

# LEVERAGING DIFFERENTIATED ART DELIVERY MODELS FOR STABLE CLIENTS TO SCALE UP TB PREVENTIVE THERAPY



## Preface

This supplement to *A Decision Framework for antiretroviral therapy delivery* outlines how models of differentiated antiretroviral therapy (ART) delivery can be leveraged towards scaling up TB preventive therapy (TPT). The aim is to provide:

- An overview of the principles of differentiated service delivery (DSD)
- Guidance on how TPT may be integrated into differentiated ART delivery models for clinically stable clients

- Key questions that should be asked when considering the integration of TPT into differentiated ART delivery models for clinically stable clients
- Case studies and examples of how TPT has been integrated into differentiated ART delivery models for clinically stable clients.

This supplement is intended for the use of national and district ART programme managers, implementing partners, community partners and donors. It should be read in conjunction with the comprehensive *A Decision Framework for antiretroviral therapy delivery*.

## INTRODUCTION

While TPT for people living with HIV has been recommended for a number of years, scale up and access to TPT remains below global targets. Since 2016, the World Health Organization (WHO), acknowledging the diverse needs of people living with HIV, has recommended a differentiated service delivery approach to providing ART. Today, a growing number of people on ART are accessing their HIV care through a differentiated ART delivery model. Concurrently, there is

renewed emphasis on ensuring that all people living with HIV have TPT. In this document, considerations for how to increase TPT uptake in the context of differentiated ART delivery are described. The goal is to improve both TPT coverage and access to differentiated ART delivery to meet the needs and expectations of clients while reducing unnecessary burdens on the health system.

## DIFFERENTIATED ART DELIVERY FOR CLINICALLY STABLE CLIENTS

Differentiated service delivery is a client-centred approach that simplifies and adapts HIV services across the cascade in ways that both serve the needs of people living with HIV and reduce unnecessary burdens on the health system.

For clinically stable clients on ART, four common models of differentiated ART delivery have been scaled up by ministries of health:

- **Facility-based individual models**, such as fast-track refills
- **Out-of-facility individual models**, such as mobile ART services or fixed community distribution points, for example, community pharmacies

- **Healthcare worker-managed groups** in facilities or communities, such as adherence clubs, ART refill support groups or teen clubs
- **Client-managed groups**, such as community ART groups.

Further details of these models can be found in the previously published *A Decision Framework for antiretroviral therapy delivery*. This document will explore how these models may be leveraged to scale up the coverage of TPT.

# KEY CONSIDERATIONS FOR TPT IN THE CONTEXT OF DIFFERENTIATED ART DELIVERY FOR CLINICALLY STABLE CLIENTS

## Which TPT regimen?

WHO recommends that all adults and adolescents living with HIV receive care and concurrently TPT as part of a comprehensive package. The TPT regimen choice may vary according to the context, including whether TB prevalence is high or low. The current WHO recommended regimen options for TPT include:

- Isoniazid (INH) monotherapy for six months
- Rifapentine and isoniazid weekly for three months may be offered as an alternative to six months of isoniazid monotherapy
- Rifampicin plus isoniazid daily for three months for children and adolescents younger than 15 years in countries with a high TB incidence
- The following options are recommended for treatment of latent TB infection in countries with a low TB incidence as alternatives to six months of INH: nine months of INH; a three-month regimen of weekly rifapentine plus isoniazid; 3-4 months of isoniazid plus rifampicin; or 3-4 months of rifampicin alone

- In settings with high TB incidence and transmission, adults and adolescents living with HIV who have an unknown or a positive TST and are unlikely to have active TB disease should receive at least 36 months of INH, regardless of whether they are receiving ART.

Today, the most common regimen implemented is six months of INH. However, countries may soon begin to transition to new regimens. In summary, there are a number of TPT regimen options recommended and country guidelines vary on the duration of TPT required and whether or not TPT should be offered once (as in South Africa, for example) or at routine internals (for example, as Zambia recommends, every three years). These variations have an impact on how best to incorporate TPT within the context of differentiated ART delivery models.

