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MINISTRY OF HEALTH · ETHIOPIA
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HEALTHIER CITIZENS FOR PROSPEROUS NATION!

# National Tuberculosis and HIV Programmatic management of LTBI

## Addendum to the National TB and HIV Guidelines

**MINISTRY OF HEALTH, ETHIOPIA**

**MAY 2020**

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## Forward

Tuberculosis is a major public health problem throughout the world by infecting an estimated one-third of the world's population and putting them at risk of developing active disease during their lifetime. Globally, Tuberculosis has been one of the leading causes of deaths every year among the infectious disease. According to the Global TB Report 2019, 10 million people are estimated to have fallen ill with TB in 2018 while an estimated 1.2 million people died of TB.

Ethiopia is among the 30 High TB, HIV and MDR-TB Burden Countries, with annual estimated TB incidence of 151/100,000 populations and death rate of 22 per 100,000 populations for 2018. It has notified 114,233 new TB cases in 2018. Although the majority of TB cases has affected the productive age group, 10% of the cases were reported among children aged under 15 years. Of the total TB cases notified 62% were bacteriologically confirmed pulmonary TB cases.

HIV co-infection impedes the TB control efforts contributing to around 5% of annually notified TB cases. In Ethiopia, only 49% of the PLHIV newly enrolled in care and 22 % of under 5 children who are contacts of bacteriologically confirmed PTB cases were started on isoniazid preventive therapy in 2018.

The Federal ministry of health expresses its strong governmental commitment towards control of TB by introducing the most up-to-date national strategies, recommendations, clinical and programmatic practices towards provision of patient-centered quality TB care. It has adopted the recommendations of the WHO consolidated guideline on programmatic management of LTBI released in 2018. Moreover, the country has continued its commitment to ending TB by enhancing the concerted efforts to achieve the minimum target set at UN HLM to provide TB preventive therapy to a total of 490,000 high risk individuals between 2018-2022.

This addendum has been developed to align the current national guidelines and practices of LTBI management with the global updates. Thus, it aims to provide the latest updates and guidance in the programmatic management of LTBI among high risk groups particularly PLHIV living in Addis Ababa, SNNP and Oromia regions who are getting HIV care and treatment from selected 138 pilot health facilities and TB exposed children with infectious TB cases from 32 selected pilot sites. It incorporates the use of shorter course treatment regimens including 3HP for eligible individuals with LTBI in line with the WHO recommendations.

Finally, I would like to call for all actors involved in the TB prevention for the strong and continued efforts and support towards scaling up TB preventive treatment to the most at-risk population to develop active TB and contribute to ending the TB epidemic by 2035.

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Ministry of Health

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**Acknowledgment**

This addendum was developed with the coordination of the national TB and HIV programs with engagement and consultations of relevant stakeholders. The federal ministry of health would like to express its warm appreciation to the following technical experts for their commitment and contribution in the review and write up of the document:

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Ministry of Health of Ethiopia would like to express its heartfelt thanks to Unitaid funded IMPAACT4TB/KNCV for the technical and financial support required for the development and production of this document.

## Abbreviations

| | |
|---|---|
| ART | Anti-Retroviral Therapy |
| AE | Adverse Event |
| CXR | Chest x-ray |
| DTG | Dolutegravir |
| DRTB | Drug Resistant Tuberculosis |
| EFDA | Ethiopia Food and Drug Authority |
| EFV | Efavirenz |
| EMR | Electronic Medical Record |
| HEW | Health Extension Worker |
| HIV | Human Immuno Deficiency Virus |
| IGRA | Interferon-Gamma Release Assay |
| IPT | Isoniazid Preventive Therapy |
| LTBI | Latent TB Infection |
| LPV/r | Ritonavir boosted Lopinavir |
| Mtb | Mycobacterium Tuberculosis |
| NVP | Nevirapine |
| PI | Protease Inhibitor |
| PLHIV | People Living with HIV |
| SAE | Serious Adverse Event |
| TB | Tuberculosis |
| TBL | Tuberculosis and Leprosy |
| TNF | Tumour Necrosis Factor |
| TPT | Tuberculosis Preventive Therapy |
| TST | Tuberculin Skin Test |
| WHO | World Health Organization |

**Summary**

Latent tuberculosis infection (LTBI) is the persistent immune response to stimulation of *Mycobacterium tuberculosis* antigens without evidence of clinically apparent active Tuberculosis (TB). Estimates show a quarter of the global population is infected with tuberculosis, where most cases are asymptomatic and non-infectious. Studies show that on average, 5-10% of these latently infected persons have risks of progressing to develop active TB, usually within the first five years of initial infection. However, risks of progression by and large depend on immunological status.

Treatment of LTBI, to prevent progression to active disease, is one of the global key strategies to ending the TB epidemic. Increasingly, eligible targets and treatment options are expanding, with significant implications in the programmatic management of LTBI. In 2018, the World Health Organization (WHO) published *Updated and Consolidated guidelines for programmatic management* of *LTBI*[1]. This addendum to the national TB and HIV guidelines (For HIV program the addendum will work only for the pilot sites especially for the implementation of 3HP), provides guidance that is consistent with these global WHO recommendations and has also considered feasibility of options for the management of LTBI in the context of Ethiopia.

[1] Latent TB infection: Updated and consolidated guidelines for programmatic management. Available at: https://www.who.int/tb/publications/2018/latent-tuberculosis-infection/en/

## 1. Introduction

Programmatic management of LTBI consists of a set of systematically implemented interventions to identify and treat those with the infection. Three key considerations are addressed in this addendum:

1. Determination of priority eligible populations in Ethiopia. This is decided based on a national consultation and deliberation on risk, effectiveness, cost, and outcomes in the national context.
2. Clinical (or any other) criteria to identify persons eligible for LTBI treatment, from priority populations, which also considered effectiveness and feasibility of available options in Ethiopia.
3. LTBI treatment options, their effectiveness, cost and practicality in Ethiopia.

