

The guidance for PHC doctors on organizing and delivering TB services

DRAFT

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Introduction

Engagement of primary care providers is a critical strategy for improving detection and care of tuberculosis (TB). In Georgia, there is a need for greater involvement of family physicians and nurses in TB management to more quickly identify TB cases, support treatment, and achieve successful outcomes. More than 90% of Georgian citizens can access primary care providers within 20 to 30 minutes while TB specialists are only available at district levels that are not easily reachable for remote-dwellers. Strengthening PHC capacity for TB detection and treatment supervision is a significant step towards improving access to and quality of TB services.

This guideline intends to support engagement of primary care providers in TB prevention, detection, treatment and care and support activities by defining a clear operational framework for implementation of TB control activities at outpatient and community levels.

The guidance complements the national TB case management guideline adopted by Ministry of Labor, Health and Social Affairs in May 2018. The guideline recommendations and approaches are based on the people-centered care model (elaborated by Georgia Family Medicine Association in January 2018) that is evidence-based, feasible and relevant to Georgian health care settings.

For the purposes of this guidance 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”**.¹

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

Purpose of the guidance

Purpose of the guidance is to improve TB case management by primary care providers and community based organizations by creating an agreed framework for TB case detection, referral, confirmatory testing, treatment administration and follow up care.

¹. A People-Centered Model of Care, Blueprint for EECA countries, first edition, 2017, WHO

Objectives of the guidance

The following are main objectives of this guidance:

1. Define roles and responsibilities for TB service providers in TB detection, diagnosis, treatment and follow up care
2. Outline the referral mechanisms between primary care providers and TB specialized and outpatient services
3. Define collaboration mechanisms between primary care and community based organizations engaged in TB service delivery including peer educators and patients
4. Identify major areas for quality improvement for effective TB control at the community by primary care providers and community based organizations.

Target audiences

This guideline is intended to (1) primary care physicians, nurses and managers; (2) TB Hospital service providers (3) TB specialized outpatient services providers (4) Community based organizations implementing TB related activities at the community level

What is the role of primary care providers in TB control?

Review/background

As front line health care providers, primary care workers (Family Physicians, district internists and pediatricians) can play significant role in TB detection and follow up care. PHC providers are best placed in the system to recognize TB presumptive cases, organize timely referral and facilitate smooth progression of individuals with the disease across the continuum of care. TB control targets can hardly be achieved without integration of TB prevention, diagnostic and treatment services into the PHC system.

In general, primary care providers are expected to take continuing responsibility for providing the patients' comprehensive care by identifying and addressing medical, social, psychological and spiritual needs. A people-centered TB care model can hardly be implemented without active engagement of primary care physicians and nurses in TB service delivery.

Although benefits of greater integration of TB services into primary care service package were proved through various successful examples,^{2, 3,4} the implementation of PHC based TB care models requires substantial efforts. Despite being competent, PHC providers are not always able to fully apply their knowledge and skills in TB (particularly DR-TB) care as there are many systemic barriers which hinder

2. Guidelines for the programmatic management of drug-resistant tuberculosis. Emergency update 2008. Geneva: World Health Organization; 2008

3. Mitnick, C., Bayona, J., Palacios, E., Shin, S., Furin, J., Alcántara, F., et al. (2003, January 9). Community-Based Therapy for Multidrug-Resistant Tuberculosis in Lima, Peru. *The New England Journal of Medicine*.

4. Guidelines for treatment of drug-susceptible tuberculosis and patient care, 2017 update ISBN 978-92-4-155000-0 © World Health Organization 2017

effective TB service delivery. Low financial motivation and lack of incentives for good performance, inadequate physical infrastructure and deficient infection control measures at outpatient facilities, lack of transportation and communication means, weak linkages with TB specialized services, no cooperation model with community social organizations (CSOs) all are factors which prevent PHC providers to deliver quality services to TB affected individuals and communities.⁵

Greater engagement of primary care providers in DR TB service delivery requires some necessary preconditions to be met for safe and effective task shifting. See figure 1.

Figure 1. Preconditions for safe and effective task shifting from TB specialized to Primary Care Services

- **DR-TB management guidelines, protocols and jobs aids defining scope of works and specific responsibilities of PHC providers in managing DR-TB available for primary care providers.¹**
- **Referral mechanisms established between primary care and specialized services**
- **PHC Providers should be trained in TB and DR TB case detection, DOT administration and treatment follow up, contact tracing and TB infection control.**
- **PHC Provider should have transportation and communication means to implement community outreach for active case finding and treatment adherence support**
- **Primary care providers receive regular performance review and supportive supervision from the National TB Program or relevant professional bodies. Thus quality of DR TB care provided by PHC providers and compliance with best DR TB care standards is regularly monitored and evaluated.**
- **PHC providers have access to an integrated TB data management information systems**
- **PHC providers have information, education, communication materials readily available**
- **PHC providers have access to personal protective equipment and know how to use them**

Recommendations

R.1. In line with their core competencies in TB control, primary care providers should accomplish the following clinical and administrative tasks to ensure early case detection, timely referral for confirmatory testing, treatment administration, care and support. (Table 1)

R.2. The tasks outlined in table 1 should be distributed between primary care physicians and nurses. While a physician remains responsible for clinical management of presumptive and diagnosed TB cases including organizing referrals; a nurse can play a key role in patients education, primary and follow up counselling as well as DOT administration.

