Evaluation of Tuberculosis Preventive Treatment Initiation, Adherence and Completion in Country of Georgia

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ABSTRACT

Background: Latent tuberculosis infection (LTBI) treatment is essential for preventing active tuberculosis (TB) but remains underutilized in Low- and middle-income countries (LMICs). In 2020, Georgia transitioned to a three-month Rifapentine-based regimen. This study assessed the LTBI care cascade among TB contacts in Georgia (2020-2021).

Methods: A mixed-method cohort study examined TPT recommendations and completion rates among contacts of active TB cases. Study was conducted in five TB-units of Georgia (National Center for Tuberculosis and Lung Disease (NCTLD), Shida Kartli, Kvemo Kartli, Gori, Kutaisi).

Results: Among 611 contacts, 338 (55.3%) were female, and 83 (13.5%) were children under five. Tuberculosis preventive treatment (TPT) was recommended for 439 (74.5%), with 275 (65%) initiating treatment and 131 (47%) completing it. Six participants developed active tuberculosis later, who did not initiate tuberculosis preventive treatment.

Conclusions: LTBI treatment uptake in Georgia remains low, underscoring the need for improved monitoring and adherence strategies. High TB incidence in untreated contacts highlights the importance of preventive treatment.

Keywords: latent tuberculosis, preventive treatment, contact investigation, rifapentine treatment.

INTRODUCTION

A key component of the END TB Strategy is to prevent new tuberculosis (TB) cases through TB preventive treatment (TPT) (WHO. End TB strategy). Implementing this intervention is critical given that the World Health Organization (WHO) estimates a quarter of the global population has latent tuberculosis infection (LTBI) thus serving as a large reservoir for incident TB cases (Global tuberculosis report 2023). Historically, due to limited resources and inadequate tools, high burden countries have focused on diagnosing and treating active TB cases with a lower priority placed on LTBI (Getahun H, et al., 2015). In 2022, an estimated 13 million (95% UI: 12–13 million) household contacts of bacteriologically confirmed pulmonary TB cases were identified globally. However, only 8.9 million were reported, a 14% increase from 7.9 million in 2021. Among these, 7.1 million (80%) were evaluated for TB infection and disease, a 12% rise from 6.4 million in 2021, with evaluation rates varying widely across countries. Globally, 1.9 million contacts received TPT in 2022, representing 21% of the 8.9 million reported and 15% of the 13 million estimated. Substantial variation existed across countries in the percentages of contacts evaluated and those provided with TPT (Harries AD, et al., 2018) (Global tuberculosis report 2020).

Since 2015, the country of Georgia no longer belongs to the high burden countries; however, the number of drug resistant TB cases remains the major problem. According to the WHO in 2023 the number of TB cases in Georgia was 1,448. Only 13% of contacts from all TB index cases initiated TB preventive treatment (TPT) (WHO operational handbook on tuberculosis: module 1: prevention: tuberculosis preventive treatment) (Global Tuberculosis Report 2022). Tuberculosis Preventive Treatment (TPT) is a strategy to prevent the progression from latent tuberculosis infection (LTBI) to active TB disease in individuals at high risk. It is a cornerstone of TB control efforts and a critical part of the World Health Organization's End TB Strategy (Global Tuberculosis Programme) TPT primarily targets groups such as people living with HIV, household contacts of TB patients, and individuals with compromised immune systems. TPT includes various regimens, such as daily or weekly combinations of rifampicin or rifapentine with Isoniazid, which range from one to six months in duration. (WHO consolidated guidelines on tuberculosis Module 1: prevention – tuberculosis preventive treatment, second edition) (TB prevention and screening) Preventive treatment is currently the only option that protects people in risk groups from developing active tuberculosis in the future. Effect of available TB preventive treatment ranges between 60–90% worldwide. (Organization WH. WHO consolidated guidelines on tuberculosis: tuberculosis preventive treatment)

Georgia follows WHO`s recommendations and updates national TB strategy based on the newest recommendation. Until 2020 TPT was recommended only for two prioritized groups of people, HIV positive patients and children aged 0–5, who was close contacts of bacteriologically confirmed drug sensitive (DS-TB) TB cases. TPT regimen was 6INH (6-month Isoniazid treatment). Previous study results showed a very low rate of TPT initiation and completion, in addition 4 children among 135 who were recommended for TPT developed an active TB in one

year of period. All children were from the group which did not initiate the preventive treatment (LTBI preventive treatmen in children in country of Georgia).