This addendum to the national TB and HIV technical guidelines provides recommendations in all these three key aspects of the programmatic management of LTBI. It replaces all previous national recommendations in relation to the management of LTBI, which may also be called as TB preventive therapy (TPT, referring to all the treatment options) or INH preventive therapy (IPT, specifically referring to TPT using isoniazid). For HIV program, this addendum will apply for selected pilot sites /facility of Addis Ababa, SNNP and Oromia regions especially use 3HP for preferred drugs for PLHIV.

## 2. Objective

The aim of this addendum is to provide updated guidance and national recommendations for the programmatic management of LTBI in Ethiopia.

### 2.1 Target audience

The target audiences for this addendum are:

- TB and HIV programme and supply managers at all levels for Tb program and selected pilot RHB, Zone Wereda and health facilities for HIV program
- Healthcare providers in public and private settings
- Clinical and laboratory professionals; and
- Partners and funding agencies

## 3. Key updates

- New alternatives for TPT regimens have been included
    - 3HP for those aged 2 and over
    - 3HR for those aged under 2
- Expansion of eligible groups
    - People aged between 5 and 15 who are HIV negative and who have been exposed to an index case with pulmonary TB

- Updates to recording and reporting tools to reflect these updated alternative regimens and eligible groups.

### 3.1 Consolidated recommendation

**Priority population for programmatic management of LTBI:**

**A) People living with HIV: For pilot sites only**

- Adolescents and adults living with HIV who are unlikely to have active TB based on symptom screening should receive TB preventive therapy as part of a comprehensive package of HIV care. Treatment should be given irrespective of degree of immunosuppression, and also to those on antiretroviral therapy (ART), those who have been previously treated for TB at least 3 years prior, and pregnant women living with HIV.
- Children 12 months or older who are living with HIV and are unlikely to have active TB based on symptom screening should receive TPT as part of comprehensive HIV care package whether they have been in contact with a case of PTB or not.
- Infants younger than 12 months who are living with HIV and who have been exposed to an index TB case* and are investigated for TB should receive TPT if the investigation shows no active TB.

**B) HIV-negative children and adolescents who have been exposed to TB:**

- HIV negative children and adolescents (<15 years of age) who have been exposed to an index PTB case*who are found not to have active TB disease should receive TPT.

**C) Others:**

- Patients initiating anti-TNF therapy, receiving dialysis, preparing for organ or hematologic transplant and patients with silicosis should be systematically investigated for TB and should receive TPT after excluding active TB disease.

**Identification of those eligible for TPT:**

- All priority populations should be screened for TB based on a clinical algorithm (Figures 1, 2, 3) to determine eligibility for TPT. In general, those without symptoms are unlikely to have active TB and should receive TPT. Those with symptoms should be evaluated for TB and others diseases that cause such symptoms. If subsequent evaluation excludes TB, they should be offered TPT along with any other appropriate treatment.
- Adults and adolescent living with HIV who do not report any of the symptoms of current cough, fever, weight loss or night sweats are unlikely to have active TB and should receive TPT.
- Infants <12 months of age living with HIV who do not report any of the symptoms of poor weight gain or failure to thrive, fever, or current cough, and who do not have history of contact with an index PTB case are unlikely to have active TB or LTBI and should not receive TPT.
- Children ≥ 12 months of age living with HIV who do not report any of the symptoms of poor weight gain or failure to thrive, fever, or current cough, are unlikely to have active TB and should receive TPT regardless of the contact history.

- Infants and children who have been exposed to an index PTB case and who do not report any of the symptoms ofcough, fever, not eating well/anorexia, weight loss/failure to thrive, fatigue, reduced playfulness or decreased activity are unlikely to have active TB and should receive TPT.
- Adolescents (< 15 years of age) who have been exposed to an index PTB case and who do not report any of the symptoms of persistent cough of at least two weeks duration, haemoptysis, fever, night sweats, weight loss, chest pain, shortness of breath are unlikely to have active TB and should receive TPT.
- Patients initiating anti-TNF therapy, receiving dialysis, preparing for organ or hematologic transplant and patients with silicosis who do not report any of the symptoms of cough, haemoptysis, fever, night sweats, weight loss, chest pain, shortness of breath or fatigue are unlikely to have active TB and should receive TPT.
- Test of TB infection using Tuberculin skin test (TST) or interferon-gamma release assay (IGRA) is **not** required for initiating TPT in eligible individuals as identified above.

**LTBI treatment regimens in Ethiopia**

- Current regimens recommended for treatment of LTBI includes: 3HP, 3RH and 6H
- Three months of weekly isoniazid plus rifapentine (3HP) is the preferred regimen for TPT in all PLHIV aged 15 years and above who are not receiving protease inhibitor or NVP based regimen, and who do not have any other contraindication for 3HP.
- Six months of isoniazid preventive therapy (IPT) should be offered to children, adolescents and adults living with HIV who are receiving ART regimen with protease inhibitor or existence of other contraindication for 3HP.
- Three months of weekly isoniazid plus rifapentine (3HP) is also the preferred regimen for TPT in eligible HIV-negative children and adolescents (2- 14 years of age inclusive).
- Three months of daily isoniazid plus rifampicin (3HR) is the preferred regimen for eligible HIV-negative children<2 years of age.
- Six months of isoniazid preventive therapy (IPT) should be offered to HIV-exposed infants receiving nevirapine-based prophylaxis who are also exposed to pulmonary TB case
- IPT may be used for all eligible individuals if 3HP or 3HR are not available or contraindicated

## 4. Algorithms for identification and management of those eligible for TPT

In clinical settings, two critical considerations are important in initiating treatment for LTBI.