R.3. The responsibilities of primary care nurse for DOT administration should include:

- DS and DR TB patients education
- Home visits for family education, assessing home environment and providing infection control advice
- Develop DOT plan for each individual patient: Discuss possible DOT options with patients as per national guideline and help them to decide on most suitable option.

5. A Situation Analysis Report of the existing access barriers to quality TB Services for Key Affected Populations (KAP),GFMA, TB REP Project 2016

- Secure needed drugs: closely coordinate with district TB units for adequate supply management in line with the National TB Program procedures. Be aware of anticipated shortage of drugs and make timely actions to avoid this.
- Actively screen patients on adverse events during DOT sessions
- Inform the primary care physician about any moderate or severe adverse events (see a subsection on active drug safety monitoring for additional details)
- Schedule follow up tests treatment monitoring as per national guideline, inform the patient about the schedule and discuss with him/her if there are any reasons for not attending the tests as planned

Table 1. TB related clinical and administrative tasks of primary care providers

Clinical tasks	Organizational and administrative tasks
Physicians	
<ul style="list-style-type: none"> • Active verbal screening on TB presumptive signs and symptoms among patients who attend health clinic⁶ • Primary counselling of patients with presumptive TB on the necessity of confirmatory testing • Referral for TB diagnostic tests to district level outpatient TB services • Repeated counselling upon confirmation of TB diagnosis • Follow up counselling on TB treatment adherence as well as on smoking • Providing support to patients on DS and DR TB treatment to initiate regimen as prescribed by TB specialist • Treatment administration through DOT in close collaboration with district TB teams • Adverse events screening • Adverse events monitoring • Adverse events management in close collaboration with district TB teams • Referral to TB specialist as needed • Referral to other specialists (not TB specialist) • Management of comorbidities • Treatment follow up 	<ul style="list-style-type: none"> • Elaborate an individualized patient management plan • Get familiar with recording and reporting requirements with the National TB Program and obtain all necessary form from local public health departments • Coordinate TB management plan with plans for managing other comorbidities • Coordinate with outpatient TB health services and actively engage in the multidisciplinary team composed of primary care physicians, nurses, TB specialist, community based organizations . These teams can be coordinate by TB specialists from district outpatient clinics or Primary care physicians • Establish an integrated team with CSOs working in the area • Coordinate and oversee operations of an integrated team
Nurses	
<ul style="list-style-type: none"> • Active verbal screening on TB presumptive signs and symptoms among 	<ul style="list-style-type: none"> • Ensure adequate recording and reporting in line with the NTP requirements and forms

6. See Hep C, HIV and TB Integrated Screening Protocol for Primary Care Providers, currently piloted in Samegrelo Region with the Georgia Global Fund TB Grant (Implemented by Georgia Family Medicine Association)

- patients who attend health clinic**
- **Initial patient and family counselling before starting DOT sessions**
 - **Active screening for adverse events during DOT sessions**
 - **Referral to Primary Care Physician when needed for adverse events management**
 - **Ongoing counseling to ensure good treatment adherence**
 - **Regular home visits to assess the home environment and provide advice on necessary infections control measures**
- Schedule DOT sessions and negotiate with the patient a preferred time and possibly location
 - Schedule clinical investigations for treatment monitoring and make the schedule readily available for patients
 - Monitor TB drug stock at primary care facility and submit requests on needed drugs on time in line with the National TB Program requirements.

Collaboration with Public Health Services

According to the TB control law public health service units at each district are responsible to undertake TB related educational campaigns in their respective settings, implement contact tracing activities and assist health care providers in managing non-adherent cases (this includes their roles in executing involuntary isolation when applicable by law).

Recommendations

R.4. Primary care providers should establish effective collaboration with public health services and assist them in contact tracing as well as adherence support activities. It is recommended for primary care providers to set a date for regular monthly meetings with public health service units to discuss TB control challenges at each district and report back on individual cases managed at primary care level.

Detection of TB presumptive cases and organizing referrals

Positive findings on Xray and clinical examination are not sufficient for confirming TB diagnosis. This can be done based on bacteriological investigation of sputum or other biological samples. As primary care providers currently do not have a direct access to TB confirmatory testing it is necessary to organize timely referral if TB suggestive symptoms are manifested. The patient should be referred to a facility delivering TB outpatient or inpatients services within the State TB Program. All costs related to TB diagnostic investigations are covered by the National TB Program and are free for patients at the point of delivery.