After March of 2020 the strategy of TPT was updated based on WHO`s guidance, which means all contact persons of active TB cases in any age are recommended to start TPT: not only the contacts of DS-TB patients, but Multi drug resistant (MDR)-TB cases were also included. In addition, treatment regimen 6INH is replaced with 3PH (3-month rifapentine) for DS contacts and 6lfx (6-month levofloxacin) - for MDR contacts. Beside this, targets of recommendation were widened. Risk groups such as - (1) HIV positive people, who are initiating anti-TNF treatment; (2) receiving dialysis, (3) preparing for an organ or (4) hematological transplant, (5) who have silicosis should be systematically tested and treated for LTBI (Gabunia T., 2019).

Georgia is a small country located in the South Caucasus region, bordered by Russia, Turkey, Armenia, and Azerbaijan. It is administratively divided into several regions, including Kakheti, Imereti, Kvemo Kartli, Shida Kartli, and the capital city, Tbilisi. These regions vary in terms of population density, access to healthcare services, and TB burden. Tbilisi, as the capital and largest urban center, hosts the National Center for Tuberculosis and Lung Disease and plays a central role in national TB care. The inclusion of both urban and regional TB units in this study allows for the comparison of preventive treatment uptake across diverse geographic and healthcare settings in Georgia.

After the mentioned reform, it became important to study this issue. According to the National Tuberculosis Program of Georgia (NTP) we aimed evaluating the LTBI care cascade among people who are recommended for TPT at the National Center for Tuberculosis and Lung Disease in four regions of Georgia such as: Kakheti, Kvemo Kartli, Shida Kartli and Imereti.

METHODS

We used a mixed method of a cohort study during 2021-2022. Study initial site was National Center for Tuberculosis and Lung Disease, Tbilisi. An eligibility criterion was a recommendation for TPT. We wanted to evaluate the LTBI care cascade among people who are recommended for TPT at the NCTLD and in four regions of Georgia: Kakheti, Kvemo Kartli, Shida Kartli and Imereti. We cover different geographical units, both west and east parts of Georgia, with total of 10 TB-units countrywide (2). A large number of TB patients (3) and, densely populated villages which helped us to achieve our sample size. We enrolled into a study all close contacts of active TB patients and people from other risk groups who were recommended for TPT(WHO consolidated guidelines on tuberculosis. Module 1, Module 1).

Settings and procedures

TB hot-spot contact investigation is performed by the National Center for Disease Control and Public Health (NCDC) epidemiologists. During contact investigation epidemiologists refer all close family contact to the specialized TB service clinics for further investigation and ruling out

the active TB. In parallel pulmonary TB patients are asked to bring their family and close contacts for investigation at specialized TB facilities. This is the countrywide practice including the National Center for Tuberculosis and Lung Disease.

After excluding active tuberculosis, TB contacts are consulted to receive preventive treatment. Preventive treatment regimen depends on the age group of contact person and drug sensitivity or resistance of index case. Children under two years, who are contacts of drug sensitive pulmonary TB cases are receiving six-month INH therapy while, other contact persons three-month (12 dose) Rifapentine. Contact persons with MDR index cases are recommended to start 6-month Lfx treatment.

Baseline visit includes TST (skin test) or IGRA test (Interferon-Gamma Release Assays), Chest X-Ray and examination by a doctor, collection of anamneses. Patients under treatment visit their personal doctor every month for further analysis and examination, which are blood and urine tests, biochemistry as well as the X-ray if needed. (Detection and treatment Latent tuberculosis Infection in Georgia).

Data collection

Special data collection tools (eCRFs) were developed for the primary data collection. The baseline form included socio-demographic information, details on co-morbidities and other risk factors for developing active Tuberculosis diseases, also TST status and information on chemoprophylaxis. Close ended questionnaire included "yes/no" or multiple choice of questions. Data from 2020 were collected retrospectively to have complete data on new treatment regimens. Patients' medical charts were collected for research relevant information, which are currently stored in TB units´ archives.

