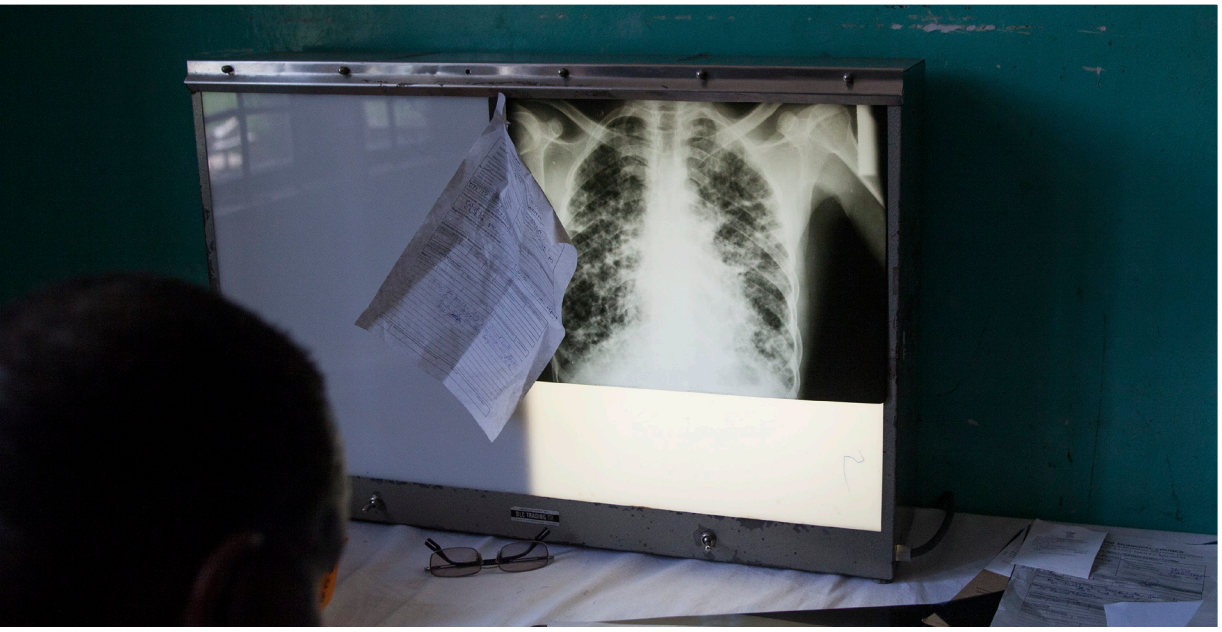
Integrating Intensive TB Case Finding and TB Preventive Treatment Services into Differentiated ART Models

Framework for Implementation

CQUIN TB/HIV Community of Practice
November 2019



ICAP Columbia University Mailman School of Public Health

HIV LEARNING NETWORK
The CQUIN Project for Differentiated Service Delivery

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Acronyms

AKA	Also known as
AIDS	Acquired immunodeficiency syndrome
ART	Antiretroviral therapy
CAG	Community antiretroviral group
CARG	Community antiretroviral refill group
CDC	The U.S. Centers for Disease Control and Prevention
CQUIN	The Coverage, Quality and Impact Network
DART	Differentiated antiretroviral therapy
DSD	Differentiated service delivery
HCW	Health care worker
HIV	Human immunodeficiency virus
IAS	International AIDS Society
ICAP	ICAP at Columbia University
ICF	Intensive case finding
INH	Isoniazid
IPT	Isoniazid preventive therapy
MCH	Maternal and Child Health
MMS	Multi-month scripting
PBFW	Pregnant and breastfeeding women
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PLHIV	People living with HIV
ROC	Recipients of care
SSA	Sub-Saharan Africa
TB	Tuberculosis
TPT	TB preventive treatment
WHO	World Health Organization

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I. Introduction and Rationale

Tuberculosis (TB) is the leading cause of death for people living with HIV, responsible for a third of global AIDS deaths in 2017 despite the scale-up of antiretroviral therapy (ART). TB incidence is also 20-fold higher in HIV-positive compared to HIV-negative populations. Among people with HIV-associated TB, nearly half fail to receive treatment for TB disease, and less than one third of those enrolled in HIV care initiated TB preventive treatment (TPT) in countries that reported in 2017.

Sub-Saharan Africa (SSA) has a high burden of HIV-associated TB, and without markedly expanding access to TB prevention and treatment for people living with HIV, the ambitious global goals to reduce TB incidence and mortality in the next decade will not be met. Thus, expanding the coverage and quality of TB/HIV services is a high priority for ministries of health around the world.

These revitalized efforts to improve TB services for people living with HIV are taking place at the same time as innovative changes in the design of HIV treatment programs spreads within and across countries. The scale-up of HIV differentiated service delivery (DSD) has important implications for TB programs. DSD models tailor services to groups of patients depending on clinical need, demographic characteristics, and context. Less-intensive differentiated treatment models aim to simplify service delivery for people doing well on treatment and aim to improve both quality and efficiency by adapting service location, frequency, the use of individual *vs.* group appointments, health care worker (HCW) cadre, and the use of peer-led services. More-intensive models are recommended for people initiating ART, those with advanced HIV disease and/or co-morbidities, and those with other reasons for frequent clinical follow-up, including pregnant women, children and adolescents, and other groups.

Shifting "stable" recipients of HIV care to less intensive models is expected to improve client satisfaction, relieve health care provider workload, and increase health system efficiency as a result of people on ART spending less time at health facilities. DSD models such as appointment spacing and fast-track services require fewer and shorter clinic visits. Models such as community antiretroviral groups (CAGs) provide many services at the community level.

These changes create both challenges and opportunities for TB service delivery. Will less-intensive differentiated ART (DART) models be able to provide effective intensive case finding (ICF) through TB screening and referrals? Can TPT be delivered in community settings? Can DART make TPT more client-centered, improving coverage and completion? While the evidence base is scarce, DART may provide an exciting opportunity to enhance the coverage and quality of TPT services and to empower self-management of TPT by recipients of care (ROC).

DART may also create challenges for ICF and TPT. For example, in some models, such as six-month multi-month scripting (MMS), TB symptom screening by a health care provider may occur less frequently than in more intensive models. Another challenge is that those receiving care in a DART model with less frequent healthcare worker contact may at times be an exclusion criterion for TPT; meaning that a relatively large cohort of HIV-positive people who are adherent, retained in care, and virally suppressed could be excluded from TPT scale-up efforts. In many countries, TPT requires monthly health facility visits, and TPT prescribing/dispensing is not aligned with ART

schedules. Having to "leave" a DART model for one with more frequent follow-up, or to defer DART entry until TPT is completed could be a disincentive for ROC.

