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Tuberculosis preventive treatment uptake among patients initiating antiretroviral therapy in Malawi: Children left behind

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Background: Tuberculosis preventive treatment (TPT) is recommended for people living with HIV (PLHIV) to reduce the tuberculosis (TB) incidence in regions with a high prevalence of TB. We evaluated the uptake and completion of TPT among newly initiated antiretroviral therapy (ART) patients in a programme setting in Malawi.

Objectives: To describe TPT initiation and completion rates, and explore factors associated with TPT initiation and completion among newly initiated ART patients.

Method: We conducted a retrospective cohort study analysing routinely collected data from 10 ART facilities. We included all patients who initiated ART between January 2023 and March 2023, with follow-up for 12 months. We used descriptive statistics to summarise demographic and clinical characteristics, and logistic regression to assess factors associated with TPT initiation and completion.

Results: A total of 1289 patients were enrolled; 1015 (78.7%) were eligible for TPT. Of these, 820 (80.8%) initiated TPT; 610 (74.4%) completed treatment. Children (<10 years), adolescents (10–19 years), patients presenting with WHO HIV clinical stage three or four conditions, and urban residents were less likely to initiate TPT: adjusted odds ratio (aOR) 0.12 (95% confidence interval [CI] 0.06–0.22), aOR 0.30 (95% CI 0.15–0.59), aOR 0.35 (95% CI 0.21–0.60), and aOR 0.56 (95% CI 0.34–0.90), respectively. Patients who received daily isoniazid for 6 months had reduced odds of completing TPT (aOR 0.22; 95% CI 0.11–0.42) compared with weekly isoniazid plus rifapentine for 3 months.

Conclusion: High TPT initiation and completion rates were observed among eligible patients initiating ART in Malawi. However, children lag in TPT initiation. Targeted interventions that improve TPT uptake among paediatric patients are required.

Keywords: HIV; ART; tuberculosis preventive therapy; 3HP; 6H; Malawi; TB/HIV co-infection.

What this study adds: Our study findings highlight the need for interventions that focus on improving TPT uptake in paediatric ART patients when implementing TPT programmes among PLHIV.

Introduction

Tuberculosis (TB) remains a leading cause of morbidity and mortality among people living with HIV (PLHIV).[1] In 2023, an estimated 161 000 PLHIV died from TB.[2] PLHIV are at a higher risk of TB infection than those HIV-negative people living in the same communities.[3,4,5] Globally, approximately one-quarter of TB-related deaths occur among HIV-infected individuals, underscoring the need for integrated TB and HIV interventions.

Tuberculosis preventive treatment (TPT) reduces the incidence of active TB by up to 90% among PLHIV when given together with antiretroviral therapy (ART), in prevalent TB regions.[6,7,8] Consequently, providing TPT, especially for PLHIV, is a key global health priority, as outlined in the Global HIV/AIDS Strategy 2021–2026,[9] and the World Health Organization (WHO) End TB strategy.[10] Several TPT regimens are available, including daily isoniazid for 6 months (6H) in adults and children living with HIV, or weekly isoniazid and rifapentine for three months (3HP) in adults living with HIV (ALHIV), for TPT.[11]

Shorter TPT courses improve adherence and completion rates among ALHIV because of the lower pill burden and better tolerability.[12,13,14,15] Scale-up of TPT programmes in PLHIV remains challenging in many low- and middle-income countries (LMICs), with reported low initiation and retention rates among eligible patients.[16,17] Patients' lack of understanding of TPT's role in the prevention of TB in the absence of symptoms, ineffective communication with healthcare workers, access to new and optimised drug formulations, and inefficient health service delivery, contribute to poor retention of patients on TPT.[18,19]

