



Webinar

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



Webinar: Leveraging differentiated ART delivery models for TB preventive therapy,

24 March 2020

Host: Anna Grimsrud, International AIDS Society



Webinar overview

1. **Guidance on leveraging DSD models for stable clients to scale up TB preventive therapy**, Helen Bygrave, IAS, UK
2. **Integration of TPT into individual facility fast-track models**, Mpande Mukumbwa-Mwenechanya, CIDRZ, Zambia
3. **Three-monthly TPT and ART refills in differentiated ART delivery**, Irenio Gaspar, Ministry of Health, Mozambique
4. **TPT integration in South Africa's differentiated ART delivery models in new national TPT guidelines**, Harry Hausler, TB HIV Care, South Africa
5. **Reflections and TPT guidance from the World Health Organization**, Vindi Singh, WHO, Switzerland
6. **Q&A**, moderated by Anna Grimsrud, IAS, South Africa



Housekeeping rules





Leveraging DSD models for stable clients to scale up TB preventive therapy

Webinar: Leveraging differentiated ART delivery models for TB preventive therapy,
24 March 2020,
Helen Bygrave, IAS, UK



Why is this important?

1. Push to increase TPT uptake

2. Scale-up of differentiated ART delivery models

4x

- Clients in differentiated ART delivery models have less frequent clinical visits and may be excluded for accessing TPT
- DSD models for clinically stable clients may provide an opportunity to make sure clients have initiated and completed TPT successfully

Started TPT in FY17	Completed TPT in FY18	Complete TPT in FY19 (target)	Complete TPT in FY20 (target)
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22 PEPFAR-Supported Countries

Source: Adapted from Tomlinson, IAS 2019



Three scenarios for integration of TPT in DSD models

SCENARIO 1

TPT is started at ART initiation, and completion is required to be eligible for enrolment into a clinically stable differentiated ART delivery model

SCENARIO 2

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

SCENARIO 3

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

Briefer gives example for each of these scenarios



Key questions when considering TPT and differentiated ART delivery models

1. Should **TPT completion be part of eligibility criteria** for stability to access differentiated ART delivery for clinically stable clients?
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?
3. Can the **TPT refill duration be aligned for all members on TPT in a group** differentiated ART delivery model for clinically stable clients?



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

TPT refill = ART refill

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 in 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



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



TPT and DSD in the context of COVID-19

- Currently no direct evidence that PLHIV are at higher risk of COVID-19 or of severe disease if infected
- Prevention of TB even greater priority
- PEPFAR guidance
 - For those already on TPT ensure they have remaining doses needed to complete the course of treatment
 - Ensure that side effect monitoring can be done via telephone, SMS or electronically
 - DSD models if in place may be utilized for community distribution and adherence support as long as they adhere to social distancing guidance



TPT and DSD resources

Leveraging Differentiated ART delivery models for stable clients to scale up TB preventive therapy

Integrating Intensive TB Case Finding and TPT into Differentiated ART models

Leveraging Differentiated HIV service delivery to expand TPT: A call for action

SUPPLEMENT

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 considered for integration of TPT into DSD for clinically stable clients
- Case studies and examples of differentiated service delivery models integrated into differentiated ART delivery for clinically stable clients

This supplement is intended for ART programme managers, implementers, and donors. It should be used in conjunction with the comprehensive A Decision Framework for antiretroviral therapy delivery.

Integrating Intensive TB Case Finding and TB Preventive Treatment Services into Differentiated ART Models

Framework for implementation

CQUIN TB/HIV Community of Practice
November 2019

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 people living with HIV have TPT. In this document, we describe TPT uptake in the context of differentiated service delivery models. The goal is to improve access to differentiated ART and TPT, and to meet the expectations of clients while reducing the burden on the health system.

ICAP Columbia University Mailman School of Public Health

HIV LEARNING NETWORK
The CQUIN Project for Differentiated Service Delivery

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PERSPECTIVE

Leveraging differentiated HIV service delivery to expand tuberculosis preventive treatment: a call to action

M. Rabkin,^{1,2} A. A. Howard,^{1,2} P. Ehrenkrantz,³ L. G. Fernandez,⁴ P. Preko,⁵ V. Singh,⁶ H. L. Tomlinson,⁷ W. M. El-Sadr^{1,2}



Integration of TPT into individual facility fast-track models in Zambia

Webinar: Leveraging differentiated ART delivery models for TB preventive therapy,

24 March 2020

Mpande Mukumbwa-Mwenechanya, CIDRZ, Zambia



Differentiated ART delivery and TPT in Zambia

Differentiated ART delivery

- In 2018 Zambia began scaling up DSD for all PLHIV
- Stable PLHIV receive 3-6month ART refills.
- MoH has approved many facility and community differentiated ART delivery models for implementation and scale up
 - MMSD, FT, HP, UAG, adolescent support models, CAGs, etc.

