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The implementation of tuberculosis preventive therapy in HIV care clinics in Africa, Asia and Latin America: a multiregional site survey

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SUMMARY

Introduction Towards the 'End TB Strategy' targets, the WHO recommends the provision of tuberculosis (TB) preventive therapy (TPT) for high-risk groups including people living with HIV (PLWH). 3 years after the release of the updated 2020 WHO guidelines, we investigated the implementation of TPT services at HIV clinics in low-income and middle-income countries (LMICs), focusing on TB screening, populations eligible for TPT and available TPT regimens.

Methods In 2023, we surveyed HIV care clinics in the International Epidemiology Databases to Evaluate AIDS consortium in Africa, the Asia-Pacific and Latin America and the Caribbean. We used descriptive statistics to summarise TPT implementation according to WHO guidelines and multivariable logistic regression models to estimate associations with clinic characteristics.

Results Of 172 HIV clinics included, 142 (83%) were in Africa, 22 (13%) in the Asia-Pacific and 8 (5%) in Latin America; 108 (63%) were located in urban areas. After ruling out active TB, TPT was reportedly offered to PLWH (122 clinics, 71%), household contacts of individuals with active TB (120 clinics, 70%) and other high-risk populations. TPT for PLWH was more frequently available in clinics in lower-income and low-middle-income countries, in high TB burden countries, and in district hospitals compared with other facility types. Clinics reported use of isoniazid-based (160 clinics, 93%) and shorter rifamycin-based (129 clinics, 75%) TPT regimens. Reported barriers to TPT initiation included patient refusal at 71 (41%) and drug shortages at 67 (39%) clinics.

Conclusions TPT was available at most HIV care clinics in LMICs but further efforts are needed to reinforce WHO recommendations and ensure that TPT is consistently accessible to people at higher risk of developing active TB, especially PLWH.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Tuberculosis (TB) preventive therapy (TPT) is a safe, efficacious and cost-effective measure to prevent TB.
⇒ The WHO recommends TPT for populations at higher risk of developing active TB, in particular people living with HIV (PLWH) and household contacts of individuals diagnosed with TB.
⇒ We surveyed a geographically diverse sample of HIV care clinics in low-income and middle-income countries to assess the implementation of the WHO recommendations for TPT.

WHAT THIS STUDY ADDS

⇒ TPT was available at HIV care clinics in low-income and middle-income countries, but only partly offered to people at the highest risk of developing TB, especially PLWH.
⇒ TPT for PLWH was associated with country income level, TB burden, region and clinic size.
⇒ The most commonly reported barriers to TPT initiation were patient refusal and drug shortages.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study identified gaps in the implementation of TPT that need to be addressed to ensure the success of the End TB Strategy.
⇒ We showed the importance of supporting and monitoring TPT implementation to ensure that people who would benefit most from TPT can readily access it, in particular PLWH.
⇒ Greater efforts should be made to reduce barriers to TPT and to scale up shorter regimens.