Malawi, a low-income country in southern Africa with 12 000 new HIV infections among adults and children in 2023,[20] has one of the highest TB-HIV co-infection rates globally.[21] The country's Ministry of Health introduced TPT for PLHIV, adopting 6H in 2019 and 3HP in 2021 as a first-line intervention for TPT in all newly initiated ART patients. Both regimens were implemented in ART facilities with staff who were trained on the current Malawi Integrated Clinical Management of HIV guidelines,[22] focusing on newly initiated ART patients. At the time of writing, TPT was offered to all eligible patients at no cost to the patients. Notably, as of 2024, 3HP was only available to patients in the country weighing at least 25 kg.[22]

There is limited information on the TPT uptake among PLHIV in Malawi. A study by Gunde et al., based on the Malawi Population-based HIV Impact Assessment (MPHIA) survey, showed 38.8% of ALHIV in 2020 reported having ever taken TPT.[23] At the time of the study, 3HP was yet to be introduced in the country. These findings were limited by recall bias and lack of data on TPT uptake in children and adolescents. The current national guidelines prioritise TPT in newly initiated ART patients. We sought to assess the TPT policy implementation among PLHIV initiating ART, in a real-world setting in Malawi, exploring the uptake, completion, and outcomes in this group.

Research methods and design

Study design and setting

Using a retrospective study design, we conducted a secondary analysis of routinely collected data. We purposively selected 10 high-volume primary and secondary healthcare facilities in which the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) supports HIV programmes in Blantyre, Zomba, Chiradzulu, Mwanza, Thyolo, Ntcheu, Dedza, and Mchinji districts in the central and southern regions of Malawi. These 10 facilities, which were Bangwe Health Centre, Chiradzulu District Hospital, Dedza District Hospital, Limbe Health Centre, Matawale Health Centre, Mchinji District Hospital, Mwanza District Hospital, Ndirande Health Centre, Ntcheu District Hospital, and Thyolo District Hospital, represented about a quarter of the ART cohort where EGPAF supports HIV care and treatment, and were some of the highest HIV- and TB-burdened facilities supported by EGPAF. We included all PLHIV who initiated ART in these facilities between January 2023 and March 2023 in this analysis.

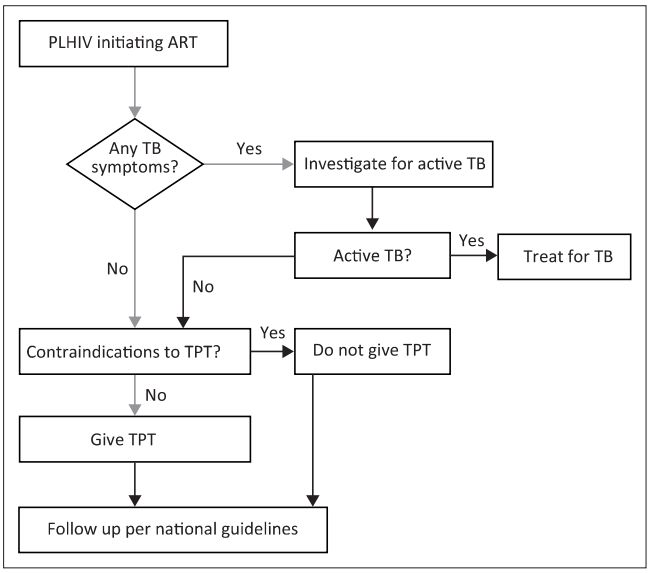
Initiation and follow-up of tuberculosis preventive treatment

All patients initiating ART were eligible for TPT except those with active TB disease, chronic liver disease, peripheral neuropathy, and pregnant women until 3 months post-delivery, per the Malawi National TB and Leprosy Guidelines.[22]

Eligible PLHIV initiating ART were offered TPT following a counselling session on the benefits and potential adverse effects of TPT as part of routine care. The patients were given either 3HP or 6H, based on the availability of drugs, provider recommendation, and patient choice. To ensure coordinated care, the TPT drug dispensing was aligned with ART (i.e. if the patient was given a 1-month supply of ART, they were also prescribed a 1-month supply of TPT). TPT dispensing was documented in the facility's electronic medical records system (EMRS). Completion of TPT was defined as taking 6H for at least 6 months or taking 3HP for 12 weeks. Figure 1 summarises the TPT algorithm for ART patients.[22]

