 100%) of the incentive payments from GFATM.

Procurement of second- and third-line anti-TB drugs; timeline: 2016–2020 (75% takeover by the end of 2018 and 100% by the end of 2020; note that 25% have already been procured by the government)

With 18 months to go until 50% takeover is required, work towards this intervention has not yet started; however, this is not perceived as an issue.

Other financing and planning considerations include the intended takeover of CCM following GFATM withdrawal. GoG has considered how the CCM could be integrated into the MoLHSA. It was noted that the strength and competency of the CCM Secretariat had been crucial to its success, but it was also noted that CCM Secretariat salaries are paid by GFATM and are significantly higher than GoG staff remuneration. As such, these valuable staffers may be drawn to higher-paying jobs in the private sector and the CCM could subsequently lose institutional memory. It is hoped that the MoLHSA can offer better salaries when GFATM leaves, although no plan or budget is in place to support this.

Another option is that the CCM could be integrated into a broader coordinating body after GFATM withdrawal. Such a body could include coordination of all primary health care at a higher level than that of the existing CCM, with a CCM-type remit that includes but is not restricted to TB. The new CCM's mandate could shift depending on changes in the burden of disease. It was widely agreed that GoG could and should finance the new CCM Secretariat for further strengthening and to prevent loss of institutional memory.

Medicine procurement

An uninterrupted supply of high-quality anti-TB drugs has been ensured for all patients in need and stock outs have not been observed. Procurement of first-line drugs has been covered by the state since 2015, but the budget for 75% of second-line drugs is covered by the GFATM grant. There is plan for gradual takeover by the state budget: 25% in 2017, 50% in 2018, 75% in 2019 and 100% in 2020. Anti-TB drugs are currently procured with financial support from the GFATM. Currently, the drug management system for first- and second-line anti-TB drugs (including quantification method, procurement, import and storage) is carried out with GFATM support.

Responsibilities for the storage and countrywide distribution of first-line anti-TB drugs have been assigned to the NCTBLD, after GoG started purchasing them. However, no budgetary provision was made for this service and the NCTBLD is providing it without reimbursement. The staff involved in this process are payed through GFATM project.

Drug management at district level in some regions is challenging because of a shortage of well-trained staff. Outpatient TB services in rural Georgia are provided

by primary health care staff in private facilities. In general, National Tuberculosis Programme (NTP) staff is concerned by the lack of control over TB patient services in private clinics, including anti-TB drug storage.

There is also concern about the continued smooth functioning of the drug management system after GFATM withdrawal. NCTBLD does not have any legal responsibilities for anti-TB drug provision countrywide, and no entity in the country other than the GFATM Project Implementation Unit in the National Center for Disease Control has been assigned this task.

The Law on Procurement in Georgia theoretically provides an equal opportunity for all organizations to procure drugs (e.g. CSOs, nongovernmental organizations, private organizations). However, in practice a bank guarantee for 1% of the total budget is required from any procurement partner. This represents a financial barrier that prevents smaller nongovernmental organizations and CSOs from engaging in procurement activities.

Supervision, monitoring and surveillance

Monitoring and evaluating the epidemiological situation and implementing TB activities are jointly carried out by two institutions: NCTBLD and NCDCPH. These are responsible for separate, dedicated areas of TB control.

NCTBLD is the national centre for TB clinical management, and is also responsible for supervising specialized TB services, mentoring TB medical personnel and monitoring of quality of services, including field supervision and routine recording and reporting on TB. Supervision from the central to peripheral level is conducted by a dedicated monitoring and supervision team at NCTBLD; this takes place twice yearly in each region of the country. Regional supervisory visits at the district level are conducted on a quarterly basis by regional TB coordinators. Supervisory visits at all levels are established and have been supported until now by GFATM. However, the future of supervisory visits is unclear after GFATM support ends, and this issue has not been addressed in any strategic document. The legal status of the monitoring and supervision team at NCTBLD is also undecided, although the position of regional TB coordinators is acknowledged in the state programme.

NCDCPH is responsible for disease surveillance, the laboratory network, contact investigations, research and providing expert advice. It is the principal recipient of the new TB grant under the GFATM new funding model.

Currently, TB surveillance in Georgia is a combined paper-based and electronic system. TB doctors at the district level notify TB cases at the regional level using paper-based forms, which are sent on a weekly basis. Regional TB coordinators are responsible for data entry into the e-TB database, after validation. The database manager at NCTBLD is responsible for the overall validation and processing of the

whole dataset, as well as for overall coordination across the reporting entities. With GFATM support, a plan to expand/upgrade the current e-TB database to district level could be developed. However, ensuring compatibility and linking with the MoLHSA e-health national system would be absolutely essential for this.