The data were collected by the Research Electronic Data Capture – REDCap[1]. The analysis are xdone using the SPSS software after the one-year follow-up period to detect active TB cases from the study group. The uni-variable and bi-variable analysis was performed to look at the potential risk factors for incidence of TB disease and barriers for IPT start/completion.

Data Analysis

Depending on the variable, ORs and CIs were calculated using either cross-tabulation with chi-square tests or binary logistic regression analysis.

All data were entered into an online RED Cap database, and analysis was performed using SPSS and R (version 3.6.2). Differences in categorical variables were assessed using either Fisher's exact test or the chi-square test, as appropriate. For continuous variables, the Mann-Whitney U test or two-sample t-test was applied based on data distribution. Descriptive statistics were utilized to evaluate the rifapentine preventive therapy (3PH) care cascade. Active tuberculosis

(TB) development was monitored through follow-up one year after data collection. The last day of checking into an electronic national TB data base of Georgia was performed on 15.08.2024.

Ethics

Permission for the study is obtained at the Local Ethics Committee of the National Center for Tuberculosis and Lung Diseases. Patient informed consent was developed and each patient who went through ICF procedure. Only those who provide signed informed consent were considered in the study further based on eligibility criteria. All obtained information are anonymized and unique identifiers are used for the records in the study database without possibility to identify the person. The electronic databases are kept on a password protected computer of the principal investigator. There are no direct benefits or any cash incentives.to those individuals included in the study.

RESULTS

Descriptive analysis

The study analyzed demographic and clinical characteristics of contacts screened under the National Tuberculosis Program (NTP) and assessed their participation in tuberculosis preventive treatment (TPT). **Table 1** Shows descriptive results of study. Overall, from 678 participants data of 611 contacts was analyzed. Data of 48 participants were missing or incomplete. 19 participants were excluded based on the baseline diagnosis with TB. Among 611 participants females accounted for 55.3%, and males represented 44.7%. Geographically, Kakheti contributed the highest proportion of participants (34.2%), followed by Imereti (21.6%), Kvemo Kartli (17.0%), NCTLD (14.7%), and Shida Kartli (12.4%).

By age group, adults constituted the majority (57.6%), while children aged 5–18 years and children less than 5 years represented 28.7% and 13.5%, respectively. The majority of contacts were family members (81.1%), with 76.0% living in the same household as the index TB case, and 26.9% were other contacts, such as relatives or neighbors.

TST (tuberculin skin test) was performed on 51.0% of contacts, with 44.6% of those tested showing positive results (>10mm). Among all contacts, 74.5% were recommended for TPT, 65.0% of this initiated treatment, and 47.0% completed it. This equates to a TPT completion rate of 21.0% for the total cohort. Gender analysis revealed that males had a higher TPT completion rate (58.0%) compared to females (42.0%).

Table 1.

Category	Absolute Numbers	%
Gender		
Female	338	55.3
Male	273	44.7
Geographic Distribution		
NCTLD[1]	90`	14.7
Kakheti	209	34.2
Imereti	132	21.6
Kvemo Kartli	104	17.0
Shida Kartli	76	12.4
Age groups		
Children (<5 years)	83	13.5
Children (5-18 years)	176	28.7
Adults	352	57.6
Type of contacts		
Family member	454	81.1
Living in the same household	447	76.0
Other contacts (Relative, neighbors)	164	26.9
TST[2]		
TST performed	304	51.0
TST positive (>10mm)	128	44.6
TPT[3] (Tuberculosis preventive treatment)		
Recommended for TPT	439	74.5
Initiated TPT	275	65.0 (of recommended)
Completed TPT	131	47.0 (of initiated) / 21.0 (of total)
TPT completion by gender		
Female	55	42.0
Male	76	58.0

1=National Center for Tuberculosis and Lung Disease, 2=Tuberculin skin test, 3=tuberculosis preventive treatment.

Among 270 index-cases 127 were culture and DST positive. Five Contacts of DS-TB cases were treated with 6INH, 143 with 3PH and among 24 MDR-TB index-cases six were initiated a 6Lfx.

Bivariable analyzes

TPT initiation rates varied widely across regions ($p<0.001$). The highest initiation rates were observed in Shida Qartli (52.6%) and Tbilisi (44.4%), while Kakheti had the lowest rate (10.5%). These highlights substantial differences in program uptake, potentially influenced by regional disparities in access to healthcare services and program implementation.

