The Republic of Uganda

Ministry of Health

Guidelines for Programmatic Management of Latent TB Infection in Uganda

"Closing the TB tap"

A Health Worker Guide

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Foreword

Uganda is one of 30 high burden TB/HIV countries with a TB/HIV co-infection rate of forty percent in 2018. There were an estimated one million four hundred thousand people living with HIV in 2018, of whom eighty four percent knew their HIV status, seventy two percent were on antiretroviral treatment and sixty four percent were virally suppressed. There were 53,000 new HIV infections and 23,000 AIDS related deaths in 2018. There were an estimated 86,000 people that developed TB in 2018, with only 57,756 being notified to the Ministry of Health, representing a treatment coverage of 65%. Of those an estimated 19,600 died, a case fatality ratio of 24% and 44% of those deaths were among the HIV co-infected. The TB treatment success rate among new & relapse TB patients that started TB treatment in 2017 was 72% compared with 69% among the TB/HIV coinfected. The ART coverage for TB/HIV co-infected patients in 2018 was 97%.

TB remains the leading cause of death among people living with HIV, and PLHIV are 17-23 times more likely to fall ill due to TB compared with those without HIV. PLHIV face the threat of drug resistant TB and when diagnosis is delayed there is increased risk of mortality from multi-drug resistant and extensively drug resistant TB.

The Ministry of Health first developed guidance (NTLP Manual) for isoniazid preventive therapy for under-5-year-old household contacts of smear positive TB patients in 1992. Later in 2006, the country rolled out management of TB/HIV co-infection, with among other objectives, to reduce the burden of TB among people living with HIV. It updated its national guidelines for collaborative TB/HIV activities in 2013 with recommendations on intensifying

TB case finding among PLHIV, TB infection control in HIV care settings and isoniazid preventive therapy to prevent reactivation of latent TB among people living with HIV. Additionally, the country developed an implementation guide (2014), and rolled out isoniazid preventive therapy among PLHIV in 2015. In 2018 & 2020 WHO updated its recommendations on eligible groups, tests and treatment regimens for latent TB infection. This guide incorporates updates in evidence since 2014 and new WHO & national recommendations for Programmatic Management of TB Preventive Treatment among household & close contacts of TB patients and people living with HIV (including co-administration of TPT and ART within differentiated service delivery models).

I hereby extend my sincere gratitude to the joint teams from the TB/Leprosy and AIDS Control Divisions and their partners that provided technical expertise during the development of these guidelines. Secondly, this is to appreciate the partners that provided financial support during the review process that resulted in the finalization of these guidelines.

I now urge all health care workers to read & continuously refer to this guide so as to provide quality TB preventive treatment to all targeted at-risk populations including people living with HIV and contracts of pulmonary bacteriologically confirmed TB patients, to follow them up while they are on treatment and document properly their management and to report the outcomes of their preventive treatment.

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Acknowledgments

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Abbreviations

ACP	AIDS Control Programme
ART	Anti-Retroviral Treatment
CLHIV	Children living with HIV
DSD	Differentiated Service Delivery
HIV	Human Immunodeficiency Virus
IEC	Information, Education and Communication
IGRA	Interferon-Gamma Release Assay
IPT	Isoniazid Preventive Treatment
LTBI	Latent Tuberculosis Infection
MDR TB	Multi Drug Resistant Tuberculosis
M&E	Monitoring and Evaluation
NTLP	National Tuberculosis & Leprosy Programme
PBC	Pulmonary Bacteriologically Confirmed
PLHIV	People living with HIV
RoCs	Recipients of care
TB	Tuberculosis
TPT	Tuberculosis Preventive Treatment
TST	Tuberculin Skin Test
WHO	World Health Organization

Glossary of terms

Term	Working Definition
Active Tuberculosis	A person with symptoms and signs of ttuberculosis confirmed by a laboratory test or doctor's judgement
Adolescent	A person aged 10–19 years
Adult	A person over 17 years of age
Bacteriologically confirmed TB	TB diagnosed in a biological specimen by smear microscopy, culture or a WHO-approved molecular test such as Xpert MTB/RIF
Child	A person under 18 years
Contact	Any person who was exposed to a patient of TB
Contact investigation	A systematic process for identifying previously undiagnosed patients of TB among the contacts of an index patient. The goal includes testing for Latent TB Infection to identify candidates for preventive treatment. Contact investigation consists of identification and prioritization and clinical evaluation
Current Cough	A person with cough of 24 hours or more
Eligibility	A person who meets the criteria to be offered TB preventive treatment
Gene Xpert	A WHO-approved cartridge-based rapid diagnostic that uses molecular technique to simultaneously detect Mycobacterium tuberculosis (MTB) and resistance to Rifampicin.
Household or close contact	A person who shared the same enclosed living or working space as the index patient for one or more nights or for frequent or extended daytime periods during the 3 months before the start of current treatment
Index TB patient	The initially identified patient of new or recurrent TB in a person of any age, in a specific household or other comparable setting in which others may have been exposed. An index patient is the patient on which a contact investigation is centred but is not necessarily the source patient
Infant	A child under 1 year of age
Latent tuberculosis infection	A state of persistent immune response to stimulation by Mycobacterium tuberculosis antigens with no evidence of clinically manifest active TB.
MDR TB	TB that is resistant to at least Isoniazid and Rifampicin
Poor Weight Gain	A child with reported weight loss or very low weight for age or underweight or confirmed weight loss more than 5% since the last visit or a flattened growth curve, or a yellow or red mid-upper arm circumference (MUAC)
Presumed TB	A person with symptoms of TB disease
Recipient of Care	For the purposes of this guide a recipient of care is someone receiving TPT care
TB Completion	A TB patient who completed anti-TB treatment without proof of cure (No sputum results are available on at least 2 occasions prior to completion of treatment).
TB Preventive Treatment	The administration of medicine to individuals with latent infection with M. tuberculosis in order to prevent progression to active TB disease
Tuberculosis	The disease state due to Mycobacterium tuberculosis. In this document, commonly referred to as "active" TB or TB "disease"
Tuberculin Skin Test	A skin test to determine past or present infection with the tuberculosis bacterium; based on hypersensitivity of the skin to tuberculin.

1.0 Summary action points in this guide

All adults, adolescents and children living with HIV and household contacts of Pulmonary Bacteriologically Confirmed (PBC) TB patients should be routinely screened for symptoms of active TB disease.

All adults, adolescents & children living with HIV and all household contacts of PBC TB patients, who report any one of the symptoms of current cough, fever, weight loss, or night sweats may have active TB. These individuals should be evaluated for TB.

All adults, adolescents, children, and infants living with HIV with no symptoms of TB are unlikely to have TB and should be offered TB preventive treatment as part of a comprehensive package of HIV care. These also include;

- People living with HIV (PLHIV) that have completed drug-sensitive TB treatment
- Pregnant women living with HIV with a CD4 count <200 or WHO stage III or IV or pregnant women living with HIV who have a history of contact with a PBC TB patient.
- Infants living with HIV <12 months should be offered TB preventive treatment if they have history of contact with a TB patient, and they have no symptoms of TB.

All HIV negative children <5 years of age that are household contacts of PBC TB patients, should be offered TB preventive treatment, if they have no signs & symptoms of TB.

All HIV negative adults, adolescents and children ≥5 years of age that are household contacts of PBC TB patients, should be tested for latent TB infection and offered TB Preventive Treatment if found with latent TB infection, but the unavailability of the tests should not be a barrier to treat people who are judged to be at higher risk.

Either a tuberculin skin test (TST) or interferon-gamma release assay (IGRA) may be used to test for latent TB infection (LTBI).

Latent TB infection (LTBI) testing by TST or IGRA is not a requirement for initiating preventive treatment among people living with HIV or <5-year-old household contacts of TB patients.

Options for TB preventive treatment for adults, adolescents and children include;

- Isoniazid daily for six (6) months.
- Rifapentine/isoniazid combination once weekly for three (3) months may be given as an alternative to isoniazid monotherapy.
- Rifapentine/isoniazid combination once daily for one (1) month may be given as an alternative to isoniazid monotherapy.
- Rifampicin/isoniazid combination once daily for three (3) months may be given as an alternative to isoniazid monotherapy.

2.0 Introduction

2.1 Background

Latent tuberculosis infection (LTBI) means a person has the TB bacteria in their body, but those bacteria have been confined by the immune system and prevented from causing tissue damage that is evidenced by physical signs and symptoms, or radiological signs or laboratory confirmation of TB. Up to one quarter of the world's population is estimated to have LTBI, and the vast majority have no active TB disease and are not infectious, although they are at risk of transition to active TB disease[1]. On average, 5–10% of those infected with the TB germ will develop active TB disease over the course of their lives, usually within the first 5 years after initial infection. The risk for active TB disease after infection depends on several factors, the most important being immunological status. Preventing development of new active TB disease by treatment of latent TB infection is a critical component of the WHO End TB Strategy[1].

Management of LTBI involves a comprehensive package of interventions including: identifying, assessing/evaluating and testing those individuals who should be tested, delivering effective, safe treatment in such a way that the majority of those starting a preventive treatment regimen will complete it with no or minimal risk of adverse events, and monitoring and evaluation of the processes[2].