Recommendations

R.5. If primary care physician considers the patient to be TB presumptive the following actions should be undertaken:

(A) A Physician should complete the referral form #100. The form should include the following details:

- TB Presumptive signs and/or symptoms
- History and timing of the symptoms occurrence
- TB Risk factors if any

- Clinical and laboratory investigation conducted by PHC provide for differential diagnosis
- Treatment history before a referral
- Has the patient been tested on HIV, if yes what is the result
- Has the patient been tested on Hep C, if yes what is the result
- Any concomitant conditions

(B) A primary care provider should explain to the patient that a medical consultation by TB specialist and all TB related investigations are free of charge

(C) A primary care physician or a nurse should provide details about the nearest referral point, including address, phone number and name of the TB specialist. Other referral options should also be discussed.

(D) After referring the patient to TB specialist, a PHC provider should contact the patient to make sure that referral was accomplished. It is highly recommended to also contact TB specialist to who the patient was referred to avoid initial loss to follow up.

(E) If a primary care provider receives no feedback from TB specialist about the referral, He/she should contact TB service unit and request the status update. Being responsible for the patient, families and communities, for each confirmed case a primary care provider in collaboration with public health services should engage in family education, infection control and contact tracing activities.

Access to Rapid Molecular technologies and alignment with FAST protocol

Congregate settings are considered as high risk areas due to increased exposure to TB. Schools, shelters, workplaces are examples of such areas. Healthcare facilities require special attention due to the risk of disease transmission to other patients or health care workers.

FAST (“Find cases Actively, Separate safely, and Treat effectively”) strategy aims to reduce disease transmission in healthcare facilities by tracing patients with TB disease, or presumptive TB cases, their timely separation and treatment. The approach is relevant for both outpatient and hospital care settings. This strategy is built around the notion that prompt diagnosis and effective treatment is by far the most important activity for preventing the spread of TB. Access to new molecular tests that allow rapid diagnosis of TB and drug resistance is essential for the effective treatment that will rapidly stop its spread.

Recommendations:

R.6. Implement the following activities within a FAST package

Find	Health care provider should ask patients about TB symptoms, such as prolonged cough, fever, night sweats, loss of appetite, loss of weight. Health care providers should also ask if anyone close to the patient (family or friends) has or is experiencing these symptoms. Observe patients with cough in waiting areas, departments or wards.
Actively	Daily assigned nursing and auxiliary staff whose responsibility is to identify patients with current cough, fast track them to be screened for other symptoms suggestive of TB, promptly collect sputum of those with presumptive TB for lab investigations, as per national guidelines.
Separating safety	While waiting for a laboratory diagnosis, patients identified through cough surveillance should be educated on respiratory hygiene (cough etiquette and separation), and move to a designated, well-ventilated area away from other patients to prevent further spread of TB.

Treat effectively Effective treatment is the most important part of FAST strategy and it should be provided in accordance with the national guideline

Treatment under direct observation

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.

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 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.

Recommendations:

- R.7. Health education and counselling on the disease and treatment adherence should be provided to patients on TB treatment
- R.8. 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
- R.9. 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).

R.10. 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).

DR-TB treatment administration by primary care providers and Active drug safety monitoring

One of the major concerns related to the expansion of DR TB care beyond hospitals is how to provide adequate clinical monitoring on safe and effective use of anti TB drugs. This issue became even more acute with introduction of new TB drugs (bedaquiline and delamanide). The WHO recommends that for active drug safety monitoring all patients receiving M/XDR TB treatment should undergo active and systematic clinical and laboratory assessment during treatment to detect drug toxicity and Adverse Events (AEs). All AEs detected should be managed in a timely fashion in order to deliver the best possible patient care. Standardized data should be systematically collected and reported for any SAE detected--these will eventually be used to characterize the types of Serious Adverse event (SAEs), assess the safety of the treatment and to inform future policy on the use of these medicines.

There are three levels of monitoring in aDSM:

1. **Core package:** requiring monitoring for and reporting of all SAEs
2. **Intermediate package:** includes SAEs as well as AEs of *special interest*
3. **Advanced package:** includes all AEs of *clinical significance*.

All sites involved with programmatic management of DR TB (PMDT) treating eligible patients with new anti-TB drugs, novel MDR-TB regimens or for XDR TB should apply the Core package. These treatment centers should, as a minimum, also be taking part in spontaneous reporting of ADRs as required by local regulations. Expansion of aDSM should be implemented in a phased-in approach as resources permit.

Forms used for reporting SAE and AE vary across counties; however, they all contain common elements to reflect seriousness, severity, describe the events, and also provide specific information for causality assessment. These forms are usually completed by attending physicians and referred to the national PC body in the country. However, recording and reporting arrangements may vary depending on a country Pharmacovigilance system (PV) design and operational characteristics.