Data collection and statistical analysis

Data were collected in August 2024 using a digital data collection tool, ODK Collect® version 2024.1.3 (Open Data Kit, University of Washington, Seattle, Washington, United States), and exported to Stata® version 18.0 (StataCorp LP, College Station, Texas, United States) for data analysis. The data were abstracted from facility-based EMRS and anonymised at the point of abstraction. We used a significance level of 0.05 for all statistical tests. Differences in categorical variables were compared using Pearson's



Source: Ministry of Health (MOH) Malawi. National tuberculosis and leprosy guideline [homepage on the Internet]. Lilongwe: Ministry of Health and Population, Malawi; 2024 [cited 2024 Oct 01]. Available from: https://www.kuhes.ac.mw/wp-content/uploads/2024/07/TB-and-Leprosy-Guidelines_Final_JUNE2024.pdf

PLHIV, people living with HIV; ART, antiretroviral therapy; TPT, tuberculosis preventive treatment; TB, tuberculosis.

FIGURE 1: Tuberculosis preventive treatment algorithm for people living with HIV initiating antiretroviral therapy in Malawi.

Chi-square test. We used descriptive statistics to summarise patient demographic and clinical characteristics. Factors associated with TPT initiation were assessed using multivariate logistic regression, adjusting for the following characteristics: sex, age group, facility location, and WHO HIV clinical staging at ART initiation. Factors associated with TPT completion were assessed using multivariate logistic regression, adjusting for the following characteristics: sex, age group, facility location, WHO HIV clinical staging at ART initiation, and TPT regimen given. Patients who transferred to other facilities were excluded from the logistic regression model.

Ethical considerations

This evaluation was conducted under the protocol titled 'Evaluation of Outcomes Achieved through Integrated HIV/AIDS and TB Prevention, Care, and Treatment Programs in Malawi'. Ethical approval was obtained from the Malawi National Health Sciences Research Committee (protocol number 18/09/2130) on 12 September 2018, and the Advarra Institutional Review Board in the United States (protocol number Pro00040441) on 22 November 2019. Additionally, the study was reviewed by the United States Centers for Disease Control and Prevention (CDC), and carried out in compliance with applicable federal law and CDC policy. A waiver for informed consent was granted, as the study retrospectively analysed routinely collected data without any direct patient interaction.

Results

Overall, 1289 newly initiated ART patients were enrolled in the study; their baseline characteristics are shown in Table 1. The median age of patients was 33 years (interquartile range: 26–40). A total of 1015 (78.7%) patients were eligible for TPT. Of these, 1015 eligible patients, 820 (80.8%) initiated on TPT. Among the patients ineligible for TPT, 26 (9.5%) had active TB and the rest were either pregnant or less than 3 months postpartum. The majority (94.3%) were started on the weekly 3HP regimen (Table 1). In multivariate analysis (Table 2), the likelihood of TPT initiation was significantly lower in children (< 10 years) (adjusted odds ratios [aOR] 0.15; 95% confidence interval [CI] 0.08–0.29) and adolescents (10–19 years) than patients aged 20 years or older (aOR 0.30; 95% CI 0.15–0.59). Patients with WHO HIV clinical stage three or four at ART initiation had lower odds of initiating TPT compared to those with stage one or two disease (aOR 0.35; 95% CI 0.21–0.60). Patients in urban facilities were less likely to initiate TPT than those in rural facilities (aOR 0.56; 95% CI 0.34–0.90).

