Concept Note
A people-centered TB care model for Georgia

February 2018

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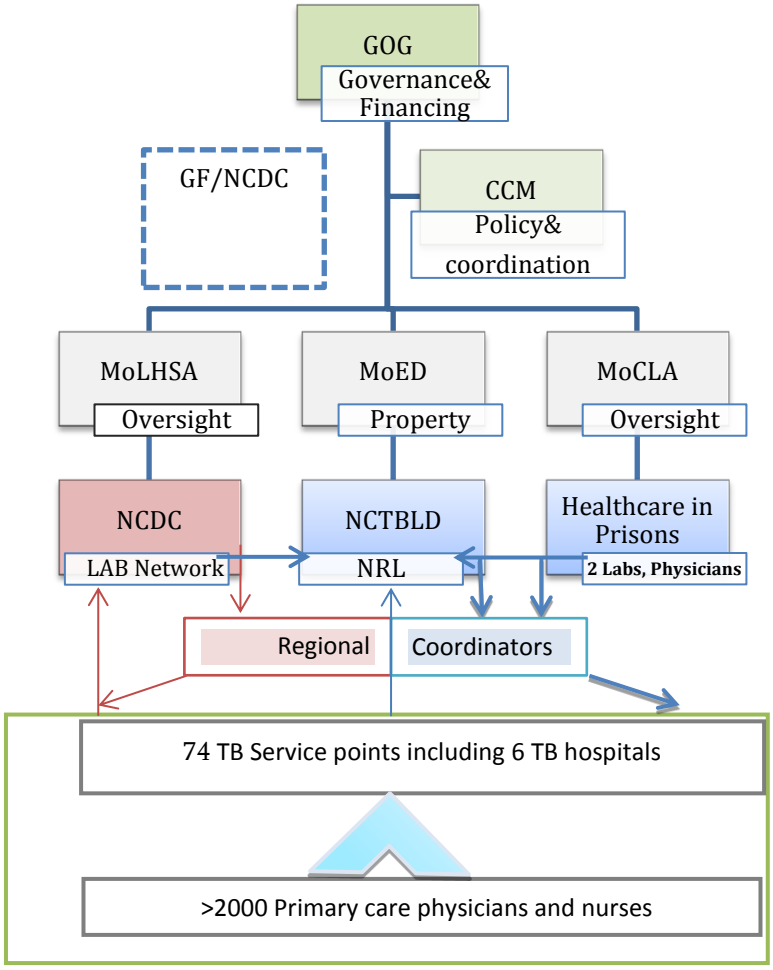
1 Background