For expanding DR TB treatment to peripheral sites in outpatient settings, NTP's should ensure that access is provided to all necessary clinical tests (See table 2) to be conducted for detecting adverse events of clinical significance or special interest listed below:

- R.1. All Serious AEs (if it falls in any of the following categories: an AE which either leads to death or a life-threatening experience; to hospitalization or prolongation of hospitalization; to persistent or significant disability; or to a congenital anomaly)
- R.2. All AEs of special interest:

- Peripheral neuropathy (paraesthesia),
- Psychiatric disorders and central nervous system toxicity
- Optic nerve disorder (optic neuritis) or retinopathy
- Ototoxicity
- Myelosuppression
- Prolonged QT interval
- Lactic acidosis
- Hepatitis
- Hypothyroidism,
- Hypokalaemia,
- Pancreatitis
- Phospholipidosis
- Acute kidney injury (acute renal failure)

R.3. Adverse events leading to treatment discontinuation or change in drug dosage

R.4. Adverse events not listed above but judged as otherwise clinically significant by the clinician.

Recommendations:

R.11. TB specialists or general practitioners in outpatient settings can successfully manage mild to moderate adverse effects. However, management of relatively severe endocrine, mental or cardiac disorders may require involvement of relevant specialists and organizing referrals. Severe adverse effects should be managed at a hospital through careful monitoring of vital functions and other clinical findings.

R.12. Refer to MoLHSA aDSM protocol for additional details (Approve in May 2018)

Table 2. Baseline and follow up investigations in patients on MDR/XDR TB treatment

	Baseline	Intensive phase	Continuation phase	Role of PHC provider
Written Informed Consent	X			Discuss with the patient if he/she has any concerns related to signing the consent form
Clinical evaluation				
Doctor's visit and full physical examination	X	Repeat when clinically indicated	Repeat when clinically indicated	Conduct when indicated
Psychosocial consultation	X	Repeat as indicated. Refer to Psychiatrist when indicated		Regularly
Weight	X	Monthly	monthly	PHC nurse monitors weight
Neurological examination	X	Monthly	Monthly while on Lzd	Be aware of possible side effects if on Lzd
Audiometry	X	Monthly while on injectable		Coordinate with specialized services, conduct on site if equipment available
Visual Acuity Test and Ishihara Colour Test	X	Once in every three months		Coordinate with specialists, conduct on site when possible
Tests				
Electrocardiogram	X	Weekly in the first month, then once per month if ECG shows no abnormal findings. If ECG	Continue if clinically indicated	Conduct on site if equipment available and monitor QT interval

		shows abnormal findings, could be followed up based on the need.	
Hb and WBC count	X	At least monthly	Conduct on-site if possible, organize referral to TB outpatient service units for regular check up
Creatinine	X	At least monthly	Inform the patient that the tests below are covered by the State TB control program and incurs no fee for patients. A PHC nurse should develop a clinical monitoring plan and have it agreed with the patient and TB service unit responsible for treatment.
Serum Potassium	X	At least monthly	
Serum magnesium and calcium	X	At least monthly	
Liver enzymes (ALT, AST, total bilirubin)	X	At least monthly	
TSH	X	At least monthly monitoring for clinical signs, Every three months TSH level if receiving ethionamide/prothionamide and p-aminosalicylic acid (PAS). Every six months if receiving ethionamide/prothionamide or PAS, but not both together.	
Serum albumin	X	If low monitor whilst on treatment, for patients on Delamanid	
Lipase/amylase	X	If clinically indicated to rule out pancreatitis in patients on linezolid, bedaquiline, D4T, ddI or ddc	
Viral hepatitis serology (Hep B and C)	X	At Baseline and if clinically indicated	
HIV	X	Repeat if clinically indicated	
Pregnancy test	X	As needed	As needed
Blood Sugar	X	At least monthly	Monitor regularly on site if equipment available. Use the nearest referral point if on-site blood sugar monitoring is not feasible.

Integrated care

Primary care providers should employ integrated care approaches to achieve early TB detection in high risk groups and improve co-management of various chronic conditions in patients with concomitant abnormalities.

Recommendations:

R.13. The following medical conditions should⁷ be considered for TB screening by primary care providers:

- underweight persons;
- diabetes mellitus;
- chronic renal failure or hemodialysis;
- pregnancy;
- alcohol dependence;
- intravenous drug use;
- tobacco smoking;
- advanced age;
- previously treated TB.
- In addition, the medical providers may consider patients with other medical problems such as gastrectomy, malignancies, immunosuppressive disorders, solid organ transplantation and other conditions requiring immunomodulatory therapies.

R.14. TB Screening should be undertaken as part of the integrated screening program for HIV, HeP C and TB in line with the National Integrated Screening protocol.