TPT

- 2019 revised national guidelines around TPT for stable PLHIV
 - TPT dispensing schedule is 2 weeks, 2 and 3 months
 - TPT dispensation repeated every 3 years
- **Asynchronous appointment schedules disrupts and threatens the “patient centered” approach**



ZISAMALE NA TPT

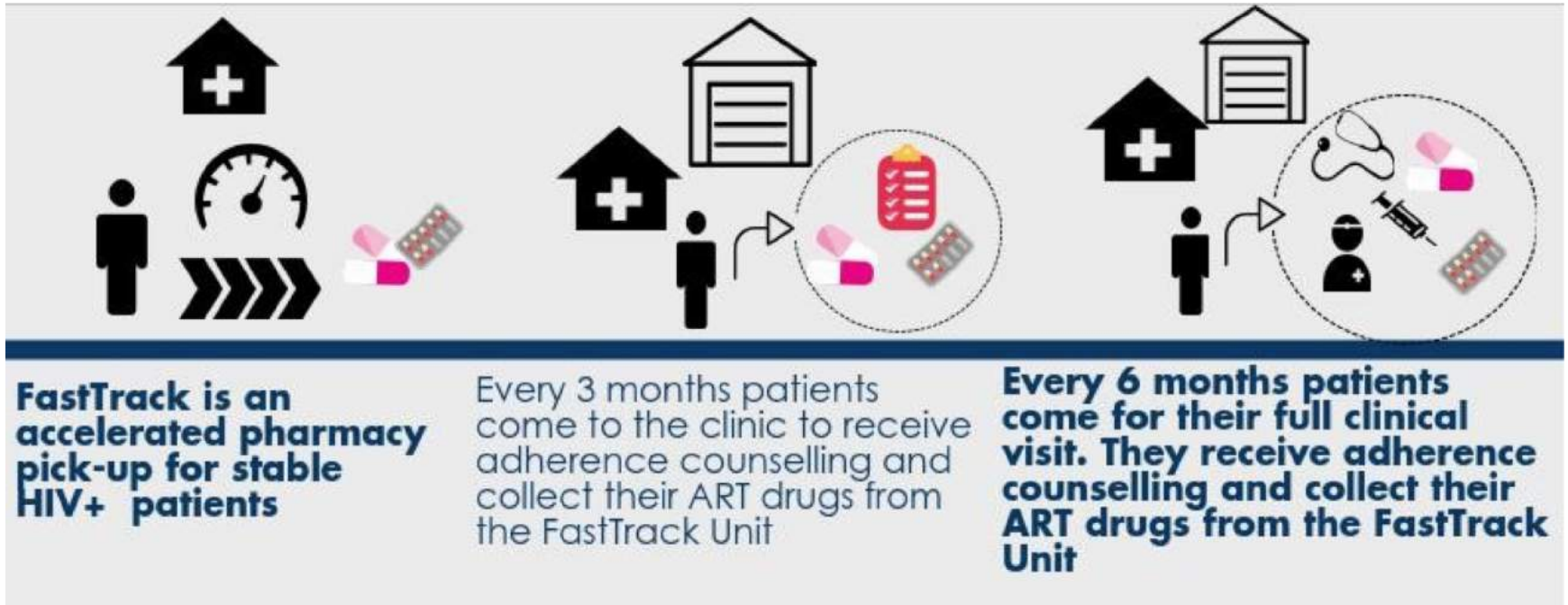
Shark tank quality improvement (QI) pilot study

- Objectives:
 - To assess the feasibility and processes around introduction of TPT into a differentiated ART delivery model with 3-6 month ART refills
 - To determine the uptake of TPT among the stable PLHIV
 - To train clinic staff to actively screen for TB and use of structured information approach for delivering messages designed to empower PLHIV

Lessons from the project will inform scale up of TPT in Zambia



FastTrack



<http://www.cidrz.org/wp-content/toolkits/commart/model-types.html>



Zisamale na TPT: Building Blocks

	Screening for TB	Initiation of TPT	TPT refill	Completion of TPT
WHEN	At enrolment , 2 weeks and then monthly during follow ups	At a clinical visit	6 months' supply at clinical visit <i>Follow-up monthly</i>	Next clinical visit after 6 months
WHERE	Facility and via a phone call during follow ups	Primary care clinic or hospital	Follow-up phone to client at 2 weeks and months 1, 2, 3, 4 and 5	Primary care clinic or hospital
WHO	Clinician during enrolment Peer via phone	Nurse, clinical officer, doctor	Peer educator, Pharmacist, pharmacy technologist, doctor if clinical issues raised	Doctor, clinical officer, nurse, pharmacist, pharmacy technologist
WHAT	Verbal symptom screen Referral to facility if required	TPT eligibility assessment, Scripting INH and ART for 6 months, Provision of TPT and ART refill, Register TPT start, TPT treatment literacy	TPT refill, TPT adherence check, TPT follow-up assessment (side-effects and/or TB symptoms)	TB symptom assessment, completion of documentation

