

REPUBLIC OF KENYA



MINISTRY OF HEALTH

**NATIONAL ISONIAZID PREVENTIVE
THERAPY STANDARD OPERATING
PROCEDURE**

March 2015



REPUBLIC OF KENYA



MINISTRY OF HEALTH

National Isoniazid Preventive Therapy Standard Operating Procedure

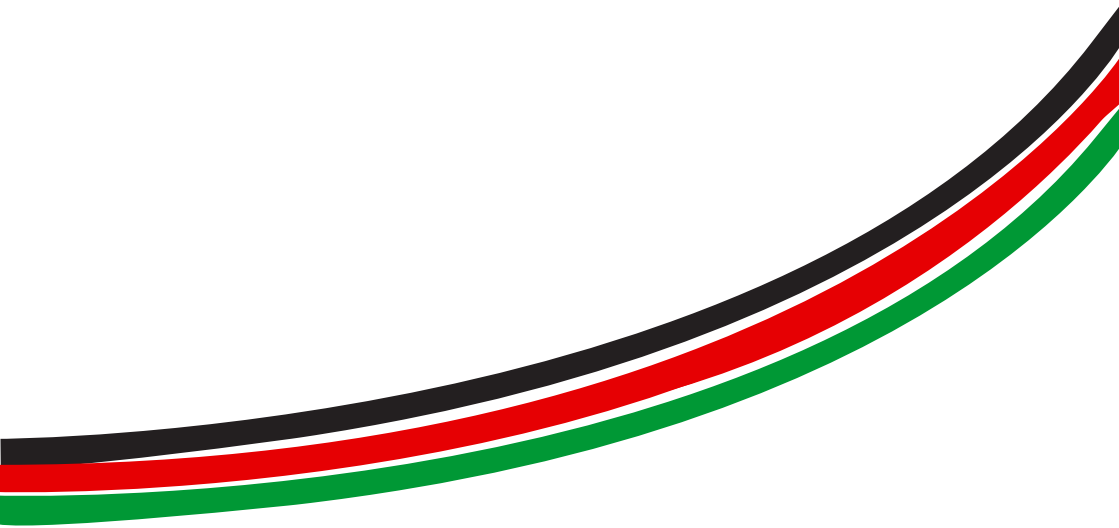


Table of Contents

| | |
|--|----|
| Foreword | 5 |
| Acknowledgments..... | 6 |
| Acronyms..... | 7 |
| IPT at a Glance..... | 9 |
| Implementing Isoniazid Preventive Therapy..... | 11 |
| 1. TB Screening | 11 |
| 2. Use of Xpert MTB/Rif (GeneXpert) in Diagnosis of TB | 13 |
| 3. Indications for Isoniazid Preventive Therapy | 15 |
| 4. Contraindications to IPT | 16 |
| 5. Initiation of IPT | 16 |
| 6. Follow Up of Patients on IPT | 18 |
| 7. Management of Complications of IPT | 19 |
| 8. Restarting IPT after interruption..... | 19 |
| 9. Follow up after completion of IPT | 20 |
| 10. IPT in special circumstances..... | 20 |
| 11. Commodity Management | 21 |
| 12. Monitoring and Evaluation | 23 |
| List of Contributors..... | 26 |

Foreword

The publication of the Kenya Isoniazid Preventive Therapy (IPT) Standard Operating Procedure (SOP) marks a milestone in the response towards improving management of TB/HIV co-infection. This National SOP is a cumulative effort by the National Tuberculosis Leprosy and Lung Disease Program (NTLD-Program), National AIDS and STI Control Program (NASCO), various stakeholders including county government representatives, bilateral and multilateral development partners, non-governmental organizations, civil society organizations, and tertiary medical training institutions.

The IPT Standard operating procedures follow the WHO 2011 Guidelines that recommend provision of IPT to HIV infected adults and children who are unlikely to have active TB, based on simple symptom screening.

The National Guidelines for Antiretroviral Therapy recommends Isoniazid Preventive Therapy for preventing active tuberculosis (TB) disease in all persons aged above 12 months living with HIV in whom TB is excluded and for children less than five years old exposed to a smear positive TB case.

This national IPT SOP gives guidance to healthcare workers on implementing IPT in health care settings.