- Active TB disease should be excluded before offering TPT. Clinical screening using symptom-based criteria can safely be used to identify those eligible for TPT.
- The routine use of TST and IGRA, Chest X-Ray, or other TB diagnostic tests is not recommended for diagnosis of LTBI in order to initiate TPT.

**Figure 1: Algorithm for initiating TPT in adults and adolescents ≥15 years living with HIV**

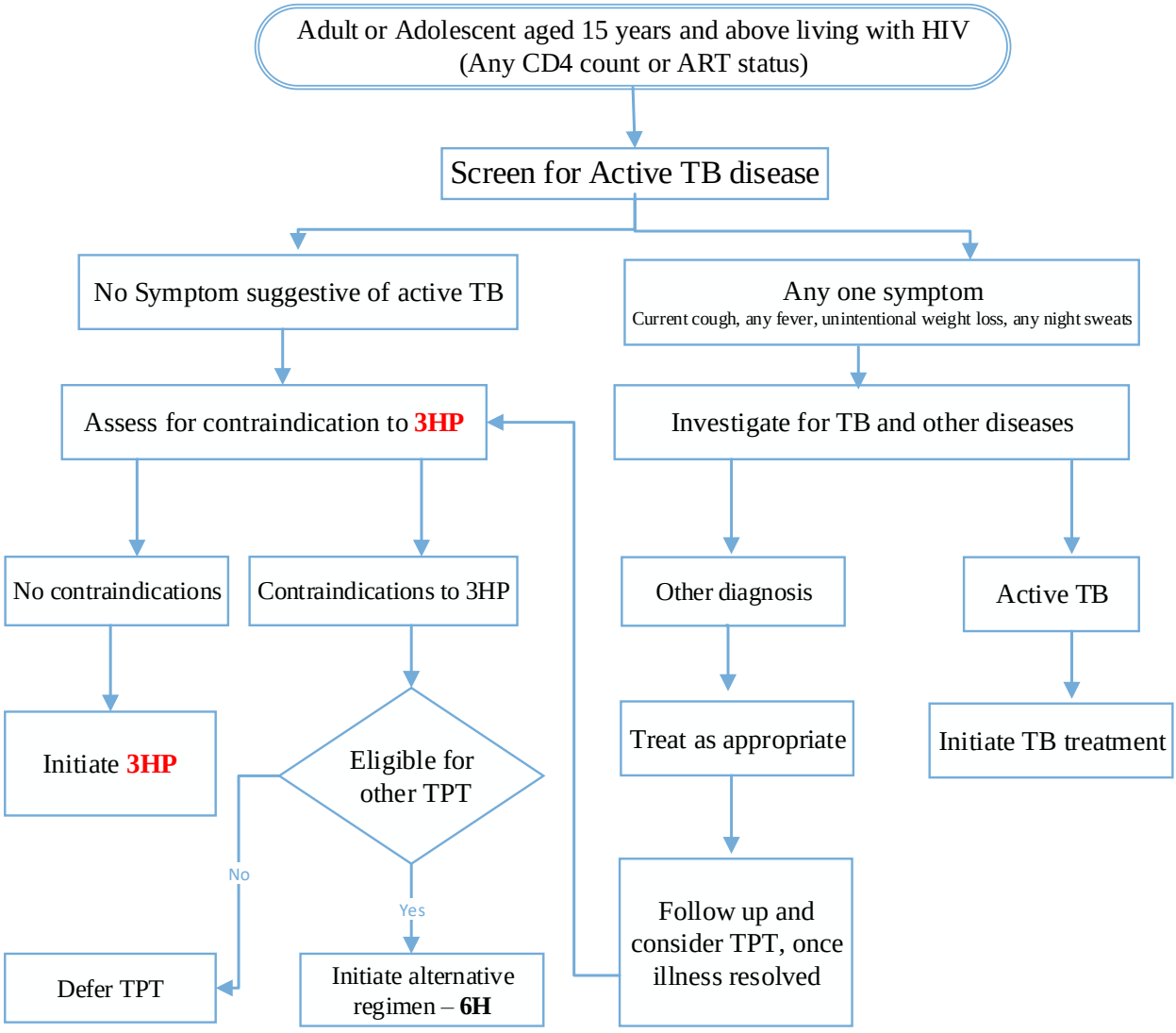


**Figure 2. Children <15 years living with HIV and without household TB exposure**

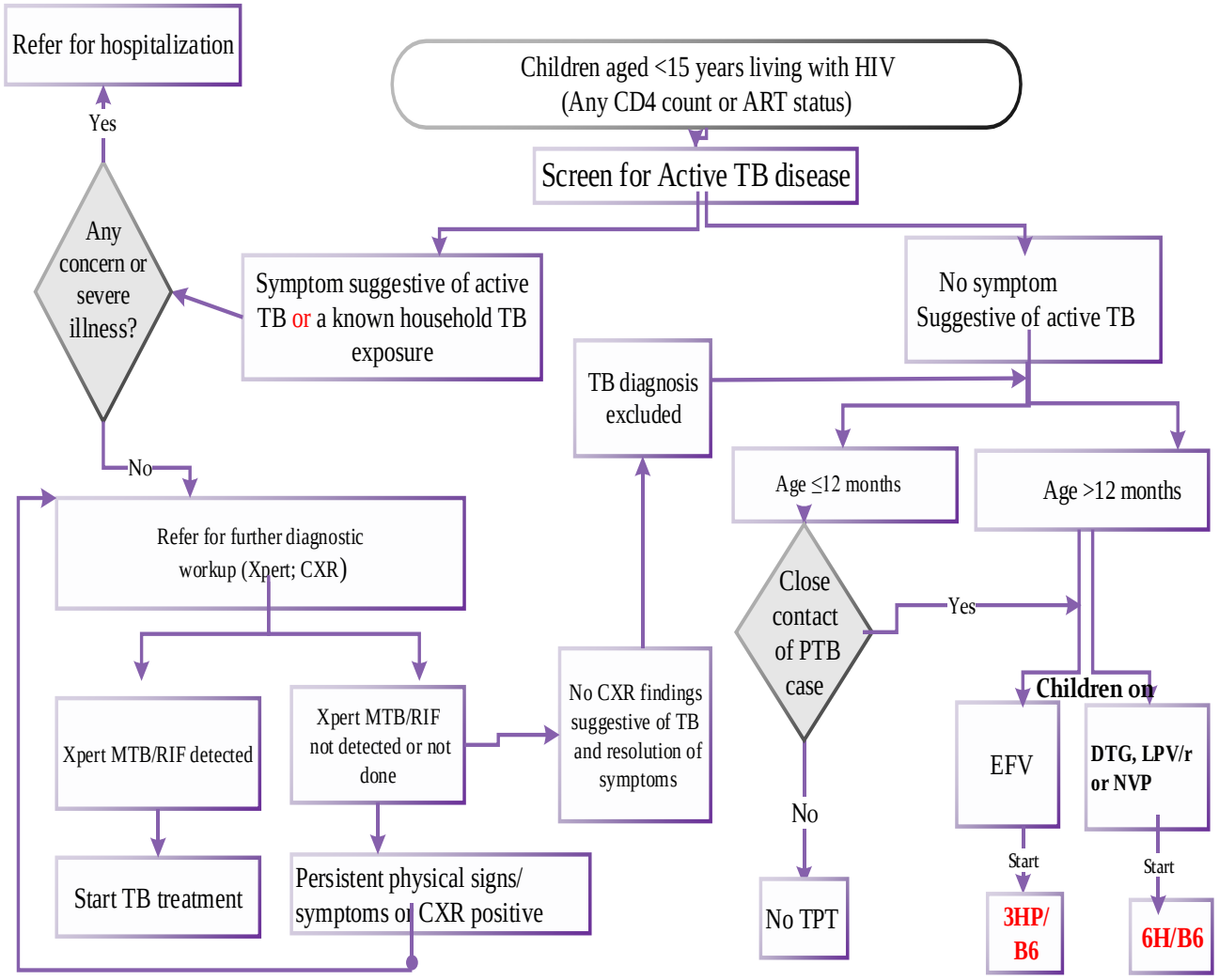
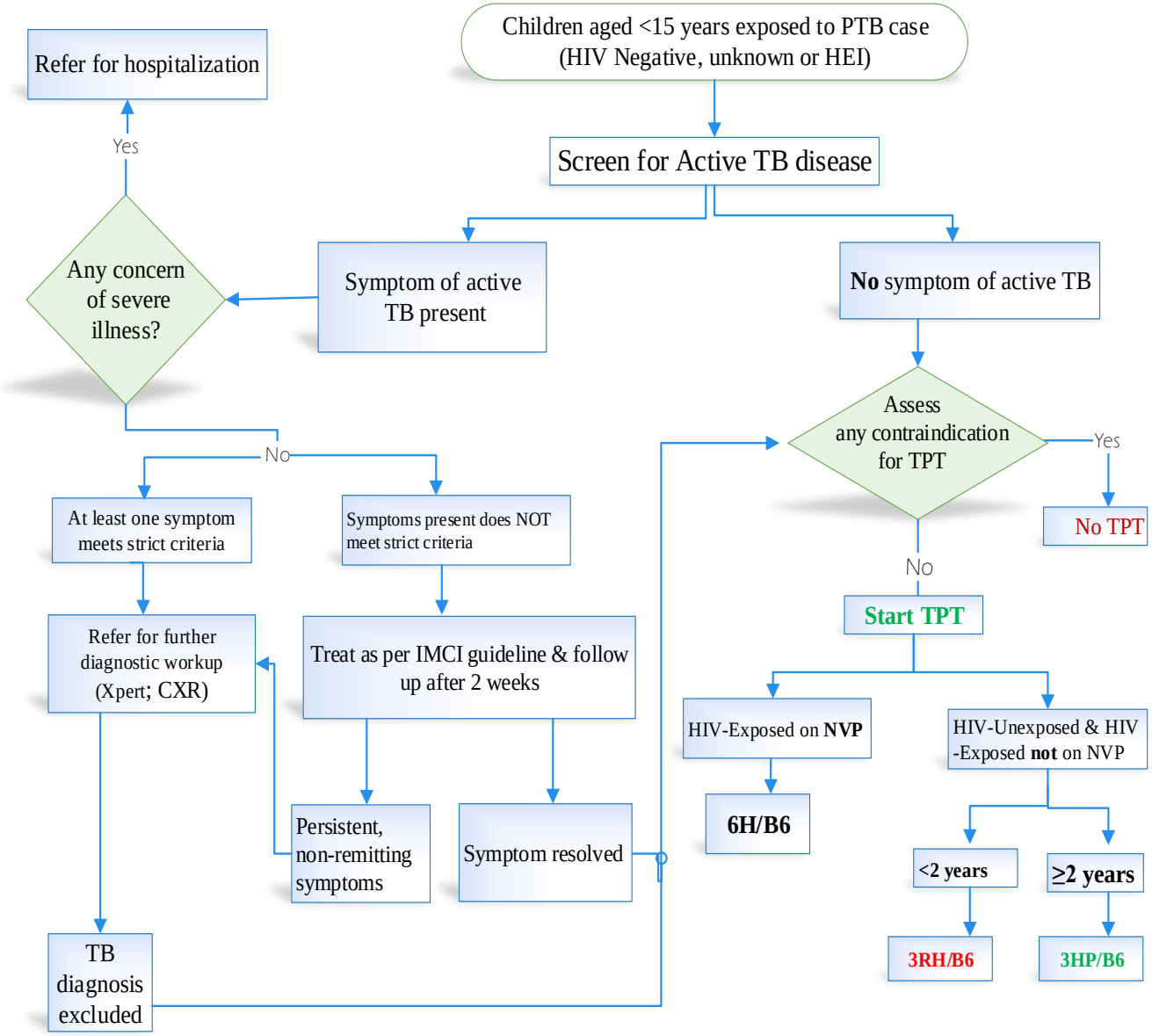