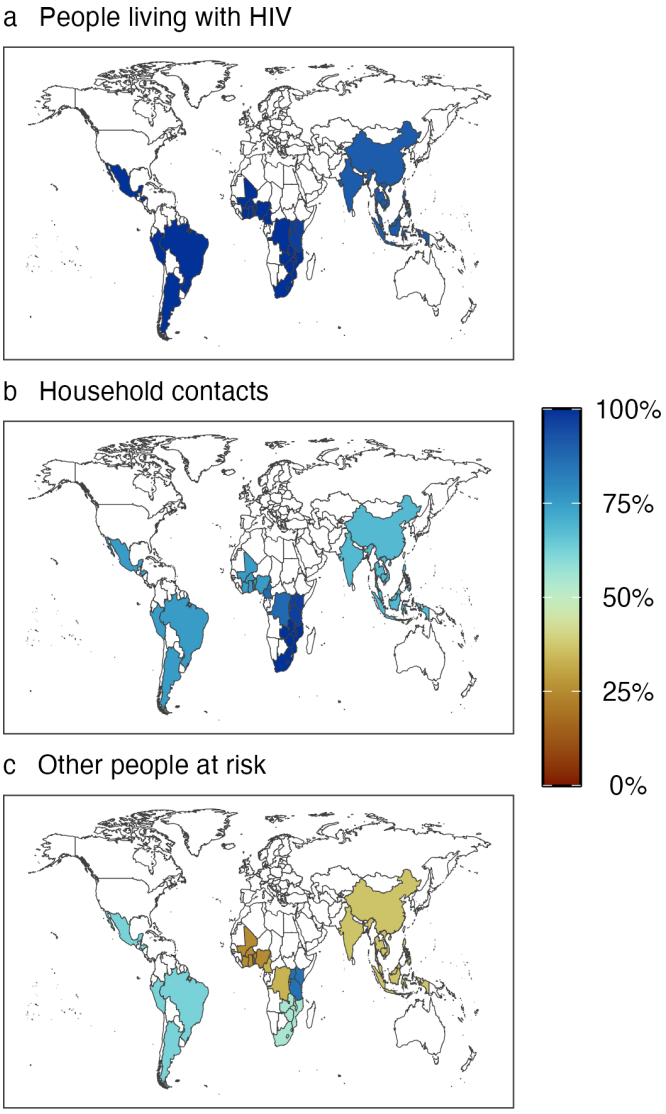

Figure 1 Maps showing the countries represented by the 172 participating HIV care clinics and the populations eligible for tuberculosis preventive therapy (TPT), according to the priority groups defined in the WHO's recommendations.[15] (a) Proportion (region-specific) of clinics offering TPT to any of the subgroups of people living with HIV; (b) Proportion of clinics offering TPT to any of the subgroups of household contacts of people with active tuberculosis; (c) Proportion of clinics offering TPT to any of the subgroups of other people at risk. See figure 2 for TPT proportions per subgroups within PLWHIV, household contacts and other subgroups.

INTRODUCTION

It is estimated that about one-quarter of the world's population is prevalently infected with *Mycobacterium tuberculosis*.[1 2] People with immune weaknesses and people living with HIV (PLWH) are at higher risk of developing active tuberculosis (TB), and TB is one of the leading causes of death among PLWH.[3 4] Globally, 6.1% of incident TB was recorded among PLWH in 2023, with large regional disparities, exceeding 50% of TB among PLWH in parts of Southern Africa.[5] Furthermore, the global mortality attributable to TB almost doubled the one attributable to HIV.[5]

Since 2004, the WHO has recommended TB preventive therapy (TPT) for PLWH and for other individuals at increased risk of developing TB. TPT is a prophylaxis that can be taken orally to prevent TB infection. TPT reduces TB incidence, especially in low-income and middle-income countries (LMICs) with high prevalence of HIV-associated TB, thereby contributing to the WHO's 'End TB Strategy'.[6–8] Yet, in 2023, the TPT coverage was estimated to have reached 21% among household contacts of people diagnosed with TB, and 56% among PLWH, both below the 90% global target to be reached by 2027.[5]

TPT is particularly important for PLWH because of their higher risk of developing TB.[3 4] Clinical efficacy and cost-effectiveness of TPT have been shown using 6-month isoniazid-based TPT or shorter rifamycin-containing regimens.[9–14] Shorter TPT regimens have the advantage of being less toxic than longer isoniazid monotherapy, reducing adverse events and treatment discontinuation.[11 15] Clinic-level provision of TPT may be limited by gaps in screening practices to exclude active TB, drug shortages and insufficient resources, which can contribute to challenges in TPT uptake and completion, as well as substantial losses along the TPT care cascade.[16 17] To improve accessibility and retention in care, especially since the COVID-19 pandemic, HIV services, including the provision of TPT, have increasingly moved to client-centred care, for instance, through differentiated service delivery, which allows care to be delivered in and through communities rather than clinics.[18 19]

In 2020, the WHO updated their guidelines on TB prevention, which specifically recommended shorter TPT regimens and identified three major eligibility groups for TPT[15]: (1) PLWH, irrespective of their age and degree of immunosuppression, even if testing for TB infection is unavailable; (2) household contacts exposed to a person with pulmonary TB, regardless of their HIV status and (3) other people at risk, including healthcare workers and people in prisons, people on immunosuppressive therapy or dialysis. Little is known about the global implementation of TPT, especially in LMICs where the burden of TB and HIV is high. In this study, we used data from a site-level survey to evaluate the implementation of TPT in a global sample of HIV care clinics in LMICs from the International Epidemiology Databases to Evaluate AIDS (IeDEA) consortium in Africa, the Asia-Pacific and Latin America and the Caribbean, with a focus on TB screening and testing, eligible populations and TPT regimens available.