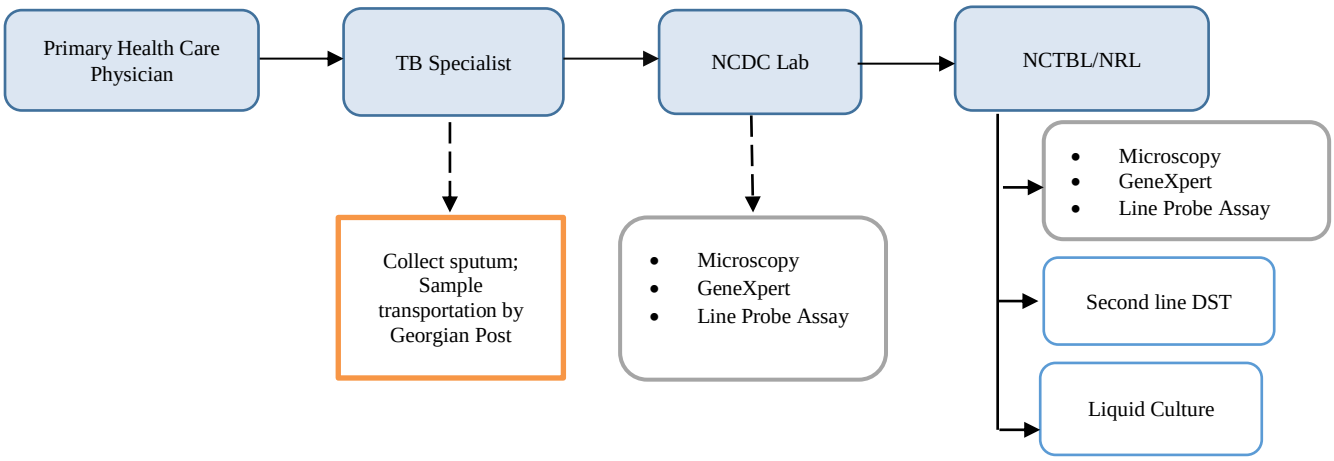
National TB Program in Georgia is implemented by multiple partners including the Ministry of Labor, Health and Social Affairs (MOLHSA), the National Centre for Disease Control and Public Health (NCDCPH), the National Centre for Tuberculosis and Lung Diseases (NCTBLD), and the Ministry of Corrections and Legal Advice (MCLA).
TB services are delivered by specialized outpatient and in-patient clinics. There are 69 TB service points staffed by a TB specialist and a nurse in each district of Georgia. In 2011 a vast majority of TB dispansaries in regions were integrated into public and private general hospitals. However, in Tbilisi, outpatient TB care is being provided by a network of TB dispensaries and a number of DOT spots at primary care facilities. In 2015 standalone TB dispensaries were merged with the National Center for Tuberculosis and Lung Diseases and currently they operate under one management umbrella. TB service points can offer a full range of diagnostic services to confirm the diagnosis and provide follow-up care and clinical monitoring for individuals with confirmed TB. (See figure 1 for organization of TB services). TB specific diagnostic tests (including sputum microscopy, GeneXpert and culture) are conducted at NCDCPH public health laboratories and the National Reference Laboratory in Tbilisi. A well functional sputum transportation system via Georgian Post allows for timely transfer of the sputum samples from district level facilities to labs. (Figure 2)

Figure 1. Organization of TB Services



CCM-Country Coordinating Mechanism for HIV/AIDS, TB and Malaria
GoG-Government of Georgia
GF-Global Fund
MoED-Ministry of Economic Development
MoCLA-Ministry of Corrections and Legal Advice
NCDC-National Center for Disease Control and Public Health
NCTBLD-National Center for TB and Lung Diseases
NRL-National Reference Laboratory

Figure 2. Flow of TB presumptive case screening and sputum testing services

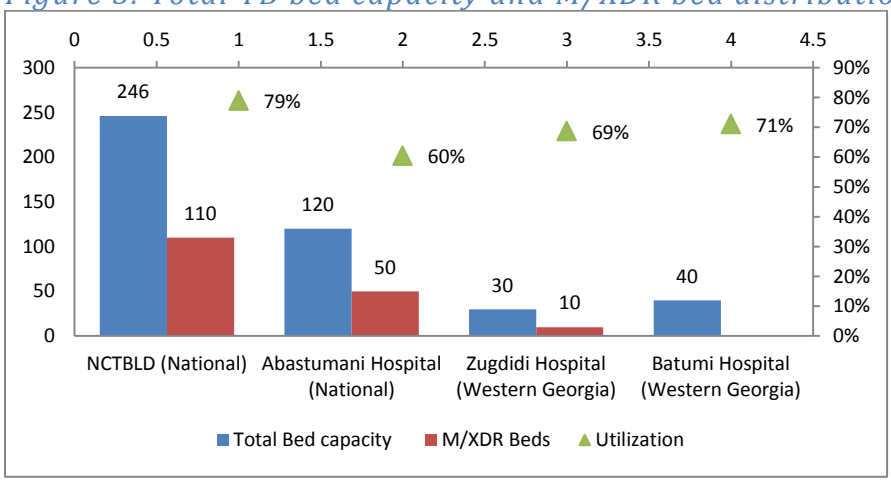


Primary care providers (PCPs) are responsible for early recognition and timely referral of TB presumptive cases to specialized services. If TB is confirmed, then primary care physicians and nurses with support and supervision of the district TB teams are expected to provide DOT in the community. Despite the availability of a wide network of PCPs across the country, patients often bypass primary care services and go directly to hospitals. Possible reasons for low utilization of primary care services include poor physical infrastructure, high level of TB related stigma and general belief that TB should be treated by "phtysiatrists." Furthermore, PCPs consider TB service delivery beyond their competencies and are often reluctant to actively collaborate with NTP staff.

