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<td>DATIM</td>
<td>Data for Accountability, Transparency, and Impact Monitoring (i.e. database)</td>
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<td>TPT regimen consisting of weekly isoniazid and rifapentine (12 weeks total)</td>
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<td>3HR</td>
<td>TPT regimen consisting of daily isoniazid and rifampicin (12 weeks total)</td>
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INTRODUCTION

WHO has estimated that two billion people – one fourth of the world’s population – are infected with tuberculosis (TB) worldwide (otherwise known as latent TB infection, or LTBI). TB preventive treatment (TPT) can reduce the risk of individuals developing TB disease and is a powerful and necessary tool to end the global TB epidemic. TPT is, in short, treatment for TB infection through a public health approach, meaning individuals with epidemiologic risk factors for TB infection receive TPT, regardless of whether they have had a positive test of TB infection.

TB is the number one killer of persons living with HIV (PLHIV); therefore, PLHIV have been prioritized to receive TPT by WHO guidelines since 1993. Despite these recommendations, access to and implementation of TPT has been limited.

The US President’s Emergency Plan for AIDS Relief, or PEPFAR, is committed to scaling up TPT for all PLHIV in PEPFAR-supported countries. PEPFAR has successfully provided more than 13 million PLHIV with antiretroviral treatment (ART). However, despite the success of ART scale-up, TPT scale-up has lagged behind. TPT has been shown to be effective at preventing TB in PLHIV and should be considered part of a comprehensive HIV treatment plan.

This TB Preventive Treatment Implementation Guide and Toolkit is intended for use by PEPFAR teams and implementing partners who support the programmatic scale-up and improvement of TPT for PLHIV. This guide includes a TPT implementation roadmap (“TPT Roadmap”), along with evidence-based tools (collectively referred to has the “TPT Toolkit”) to assist countries in both TPT implementation and program quality improvement.

HOW TO USE THIS IMPLEMENTATION GUIDE

The TPT Implementation Guide consists of a TPT Implementation Roadmap and a collection of diverse TPT-related, programmatically-focused work aids, or “tools.” These tools are living documents and/or other files to be shared with PEPFAR teams and implementing partners for adaptation and use. These documents may change over time based on field experience and to address new programmatic needs and/or evolving evidence.

The TPT Roadmap attempts to divide the TPT implementation and scale-up process into chronologic, programmatic stages. These stages are as follows:

1. Policy development and planning
2. Pre-implementation
3. Preparations for implementation and training
4. Early implementation
5. Routine implementation and scale-up
As scale-up occurs, TPT implementation eventually becomes less linear and more of a cyclical process with ongoing programmatic and clinical quality improvement. Because this process is ongoing, this implementation guide and tools will also change over time.

The various tools have different programmatic purposes and different intended users. Some tools provide key information and evidence-based frequently asked questions (FAQs) on TPT-related topics; others are clinical algorithms that can be incorporated into national guidelines or shared with implementing partners for creation of job aides. Other tools may be used by PEPFAR teams during the process of developing Country Operating Plans (COPs) for target-setting and budgeting. In the future, tools that focus on the monitoring and evaluation aspects of TPT will be added to the Toolkit, such as data capture tools and/or processes to improve data quality.

We welcome feedback and user input as experience is gained in bringing TPT to scale. These contributions will inform revisions and additional tools. Inputs and suggestions should be sent to TPTunit@cdc.gov. We plan to track use of this guide and Toolkit, its utility and impact, and to continuously make improvements as dictated by program needs.
Figure 1: TB Preventive Treatment Roadmap, with and without Tools Included

Disclaimer: New studies and publications are constantly evolving, and these tools are designed to be data-driven. The tools will be updated regularly, although there may be a short lag time for updates given this is a rapidly evolving area of operational research.
Policy and Planning

Country Consultation

01 TPT BASELINE ASSESSMENT

**Intended end-user(s):** CDC or other United States Government (USG) agency headquarters-based staff providing technical assistance, and CDC or other USG agency country team programmatic staff

**Purpose:** To identify potential gaps in initiating, implementing, and monitoring TPT performance as part of routine PEPFAR-supported activities.