METHODS

Study setting

The IeDEA (www.iedea.org) was established in 2006 and comprises close to 400 HIV care and treatment sites in 44 countries that contribute longitudinal data for more than 2 million individuals living with and at risk for HIV, including adults and children.[20] IeDEA conducts periodic surveys every 2–3 years at participating clinics to collect data on site characteristics and topics related to HIV. This study was conducted

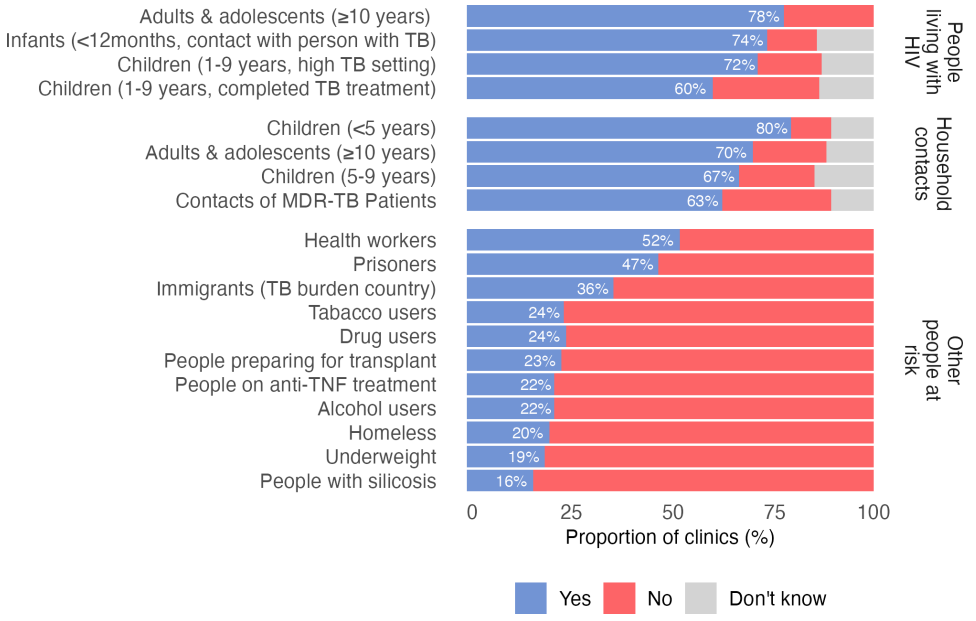

Figure 2 Proportion of HIV care clinics offering tuberculosis preventive therapy for the priority groups defined in the WHO's recommendations.[15] TB, tuberculosis; MDR, multidrug resistant.

at HIV care clinics in LMICs from the IeDEA consortium in Africa, the Asia-Pacific and Latin America and the Caribbean.[21]

Data collection and definitions

The survey was conducted between 3 August and 31 December 2023. Each participating clinic submitted one survey. Respondents were knowledgeable about the clinic capacity and the services offered within the HIV clinic and were encouraged to consult colleagues at their site if necessary. In addition to clinic characteristics, we collected data on TPT availability, eligibility and regimens as well as barriers to TPT implementation. The survey was provided in English and French as an online questionnaire or on paper. All survey data were collected and managed using Research Electronic Data Capture (REDCap), a secure, web-based software.[22 23] Questions were asked with prefixed answer options, and in the case of 'others', there was also an option for free text. The income level for each country is classified according to the World Bank Country and Lending Groups classifications for the 2024 fiscal year into low-income, lower-middle-income and upper-middle-income economies.[24] We obtained country-level HIV prevalence data—the estimated percentage of adults aged 15–49 PLWH—from the UNAIDS website in 2023.[25] We classified countries as having low (<1%), medium (1%–5%) and high HIV prevalence (>5%). We classified TB burden according to the WHO list of High Burden Countries (HBC) for TB, HIV-associated TB and drug-resistant TB.[26] We defined high-TB-burden countries as those included in any of these lists. We defined the degree of TB and HIV service integration as 'full integration' (TB diagnostics and treatment available at the same facility as HIV care services), 'partial integration' (either TB diagnostics or treatment available) or 'not integrated' (TB diagnostics and treatment not available at the participating HIV care clinic).[27]