As the country transitions from one national to a 47 devolved government system, TB/HIV collaborative activities need to be strengthened at county level which includes; strengthening integration of TB/HIV services, closing gaps in HTC, ensuring universal access to immediate ART, optimizing intensified TB case finding, expanding access to more rapid and sensitive TB diagnostic tools, TB infection control, provision of Isoniazid Preventive Therapy (IPT), Drug Resistance TB surveillance and monitoring and evaluation.




DR. JACKSON KIOKO

Head, Directorate of Preventive and Promotive Health Services
Ministry of Health

Acknowledgement

The Kenya IPT SOP was developed through the effort of dedicated stakeholders led by the Ministry of Health's NTLD-Program and NASCOP who discussed, developed, edited and reviewed the content herein.

We wish to make special mention of the following partners of the NTLD-Program and NASCOP, United States Centers for Disease Control and Prevention (CDC), United States Agency for International Development (USAID), Centre for Health Solutions - Kenya (CHS), who provided a multi-sectorial and partnership approach that ensured that the IPT SOP represents the collective best thinking of a broad range of stakeholders.



Dr. Martin Sirengo
Head
National AIDs and STI Control
Program(NASCOP)
Ministry of Health



Dr. Enos Masini
Head
National TB Leprosy and Lung
Disease Program
Ministry of Health

Acronyms

| | |
|----------|---|
| AIDS | Acquired Immune Deficiency Syndrome |
| AMC | Average Monthly Consumption |
| ART | Anti Retroviral Therapy |
| ARV | Antiretrovirals |
| CASCO | County AIDS and STI Coordinator |
| CAT 1 | Category 1 |
| CAT 2 | Category 2 |
| CCC | Comprehensive Care Centre |
| CHS | Centre for Health Solutions - Kenya |
| CHMT | County Health Management Team |
| CLHIV | Children Living with HIV |
| CPT | Cotrimoxazole Preventive Therapy |
| CQI | Continuous Quality Improvement |
| CTLC | County TB and Leprosy Coordinator |
| DAR | Daily Activity Register |
| D/F-CDRR | District/Sub-county/facility Consumption Data Report and Request |
| D/F-MAPS | District/Sub-county/facility Monthly ARV Patients Summary |
| DHIS | District Health Information System |
| DQA | Data Quality Assessment |
| DST | Drug Susceptibility Testing |
| HIV | Human Immunodeficiency Virus |
| ICF | Intensified Case Finding |
| INH | Isoniazid |
| IPC | Infection Prevention and Control Pyrazinamide |

| | |
|--------------|---|
| IPT | Isoniazid Preventive Therapy |
| LfxCsPtoZ | Levofloxacin, Cycloserine, Prothionamide, |
| LMIS | Logistic Management Information System |
| LTBI | Latent Tuberculosis Infection |
| MDRTB | Multi Drug Resistant TB |
| MOH | Ministry of Health |
| NASCOP | National AIDS and STI Control Program |
| NTLD-Program | National Tuberculosis, Leprosy and Lung Disease Program |
| OI | Opportunistic Infection |
| PLHIV | People Living with HIV |
| RH | Rifampicin, Isoniazid, |
| RHZE | Rifampicin, Isoniazid, Pyrazinamide, Ethambutol |
| SCASCO | Sub County AIDS and STI Coordinator |
| SCTLC | Sub County TB and Leprosy Coordinator |
| SOPs | Standard Operating Procedures |
| SS +ve | Sputum Smear positive |
| SS-ve | Sputum Smear Negative |
| TB | Tuberculosis |
| USAID | United States Agency for International Development |
| WHO | World Health Organization |

IPT at a Glance

Isoniazid Preventive Therapy, or IPT, refers to the use of Isoniazid (INH) to treat patients who have Latent TB Infection (LTBI) but do not have active TB disease. It is national policy to provide IPT to all asymptomatic PLHIVs aged over 12 months and all children aged less than 5 years, regardless of their HIV status, exposed to sputum smear positive TB. Before initiation of IPT, all eligible persons should be subjected to symptomatic screening to rule out active TB, to prevent Isoniazid mono therapy and emergence of resistance.