Although normative guidelines, strategic planning documents and implementation tools exist for TB/HIV services in general, and, in particular, for TPT for people living with HIV, there are currently no resources designed specifically to support the integration of TPT into DART. The CQUIN TB/HIV community of practice has thus prioritized the development of a toolkit to serve as a practical resource. Building on the formative work, including that of the International AIDS Society (IAS), this document will also complement other practical tools that can be adapted by countries and programs and tailored to local context. The U.S. Centers for Disease Control and Prevention (CDC) developed an addendum guide to the TPT Toolkit for incorporating TPT into DSD which also informed this document.

II. General Considerations

Cross-cutting principles

1. All TB/HIV services should be aligned with national and World Health Organization (WHO) guidelines.
2. Everyone should have equal access to affordable and high-quality TB/HIV services, irrespective of DART model. The "what" of ICF and TPT should not vary by model—it is the "who, when and where" that will differ.
3. People currently receiving HIV treatment via DART models should be screened for TB and offered TPT as indicated with minimal disruption of their existing routine.
4. People currently receiving TPT can be considered eligible for DART models of care if they are otherwise ready to be transitioned.
5. People eligible for less intensive DART models and TPT should be empowered and supported to make an informed choice about their care.

Common programmatic scenarios

1. **TPT before DART transition:**
   In general, people initiating ART are not immediately eligible for less-intensive DART models. Most countries require successful completion of six or 12 months of ART prior to assessing DART eligibility. For countries with high TPT coverage rates amongst people who are newly initiating ART, most people will complete TPT *before* they are assessed for DART eligibility. In this context, one option would be to consider TPT completion as a DART eligibility criterion.
2. **Overlapping TPT and DART transition:**
   Some people on ART will have started but not completed TPT at the time they are assessed for DART eligibility. As above, those who are eligible for less-intensive models and still on TPT should be offered the opportunity to transition to a DART model while completing their course of TPT. Here, all efforts should be made to integrate TPT services into whatever DART model is preferred by the recipient of care.
3. **DART transition before TPT**:
   In some countries, such as Zimbabwe, large numbers of people have transitioned to less-intensive DART models without having received TPT. In this context, Ministries of Health

(MOHs) will need to design TPT strategies for each less-intensive DART model, with the opportunity to align TPT initiation for all DART model members in order to simplify follow-up.

Minimum essential package for TB/HIV services (the "what")

1. **Infection prevention and control (IPC)** best practices should always be observed in all DART models, including:
   - Administrative controls for people who screen positive for TB symptoms and people with known TB (*e.g.* respiratory hygiene, respiratory separation/isolation).
   - Environmental controls (*e.g.* ventilation systems) at health facilities and community-based meeting spaces.
   - Respiratory protection through ensuring the availability of appropriate protective equipment (*e.g.* particulate respirators) for clients and HCW in settings with a high risk of transmission.
2. **Intensified TB case finding (ICF)** should continue within all DART models. Key components of ICF include:
   - Enhanced treatment literacy on symptoms and signs of TB to empower and encourage people to present for care when they have 'red flag' symptoms.
   - Regular screening for TB symptoms (current cough, fever, night sweats or weight loss) at intervals consistent with national guidelines.
   - Robust referral processes for those who screen positive, including enhanced linkage for evaluation—*e.g.* via accompaniment—and close follow-up to ensure linkage completion.
   - Appropriate follow-up after evaluation, including swift initiation of TB treatment for those who test positive, and referral for TPT for those who test negative.
3. **TB preventive treatment (TPT)** should be provided for those who are eligible according to national guidelines. Key components of TPT provision include:
   - TPT eligibility assessment, including TB screening, evaluating for medical contraindications to TPT (*e.g.* active hepatitis, heavy alcohol use, peripheral neuropathy or use of other hepatotoxic medications) and review of history/records for any previous courses of TPT.
   - Client education and preparation, including counseling on alcohol intake during TPT, the role of vitamin B6, and adherence, routine self-screening, and reporting of TB symptoms and side effects.
   - TPT initiation.
   - Ongoing adherence assessments and counseling.
   - Clinical reviews while on TPT, including TB symptom screening and side effect monitoring.
   - TPT refills.
   - Ongoing monitoring and documentation while on TPT and final documentation of TPT outcomes (including discontinuation or completion).

Integration of TB/HIV services into DART models (the "how")

In addition to the "what" of TB/HIV services described above, programs must determine *when* (*i.e.* how many times per year and at what intervals), *where* services will be delivered, and by *whom* (*i.e.* by

what cadre of HCW, layperson and/or peer), as illustrated in Figure 1. Given the diversity of DART approaches (Table 1), these decisions must be tailored to specific models, as discussed in more detail in the following sections.