Statistical analyses

We assessed the implementation of TB screening and testing services, provision of TPT to eligible populations according to the 2020 WHO recommendations,[15] barriers for TPT implementation, and availability of different TPT regimens. Survey results were summarised across subgroups (PLWHIV, household contacts and other risk groups) by the number and proportion of clinics. In an exploratory analysis to highlight patterns across our diverse sample of HIV clinics, we used multivariable logistic regression models to estimate the association of TPT implementation for priority groups as defined by the WHO (PLWH, household contacts of people diagnosed with TB, other persons at high risk of TB) and use of short-course TPT regimens (defined as rifamycin-based regimens of less than 6 months) with clinic characteristics. We started with the full model, which included all variables, and then removed any covariates that were collinear, as indicated by a variance inflation factor greater than four. The only exclusion was national HIV prevalence. Associations were reported as odds ratios (ORs) with 95% confidence intervals (95% CIs), derived from univariable and multivariable models. All analyses were performed in R V.4.4.0.[28]

Patient and public involvement

We discussed the objectives, the content and the study design with the relevant working groups within the

Table 1 Associations between the implementation of TPT for each of the three target groups defined by the WHO recommendations[15] and site characteristics at 172 HIV care clinics

	People living with HIV			Household contacts			Other people at risk		
Variable	**OR**	95% CI	**P value**	**OR**	95% CI	**P value**	**OR**	95% CI	**P value**
Level of integration			0.116			0.294			0.175
No	1.00	Reference		1.00	Reference		1.00	Reference	
Full	0.30	0.08 to 1.21		2.01	0.86 to 4.70		1.80	0.92 to 3.53	
Partial	0.32	0.08 to 1.31		2.01	0.82 to 4.91		1.70	0.85 to 3.37	
Income level			0.003			0.792			<0.001
Upper middle	1.00	Reference		1.00	Reference		1.00	Reference	
Low	2.43	1.18 to 5.00		0.74	0.33 to 1.65		1.72	1.08 to 2.74	
Low middle	2.94	1.59 to 5.45		0.82	0.41 to 1.64		3.24	2.12 to 4.93	
TB high burden country			0.024			0.337			<0.001
No	1.00	Reference		1.00	Reference		1.00	Reference	
Yes	1.87	1.10 to 3.19		1.33	0.78 to 2.27		2.40	1.70 to 3.39	
TPT training			0.512			0.824			0.004
No	1.00	Reference		1.00	Reference		1.00	Reference	
Yes	1.36	0.68 to 2.70		0.86	0.37 to 2.00		1.73	1.18 to 2.55	
Facility level of care			0.024			<0.001			<0.001
District hospital	1.00	Reference		1.00	Reference		1.00	Reference	
Health centre	0.32	0.10 to 1.00		0.39	0.13 to 1.24		0.61	0.44 to 0.87	
Regional/provincial/ university hospital	0.24	0.07 to 0.80		0.16	0.05 to 0.52		0.31	0.20 to 0.48	
Region			0.897			0.183			0.042
Africa	1.00	Reference		1.00	Reference		1.00	Reference	
Asia-Pacific	0.88	0.43 to 1.83		0.78	0.37 to 1.67		0.57	0.36 to 0.92	
Latin America	1.30	0.36 to 4.64		0.35	0.11 to 1.09		1.25	0.53 to 2.95	

The estimates were derived from multivariable logistic regression models which included the following variables: level of integration, income level, TB burden, TPT training, level of care at the facility and region (National HIV prevalence was omitted due to collinearity). The results from the univariable models are shown in online supplemental table 4.
TB, tuberculosis; TPT, tuberculosis preventive therapy.

global IeDEA consortium (including the Site Assessment and the Tuberculosis and Lung Health working groups). The site survey was pilot-tested at selected representative sites to optimise the data collection procedures. Patients were not involved in the design, recruitment or conduct of this survey study. We will disseminate the results of this study to the participating HIV clinics and our broader research networks.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation or writing of the report.

RESULTS

Participating HIV care clinics

The survey was distributed to 180 HIV care clinics in LMICs, and 178 completed the questionnaire (99%); 6 (3%) facilities reported that TPT was not available at their site and were therefore excluded from subsequent analysis (online supplemental table 1). Of the remaining 172 clinics providing TPT, 16 (9%) were in West Africa, 24 (14%) in Central Africa, 71 (41%) in East Africa, 31 (18%) in Southern Africa, 22 (13%) in the Asia-Pacific and 8 (5%) in Latin America and the Caribbean. Most clinics were in urban settings (108, 63%), and fully integrated TB care as part of HIV services was available at 107 clinics (62%) (online supplemental table 2). The provision of any TPT training to healthcare workers varied from 50% to 100% depending on the region (online supplemental table 3). In providing TPT, almost all clinics (171/172) reported using symptom screening to identify patients with active TB who require a full TB treatment regimen (online supplemental table 3). Only 29 sites (17%) reported having TB infection testing available to assess the eligibility of PLWH for TPT.