For these patients, a six-month course of INH mono therapy significantly reduces the risk of progression from LTBI to active TB disease. Providing IPT for people living with HIV (PLHIV) not only reduces the individual patient's risk but also helps to mitigate TB transmission to others. The WHO 2011 Guidelines on intensified case finding (ICF) and IPT strongly recommends the provision of IPT to HIV-infected adults and children who are unlikely to have active TB based on simple symptom screening.

Intensive Case Finding

Every child under the age of 5 years exposed to sputum smear positive TB should be screened for TB. Likewise, PLHIVs should be screened for TB on every visit using the standard MOH ICF/IPT tool

- **Ask** the adult patients for cough of any duration, fever, night sweats, noticeable weight loss.
- **Ask** for history of cough of any duration, fever, night sweats, weight loss or poor weight gain, less playfulness and history of TB contact in children.
- If the patient says “yes” to any of the above, investigate appropriately based on the Algorithm for TB screening and IPT and manage.
- For those who screen negative to all the above questions, they should be worked up for IPT as follows.

IPT work up

- **Ask** the patient for signs of liver disease (yellowness of eyes) and neuropathy (persistent numbness and burning sensation in the feet and hands).
- **Examine** the patient for jaundice and tenderness in the right upper quadrant of the abdomen.
- Where available, routine liver function tests/ALT should be offered, but lack of LFTs/ALT results should not delay the initiation of IPT in asymptomatic patients.
- If the patient does not have any abnormality based on the assessment above, assess for adherence using the criteria on the backside of the ICF/ IPT card.

Initiating IPT

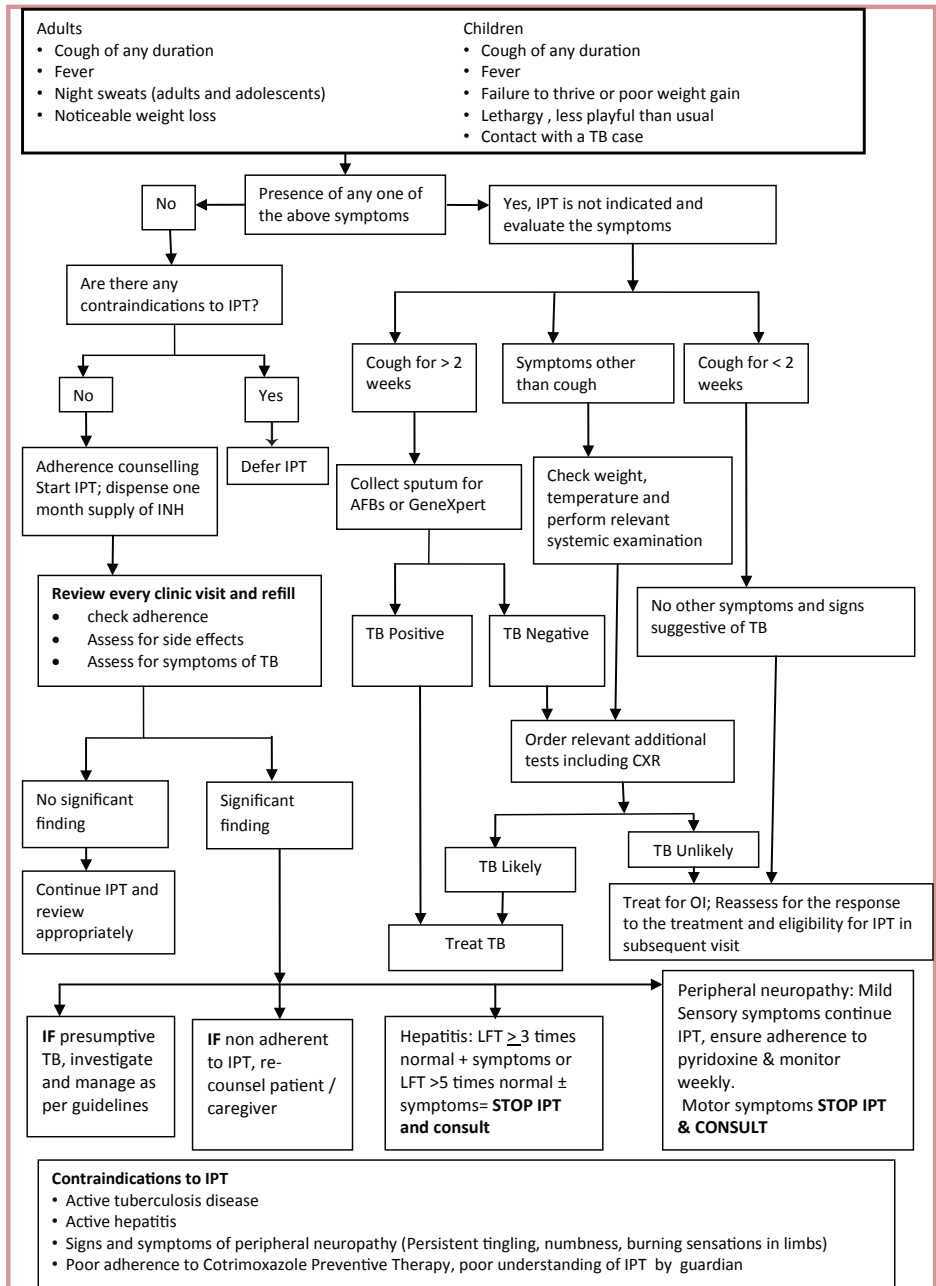
- Start the client on 10mg of Isoniazid per kg, maximum 300mg once daily and pyridoxine. Record the indication of IPT in the ICF /IPT card and IPT register and book the patient for clinical review.
- On every subsequent visit, screen the patient for TB using the ICF/IPT card and assess for hepatotoxicity, peripheral neuropathy, rash and adherence. Record these findings at every visit, at the back of the ICF/IPT card.
- If you notice any of the toxicities, manage appropriately.
- Harmonize IPT review visits with routine CCC visits.
- On every subsequent visit, update the register and IPT card.
- Currently, IPT is recommended once in a life time for the duration of 6 months.
- IPT can be started at any time during pregnancy and should be completed if a woman falls pregnant while taking it.