LTBI screening and treatment

Screening for Latent TB Infection(LTBI) and LTBI treatment is among National TB Control Program priorities. On the basis of the latest evidence and benefit-risk considerations, the following seven groups have been identified for systematic testing and treatment of LTBI in Georgia⁷:

1. People living with HIV
2. Child and adult contacts of pulmonary TB cases
3. Persons detained in correctional facilities (prisoners)
4. Patients with the following diseases or treatment conditions: silicosis, renal dialysis, treatment with anti-tumor necrosis factor (TNF) inhibitors, and preparation for organ or hematologic transplantation
5. People who inject drugs (PWID)
6. Health care workers
7. Immigrants from high TB burden countries

Recommendations:

R.15. Primary care provider should ensure screening for symptoms among persons with HIV infection for identifying both active TB cases and persons who should receive preventive therapy. PLHIV who do not have active TB disease at screening, should receive testing for LTBI and, if positive,

7. Georgia National TB Strategy for 2016-2020, Approved by the GoG in 2016

preventive treatment. Close collaboration between outpatient TB services and primary care providers is required to implement LTBI treatment at the communities.

- R.16. Primary Care Providers should collaborate with public health and specialized TB services to test and treat children with LTBI.
- R.17. Primary care providers should be equipped with relevant knowledge and skills to counsel parents on benefits and risks associated with LTBI treatment in line with the National TB Control guideline.
- R.18. Regular refresher training for primary care provides on LTBI screening and treatment should be organized in every 2 years.

The Role of Community Based Organizations in TB Service Delivery

Background/review

The role of community based organizations (CSOs) in TB service delivery is well recognized globally and is believed to be an important factor for achieving the End TB strategy targets. The extent of CSOs involvement in TB service delivery, as well as the scope and mechanisms for their operations vary from country to country. This variation can be explained by diverse skill mix, experience and motivation of community health workers, availability of resources, different models of collaboration with the National TB Programs (NTPs) and the level of TB related stigma that often prevents people from effective utilization of services offered by CSOs in their own communities.

CSOs can successfully implement a wide array of TB services including early detection, health education, companionship and social support and treatment adherence. Examples of CSOs activities include but are not limited to the following:

- Early case finding through community outreach and door to door campaigns, women's groups, health clubs, farmers' groups etc.
- Providing treatment support including nutritional and psychosocial support
- Promoting health seeking and adequate infection control behaviors
- Facilitating linkage to TB and HIV services for key affected communities
- Implementing agriculture and income generation programs to help patients with TB to avoid devastating consequences of poverty
- Organizing educational programs on TB signs and symptoms and the ways of its management at schools and universities
- Implementing advocacy for sustainability of TB response interventions

The scope for CSOs' activities should be defined based on local needs, CSOs capacity and regulations enabling involvement of civil society actors in TB control.

The extent of integration of CSO/NGO services with formal NTP service delivery network is an important consideration. Synergy between the NTP and CSOs activities can yield significant results in TB control. The effective cooperation between the formal health care providers and community based organizations can only be achieved through improving transparency and accountability as well as establishing mechanisms for engagement of civil society representative in quality related discussions at all levels of health systems-locally, regionally, nationally. Community- based initiatives should be

informed by in-depth situation analysis and knowledge of gaps in access to and coverage with TB services of key affected population (KAP) groups and hard to reach communities. CSOs have the unique advantage of reaching marginalized populations with services where they live, integrating cultural preferences into service delivery, and successfully testing unconventional approaches to service provision.⁸ Targets should be set and quality report produced for each KAP individually to better illustrate gaps and come up with needs-based solutions.

Evidence indicates that supervisory support, positive community feedback, opportunity for developing new skills, incentives, and sustainability are key factors influencing community workers performance and can result in better outcomes.⁹ These factors along with regular quality monitoring and progress review should be incorporated into the quality improvement framework for CSOs/NGOs to maximize the positive impact of community-based TB control interventions.

Recommendations

- R.19. CSOs should implement TB control activities in close collaboration with primary care and TB service providers (outpatient and inpatient). A collaboration agreement or memorandum of understanding can be established between CSOs and other parties to formulate the aim and objectives of this collaboration and develop an agreed action framework.
- R.20. Primary Care Providers and TB specialized services should actively look for CSOs active in the neighborhood and encourage their engagement with TB education and adherence support.
- R.21. The list of activities that can effectively be implemented by CSOs includes but is not limited to the following (see box 1).¹⁰
- R.22. In order to comprehensively address social, psychological and medical needs of DR TB patients it is recommended that the treatment support team is composed of a social worker, peer educator/former TB Patient and psychologist.
- R.23. Treatment support teams should at minimum offer the following services¹¹:
- Individual or group psychosocial counselling
 - Support to address social barriers that may prevent good treatment adherence
 - Physiological counselling
 - Legal counselling
 - Voluntary counselling and testing on HIV, Hep C and B, Syphilis
 - Moral/emotional support

Box 1. Role of CSOs and Former TB Patients in TB control

- Organize meeting TB patients in hospital before discharge for information and counseling
 - Maintain links with the TB hospital “treating physician”
 - Establish peer support groups for TB patients, train peer educators to educate TB patients and their
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8. Strategic alliances: The role of civil society in health, WHO 2001