## TPT in the era of differentiated ART delivery models

Three scenarios for providing TPT in the context of differentiated ART delivery models should be considered (Figure 1):

Figure 1: Three scenarios for integrating TPT and stable client DSD models

SCENARIO 1	SCENARIO 2	SCENARIO 3
TPT is started at ART initiation, and completion is required to be eligible for enrolment into a clinically stable differentiated ART delivery model	Clients are eligible for enrolment in clinically stable differentiated ART delivery models while TPT is ongoing, and TPT must be integrated within the differentiated ART delivery model	Clients already in a differentiated ART delivery model for clinically stable clients are eligible for TPT, and are initiated on TPT, followed up and complete treatment within the model

### SCENARIO 1: TPT started at ART initiation and completion required to be eligible for enrolment into a clinically stable differentiated ART delivery model

WHO guidelines recommend an assessment of TB status at the time of HIV diagnosis. For those clients with a negative TB screen, TPT should be offered. Most differentiated ART delivery models require the client to have been on ART for at least six months and often for one year, and have evidence of treatment success (for example, a suppressed viral load)

in order to be eligible for enrolment. If TPT is started at ART initiation and the regimen duration is six months or less, TPT completion may be considered as part of the eligibility criteria for entering a differentiated ART delivery model. See Case Study 1 from Kenya.



#### Case Study 1: Completion of TPT prior to enrolment in a differentiated ART delivery model, Kenya

In Kenya, the recommended TPT regimen is six months of INH. Clients are screened for TB at ART initiation and if no TB symptoms are present, they are started on INH. Clients become eligible for a stable client differentiated ART delivery model if, after 12 months on their current ART regimen, they have had no active opportunistic infections in the previous six months (including TB), have been adherent to scheduled clinic visits for the previous six months and their most recent viral load is suppressed. In addition, clients must have completed their six-month course of TPT.

## SCENARIO 2: Clients are eligible for enrolment in clinically stable differentiated ART delivery models while TPT is ongoing and TPT is integrated within the differentiated ART delivery models

In some contexts, TPT courses are longer than six months. In addition, eligibility for clinical stability and access to differentiated ART delivery may not require completion of TPT. Further, some clients may start TPT after ART initiation. In these contexts, clients will need to continue

receiving their TPT *within* their differentiated ART delivery model. To enable this, policies should be adapted to support continuation and alignment of TPT refills with ART refills. See Case Study 2 from South Africa.



### Case Study 2: TPT ongoing when enrolling in a differentiated ART delivery model, South Africa

In South Africa, one of the recommended TPT regimens is one course of 12 months of INH. Clients should be screened for TB at ART initiation and, if no TB symptoms are present, be started on INH. Clients become eligible for longer ART refills from six months on ART if they are virologically suppressed. After 12 months on ART, clients can qualify for simplified ART refill collection strategies, including spaced fast lane, adherence clubs or external pick-up points. At the clinical consultation following the six-month viral load assessment, clinicians assess the client's eligibility for longer ART refills and complete a TPT review. Provided there are no contraindications, the clinician should extend the client's INH refills to align with the longer ART refills.

## SCENARIO 3: Clients eligible for TPT within differentiated ART delivery models for clinically stable clients are initiated on TPT, followed up and complete TPT within their differentiated ART delivery model

Where clients are in a differentiated ART delivery model for clinically stable clients but have not ever received TPT or are in settings that recommend repeating TPT, TPT refills should be integrated into the differentiated ART delivery model in a way that has minimal impact on the way the ART refill

works. Group differentiated ART delivery models present an opportunity for group screening and alignment for all members to initiate TPT at the same time and to have aligned clinical consultations and aligned TPT and ART refills. See Case Study 3 from Mozambique.