IMPLEMENTING ISONIAZID PREVENTIVE THERAPY

1. TB screening

All persons living with HIV (PLHIV) should be screened for TB using symptom based approach. Those who do not have any symptoms are unlikely to have active TB disease. INH preventive therapy is indicated for such patients as indicated in the subsequent sections.

The following Algorithm summarizes the steps for TB screening and follow- up of the patients.



2. Use of Xpert MTB/Rif (GeneXpert) in Diagnosis of TB for PLHIV

Patients with symptoms suggestive of TB should be investigated to rule out active TB disease. GeneXpert is a molecular diagnostic test for TB disease that can detect *Mycobacterium Tuberculosis* DNA and Rifampicin resistance from sputum specimens in less than 2 hours. GeneXpert is increasingly available in Kenya in the public health sector and is now recommended for TB diagnosis. This technology is more sensitive than sputum microscopy in detecting TB.

Indications for GeneXpert

1. TB Diagnosis

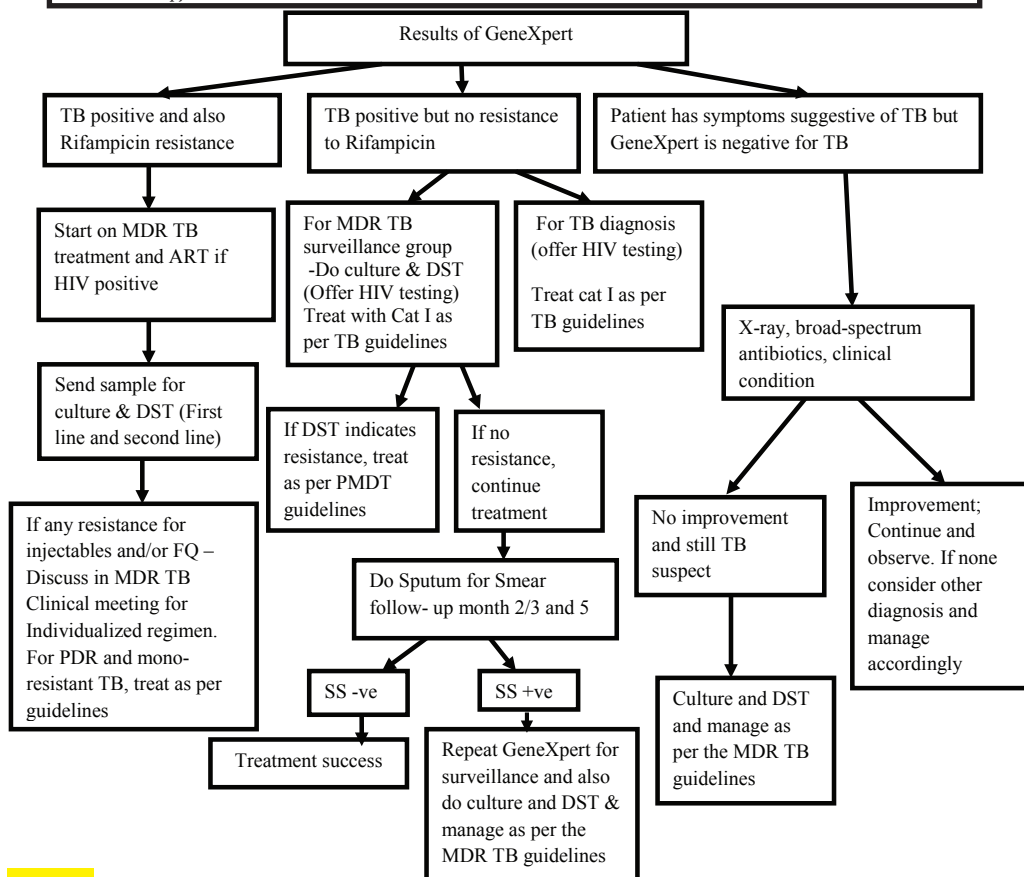
- HIV positive with TB symptoms
- Children under 15 years with TB symptoms
- All smear negative TB cases

2. MDR TB surveillance

- All previously treated patients: a. failures; b. relapses; c. treatment after loss to follow up
- DR TB contacts
- Health care workers with TB symptoms
- Patients who develop TB on IPT
- Refugees with symptoms of TB
- Smear positive at 2 months
- Prisoners with TB symptoms

In areas where GeneXpert is available: this should be the first test. Patients diagnosed with GeneXpert should be followed up with microscopy

Results of GeneXpert



Note:

1. Carry out first line and second line culture and DST in all patients under the MDRTB surveillance group found to have TB.
2. Carry out first line and second line culture and DST in all patients found to have TB and Rifampicin resistance whether in MDR TB surveillance or in TB diagnosis group. Treat TB patients without Rifampicin resistance with CAT 1 (2 RHZE/4RH).
3. Record patients with Rifampicin resistance, as RRTB and treat them with MDR TB regimen (8KmLfxCsPtoZ/12 LfxCsPtoZ).

3.Indications for Isoniazid Preventive Therapy

- Children living with HIV who are >12 months of age who screen negative for TB using the ICF tool.
- Children living with HIV who are <12 months of age, who have contact with a smear positive TB case and screen negative for TB using the ICF tool.
- All HIV negative children under 5 years who have contact with a smear positive TB case and screen negative for TB using the ICF tool.
- All PLHIV above 12 months of age who screen negative for TB using the ICF tool.
- Prisoners, irrespective of HIV status who screen negative for TB using the ICF tool.

Note:

- IPT can be started at any time after successful completion of TB treatment.
- IPT has not been shown to increase the risk of developing isoniazid-resistant TB.
- IPT is safe to use during pregnancy and people with a past history of TB treatment.
- Avoid alcohol consumption while on IPT due to increased risk of hepatotoxicity.