9. Daniel G. Datiko, Mohammed A. Yassin, Olivia Tulloch, Girum Asnake, Tadesse Tesema, Habiba Jamal, Paulos Markos, Luis E. Cuevas and Sally Theobald., Exploring providers’ perspectives of a community based TB approach in Southern Ethiopia: implication for community based approaches., BMC Health Services Research 2015, 15:501

¹⁰ Civil Society engagement, Advocacy, Communication and Social Mobilization for TB Control, Global Fund Grant Making in Georgia, WHO Mission report prepared by Viorel Soltan, April 13-16, 2016

11. Georgia TB Control Guidelines, Update 2018, Approved by MoLHSA in May 2018.

relatives on the realities of TB

- d. Assess social needs before discharge and link to appropriate existing services/projects for TB patients (e.g. housing, documentation support, workplace issues etc.)
 - e. Ensure constant support and follow-up of MDR-TB patients during the treatment (e.g. psychosocial support, regular meetings, consultations, infection control in home conditions, reminders for regular check-up, education sessions etc.)
 - f. Organize Education session with families/households of MDR-TB patients
 - g. Loss to follow up tracing by peers and support groups (see below)
 - h. To design, develop contents and distribute printed materials according to specifications: informational leaflets for general public to be distributed to MDR-TB patients and their families/households
 - i. To organize health education sessions as part of discharge program in all prisons to all TB patients
 - j. Work closely with NCDCPH and health personnel at DOT facilities to facilitate linking all released TB patients from prison to civilian services.
 - k. Support and follow up closely with all TB patients released from prison and their family members, provide psychosocial support and juridical support.
 - l. Design, develop contents and distribute printed materials according to specifications: informational leaflets for discharged TB patients from prison.
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Picture 1. Nikoloz Mirzashvili, Peer Educator and Founder of Georgia Patients Union Conducts Patient Education Session by using a tablet based digital TB educational module for patients, 2017 (Provided by GPU)

Setting quality standards and targets for priority TB control interventions at primary care level

Quality of Active Case Finding by Primary Care Providers

1. Quality Statement: Primary care physicians should actively screen patients attending their clinics for cough and other symptoms suggestive of tuberculosis

Inputs	Quality Measures
<ul style="list-style-type: none"> • PHC provider is aware of and follows MoLHSA approved protocol for detecting TB presumptive cases • PHC provider has a form #100 readily available to organize referral to the nearest TB outpatient clinic for confirmatory testing • Referral recorded in the TB electronic registry (if possible) or in a paper based registry 	<ul style="list-style-type: none"> • Positively assessed if elements listed in the first column are in place
Processes	Quality Measures
<p>Active cough surveillance –ask if cough for more than two weeks? Other symptoms suggestive TB? Diagnostic algorithms for TB presumptive cases Access to GeneXpert for rapid detection of rifampicin resistance, if implements the NCDCPH FAST program</p>	<ul style="list-style-type: none"> • Proportion of individuals with cough ≥ 2 weeks presumptive of tuberculosis • Proportion of individuals with cough ≥ 2 weeks referred for (a) sputum smear microscopy and (b) Chest X Ray and/or (c) GeneXpert testing as per national algorithms • Proportion of individuals who are presumptive (based on TB presumptive symptoms as per WHO/national guidelines) of tuberculosis referred for (a) sputum smear microscopy and (b) Chest X Ray and/or (c) GeneXpert testing as per national algorithms
Outcomes	Quality Measure
<p>Active TB and DT TB cases identified among contacts and high risk groups</p>	<p>Number /% of TB presumptive cases identified with TB</p> <p>Number /% of presumptive TB DR cases identified with rifampicin resistance</p> <p>Data stratified by Testing method (smear microscopy, GeneXpert) And risk groups</p>

Quality of Patient counselling by primary care providers

Quality Statement: Primary Care Physicians and Nurses provide quality TB related counselling to ensure timely referral for (a) confirmatory diagnoses and (b) treatment adherence

Inputs	Quality Measures
<ul style="list-style-type: none"> PHC providers are trained in TB specific counselling PHC providers devote substantial time to counselling sessions 	<ul style="list-style-type: none"> Last training within previous 2 years Appointment scheduled for TB patients recently initiated on treatment is at least 30 minutes
Processes	Quality Measures
<p>Quality of counseling and interpersonal communication should be assessed through direct observations.</p> <p>This is integrated in the PHC performance review regularly conducted by the Georgia Family Medicine Association</p>	<ul style="list-style-type: none"> What information is provided Does the TB service provider use charts or other tools to educate patients about the following: <ul style="list-style-type: none"> What are the signs and symptoms of TB TB side effects and their management Why the patient needs to continue taking the TB medication (adherence) Who in the family (adults/children) need to be screened for TB actively When should the patient come back for follow up visit Does counsellor elucidate and addresses social and medical problems that may affect treatment adherence (Alcohol and drug abuse, depression, anxiety or other mental disorders)
Outcomes	Quality Measure
<p>Should result in reduced initial loss to follow up and improved treatment success rate</p>	<p>No direct outcome measure apply</p>

Quality of TB treatment services at primary care level

Quality Statement: Primary Care Teams deliver quality DOT services adjusted to individual patients' needs and preferences.