Figure 1: Adapted from IAS Decision Framework for ART Delivery

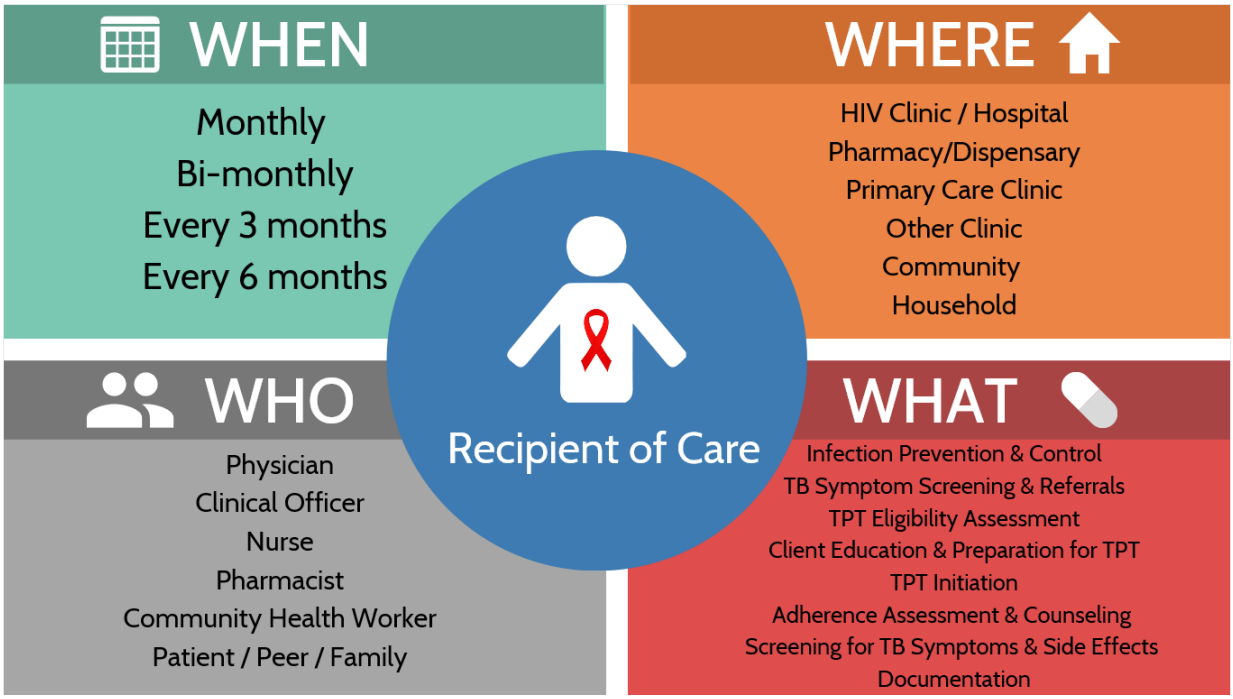


Table 1: Differentiated ART Models

Category	Examples	Notes
More-intensive models		
Conventional models	Facility-based individual models with relatively frequent follow-up	These include models for ROC who: (a) are not yet eligible for less intensive DSD models (b) have not yet been assessed for eligibility for less intensive DSD models and/or (c) have chosen not to enroll in a less-intensive DSDM. Also known as (AKA) facility-based individual model and comprehensive clinical evaluation in Uganda, "mainstream" ART in Eswatini, and the "conventional" model in Zimbabwe.
Tailored models	Virologic clinics Pediatric clinics PMTCT programs	Other more-intensive models include those for ROC who are not virologically suppressed; those with advanced disease; models for families, children and adolescents; models for women who are pregnant/breastfeeding; models for key populations
Less-intensive models		
Facility-based individual models	Appointment spacing without fast-track	For ROC who meet specified eligibility requirements, clinical visits are less frequent than in the conventional model and ROC receive 3-6 months of ART at a time through MMS. Unlike the fast-track model, all appointments include a full clinical consultation. Examples: Ethiopia's 6-month appointment spacing model, Malawi's 3-month appointment spacing model. *NB that it is not the visit interval that defines this model, but the fact that it is available only to people who meet specific "stability" criteria.*

Category	Examples	Notes
Facility-based individual models	Fast-track + appointment spacing	These models combine appointment spacing (with 1-2 clinical visits per year) with interim "fast-track" visits, which generally involve only ART pick up and brief screening questions re: adherence and the presence/absence of new symptoms or issues. The visit is designed mainly for swift ART pick up at the health facility and includes ART pick-ups that occur only at the pharmacy and/or during extended hours (early mornings, evenings, weekends). AKA "spaced and fast lane" in South Africa and "6 monthly appointments" in Kenya.
Facility-based group models	ART clubs	Health care worker (HCW)-led ART distribution to multiple people at a group appointment. The groups meet at the facility either after-hours or during clinic hours at a designated place where they have group adherence counseling, psychosocial counseling, and other clinical services, and then receive their ART. The groups can be diverse or gender-specific or designed with specific needs such as those with both HIV and non-communicable diseases. AKA "facility adherence clubs" in Cote d'Ivoire and "urban adherence clubs" in Zambia.
	Facility-based teen clubs	HCW-led group ART distribution for adolescents living with HIV. Services often include group psychosocial support, adherence counseling, and ART refills
Community-based individual models (include clinical assessments every 6-12 months)	Outreach model	HCW-led community ART distribution + streamlined clinical services. Examples include mobile ART distribution in Zambia, outreach ART in Eswatini, outreach model in Zimbabwe
	Community drug distribution	ART distribution only, no/minimal clinical services (e.g. limited to TB screening, adherence review and assessment of pregnancy status). Examples include: CCMDD[1] (South Africa + Zambia), CDDP[2] (Uganda), OFCAD[3] (Zimbabwe), Community retail pharmacy model (Zambia), Home ART delivery (Zambia), PODI *(Postes de distribution communautaire d'ARV)* model (DRC): Peer-led drop-in centers for ART distribution + adherence/symptom check
Community-based group models (include clinic visits every 6-12 months)	Community ART groups (peer-led)	This is a peer-led model for small groups of individuals on ART, who meet regularly in the community every 1-3 months. One member of the group collects the drugs on behalf of the group from the health facility and the group members meet in the community to collect and sign for the ART. AKA CAG[4], CARG[5] (Zimbabwe), CAG (Mozambique), CCLAD[6] (Uganda)
	Family model	ROC pick up ART in facilities and distribute to family members. AKA "family centered model" (Eswatini), "family ART group refill" (Zimbabwe).
	Community-based clubs (HCW-led)	This is similar to facility-based clubs except the meetings happen at a venue within the community.

[1] CCMDD = chronic centralized medication dispensing and distribution (SA and Zambia)
[2] CDDP = community drug distribution points (Uganda)
[3] OFCAD = out of facility community ART distribution (Zimbabwe)
[4] CAG = community ART group
[5] CARG = community ART refill group (Zimbabwe)
[6] CCLAD = community client-led ART delivery (Uganda)

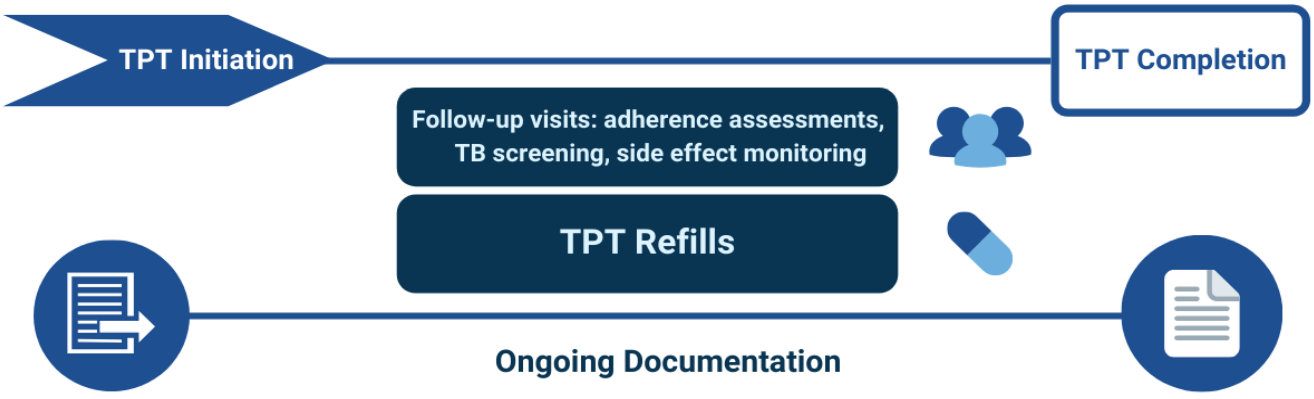
General Programmatic Considerations for ICF:

- ***When***: How frequently/at what intervals should TB symptom screening be performed?
  - Most national and global guidelines state that people living with HIV should be screened at every encounter with a HCW, but do not specify a minimum number of times per year or minimum length of time between screenings.
  - As people on ART select different DART models, the number of clinical visits per year will become less standardized. Countries will need to specify a minimum number of times per year that TB symptom screening should be performed.
- ***Where:*** At what locations should TB symptom screening take place?
  - TB symptom screening should be provided in both facility and community settings; issues of IPC must be considered irrespective of setting.
  - Remote monitoring via phone, text and video may be increasingly feasible, even in low-resource settings.
  - Regardless of setting, linkage to TB diagnostic services must be assured for people who screen positive. This linkage process may be easier/faster for people in facility-based DART models than community-based models.
- ***Who:*** which persons should perform TB symptom screening?
  - ROC and their families and friends should also be empowered to monitor their TB symptoms and present for further evaluation if warranted; this can be supported with appropriate educational materials, reminder systems (*e.g.* automated SMS/text messages) and information on how to seek further evaluation.
  - Although TB symptom screening *may* be of higher quality when performed by HCW *vs.* laypeople such as peer educators or CAG leaders, the evidence base is scarce.
  - In some DART models, contact with HCW is infrequent—enabling other cadres to perform TB symptom screening (*e.g.* community health workers [CHW], peers, CAG leaders or community group members) and/or allowing for remote TB screening by HCW (*i.e.* by phone or SMS/text message) would expand access and improve convenience.

General Programmatic Considerations for TPT:

TPT service delivery involves a few component activities, each of which need to be adapted within DART models, as depicted in Figure 2. The "when, where, and who" considerations for components of TPT within each type of DART model are discussed in more detail in Section III below.

Figure 2: Components of TPT service delivery to be adapted for each DART model



General considerations and issues to be addressed for each of these component activities are:

- How can determination of TPT eligibility and TPT initiation be optimized in each model?
    - ***When***: As above, many people on ART will complete TPT prior to DART eligibility. For those who transition to less-intensive models *during* TPT, or who initiate TPT after transitioning to DART, options include TPT eligibility screening and initiation at routine appointments and initiatives to call clients back for special screening and initiation visits, using a 'campaign' model. The latter strategy has been implemented in some countries in coordination with transition to new ART regimens (*e.g.* dolutegravir-based ART) and is being considered in some countries planning to introduce new TPT regimens (*e.g.* 3HP).
    - ***Where***: TPT initiation is generally performed at a health facility by a HCW, although emerging data suggest it can be safely and effectively initiated at the community level.
    - ***Who***: As above, diverse cadres can conduct TB symptom screening. However, many countries require that TPT eligibility be determined by a clinician (nurse, medical officer, or physician). An eligibility assessment may also require access to previous medical records, further limiting who can make this determination.
- How can client management and follow-up be optimized in each model?
    - ***When***: Traditionally, isoniazid preventive therapy (IPT) has required monthly visits to the health facility. However, this schedule may be a disincentive to participate in TPT for clients in less-intensive DSD models who are currently coming to the clinic every 3-6 months. Follow-up visits within 2-4 weeks of TPT initiation are recommended to screen for side effects and reinforce adherence, but subsequent visits may not need to take place monthly, particularly for clients in community-based DART models that can provide monitoring and adherence support at the community level and/or for clients who can be followed up by phone/text. South Africa, Malawi, Uganda and Zambia are among the countries using multi-month IPT refills, aligned with ART refill schedules.
    - ***Where***: There is increasing interest in providing TPT services in community settings, as well as at health facilities, especially for models in which ART is also dispensed in the community. Follow-up in the community should be accompanied by strong referral procedures to further evaluate any side effects or TB symptoms reported. As above, remote monitoring via phone, text and video may be increasingly feasible, even in low-resource settings.
    - ***Who***: Monitoring for TPT-related side effects has typically been performed by clinicians and pharmacy staff, but the potential to leverage the systems and solidarity of peer-led group DART models has spurred interest in this approach in several countries. In these settings, consideration is being given to training group leaders to screen for TPT side effects (as well as TB symptoms) and to provide adherence support for TPT. Zambia is piloting the use of mobile phones by CHWs, who provide monitoring and support via phone and text messaging.
- How can TPT medication prescribing, dispensing and monitoring be optimized in each model?
    - ***When***: In many countries, it is customary to dispense only a one-month's supply of TPT, requiring clients to obtain frequent refills. Providing larger supplies may increase adherence and TPT completion, especially later in the course of TPT for people who have been adherent and have not had side effects. Aligning TPT and ART dispensing schedules is a recommended approach, given its increased convenience for ROC.

- ***Where***: TPT medication is often dispensed and distributed at a facility-based pharmacy, but community-based distribution has been shown to be feasible in pilot studies and may be less disruptive for people in DART models, particularly in the later months of TPT. Distribution at community-based pharmacies and/or home-based distribution may also be an option. Ensuring that ART and TPT medication can be dispensed from the same pick-up points is also a way to improve integration of services.
- ***Who***: Medication prescribing and dispensing are closely regulated and limited to specific cadres in each country, but there are more options for distribution of pre-packed medication. In theory, TPT medication could be distributed by more diverse cadres, including community health workers and peer educators.

- How can recording and reporting be optimized in each model?
  - ***When:*** Documentation of TPT adherence, total number of doses received, TB screening results and presence/absence of side effects should be recorded at the time of every follow-up and/or refill visit. If clients stop and restart TPT, documentation of these events is also critical, as is documentation of TPT completion. As models diversify, these data may be acquired by phone/text as well as at in-person visits.
  - ***Where***: As TPT is integrated into DART models, data collection may take place in the community as well as at the facility. Registers and tools will likely need to be adapted for this purpose and whenever possible should be integrated into ART records used in these locations.
  - ***Who***: In addition to determining which cadres will be collecting relevant data, programs will likely need to integrate data from multiple sources. For example, adherence data may be collected in the community by HCW, CHWs and laypeople, while health facility-based staff might collect data on TB screening and side effects.
- How will the availability of new TPT regimens, such as 3HP and 3RH, affect the questions above?
  - The shorter courses required by these models may facilitate TPT completion during ART start-up (*i.e.* prior to DSD eligibility).
  - The shorter timeframe for TPT using 3HP and 3RH may make it less disruptive for clients to receive facility-based TPT while in less-intensive DSD models.

III. Integrating ICF and TPT into Facility-based Models

Less-intensive DART models based at health facilities include *individual models* such as fast-track and multi-month dispensing and *group models*, such as ART clubs. Table 2a and 2b illustrates some of the key issues related to the "what, when, where, and who" of TB/HIV services in these contexts.

Facility-based Individual Models

The most common facility-based individual models for less-intensive DART include appointment spacing and multi-month ART dispensing, with or without fast-track visits (Table 1).

Opportunities

- Appointment spacing models are more convenient than "conventional" models for people doing well on ART and are often associated with higher retention rates and cost savings. By decreasing loss to follow-up, the models may increase opportunities to provide TPT.

- By decompressing health care facilities, these (and other less-intensive DART models) may enable HCW to spend more time with clients, potentially increasing opportunities to provide TB symptom screening and TPT initiation.