This baseline assessment questionnaire was developed to address all aspects of TPT implementation in a local jurisdiction, from inclusion in national guidelines through the status of implementation and reporting. An aggregated summary of the baseline assessment results is under peer-review for dissemination and will be incorporated into this tool once it is published.

The results from these assessments identified key gaps and areas where additional programmatic support was needed; ultimately, this led to the creation of this toolkit.

This questionnaire may be used by other CDC or USG agency country offices interested in performing a baseline assessment; it also may be adapted and used to track progress on TPT implementation over time.

The TPT Baseline Assessment tool, as well as additional instructions are found here: [01 TPT Baseline Assessment](#)

02 TPT MYTH BUSTERS

**Intended end-user(s):** CDC or other USG agency headquarters-based staff providing technical assistance, CDC or other USG agency country team programmatic staff, National TB Program staff, National HIV Program staff, clinical staff or health care workers, and other donor agencies and implementing partners

**Purpose:** To provide evidence-based answers to common questions or misconceptions about the use of TPT to facilitate in-country discussions when similar questions arise. This tool can help ensure all PEPFAR stakeholders and partners have easy access to comprehensive evidence surrounding various aspects of TPT should questions arise.

This presentation-style tool addresses common questions and misconceptions related to TPT; more specifically, it provides **evidence-based answers** to these concerns. This presentation may also serve as an overview of TPT. Country team staff are encouraged to use this presentation for local use, and as
needed for meetings with key stakeholders and partners, or to adjust the content to address specific concerns related to TPT as needed.

The “TPT Myth Busters” slide deck, as well as additional instructions are found here: 02 TPT Myth Busters

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**03 TPT FAQs FOR PROGRAMS**

**Intended end-user(s):** CDC or other USG agency country team programmatic staff, National TB Program staff, National HIV Program staff, and other donor agencies and implementing partners

**Purpose:** To answer frequently asked questions about TPT implementation as referenced in the WHO LTBI Guidelines. The FAQs highlights evidence-based TPT implementation as an integral component of quality HIV care delivery and is consistent with normative guidelines. This tool can be applied to national, sub-national (e.g. regional), and site-level programs.

The TPT FAQs for Programs tool, as well as additional instructions can be found here: 03 TPT FAQs for Programs

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**04 TPT EMERGING CLINICAL CONSIDERATIONS (PREGNANCY/ADHERENCE/TLD)**

**Intended end-user(s):** CDC and other USG agency headquarters-based staff providing technical assistance, CDC and other USG agency country team programmatic staff, National TB Program, National HIV Program, Clinical staff or health care workers, and other donor agencies, and implementing partners

**Purpose:** To provide informational briefs on common clinical factors that may affect programmatic TPT scale up. Current briefs include:

1. Isoniazid Preventive Therapy (IPT) and Pregnancy: updated considerations of IPT among pregnant women living with HIV
2. TPT Adherence: considerations for programs and providers
3. Updated considerations of TB preventive treatment (TPT) with newer antiretroviral treatment (ART) regimens (including dolutegravir)

The goal of the “IPT and Pregnancy” brief is to provide talking points about the potential safety concerns related to IPT use among pregnant women living with HIV. The “TPT Adherence” brief shares important considerations to optimize TPT adherence and completion. The “Updated considerations of TB preventive treatment (TPT) with antiretroviral treatment (ART) (including dolutegravir) brief provides talking points about the selection of appropriate TPT regimens for patients treated with various ART regimens, including dolutegravir.
The three briefs can be found here: 04 IPT Pregnancy Brief, 04 TPT Adherence Considerations Brief, and 04 TPT TLD Brief

Other briefs may be added based on future implementation considerations and concerns.