Inputs	Quality Measures
<ul style="list-style-type: none"> TB and DR TB Treatment guideline and protocols available at treatment sites PHC providers receive regular training (once in 2 years) in DS and DR TB treatment administration Quality assured drugs available at all DOT sites Fixed Dosed Combinations available Pediatric dose formulations available Ancillary drugs available for side effects management Adequate premises for DOT sessions respecting 	<ul style="list-style-type: none"> Positively evaluated if all components listed in the first column are in place

<p>patients' privacy and confidentiality</p> <ul style="list-style-type: none"> • Access to clinical and sputum diagnostic tests to monitoring progress and treatment side effects • TB recording and reporting forms available in line with WHO recommendations and National Guideline • Electronic patient registries and TB information management systems functional • PHC providers have access to tests needed for active monitoring of anti-TB drug side effects • Communication means to contact patients who miss DOT sessions 	
<p>Processes</p> <ul style="list-style-type: none"> • An individualized patient management plan developed • Collaboration with a hospital treating physician or outpatient TB specialists established • DOT sessions delivered at health facility • DOT sessions delivered at home (mobile DOT service) • Video DoT • Infection control measures are in place at inpatient, outpatient and home settings 	<p>Quality Measures</p> <p>Number and % of patients receiving facility based DOT</p> <p>Number and % of patients receiving home based DOT by primary care nurse of community supporter/trained peer</p> <p>Number and % of patients receiving VOT</p>
<p>Outcomes</p>	<p>Quality Measure</p> <p>Conversion rate at the end of the intensive phase of treatment</p> <p>Treatment success rate</p>

Treatment adherence support

Quality statement: All DS and DR TB patients have access to community based social support services.

<p>Inputs</p> <ul style="list-style-type: none"> • Access to counselling services by mental health professionals, psychologist and peer educators (e.g. former TB patients) 	<p>Quality Measures</p> <p>Funding sources for counselling services are identified</p> <p>Number of districts/facilities with specialized counseling services available</p>
<p>Processes</p> <ul style="list-style-type: none"> • Individuals with TB and MDR TB receive counselling from peer (e.g. former TB patient) in line with the National TB Management Guidelines • Individuals with TB and MDR TB receive counselling from peer (e.g. former TB patient) in line with the National TB Management Guidelines • Individuals with MDR TB receive companionship support • Individuals with TB and MDR TB enrolled in 	<p>Quality Measures</p> <ul style="list-style-type: none"> • Proportion of individuals with TB and MDR TB counseled by (1) health care worker (2) mental health specialist (3)psychologist, (4) peer as per national guideline • Proportion of individuals receiving material support per type of support (cash, food package, transportation costs e.t.c.)

cash incentives scheme	
<ul style="list-style-type: none"> • Individuals with TB and MDR TB receive transportation costs to attend DOT sessions 	
Outcomes	Quality Measure
Good social support will contribute towards improved treatment adherence	Treatment outcomes

Active drug safety monitoring

Quality Statement:

All patients receiving M/XDR TB treatment at primary care settings should undergo active and systematic clinical and laboratory assessment during treatment to detect drug toxicity and Adverse Events (AEs). Primary care sites providing DOT to DR-TB patients should systematically collect and report any serious adverse events in line with the Ministerial decree (as of 17.05.2016 N 01-18/6 Annex 2) and TB management guideline approved by the Ministry.

Inputs	Quality Measures
<p>Access to the following clinical tests guaranteed either on site or through referral to the district level health facility:</p> <ul style="list-style-type: none"> • Weight • Neurological examination • Audiometry • Visual Acuity Test and Ishihara Color Test • Tests • Electrocardiogram • Hb and WBC count • Creatinine • Serum Potassium • Serum magnesium and calcium • Liver enzymes (ALT, AST, total bilirubin) • TSH • Serum albumin • Lipase/amylase • Viral hepatitis serology (Hep B and C) • HIV • Pregnancy test • Blood Sugar 	<p>Primary care provider can monitor QT prolongation on site</p> <p>Primary care provider is able to do on site audiometry or refer the patient on DR TB treatment for audiometry screening as indicated</p> <p>Primary care provider has clinical monitoring schedule indicating planned and accomplished clinical tests for each DR TB patient available</p>
Processes	Quality Measures
<ul style="list-style-type: none"> • DR TB patients receiving DOT from primary care provider adhere to their clinical monitoring schedule 	<ul style="list-style-type: none"> • Number and proportion of DR TB patients with at least one ECG done over the last month • Number and proportion of DR TB patients with audiometry done as indicated per national guidelines
Outcomes	Quality Measure
Serious Adverse Events monitored	<p># of serious Adverse Events recorded and reported to the National DR-TB PV committee at National Center for TB and Lung Diseases</p> <ul style="list-style-type: none"> • <i>Type and frequency</i>

TB Infection Prevention and Control

Quality Statement: Primary care provider adheres to infection prevention and control guidelines approved by the Ministry of Internally Displaced Persons from Occupied Territories, Labor, Health and Social Affairs.