In addition to outpatient TB service delivery points which are part of district level general hospitals (private and public), there are six specialized TB hospitals in Tbilisi, Batumi, Zugdidi, Abastumani and Poti. The total bed capacity amounts to 466 beds (out of which 170 beds are for M/XDR TB cases). (See figure 3).

A vast majority (70%) of new smear-positive TB cases and almost all (90%) of MDR TB care are still hospitalized during an intensive phase of treatment. The average length of stay at National Center for TB and Lung Diseases was 25 for sensitive and 60 days for MDR TB cases (MoLHSA Assessment report issued in 2015). Average length of stay at all hospitals reported in 2015 was 120 for M/XDR TB cases.[1]This is lower compared to many other countries in the region. However, out of government expenditures on TB control, the highest share (63.1% in 2014) is spent on inpatient curative care compared with outpatient care.

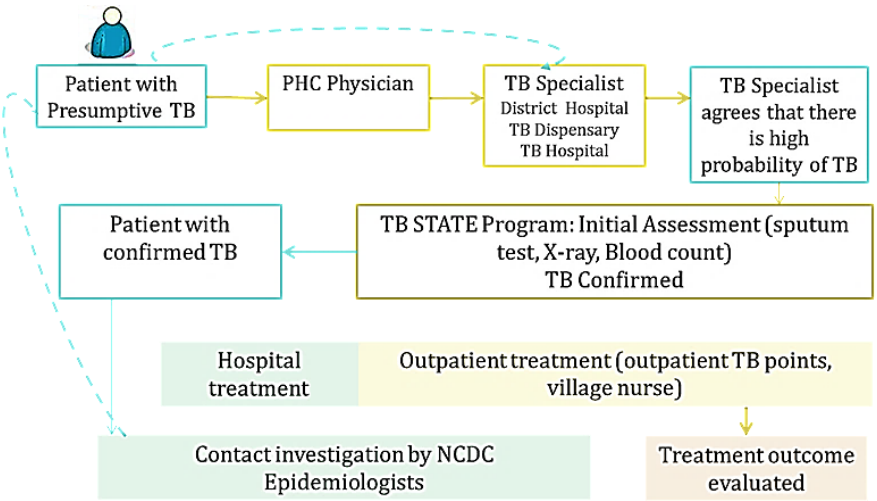
Figure 3. Total TB bed capacity and M/XDR bed distribution (2015 MoLHSA)



1 Global Tuberculosis Report 2016, World Health Organization

District level public health centers have been increasingly involved in contact tracing since late 2012. TB specialists are obliged to notify public health services about a confirmed TB case within 24 hours. Then public health personnel are responsible for visiting patients' households and referring eligible contacts to TB services for a diagnostic workup. Epidemiologist are expected to provide close follow up to make sure that a contact reaches TB services and takes necessary tests.
Figure 4 describes a patient pathway within the Georgian health care system from the first contact with organized health services to final treatment outcome. Dashed lines on figure 4 indicate that patients with TB presumptive symptoms can directly access TB specialist services at TB hospitals or outpatient service delivery points. PHC providers often remain unaware of the fact that TB is diagnosed to someone in their catchment population neither they can assist with contact tracing or health education to families at risk. A patient care pathway should be streamlined through strengthening a gatekeeping role of primary care providers and establishing effective referral and counter referral mechanisms between primary care and specialized TB services both outpatient and inpatient.