### 05 TPT TECHNICAL ASSISTANCE REQUEST TEMPLATE

**Intended end-user(s):** CDC or other USG agency headquarters-based staff providing technical assistance, CDC or other USG agency country team programmatic staff

**Purpose:** To reduce the time required to prepare for a technical assistance visit and suggest program areas that may need attention during these visits.

This tool supports TPT-related technical assistance planning and coordination between the field and headquarters (HQ). It can also be used to reduce time spent on trip reports after travel is completed.

This template can be customized for a specific country prior to any TDY to ensure all partners (HQ and country team members) have the same baseline information and understand country-specific issues and goals for the TDY. The HQ staff member leading the TDY should work with their in-country contact (TB/HIV advisor and/or HIV Care and Treatment staff) to complete this ahead of time.

The template can be found here: 05 TPT Technical Assistance Request Template

### 06 TPT IMPLEMENTATION CHECKLIST

**Intended end-user(s):** CDC or other USG agency headquarters-based staff providing technical assistance, CDC or other USG agency country team programmatic staff, CDC or other USG agency country team strategic information staff, National TB Program staff, National HIV Program staff, other donor agencies, and implementing partners

**Purpose:** To outline the major steps required for successful TPT program initiation and successful scale up. It can be used to facilitate stakeholder discussions and technical assistance visits by reviewing what is required at each step, to ensure main activities discussed with a plan for action, as needed.

The checklist can be found here: 06 TPT Implementation Checklist

### Partner Management

Partner management and coordination activities should be led by CDC and/or other USG agencies assigned to country offices. CDC and/or other USG agency subject matter experts based at headquarters may be requested for assistance as needed.
Budget Planning

07- TPT COSTING TOOL

**Intended end-user(s):** CDC or other USG agency headquarters-based staff providing technical assistance, CDC or other USG agency country team programmatic staff, National TB Program staff, National HIV Program staff, other donor agencies and implementing partners

**Purpose:** To assist PEPFAR and national TB and HIV programs in estimating the budget required for TPT implementation and scale-up. Whenever possible, PEPFAR teams should use pre-existing, in-country supply chain mechanisms for procuring and distributing TPT-related commodities (e.g. USAID GHSC-PSM, CDC MAUL Uganda, Kenya Pharma). In some instances, the Global Fund may be considered as a mechanism for procuring and distributing TPT-related commodities via the Global Drug Facility (GDF). We have referenced tablet doses and prices listed in this tool using published 2019 GDF catalogs; exact availability and prices should be verified independently by country offices. The tool can be found here: 07 TPT Costing Tool
Pre-Implementation

Set Targets

08 TPT TARGET-SETTING CONSIDERATIONS

Intended end-user(s): CDC or other USG agency headquarters-based staff providing technical assistance, CDC or other USG agency country team programmatic staff, CDC or other USG country team strategic information staff, and other donor agencies and implementing partners

Purpose: To calculate rational targets for the TB_PREV Monitoring, Evaluation, and Reporting (MER) indicator for PEPFAR countries.

This document provides considerations for inputs and assumptions for TPT target-setting and scale up, outlines an algorithm to help staff calculate TPT eligibility, and includes clarifying visual to aid target-setting.

The target-setting considerations and tool can be found here: 08 TPT Target-Setting Considerations and 08 TPT Target-Setting Tool

Monitoring and Evaluation Preparations

09 TPT INDICATORS SLIDEDECK

Intended end-user(s): CDC or other USG agency headquarters-based staff providing technical assistance, CDC or other USG agency country team programmatic staff, CDC or other USG agency country team strategic information staff, and other donor agencies and implementing partners

Purpose: To support understanding of TPT program monitoring, evaluation, and reporting.