Completion rates among those who initiated TPT also varied significantly ($p=0.006$). Imereti had the highest completion rate (96.4%), followed by Kakheti (87.5%) and Qvemo Qartli (88.9%).

In contrast, Tbilisi had the lowest completion rate (60.0%), despite a relatively high initiation rate. (See Table 2.)

Table 2.

			TPT Initiation		Total	Chi-square
			No	Yes		
Region	Imereti	Count	92	40	132	
		%Within region	69.70%	30.30%	100.00 %	
		%Within start TPT	20.70%	24.10%	21.60%	
	Kakheti	Count	187	22	209	
		%Within region	89.50%	10.50%	100.00 %	
		%Within start TPT	42.00%	13.30%	34.20%	
	Qvemo qartli	Count	80	24	104	
		%Within region	76.90%	23.10%	100.00 %	
		%Within start TPT	18.00%	14.50%	17.00%	
	shida qartli	count	36	40	76	
		%Within region	47.40%	52.60%	100.00 %	
		%Within start TPT	8.10%	24.10%	12.40%	
	Tbilisi	count	50	40	90	
		%Within region	55.60%	44.40%	100.00 %	
		%Within start TPT	11.20%	24.10%	14.70%	
total		Count	445	166	611	
		%Within region	72.80%	27.20%	100.00 %	
		%Within start TPT	100.00%	100.00 %	100.00 %	69.267

			TPT Complete		Total	Chi-square
			No	Yes		
Region	Imereti	Count	1	27	28	
		% Within region	3.60%	96.40%	100.00%	
		% Within TPT+	4.20%	25.20%	21.40%	
	Kakheti	Count	2	14	16	
		% Within region	12.50%	87.50%	100.00%	
		% Within TPT+	8.30%	13.10%	12.20%	
	Qvemo qartli	Count	2	16	18	
		% Within region	11.10%	88.90%	100.00%	
		% Within TPT+	8.30%	15.00%	13.70%	
	Shida Qartli	Count	7	32	39	
		% Within region	17.90%	82.10%	100.00%	
		% Within TPT+	29.20%	29.90%	29.80%	
	Tbilisi	Count	12	18	30	
		% Within region	40.00%	60.00%	100.00%	
		% Within TPT+	50.00%	16.80%	22.90%	
Total		Count	24	107	131	
		% Within region	18.30%	81.70%	100.00%	
		% Within TPT+	100.0%	100.0%	100.00%	14.484 (.006)

Table 3. Indicates that the likelihood of initiating TPT varied significantly by the type of contact (p=0.010). Most participants had contact with family members, where 28.2% initiated TPT, accounting for 89.5% of all initiations. In contrast, lower initiation rates were observed among

children with contact through relatives (20.4%), neighbors (12.5%), and classmates or coworkers (6.8%). Despite their smaller representation, non-household contacts highlight an area of concern for underutilization of TPT.

Among those who started TPT, completion rates were consistently high across all contact types, with no statistically significant differences (p=0.706). Participants exposed to family members completed TPT at a rate of 78.0%, contributing to the majority (87.6%) of total completions. Other contact groups, such as relatives, neighbors, and classmates, also showed high completion rates (88.9–100%), though their numbers were relatively small.

Table 3.

		TPT Initiation		Total	Chi-square
		No	Yes		
Family member	count	326	128	454	
	%Within new contact	71.80%	28.20%	100.00%	
	%Within start TPT	78.20%	89.50%	81.10%	
Relative Count	count	43	11	54	
	%Within new contact	79.60%	20.40%	100.00%	
	%Within start TPT	10.30%	7.70%	9.60%	
Neighbor	count	7	1	8	
	%Within new contact	87.50%	12.50%	100.00%	
	%Within start TPT	1.70%	0.70%	1.40%	
Classmate/worker	count	41	3	44	
	%Within new contact	93.20%	6.80%	100.00%	
	%Within start TPT	9.80%	2.10%	7.90%	
Total	Count	417	143	560	
	%Within new contact	74.50%	25.50%	100.00%	11.266
	%Within start TPT	100.00%	100.00%	100.00%	