Among the 820 patients who initiated TPT, 105 (12.8%) did not complete a full course of treatment. TPT non-completion was because of stopping of treatment (46.7%), loss to follow-up (43.8%), death (8.6%), and one who developed active TB during the course of the treatment. Notably, 105 patients transferred to other facilities before completing TPT.

TABLE 1: Demographic characteristics of patients newly initiated on antiretroviral therapy in selected Elizabeth Glaser Pediatric AIDS Foundation-supported facilities, January 2023 to March 2023.

Characteristics	*n*	%
Sex		
Female	782	60.7
Male	507	39.3
Age group (years)†‡		
0 to 9	47	3.7
10 to 19	52	4.0
≥ 20	1190	92.3
Facility location		
Rural	232	18.0
Urban	1057	82.0
WHO HIV clinical staging at ART initiation		
Stage 1 or 2	1183	91.8
Stage 3 or 4	106	8.2
TB status at ART initiation		
No TB	1248	96.8
Suspected TB	15	1.2
Confirmed TB	26	2.0
Eligible for TPT initiation		
Yes	1015	78.7
No	274	21.3
Initiated on TPT among those eligible for TPT		
Yes	820	80.8
No	195	19.2
TPT regimens		
3HP	773	94.3
6H	47	5.7
ART outcome at 12 months		
Alive in care	883	68.5
Transferred out	261	20.2
Stopped treatment	2	0.2
Lost to follow-up	114	8.8
Died	29	2.3
Diagnosed with TB within the first 12 months of ART		
Yes	8	0.9
No	877	99.1
N/A (had TB at initiation)	26	-
Missing	378	-

ART, antiretroviral therapy; TPT, tuberculosis preventive treatment; TB, tuberculosis; 3HP, weekly isoniazid and rifapentine for three months; 6H, daily isoniazid for six months; N/A, not applicable.
†, Median: 33; ‡, interquartile range: 26, 40.

Completion rates were highest among adults aged 20 years or older (83.7%) than children and adolescents. Patients who received 6H were less likely to complete TPT than those who received 3HP (aOR 0.22; 95% CI 0.11–0.42) (Table 3).

Ninety-one per cent of the patients retained in care after 12 months did not develop active TB. TB incidence was significantly lower among those who initiated TPT (0.18%) compared to those who did not (1.59%, $P = 0.02$).

Discussion

Our study provides individual-level data on the TPT initiation and completion rates among newly initiated ART

TABLE 2: Factors associated with tuberculosis preventive treatment initiation among patients newly initiated on antiretroviral therapy and eligible for TPT, in selected Elizabeth Glaser Pediatric AIDS Foundation-supported facilities, January 2023 to March 2023.

Characteristics	Initiated TPT		Crude		Adjusted		*P*
	n	%	OR	95% CI	OR	95% CI	
Sex							
Female	428	81.7	1.13	0.82–1.54	1.08	0.78–1.50	0.65
Male	392	79.8	Ref	-	1.00	-	-
Age groups (years)							
0–9	17	37.8	0.12	0.06–0.22	0.15	0.08–0.29	< 0.001
10–19	23	59.0	0.57	0.33–0.98	0.30	0.15–0.59	0.001
≥ 20	780	83.8	Ref	-	1.00	-	-
WHO HIV clinical staging at ART initiation							
Stage 1 or 2	776	82.8	Ref	-	1.00	-	-
Stage 3 or 4	44	56.4	0.27	0.17–0.43	0.35	0.21–0.60	< 0.001
Facility location							
Rural	158	86.8	Ref	-	1.00	-	-
Urban	662	79.5	0.59	0.37–0.93	0.56	0.34–0.90	0.01

TPT, tuberculosis preventive treatment; OR, odds ratio; 95% CI, 95% confidence interval; ART, antiretroviral therapy.

TABLE 3: Factors associated with tuberculosis preventive treatment completion among patients newly initiated on antiretroviral therapy who initiated tuberculosis preventive treatment in selected Elizabeth Glaser Pediatric AIDS Foundation-supported facilities, January 2023 to March 2023.