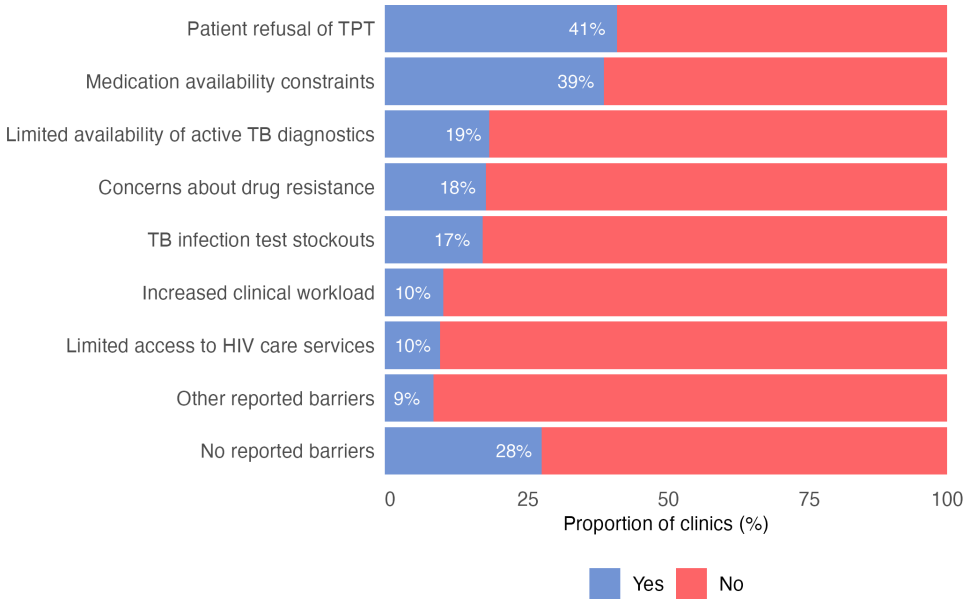

Figure 3 Proportion of HIV care clinics reporting barriers to TPT initiation. TPT, TB preventive therapy, TB, tuberculosis.

Implementation of TPT according to WHO recommendations

Eligible populations, associated factors and barriers to TPT uptake

Most HIV care clinics reported providing TPT to PLWH (mean across subgroups: 122, 71%; range 60%–78%), and to household contacts of people with active TB (mean across subgroups: 120, 70%; range 63%–80%). TPT was less often provided to other populations at risk (mean across subgroups: 48, 27%; range 16%–52%) who were also eligible for TPT regardless of their HIV status, including healthcare workers at 90 (52%) clinics, prisoners at 81 (47%) and immigrants from high TB burden countries at 62 (36%) clinics (figures 1 and 2). The proportions stratified by region, TB burden, national HIV prevalence and by the level of HIV/TB service integration are shown in online supplemental figure 1. Provision of TPT for the three priority groups was associated with clinic and contextual characteristics, including country income level, TB burden and level of care provision (table 1, online supplemental table 4). TPT provision to PLWH was greater in low-income countries (OR: 2.43, 95% CI 1.18 to 5.00) and low-middle-income countries (2.94, 95% CI 1.59 to 5.45) compared with upper-middle-income countries, in countries with a high TB burden (1.87, 95% CI 1.10 to 3.19) compared with low TB burden countries, and was lower in health centres (0.32, 95% CI 0.10 to 1.00) and regional, provincial or university hospitals (0.24, 95% CI 0.07 to 0.80) compared to district hospitals. TPT provision to household contacts