		TPT Complete		Total	Chi-square
		No	Yes		
Family member	count	22	78	454	
	%Within new contact	22.00%	78.00%	100.00%	
	%Within start TPT	95.70%	87.60%	81.10%	
Relative Count	count	1	8	54	
	%Within new contact	11.10%	88.90%	100.00%	

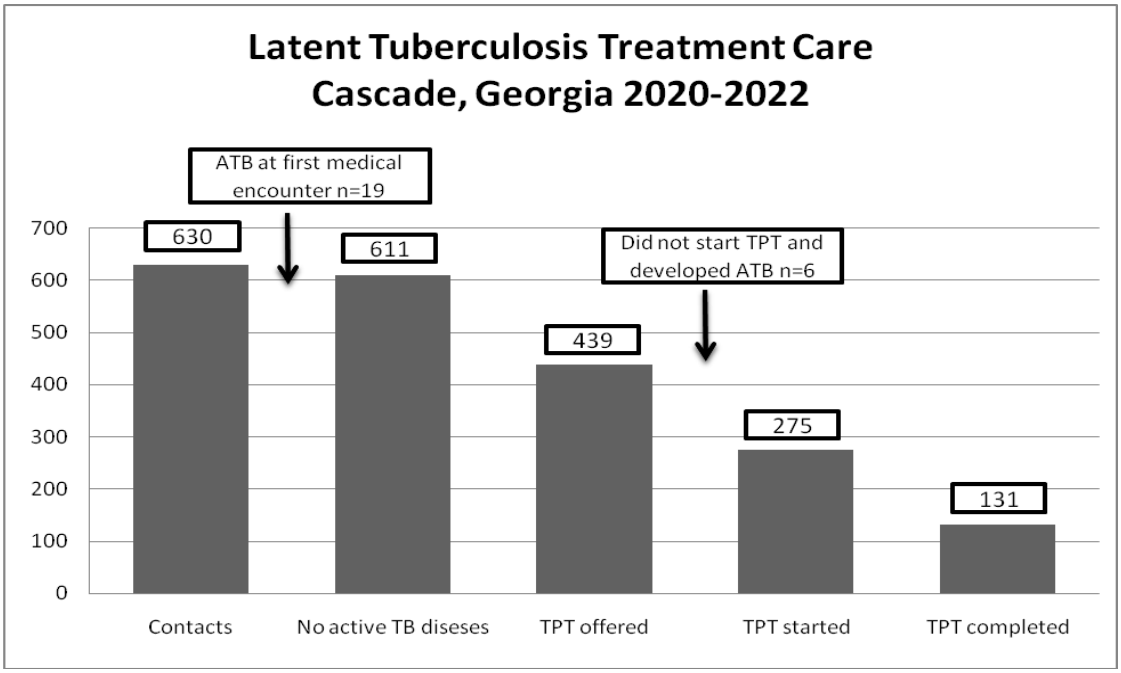
	%Within start TPT	4.30%	9.00%	9.60%	
Neighbor	count	0	1	8	
	%Within new contact	0.00%	100.00%	100.00%	
	%Within start TPT	0.00%	1.10%	1.40%	
Classmate/worker	count	0	2	44	
	%Within new contact	0.00%	100.00%	100.00%	
	%Within start TPT	0.00%	2.20%	7.90%	
Total	Count	23	89	560	
	%Within new contact	20.50%	79.50%	100.00%	1.39 (0.706)
	%Within start TPT	100.00%	100.00%	100.00%	

Analyses to see the association between contacts of index cases living in the same household and TST positive results shows very significant association OR=3 (95%CI=1.6-5.14.P-value <0.001).

Gender-specific insights and implications

Subgroup analysis by gender revealed notable differences in treatment adherence. Although females made up a larger proportion of individuals recommended for TPT, males were more likely to complete treatment. This finding highlights the importance of exploring gender-specific barriers and motivators in TB preventive care. Tailoring educational messages, follow-up strategies, and support services to address these differences may improve adherence and overall program effectiveness. Future research should consider integrating gender-sensitive approaches to optimize LTBI treatment outcomes in diverse settings.

Figure 1.



Active TB development

In the national electronic database, the last search was performed in September 2024. During two years of follow-up time overall six participants developed active TB. All TB people were from the group of no-TPT.