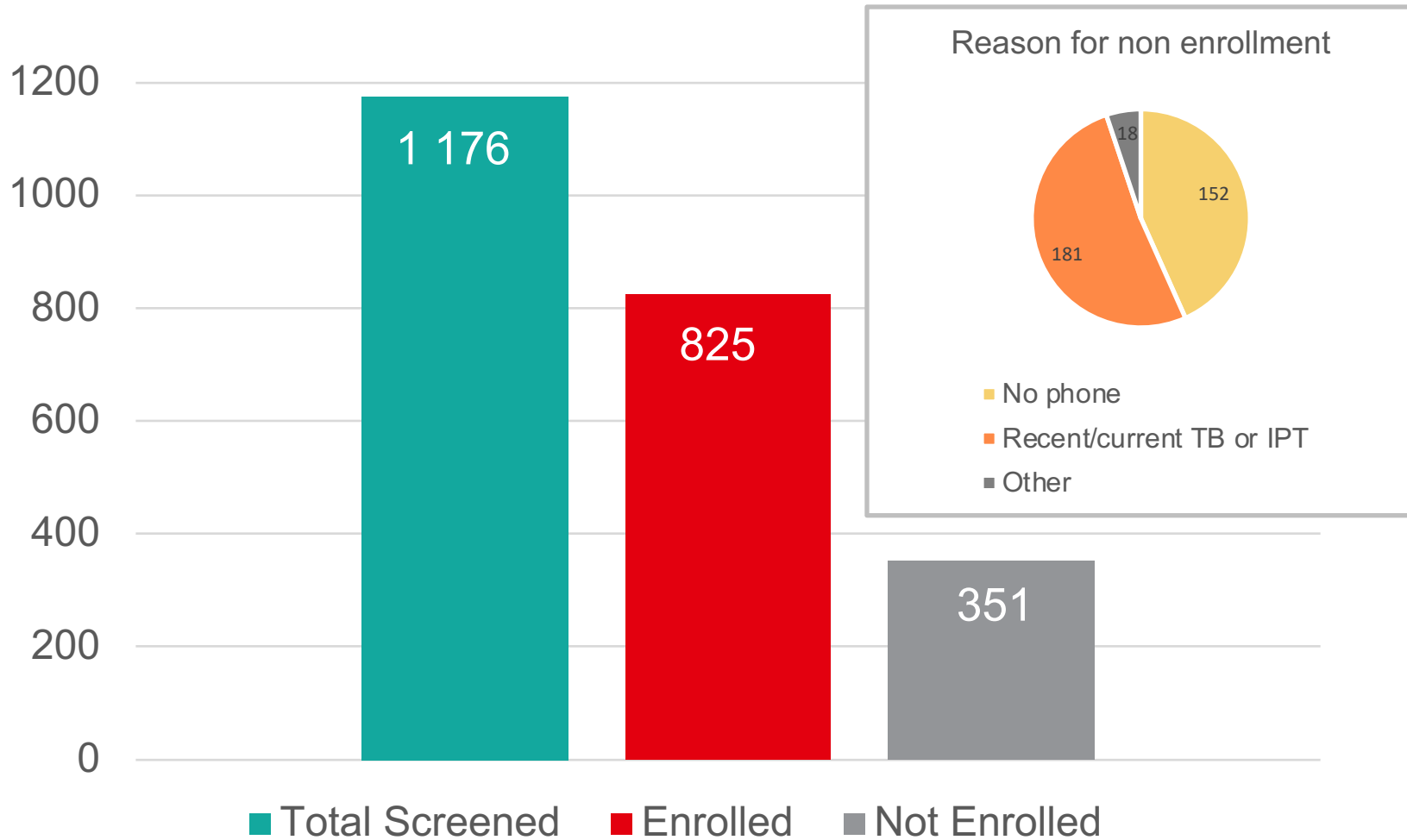


Methods

- Purposively selected one high-volume facility in Lusaka (patient load > 4,500).
- Sensitizations with various stakeholders
- Training material and SOPs were adapted
- Patients were screened for TB as per national guidelines
- Empowered with structured health education messages on:
 - TPT importance, identification, reporting of TB symptoms, expected side effects and management.
 - 3-6 months dispensation of TPT and ART
 - followed up with a phone call at 2 weeks and months 1, 2, 3, 4 and 5 in order to check for questions, concerns, and experiences