Challenges

- Less-frequent visits mean fewer opportunities for TB symptom screening and ICF, compared to more intensive or undifferentiated models.
- In some fast-track models, TB symptom screening is performed by pharmacy technicians and/or laypeople; the quality of this screening *may* be lower than that provided by health care workers.
- Absence of community-based "wrap around" services may create challenges for TPT adherence and retention, linkage to clinical services if side effects occur and/or linkage to TB diagnostic services if symptoms occur between visits.
- If ART and TPT are not on the same dispensing schedule, this may increase complexity, dis-incentivize uptake, and decrease TPT coverage.
- If monthly visits are required for TPT, this may dis-incentivize participation by people currently visiting facilities less frequently, decreasing demand and coverage.

Considerations for Improving TB/HIV Service Integration

- All DART programs should work to ensure treatment literacy, to ensure that people in DART models and their families are familiar with the signs and symptoms of TB and TPT side effects and know to contact health care workers when they occur.
- Ongoing staff training and supervision are needed to ensure high quality TB symptom screening at fast-track visits, especially for non-clinicians (*e.g.* pharmacy staff, peer educators).
- Less-frequent visits (*e.g.* for people in appointment spacing models) may need to be complemented by community-based "wrap around" services, including TB symptom screening.
- TPT initiation should occur during clinical (not fast-track) visits.
- For people receiving TPT, close contact via SMS/text and/or phone may be needed to screen for side effects and/or adherence challenges.

Facility-based Group Models

The most common facility-based group models for less-intensive DART include ART clubs, group appointments in which 8-20 clients meet with a health care worker, lay worker or peer for ART adherence assessment and support, TB symptom screening, review of new issues/challenges, and ART dispensing (Table 1).

Opportunities

- Peer support may foster increased interest in TPT services; in some cases, the group may include others on TPT which could help to "normalize" TPT.
- Aligning TPT start dates for clients within a club—*e.g.* starting groups of people on TPT at the same time—may foster additional peer support and simplify club management.
- Aligning TPT and ART dispensing schedules will be more convenient for clients and may increase adherence.

Challenges

- Less-frequent visits mean fewer opportunities for TB symptom screening and ICF, compared to more-intensive or undifferentiated models.
- Absence of community-based "wrap around" services may create challenges for TPT adherence and retention, linkage to clinical services if side effects occur and/or linkage to TB diagnostic services if symptoms occur between visits.
- If monthly visits are required for TPT, this may dis-incentivize participation by people currently visiting facilities less frequently, decreasing demand and coverage.
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Considerations for Improving TB/HIV Service Integration

- As with all models, close attention to IPC is required for group visits (*e.g.* ventilation systems, cough triage, availability of particulate respirators).
- The group model provides an opportunity for peer support and improved treatment literacy for those on TPT and peer modeling with regards to reporting TB symptoms and/or TPT side effects.
- Synchronizing TPT—*e.g.* starting multiple members of the group on TPT at the same time—can simplify monitoring and reporting and may foster solidarity. This could be done either by scheduling all group members for a special clinic visit on the same day, or by having HCWs come to the meeting point in the facility to conduct evaluations and initiation.

Table 2a: Facility-based individual models: the what/when/where and who of ICF and TPT service integration

	Facility-based Individual Models (*e.g.* Fast-Track +/- MMS)			
	ICF*	**TPT initiation**	**TPT refills**	**Follow-up visits**
What	TB symptom screen	Eligibility assessment TB symptom screen Education and instructions for follow-up	Medication refill	TB symptom screen Adherence check Side effect monitoring Documentation of adherence and completion
When	At each visit to health facility	During routine clinical visits In some contexts, may schedule special recall visit to screen for TPT eligibility and initiate TPT	Harmonized with ART refill schedule	Every month after initiation for the first 3 months, then with every regular ART refill visit until TPT completion
Where	Clinic	Clinic	Facility-based pick-up location (often but not always the pharmacy)	Facility-based pick-up location Telephone calls between pickups (in some models)
Who	Clinician	Clinician	Pharmacy staff	Clinician

*In addition to continuous self-screening by clients

Table 2b: Facility-based group models: the what/when/where and who of ICF and TPT service integration

	Facility-based Group Models (*e.g.* ART Clubs)			
	ICF*	**TPT initiation**	**TPT refills**	**Follow-up visits**
What	TB symptom screen	Eligibility assessment TB symptom screen Education and instructions for follow-up	Medication refill	TB symptom screen Adherence check Side effect monitoring Documentation of adherence and completion
When	At each group appointment at health facility	During routine clinical visits In some contexts, may schedule special recall visit to screen for TPT eligibility and initiate TPT	Harmonized with ART refill schedule	Every month after initiation for the first 3 months, then with every regular group visit until TPT completion
Where	Clinic	Clinic	Group meeting venue at health facility	Group meeting venue at health facility Telephone calls between pickups (in some models)
Who	Clinician Lay worker Group leader(s)	Clinician	Medications often pre-packed by pharmacy and dispensed by group facilitator	Group facilitator (generally a nurse or other HCW)

*In addition to continuous self-screening by clients

IV. Integrating ICF and TPT into Community-based Models

Less intensive DART models based in the community include individual models, such as outreach, PODI, and community drug distribution models, and group models, such as community ART groups (CARGs). Tables 3 and 4 illustrate some of the key issues related to the "where, who, what and when" of TB/HIV services in these contexts. An important distinction is that some community-based models are led by HCW while others are led by laypeople (*e.g.* peers).

Issues of documentation, monitoring and evaluation are discussed at greater length in Section VII. In brief, key considerations related to community-based documentation include:

- Community-based models can present challenges for data collection and harmonization with clients' facility-based medical records. Some countries have standards for entering community-collected data into facility-based systems; Uganda requires this to be done within 72 hours, for example.
- Data flow systems should be developed to ensure an uninterrupted flow of data from community-based models to facility-based registers and client records.
- Existing tools used for community-based DART models should be enhanced to capture TB screening and TPT provision.
- Referral mechanisms need to be in place to ensure there is active and documented referral of clients to facilities for TB evaluation if identified with presumptive TB, or for care if clients have TPT side effects.
- Simple streamlined data collection systems are particularly important for models led by laypeople. Use of electronic data systems can improve data flow and decrease the data entry burden.

Community-based Individual Models

There are diverse community-based individual models for less-intensive DART, which generally fall into two categories (Table 1). In the outreach model, HCW come to the community to provide clinical services, dispense ART and sometimes collect specimens for laboratory testing. In community drug distribution models, ART is dispensed at community pharmacies or other pick-up points, accompanied by "light touch" services such as TB symptom screening and adherence assessment, but not clinical care (Table 3a and 3b).