DISSCUTION

The findings of this study reveal significant regional disparities in TPT initiation and completion rates across Georgia, underscoring the challenges in achieving equitable program uptake. Shida Kartli and Tbilisi demonstrated the highest initiation rates, while Kakheti had the lowest, suggesting variations in regional healthcare access and program implementation effectiveness. Factors such as healthcare infrastructure, availability of trained personnel, and awareness among both healthcare providers and the population could be contributing to these differences. Targeted interventions to address these disparities, particularly in regions like Kakheti, are essential for improving overall program uptake.

Completion rates among those who initiated TPT were generally high, with Imereti leading at 96.4%. However, Tbilisi, despite its relatively high initiation rate, had the lowest completion rate (60.0%). This discrepancy could be attributed to urban-specific challenges such as patient mobility, loss to follow-up or competing healthcare priorities in metropolitan areas. The high completion rates in regions like Kakheti (87.5%) and Kvemo Kartli (88.9%) suggest that once individuals begin treatment, supportive factors, possibly including closer patient monitoring or

stronger community engagement, facilitate adherence. Addressing the barriers to treatment completion in Tbilisi is critical to enhancing the overall success of the TPT program.

The analysis of TPT initiation by type of contact highlights another dimension of disparity. While children exposed to family members accounted for the majority of initiations (89.5%) with an initiation rate of 28.2%, significantly lower rates were observed among those exposed through relatives, neighbors, or classmates. This pattern emphasizes the need for a more inclusive approach to contact tracing and TPT initiation, particularly for non-household contacts who may face barriers such as limited awareness or lack of program prioritization. Although the completion rates among all contact types were high and did not significantly differ, the underrepresentation of non-household contacts in TPT uptake warrants attention to ensure these groups are not neglected in TB prevention efforts.

The development of active TB among six participants, all from the no-TPT group, further underscores the importance of timely TPT initiation. This finding highlights the protective role of TPT in preventing the progression to active TB and serves as a compelling argument for scaling up program implementation. However, comparisons with high-income settings should be interpreted with caution, as differences in health system resources, infrastructure, and patient follow-up capacity can significantly influence LTBI treatment uptake and adherence.

According to the systematic review of Sandgren at. Al 2016 Completion rates were higher for the short rather than for long LTBI treatment regimens. In general population the rates review report are; Initiation rate (IR) with 26–99 %, completion rate with 39–96 % (CR),among them contacts of TB cases; IR 40–95 %, CR 48–82 % (Sandgren A., at. Al. 2016). Gullón Blanco at. Al. study result from Spain shows high rate of treatment initiation 86.6%, only 12 refused to perform it and 262 (88.5%) completed three month TPT(Gullón Blanco at. Al., 2022).

If we compare treatment completion rate (65%) with other countries we are far from a high rate, but considering the novelty of a program we can estimate an increased number in the future.

Overall, this study demonstrates the need for targeted, region-specific strategies to address gaps in TPT initiation and completion. Focused efforts to reduce disparities, expand contact tracing, and strengthen adherence support systems can significantly improve the effectiveness of TPT programs and contribute to the broader goal of TB elimination in Georgia.

Limitations

This study has several limitations. First, part of the data was collected retrospectively, which may have introduced recall or documentation bias due to incomplete medical records. Second, despite efforts to include multiple TB units across Georgia, the findings may not be generalizable to all regions or populations not represented in the sample. Third, adverse events related to treatment were not systematically recorded, limiting the ability to assess the safety

profile of TPT regimens. Finally, although the follow-up period was sufficient to identify short-term outcomes, longer-term monitoring would be required to evaluate sustained protection against TB progression.

Conclusion

This study evaluated the LTBI care cascade among TB contacts in five regions of Georgia following the national introduction of short-course TPT regimens. Findings revealed low treatment initiation (65%) and especially low completion rates (21% of total recommended). Notably, all active TB cases occurred in individuals who did not start TPT, highlighting its preventive potential. Significant regional disparities and gender differences were observed, with Shida Kartli showing the highest initiation and completion rates. These findings underscore the need to improve programmatic implementation, particularly in regions with lower uptake, and to explore gender-responsive strategies to enhance adherence. Strengthening follow-up systems and prioritizing patient-centered approaches are essential for maximizing the impact of TPT in Georgia.

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