2.2 Why this guide was updated

The World Health Organization in 2018 & 2020 issued new recommendations for testing & treatment (preventive treatment) of latent TB infection. The recommendations include new at-risk populations, novel tests for latent TB infection and shorter regimens. Furthermore, the Ministry of Health in 2017 & 2018 documented outbreaks of TB disease in congregate places such as schools[3] and prisons[4]. Additionally, the TB notification rate among health workers in 2018/2019 was three times higher than that in the general population[5]. Also, up to 3% of household contacts of drug-resistant-TB patients in Uganda in 2018/2019 were found with TB disease[5]. And whereas there was no national level data on contact tracing among drug-sensitive-TB patients, 3.1% of household contacts in Kampala, Wakiso and Mukono districts in October 2018 to September 2019 were found with active TB disease[6]. Moreover, 32% of HIV deaths were from TB[7] and 40% of TB patients were co-infected with HIV[5]. In addition, the Ministry of Health rolled out differentiated models HIV service delivery including facility-based and community-based models including multi-month ARV refill schedules[8].

Thus, providing preventive treatment to PLHIV and to contacts of infectious TB patients in households, prisons, schools, health centers, etc, would contribute to a reduced TB incidence in those populations and contribute to the goals of the WHO End TB Strategy, the Vision 2040, the National Development Plan, the Health Sector Development Plan and the TB/Leprosy Strategic Plan 2020/2021-2024/2025. Thus, Ministry of Health updated its 2014 isoniazid preventive therapy guidelines to reflect the new recommendations and to address the high incidence of TB among PLHIV and contacts of PBC TB patients including those in congregate settings.

2.3 What is the purpose of this guide?

The purpose of this guide is to provide step wise guidance for health workers on management of latent TB infection.

2.4 What are the objectives of this guide?

The guide focuses on five specific objectives:

1. To provide guidance to health workers on how to screen for active TB among PLHIV and contacts of TB patients
2. To guide health workers to assess for contraindications to TB preventive treatment medicines
3. To direct health workers on how to assess client's willingness and readiness to take TB Preventive Treatment
4. To illustrate to health workers on how to initiate eligible people on TB preventive treatment
5. To show health workers on how to monitor & provide psychosocial support to recipients of care on TB preventive treatment.

2.5 Who can use this guide?

This guide has been designed for doctors, clinical officers, nurses, midwives, and pharmacists, and pharmacy technicians providing HIV & TB prevention, care and treatment services.

2.6 What is the use of this guide?

This guide can be used as a job aide or reference guide for training, health education and research.

2.7 What is the structure of this guide?

The guide is divided into the following sections; summary action points of this guide, at-risk-populations for TPT, algorithms for ruling out active tuberculosis, testing for latent TB infection, treatment options for latent TB infection, follow up of clients on TB preventive treatment, program monitoring & evaluation, the community engagement and the annexes.

3.0 Populations targeted for TB Preventive Treatment

This section describes at-risk populations for whom TB Preventive Treatment is recommended.

3.1 People with elevated risk of progression from infection to TB disease

3.1.1 People living with HIV

3.1.1.1 Adults and adolescents living with HIV

Adults and adolescents living with HIV that are considered unlikely to have active TB disease should receive preventive treatment for TB as part of a comprehensive package of HIV care. TB preventive treatment (TPT) should be given to these individuals irrespective of the degree of immunosuppression including those on antiretroviral treatment (ART), those **previously treated for TB** even if LTBI testing is unavailable.

3.1.1.2 Infants <12 months living with HIV

Infants aged < 12 months living with HIV who are in contact with a TB patient and for whom active TB has been excluded using the TB diagnostic algorithm for children should receive tuberculosis preventive treatment (TPT).

3.1.1.3 Children living with HIV

Children aged ≥ 12 months living with HIV who are considered unlikely to have active TB disease on evaluation should be offered TPT as part of a comprehensive package of HIV prevention and care irrespective of the degree of immunosuppression including those on antiretroviral treatment (ART), regardless of contact with TB.

3.1.1.4 Children living with HIV that have completed TB treatment

All children living with HIV who have successfully completed treatment for drug sensitive TB disease may receive TB preventive treatment.

3.1.1.5 Pregnant women living with HIV

The following HIV positive pregnant women should receive TB Preventive Treatment after ruling out active TB;

(i) those in close contact with a person with active PBC TB disease and
(ii) those with a WHO Stage 3 or 4 event and/or CD4<200.

Note:

- For HIV positive women **on TPT who get pregnant**, continue and complete the TPT and monitor for adverse infant & maternal outcomes.
- For HIV positive pregnant women with no history of close contact with a person with active TB disease, nor those with a WHO Stage 3 or 4 event nor CD4<200, defer TPT until 3 months after delivery.

Key Message

All people living with HIV with no signs and symptoms of TB should be offered TB Preventive Treatment, if they fulfil any of the eligibility criteria outlined above.

3.1.1.6 Other HIV negative at-risk groups

Other HIV negative at-risk groups such as patients initiating anti-TNF treatment, patients receiving dialysis, patients preparing for an organ or hematological transplant and patients with silicosis who have no evidence of TB disease on clinical evaluation, should be offered a test for latent TB infection (TST or IGRA). If they are found with latent TB infection (positive) they should be offered TB preventive treatment.

3.2 People with increased likelihood of exposure to TB disease

3.2.1 Household contacts of pulmonary bacteriologically confirmed TB patients regardless of HIV status

3.2.1.1 Children < 5 years of age who are household contacts of PBC TB patients

All children aged < 5 years who are household contacts of people with bacteriologically confirmed pulmonary TB and who are found not to have active TB on clinical evaluation should be given TB preventive treatment.

3.2.1.2 All children ≥ 5 years of age, adolescents and adults that are contacts of PBC TB patients

All children aged ≥ 5 years, adolescents and adults who are household contacts of people with bacteriologically confirmed pulmonary TB (PBC) who are found not to have active TB on clinical evaluation, should be offered a test for latent TB infection, and those testing positive should be offered TB preventive treatment, but the unavailability of the tests should not be a barrier to treat people who are judged to be at higher risk.

3.2.1.3 People living or working in high-risk situations

All people who live or work in special high-risk situations such as those living in crowded schools or institutions, health workers and prisoners, and who are found not to have active TB by an appropriate clinical evaluation, should be offered a latent TB infection test (TST or IGRA). Those found to have latent TB infection (positive) should be offered TB preventive treatment, but the unavailability of the tests should not be a barrier to treat people who were judged to be at higher risk.

Key Message

All PLHIV, people with history of contact with a PBC TB patient, those living in special high-risk situations and those among the at-risk populations outlined above, should be offered TB Preventive Treatment, if found eligible according to the criteria above.

4.0 Eligibility for TB Preventive Treatment

4.1 Exclusion of Active Tuberculosis

4.1.1 Screen all PLHIV & TB contacts to rule out active TB before starting TB preventive treatment (TPT)

- All people living with HIV should be regularly screened for signs & symptoms of TB disease.
- All HIV negative people with history of contact with PBC TB patients, those living & working in high-risk situations and those among special high-risk populations should be regularly screened for signs & symptoms of TB disease.
- All adults, adolescents & children living with HIV and all household contacts of PBC TB patients, who report any one of the symptoms of current cough, fever, weight loss/poor weight gain, or night sweats may have active TB. These individuals should be evaluated for TB disease.
- All PLHIV ≥ 1 year are eligible to receive TPT if, they are found with no signs or symptoms of TB disease.
- All children < 5 years with history contact with a PBC TB patient are eligible to receive TB Preventive Treatment if, they are found with no signs or symptoms of TB disease.
- All contacts of PBC TB patients ≥ 5 years with no signs or symptoms of TB disease should be tested for latent TB infection, and those that test positive should be offered TB preventive treatment, but the unavailability of the tests should not be a barrier to treat people who are judged to be at higher risk.
- Other people at risk such as prisoners or health workers should be systematically tested for latent TB infection (LTBI) and offered TPT if they are LTBI positive.
- All clients on TB preventive treatment should be screened using the intensified case finding guide at every encounter with a health worker at the health unit or in the community.
- A chest x-ray where easily accessible may be used to rule out active TB disease in PLHIV or contacts of PBC TB patients, people in congregate setting or special high-risk populations.

Key Message

***Screening for TB*:**

- **Is important regardless of whether they have received or are receiving TPT.**
- **Is important regardless of whether they are PLHIV receiving ART.**
- **Is essential to exclude active tuberculosis in every PLHIV or contact of index PBC TB patients prior to starting TB preventive treatment.**
- **Is critical to avoid giving one or two anti-tuberculosis drugs to patients with active TB disease who require a full treatment regimen (4 or more medicines).**

A chest x-ray is desirable, but not a requirement for excluding active TB disease among people living with HIV or contacts of PBC TB patients before initiation of TB preventive treatment.