This tool was developed as a reference for all programs that use TB/HIV PEPFAR Monitoring, Evaluation, and Reporting (MER) and WHO indicators. This tool provides: 1) TB/HIV cascade visual mapped with relevant PEPFAR and WHO indicators, potential data sources, and country examples; 2) cheat sheet definitions for all TB/HIV cascade indicators; 3) details for recommended custom indicators; 4) data entry screen visuals for PEPFAR TB/HIV indicators; and 5) detailed indicator guidance for relevant PEPFAR/WHO indicators.

The TB/HIV Indicators Slidedeck can be found here: 09 TPT Indicators Slidedeck
10 DATA FLOW ASSESSMENT

Intended end-user(s): CDC or other USG agency headquarters-based staff providing technical assistance, CDC or other USG agency country team programmatic staff, CDC or other USG agency country team strategic information staff, and other donor agencies and implementing partners

Purpose: To map out the data reporting flow from the patient to national (and global, as applicable) level.

This tool provides an aid to 1) understand and visually map out reporting details at each level of data reporting; 2) provide standardized interview guide in site and above-site reporting assessment domains involving data aggregation, linkage and reporting, validation and review, and reporting feedback systems; and 3) identify program areas that need strengthening.

The Data Flow Assessment can be found here: 10 TPT Data Flow Assessment

11 TPT REGISTER EXAMPLE

Intended end-user(s): CDC or other USG agency headquarters-based staff providing technical assistance, CDC or other USG agency country team programmatic staff, CDC or other USG agency country team strategic information staff, National TB Program staff, National HIV Program staff, other donor agencies and implementing partners

Purpose: To provide examples of TPT data recording (at both patient level and site level) and data reporting (at site level) tools for use by site-level clinical and data management staff. These tools can be used as displayed or adapted to fit country-specific needs or to capture specific indicators.

All three tools can be found here: 11 TPT Register Example
Preparations for Implementation & Training

Initial Training

TPT training modules to be developed by CDC and/or other USG agency country teams to account for variations in national guidelines related to TPT. Headquarters assistance may be requested as needed.

Job Aids

12 TPT ADULT CLINICAL ALGORITHM

**Intended end-user(s):** CDC or other USG agency headquarters-based staff providing technical assistance, CDC or other USG agency country team programmatic staff, National TB Program staff, National HIV Program staff, clinical staff or health care workers, and other donor agencies and implementing partners

**Purpose:** To support clinicians and relevant program staff in creating clinical algorithms for TB screening and TB preventive treatment for adults. This tool is designed as a basic algorithm; adjustments may be required as per local guidelines/needs.

The TPT Adult Clinical Algorithm Tool can be found here: [12 TPT Adult Clinical Algorithm](#)

13 TPT PEDIATRIC AND ADOLESCENT CLINICAL ALGORITHM

**Intended end-user(s):** CDC or other USG agency headquarters-based staff providing technical assistance, CDC or other USG agency country team programmatic staff, National TB Program staff, National HIV Program staff, clinical staff or health care workers, other donor agencies and implementing partners

**Purpose:** To support clinicians and relevant program staff in creating clinical algorithms for TB screening, diagnosis, treatment and prevention specifically for children and adolescents. This tool provides medication and dosing guidelines for TB treatment and TPT— for both HIV-uninfected and HIV-infected children and adolescents on ART. Various options for treating TB disease in children and adolescents are also provided. This tool is designed as a basic algorithm; adjustments may be required as per local guidelines/needs.

This tool can be printed as either a pocket card which can be found here: [13 TPT Pediatric and Adolescent Clinical Algorithm (Pocket card)](#) or printed as a poster and used as a job aid for clinicians working in ART and TB clinics, which can be found here: [13 TPT Pediatric and Adolescent Clinical Algorithm (Poster)](#)
### 14 TPT FAQs FOR PATIENTS

**Intended end-user(s):** CDC or other USG agency headquarters-based staff providing technical assistance, CDC or other USG agency country team programmatic staff, National TB Program staff, National HIV Program staff, clinical staff or health care workers, other donor agencies and implementing partners, and patients

**Purpose:** To provide basic educational material for TB patients; including frequently asked questions (FAQs) about TPT, importance of treatment adherence, and most common potential side effects of TPT.