### Case Study 3: Three-monthly TPT and ART refills in differentiated ART delivery, Mozambique

In Mozambique, the Ministry of Health plans to align INH and ART refills within differentiated ART delivery models. The plan is to provide three-monthly INH refills alongside three-monthly ART refills to increase the proportion of clients on TPT and not disrupt or increase visit frequency for the clients who are in a differentiated ART delivery model with three-monthly refills. TB screening will be done as part of the visit, and the clients will be educated to return to the health facility if they develop signs and symptoms related to the INH during the time they are at home. This will be a shift from previous practice, where the longest duration of INH dispensed was monthly and the screening was also done monthly at the health facility.

## Key questions when considering TPT and differentiated ART delivery models

There are three key questions to ask when considering TPT in the context of differentiated ART delivery models:

1. **Should TPT completion be part of the eligibility criteria for stability to have access to differentiated ART delivery for clinically stable clients? (Case Study 1 from Kenya)**
2. **Can the duration of TPT refill be adapted to align with the ART refill and facilitate integration within differentiated ART delivery for clinically stable clients? (Example 3 from Zambia)**
3. **Can the TPT refill duration be aligned for all members on TPT in a group differentiated ART delivery model for clinically stable clients? (Example 1 from South Africa)**

## COMPONENTS AND BUILDING BLOCKS OF TPT INTEGRATION INTO DIFFERENTIATED ART DELIVERY

To deliver TPT to the client, four components of TPT delivery must be considered: screening for TB; assessment and initiation of TPT; TPT refill; and completion of TPT. Differentiated ART delivery models are built by adapting the “building blocks” of

“when” (service frequency), “where” (service location), “who” (service provider) and “what” (service package). In Figure 2, the building blocks adapted to integrate the four components of TPT within differentiated ART delivery are described.

Figure 2: The building blocks of TPT integration in DSD

	Screening for TB	Initiation of TPT	TPT refill	Completion of TPT
WHEN	Every ART refill/ clinical visit	Clinical visit	Aligned with ART refill	Clinical visit
WHERE	Facility Community	Facility Community	Facility Community Home	Facility Community
WHO	Peer, lay worker, nurse, clinical officer, doctor	Nurse, clinical officer, doctor	Peer, lay worker, nurse, pharmacist, clinical officer, doctor	Nurse, clinical officer, doctor
WHAT	Verbal TB screen and TB tests according to local TB diagnostic algorithm	TPT eligibility assessment (incl. contraindications for TPT); treatment literacy for TPT side-effects; and TB symptoms Script for TPT refills and align with ART refills Register TPT start	Provision of TPT and ART refills TPT follow up TPT side-effects/TB symptoms) Register TPT follow up	TB symptom assessment Register TPT completion documentation



## WHEN – TB screening and TPT within differentiated ART delivery models

TB screening should be performed at every clinical visit. Where clients are receiving ART refills from a non-clinician, including in a community setting, TB screening may be carried out by peers, community health workers and other cadres supporting ART refill distribution. According to the three scenarios outlined on Page 2, TPT may be initiated alongside ART initiation, at some point prior to enrolment in a DSD model, or within differentiated ART delivery models either as a “catch up” for clients who have not had TPT or for repeated TPT in countries that recommend TPT at routine intervals.

A key issue to enable TPT integration into differentiated ART delivery models is to align the duration of TPT refills with ART refills. Many guidelines currently recommend a monthly review

of people on TPT, which would require a significant increase in clinic visits for clients in many differentiated ART delivery models. Ensuring adequate treatment literacy and empowering clients and peers to recognize the side-effects of TPT and the symptoms of TB will be critical to successfully extending TPT refills without negative outcomes.