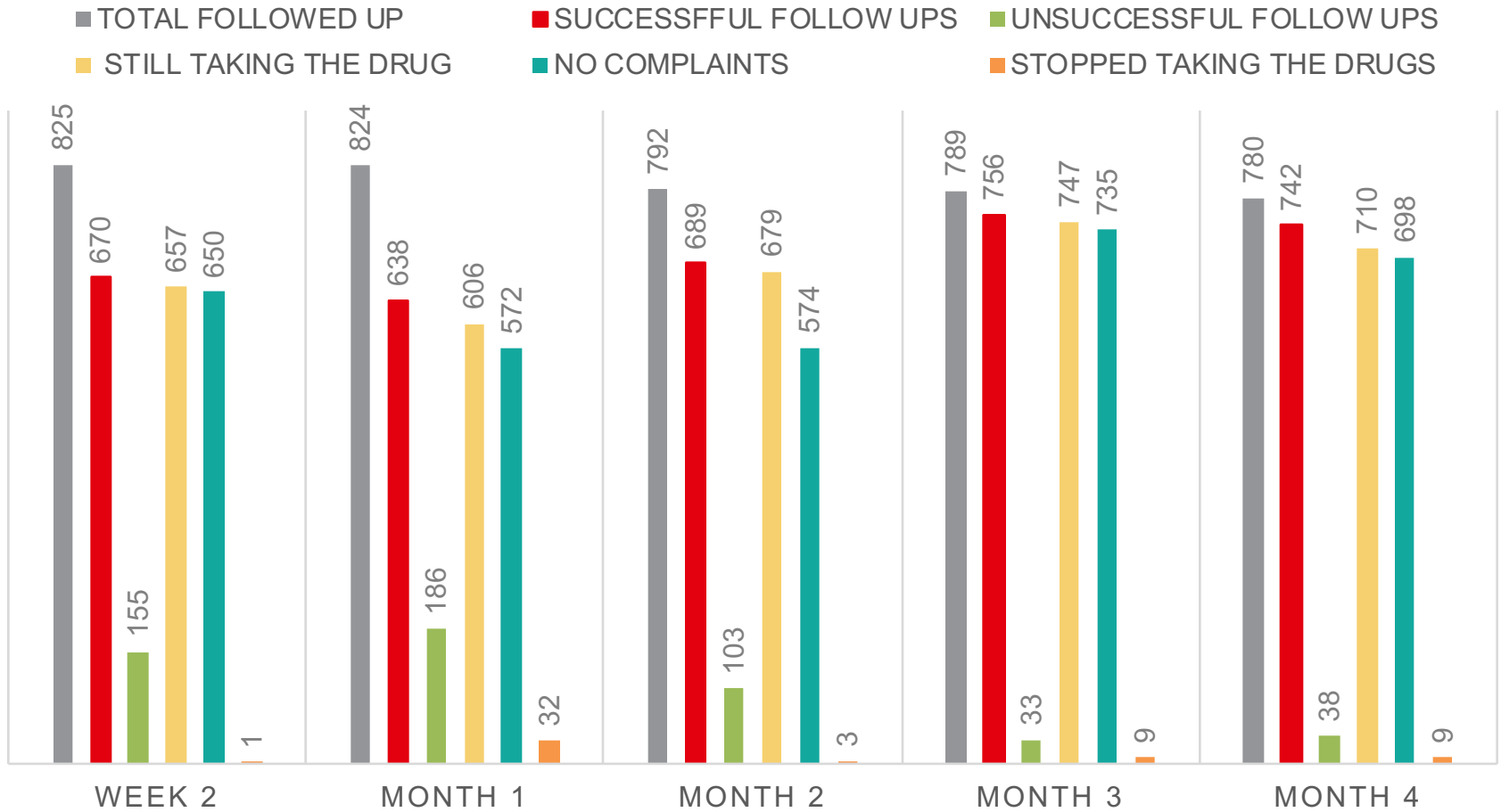


Screening and enrollment data





Follow up outcomes





Conclusion

- Treatment literacy should be ongoing
- Strong civil society involvement is necessary to build and establish trust with communities.
- Phone usage is critical for program effectiveness and sustainability.
- An integrated MMSD/TPT model offers a promising public health strategy to improve TB control and treatment among ART patients at scale.