This tool is simple and written in plain English; adjustments may be required as per local culture and language.

The TPT FAQ for Patients tool can be found here: [14 TPT FAQ for Patients](#)

### 15 TPT ADVERSE EVENTS

**Intended end-user(s):** CDC or other USG agency headquarters-based staff providing technical assistance, CDC or other USG agency country team programmatic staff, National TB Program staff, National HIV Program staff, and other donor agencies and implementing partners

**Purpose:** To summarize adverse event monitoring as referenced in the WHO updated and consolidated guidelines for the programmatic management of tuberculosis infection and provide a framework for adapting these guidelines in PEPFAR-supported countries.

The slide deck can be found here: [15 TPT Adverse Events](#)

### 16 TPT Differentiated Service Delivery (DSD) Model Considerations

**Intended end-user(s):** CDC or other USG agency headquarters-based staff providing technical assistance, CDC or other USG agency country team programmatic staff, National TB Program Staff, National HIV Program Staff, and other donor agencies and implementing partners

**Purpose:** To provide information on differentiated service delivery (DSD) models for HIV care, outline program considerations in the implementation of TPT within DSD models, and to provide examples of delivery of DSD-based TPT models. This document (including examples provided) can be adapted to fit country-specific needs.

The TPT DSD tool can be found here: [TPT DSD Model Considerations](#)
Readiness Checklist

17 TPT COMMODITY FORECASTING TOOL

**Intended end-user(s):** CDC or other USG agency headquarters-based staff providing technical assistance, CDC or other USG agency country team programmatic staff, National TB Program Staff, National HIV Program Staff, and other donor agencies and implementing partners

**Purpose:** To assist PEPFAR country teams and national governments in forecasting anticipated budgets and commodities needed to reach TPT targets. The tool allows users to select PEPFAR or national targets, include or exclude HIV-negative individuals, and select from a variety of drug regimens.

This tool as well as in-depth instructions on how to use it can be found here: [16 TPT Commodity Forecasting Tool](#).

Commodity Distribution

18 TPT CLINICAL SITE ASSESSMENT TOOL

**Intended end-user(s):** CDC or other USG agency headquarters-based staff providing technical assistance, CDC or other USG agency country team programmatic staff, National TB Program staff, National HIV Program staff, and other donor agencies and implementing partners

**Purpose:** To provide an interview and data review guide for HQ and in-country staff to assess clinical treatment sites for completeness and to identify gaps in TB preventive treatment to PLHIV. The tool is intended to provide standardized questions in different site assessment domains, including strategic approach, clinical training/competency, community/patient education, patient management (including chart review), and commodities; and identify program areas that need strengthening. This tool can be used as a guide for staff performing a site assessment and to direct questions to site point(s) of contact (POC) about different domains of site assessment.

The Clinical Site Assessment Tool can be found here: [17 TPT Clinical Site Assessment Tool](#).
Early Implementation
Initial Monitoring and Evaluation (MER Indicators)

Historically, TB/HIV MER indicators have not received the same level of data quality scrutiny as HIV MER indicators. Measuring the success of PEPFAR’s global TPT initiative will require strong data monitoring systems that produce high quality data. Efforts to ensure data quality as part of routine TB/HIV data management are under development. Most countries are unable to calculate accurate estimates of TPT completion due to gaps in data availability and quality. It is essential to identify gaps in the data collection, management, and reporting practices of TB/HIV variables, which will help to establish high-quality data, encourage site-level data use, and maximize program impact.

Data Review

To successfully scale-up TPT for all PLHIV as an integral and routine part of the HIV clinical care package, data validation activities are vital for assuring the quality of collected, reported and analyzed TB/HIV data. This may be further accompanied by a standardized, routine data monitoring process at sites that offer TPT where HIV services are delivered.