Opportunities

- By providing quarterly HCW-led community-based TB symptom screening, the outreach model may provide the "best of both worlds" in terms of quality and frequency of ICF.
- Dispensing ART and TPT on the same schedule may increase demand and uptake.
- Decreasing the frequency of visits to health facilities may decrease the risk of acquiring TB.
- Providing integrated community-based services may decrease the stigma associated with HIV-specific services.

Challenges

- Additional training and supervision may be required to ensure that TB screening performed by laypeople is equal in quality to that provided by HCWs.
- Additional training and supervision may be required to ensure that documentation/data collection led by laypeople is equal in quality to that conducted by HCWs.
- If TB symptom screening is not part of the package of care delivered at the community level, less-frequent health facility visits mean fewer opportunities for ICF.
- If ART and TPT are not on the same dispensing schedule, integration of TPT into these models may increase complexity, dis-incentivize uptake, and decrease TPT coverage.
- The absence of community-based "wrap around" services in individual models may create challenges for TPT adherence and retention and linkage to TB diagnostics if symptoms occur between outreach visits/ART pickup.

Considerations for Improving TB/HIV Service Integration

- Ongoing training and supervision are needed to ensure high quality TB symptom screening at community-based visits, especially for non-clinicians (*e.g.* peer educators). This can be supported by the development and use of job aids for a variety of literacy levels.
- Pilot studies have shown that TPT initiation and follow-up in outreach-type models can be as or more successful than in facility-based models.
- In most settings, only clinicians can initiate TPT, precluding initiation in peer-led models.

Community-based Group Models

Community-based group models go by many names and meet at different intervals (Table 1). Most are peer-led, including the well-known CAGs first piloted in Mozambique more than a decade ago. Less often, community-based groups are facilitated by HCWs or community health workers (Table 4a and 4b). Family models enable one family member to pick up ART for others as well as themselves; in practice, this often translates into a woman picking up medications for her partner and/or children.

Opportunities

- Group leaders/peers can provide education and counseling regarding the importance of TPT, including dispelling myths, answering questions and sharing their own experience, all of which could improve uptake.
- With sufficient training and support tools, group leaders/peers could provide TB symptom screening at regular intervals.
- For HCW-led groups, quarterly community-based TB symptom screening by HCW might be the 'best of both worlds' in terms of quality and frequency.
- With sufficient training and support tools, group leaders/peers could evaluate members on TPT for medication side effects and support adherence.
- Group models may enhance treatment literacy and empower clients to self-screen (*i.e.* to be aware of important symptoms and report them promptly if they occur).
- Dispensing ART and TPT on the same schedule, may increase demand and uptake.

- Aligning TPT start dates for clients within a community group—*e.g.* starting groups of people on TPT at the same time—may foster additional peer support and simplify group medication management.
- Decreased frequency of visits to health facilities may decrease the risk of acquiring TB in health care settings.

Challenges

- Less-frequent health facility visits may mean fewer opportunities for TPT evaluation and initiation, especially in groups not led by HCWs.
- In the family pick-up model, if the same family member comes to the health facility each time, the others may receive HCW-led TB symptom screening and TPT evaluation as infrequently as once a year.
- Peer-led screening for TB symptoms and side effects of TPT medication *may* not be as effective as that provided by HCW, although data are scarce.
- If ART and TPT are not on the same dispensing schedule, this may increase complexity, dis-incentivize uptake, and decrease TPT coverage.
- Staggered visiting of group members to the health facility also limits TPT start date alignment, adding complexity to the monitoring and refill process.

Considerations for Improving TB/HIV Service Integration

- Ongoing training and supervision are needed to ensure high quality TB symptom screening and side effect monitoring at community-based visits, especially for non-clinicians (*e.g.* peer educators). This can be supported by the development and use of job aids for a variety of literacy levels.
- In most settings, only clinicians can initiate TPT, precluding TPT initiation in peer-led models. Therefore, systems should be in place to ensure group members are evaluated for TPT initiation when they are scheduled to go to the health facility. In contexts where all group members are booked together for the clinical visit (as in Zimbabwe), TB screening, TPT initiation, and medication dispensing can be aligned for the whole group.
- If TPT and ART medication pickups are done by a single group member, then information about which group members are on TPT, and for how long, must be carefully tracked and medication should be pre-packaged appropriately by the pharmacy for these members. Aligning members' TPT initiation may significantly simplify this.
- An alternate approach to staggered TPT initiation for peer-led sessions is to plan to have a HCW attend a group session, specifically to initiate TPT for all group members who are eligible, which can simplify TPT management and follow-up appointments going forward.
- Strong referral processes should be in place for those with TB symptoms or medication side effects, and this information should constantly be reinforced and accessible for all group members (*e.g.* a drop-in appointment, hotline, etc.).

Table 3a: Community-based individual models (HCW run): the what/when/where and who when of ICF and TPT service integration

	Community-based Individual Models Health Care Worker Run (*e.g.* Outreach Model)			
	ICF*	**TPT initiation**	**TPT refills**	**Follow-up visits**
What	TB symptom screen	Eligibility assessment, TB symptom screen, education and instructions for follow-up	Medication refill	TB symptom screen Adherence check Side effect monitoring Documentation of adherence and completion
When	At every visit with HCW (typically every 1-3 months)	During regular clinical visits	Harmonized with ART refill schedule	Every month after initiation for the first 3 months, then with every ART refill visit until TPT completion
Where	Community	Clinic or community	At present, most countries require that TPT refills take place at the facility, but in theory, the outreach team could provide refills in the community	At present, most countries require that follow-up take place at the facility, but in theory, the outreach team could provide follow-up in the community
Who	Clinician	Clinician	Pharmacy staff Medications could be pre-packed by pharmacy staff and dispensed by HCW	Clinician

*In addition to continuous self-screening by clients

Table 3b: Community-based individual models (lay person/peer run): the what/when/where and who when of ICF and TPT service integration

	Community-based Individual Models Lay Person/Peer Run (*e.g.* PODI model)			
	ICF*	**TPT initiation**	**TPT refills**	**Follow-up visits**
What	TB symptom screen	Eligibility assessment, TB symptom screen, education and instructions for follow-up	Medication refill	TB symptom screen using adapted tools and job aids Adherence check using adapted tools and job aids Side-effect monitoring using adapted tools and job aids Documentation of adherence and completion
When	At each meeting with peer	During regular clinical visits	Harmonized with ART refill schedule	Every month after initiation for the first 3 months, then with every clinical visit until TPT complete Symptom screening, adherence support at every visit with peer until TPT completion
Where	Community	Clinic	At present, most countries require that TPT refills take place at the facility	At present, most countries require that follow-up take place at facility level In theory, the peer worker could also provide follow-up in the community In theory, follow-up could also be conducted remotely by facility staff (e.g. through calls, SMS/text message)
Who	Peer	Clinician	Pharmacy staff	Clinician conducts initial follow-up Lay worker at PODI

*In addition to continuous self-screening by clients

Table 4a: Community-based group models (HCW run): the what/when/where and who of TB/HIV service integration