Quality, safety and standards

GoG funds the procurement of first-line anti-TB drugs but does this via the GFATM procurement platform. Significant risk is involved in a rapid transition to national-led procurement of effective and affordable drugs and diagnostics, and GoG requires significant assistance to mitigate potential harm caused by changing policies on the national procurement of affordable, high-quality medicines and diagnostics.

The risks facing GoG are not limited to losing access to the GFATM procurement platform after transition but extend to losing access to price guarantees and consistent pricing for anti-TB drugs, which could have a serious impact on the volume and quality of drugs that GoG is able to procure. In turn, this could negatively affect TB incidence, case complexity and patient outcomes.

While GoG has access to the GFATM's procurement platform, the price and quality of drugs remains consistent. However, Georgia is too small to demand a high number of suppliers to compete for their business, meaning market forces are likely to result in GoG paying higher prices for drugs after transition. Further, there is currently not a quality requirement for drugs in Georgia, meaning that GoG can procure drugs from anywhere with little guarantee of quality. Although not a requirement, different mechanisms of purchasing high-quality medicines are sometimes used in different programs, including WHO prequalification and GMP certification. One option to address quality-related issue would be to include a requirement for WHO prequalification or another minimum standard of quality. This would reduce the risk of a budgetary limitations and fluctuating prices forcing a shift to poorer quality drugs in a post-transition landscape.

GFATM withdrawal may present barriers to GoG in providing new anti-TB drugs (in particular, more expensive drugs against X/MDR-TB) to patients, and limit the country's ability to procure and use quality and affordable anti-TB drugs and diagnostics. GoG needs help to demonstrate that the risk of poor quality and/or price fluctuations could cripple NTP performance. Further, although GoG is willing to and capable of financing the TB programme, this does not extend to the maintenance, upkeep and introduction of new devices or machinery such as X-ray equipment and health information systems. All new computers, gene expert machines and vehicles (vital for regional outreach activities) have been financed by GFATM, but there is concern about GoG capacity for the long-term maintenance of this equipment and the impact this may have on quality of care and safety.

Health system strengthening: service delivery and links with other interventions

Multiple issues pertaining to service delivery were discussed, including outpatient service delivery and issues related to Georgia's private providers operating within the vertical TB structure. This means that some programmes are wholly paid for by the government but delivered by private clinics.

In terms of financing service delivery, Georgia appears to be relatively stable. However, serious programmatic issues are associated with service delivery, service integration and health system strengthening. One of the most pertinent relates to the complexity of having a vertical TB programme operating in a privatized horizontal system. This is further complicated by the fact that the Private Provider Agreement is due to expire in 2018. This means that private providers might abandon TB service delivery from their offerings from 2018. All GoG stakeholders understand the importance of this, but there is no agreement in place. Negotiations with service providers have started and the Memorandum of Understanding on continuing service delivery is planned to be concluded in September 2018.

Almost all medical centres have been privatized: the only centres remaining under the state umbrella are NCTBLD and the Infectious Diseases Hospital in Batumi. However, the government pays for 70% of TB services, and the remaining 30% is privately funded (out-of-pocket expenses). There is one TB referral centre (200 beds) in Tbilisi, 10 regional treatment centres and 56 outreach facilities (approximately 400 beds in total).

Access to outpatient services in rural areas is poor. The main reason for this is a lack of TB health care workers, exacerbated by their high average age (and impending retirement). The issue of staff remuneration (particularly in regional areas) also creates issues in service delivery. For staff to be effective, their salaries should be appropriate; although GoG has increased the salaries of TB worker in Tbilisi, this is yet to extend to regional workers.

The privatized nature of Georgia's health care system (private medical service providers form more than 80% of the total) presents another layer of complexity in terms of TB service delivery. Private institutions operate within the vertical TB structure, but have a low level of commitment to actually delivering those services.

A potential solution to this problem could be to create a programme, requirement, regulation or incentive that demands/encourages more commitment from private service providers to deliver TB services. The reasons for the lack of commitment relate to the stigma associated with TB patients and the opportunity cost associated

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 $^{^{10}}$ A survey conducted in 2015 (and cited in NSP) points at 5% OOP payments with a decreasing trend.

with treating them (i.e. higher profit margins can be obtained by treating patients with other conditions).