**Wherever possible, the duration of TPT refills should be aligned with the duration of ART refills.**

**In group models, alignment of group members to receive TPT together may support adherence and completion through peer support.**

### Example 1: TPT integration into healthcare worker-led groups, South Africa

In Cape Town, South Africa, healthcare worker-led groups known as adherence clubs have been implemented since 2011. One-third of ART clients are managed within City of Cape Town clinics, with the rest accessing care through clinics supported by the provincial health department. In 2019, 46% of the 67,500 ART clients in city clinics received their care in adherence clubs. Adherence clubs are comprised of up to 30 clinically stable clients on ART and meet five times a year. Clients are seen annually for a comprehensive clinical consultation and are screened routinely for TB at each visit by the lay club facilitator. In 2014, the provision of TPT was integrated into adherence clubs (Figure 3). Information on TPT is given to each

adherence club, with clients screened individually for TPT eligibility by a nurse or doctor. To align with the ART refill, two-monthly refills for INH and pyridoxine are prescribed. Clients are advised to report to the clinic if they experience any side-effects and are then subsequently followed up by the lay facilitator at the next adherence club visit where all club patients are routinely screened specifically for TB symptoms and generally for any other problems; clients with any concerns are referred to and reviewed by the club nurse. Details of TPT are integrated within the adherence club registers and the timing for stopping TPT is reviewed using the register with each routine scripting cycle.

Figure 3: Building blocks of TPT within adherence clubs

	Screening for TB	Initiation of TPT	TPT refill	Completion of TPT
WHEN	Every two months; for TPT catch up, whole group screened at one meeting for eligibility	Aligned for group	Every two months in line with ART refill (prepacked together)	After 12 months
WHERE	Club meeting space at facility	Club meeting space at facility	Club meeting space at facility	Club meeting space at facility
WHO	Lay worker who facilitates group	Nurse or doctor	Lay worker who facilitates group	Prescribing nurse or doctor
WHAT	Verbal symptom screen	TPT eligibility assessment Initiation of INH and pyridoxine Scripting INH to align with club ART refills TPT start reflected in club register TPT group treatment literacy (by lay club facilitator)	Continued TPT group literacy TPT follow-up assessment (TPT side-effects and/or TB symptoms) Refill of INH and pyridoxine Completion of TPT refill in club register (six-monthly INH and ART rescripting done by nurse or doctor)	TB symptom assessment TPT completion documented in M&E systems



## WHERE – TB screening and TPT within differentiated ART delivery models

TB screening and TPT refills should take place in the same location as the differentiated ART delivery model: at the facility; or in the community where groups meet (for example, at fixed community ART distribution points, mobile outreach settings

or community venues). Decentralization of TB screening and TPT refills will facilitate the integration of TPT into community-based models.

### Example 2: Integration of TPT into community-based ART distribution points (PoDi+), DRC

In the Democratic Republic of Congo (DRC), three differentiated ART delivery models for clinically stable clients are offered: fast-track refills; ART refill support groups; and community-based distribution points. Clients collect ART every three months and are screened for TB at each visit; 97% of clients are documented as having received TB screening. If a client screens positive for TB, they are

referred to the health facility. If a client is eligible for TPT, they receive INH from the community site monthly for six months. ART refills continued to be given every three months. ART and INH are dispensed by peer educators who are trained to recognize the signs and symptoms of side-effects of both ART and INH. If clinical problems arise, the peer educator escorts the client to the health facility.

Figure 4: Building blocks of TPT within the PoDi+

	Screening for TB	Initiation of TPT	TPT refill	Completion of TPT
WHEN	Every three months	For newly initiated, start at baseline and complete prior to entry into PoDi model If not had TPT, receive it at next negative TB screen	Every month	After six months
WHERE	Community ART distribution point	Community ART distribution point	Community ART distribution point	Community ART distribution point
WHO	Peer educator	Peer educator	Peer educator	Peer educator
WHAT	Verbal symptom screen	TPT eligibility assessment Initiation of IPT and pyridoxine TPT treatment literacy	Continued TPT treatment literacy TPT follow-up assessment (TPT side-effects and/or TB symptoms) Refill of INH and pyridoxine (only aligned every third month with ART refill)	TB symptom assessment TPT completion documented in M&E systems

**“When I pick up my drugs at the community ART distribution point (PoDi) I am supported and not stigmatized”**

– Female client, Kinshasa, DRC



## WHO – TB screening and TPT within differentiated ART delivery models

To enable the integration of TB screening and TPT delivery into differentiated ART delivery models, task sharing of the four components should be considered. Lay workers and expert

clients can perform the screening for TB and side-effects of TPT, while a clinician may still have to perform the medical assessment for initiation and completion of TPT.