Figure 4. TB care pathway in Georgia



2 Introduction

In line with the End TB and National TB Strategy for Georgia this concept note defines key features of the people-centered TB care model that is evidence-based, feasible and relevant to Georgian health care settings.

A People-Centered model of care is defined as **"an efficient and integrated set of affordable, accessible and acceptable health services, provided in a supportive environment to prevent, diagnose and treat TB".**[2]
A people-centered model of TB care should be designed to ensure that:

- Services meet patients' and their families' needs and expectations;
- Social determinants of health are taken into consideration;
- Services, tasks and responsibilities are defined for each setting and within different facilities,
- while recognizing the need for flexibility to respond to the needs of individual patients;
- Well-functioning systems for referral are in place across various settings and facilities;
- The model of care is acceptable to service users;
- A robust data-reporting system is in place to monitor performance, including diagnostic delay and loss to follow-up;

2. A People-Centered Model of Care, Blueprint for EECA countries, first edition, 2017, WHO

- Patients and their families are protected from catastrophic financial expenses.

3 Components of a people centred model of TB care

The spectrum of health care professionals to be involved in outpatient TB care delivery to comprehensively address all needs TB patients have is quite broad. This includes medical doctors and other health and social care workers (Table 1).

Table 1. Health workforce involved in TB care

Medical doctors	Other health care professionals	Patients`supporters	Administrative personnel
Pulmonologist and TB specialist Family Physician Physicians of different specialties for comorbidity and adverse event management	Nurses Psychologists Nutritionists Public Health Workers/Epidemiologists	Social Workers CSO staff/volunteers/people with TB experience	Program managers Ancillary staff Financial management staff Legal experts

Table 2 sets out the various components of a model of TB care and describes how key TB control functions should be distributed to make the model more outpatient care oriented and peoplet centered. Health facilities to be involved in outpatient TB care delivery in Georgia include TB specialized outpatient care units which operate in urban and semi-urban (districts) areas, standalone TB clinics in Tbilisi, primary care providers in urban and rural areas. Clinical tests and TB specific investigations can be done at public health laboratories, labs at TB hospitals and clinical labs functional at large primary care sites and district general hospitals. The role of CSOs and patients with TB experience in TB service delivery has yet to be recognized by the National TB Program and institutionalized through relevant regulatory mechanisms (including National TB Management Guidelines).

Table 2. Proposed Distribution of TB control functions among different types health care providers in Georgia

Type of service	Provided by whom								
	Community providers	Primary care providers		Outpatient providers				In-patient providers	
	CSOs/ NGOs/Social Workers	Rural	Urban	Specialized TB	Non TB	General lab/Diagnostics	TB Lab and diagnostics	Non TB hospitals	TB hospitals
Prevention, promotion and protection									
Health promotion and education	X	X	X	X	x				X
Immunization			X					X	X
Latent TB infection screening	X	X	X	X	X	X			X
Latent TB infection prescription		X	X	X					X
Latent TB infection treatment administration		X	X	X					
Detection and diagnoses									
Active case finding	X	X	X					X	X
Passive case finding referral		X	X	X	X			X	X
Clinical evaluation		X	X	X					X
TB Lab									
Microscopy							X		X
Culture and DST							X		X
Gene-Xpert			X	X			X	X	X
X-ray and others as needed			X	X		X		X	X
Treatment and support									
Treatment initiation				X					X
Treatment administration and observation	X	X	X	X					X
Monitoring treatment progress and response			X	X				X	X
Prevention and detection of adverse events and comorbidities		X	X	X				X	X
Treatment lab monitoring			X			X		X	X
Counselling and psychological support	X	X	X	X				X	X
Social support	X	X	X	X					