Georgia's privatized system also influences the country's ability to follow the WHO recommendation to have an NTP manager (who is the NTP Director) with power over decision-makers (including private medical providers). In Georgia, the only role that comes close to fulfilling this remit in terms of power and decision-making is the Deputy Minister of Labour, Health and Social Affairs. The MoLHSA acknowledges that it does not have adequate influence over the private sector, but that the state's purchasing/negotiating power, regulatory and licensing mechanisms could be used to address this.

Evidence-based TB policy and practice

A pilot project on TB-specific, results-based financing is being actively pursued by Curatio International Foundation in partnership with LSHTM. Given that demand-side incentives are already in place via payments for patient adherence, this project seeks to address supply-side issues by motivating TB health care workers to promote TB treatment.

The project is developing a costing and cost–effectiveness analysis of interventions to assess incentives for health care workers. The pilot study involves 10 control units and 10 intervention units for outpatients only, and will be assessed over a four-year period. Intervention will start in 2018 and follow patients for a two-year treatment period plus follow-up, and will allow time for changing the intervention. GoG will then decide whether supply-side incentives are cost-effective and affordable.

The project is also exploring ways to link Georgia's vertical TB programme with primary health care practice.

Communications and advocacy

CCM is vital (current the only platform) for including CSOs in decision-making and for communicating advice to decision-makers. GFATM is providing technical assistance to CSOs to help them advocate more effectively. Despite this, the CCM–CSO relationship is not well balanced, although this extends beyond CCM and TB to all CSO engagement in Georgia. Addressing this requires further assistance to motivate and enable CSOs to engage more proactively and thereby fulfil their potential.

Recommendations

Financing and planning

The Curatio International Foundation and MoLHSA of Georgia should advocate for GoG endorsement of the TSP led by the Curatio International Foundation before the end of 2017.

NCTBLD should lead efforts to update guidelines (e.g. M/XDR-TB clinical guidelines to address the implementation of shorter MDR-TB regimens, palliative care guide) by end July 2018 to reflect current best standards of care.

The WHO Regional Office for Europe should provide technical assistance to departments in need to ensure that health budgets can be planned and maintained at the necessary level of detail. Engagement in specifying requirements for technical assistance should begin immediately and should be integrated throughout 2018 to fully benefit the last two years of the current NSP for TB (2019–2020).

An advocacy coalition comprising relevant stakeholders should be formed immediately to communicate to the Parliament of Georgia the enormous implications of the President Decree on the Minimum Wage. Addressing these could incentivize young medical students to pursue a career in TB and thus mitigate the ageing TB workforce. CSOs, the Curatio International Foundation, GFATM, MSF and the WHO Regional Office for Europe should make full use of existing data and evidence to demonstrate possible scenarios (related to downstream health care costs and health outcomes) associated with (i) changing the law (to improve long-term sustainability of the health care workforce and TB control); or (ii) maintaining the status quo (extreme shortage in supply of health care workers leading to a lack of health system sustainability, TB control and overall population health).

GFATM should engage relevant GoG staffers and departmental heads in discussions to agree on clear, fair stipulated roles and responsibilities for stock management, distribution and budgeting. These should be formally documented. Development partners (GFATM, MSF, WHO) should immediately and explicitly acknowledge and address non-finance-related gaps in TB services. Perhaps most importantly, they should (i) support GoG in creating policy solutions that hold private clinics accountable for providing services and care to TB patients; and (ii) assist NCTBLD in establishing a reliable reimbursement system for expenditure to avoid anti-TB drug storage and strengthen countrywide distribution services.

GoG should immediately commence working on a plan to take over the financial responsibility for 50% of laboratory supply procurement and 75% of second- and third-line anti-TB drug procurement by the end of 2018. By the beginning of 2018, GoG should have developed a clear action plan with milestones, a timeline, responsibilities, stakeholders for engagement, and the resources required using a T-minus approach to timing; October 2018 should be included as the soft-deadline for achieving co-financing requirements.

MoLHSA should advocate for a plan or budget to support better salaries for CCM staffers following GFATM withdrawal to avoid losing them (and the associated institutional memory). This could be in the form of a short policy brief outlining the potential scenarios and unintended consequences related to programme sustainability and transition success. A feasible scenario for inclusion in this brief is the option to integrate CCM into a broader, more flexible and adaptive coordinating body that oversees all primary health care. The brief should be delivered to decision-makers by end the first quarter of 2018.

MoLHSA should provide documentation to members of parliament in the form of a case study (e.g. of the TB Patient Coalition) highlighting the negative impact the Public Procurement Law (requirement for a bank guarantee for 1% of the total budget) has on procurement activities in the country. This should be delivered by the beginning of 2018.