Characteristic	Completed TPT		Crude		Adjusted		*P*
	n	%	OR	95% CI	OR	95% CI	
Sex							
Female	328	76.6	1.27	0.93–1.75	1.26	0.92–1.75	0.153
Male	282	71.9	Ref	-	1	-	-
Age group (years)							
0 to 9	8	47.1	0.30	0.11–0.78	0.29	0.18–1.67	0.53
10 to 19	17	73.9	0.94	0.37–2.43	0.97	0.36–2.6	0.947
≥ 20	585	75.0	Ref	-	1	-	-
WHO HIV clinical staging at ART initiation							
Stage 1 or 2	579	74.6	Ref	-	1	-	-
Stage 3 or 4	31	70.5	0.81	0.41–1.27	0.74	0.37–1.49	0.406
Facility location							
Rural	129	81.7	Ref	-	1	-	-
Urban	481	72.7	0.60	0.39–0.93	0.634	0.40–0.99	0.046
TPT regimen							
3HP	592	76.6	Ref	-	1	-	-
6H	18	38.3	0.17	0.09–0.31	0.21	0.11–0.40	< 0.001

TPT, tuberculosis preventive treatment; OR, odds ratio; 95% CI, 95% confidence interval; ART, antiretroviral therapy; 3HP, weekly isoniazid and rifapentine for three months; 6H, daily isoniazid for six months.

patients in Malawi. Most of the eligible patients initiated TPT and nearly three-quarters completed their treatment regimen. Most of the patients took the shorter regimen of weekly 3HP. TPT initiation was associated with age, facility location, and WHO HIV clinical stage, while TPT completion was associated with age and location.

Malawi's national policy prioritises providing TPT to PLHIV who are newly initiating ART, as TB incidence is highest during the first year of ART initiation and decreases significantly in the following years.[24] Our findings are comparable with other studies from other LMICs and sub-Saharan Africa, which reported TPT initiation rates ranging from 61% to 79% and completion rates of up to 89%, suggesting an increase in the uptake of TPT among PLHIV in recent years.[25,26,27,28] This improvement may be attributable to the global commitment to reducing the burden of TB in this group, including scaling up more tolerable TPT regimens. Nonetheless, approximately a quarter of the eligible patients did not initiate TPT, and active TB was more incident among these patients than those who initiated TPT. These outcomes continue to establish the benefits of TPT in our study population, highlighting the need to improve the uptake of TPT among PLHIV.

The preference for 3HP over the daily isoniazid regimen likely reflects both patient and provider preferences, as 3HP has been shown to have higher completion rates because of its shorter duration and more convenient weekly dosing schedule. The higher odds of completion among patients who received 3HP than 6H aligns with findings from other high-burden TB countries, where shorter-course TPT regimens have demonstrated better adherence and outcomes.[12,13,14,15] Countries that have integrated 3HP into their national TPT strategy have reported higher patient acceptability because of its once-weekly dosing, shorter treatment duration, and perceived safety, leading to greater overall acceptance. Additionally, 3HP presents fewer logistical challenges compared to long-term treatment regimens, further supporting

its widespread adoption.[29] However, the scope of our study could not assess the reasons for increased uptake of 3HP over 6H. Factors such as medication availability, provider recommendations, patient perceptions of side effects, and system-level influences (e.g. supply chain consistency and integration into HIV care) may have played a role in this trend.

Our study highlights significant disparities in TPT uptake and completion, particularly among children (<10 years) and adolescents (10–19 years). This mirrors global data showing that children are often left behind in TB prevention efforts.[30,31] This may be because of several factors, including difficulties in ruling out active TB disease in this population, lack of paediatric formulations for 3HP as it was only available for patients weighing at least 25 kg, and challenges with adherence to treatment especially in LMICs.[22,32] The finding is particularly concerning as children are at a higher risk of progression to active TB disease post *Mycobacterium tuberculosis* infection than adults.[33,34] Improving the TPT coverage in this high-risk group is critical to reducing the burden of TB in TB-endemic regions.