Table 3 presents an outline for proposed tasks distribution between **health professionals** involved in TB care across the care continuum at different health facilities. No legal barriers exist in Georgia for family physicians to full fill tasks listed below. The competency framework for general practice/family medicine specialists includes TB case detection and treatment monitoring as essential functions to be accomplished in collaboration with Pulmonologists and TB specialists. Therefore, shifting various tasks from specialized to primary care services can be achieved through inter professional collaboration, skills building and establishing well functional referral and counter referral linkages. These roles can be reassigned to other professionals (as illustrated with asterisk) if not all groups exist at all levels. For instance a village family physician can administer TB treatment via DOT if there is no nurse available. Family physician can be responsible for adverse events monitoring and management if for some reasons it is difficult to access TB specialists.
The role of meaningful and adequate financial stimulus cannot be underestimated in this discussion. Ministry of Labor, Health and Social Affairs of Georgia with technical assistance from Curatio International Foundation is working on introducing results based financing schemes to encourage primary care and outpatient TB service providers to improve treatment adherence support and consequently treatment outcomes. This scheme will be operationalized in 2018-2020 and will provide evidence to inform policy and programmatic decisions on funding outpatient care providers for TB service delivery.

Table 3. Tasks distribution between health care professionals across the care continuum

Essential case management tasks	Pulmonologist and TB Specialist	DOT nurse in rural/district level	Family Physician in Rural/District level	Family physician in a village	General Practice nurse in a village	Manager
Clinical tasks						
Primary counselling upon confirmation of TB diagnosis	√		*	*		
Follow up counselling on TB treatment adherence as well as on smoking	√	√	√	√	√	
Initiation of TB treatment	√					
Treatment administration through DOT	*	√	*	*	√	
Adverse events screening	√	√	√	√	√	
Adverse events monitoring	√		*	√		
Adverse events management	√		*			
Referral to TB specialist		√	√	√		
Referral to other specialists (not TB specialist)	√			√		
Management of comorbidities			√	√		
Treatment follow up			√	√		
Organizational tasks						
Elaborate an individualized patient management plan	√		√	√		
Coordinate TB management plan with plans for managing other comorbidities			√	√		
Coordinate multidisciplinary team	√		*	*		
Administrative						
Establish an integrated team	*		*	*		√
Coordinate and oversee operations of an integrated team	*		*	*		√

4 Immediate actions for supporting shift towards outpatient care delivery

The TB management guideline for Georgia endorsed by the Ministry in 2016 does not include provisions on how TB service delivery should be organized. The National TB Program initiated the guideline update early in 2017 with the Global Fund support. The WHO guidelines for treatment of drug-susceptible tuberculosis and patient care, 2017 update [3] provides a set of recommendations on how TB services can be organized to achieve best possible outcomes through introducing patient friendly services and eliminating barriers to access to DOT services. In line with the WHO recommendations, GFMA and Georgia TB coalition consider necessary to include the following provisions in the updated TB control guideline to improve quality of services and ensure that patients are informed well enough to make choice and effectively manage their own health problems.

4.1 Outpatient care for patients with confirmed TB

WHO recommends that treatment of TB – regardless of smear and DST status – can be performed in ambulatory settings from day one, including for sputum smear-positive cases, to reduce the risk of nosocomial transmission of strains in inpatient facilities and improve patient adherence to treatment. In the Georgian context, given good coverage with primary care and general health services, outpatient care should be set up if the patient lives in proximity to the facility where he or she can be treated (within walking distance or with available transportation). MoLHSA requires all outpatient TB service points to meet certain criteria for adequate infection control and patient safety. Currently, there are no minimum safety or service delivery standards defined for small primary care providers in rural areas in general, neither specifically for TB. With further expansion of TB diagnostic and treatment services to primary care level, introducing a simple set of basic safety requirements for primary care facilities may be considered by MoHSA.

