TPT | TUBERCULOSIS PREVENTIVE TREATMENT

What is TPT?

1. TB Preventive Therapy (TPT), previously referred to as Isoniazid preventive therapy (IPT) is the treatment offered to individuals who are considered to be at risk of developing active TB disease, in order to reduce that risk.
2. TPT is considered one of the most critical public health measures to protect both individuals and the community from TB.
3. TPT is given to persons who are infected or at high risk of developing TB, such as persons with weakened immunity e.g. children under 5 years, people living with HIV (PLHIV), persons on immunotherapy, etc.
4. Tuberculosis Preventive Treatment (or TPT) consists of a course of one or more anti-tuberculosis medicines given to prevent someone who is a close contact of someone diagnosed with TB from coming down with TB disease.
5. TPT prevents people with TB infection from progressing to active TB disease.
6. TPT should not be given when there is active TB.
7. TPT is given FREE at the health facility to all eligible household and close contacts of persons diagnosed with TB.

Who should take TPT?

1. People with elevated risk of progression from TB infection to TB disease:
   - People living with HIV.
   - Patients with immunosuppressive conditions.
2. People with increased likelihood of exposure to TB disease:
   - Household contacts of people with bacteriologically confirmed TB, usually subdivided into:
     a. Children below five years of age
     b. Children five years and above, adolescents and adults
   - Persons who live or work in institutional or crowded settings, such as persons incarcerated and their staff, health workers, recent immigrants from countries with a high TB burden, homeless people and people who use drugs.

Who should NOT be given TPT?

1. Persons with presumed or confirmed active TB.
2. Anyone who has signs and symptoms suggestive of liver disease (active hepatitis, liver damage)
3. Anyone with known heavy alcohol consumption.
4. Anyone with severe peripheral neuropathy
5. Anyone who experienced previous adverse events or an allergic reaction to Isoniazid and Rifamycins i.e Rifapentine and Rifampicin)

How long should TPT be taken?

TPT can be taken for a duration of between one to six months, daily or weekly; depending on the type of medicine.

The following are the available medicines and regimen:

a. Isoniazid daily for 6 months (6H)
b. Isoniazid and rifampicin daily for 3 months (3HR)
c. Isoniazid and rifapentine weekly for 3 months (3HP)
d. Isoniazid and rifapentine daily for 28 days (1HP)

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COUNSELLING TIPS FOR HEALTH CARE WORKERS PRESCRIBING TPT

Why are you prescribing TB Preventive Treatment

- PLHIV and close/household contacts are at high risk of developing TB (especially those aged under 5)
- TPT prevents persons at risk from getting sick with TB
- TB Preventive Therapy is SAFE and effective

What are the TPT Regimen?

- Describe which regimen you are prescribing
  - Isoniazid daily for 6 months (6H)
  - Isoniazid and rifampicin daily for 3 months (3HR)
  - Isoniazid and rifapentine weekly for 3 months (3HP)
  - Isoniazid and rifapentine daily for 28 days (1HP)
  - Rifampicin daily for 3-4 months (3-4R) as an option for persons who have resistance and intolerant to Isoniazid.
- TPT could be taken with ART and CPT for PLHIV

What are the side effects

- Side effects are UNCOMMON
- Red/orange discoloration of urine and other body fluids is normal and harmless during treatment containing rifamycins (Rifampicin and Rifapentine e.g 3HP, 3HR)
- Liver toxicity

  Points to mention:
  - EARLY symptoms: persistent fatigue, weakness, nausea/vomiting, fever, loss of appetite
  - Late symptoms of liver toxicity: vomiting, dark stool, yellowing of the skin and eyes, abdominal pain and swelling.
  - Don't wait for the late symptoms (jaundice etc) to occur, seek help EARLY
- Flu like symptoms. Points to mention:
  - Mild and self-limiting
  - Usually after 3-4 doses
  - Acute onset a few hours after the dose, resolves in 8-12 hours
  - Almost all patients quickly recover and can continue with TPT
- Pellagra (Viamin B3 or niacin deficiency)
- Peripheral neuropathy
- Severe problems – seek urgent care from a healthcare worker

Guidance for giving TPT to children

- Children generally tolerate TPT well and should be encouraged to take it.
- For older children and adolescents, include them in counselling wherever possible
- Crush the tablet with a small amount of tasty fatty foods (avoid fruits)
- If the child vomits the dose within 30 minutes, you should give another dose
- A small incentive can be useful to encourage children to take the medicine

What to do in case of Treatment Interruption?

- For 6H and 3HR regimens, if a client misses a dose or doses, and the period of interruption is <2 weeks, he/she should continue as soon as he/she remembers and add the number of days of missed doses to the treatment duration. If period of interruption is >2 weeks, client should contact caregiver for guidance.
- For 3HP TPT, if a client misses a dose by 1-2 days, client should take the dose when he/she remembers and continue on the original day the next week. However, If a client misses a dose by 3 or more days EITHER skip the week OR take when he/she remembers and then continue after 7 days (on the same day of the week as you remember)
- For 1HP, if a client misses a dose by 3 or more days he/she should notify his/her caregiver immediately for guidance.

Note: Healthcare worker to refer to section on management of TPT interruption in NTBLCP SOP for Contact Investigation and TPT for guidance.