Next steps

- Began 6 months follow-ups.
- Will conduct qualitative methods to determine acceptability, appropriateness and feasibility of introducing TPT 3 and 6months dispensations into DSD models.



Thank You

- Acknowledgements:
 - Zambian MoH, DSD Task Force, Facility Staff, Patients
 - BMGF
 - CQUIN



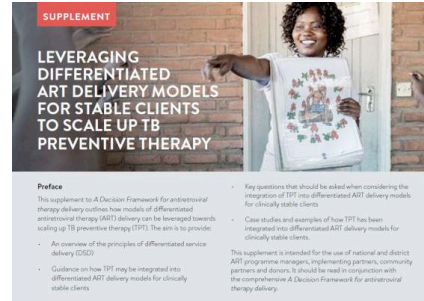
TPT and DSD resources

[Leveraging Differentiated ART delivery models for stable clients to scale up TB preventive therapy](#)

[Integrating Intensive TB Case Finding and TPT into Differentiated ART models](#)

[Leveraging Differentiated HIV service delivery to expand TPT: A call for action](#)

[WHO Operational Handbook on TB: TPT](#)



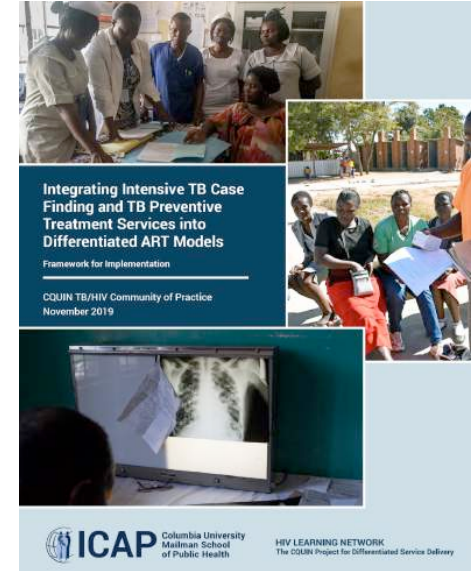
INTRODUCTION

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.

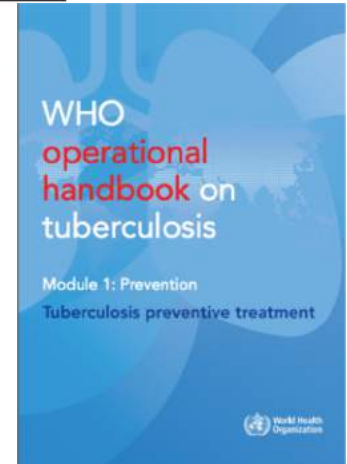
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Leveraging differentiated HIV service delivery to expand tuberculosis preventive treatment: a call to action

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PERSPECTIVE





Three-monthly TPT and ART refills in differentiated ART delivery

Webinar: Leveraging differentiated ART delivery
models for TB preventive therapy,

24 March 2020,

Irénio Gaspar, Ministry of Health, Mozambique



Differentiated ART delivery and TPT in Mozambique

- DSD for PLHIV have been scaled up for a number of years
- Now there is the need to ensure that all PLHIV have TPT
- Historically TPT coverage is low (67% in 2019)
- We aim to improve TPT coverage and completion through DSD models



TPT regimens

- WHO recommends a comprehensive package with different regimens for TPT according to the country context
- Mozambique has a high incidence of TB
- We use isoniazid (INH) monotherapy for six months
- We will start implementing rifapentine and isoniazid in 1 province



Eligibility for TPT in DSD models

- People living with HIV
- Be in 3 month dispensing (3MMD) or Community Adherence Group (CAG)
- New patients in 3MMD
- Patients already in 3MMD
- Without TB signs and symptoms



Building Blocks of TPT integration in DSD model

	Screening for TB	Initiation of TPT	TPT refill	Completion of TPT
WHEN	Clinical consultation – month 1 and 3 months later	Clinical consultation – month 1	3 months after the initiation	6 months after TPT initiation
WHERE	Health facility – clinical consultation	Health facility – clinical consultation	Health facility pharmacy	6 months after initiation – health facility (clinical consultation)
WHO	Clinician (doctor, nurse, clinical technician)	Clinician (doctor, nurse, clinical technician)	Pharmacy technician	Clinician (doctor, nurse, clinical technician)
WHAT	Verbal TB screen and TB tests according to local TB diagnostic algorithm	TPT eligibility assessment for TPT Script for TPT refills aligned with ART refills Register TPT	TPT and ART refills TPT follow up screening Register TPT	TPT completion register



Pilot preparations

- Guidelines finalization and wrapping
- Phased expansion (in the HFs implementing 3MMD)
- Providers training
- Tools development, replication and distribution
- Funding
- DSD implementation