DOT Providers: Currently WHO defines DOT as any person observing the patient taking medications in real time. The treatment observer does not need to be a health-care worker, but could be a friend, a relative or a lay person who works as a treatment supervisor or supporter. Observed treatment may also be achieved with real-time video observing and video recording (VOT). VOT is increasingly used in Georgia for treatment monitoring in a cohort of patients who can easily use computer technologies. However, DOT providers are still health care professionals exclusively. The recognition of community volunteers and former TB patients as DOT providers is important in the Georgian context. The low treatment success rate particularly among MDR TB patients indicates that health care providers alone fail to handle issues related to TB treatment adherence. National TB management guideline should incorporate provisions about DOT delivered by **trained lay providers** (CSOs/community volunteers/former TB patients). This should then be supported by adequate funding through national TB program and/or international partners.

DOT location: DOT in Georgia is largely facility-based. Home based DOT is provided to a limited number of homebound patients which for health reasons cannot attend DOT clinics. The TB management guideline in Georgia should support DOT delivery at home or in the community and by a health-care worker or trained lay provider. DOT delivered at a health facility, DOT provided by a family member and unsupervised treatment can be considered but are not preferable options.

Combined treatment adherence interventions: The National TB Program in Georgia should ensure access to a comprehensive package of treatment adherence interventions including patient and family education, material support (cash incentives to DS and DR TB patients is mandated by TB law in Georgia), psychological support and counselling. Use of digital health communications (SMS, phone calls) or a medication monitor should be encouraged.

3. Guidelines for treatment of drug-susceptible tuberculosis and patient care, 2017 update. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO

Based on the considerations above the following recommendations should be incorporated into the TB management guideline for Georgia.[34]

- Health education and counselling on the disease and treatment adherence should be provided to patients on TB treatment (Strong recommendation, moderate certainty in the evidence)
- A package of treatment adherence interventions may be offered to patients on TB treatment in conjunction with the selection of a suitable treatment administration option (Conditional recommendation, low certainty in the evidence)
- One or more of the following treatment adherence interventions (complementary and not mutually exclusive) may be offered to patients on TB treatment or to health-care providers:

    1. tracers and/or digital medication monitor (Conditional recommendation, very low certainty in the evidence)
    2. material support to patient (Conditional recommendation, moderate certainty in the evidence)
    3. psychological support to patient (Conditional recommendation, low certainty in the evidence)
    4. staff education (Conditional recommendation, low certainty in the evidence).

- The following treatment administration options may be offered to patients on TB treatment:

(a) Community- or home-based DOT is recommended over health facility-based DOT or unsupervised treatment (Conditional recommendation, moderate certainty in the evidence).
(b) DOT administered by trained lay providers or health-care workers is recommended over DOT administered by family members or unsupervised treatment (Conditional recommendation, very low certainty in the evidence).
(c) Video observed treatment (VOT) may replace DOT when the video communication technology is available and it can be appropriately organized and operated by health-care providers and patients (Conditional recommendation, very low certainty in the evidence).

4.2 Decentralized model of care for MDR TB

In line with the National TB Strategic Plan for 2016-2020 Georgia support decentralization of MDR TB service by developing capacity for MDR TB diagnoses and care at outpatient service delivery points at district level. A set of actions towards decentralization of MDR TB services include GeneXpert roll out, improving infection control measures at outpatient service delivery points at general district hospitals, mobile treatment committee to support peripheral sites in clinical decision making, training of primary care physicians and nurses in DOT for MDR TB patients and engaging CSOs, people with TB experience, social workers and psychologists in adherence support for MDR TB patients. There are still some legal limitations to decentralized MDR treatment delivery in community or home settings. This relates to restrictions on performing injections at home. Additional consultations with the Ministry of Health will be required to address this issue.
Along with the decentralization of MDR TB care, actions should be taken to ensure rational use of available hospital capacity.