4.1.1.1 Active TB screening prior to preventive treatment in adults, adolescents and children

4.1.1.1.1. Active TB screening prior preventive treatment in adults, adolescents & children ≥ 5 years

Prior to initiation of TB preventive treatment in all HIV positive & negative adults (including pregnant women), adolescents & children ≥ 5years, screening for the following signs and symptoms of active TB disease should be done:

- Current cough (cough within 24 hours or more)
- Fever
- Weight loss/Poor weight gain
- Profuse night sweats (more than usual sweating)

4.1.1.1.2 Active TB screening prior to preventive treatment in children < 5 years

For children < 5 years of age and living with HIV or < 5-year-old-contacts of PBC TB patients, screen for TB with any one of the following symptoms:

- Poor weight gain [reported weight loss, very low weight for age or underweight or confirmed weight loss more than 5% since the last visit or growth curve flattened; mid-upper arm circumfluence (MUAC) yellow or red]
- Fever
- Current cough (cough within 24 hours or more)

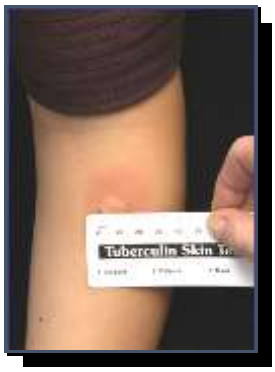
4.2 Testing for latent tuberculosis infection (LTBI)

Either a tuberculin skin test (TST) or interferon-gamma release assay (IGRA) may be used to test for latent TB infection (LTBI). These tests are dependent on the strength of the immune system. That is why they are not a requirement for initiating TPT among PLHIV or < 5-year-old contacts.

Tuberculin skin test (TST)

- 0.1mls of a solution containing 5 units of tuberculin purified protein derivative (PPD) is injected into the inner surface of the forearm through intradermal route.
- It should be administered two (2) or more inches from the elbow, wrist, or any other injection site.
- An elevation of the skin (6 to 10 mm diameter) known as ‘wheal’ is formed
- The patient should avoid scratching or rubbing the area and should keep the site uncovered and clean.
- Documentation of the injection site, date and time of test administration, person placing the test, and product lot number and manufacturer, should be done.
- The reaction starts at 5 - 6 hours, with a peak effect at 48-72 hours after which it begins to subside. The right time to read the test is after 48-72 hrs.

Reading the Tuberculin Skin Test (TST)



- Measure the reaction in 48 to 72 hours.
- Measure the induration (swelling), not the erythema (redness).
- Record the diameter of the reaction in millimeters, not "negative" or "positive".

Interpreting the tuberculin skin test (TST) reaction

A TST is positive when the induration is of diameter 5 mm or more in an HIV positive person and 10 mm or more in an HIV negative person.

False positive TST reaction

Since the TST test has low specificity, low-risk individuals with a positive test may be false positives. TST skin test is false positive when the test is positive in the absence of infection with Mycobacterium tuberculosis.

A false positive may be seen in a person with;

- Previous vaccination with BCG
- An infection with non-tuberculous bacteria
- Improper administration of the test
- Incorrect reading/interpretation of the test

IGRA test may be considered in individuals with prior BCG vaccination, because the result of the IGRA test is not altered by childhood BCG vaccination.

False negative TST reaction

This is inadequate response or no reaction to tuberculin protein in the presence of Mycobacterium tuberculosis infection.

A false-negative reaction may be seen in a person with;

- Inadequate T-cell response or cutaneous anergy secondary to immunosuppression or natural waning
- Recent tuberculosis infection (less than 8 weeks of exposure)
- Old tuberculosis infection (i.e. many years ago) may not be detected by this skin test
- Recent viral illness (for example, chickenpox, measles, etc)
- Improper administration of the test
- Incorrect reading of the test

Interferon-Gamma Release Assay (IGRA)

This is a whole-blood test that measures and compares amount of interferon-gamma (IFN-γ) released by blood cells in response to antigens.

It entails mixing blood samples with antigens from *M. tuberculosis* and from controls.

Interpretation of IGRA test results

IGRA Test	**Results reported as**
QFT-Plus	Positive, negative indeterminate
T-Spot	Positive, negative indeterminate, borderline

Those with a positive IGRA test should be offered TPT after ruling out active TB.

If the IGRA test is indeterminate, repeat the test after 3 weeks.

Who should be tested for LTBI?

All children ≥ 5 years of age, adolescents and adults that are contacts of PBC TB patients who are found not to have active TB on clinical evaluation

People who live or work in crowded schools or institutions, health workers and prisoners who are who are found not to have active TB on clinical evaluation

People among HIV negative at-risk groups for TB such as patients initiating anti-TNF treatment, patients receiving dialysis, patients preparing for an organ or hematological transplant and patients with silicosis who have no evidence of TB disease on clinical evaluation.

Note: Avoid testing of groups that are not at high risk for TB.

Neither TST nor IGRA can be used to diagnose active TB disease nor for diagnostic workup of adults suspected of having active TB.

People living with HIV who have a positive test for LTBI benefit more from preventive treatment than those who have a negative LTBI test. LTBI testing can be used, where feasible to identify such individuals.

33% & 49% of household contacts of TB patients in Uganda are IGRA & TST positive respectively. Whenever feasible, household contacts of PBC TB patients > 5- years with no signs and symptoms of TB should be tested for TB infection with TST or IGRA before being offered TPT.

Key Message

At-risk people that test positive for latent TB infection (TST or IGRA) should be offered TB preventive treatment.
Latent TB infection (LTBI) testing by TST or IGRA is not a requirement for initiating preventive treatment among people living with HIV or < 5-year-old household contacts of TB patients.

4.3 Contra-indications to TB preventive treatment

Do not give TPT if the person has any one of the following conditions. The health worker should rule out the conditions below before starting TB preventive treatment.

- Person has symptoms of TB, or a TB diagnosis or is on TB treatment.
- History of MDR-TB treatment
- Acute or chronic liver disease (symptoms of liver disease may include loss of appetite, nausea, vomiting, right upper quadrant abdominal pain, dark urine, pale stools, yellow eyes)
- Alcoholism (alcohol dependence)
- Known or suspected hypersensitivity to isoniazid, rifamycin or other TPT medicines
- History of convulsions
- History of psychosis
- Moderate or severe peripheral neuropathy [burning sensation, pins & needles (tingling) or numbness of the hands or feet (glove & soaks syndrome)]
- Concomitant medication:
    - Anti-convulsant: phenytoin, carbamazepine
    - Anti-fungal medicine: ketoconazole, itraconazole.
    - Anti-depressants: selective serotonin re-uptake inhibitor antidepressants (e.g. citalopram, fluoxetine, paroxetine, sertraline)
    - Anti-coagulant: warfarin
    - Others: Theophylline, disulfiram

Key Message

Key inclusion criteria for TPT are;

a) **Absence of symptoms and signs of active TB disease**
b) **Absence of contraindications to TPT medicines**

If a person does not have any of the above contra-indications prepare him or her for TB preventive treatment.

5.0 Treatment of latent TB infection (TB preventive treatment)

Isoniazid monotherapy for 6 months (6H) is recommended for TB preventive treatment in both adults and children.

- Isoniazid may be administered with pyridoxine and cotrimoxazole in a fixed doze combination called Q-TIB to PLHIV new on ART, 0-15 years, pregnant & lactating, with WHO clinical stage 3 or 4, or with suspected ART treatment failure.

Rifapentine and isoniazid once weekly for 3 months (3HP) may be offered as an alternative to 6 months of isoniazid monotherapy as preventive treatment for both adults, adolescents and children ≥ 2 years.

Rifapentine and isoniazid once daily for 1 month (1HP) may be offered as an alternative to 6 months of isoniazid monotherapy as preventive treatment for people 13 years or older. 1HP may be used where a shorter duration is required such as among prisoners, patients awaiting start of anti-TNF treatment or preparing for transplantation. It is more costly & has more adverse events than 3HP.

Rifampicin and isoniazid once daily for 3 months may be offered as an alternative to 6 months of isoniazid monotherapy as preventive treatment for children <15 years.

Switching of TB preventive treatment regimens is not recommended. The health worker should not start a client on any option of TB preventive treatment unless there is sufficient stock of the particular regimen at the health facility for the client to complete treatment.

Preferred options for TB Preventive Treatment

TPT medicine option	Target population (active TB ruled out)
Isoniazid monotherapy	1. Contacts of PBC TB patients < 5 years of age 2. PLHIV on protease inhibitors 3. Pregnant women living with HIV with; a. history of contact with a TB patient b. CD4 < 200 cells/ml c. WHO stage 3 or 4
Isoniazid/co-trimoxazole/pyridoxine (Q-TIB)	PLHIV; a. new (<12 months) in care b. CD4 < 200 cells/ml c. WHO stage 3 or 4
Rifapentine/Isoniazid	1. PLHIV a. ≥ 2 years of age b. not on protease inhibitors (PI) 2. Contacts of PBC TB patients ≥ 5 years
Isoniazid/Rifampicin	1. < 15-year old CLHIV or < 5 PBC TB contacts