Considering the high prevalence of TB infection in Kenya, all HIV infected people above 12 months of age with no signs or symptoms suggestive of active TB are eligible for TB preventive therapy

4. Contraindications to IPT

1. Active hepatitis (acute or chronic).
2. Symptoms of peripheral neuropathy (In adults and older children; persistent numbness, tingling or burning sensation in limb/s, in younger children; regression in motor milestones, refusal to crawl, walk, or run).
NB. If the client has any of the above contraindications, defer IPT: manage the underlying condition and re-evaluate for IPT on the next visit.
3. Contacts of Drug Resistant TB and PLHIV who have completed DRTB treatment

5. Initiation of IPT

Before initiating IPT

- Symptom-based TB screening using ICF tool **must** be conducted for all PLHIV at every visit and for all children less than 5 years of age who have had contact with infectious TB to rule out active TB.
- Rule out hepatitis (jaundice, right upper quadrant tenderness and other appropriate tests).
- Rule out peripheral neuropathy.
- Chest radiography, Alanine Aminotransferase (ALT) and Tuberculin Skin Test (TST) are not mandatory as part of routine screening for IPT. Liver function tests should however be conducted if the patient develops symptoms suggestive of hepatitis while on IPT (anorexia, nausea, vomiting, jaundice and abdominal pain).
- Investigations for TB should be performed using Xpert MTB/RIF (Gene Xpert) as the preferred first line test for those found to have symptoms of TB. Smear microscopy can be used in absence of Xpert MTB/RIF (Gene Xpert).
- Infection control measures should be given priority to reduce TB transmission in all settings that provide patient care.

Duration and dose of Isoniazid

IPT should be given at a dose of 10 mg/kg/day (maximum 300 mg) for a duration of 6 months. Children should be weighed at every visit and their dose adjusted according to their weight.

Dose of INH for IPT

| Weight range (kg) | Dose in mg | Number of 100mg INH tablets | Number of 300mg (Adult) tablet |
|-------------------|------------|-----------------------------|--------------------------------|
| <5 | 50 | ½ tablet | - |
| 5.1-9.9 | 100 | 1 tablet | - |
| 10-13.9 | 150 | 1 ½ tablet | or ½ tablet |
| 14-19.9 | 200 | 2 tablets | - |
| 20-24.9 | 250 | 2 ½ tablets | - |
| >25 | 300 | 3 tablets or | or 1 tablet |
| Adults | 300 | 3 tablets or | or 1 tablet |

The current recommendation for use of IPT is once in a lifetime for PLHIV. However, children below the age of 5 in close contact with a smear positive TB patient should receive a repeat dose of INH for 6 months even if they had received IPT previously

Dosing of Pyridoxine for all patients taking Isoniazid

All patients taking INH (whether for IPT or TB treatment) should preferably also receive daily pyridoxine to reduce the risk of developing peripheral neuropathy.

Dosages for Pyridoxine

| Weight (kg) | Number of tablets of pyridoxine (50mg) |
|-------------|--|
| 1-13.9 kg | Quarter tablet daily |
| 14-25 kg | Half a tablet daily |
| >25 kg | One tablet daily |
| Adults | One tablet daily |

6. Follow Up of Patients on IPT

- Explain the TB disease process and the rationale of IPT, and emphasize the importance of completing the treatment.
- Assess for their adherence.
- Emphasize importance of adherence and give adherence messages during clinic visits.
- Screen for active TB during each clinic visit using symptom based intensive case finding (ICF) card.
- Update their ICF cards and IPT register at every visit and document the outcome on completion of therapy.
- Monitor for INH side effects at every visit and manage accordingly.

Advise to return immediately if they develop complaints of: -

| | |
|---|--|
| Rash | Fever |
| Consistent fatigue or weakness lasting more than 3 days | Persistent tingling and numbness of hands and feet |
| Dark urine | Cough |
| Jaundice | Night sweats |
| Loss of appetite | Chest pain |
| Nausea | Difficulty in breathing |
| Abdominal pain | Reduced playfulness in children |
| Vomiting | |

- **If a patient develops signs and symptoms of TB:**
 Stop IPT and evaluate for TB disease (Obtain sputum for GeneXpert or AFB microscopy, obtain any other relevant specimen, Culture and DST (To rule out DR TB) and if confirmed, classify and manage as per the TB guidelines.