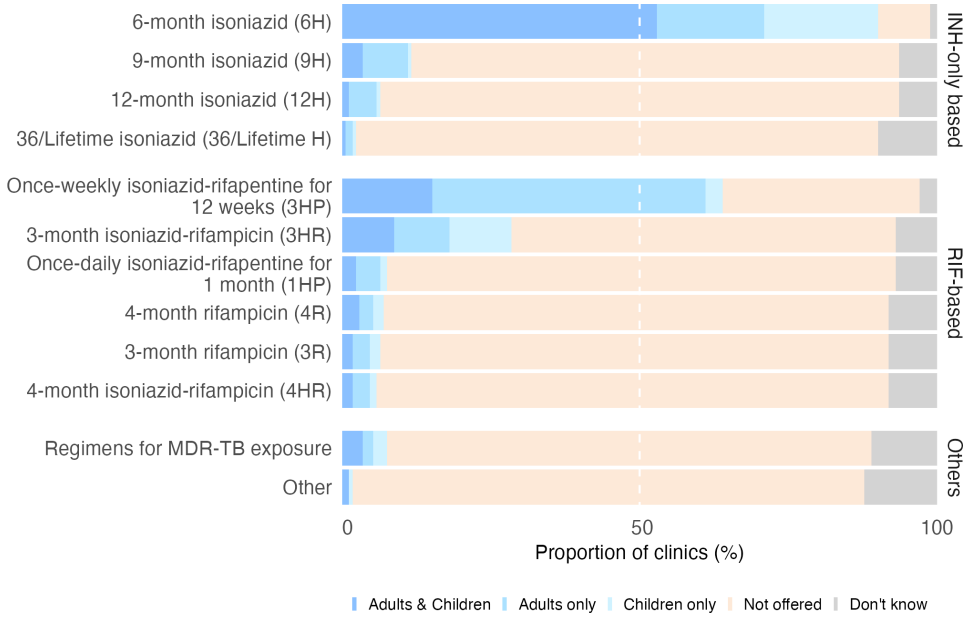

Figure 4 Availability of TB preventive therapy regimens for adults and children at HIV care clinics, presented as proportions of clinics. INH, H, isoniazid; RIF, R, rifamycin; MDR, multidrug resistant; TB, tuberculosis.

of people diagnosed with TB regardless of their HIV status was higher in district hospitals. TPT provision to other people at increased risk of TB regardless of their HIV status was greater in low-income/low-middle-income countries, in countries with high TB burden, in clinics with TPT training and in district hospitals. The complete association analysis with the corresponding reference groups is shown in table 1. The results from multivariable (table 1) and univariable (online supplemental table 4) analysis showed broadly similar associations between TPT implementation and clinic characteristics.

The most frequently reported barriers to TPT uptake were patient refusal (71, 41%), followed by insufficient drug availability or shortages (67, 39%). 48 clinics (28%) reported no barriers to TPT uptake (figure 3).

Available TPT regimens and associated factors

The 6-month isoniazid monotherapy TPT regimen was the most widely offered (155, 90%), followed by the 3-month once-weekly isoniazid-rifapentine regimen (110, 64%). Other short rifamycin-based regimens such as 3-month rifampicin monotherapy were available at 11 (6%) clinics (figure 4). The availability of TPT regimens stratified by region, TB burden, national HIV prevalence and by the level of HIV/TB service integration is shown in online supplemental figure 2. The use of any short-course rifamycin-based regimen was not clearly associated with clinic characteristics, including region, TB burden or country income level (online supplemental table 5).

DISCUSSION

The prevention of active TB disease through TPT is crucial to the WHO's 'End TB Strategy' and to global TB elimination efforts. Our survey of 178 HIV care clinics within the global IeDEA consortium assessed the implementation of TPT following the 2020 WHO guidelines recommending TPT for risk groups including PLWH and household contacts, as well as the use of shorter rifamycin-based TPT regimens. We found that TPT was available in nearly all surveyed clinics, yet there were gaps in implementation. Despite fully or partially integrated TB services being offered at the majority of participating HIV care clinics, more than a quarter of clinics did not offer TPT to PLWH who are at high risk of developing TB, more than a quarter did not offer it to household contacts of people with active TB, and more than two-thirds did not provide TPT to other at-risk populations. Shorter and more tolerable rifamycin-based TPT regimens were offered at three quarters of the clinics.