Co-administration of ART and TPT

TPT regimen for adolescents ≥ 15 years and adults on ART		
ARV Drug Regimen	**TPT regimen Options**	**Rationale for TPT regimen**
TDF or AZT or ABC + 3TC + DTG	Isoniazid (6H) or Isoniazid-Rifapentine- based regimens	No dose adjustment of DTG with Isoniazid-Rifapentine-based regimen
TDF or AZT or ABC + 3TC+ ATV/r TDF or AZT or ABC + 3TC + LPV/r	Isoniazid (6H)	Co-administration of rifamycins (such as rifampicin) with protease inhibitors has been associated with reduction in plasma levels of protease inhibitors.
TDF or AZT or ABC + 3TC+EFV	Isoniazid (6H) or Isoniazid/Rifapentine- based regimens	A higher dose of EFV, i.e. 600mg is recommended if Isoniazid/Rifapentine-based regimen is used
For children < 15 years on ART		
ARV Drug Regimen	**TPT regimen Options**	**Rationale for TPT regimen**
ABC or AZT +3TC+LPV/r ABC or AZT+3TC +ATV/r	Isoniazid (6H)	Co-administration of rifamycins (such as rifampicin) with protease inhibitors has been associated with reduction in plasma levels of protease inhibitors.
ABC or AZT+ 3TC+DTG	Isoniazid (6H) or Rifampicin/ Isoniazid (3RH) or Isoniazid/Rifapentine- based regimens ***(for children aged > 2 years)***	Double the dose of DTG if 3RH is used Lack of data to support the use of Rifapentine among children aged < 2 years.
ABC or AZT +3TC+ EFV	Isoniazid (6H) or Rifampicin/ Isoniazid (3RH) or Isoniazid/Rifapentine- based regimens ***(for children aged > 2 years)***	Lack of data to support the use of Rifapentine among children aged < 2 years.
ABC or AZT + 3TC+RAL	Isoniazid (6H) or Rifampicin/ Isoniazid (3RH) or Isoniazid/Rifapentine- based regimens ***(for children aged > 2 years)***	Double the dose of RAL if 3RH is used Lack of data to support the use of Rifapentine among children aged < 2 years.

Timing of TPT in children

Co-administration of DTG and TPT

Contacts of known TB patients: Initiate TPT immediately (or within 2 weeks of ART initiation if newly identified HIV positive)

Virally suppressed children currently on NNRTI: Initiate TPT as soon as possible and complete course before ART optimization.

Virally suppressed children currently on PI or DTG: Initiate TPT if the child has been on ART for at least 3 months.

Newly initiating ART: Initiate TPT prophylaxis after 3 months on ART. Although studies have found that the co-administration of DTG and INH is well tolerated, liver injury is a recognized adverse effect of each of these drugs. Since there is potential for hepatotoxicity, the following are recommendations for co-administration.

- **New Patient:** For newly identified patients, start on TLD with active symptomatic monitoring for adverse events (Chapter 6). Initiate TPT after 3 months to allow time for potential unmasking of TB and to monitor any toxicities that may arise from DTG, prior to initiation of TPT.

- **For stable patients already transitioned to DTG**: If patient has been on TLD for 3 months or more, initiate TPT immediately.

If person is **already on TPT** and a non-DTG based regimen: Optimization to DTG will be deferred until completion of TPT.

Stable patients for DTG transition and have not received TPT before:

In case TLE stock is available: First complete TPT and then transition to DTG.

In case TLE stock is not available: Transition to DTG and initiate TPT after 3 months.

Note: All patients receiving INH prophylaxis and DTG+INH should be closely monitored for signs and symptoms of liver toxicity as specified in the pharmacovigilance guidelines.

5.1 TB preventive treatment dozing chart

Medicine frequency & duration	Formulation	Dose of TPT medicine (mgs)	Dose/ weight	Recommended number of tablets per body weight in kilograms								
3HP (once weekly rifapentine plus isoniazid for 3 months)	Fixed Doze Combination (FDC) Tablet	Rifapentine 300mg/ Isoniazid 300mg		**3–5.9 kgs**	**6–9.9 Kgs**	**10–15 kgs**	**16–23 kgs**	**24–30 kgs**	**31-34 kgs**	**35-45 kgs**	**>45 kgs**	
						1	1.5	2	2.5	3	3	
	Single medicine tablet	Pyridoxine 25mg/day				1	1	1	1	1	1	
6H (daily isoniazid for 6 months)				**3–5.9 kgs**	**6–9.9 Kgs**	**10–13.9 kgs**	**14–19.9 kgs**	**20–24.9 kgs**	**25-34.5 kgs**	**35-44.5 kgs**	**45-49.9 kgs**	**≥50 kgs**
	Single medicine tablet	Isoniazid 100 mg	<10 years 10mg/kg	0.5	1	1.5	2	2.5				
			> 10 years 5mg/kg						1.5	2	2.5	
		Isoniazid 300 mg	≥ 10 years 5mg/kg									1
	Single medicine tablet	Pyridoxine 25 mg		0.5	0.5	1	1	1	1	1	1	1
3RH (daily Rifampicin Isoniazid for 3 months)				**< 4 kgs**	**4-7 Kgs**	**8-11 kgs**	**12-15 kgs**	**16–24 kgs**	**25-32 kgs**	**33-39 kgs**	**40-54 kgs**	
	Fixed Doze Combination (FDC) Tablet	RH 75mg/50mg	< 10 years R - 15mg/kg H - 10mg/kg	0.5	1	2	3	4	4			
		RH 150mg/75mg	≥ 10 years R - 10mg/kg H - 5 mg/kg							2	3	
	Single medicine tablet	Pyridoxine 25mg/day		0.5	1	1	1	1	1	1	1	

TB preventive treatment dozing chart continued

Medicine frequency & duration	Formulation	Dose of TPT medicine (mgs)	Dose/ weight	Recommended number of tablets per body weight in kilograms		
					35-45 kgs	**>45 kgs**
1HP (once daily rifapentine plus isoniazid for 1 month - 28 days) for adolescents >13 years & adults	Single medicine tablets	One Isoniazid (H) 300mg tablet	Regardless of weight band		1	1
		4 Rifapentine (P) 150mg tablets / day			4	4
		Pyridoxine 25mg/day			1	1

5.2 Managing adverse events

While providing TB preventive treatment side effects might occur. Most of these reactions are minor and occur rarely. Close monitoring and patient education are needed for early detection and management of side effects. The risk for adverse reactions during preventive treatment should be minimized by screening patients for risk factors for adverse reactions.

Table on management of adverse events

Management of adverse events following treatment with rifapentine/isoniazid (HP)

Adverse event	When to stop 3HP or 1HP
Flu-like syndrome (attacks of fever, chills and malaise, sometimes with headache, dizziness or bone pain)	If moderate to severe symptoms, consider alternative TPT options without a rifamycin (such as 6H)
Drug-associated fever only	If fever > 39^{o}C after previous episode of drug-associated fever
Persistent nausea, frequent vomiting and/or persistent episodes of unformed watery stools	If there is nausea, vomiting or diarrhoea which requires aggressive rehydration
Cutaneous reactions	If there are extensive bullous lesions/ulceration of mucous membranes/Stevens Johnson or toxic epidermal necrolysis, contact a specialist and use steroids
Other hypersensitivity reactions (hypotension, acute bronchospasm, conjunctivitis, thrombocytopenia)	Assess the clinical severity of the symptoms and if severe consider alternative TPT options without a rifamycin (6H)
Hepatitis (early symptoms of weakness, fatigue, loss of appetite, persistent nausea)	**STOP** if there is presence of aforementioned symptoms*

Management of adverse events due to isoniazid following 3HP, 1HP or 6H LTBI treatment

Psychosis	**STOP** 3HP, 1HP or 6H and provide pyridoxine therapy. Do psychiatric evaluation and manage accordingly.
Seizures	**STOP** 3HP, 1HP or 6H. Do clinical evaluation. Consider pyridoxine therapy 100-200mgs daily, till symptoms resolve.
Peripheral neuropathy [numbness, tingling/pins & needles or burning sensation]	Prescribe vitamin B6 (pyridoxine) 100-200mg daily till symptoms subside, then continue vitamin B6 12.5mgs in <6kgs and 25mg in ≥6kg children, adolescents and adults daily to prevent recurrence
Arthralgia	Ibuprofen should be provided 4-10mg/kg/day. Three times daily.
Dizziness	Encourage oral fluids.
Red, orange, or brown discoloration of skin, tears, sweat, saliva, urine, or stools	Reassure patient, that discoloration is due to medicine and is not harmful.

*At health units where monitoring of liver function tests is feasible, **STOP** if.

- ALT/AST is ≥ 5 times the upper limit of normal in the absence of symptoms
- ALT/AST is ≥ 3 times the upper limit of normal in the presence of symptoms

7.0 TPT initiation & follow up

3.7 When and how to start TB preventive treatment

Start TB preventive treatment	When a client has been screened and active TB excluded. When contraindications to TB preventive treatment have been excluded. When the client is well counseled and willing to start TB preventive treatment.

The health workers should use the **5 A's** to prepare eligible people for TB preventive treatment.

Assess for	Signs and symptoms of active TB. Use of other medications. Signs and symptoms of liver disease, peripheral neuropathy & mental illness. Heavy alcohol consumption.
Advise	Give information about benefits of TB preventive treatment, side effects, regimen and duration of TB preventive treatment, in preparation for self-management. This includes treatment advice and counseling.
Agree	Ensure recipient of care understands, wants and agrees to the TB preventive treatment plan. This is the basis for forming a partnership with the recipient of care & supporting good self-management while on TB preventive treatment.
Assist	Provide help to the recipient of care in terms of skills to adhere to TB preventive treatment & overcome barriers. Treatment buddies offer added benefit for adherence.
Arrange	Prepare follow up visits according to the schedule in table 1 & 2 below. Record initiation date in the TPT client held card, TPT care card, TPT register, HIV care/ ART card, and ART registers. Record appointments in the TPT register & appointment book Make linkages and referrals for necessary care & support.