4.3 Optimization of an inpatient service delivery network

The National TB Management Guidelines for Georgia issued in 2016 do not regulate hospitalization and patient discharge. The criteria included in this concept note derive from "A People-Centered Model of Care, Blueprint for EECA countries" (2017) and are in line with current WHO policies. The latter indicates that patients with tuberculosis (TB), including isoniazid-resistant, rifampicin-resistant and multidrug-resistant TB (RR/MDR-TB), should be treated using mainly ambulatory care rather than models of care based principally on hospitalization. Hospitalization and patient discharge criteria (Annex 1) were adapted by the Georgia Guideline Development Working Group and incorporated into

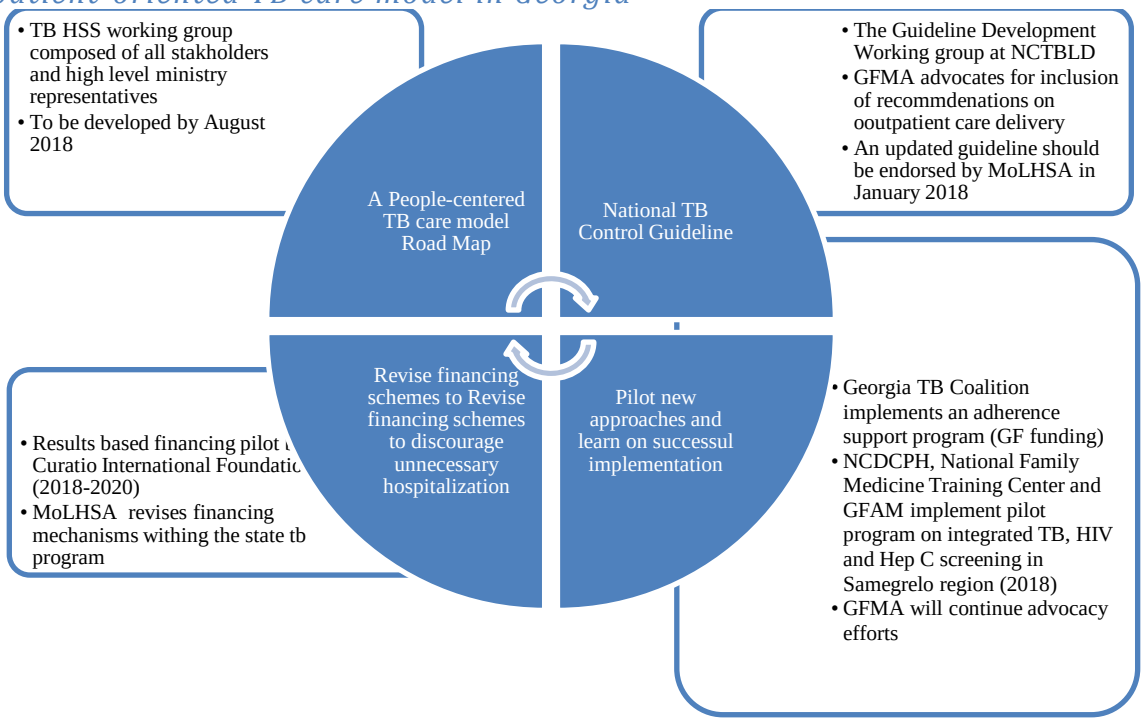
4. Guidelines for treatment of drug-susceptible tuberculosis and patient care, 2017 update. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO

the revised TB management guidelines for Georgia and will be endorsed by MoLHSA early 2018. The implementation of new hospitalization and discharge criteria should be closely monitored by relevant national health authorities as well as civil society partners.

5 Steps for a TB outpatient care model roll out

Figure 5 below outlines key national partners and their potential contribution to a TB outpatient-oriented model development and roll out in the immediate to medium term.

Figure 5. Activities and major actors to support introduction and roll out of an outpatient-oriented TB care model in Georgia



The first and immediate step for TB outpatient care model roll out is to incorporate provisions on organizations of TB service delivery including the patients' hospitalization and discharge criteria into the National Guidelines.