The geographic disparities observed in our study, with urban patients less likely to initiate TPT than rural patients, may reflect systemic issues such as overcrowded urban health facilities, higher patient loads, and limited time for counselling. These factors can hinder patient-provider engagement, reducing opportunities for adherence support and follow-up. This is consistent with prior research showing that uptake of HIV services, and treatment outcomes often differ significantly between rural and urban settings in the country.[35,36] Addressing these disparities requires targeted strategies to improve TPT access and support in urban healthcare facilities, ensuring equitable treatment for all populations. Further investigation is required to understand barriers to HIV service delivery in urban areas in the country.

Our study found that patients with advanced HIV disease, as classified by WHO HIV stage three or four had reduced odds of initiating TPT than those with WHO HIV clinical stage one or two. Typically, patients who presented with WHO clinical stage three or four conditions would have been undergoing treatment for additional conditions at the time of ART initiation, making TPT initiation a lower priority. Furthermore, some of these patients may have presented with symptoms suggestive of TB. In most facilities in sub-Saharan countries, TB diagnosis requires at least 2 days because of limited availability of on-site testing and challenges such as sputum production on the initial visit, often necessitating sample referral to external laboratories and resulting in delayed results.[37,38] Consequently, these delays may have led to missed opportunities for TPT initiation at the start of ART with further opportunities being overlooked during subsequent visits. While our study could not comprehensively assess all reasons for TPT non-initiation among eligible patients, implementing digital clinical decision support systems that flag eligible patients not yet on TPT could help address this gap.

Our study demonstrated considerable TPT initiation and completion rate variations across the sites in Malawi. The present gap needs to be bridged by implementing future qualitative research probing into various sociocultural dynamics and cues unique to urban populations. Targeted interventions are needed to effectively address the gaps identified by our findings. First, increasing access to paediatric-friendly formulations of TPT among eligible patients in LMICs, such as dispersible tablets and flavoured syrups which are already approved and available on the market, could enhance the TPT uptake in children.[39] Furthermore, enhancing healthcare worker training on emphasising the importance of TPT for children and adolescents during adherence counselling sessions could help improve initiation and completion rates in the country.[40]

We acknowledge some limitations of our study. Using programme data presented a higher chance of documentation error and missing data than in a controlled setting. The significant proportion of patients transferring out to other facilities where we could not determine their treatment outcomes may have presented a selection bias. Also, our study was limited to high-volume EGPAF-supported facilities in the southern and central regions of the country, and the findings need to be generalised with caution. However, these facilities represent some of the highest HIV-TB co-infection rates in the country. Therefore, we believe our approach best evaluates the implementation of TPT in newly initiated ART patients in high-burden facilities in Malawi.

In conclusion, while our findings suggest substantial progress in TPT uptake and completion among newly initiated ART patients in Malawi, much work remains to ensure that subpopulations, particularly children, are not left behind. Future efforts should address the barriers to paediatric TPT uptake and close the geographic gap in access to TB preventive services among PLHIV.

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Competing interests

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Authors' contributions

L.M., N.B., and P.N. conceptualised the study. L.U.K., G.S., and L.M. curated and analysed the data. T.M. secured the funding, and L.M., L.U.K., and P.N. conducted the investigation. L.M., T.M., and L.U.K. developed the methodology. Project administration was handled by M.K., and P.N., with resources provided by T.M. L.U.K. managed the software, and T.M., and N.B. supervised the work. T.M., and N.B. carried out validation, and L.U.K., and L.M. did visualisation. L.M. wrote the original draft and all authors reviewed and edited the article.

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Data availability

Anonymised patient data will be made available upon requests directed to the corresponding author, L.M.

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