The efficacy of TPT in preventing the development of active TB has been shown,[12 13] but implementation remains challenging.[29–32] The effectiveness of TPT depends on appropriate identification of people at high risk who would benefit most, use of regimens of proven efficacy, and maximising adherence to and completion of treatment.[33–35] We showed that TPT implementation varied across regions and healthcare settings. Furthermore, we observed a broad reliance on symptom-based screening to exclude TB before initiating TPT. Only a few sites reported using tuberculin skin tests and interferon-gamma release assays to determine TPT eligibility. This is in line with the WHO guidelines which recommend—but do not require—using such tests, and reflects previous evidence showing the challenges and costs associated with TB infection testing in high-TB-burden settings.[30 36]

Our data showed that a significant proportion of clinics did not offer TPT to the populations at the highest risk of developing TB, especially PLWH and household contacts of people diagnosed with TB, despite WHO recommendations.[15] A previous study in South Africa also showed that TB screening and TPT initiation were rare among close contacts of confirmed TB patients.[37] A study in Uganda reported good TB screening practices, but poor levels of TPT initiation among PLWH.[38] Even though the added value of prescribing TPT to PLWH is widely accepted, our results confirmed the insufficient implementation and use of TPT among PLWH.[39 40] These findings highlight difficulties in implementing TPT according to WHO recommendations, putting vulnerable people at greater risk of developing and transmitting TB, especially in places with high prevalence of HIV-associated TB. Although household contacts of people with TB are not the main target population of HIV clinics, they can be an important entry point for scaling up TPT services.

The majority (129, 75%) of clinics in our study offered shorter rifamycin-based TPT regimens, although mainly for adults. In the last IeDEA site assessment conducted in 2020 (before the COVID-19 pandemic's impact on service delivery), 143 clinics (70%) reported providing TPT to individuals who screened negative for TB disease. Of those, less than 20% reported offering at least one rifamycin-based short-course regimen and less than 10% offered the 3-month regimen of isoniazid-rifapentine.[41] Provision of 3HP, a short rifamycin-based regimen (3 months isoniazid/rifapentine) has increased more than sixfold to 64% in this study, reflecting global efforts to expand access to short-course TPT regimens. These rifamycin-based TPT regimens have been shown to improve patient adherence and reduce treatment-related adverse events, compared with isoniazid-containing regimens.[42 43] Yet, drug–drug interactions between rifamycin-based TPT and some antiretroviral therapy regimens may need to be carefully considered.[13 15 39] Overall, the expansion of shorter and less toxic TPT regimens follows growing recognition that TPT should be more patient-friendly, which is crucial for improving TPT uptake and completion rates.[33 44]

Beyond maintaining high levels of TPT initiation, loss to follow-up and TPT interruptions may hinder completion rates of TPT, which is another important indicator in the TB preventive cascade.[17 45]

Respondents in this study reported that the main barriers to TPT initiation were both individual (patient refusal) and institutional (drug shortages). Patient engagement is critical to the successful scale-up of TPT. Adopting a patient-centred approach will ensure that programmes are tailored to patient needs. Empowerment of patient representatives to provide input into TPT programmes will enhance the quality of care and ultimately improve participation. The growing number of therapeutic options available to patients also enables a more patient-centred approach to TPT.[46] Furthermore, barriers at the healthcare-provision level, such as insufficient training of healthcare providers, lack of regulatory approval of newer regimens and supply chain inefficiencies, have been previously shown to impede TPT implementation.[8 16 30]

Our study has limitations. Although the analysis of our sample of HIV care clinics provides a broad overview of TPT implementation 3 years after the release of the 2020 WHO recommendations in a diverse set of clinics, including smaller and rural clinics, the HIV care clinics participating in IeDEA may not be fully representative of HIV care globally, which may limit the generalisability of our results. The survey responses did not include clinical practices of ART regimen prescription which may also influence the choice of TPT regimens. Comedications and drug–drug interactions at the individual level are an important aspect to consider.[13 15 39] Finally, we did not examine the practices of individual clinicians towards prescribing TPT or patients' perceptions of and adherence to TPT.

3 years after the release of updated WHO guidelines for the prevention of TB, most of IeDEA's HIV clinics surveyed in Africa, the Asia-Pacific and Latin America and the Caribbean reported offering TPT, but its implementation only partly followed the latest WHO recommendations in place by then. However, efforts are needed to ensure that people who are at the highest risk of developing active TB receive TPT, particularly PLWH and close contacts of individuals with active TB. Our study highlights the importance of integrating HIV and TB services to improve TB infection diagnostic practices, improving TPT access for at-risk populations and increasing access to patient-friendly TPT regimens, which are essential for achieving the goals of the 'End TB Strategy'.

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