It is expected that the National Health Systems Strengthening (TB HSS) Working Group[5] established under the umbrella of Country Coordinating Mechanism will come up with a comprehensive road map for a people-centered TB care model development in Georgia. The road map will identify additional legal and technical gaps to be addressed for effective task shifting from in patient to outpatient care providers. Work is underway on introducing results-based financing schemes for stimulating engagement of outpatient and primary care providers in TB treatment and care. In line with the national strategy, a funding mechanism for TB hospitals will change to discourage unnecessary hospitalization. The Georgia TB Coalition will continue active advocacy for inclusion of peer counseling as a type of service within the National TB Program. This approach is currently being piloted by the National Center for Disease Control and Public Health through the Global Fund TB program. Georgia Patients Union along with social workers and psychologists provides adherence counselling to MDR TB patients within the pilot. Results of this project will inform programmatic decisions on its roll out from domestic financial sources.

5. TB HSS working group was established in 2016 within TB REP initiative

Annex1. KEY CRITERIA FOR ADMITTING TB PATIENTS TO HOSPITAL IN GEORGIA

Key criteria for hospital admissions include[6]:

- Complicated forms of TB that require hospitalization– conditions related directly to TB disease that require hospital treatment (i.e. respiratory failure and conditions requiring surgical interventions such as haemorrhage, pneumothorax and pleuritis);
- Severe forms of diseases including disease with severe clinical manifestations of comorbidities that require hospitalization – conditions related to pre-existing comorbidities that have been exacerbated by TB and cannot be managed in outpatient settings (liver disease, renal disease and uncontrolled diabetes)
- Life-threatening and serious medical events resulting from adverse effects of TB drugs (such as life-threatening arrhythmias, psychosis, renal failure and hearing loss).

Additional considerations include:

- Cases where effective and safe treatment cannot be ensured in outpatient, community and home settings (i.e. in severe cases of homelessness, overcrowding, exposure of children aged under 5 years and pregnant women in households) and/or that have issues of geographical accessibility (such as a long distance to an outpatient facility);
- As last resort measure only, involuntary isolation of non-adherent patients once all other care options have been used/applied exhaustively (in line with the Georgian TB control Law).

Note: these additional considerations should be applied only in very rare and extreme exceptional cases. All providers should strive at maximum for ambulatory treatment.

Those admitted should be cared for in single rooms. In hospital settings, people with presumed infectious TB or confirmed pulmonary TB should be assessed quickly for MDR-TB, following which:

- People deemed to be at low risk for RR/MDR-TB should be placed in single rooms;
- People deemed to be at high risk for RR/MDR-TB should ideally be placed in a negative-pressure room, and rapid diagnostic tests, such as nucleic acid amplification tests, should be performed immediately.

HOSPITAL DISCHARGE CRITERIA

A TB patient should be discharged from hospital if:

- there is no continuing clinical need for inpatient treatment (i.e. the key criteria for admission are not met) and clinical improvement is observed after administration of effective therapy, including:
    - improvement of symptoms (i.e. normal body temperature, improvement of overall health status translated by stabilization of body weight or weight gain);
    - reduction of respiratory symptoms (cough, sputum production);
    - reduction of clinical manifestations of comorbidities;
    - reduction of severity of adverse effects of TB drugs, if previously observed or reported by a health care worker and/or the patient;
- Effective treatment has been ensured (treatment regimen is based on credible drug-susceptibility testing (DST) result and well tolerated) and continuity of care and DOT have been ensured in outpatient, home or community settings.
- For people with confirmed TB whose overall symptoms have improved and who are unable to produce sputum, any discharge decisions should be taken by a multidisciplinary team based on the best available data and evidence, in a mutually agreed fashion.
- Earlier discharge for people with confirmed MDR-TB should be considered if suitable mechanisms are in place for home care and if the patient can adhere to the defined TB care plan. Before deciding to discharge a patient with presumed or confirmed MDR-TB from hospital, agreement should be made with the patient and care providers, and secure arrangements for uninterrupted medical and psychosocial care and DOT in an outpatient setting should be ensured.

6. A People-Centered Model of Care, Blueprint for EECA countries, first edition, 2017, WHO