### Example 3: Integration of TPT into individual facility fast-track model, Zambia

The Ministry of Health in Zambia, in collaboration with supporting partners, is conducting a pilot quality improvement project aligning six months of TPT with ART refills as clients enrol in a fast-track ART refill model. The specific aims are: 1) to assess the feasibility and processes around introduction of six months of TPT in the fast-track model; 2) to determine the uptake of six months of TPT among clients; and 3) to train staff to actively screen for TB and use a structured information approach for delivering TB messages designed to increase knowledge and empower clients. The project is being implemented by the Zambian national DSD task force with implementation support from the Centre for Infectious Disease Research in Zambia

(CIDRZ), a local implementing partner. This pilot has enrolled 825 clients and will assess their HIV outcomes and TPT completion. Treatment literacy on TB symptoms and side-effects of TPT is provided. A peer educator then does follow up of clients by phone at two weeks, after one month, and then monthly thereafter. If problems are raised, the client is encouraged to return to the clinic for a clinical review. Clients are also encouraged to seek medical attention if they experience any side-effects or adverse events while taking TPT. Monitoring and evaluation (M&E) tools for TPT have been adapted, and completion of TPT is documented at the next clinical visit in six months' time.

**Figure 5: Building blocks of TPT alignment with facility fast track, Zambia**

	Screening for TB	Initiation of TPT	TPT refill	Completion of TPT
WHEN	Every clinical visit, during every phone call	At clinical visit	Given six months' supply at clinical visit Follow up by phone at two weeks, then one month, then monthly	Next clinical visit after six months
WHERE	Primary care clinic or hospital	Primary care clinic or hospital	By phone to client at home	Primary care clinic or hospital
WHO	Nurse, clinical officer, doctor	Nurse, clinical officer, doctor	Pharmacist, pharmacist technologist Peer educator, doctor if clinical issues raised	Nurse, clinical officer, doctor
WHAT	Verbal symptom screen	TPT eligibility assessment Scripting INH and ART for six months Provision of TPT and ART refill Register TPT start TPT treatment literacy	TPT adherence check TPT follow-up assessment (side-effects and/or TB symptoms)	TB symptom assessment TPT completion documented



## CONCLUSION

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Access to TPT, a key prevention strategy for TB in people living with HIV, must be urgently scaled up. Leveraging DSD models for stable clients to do this is an opportunity to increase coverage. Advocacy for this to happen must address access to the commodities and include investment in adequate treatment

literacy on TPT delivery, along with national policies to overcome barriers related to how TPT is delivered. This should include assessment of policies related to the duration of TPT refills, task sharing and decentralization of TPT services in order to more effectively integrate TPT into these models.

### Key takeaways for the integration of TPT in differentiated ART delivery models for clinically stable clients

1. Differentiated ART delivery models for clinically stable ART clients can be leveraged to improve TPT coverage.
2. TPT can be continued or started for clients enrolled in both facility and community differentiated ART delivery models.
3. Investment in treatment literacy around TB symptoms and TPT side-effects is needed to enable less frequent clinical visits.
4. TPT refills should be aligned with ART refills to support client adherence by limiting the number of required facility visits.
5. TB screening, TPT refills, TPT follow up and treatment literacy can be provided by lay healthcare workers, expert clients or peers within differentiated ART delivery models.

For more information on differentiated service delivery, including the latest best practices, normative and clinical guidelines and tools to support country implementation, visit [www.differentiatedservicedelivery.org](http://www.differentiatedservicedelivery.org)



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