Where to provide TB preventive treatment

HIV clinic	HIV infected children, adolescents and adults.
Mother-Baby Care Point	HIV infected pregnant & lactating mothers and their HIV positive children under 2 years.
TB clinic	Contacts of TB patients.

TPT Initiation and follow up for PLHIV

A qualified health worker screens client for active TB & contraindications to TPT, and initiates those that are eligible & ready on TB Preventive Treatment. PLHIV will receive their TPT refill along with their ARVs.

Table 1: TPT follow up schedule for HIV positive recipients of care by DSD model

DSD Model	Interval of TPT medicine refills & adherence assessment	Monitoring of TB symptoms & adverse events			
		Who	Method	Interval	
				Initial	Continuous
Facility Based Individual Management	Monthly	Client	Self-report	As soon as new side effect occurs	
		Health worker	Clinical evaluation	Monthly for unstable & stable clients	
Facility Based Group	Monthly	Client	Self-report	As soon as new side effect occurs	
		Health worker	Phone call	Two-weekly for 1st month	Monthly
			Clinical evaluation		Monthly
Fast Track Drug Refills	3-monthly	Client	Self-report	As soon as new side effect occurs	
		Health worker	Phone call	Two-weekly for 1st month	Monthly
			Clinical evaluation		3-monthly
Community Client Led ART Delivery (CCLAD)	3-monthly	Client	Self-report	As soon as new side effect occurs	
		CCLAD Leader	Phone call	Two-weekly for 1st month	Monthly
			CCLAD meeting or home visit or phone call	Monthly	
Community Drug Distribution Point	3-monthly	Client	Self-report	As soon as new side effect occurs	
		Health worker	Phone call	Two-weekly for 1st month	Monthly
			Community clinical evaluation		3-monthly

If a client gets any adverse event, they should immediately contact the health facility.

Pre-packing of TPT medicines

TPT medicines should be pre-packed with ARVs the day before the client visits the health unit or CDDP.

Table 2: TPT Follow up for HIV negative contacts of TB patients

Age group	TPT follow up interval						
	1st month		2nd month	3rd month	4th month	5th month	6th month
	1st two weeks	2nd two weeks					
Adults, adolescents and children ≥ 5-years	x	x	X	x	x	X	x
Children < 5-years	x	x	X	x	x	X	X

What to do during follow-up visits

- Look for any contraindications to TB Preventive Treatment.
- Look out for adverse effects of TB Preventive Treatment.
- Screen for symptoms of active TB.
- Assess adherence and categorize as good (≥95%), fair (95-85%) or poor (<85%).
- Record prescription and medicines dispensed at every visit.

Managing TB preventive treatment interruptions:

6H	3HP	3RH	1HP
If interruption ≤ **1-month,** counsel and reassure client to continue TB preventive treatment. Compensate for lost days.	If interruption is **within 3 days** stick to same day of the week e.g. Sunday. If you missed Sunday take the medication within 3 days and go back to your normal Sunday routine.	If interruption is ≤ **1 month,** counsel and reassure client to continue TB preventive treatment. Compensate for lost days	If interruption ≤ **1-23 days,** counsel and reassure client to continue TB preventive treatment. Compensate for lost days.
If interruption **> 1 month** Reassess, rule out active TB, seek client's consent and cooperation for resuming TB preventive treatment. Resume TPT and compensate for lost days.	If interruption **> 3 days;** Take your next doze on your usual day: This means you have skipped a week and you will need to continue the medication for an additional week.	If interruption **> 1 month,** reassess, rule out active TB, seek client's consent and cooperation to resume TB preventive treatment. Restart 3-months of TPT.	If interruption **> 23 days r**eassess, rule out active TB, seek client's consent and cooperation to restart TPT all over again.
6H should be **completed** within 9 months or else TPT should restarted all over again.	3HP should **completed** within 4 months or else TPT should restarted all over again.	3RH should be **completed** within 4 months or else TPT should restarted all over again.	

When to stop TB preventive treatment

- When client develops active TB.
- When severe adverse events to TB preventive treatment medicine occur.
- When client develops conditions that contraindicate TB preventive treatment.
- After completion of a full course of TB preventive treatment.

If client develops TB symptoms while on preventive treatment

- Evaluate for TB disease.
- If the client is confirmed to have TB disease, **STOP** TB preventive treatment.
- Counsel and initiate on standard appropriate first or second-line TB regimen.

8.0 Community engagement for TPT

Engagement of all stakeholders is key to the success of TB prevention. The district health team should consider the following to improve uptake of TB Preventive Treatment;

WHO the stakeholders are?

They include;

- Patient groups including expert patients or peers
- Religious leaders
- Cultural leaders
- Local council leaders, opinion leaders and political leaders
- Civil Society Organizations
- Other health workers, village health teams, community health extension workers, and linkage facilitators

HOW to engage the community?

Through;

- Mass community outreaches e.g. family health days
- Community dialogues e.g. house to house or at religious & cultural gatherings
- Mass media e.g. community radios, FM stations, & TV shows
- Distribution of Information Education Communication materials
- School health programmes
- Interpersonal communication e.g. SMS, one on one talks, etc.
- Social media

WHERE to find the stakeholders?

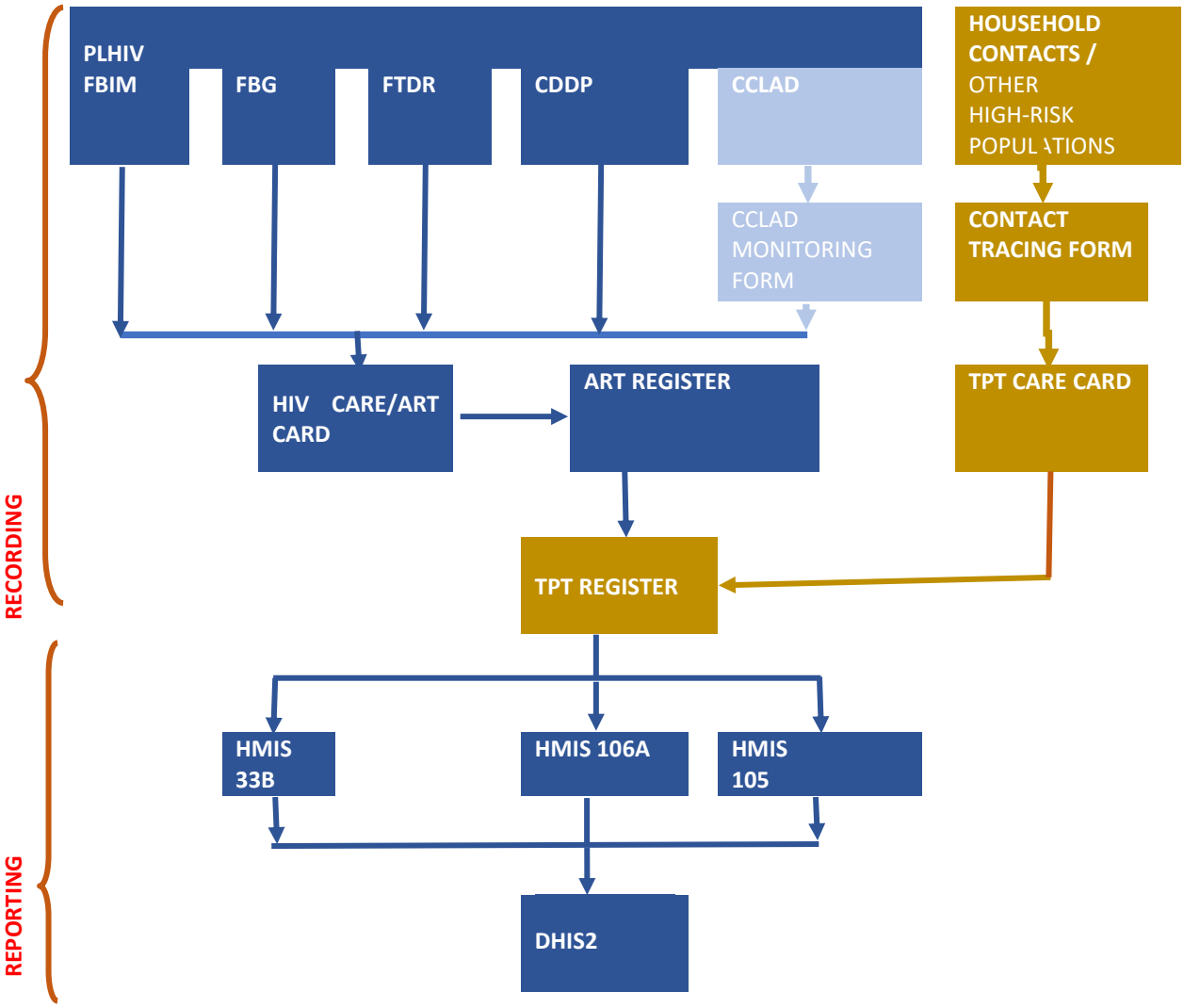
- Schools, slums, fishing villages, school associations, churches, mosques, etc.