Early lessons/challenges

- INH stocks and quantification
- Development of reporting tools
- Planification (COP and other)
- 3HP vs INH vs other regimens
- Adaptation of the DSD model for each regimen
- Clearly definition of the screening protocol (if possible screen in the community)
- Literacy on TPT is an important barrier to overcome



Next steps

- Start implementation!
 - Pending funds
 - Replication of M&E tools



TPT integration in South Africa's differentiated ART delivery models in new national TPT guidelines

Webinar: Leveraging differentiated ART delivery models for TB preventive therapy,

24 March 2020,

Harry Hausler, TB HIV Care, South Africa



Differentiated ART delivery and TPT in South Africa

- To date, there is not guidance on TPT integration into DSD models for ART patients other in than the Western Cape province
- TPT refills have not been pre-dispensed with ART refills for ART patients enrolled in DSD models
- South Africa's DSD guidelines have recently been revised and new TPT guidelines are close to finalization



Draft TPT regimens

The draft new TPT regimens include the following options:

- Isoniazid 300 mg daily x 6 months (6H) for people not infected with HIV who are household contacts or immunocompromised
- Isoniazid 300 mg daily x 12 months for people living with HIV (PLHIV) who do not have symptoms of TB including those newly initiated on ART (TLD)
- Isoniazid and rifampicin daily for children who are TB contacts
- Isoniazid and rifapentine weekly x 3 months (3HP) PLHIV stable and virally suppressed or household contacts over 15 years old
- TPT should be provided for HIV-positive pregnant women with $CD4 \leq 350$ during pregnancy and deferred until 6 weeks for pregnant women with $CD4 > 350$



What's new in SA's updated national TPT guidelines?

1. Eligibility: PLHIV, all household contacts (regardless of age or HIV status), clinical indications (silicosis, anti-TNF treatment, dialysis, transplantation), pregnant women with $CD4 \leq 350$
2. Algorithm to rule out active TB – symptom screen, no TST/IGRA, CXR optional
3. Treatment options: 12H for PLHIV (initiate with ART), 6H for household contacts, 3RH for children and adolescents under 15, 3HP for stable virally suppressed on ART and HH contacts
4. Integration of TPT into national DSD models for ART patients



Background to revised DSD guidelines in SA

- Clinically stable ART patients eligible after 6 months on ART for one of three Repeat Prescription Collection Strategies (RPCs):
 - Facility pick-up points (fast track)
 - Facility or community adherence clubs
 - External pick-up points (private pharmacies, community venues and automated dispensing machines/post boxes)



Integration of TPT into RPCs models

- Differentiated between:
 - I. Completion of TPT prior to or during enrolment in DSD model
 - II. TPT initiation and completion within DSD model



I. Completion of TPT prior to during enrolment in RPCs model

- Where patient started TPT at ART start and treatment course <3m (e.g. 3HP)
 - TPT should be completed prior to enrolment in RPCs model
- Where patient on longer TPT regimen (e.g. 12H) or started after ART start and not in RPCs model
 - 3 months of TPT should be completed before enrolment in RPCs
 - Thereafter, provided patient also clinically stable on TPT, can be enrolled and TPT refill to be aligned with ART refill period and provided by same service point



II. TPT initiation and completion within DSD model (1)

- ART patients already enrolled in RCPs model and missed TPT, should be supported to complete TPT
- To be assessed at their annual comprehensive clinical consultation for TPT eligibility and start
- If eligible, initiated and scripted for 6 months of TPT with ART
- Patient to collect same length TPT refill with ART refill from same service provider but also required to return to facility 1 month after TPT start for clinical check-up
- Thereafter, RPCs patients will be screened for any TB symptoms or side effects by their RPCs service provider and referred back to their health facility should any side effects or ill health be identified for follow-up



II. TPT initiation and completion within DSD model (2)

- Guidelines place emphasis on treatment literacy at TPT start to support patient to identify any side effects and return to the facility if necessary
- Patients will have a further TPT clinical follow-up assessment at 6 months when returning for their RPCs rescripting visit
- TPT completion assessment at their next annual comprehensive clinical consultation visit