**Figure 3: HIV-exposed Children and HIV negative children and adolescents <15 years of age with household exposure to PTB case**



## 5. Regimen and dosage for treatment of LTBI

**Table 1.** Regimen for treatment of latent TB infection.

| Population group | Age group and ART regimen | Selection of TPT regimen | |
|---|---|---|---|
| | | **Preferred regimen** | **Alternative regimen** |
| **Persons living with HIV** | Adults, adolescents, children and infants of of all ages receiving a NVP or **PI-based ARTregimen** | Daily isoniazid preventive treatment (IPT) for 6 months | |
| | Children and adolescents aged <15 years receiving a **DTG-based ART regimen** | Daily isoniazid preventive treatment (IPT) for 6 months | |
| | Children and adolescents aged <15 years receiving a **EFV-based ART regimen** | Weekly isoniazid Plus rifapentine for 3 months (3HP). | - Daily rifampicin Plus isoniazid for 3 months (3RH).<br>- Daily isoniazid preventive treatment (IPT) for 6 months. |
| | Adolescents and adults living with HIV (≥ 15 years of age) receiving **non-PI based ART regimen** | Weekly isoniazid Plus rifapentine for 3 months (3HP). | - Daily isoniazid preventive treatment (IPT) for 6 months. |
| **HIV-negative persons** | Infants and children <2 years of age) | Daily rifampicin Plus isoniazid for 3 months (3RH). | - Daily isoniazid preventive treatment (IPT) for 6 months<br>- |
| | Eligible adolescents and children aged between ≥2 -14 years<br><br>(refer to eligibility criteria specified above) | Weekly isoniazid Plus rifapentine for 3 months (3HP). | - 3RH will be used as alternative to 3HP<br>- Daily isoniazid preventive treatment (IPT) for 6 months |

* Refer section 8.1 on contraindications.

* *Safety and pharmacokinetics of 3HP and DTG co-administration was studied only among PLHIV aged 15 years and above. So the evidence is not yet known among PLHIV aged < 15 years, that is why 3HP will not be used in this group.*
*Clinical data is also lacking on the safety and dosing of 3HP among children aged <2 years.*

** note that if any of the preferred TPT regimens are unavailable, other regimens (3HR or IPT) may be used depending on the eligibility

*** 3HP: should be taken with food to prevent GI upset; if patients are unable to swallow tablets (due to age or illness), the tablets can be crushed and added to a small amount of semi-solid food

# 6. Treatment initiation, monitoring and clinical care

## 6.1 Treatment initiation

The selection of treatment options for LTBI by programs and clinicians should consider the characteristics of the clients who are to receive treatment and acceptability of treatment for higher completion rate. The benefits of all the treatment options outweigh the potential harm. All the treatment options can be self-administered. An RCT showed that self-administered treatment of the 3-month regimen of weekly rifapentine plus isoniazid is not inferior to directly observed treatment. Shorter regimens are more preferable than longer ones for the individuals receiving treatment, clinicians providing treatment and program managers.

*Preventive therapy for HIV infected people:* Adults and adolescents with HIV infection should be provided to those who are unlikely to have active TB based on appropriate clinical algorithm, irrespective of CD4 count, ART status, pregnancy status or history of treatment for prior episode of TB before three years. Children and infants less than 1 year of age should be given preventive therapy only if they have a history of household contacts with a PTB case and active TB has been excluded in investigation.

*Preventive therapy for HIV negative under-fifteen children exposes to PTB case:* should be administered for asymptomatic children and adolescents aged <15 years who are household contacts of infectious TB cases within the past one year.
Clinicians should follow the algorithms for initiation and selection of regimen for the specific population groups eligible for TPT as indicated in section 6.

## 6.2 Drug-drug interactions with antiretroviral medicines

Drug-drug interactions should be cautiously considered in using rifampicin and rifapentine in persons who are receiving antiretroviral treatment (ART). Both rifampicin and rifapentine should not be administered in persons who are receiving nevirapine or Protease Inhibitor (PI) based regimen. A three-month weekly rifapentine plus isoniazid can safely be used in patients receiving efavirenz-based antiretroviral regimen without the need for dose adjustment. Studies show that co-administration of rifapentine with raltegravir and dolutegravir based regimen is both safe and well tolerated in HIV infected adults and adolescents aged ≥ 15 and do not need any dose adjustment.

## 6.3 Monitoring adverse events

Routine clinical monitoring of persons receiving TPT is necessary to ensure adherence and continuity of care. Adverse effects, including those considered as medically "minor", may be a barrier for adherence in a person who is otherwise well. TPT related adverse events (AEs), identified during the course of treatment should be properly monitored, managed and reported per national recommendation, using health facilities reporting systems.

### 6.4 Management of adverse events

Individuals receiving TPT do not have active disease and therefore their risk for adverse events during treatment must be minimized. Moreover, the regimen can be withheld while an AE is assessed, and there is time for the regimen to be recommenced and completed if safe to do so. Overall, 3HP is a safe and effective treatment for latent TB infection. Clinically significant drug reactions are rarely experienced by patients receiving 3HP, and even less commonly require discontinuation of treatment. Severe reactions are particularly rare. Nonetheless, healthcare workers should be familiar with the important drug reactions so that they can recognize rare occurrences and manage them appropriately.