Inputs	Quality Measures
<ul style="list-style-type: none"> • Infection Control Plan is in place • A person responsible for infection response plan is identified • There is an "open window" rule for waiting areas, where there is no mechanical ventilation 	Yes/no checklist
Processes	Quality Measures
<ul style="list-style-type: none"> • N95 respirators are provided for all medical staff involved in TB patient's care • The facility provides surgical masks for all patients. • The facility provides surgical masks for all visitors within the hospital. • There are posters on cough hygiene in entrances and halls • Personnel responsible for infection control measures conduct at least monthly checks for respirator compliance and adjustment 	Yes/no checklist
Outcomes	Quality Measure
NA	NA

Health Promotion and TB Prevention Outreach

Quality Statement: Primary care provider integrates TB related health promotion messages in all outreach activities within its catchment area

Inputs	Quality Measures
<ul style="list-style-type: none"> • Health education materials of TB prevention, diagnosis, treatment and care are readily available • Plan for community based outreach activities elaborated • Primary care provider is aware and has contact list of Civil Society Organizations active in TB in the catchment area 	Yes/no checklist
Processes	Quality Measures

<ul style="list-style-type: none"> • Primary care provider participates in outreach activities organized by community based organizations • Primary care provider conducts scheduled outreach activities to its beneficiaries for active TB symptom screening or assessing home environment to identify high risk patients for referral to TB diagnostic and treatment services 	<p>Number of outreach events</p> <p>Number of beneficiaries targeted</p>
Outcomes	Quality Measure
Primary care provider identified high risk patients through active outreach and assist them to timely reach TB diagnostic and treatment services	Number of TB cases identified and put of treatment through active outreach activities by primary care provider

Integrated screening for TB, HIV and Hepatitis C

Quality statement:

Inputs	Quality Measures
Primary care provider has TB, HIV and Hepatitis C integrated screening protocol in place	Yes/ no checklist
Integrated educational materials on 3 disease available	
Primary care provider trained in integrated screening through training sessions or online training course at least once during the last 12 months	
Processes	Quality Measures
Primary care provider conducts TB Screening as part of the integrated screening program for HIV, HeP C and TB in line with the National Integrated Screening protocol	Number of individuals screening for all three diseases at primary care level
Outcomes	Quality Measure
Primary care provider identifies presumptive TB cases and refers them for confirmatory testing	<p>Number of presumptive TB cases identified through integrated screening program and tested for TB, breakdown by</p> <ul style="list-style-type: none"> A.1. TB cases among HIV positive A.2. TB cases among Hep C positive A.3. TB cases among Hep C and HIV positive <p>Number of TB cases confirmed through integrated screening, breakdown by</p> <ul style="list-style-type: none"> A.1. TB cases among HIV positive A.2. TB cases among Hep C positive A.3. TB cases among Hep C and HIV positive

Collaboration and partnership with TB specialized services

Quality statement: Primary care provider develops joint TB case management plan with TB specialist and closely collaborates with him/her throughout the treatment course

Inputs	Quality Measures
Joint treatment plan with clear responsibilities for primary care providers and TB specialists is in place, The plan includes schedule for coordination calls and/or meetings	Yes/ no checklist
Processes	Quality Measures
Primary care provider has scheduled calls or meetings with TB specialist to discuss treatment response and any challenges identified throughout the treatment course	Number of meetings
Outcomes	Quality Measure
NA	NA

Supply of anti TB drugs

Quality statement: Primary care provider collaborates effectively with the National TB Program to ensure adequate TB drug supplies and management so that during the whole course of treatment the patient is provided with high-quality, effective and safe anti-tuberculosis drugs.

Inputs	Quality Measures
<ul style="list-style-type: none"> The facility has developed and implemented policies and procedures for assuring uninterrupted supply of 1st and 2nd line TB drugs to all TB patients for the duration of therapy. Facility has special drug storage area Special protocol for TB drugs storage conditions 	Yes or No
Processes	Quality Measures
<ul style="list-style-type: none"> Special conditions for TB drugs storage are implemented and followed (temperature and humidity control) Drug supply management protocols implemented 	<ul style="list-style-type: none"> Assessed and negative/positive findings documented during NTP supervision visits Drug stock out
Outcomes	Quality Measure
NA	NA

Annex 1.Roles of Different Type of Providers in TB Service delivery

Type of service	Community providers CSOs/ NGOs/Social Workers	Primary care providers		Provided by whom Outpatient providers				In-patient providers	
		Rural	Urban	Speciali zed TB	Non TB	General lab/Diagnost ics	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									
<i>Microscopy</i>							X		X
<i>Culture and DST</i>							X		X
<i>Gene-Xpert</i>			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					