The reader should refer to the TB community guidelines and communication strategy for further guidance on the engagement strategies.

9.0 TPT monitoring & evaluation

The TB preventive treatment intervention will be monitored to track coverage and quality of implementation. Record using TPT client held and TPT care card; routine reporting, aggregation, analysis & dissemination of data; tracking of performance against targets; and data quality reviews will constitute the processes involved in monitoring & evaluation.

TPT data flow chart



Indicators for monitoring the TB Preventive Treatment

No.	Indicator		Data source	Purpose
1	Proportion of children < 5 years who are household contacts of TB patients who were contact screened	**Numerator:** Total number of children < 5 years who are household contacts of TB patients who were contact screened during the reporting period	Unit TB register	Measures capacity of the health facility to do contact screening among < U5s
		Denominator: Total number of children < 5 years who are household contacts of TB patients during the reporting period	Unit TB register	
2	Proportion of children < 5 years who are household contacts of TB patients who are eligible for TB preventive treatment who have started treatment	**Numerator:** Total number of children < 5 years who are household contacts of TB patients who started TB preventive treatment during the reporting period	Unit TB register	Measures capacity of the HF to provide TPT for eligible U5 contacts
		Denominator: Total number of children < 5 years who are household contacts of TB patients who are eligible for TB preventive treatment during the reporting period	Unit TB register	
3	Proportion of people living with HIV, newly enrolled in HIV care and started on TB preventive treatment	**Numerator:** Total number of eligible living with HIV newly enrolled in HIV care who started TB preventive treatment during the reporting period	ART register	Measures capacity of the health unit to initate TPT among eligible new PLHIV
		Denominator: Total number of eligible people newly enrolled in HIV care during the reporting period	ART register	
4	Proportion of eligible individuals in at-risk populations tested for LTBI	**Numerator:** Total number of eligible individuals in at-risk populations tested for LTBI during the reporting period	Laboratory register	Measures coverage of LTBI testing among at-risk populations
		Denominator: Total number of individuals in at-risk populations who were eligible for LTBI testing during the reporting period	Unit TB register	
5	Proportion of individuals in at-risk populations with positive LTBI test who are eligible for TB preventive treatment and who have started treatment	**Numerator:** Total number of LTBI positive individuals in at-risk populations started TB preventive treatment during the reporting period	TPT register	Measures capacity of the health unit to initate treatment among at-risk populations eligible for TB preventive treatment
		Denominator: Total number of individuals in at-risk populations with positive LTBI test who are eligible for TB preventive treatment during the reporting period	Laboratory register	

Indicators for monitoring the TB Preventive Treatment continued

No.	Indicator		Data source	Purpose
6	Proportion of eligible individuals in at-risk populations with a positive LTBI test who started TB preventive treatment and completed	**Numerator:** Total number of eligible individuals in at-risk populations who completed TB preventive treatment during the reporting period	TPT register	Measures capacity of the health unit to ensure that individuals in at-risk populations adhere to the full course of treatment
		Denominator: Total number of eligible individuals in at-risk populations with a positive LTBI test due to complete preventive treatment during the reporting period	TPT register	
7	Proportion of eligible PLHIV who completed a course of TB preventive treatment	**Numerator:** Total number of eligible PLHIV who completed a course of TB preventive treatment during the reporting period	ART register	Measures capacity of the health unit to ensure that PLHIV adhere to the full course of treatment
		Denominator: Total number of eligible PLHIV who were expected to complete a course of TB preventive treatment during the reporting period	ART register	
8	Proportion of children < 5 years who are household contacts of TB patients who have completed a course of TB preventive treatment	**Numerator:** Total number of children < 5 years who are household contacts of TB patients who have completed a course of TB preventive treatment during the reporting period	TPT register	Measures capacity of the health unit to ensure that children < 5 years who are household contact of TB patients adhere to the full course of treatment
		Denominator: Total number of children < 5 years who are household contacts of TB patients who were due to complete a course of TB preventive treatment during the reporting period	TPT register	
9	TB notification rate in at-risk population	Total number of newly notified TB patients in at-risk population during the reporting period	Unit TB register	Measures the impact of the programme on the incidence of TB in at-risk population
		Total number of individuals in at-risk population	Population specific register or census report	

References

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2. Latent Tuberculosis infection. Updated and consolidated guidelines for programmatic management, 2018.

3. RK Majwala et al, 2018. Tuberculosis disease outbreak in a secondary school in Mukono District, Central Uganda, October 2017, 49th UNION Conference abstract book, page 390.

4. Uganda Prisons Services Quarterly HMIS 106a Report, Oct-Dec 2019.

5. National TB/Leprosy Programme Annual Report 2018/2019.

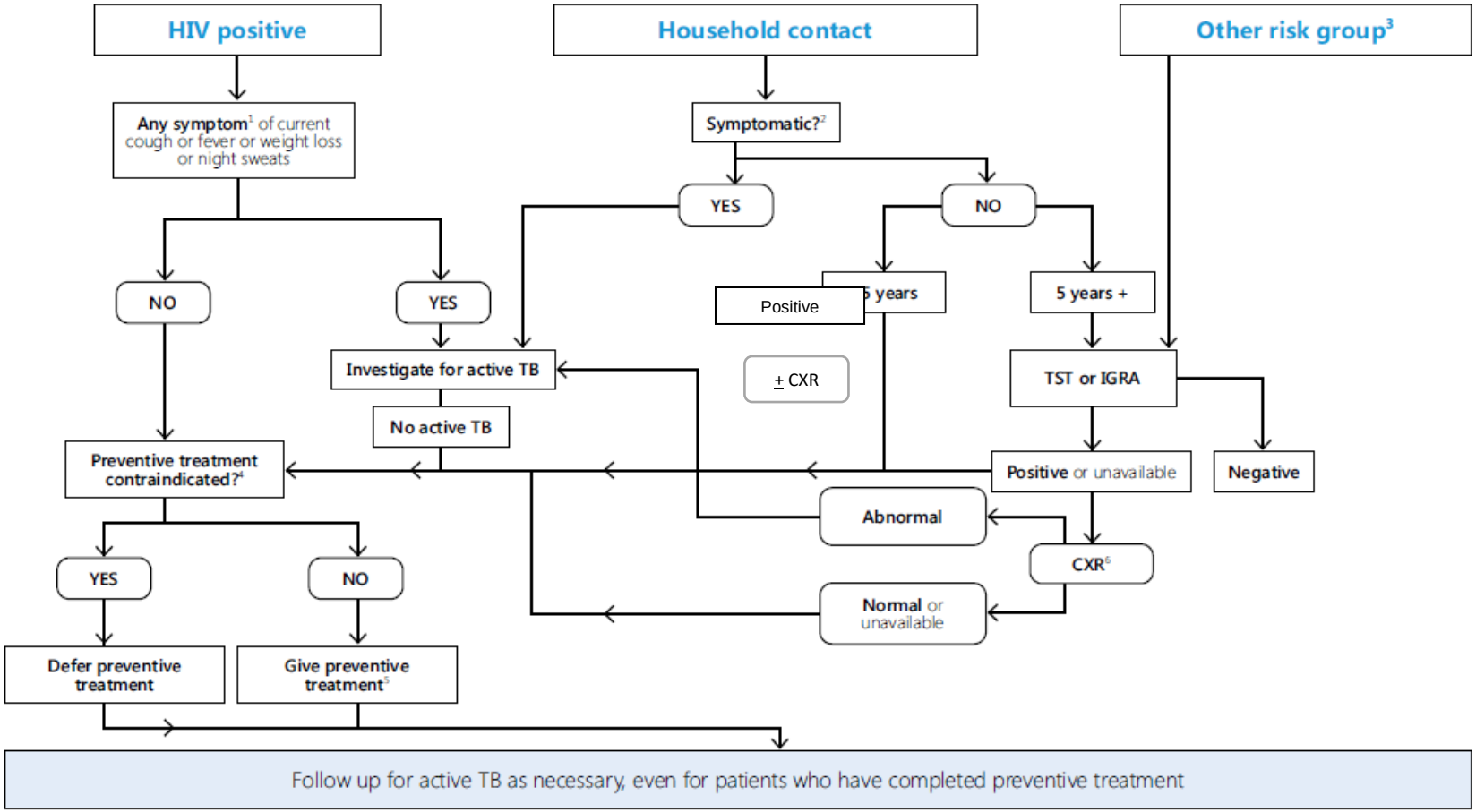
6. USAID Defeat TB Quarterly Report, Oct-Dec 2019.