Therefore, in general: *If an AE occurs while a patient is receiving 3HP, they should be advised not to take any further doses and contact the ART providers and TB focal persons of the health facilities as appropriate.*

*Minor adverse events are likely to occur in a small proportion of individuals/patients. Rarely serious adverse events may occur, and hence both the health care provider and patient should be vigilant and manage such events rapidly. This can be achieved by careful assessment of the patient prior to commencing 3HP, and routine monitoring during treatment as indicated below:*

| | |
|---|---|
| Drug reactions | The most common drug reactions with 3HP are:<br>• Liver toxicity (less common than for IPT)<br>• Flu-like reactions (more common than forIPT)<br>Drug reactions are usually mild and self-limiting, but occasionally they can be severe.<br>Children usually tolerate 3HP very well and have much lower rates of drug reactions. |
| Baseline assessment | Active TB must be ruled out before commencing 3HP. 3HP is currently not recommended in:<br>• Pregnancy<br>• Age <2years<br>Information on baseline liver function is important in the following:<br>• HIV+ (done as part of ART assessment)<br>• Daily alcohol consumption<br>• Liver disorders including viral hepatitis<br>• Postpartum period (≤3 months after delivery)<br>• Concomitant use of other hepatotoxic substances<br>Individuals at higher risk of peripheral neuropathy should be offered vitamin B6 (pyridoxine) supplementation with 3HP; if B6 is not available, this should not delay starting a course of 3HP. |

| | |
|---|---|
| | |
| Counselling for AEs | Red/orange discoloration of urine and other body fluids while receiving 3HP is normal and completely harmless.<br>If patients experience any symptoms concerning for an AE:<br>• Do not take any further doses of3HP<br>• Contact a healthcare provider for advice<br>• Only continue receiving 3HP if advised to do so by a healthcare provider Individuals should be alert to the following symptoms:<br>• Weakness, fatigue, loss of appetite, persistent nausea (early symptoms of hepatotoxicity)<br>• Flu-like, or other acute symptoms appearing shortly after receiving a dose of 3HP<br>• Symptoms of active TB (appendix1) |

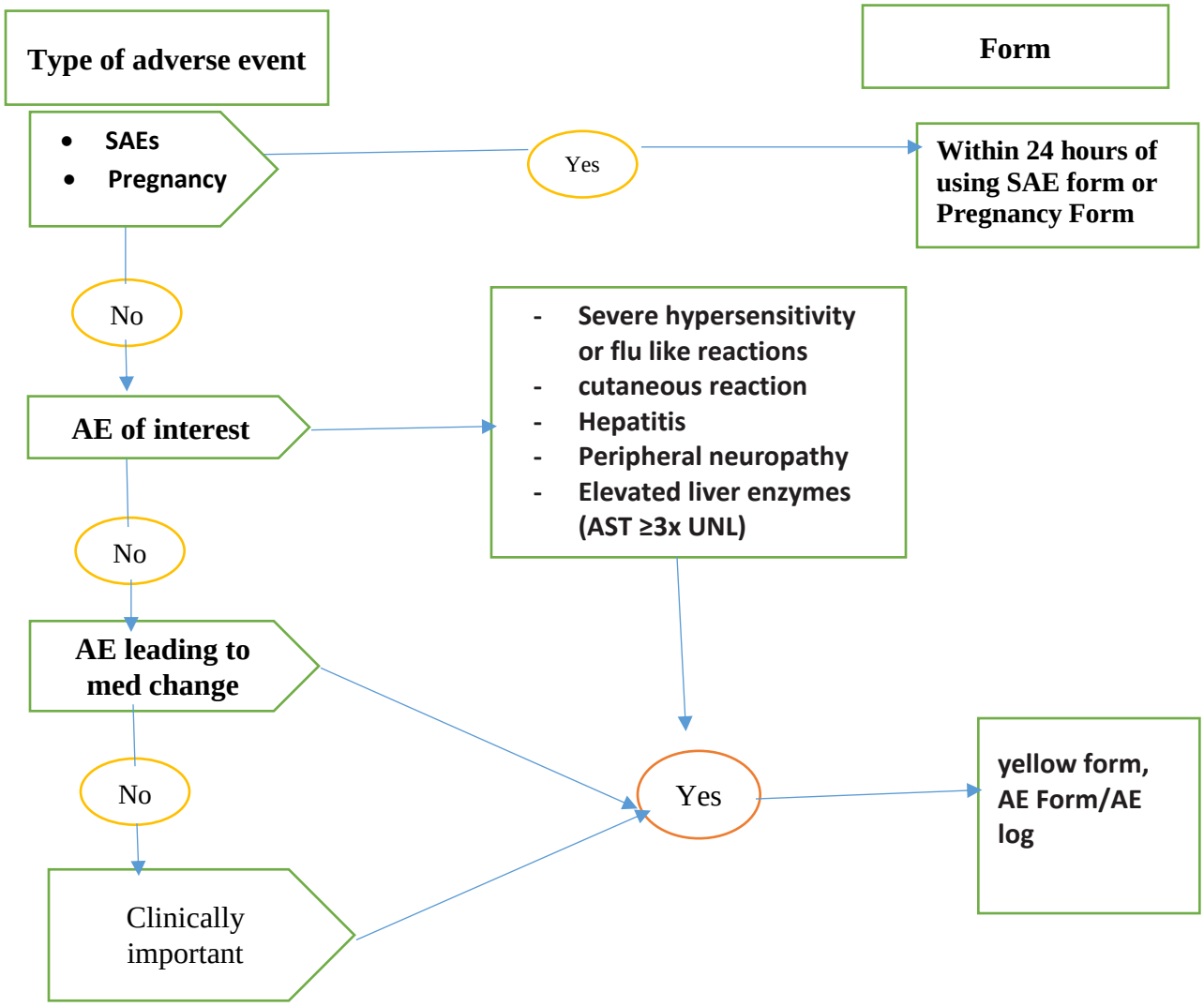
### 6.5 Reporting of adverse events

Active pharmacovigilance is part of the optimal management of adverse events through active and systematic clinical and laboratory assessment of patients while on treatment for tuberculosis. It applies to patients on treatment with new anti-TB drugs, novel MDR-TB regimens, or XDR-TB regimens, in order to detect, manage and report suspected or confirmed drug toxicities. The appropriate and timely management of all AEs and ADRs is an integral component of active pharmacovigilance and patient care.