The building blocks of TPT integration in DSD

	Screening for TB	Initiation of TPT	TPT clinical follow-up	TPT refills	Completion of TPT
WHEN	Every RPCs scheduled visit and clinical consultations at health facility	At annual comprehensive clinical consultation visit	Months 1,6 and 12	Every 2-3 months in line with ART refills	After 12 months at next annual comprehensive clinical consultation visit
WHERE	RPCs designated venue	Health facility	Health facility	RPCs designated venue	Health facility
WHO	RPCs service provider	Nurse /doctor	Nurse/ doctor	RPCs service provider	Nurse / doctor
WHAT	Verbal TB symptom screen	TPT eligibility assessment Initiation of TPT Scripting TPT to align with ART refills TPT treatment literacy	TPT follow-up assessment (TPT side effects/TB symptoms)	Continued TPT literacy TB symptom and TPT side effect screen Provision of TPT and ART refills Completion of TPT refill in RPCs documentation	TB symptom assessment Register TPT completion documentation



Transition to TLD

- For RPCs patients eligible and opting for switching to TLD, TPT eligibility should be assessed at switch
- For TPT eligible patients, 12H can be scripted and aligned with RPCs review dates



Plans for implementation (pilots and scale up)

- High burden pilot districts have been identified for initial implementation of 3HP
- New TPT guidelines expected to be finalized in the next month
- Scale up expected during the course of 2020-2021 including integration into RPCs (DSD) models



Early lessons/challenges

- Extensive consultation was required to adapt WHO guidelines for the South African context
- Delay in finalization of new TPT guidelines and need for accompanying SOPs
- TLD rollout was prioritized over TPT
- The high price of rifapentine, even at the reduced cost announced in Hyderabad has delayed implementation
- The high pill burden of single drug formulations of 3HP limit wide scale rollout and treatment literacy efforts



Next steps

- New TPT guidelines need to be approved at the National Essential Medicines List Committee and the National Health Council
- Intensive training of clinicians and treatment literacy
- Integration of TPT in RPCs (DSD) models
- National clinical records and electronic HIV and TB registers to integrate new TPT regimens and duration into the TB prevention cascade for PLHIV, TB contacts and other eligible groups
- Price reductions and fixed dose combinations of 3HP would facilitate nationwide rollout



TPT and COVID-19

In the context of the COVID-19 pandemic, new guidance from CDC PEPFAR includes the following measures:

- **Decanting:** 85% of eligible patients must be decanted to external pick up points in all CDC-supported facilities urgently to decongest facilities
- **TLD:** Initiate new ART clients on TLD and transition current ART clients on TEE to TLD
- **Weekly TX_CURR:** Maintaining each facility's total remaining on ART is critical. If ART clients begin missing appointments and dropping out of care, then Case Managers and Linkage Officers are expected to conduct immediate telephonic tracking and tracing to find and return clients to care
- **TPT should be initiated with ART** in the absence of TB symptoms



Reflections and TPT guidance from the World Health Organization

Webinar: Leveraging differentiated ART delivery
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Vindi Singh, World Health Organization, Switzerland



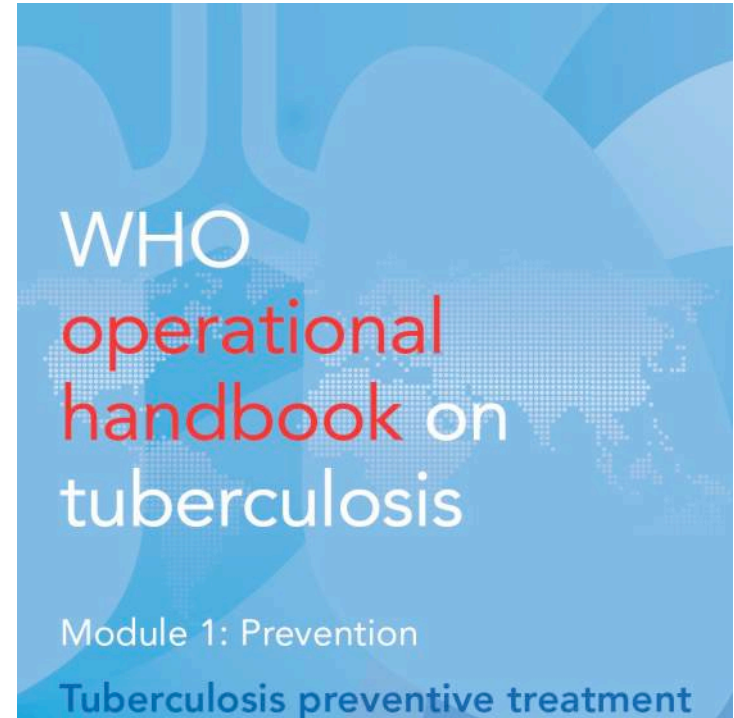
Reflections from the World Health Organization