7. WHO 2018 TB/HIV Fact Sheet.

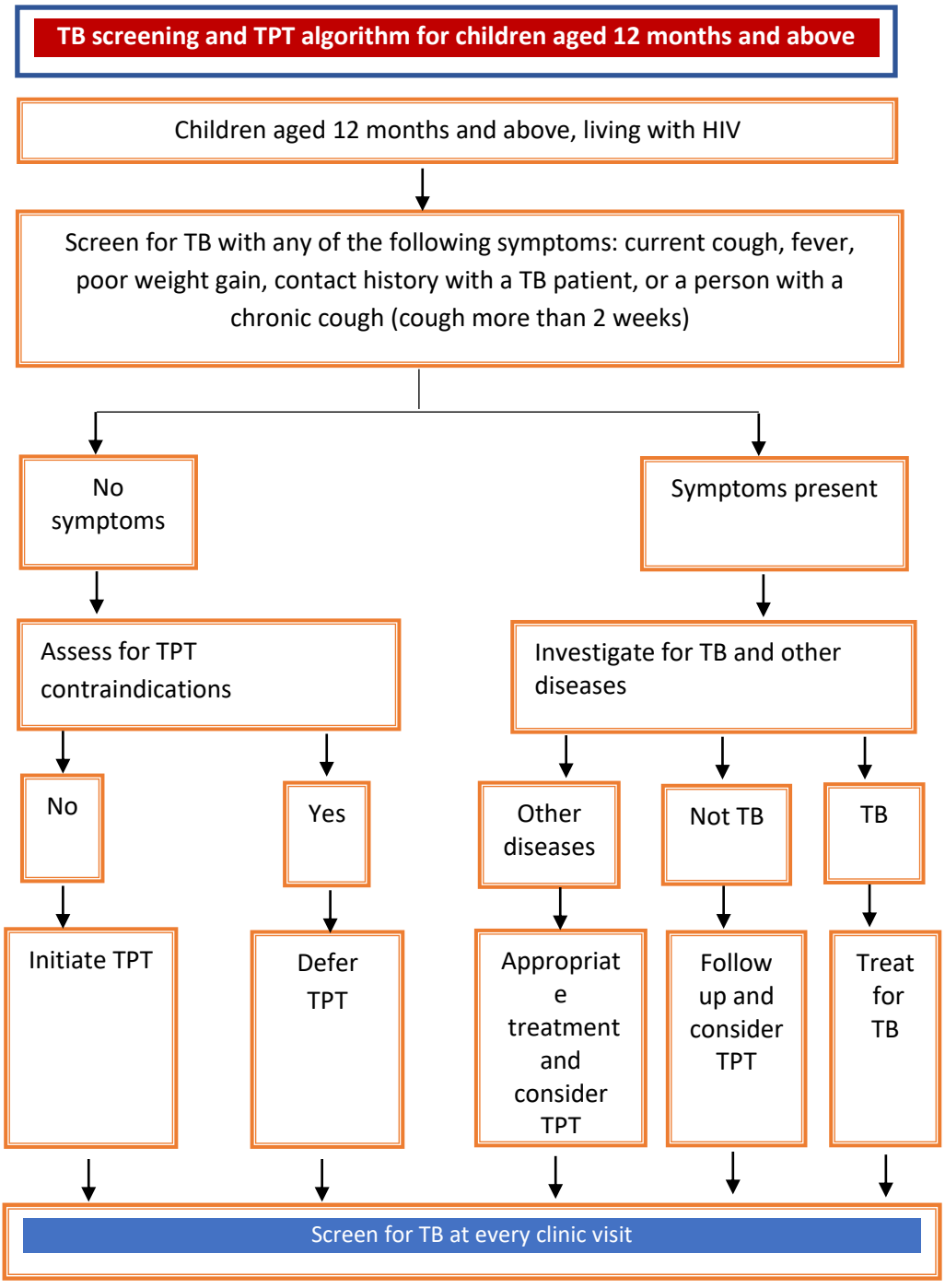
8. MOH/ACP, 2017. Implementation Guide for Differentiated Service Delivery Models of HIV Services in Uganda.

Annexes

Annex 1: TPT algorithm



Annex 2: TPT algorithm for CLHIV



Annex 2: Screening tool for TB

This SOP is to guide health workers offering HIV care to screen PLHIV for active TB and offer TB Preventive Treatment to those without presumptive or active TB

STEP 1: The health care provider conducting the assessment asks the following questions:

A). FOR ADULTS AND ADOLESCENTS

S/n	Symptoms	Yes (tick)	No (tick)
1.	Has the client been coughing within the last 24 hours or more?		
2.	Does the client have fever?		
3.	Does the client have noticeable weight loss?		
4.	Does the client report profuse night sweats more than usual?		

B). FOR CHILDREN 11 YEARS AND BELOW

S/n	Symptoms	Yes (tick)	No (tick)
1.	Has the child been coughing within the last 24 hours or more?		
2.	Does the child have fever? ***(confirm by taking temperature)***		
3.	Does the child have weight loss or poor weight gain?		
4.	Has the child had contact with an adult with pulmonary Tuberculosis disease or chronic cough?		

****The health worker is encouraged to always conduct physical examination***

ACTION POINTS:

- If **"Yes" to any one of the above,** investigate further for possible active TB disease, **DO NOT GIVE TB preventive treatment**.
- If **"No" to all questions, go to step 2**

STEP 2: Assess for contraindication to TB preventive treatment

S/n	Contraindication	Yes (tick)	No (tick)
1.	Has the client got known or suspected hypersensitivity to isoniazid or a rifamycin?		
2.	Has the client got any of the following symptoms of active hepatitis (nausea, vomiting, fatigue, right upper abdominal pain, dark/yellow urine, pale stools, yellow eyes or mucosa)?		
3.	Does the client abuse alcohol?		
4.	Does the client have history of convulsions?		
5.	Does the client have history of mental illness?		
6.	Does the client have peripheral neuropathy (burning sensation or numbness of the limbs)?		
7.	Is the client currently taking any of the following medications: oral ketoconazole or itraconazole? phenytoin, carbamazepine, warfarin, theophylline, disulfiram, selective serotonin re-uptake inhibitor antidepressants (e.g. citalopram, fluoxetine, paroxetine, sertraline)		

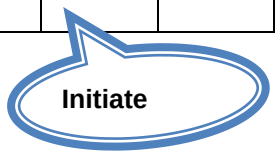
ACTION POINT:

- If **"Yes" to any one of the above,** investigate further for cause, **DO NOT GIVE TB preventive treatment, RE-assess client after 3 months.**
- **If "No" to all questions, go to step 3.**

STEP 3: Assess client's willingness to start TB preventive treatment

S/N	Question	Yes (tick)	No (tick)
1.	Does the client show willingness to start TB preventive treatment?		

ACTION POINT:



- If **"Yes" to the above,** Start TB preventive treatment
- If **"No" to the above, reassess client during the next visit (starting from STEP 1).**

STEP 4: Recording of information above

For contacts of TB patients, record this information in the TPT client's card, TPT register; this information should then be transferred to the unit TB register.

For PLHIV, record this information in the comprehensive HIV/ART card; this information should then be transferred to the ART & TPT registers.

Annex 3: Screening tool for Active Pharmacovigilance

To be placed in the recipient of care's file to be used to screen for side effects of TLD/DTG or INH/TPT at the triage point

Recipient of Care's (RoC) names…… Patient clinic #. ……..

Sex Age Medication (Tick) ☐ DTG based regimen ☐ INH/TPT ☐ DTG based regimen and INH/TPT

Date of assessment

Since you began taking the NEW medication (TLD/DTG or INH/TPT), have you noticed any changes in the following? (Ensure to ask about all side effects)
Actions to take:

- Record any side effects present & refer (RoC) to clinician to manage them.
- For females on/due for DTG, record if pregnant and refer to clinician to manage.

Month		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**Remarks**
1	**Neuropsychiatric side effects.** Does the client have any of the following (Y/N)? (Bad Dreams, Trouble sleeping/ insomnia, headaches, Anxiety or nervousness, change in memory, Change in mood)? *Younger children: Ask for irritability (in addition to the above symptoms)*													
2	**Hepatotoxicity.** Does the client have any of the following (Y/N)? (loss of appetite, nausea, vomiting, right upper quadrant abdominal pain, pale stools, yellow urine or eyes).													
3	**Peripheral Neuropathy.** Does the client have any of the following in the hands or feet (Y/N)? (Numbness, tingling, burning sensation). If any is present, record side effect in patients' file and refer to clinician. *Younger children: Ask for pain in hands and feet, regression in motor milestones - refusal to crawl, walk or run, reduced playfulness (in addition to the above symptoms)*													

4	**Hyperglycemia or diabetes.** Does the client have any of the following (Y/N)? (Increased appetite, increased thirst, and excessive urination). *Younger children: Ask for irritability (in addition to the above symptoms)*														
5	**Other Abdominal symptoms.** Does the client have any of the following (Y/N)? (Diarrhea, generalized abdominal pain).														
6	**Skin rash.** Does the patient have any new skin rash (Y/N)?														
7	**Musculoskeletal symptoms.** Does the client have any of the following (Y/N)? (Muscle or joint aches, tiredness).														
8	**General SEs.** Does the client have any of the following (Y/N)? (fever, body swelling)														
9	**Other side effect (Please specify): _____**														
	For Females on DTG, review LNMP to rule out pregnancy.														
10	**Liver Function Tests**	**Alanine Transaminase (ALT)**													
		Aspartate Aminotransferase (AST)													
Send a report on any side effect identified to national drug authority (NDA)															

Annex 5: Community Client Led ART Delivery (CCLAD) Monitoring Form

HMIS ACP 010 COMMUNITY CLIENT LED ART DELIVERY (CCLAD) MONITORING FORM

Health Facility Name:..Level...................... District:............................ Subcounty:........................... Parish...............................