	Community-based Group Models Health Care Worker Run (*e.g.* CAGs or community-based teen clubs led by HCW)			
	ICF*	**TPT initiation**	**TPT refills**	**Follow-up visits**
What	TB symptom screen	Eligibility assessment, TB symptom screen, education and instructions for follow-up	Medication refill	TB symptom screen using adapted tools and job aids Adherence check using adapted tools and job aids Side-effect monitoring using adapted tools and job aids Documentation of adherence and completion
When	At every CAG meeting (typically every 1-3 months) and at each clinical visit	During regular clinical visits	Harmonized with ART refill schedule	Every month after initiation for the first 3 months, then with every ART refill visit until TPT completion
Where	Community	Clinic	At present, most countries require that TPT refills take place at the facility	At present, most countries require that follow-up take place at the facility Follow-up for adherence and side effects could take place during regular CAG meetings
Who	Clinician or community health worker	Clinician	Pharmacy staff Medications could be pre-packed by pharmacy staff and picked up with ART for CAGs	Clinician or community health worker

*In addition to continuous self-screening by clients

Table 4b: Community-based group models (lay person/peer run): the what/when/where and who of TB/HIV service integration

	Community-based Group Models Lay Person/Peer Run (*e.g.* CAGs, CCLAD, CARGs)			
	ICF*	**TPT initiation**	**TPT refills**	**Follow-up visits**
What	TB symptom screen	Eligibility assessment, TB symptom screen, education and instructions for follow-up	Medication refill	TB symptom screen using adapted tools and job aids Adherence check using adapted tools and job aids Side-effect monitoring using adapted tools and job aids Documentation of adherence and completion
When	At each CAG meeting (typically every 1-3 months) and at each clinical visit	During regular clinical visits	Harmonized with ART refill schedule	Every month after initiation for the first 3 months, then with every clinical visit until TPT complete Symptom screening, adherence support at every visit with peer until TPT completion
Where	Community	Clinic	At present, most countries require that TPT refills take place at the facility	At present, most countries require that follow-up take place at the facility Follow-up for adherence and side effects could take place during regular CAG meetings
Who	Peers/CAG leader	Clinician	Pharmacy staff Medications could be pre-packed by pharmacy staff and picked up with ART for CAGs	Clinician conducts initial follow-up Peer/lay worker follows for TB symptoms and TPT side effects

*In addition to continuous self-screening by clients

V. Considerations for Special Subpopulations

Pregnant and Breastfeeding Women (PBFW)

PBFW with HIV are at high risk of TB which can lead to poor birth and infant outcomes. Local national guidelines for use of TPT in pregnancy and breastfeeding should be followed and where possible TPT provision should be harmonized with ART/Maternal and Child Health (MCH) visit dates, including infant follow -up visits during the postpartum period. Most countries require pregnant women to make monthly routine antenatal visits during pregnancy. In addition, transition from delivery to postpartum period is a period of high risk to follow-up and considerations around multi-month scripting during this period, for ART as well as TPT if recommended, is critical. If TPT initiation in pregnancy is warranted, TPT initiation and follow-up during pregnancy should be aligned with already scheduled visits. In most settings, a one stop model of care whereby ART is integrated into the MCH clinic has been adopted. To ensure continuity of care, it will be important to integrate TPT within MCH to avoid women having to queue up at the pharmacy for TPT refills. This will also require review of national reporting tools to ensure proper documentation of TPT within the MCH registers, HIV patient charts or consideration of a separate TB register within MCH. As women transition to postpartum period/breastfeeding with less frequent prescribed maternal follow-up visits, it will be critical to coordinate TPT follow-up visits with already schedule postnatal visits and/or child's routine visits.

Adolescents (10-19 years of age)

Adolescence is a period of distinct developmental and social change which can present multiple challenges to adherence for adolescents living with HIV. These challenges include a spectrum of issues such as disclosure, chronic illness and comorbidities, stigma from health care workers, and treatment fatigue. Youth-friendly services which include peer support, adolescent clubs, adolescent clinic days as well as services provided by health care workers trained to provide adolescent-friendly services should be engaged when considering TPT for this vulnerable population. Considerations for school-aged adolescents must also take into account refill schedules and strategies to ensure that adolescents have a continuous supply of drugs even when unable to attend regular clinic hours.

Children (<10 years of age)

Children are among those most vulnerable to TB infection yet TPT coverage in this population is low. Reasons that contribute to low coverage of TPT in pediatric populations include lack of pediatric drug formulations, pill burden, mistaken assumptions about the effectiveness of BCG vaccine, and low sensitivity of tuberculin skin tests in immunocompromised children. Health care workers face particular challenges in ruling out active TB as symptom criteria have lower sensitivity and specificity in those at greatest risk for TB disease. Strategies to improve TPT coverage in children include using a family-care model to treat family members together, sensitizing both caregivers and health care workers to the importance of TPT in children and ensuring that appropriate dosage forms for TPT are available.

VI. Implementation Considerations

Effective integration of TPT and DART services requires changes at multiple levels of the health system. This section briefly outlines considerations at the national, health facility and community levels with an eye to policies, human resources, commodities, quality assurance, and information systems.

National Level:

- As with other TB/HIV services, integration of TPT into DART models will benefit from a functional technical working group that includes members of HIV and TB departments, implementing partners, health workers, ROC and communities.
- Supportive policies will include those enabling multi-month prescribing of TPT and task-shifting to enable non-clinicians to screen for TB symptoms and TPT side effects.
- Procurement and supply chain support will be needed for multi-month TPT prescribing and dispensing.
- Guidelines, standard operating protocols and training materials will facilitate integration of TPT into DART models.
- Monitoring, evaluation and pharmacovigilance systems may need to be updated to accommodate the change in approach.

Facility Level:

- Engagement of health facility leadership and community oversight structures (if any) will be important to ensure clear communication about the integration of TPT into DART models.
- Revised standard operating protocols will be needed for clinicians, counselors, pharmacy staff, and data entry staff.
- Revised training materials and job aids and 'refresher' training on TPT may be needed for HCW and lay workers supporting less intensive DART models.
- Enhanced counseling and client education will be important for clients in less intensive DART models; education materials (*e.g.* flip charts, posters, fliers, videos) may also be needed.
- Monitoring and evaluation systems will likely need to be updated, to ensure data related to ICF, TPT initiation, TPT side effect screening and TPT refills, adherence and completion are documented at the health facility and in the community, and that data flow is swift and effective.

Community Level:

- ROC and community members should be meaningfully engaged in planning, implementation and evaluation of DSD, including integration of TPT into less intensive DART models.
- Information and education campaigns can increase community awareness of the new guidelines, and foster demand for TPT amongst those in DART models.
- Clear protocols are needed for communication and referrals between community-based staff (clinicians on outreach teams, CHWs, peer educators, and laypeople such as CAG group leaders) and health facility-based staff.