Here are several reasons for conducting a TPT data review.

1. Characterize the patient and TPT data flow, including how data related to TB screening and TPT diagnostic services is initiated and managed at each site offering HIV services.
2. Assess the quality of reported data by using PEPFAR Monitoring, Evaluation and Reporting (MER) indicator definitions. Use triangulation methods to recreate reported numbers for selected PEPFAR indicators as compared against numbers reported to PEPFAR’s MER central database, Data for Accountability Transparency Impact Monitoring (DATIM), and local data sources (e.g., clinic records, registries).
3. Review how data populates into DATIM from the national data collection system, for instance, DHIS2, if applicable.
4. Describe any data quality challenges, including any systematic problems with applied TB/HIV indicator definitions and data recording, collection, use, and reporting timelines and processes.
5. Recommend actions to improve data quality by implementing a systematic review of performance monitoring indicators, strengthening agency, partner, and site collaborations, and providing ongoing technical assistance.

For the data review, the implementing partner staff members, CDC and/or other USG agency in-country staff, working alongside Ministry of Health representatives, will use standardized processes to assess existing patient information that is routinely collected through facility- or community-based patient
monitoring systems and site assessment tools. Data validation activities are necessary for identifying discrepancies in data flows from initial data capture (e.g., patient files) to aggregation and final reporting at the national level. Triangulation methods should be used to calculate historical TPT coverage and completion at least at high yield sites. This will provide countries with a better understanding of the magnitude of TPT scale-up that will be needed to meet annual TPT targets (either WHO-defined TPT indicators or the MER indicator for TPT which is TB_PREV).

Validated data collection tools and instructional guides adapted for TB/HIV are currently in development and will be field tested in select countries prior to wide-scale dissemination (tentatively scheduled for release in early FY20).
Routine Implementation

Ongoing Monitoring and Evaluation (MER Indicators)

Performance Monitoring

Lessons learned from a data review can subsequently be used to inform performance monitoring activities. Performance monitoring indicators (PMIs) are values collected to measure progress and enable results achieved over time to be compared with planned results. Targets should be set for performance indicators and when useful for programming or learning purposes, Performance indicator data rarely match targets exactly. Failure to meet a target, however, is not necessarily a problem and likewise exceeding a target is not necessarily a success. However, if performance data are outside the expected or acceptable range around a target, it should prompt further investigation or action to understand why; such an investigation may be as simple as a discussion with implementing partners or as involved as commissioning a formal performance evaluation. Important also to keep in mind; improving data quality is inherent to this process as the data need to be sufficiently reliable in order to inform programmatic decisions effectively.

PMIs are considered indispensable indicators for making performance-based decisions. In the context of TB/HIV care, performance monitoring activities can help track the progress of TPT target achievement over time, as well as, verify the effectiveness of systemic interventions, such as introducing routine data reviews, strengthening clinical and data supervisory structures, and streamlining clinical referral processes on overall program objectives and goals.

Ongoing Training

Data Tools and Training Materials

Tools and training materials for conducting TB/HIV data reviews and performance monitoring activities are currently in development. Data collection tools and trainings will be field tested in several countries prior to dissemination. These tools and training series will expand on PEPFAR's current monitoring and evaluation work streams to include routine data quality reviews and program monitoring activities that will ensure that TB/HIV programmatic decisions are made effectively. In addition, they will focus on rapidly but prudently capacitating countries in TB/HIV data validation activities through joint field work, trainings, supervision, and sharing of data collection tools and resources.


Latent tuberculosis infection; Updated and consolidated guidelines for programmatic management. World Health Organization; Geneva, Switzerland; 2018.


van Halsema CL, Fielding KL, Chihota VN, Russell EC, Lewis JJ, Churchyard GJ, and Grant AD. Tuberculosis outcomes and drug susceptibility in individuals exposed to isoniazid preventive therapy in a high HIV prevalence setting. AIDS. 2010;24:1051-5.