CCLAD Group Code	GP Code	Unique Identifier for group members who picked drugs	group member unique identifier		Name of attending Health Worker	Name of attending Health Worker			Next Appointment Date:		DD/MM/YYYY
1	2	3			4		5				
Group Member Unique Identfier (Serial #)	Age	Facility Drug Refill Details	Date		Drug Refill Accountability		Community Pre-drug Pick-up Meeting (Assessment) Date				DD/MM/YYYY
Patient Clinic #(ART#)											
Patient Initials	Sex	Drugs given	# of Pills	# of Days	Date drugs received by Patient	Patient Signature	Patient Status	TB Status	# of pills returned	Preg./FP Status (Use codes)	MUAC
Group Unique Identifier (Serial #)	Age	ARVs Drugs			DD/MM/YYYY				ART		
Patient Clinic #(ART#)		CTX/Dapsone							CTX/Dapsone		
Patient Initials	Sex	TB Drugs							TB Drugs		
Group Unique Identifier (Serial #)	Age	ARVs Drugs			DD/MM/YYYY				ART		
Patient Clinic #(ART#)		CTX/Dapsone							CTX/Dapsone		
Patient Initials	Sex	TB Drugs							TB Drugs		
Group Unique Identifier (Serial #)	Age	ARVs Drugs			DD/MM/YYYY				ART		
Patient Clinic #(ART#)		CTX/Dapsone							CTX/Dapsone		
Patient Initials	Sex	TB Drugs							TB Drugs		
Group Unique Identifier (Serial #)	Age	ARVs Drugs			DD/MM/YYYY				ART		
Patient Clinic #(ART#)		CTX/Dapsone							CTX/Dapsone		
Patient Initials	Sex	TB Drugs							TB Drugs		
Group Unique Identifier (Serial #)	Age	ARVs Drugs			DD/MM/YYYY				ART		
Patient Clinic #(ART#)		CTX/Dapsone							CTX/Dapsone		
Patient Initials	Sex	TB Drugs							TB Drugs		
Group Unique Identifier (Serial #)	Age	ARVs Drugs			DD/MM/YYYY				ART		
Patient Clinic #(ART#)		CTX/Dapsone							CTX/Dapsone		
Patient Initials	Sex	TB Drugs							TB Drugs		
Group Unique Identifier (Serial #)	Age	ARVs Drugs			DD/MM/YYYY				ART		
Patient Clinic #(ART#)		CTX/Dapsone							CTX/Dapsone		
Patient Initials	Sex	TB Drugs							TB Drugs		
Group Unique Identifier (Serial #)	Age	ARVs Drugs			DD/MM/YYYY				ART		
Patient Clinic #(ART#)		CTX/Dapsone							CTX/Dapsone		
Patient Initials	Sex	TB Drugs							TB Drugs		
Group Unique Identifier (Serial #)	Age	ARVs Drugs			DD/MM/YYYY				ART		
Patient Clinic #(ART#)		CTX/Dapsone							CTX/Dapsone		
Patient Initials	Sex	TB Drugs							TB Drugs		

Patient status codes
1 - Attended Community Assessment,
2 - Missed Community Assessment
3 - Dead
4 - Returned to health facility

TB Status codes
1- No signs
2- Presumptive TB (Cough for more than 2 weeks, Evening fevers, Night sweats, Loss of appetite, Weight Loss)
4- Currently on TB treatment

Pregnancy/Family Planning Status codes
P- Pregnant
FP- On Family Planning
No FP- Not on Family Planning

MUAC codes
G- Green
Y- Yellow
R- Red

Print Version September 2019

Annex 6: TPT Client Held Card

TPT CLIENT HELD CARD

UGANDA NATIONAL TUBERCULOSIS / LEPROSY PROGRAMME

1. TPT Number: _____ 2. ART Number (Where applicable): _____
3. Index Patients number (if client is a TB contact): _____

4. Treatment Facility: _____ 5. Transferred Out To: _____ 6. Date (T.O): _____
7. Client Name: _____ 8. Client Phone Number: _____
9. Care-taker number: _____
10. Address :
District : _____County :_____ Subcounty :_____ Parish :_____ Village :
_____

11. Sex : a) Male b) Female , Age : _____

12. Regimen: _____ 13. Start Date: _____ 14. Date Treatment stopped: _____

Date reviewed	Comment / Remarks	Date of Next Appointment	Signature of HCW
Treatment Outcome		Record date	
Completed a) Yes b) No			

Administration of drugs (one line per month) -

Calculate % adherence (total doses taken/total to have been taken) at the end of each month. (Goal is 100% and not to fall below 80%)

	Day																															
Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Total doses for drugs Missed	% doses for drugs Missed
0																																	
1																																	
2																																	
3																																	
4																																	
5																																	
6																																	
7																																	
8																																	
9																																	

Annex 7: TPT Care Card

TB Preventive Therapy (TPT) Care Card

July 2020

Index Patient's Unit TB #/Contact Serial #: ……/ …… **Person's initials:** …… **Age:** ……

Sex: **Male** □ **Female** □ **Date of Birth:** ……/……/…… **Weight (Kg):** …… **Person's Telephone #:** ……

Nearest landmark: …… **Village:** …… **Parish:** ……

Subcounty: …… **District:** ……

Next of kin names: …… **Next of kin phone #:** ……

TPT eligibility screen for TB contacts < 5 years

Date	___/___/_____
1. Cough of any duration **(Y/N)**	
2. Fever (Y/N)	
3. Failure to thrive or **poor weight gain (Y/N)**	
4. Lethagy, less playful than usual **(Y/N)**	

TPT eligibility screen for TB contact ≥ 5 years

Date	___/___/_____
1. **Cough** of any duration (Y/N)	
2. **Fever** (Y/N)	
3. Noticeable **weight loss** (Y/N)	
4. **Night sweats** (Y/N)	

(Key: Y - Yes; N - No)
- **If "Yes" to any of the above questions, presume TB, examine the person using TB diagnostic algorithm to evaluate for active disease. Rule out other underlying conditions. Refer if necessary. Record your action below.**
- **If "No" to all questions, initate workup for TPT and repeat screening on subsequent visits.**
- **If person is 5 years or older, do a latent TB infection test (TST/IGRA).**

Action taken: Person evaluated for TB ☐, Referred for further management ☐ or Considered for TPT ☐

LTBI Test (≥5 years): Positive ☐ Negative ☐ Not done ☐

TB Preventive Therapy Client Work Up

Ask for the following	
1. Yellow coloration of eyes (**Y/N**)	
2. History of neuropathy or psychosis (numbness, regression in motor milestones (refusal to crawl, walk or run), reduced playfulness, mental confusion) (**Y/N**)	
3. History of alcoholism	
4. History of allergy to TPT medicines	
5. Taking medicine that interacts with TPT drugs (ketoconazole, phenytoin, Carbamazepine, Warfarin, Theophylline, disulfiram, citalopram, Fluoxetine, Paroxetine, Sertraline)	

Examine for the following	
1. Yellow coloration of eyes (**Y/N**)	
2. Tenderness in the upper right abdomen (**Y**/N)	
3. Liver function test normal? **(Y/N)**	

***If the client has any of the above history or examination findings, defer TPT: manage the underlying condition and re-evaluate on next visit.**
***If no to all the above initiate TPT and repeat evaluation on subsequent visit.**

Date started on TPT ___/___/_____	**TPT number** _____/_____

Indication for TPT	**(Tick √)**
1. Contact of TB patient	
2. High-risk-person with positive latent TB infection test	
3. PLHIV	
4. Other	

TPT Regimen	**Doze**	**# Tabs**
Isoniazid once daily for 6 months (6H)		
Rifapentine/isoniazid once weekly for 3 months (3HP)		
Isoniazid/Rifampicin once daily for 3 months (3HR)		
Other		

TPT FOLLOW UP ASSESSMENT

Month			**1**	**2**	**3**	**4**	**5**	**6**	**Remarks**
TPT follow up appointment date									
TPT refill date									
Weight (kg)									
TB Status (1, 2, 3, 4) 1- No TB symptoms 2- Has TB symptom(s) 3- Diagnosed with TB	**If with no TB symptoms continue TPT.** **If with TB symptoms evaluate for TB.** **If diagnosed with TB, TPT and start TB treatment.**								
Hepatotoxicity? (loss of appetite, nausea, vomiting, general weakness, right upper abdominal pain, pale stools, dark urine or yellow coloration of eyes)	Yes (Y) or No (N)								(state action taken)
Peripheral Neuropathy (Does person have any of the following in the limbs? Regression in motor milestones - refusal to crawl, walk or run, reduced playfulness, numbness, pins & needles, burning sensation (Y/N))	Yes (Y) or No (N)								(state action taken e.g treatment with pyridoxine)
Does the person have a rash?	Yes (Y) or No (N)								(state action taken)
Adherence **Measurement** Good = missed < 2 doses / month Fair = missed 2-4 doses / month Bad = missed ≥5 doses / month	Good or Fair								
	P - Poor (state action taken) e.g decision made to stop TPT, adherence couseling, etc.								(state action taken)
If person has any of the above report to NDA									
Transfer out (tick √ month)									
Where? _____									

TPT Outcome	
Event	**(Tick √)**
Completed	
Lost to Follow Up	
Discontinued**	
Died	

****Reason for discontinuation**	**(Tick √)**
Adverse drug reaction	
Active TB Disease	
Other.....	

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