The national pharmacovigilance guideline (2014) indicated adverse drug events shall be reported to the responsible authority body, Ethiopian Food and Drug Authority (EFDA). The adverse events that need to be reported includes medicine-related injuries, with at least a reasonable possibility to be caused by the direct pharmacological mechanism of a medicine, an individual's particular vulnerability, drug interactions, unexpected therapeutic ineffectiveness (e.g. resulting from drug interactions, product quality, problems or antimicrobial resistance), medication errors, and product quality defects.

In line with this, adverse events associated with the TPT drugs should be reported using either the standardized adverse event reporting format (yellow form) or electronically on e-reporting of ADR available on the apps or website of EFDA (www.fmhaca.gov.et) by health care providers and public health programs. Moreover, please refer the general reporting approach and timeline recommended for active DSM of TB drugs indicated in the national TBL, TB/HIV guideline.

**General Reporting approach and Timeline for active DSM**




### 6.7 Adherence support and monitoring

Clients receiving TPT should be supported at home level, either by adherence case managers, HEWs or family supporter. They should have monthly scheduled follow up that is coordinated with other services, such as HIV care, child and maternal health services, as necessary. At each follow-up visit, the healthcare provider should:

- Educate clients and their families about the benefit of TPT, potential side effects, and importance of returning back to a health facility for new symptom/sign or any concern.

- Evaluate and counsel clients on importance of treatment adherence and completion. Case managers, adherence supporters, and HIV care and child health service providers should support treatment adherence and monitoring, as part of comprehensive HIV care and child health services.
- Evaluate and routinely monitor drug side effects, including hepatitis, peripheral neuropathy or rash. Stop TPT if serious adverse effect is identified and manage the patient.
- Evaluate for signs and symptoms of active TB, other opportunistic infections (OIs) or diseases.
- Stop TPT, if active TB is diagnosed, which requires immediate start of anti-TB treatment.

### 6.8 Contraindications to TPT

Individuals with any one or more of the following conditions should not receive TPT:

- Symptoms compatible with tuberculosis even if the diagnosis isn't yet confirmed;
- Active hepatitis (chronic or acute);
- Regular and heavy alcohol consumptions;
- Prior allergy or intolerance to medicine(s) in the regimen and
- Symptoms of peripheral neuropathy.

In addition, rifapentine is not currently indicated for children below 2 years, PLHIV receiving PI or NVP based ART regimen, pregnant women and breast-feeding mothers.

### 6.9 Patient management after treatment interruption

TPT is said to be completed when a person took the full course of treatment within the specified period. Completion of IPT is defined as "completed" if a patient completed the full course of therapy within nine months period (i.e. the six months doses should be finished in nine months" time).If a patient has interrupted TPT without medical personnel advice, the client should be traced by health extension workers (HEW) or through the index person or other family member who is already enrolled in care, and treatment must be resumed. It is important to identify barriers and support treatment adherence. However, concern of adherence should not be a barrier to the use of TPT. If the client discontinues IPT for a period of less than three months: Resume the same course by adding for the missed doses at the end. If the client discontinues treatment for a period of more than three months: Re-initiate new course of treatment.
Completion for 3HP is defined when the patient took at least 11 doses of treatment in 16 weeks.

### 6.10 TB preventive treatment in New born

Once a pregnant woman with TB has been on treatment for TB for several weeks before delivery, it is less likely that the baby will become infected. The risk is highest if a mother is diagnosed at the time of delivery or shortly thereafter. If a pregnant woman is found to have pulmonary TB shortly before delivery, then the baby, and if possible, the placenta, should be investigated for evidence of congenital TB infection. If the result is positive, the new born should be treated accordingly. If asymptomatic, the new born should receive TB preventive treatment followed by BCG immunization. Breastfeeding can be safely continued during this period.

## 7. Program management, monitoring and evaluation of TPT

Preventive therapy for HIV negative under-fifteen children should be administered and monitored for completion in the TB clinic, and additional information on comprehensive registration, monitoring and follow-up of those receiving preventive therapy should be recorded on TB contact screening and LTBI treatment follow-up register.

Preventive therapy for PLHIV should be part of a comprehensive care for HIV positive individuals; therefore, patients should be initiated preventive therapy and monitored at ART clinic and relevant information should be documented in the patient follow up card, Pre-ART/ART register, Smartcare and performance data will be reported using HMIS reporting formats.

### 7.1 Recording TPT activities on HMIS tools:

Existing HMIS tools are designed for IPT based TPT documentation. Till existing tools are updated in the next updating cycle TPT activities are documented in the existing DHIS tools based on the following guidance:

**A. At ART and PMTCT clinics**

**1. HIV follow up form:**

- Record alternative TPT regimens monthly prescription under the 'TB prophylaxis/treatment' column as follows:
  - IPT1, IPT2, IPT3, IPT4, IPT5, IPT6, *IPTc
  - 3HR1, 3HR2, 3HR3
  - 3HP1, 3HP2, 3HP3

**2. ART register:**

- Record alternative TPT regimens in the space provided for TPT documentation similar to the above. Alongside, indicate date of monthly TPT prescription.