WHO operational handbook on tuberculosis

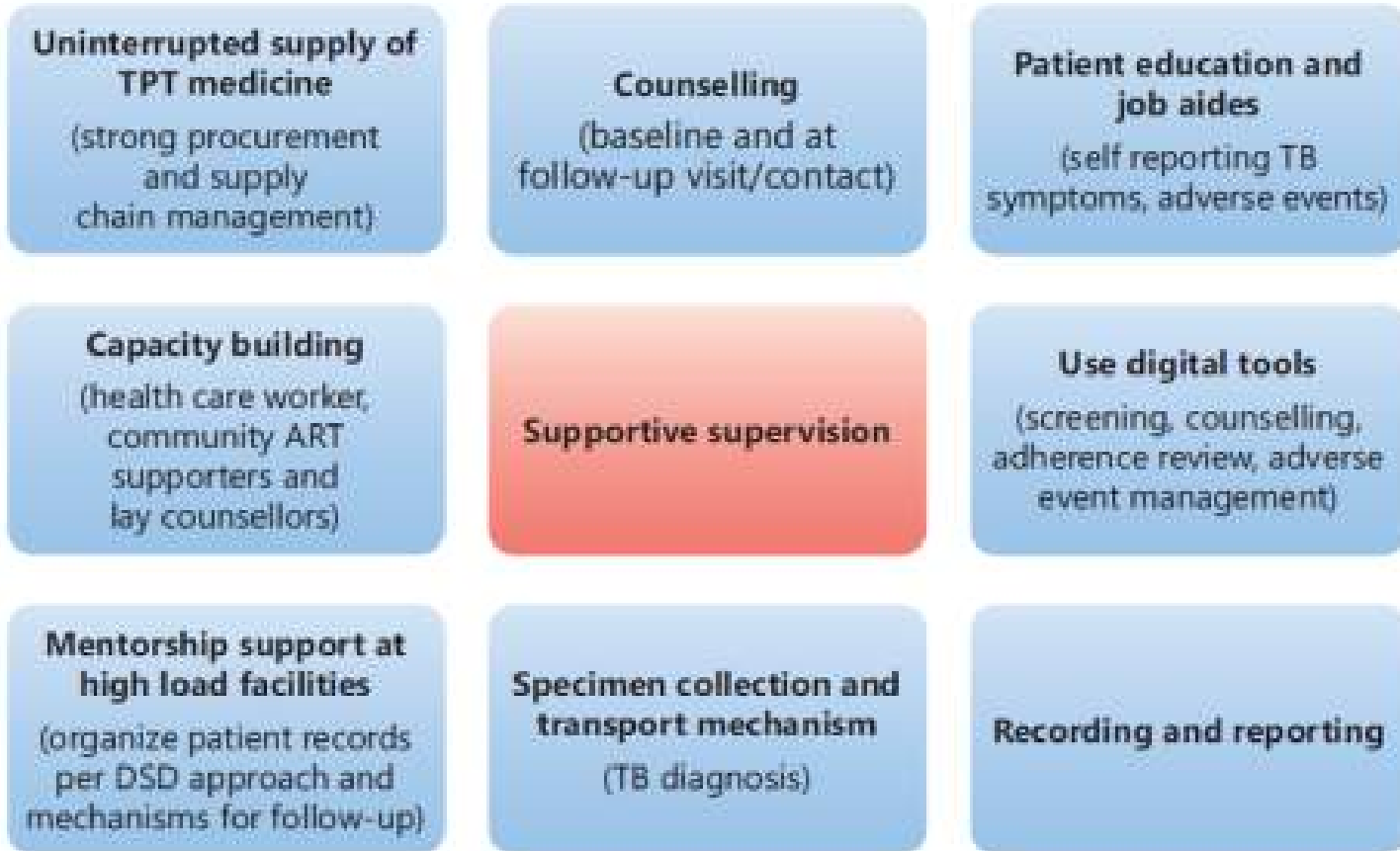
- TPT should be integrated into DSD models
- Establishing DSD should not become a reason for delaying/denying the benefits of TPT
- Patient visits should be scheduled such that they can pick up ARVs and TPT drugs at the same time



Key point: Differentiated HIV service delivery is being scaled up for ARV services. Intensified TB case finding and TPT should be integrated within these models. Establishing DSD should not become a reason for delaying or denying benefits of TPT to PLHIV. In fact, patient visits should be scheduled such that they can pick up ARV and TPT drugs at the same time.



Key Elements for Integrating TPT services into DSD models for ART



While TPT regimens of any length can be provided under DSD, it is critical to identify and manage any adverse events and document TPT indicators systematically



**DIFFERENTIATED
SERVICE DELIVERY**

Q&A

Visit www.differentiatedservicedelivery.org
for tools, resources and more.



TPT and DSD resources

[Leveraging Differentiated ART delivery models for stable clients to scale up TB preventive therapy](#)

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