Cautions

- Avoid alcohol consumption while taking TPT
- Inform your healthcare provider if you start a new medicines or develop other health issues while taking TPT.
- If experiencing TB symptoms i.e cough. 2 of two or more weeks, fever, night sweats, and weight loss.

Where to get help

- Contact your health care worker for help if needed
- Healthcare worker to refer to NTBLCP SOP for Contact Investigation and TPT for further guidance.
- Call 3340 or dial *3340# for more information

TPT | BASELINE ASSESSMENT AND MONTHLY MONITORING

Starting patients on TPT the right way is important. Once TB has been ruled out and the decision to consider TPT has been made, baseline assessment to determine the eligibility of an individual for TPT should be taken. This baseline assessment involves performing personal and medication history, physical examination and investigations as per national guidelines.

Personal History (illicit information relevant to TPT initiation and continuation)

- Allergy of known hypersensitivity to TB Drugs (Rifamycins, INH)
- HIV status and ART Regimen
- Pregnancy Status or birth control
- Comorbidity: Medical condition (Diabetes) and drugs currently being taken.
- Contact of drug resistant TB patient (Rifampicin and INH)
- Potential contra-indications to TPT i.e., Active hepatitis (acute or chronic, excessive alcohol consumptions, peripheral neuropathy

Physical Exam

- Based on History

History of Medication

- Make detailed chart of past TB and concomitant medication that may interact with TPT.

Investigations:

- Liver Function Tests: Routine LFT is not necessary prior to starting TPT but baseline testing is strongly recommended for persons at risk for clinical hepatitis including (active and chronic disease, chronic alcohol dependence, peripheral neuropathy, age >65 years)
- Offer a pregnancy test if available.

Social and financial situation

- Assess social support and financial means, provide support to overcome barriers for TPT completion.

Counselling

1. Explain to individual that he/she is eligible for TPT and provide clear messages to them and their treatment supporter such as
2. Risk and benefits of TPT
3. Inform client that TPT is free of charge through National Program.

   (See section on counselling)

Peripheral neuropathy

1. TPT is contraindicated in patients with existing peripheral neuropathy.
2. Individuals at higher risk of peripheral neuropathy should be offered vitamin B6 (pyridoxine) supplementation with TPT, these include:
   - Persons living with HIV (PLHIV)
   - Pregnant, Post Partum and exclusively breast feed infants
   - Diabetics
   - Persons with renal failure
   - Persons who are malnourished
   - Persons with chronic alcohol dependence.

Monthly monitoring

Patients taking TPT should be monitored monthly to assess tolerability and adherence.

Essential components of the visit are:

- Screen for signs and symptoms of active TB
- Screen for symptoms of Adverse Events (hepatoxicity, flu-like hypersensitivity reactions, peripheral neuropathy and assess tolerability
- Counsel about pregnancy, breastfeeding and barrier contraception
- Assess adherence and provide support as appropriate
- Assess for new medications that can interfere with TPT
- Repeat liver function test (AST) for patients who had a raised baseline test

TPT AND ADVERSE EVENTS (AES)

Most AEs associated with TPT are drug reactions due to Isoniazid, rifampicin and rifapentine. Some are also due to drug-drug interactions with other concomitant medications. Active TB, and pregnancy can occur during TPT medication use and should be carefully managed.

Drug reactions

The most common drug reactions with TPT are:

- Liver toxicity (less common than for IPT/6H)
- Flu-like reactions (more common than for IPT/6H)

Drug reactions are usually mild and self-limiting, but occasionally they can be severe. Children usually tolerate TPT very well and have much lower rates of drug reactions.

Counselling for AEs

Red/orange discoloration of urine and other body fluids while taking TPT is normal and completely harmless.

Individuals should be alert to the following symptoms:

- Weakness, fatigue, loss of appetite, persistent nausea (early symptoms of hepatotoxicity)
- Flu-like, or other acute symptoms appearing shortly after taking a dose of TPT
- Symptoms of active TB
- If a person thinks they are having an adverse event based on the symptoms above, they should contact their health care worker as soon as possible

Routine monitoring

Patients taking TPT should be monitored at monthly visits to assess tolerability and adherence. Essential components of the visit are:

- Screen for active TB
- Screen for AEs and assess tolerability
- Assess adherence and provide support as appropriate
- Assess for new medications that can interfere with TPT
- Repeat AST for patients who had a raised baseline test

Management of AEs

If an AE occurs while a patient is taking TPT, they should be advised not to take any further doses until an assessment is made of the severity and nature of the AE.

Assessment should include:

- Screen for active TB
- Past history
- History of the AE: type, onset and duration, severity
- Relevant physical examination
- Relevant investigations

Management of the AE should always be guided by the clinical judgement of the healthcare provider.

Suggested management:

- **Mild/moderate drug reactions:** reassurance, symptomatic relief, further assessment
- **Severe drug reactions:** discontinue TPT and seek urgent supportive care
- **Active TB:** discontinue TPT and start full TB treatment

Recording and reporting

Routine pharmacovigilance procedures should be used for AEs associated with TPT, where possible and according to national guidelines. AEs should also be reported according to the evaluation protocol.