Supervision, monitoring and surveillance

GFATM should work with other development partners (MSF, WHO) and GoG to ensure that supervisory visits continue after GFTAM withdrawal. These should be addressed in the NSP by the first quarter of 2018.

The GFATM plan to support the expansion and upgrade of the current e-TB database to district level and link it with MoLHSA e-health national system should be monitored and evaluated by GoG so that scalability and replicability in other countries can be considered.

Medicine procurement

GFATM and WHO should formally agree to ensure that GoG does not lose access to the GFATM procurement platform after transition to ensure that drug price and quality remain consistent; possible legislative barriers should be discussed and avoided. Concurrently, GFATM and WHO should assist GoG in developing a minimum quality requirement for drugs in Georgia via the WHO prequalification of medicines programme.

Quality, safety and standards

GFATM should put in place a maintenance and updating mechanism for health information systems, gene expert machines and vehicles (and other relevant equipment) to support Georgia's transition to a domestically financed TB programme. This mechanism should be defined as soon as possible and shared prior to the final transition.

Health system strengthening: service delivery and linking with other interventions

All relevant GoG departments should immediately commence efforts to address the Private Provider Agreement (due to expire in 2018) and prevent private providers from abandoning TB service delivery. Multiple, cross-sectoral stakeholders should be engaged and all feasible policy solutions, implications and unintended consequences should be considered, debated and documented before a decision is reached.

GoG should continue the programme of increasing staff remuneration (possibly by providing different payments for services in regional areas) to close regional access gaps, limit staff turnover and encourage the selection of TB as a specialty. A strategic decision in medical education should be taken regarding TB specialization; this could involve merge with pulmonology or infectious disease

GoG should make full use of its purchasing/negotiating power, regulatory and licensing mechanisms to ensure private service providers deliver TB services.

Evidence-based TB policy and practice

GoG should monitor the pilot project on results-based financing being implemented by Curatio International Foundation and LSHTM to see whether supply-side incentives are cost-effective and affordable. A date should be set to discuss key findings from the pilot following the publication of results.

Communications and advocacy

In 2018, development partners (GFTAM, WHO) should provide resource mobilization and advocacy training to encourage proactive CSO participation in TB policy-making processes.

Annex 1. Main institutions visited

NCTBLD

- Zaza Avaliani, Executive Director
- Nana Kiria, Clinical Director
- Nino Lomtadze, Coordinator of GFATM-related activities

MoLHSA of Georgia

- Nino Berdzuli, Deputy Minister
- Marina Darakhvelidze, Head of Health Care Department
- Ketevan Goginashvili, Head of Health Policy Division
- Ia Kamarauli, Senior Specialist, Health Care Department

Health Care and Social Issues Committee, Parliament of Georgia

 Dimitry Khundadze, Deputy Head of Health Care and Social Issues Committee, CCM for GFATM

CCM for GFATM

Tamar Gabunia, Vice-chair of CCM

National Center for Disease Control (GFATM Principal Recipient)

- Irma Khonelidze, Manager of the GFATM Grant
- Nino Vakhania, Financial specialist
- Maka Danelia, Monitoring and Evaluation specialist
- Giorgi Kuchukhidze, GFATM focal point

Curatio International Foundation

- Ketevan Chkhatarashvili, President
- Ivdity Chikovani, Research Unit Director
- Ketevan Goguadze, Director of Business Development Unit

WHO Country Office

- Marijan Ivanuša, WHO Representative, Head of Country Office
- Nino Mamulashvili, National Professional Officer

Annex 2. Agenda of visit

Financial Sustainability Analysis Mission, 19–20 June Tbilisi, Georgia

Allira Attwill, Health Economist, WHO Consultant

Dr Nikoloz Nasidze, WHO Consultant

Date	Time	Meeting
19 June 2017	9:30-12:00	Dr Zaza Avaliani, General Director,
		NCTBLD; NTP key staffer
	12:00–13:00	Lunch
	13:00-15:00	MoLHSA
		Deputy Minister, Nino Berdzuli;
		Representatives from the
		Programme Management
		Department and Department of
		Health Care,
	15:30–16:30	Tamar Gabunia, Vice-chair of CCM
	17:00–18:00	WHO Country Office
20 June 2017	9;30 -11:00	Irma Khonelidze, National Center for
		Disease Control (GFATM Principal
		Recipient)
	11:30–13:00	Curatio International Foundation
	13:00-14:00	Lunch
	14:00-15:00	Health Care and Social Issues
		Committee, Parliament of Georgia
	16:00–17:00	Ministry of Finance

The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

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