- New or adapted tools will be required to document TB screening and TPT initiation, pickups, adherence, completion and referrals. Close attention will be required to issues data flow from community to facility and data confidentiality and security.

VII. Monitoring and Evaluation

As above, DART models diversify the "who, what, when, and where" of TB/HIV services. Differentiated services can present challenges to existing M&E systems, and adaptations may need to be made to M&E tools (including those for data collection, monitoring, and reporting) and strategies to ensure accurate, complete and timely data for program monitoring, reporting and improvement. Considerations specific to DART models in general are addressed in the ICAP Approach to Differentiated Service Delivery. This section discusses adaptations related to the integration of TB/HIV services into the M&E systems of DART models, with an eye to ensuring that the key elements of the TPT cascade reported for "conventional" models are also captured within each DART model.

Adaptations to existing M&E systems may include:

1. **Updating existing health information systems (HIS) tools**, such as the client ART medical record, to capture key elements of the TPT cascade for each DART model.
2. **Introducing new tools** to capture services provided to people receiving TB/HIV services in the community.
3. **Establishing an effective data flow** between community-based documentation tools and the client's medical record.
4. **Establishing and defining indicators** to be routinely reported that adequately describe uptake and outcomes of diverse facility- and community-based services.
5. **Developing and implementing tools and systems** to generate data summaries for DART models, including data for calculating new indicators to enable evaluation of the programs.

To optimize implementation and ensure sustainability, M&E systems and tools should be developed and subsequently implemented in collaboration with the Ministry of Health (MOH) and other stakeholders. Wherever possible, these should incorporate prevailing global guidance and lessons learned from other settings. An overview of TB/HIV-specific M&E system elements for potential adaptation, along with additional M&E considerations for implementers of DART models, is presented below.

M&E Considerations for TB/HIV Services in DART Models

In general, information on TB symptom screening, evaluation for TB, diagnosis with TB and initiation on TB treatment is captured in existing ART medical records or other national M&E tools. However, data collection needs to be harmonized, especially if services such as adherence assessment and symptom screening take place in different locations within the facility or in the community. In

addition, existing M&E systems may not fully capture TPT services. Existing tools for community-based DART models may need to be updated to capture TB screening and TPT. In some cases, new M&E tools will need to be developed. Such tools should be tailored to reflect the documentation needs for individual DART models (*e.g.* facility-based adherence clubs, community ART distribution points).

TB Screening

Global and national guidelines recommend that all HIV-positive clients should be screened for TB symptoms at every contact with a HCW. Health facility tools and registers generally include fields to capture TB screening, this may be less common in tools used in the community. A field for TB screening should be added to any paper or electronic-based community-based DART model tool, such as the CAG group monitoring form, to ensure that TB screening is documented at every client encounter. For example, the Zimbabwe CARG register includes a column to document TB symptom screening for every client at every CARG meeting. Mobile apps have also been developed to capture TB screening activities.

TPT Eligibility

Guidelines specify TPT eligibility criteria, such as the absence of suspected TB disease and contraindications to TPT such as liver disease. Thus, these variables need to be assessed and documented at regular intervals and eligibility classification ("eligible" "ineligible" "completed TPT") must be recorded at each time point. Facility-based records, including the client ART record, will likely require adaptation to document clients' TPT eligibility status at regular intervals (*e.g.* every six or 12 months). For some DART models, community-based records will also need to capture the same data.

Documenting TPT Services Received

In addition to documenting eligibility for TPT, M&E tools will also need to record at each visit whether the client received TPT; whether there are any signs or symptoms of side effects; the results of the client's adherence assessment; and where the client received TPT. As many programs lack comprehensive data on TPT, they may need to implement a TPT register and TPT follow-up form for the client's medical record to document services. As TPT may be provided outside the health facility, the client's record should be updated to record the dates of client TPT pickup, supply of TPT provided, indications of side effects, and adherence assessment that did not coincide with HIV clinic visits.

Referral Systems

Facilities commonly have referral systems in place to provide intra-facility referral to another point of service. For instance, clients with presumptive TB are referred for TB evaluation. However, in community settings, systems may not be established to document a referral to a health facility for services such as TB evaluation or clinical assessment in cases of side effects due to TPT. Programs need to ensure that there are systems in place to document referral of clients to facilities for needed services, as well as the results of such referrals.

Adapting Pharmacy Tools and Systems

At facilities that support DART models, pharmacy record-keeping tools and systems may require adaptation. For example, pharmacies may implement systems to facilitate the planning for expected combined ART and TPT pickups (*e.g.* to allow for prepacking of medications).

Data Flow Between New Tools and Facility Records

For DSD models in which TB/HIV services are provided both at the health facility and in the community, data will likely be collected in both locations, using multiple tools. To facilitate effective clinical management, M&E/reporting, and quality improvement efforts, a defined set of key elements from DSD-specific registers and/or forms should be transcribed into the patient ART medical record. Thus, it will be critical to ensure that information collected is routinely transported or transmitted to the HIV facility in a timely, secure, standardized way, and that patient records or databases are promptly updated with these data, as appropriate.

Patient data from DSDM may be reported to facilities using a range of methods, depending on the available technology at each treatment site. The ICAP Approach to Differentiated Service Delivery describes strategies for paper-based records, electronic mobile technology, and adapted facility-based tools.

Performance Indicators to Monitor TB/HIV Services in Less-Intensive DART Models

Ideally, programs would be able to assess the ICF/TPT cascade illustrated in Table 5 for clients in each less-intensive DART model. These indicators can be disaggregated into meaningful sub-categories, such as age group, gender, and service delivery model. In practice, this will be very difficult for countries without electronic medical records to achieve via routine data collection. When this approach is not feasible, key indicators could be assess on an *ad hoc* basis, or at small scale in the context of quality improvement projects. Alternatively, the aggregate cascade could be evaluated at the site, program or subnational levels, and compared to the coverage of less-intensive DSD models.

Evaluation strategies and indicators should be designed with country stakeholders; reflect the elements of DART models used nationally; and respond to national priorities. Detailed guidance on calculating indicators, including numerators and denominators, should be developed for use during training and implementation.

Table 5. Indicators to Monitor TB/HIV Services in Less-intensive DART Models

Proportion of clients in less intensive DART models who:
• were screened for TB at last facility or community visit, out of those attending
• identified with presumptive TB, out of those screened for TB
• evaluated for TB, out of those with presumptive TB
• diagnosed with active TB disease, out of those evaluated for TB
• started on TB treatment, out of those diagnosed as having active TB disease
• started a course of TPT, out of those screening negative for presumptive TB + those not diagnosed with TB following evaluation
• completed a course of TPT, out of those starting TPT
Proportion of health care facilities providing services for clients that have TB infection control practices
Proportion of health care workers in community-based DART models that have received training in TB infection control practices

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