**3. PMTCT register:**

- Indicate type of regimen (IPT/3HR) and document date of TPT initiation on the space provided

**B. At TB clinic**

**TB contact screening and LTBI treatment follow-up register**

- Indicate type of regimen (IPT/3HP/3HR) and dates of monthly TPT prescription

NB: if more than one-month dosage is prescribed indicate number of months as follows (2 months IPT prescription in the first two months = $IPT_{1-2}$, three months IPT prescriptions for TPT months three to six = $IPT_{3-6}$)

** IPTc = IPT completed; 3HP= when 3HP Completed (see definition of TPT completion in section 8.8)*

### 7.2 TPT indicators

**The key indicators for monitoring of TPT include:**

- Initiation of TPT among PLHIV (new and TXCURR) disaggregated by age and regimen type
- Initiation of TPT among HIV negative children and adolescents aged < 15 years exposed to PTB cases disaggregated by regimen type
- Completion of TPT among PLHIV disaggregated by age and regimen type
- Completion of TPT among HIV negative children and adolescents aged < 15 years exposed to PTC cases disaggregated by age and regimen type

## 8. Roles and Responsibilities

**FMOH (HIV Team)**

- Lead the planning, coordination, implementation and programmatic management of pilot 3HP LTBI for selected HFs
- Lead, support and endorse the addendum developed on the programmatic management of LTBI aligned with the national guidelines for the pilot sites
- Lead and support the adaptation and development of TPT related training materials, job aids and patient education materials for pilot region and HFs
- Facilitate training of trainers based on the updated TPT guidance and training materials for selected pilot sites
- Regularly monitor, review and support the overall pilot implementation of the 3HP program

**RHBs**

- Coordinate and support the implementation of programmatic management of LTBI at regional level
- Facilitate the training of the health care providers in collaboration with partners
- Monitor and support the TPT data recording and reporting activities
- Lead and support the monitoring of TPT implementation through joint supportive supervision and performance review at regional level

**EPSA**

- Lead and support the quantification, clearance, storage and distribution of drugs for LTBI
- Regularly monitor the consumption of the drugs and manage the supply of the drugs
- Coordinate the distribution of the drugs as per the agreed upon distribution plan

**EFDA**

- Provide the necessary support to issue waiver for the importation of new drugs
- Facilitate the registration of new drugs used for treatment of LTBI
- Support the monitoring and reporting of pharmacovigilance of the drugs used for treatment of LTBI

**FHAPCO**

- Facilitate the ordering of TPT drugs including 3HP
- Support the quantification of TPT drugs with the national programs
- Participate in the monitoring and support of programmatic implementation of TPT

**Partners**

- Collaborate with the FMoH, agencies and regional health bureaus in the planning, coordination, implementation and programmatic management of LTBI
- Provide the necessary technical and financial support for the development and duplication of materials
- Support financially and technically the capacity building of health care providers and program managers through sensitization, training and mentoring
- Support the capacity building of health care providers and program managers through sensitization, training and mentoring
- Support the monitoring of TPT implementation along with the national and regional offices
- Collect data as per the national monitoring tools and submit for national team quarterly
- Follow the implementation of the pilot program
- Provide financial and technical support for the procurement and supply management of new shorter regimen, 3HP for eligible clients

## 9. Annex

**Table 2.** Dosage of medicines for treatment of LTBI.

**Dosing of rifapentine and isoniazid for treatment of latent TB infection (3HP)**

| Medicine | Formulation | Weight bands for patients 2-14 years | | | | | Comments |
|---|---|---|---|---|---|---|---|
| | | 10–15 kg | 16–23 kg | 24–30 kg | 31–34 kg | >34 kg | |
| **Isoniazid** | **100 mg** | **3** | **5** | **6** | **7** | **7** | **adult 300 mg tab. can reduce pill burden** |
| **Rifapentine** | **150 mg** | **2** | **3** | **4** | **5** | **5** | |
| **Isoniazid + Rifapentine FDC** | **150 mg /150 mg** | **2** | **3** | **4** | **5** | **5** | **FDC being developed** |

| Medicine | Formulation | Weight bands for patients >14 years | | | | | Comments |
|---|---|---|---|---|---|---|---|
| | | 30–35 kg | 36–45 kg | 46–55 kg | 56–70 kg | >70 kg | |
| **Isoniazid** | 300 mg | 3 | 3 | 3 | 3 | 3 | |
| **Rifapentine** | 150 mg | 6 | 6 | 6 | 6 | 6 | |
| **Isoniazid + Rifapentine FDC** | 300 mg / 300 mg | 3 | 3 | 3 | 3 | 3 | FDC being developed |

**Dosing of 3RH:**

| Dose per Kg body weight | # of tablets | Maximum dosage |
|---|---|---|
| **INH**<br>Adults: 5mg<br>Children: 10mg (7-15mg)<br>**Rifampicin**<br>Adult: 10mg<br>Children: 15mg (10-20 mg) | **RH 75/50mg tablet FDC**<br>4-7 Kg = 1 tab<br>8-11 Kg = 2 tabs<br>12-15 Kg = 3 tabs<br>16-24 Kg = 4 tabs<br>25 Kg and above = As adults | INH = 300 mg<br>Rifampicin = 600 mg |

**Dosing of IPT:**

| Weight Ranges(kg) | Dose Given (mg) | Tablets of INH( of 100mg) per Dose |
|---|---|---|
| < 5 Kg | 50 mg | ½ tab |
| 5.1 – 9.9 Kg | 100 mg | 1 tab |
| 10 – 13.9 Kg | 150 mg | 1 ½ tab (or ½ adult tab) |
| 14 – 19.9 Kg | 200 mg | 2 tabs |
| 20 – 24.9 Kg | 250 mg | 2 ½ tabs |
| 25 Kg and above | 300 mg | 1 adult tablet |