7. Management of Complications of IPT

Table below summarizes the management of IPT complications

| Complication | Management |
|-----------------------|---|
| Hepatitis | <p>Rule out other causes of hepatitis and do LFTs/ALT</p> <ul style="list-style-type: none"> Discontinue IPT in patients with ALT/AST more than three times the upper normal limits with signs and symptoms of liver disease or asymptomatic patients with ALT/AST more than five times the upper normal limits. |
| Peripheral neuropathy | <ul style="list-style-type: none"> In cases of mild peripheral neuropathy, double the daily dose of vitamin B6 (pyridoxine) until the symptoms disappear. If the peripheral neuropathy is severe or worsens, then discontinue Isoniazid immediately. |

8. Restarting IPT after interruption

| Scenario | Action |
|--|--|
| If patient had discontinued INH for less than 1 month | <p>Conduct adherence counseling, Conduct ICF and if asymptomatic Continue from where they left off Ensure they have completed a 6 month course</p> |
| If a patient had taken INH for less than 1 month in total and discontinued for any reason (like toxicity or loss to follow up) | <p>Conduct adherence counseling, Address reasons for discontinuation Conduct ICF and if asymptomatic Restart INH afresh Ensure they have completed a 6 month course</p> |
| If patient had discontinued INH for more than 1 month but less than 3 months | <p>Conduct adherence counseling, Conduct ICF and if asymptomatic Restart INH Ensure they complete a 6 month course within a 9 month period</p> |
| If patient discontinued for more than 3 months, or had discontinued more than once | Do not re-initiate IPT |

9. Follow up after completion of IPT

- Conduct symptom based TB screening at every clinic visit for patients who have completed IPT.
- Update 12, 18, and 24-month TB status for every patient in the IPT register.
- If patients screen positive (TB ICF) after completing IPT, manage according to national TB guidelines.

If patients screen positive (TB ICF) after completing IPT, manage according to national TB guidelines.

10. IPT in special circumstances

| Scenario | Action |
|--|--|
| Patients previously treated for TB (Secondary prophylaxis) | <ul style="list-style-type: none"> • Initiate IPT for another 6 months in PLHIV who successfully complete their first line TB treatment |
| IPT and Pregnancy | <ul style="list-style-type: none"> • Isoniazid is safe in pregnancy. Start IPT in all HIV positive pregnant women irrespective of their gestation period. • Advise women to complete IPT if a woman becomes pregnant while taking IPT. • Assure patient that IPT is safe while breastfeeding. |
| IPT and MDR-TB | <ul style="list-style-type: none"> • Contacts of MDRTB and PLHIV who have completed DRTB treatment are not eligible for IPT. <p><i>Note: Serious limitations of the quality of evidence prevent drawing any recommendations on MDR-TB preventive therapy as a public health measure. Strict clinical observation and close monitoring for the development of active TB disease for at least two years is preferred over the provision of preventive treatment for contacts with MDR-TB cases.</i></p> |
| IPT in children born to smear positive mothers: | <ul style="list-style-type: none"> • If a baby is born to a TB sputum +ve mother, assess the newborn for TB. <p><i>Non-specific features suggestive of neonatal TB include: Fever, low birth weight, hepato-splenomegally, irritability, feeding intolerance.</i></p> <ul style="list-style-type: none"> • If the child has none of the above, give IPT for 6 months. • Withhold BCG until 2 weeks after completion of IPT. |

11. Commodity Management

i) *SOP for dispensing Isoniazid (INH)*

Procedure for dispensing Isoniazid to eligible PLHIV and children under 5 with contact to smear positive TB

Responsible persons: Pharmacists, pharmaceutical technologists and other health professionals (e.g HCWs at the TB clinic/MCH)

Procedure

1. Dispense appropriate doses of Isoniazid to eligible patients at CCC pharmacy, TB clinic or MCH clinic.
2. Ensure that there is availability of a six-month dose for each patient before initiation.
 - As much as possible, store the medicines for continuing patients at separate area to avoid stock outs.
 - Alternatively, a 6 month pack of INH can be labeled and ear marked for each initiated patient.
3. Align INH refill appointments with ARV refill appointments i.e. if ARVs are dispensed for 2 months, then INH should also dispensed for 2 months.
4. Use revised ART LMIS tools(2014) i.e. DAR ARVs and OIs or electronic dispensing tools (ADT) to fully document each dispensing encounter.
5. Patients should be counselled on adherence and monitored for side effects at every visit.

ii) *SOP for reporting and ordering for INH for PLHIV and children under 5 with contact to smear positive TB*

Procedure for reporting and ordering for INH

Location: Central sites, standalone sites, satellite sites, and TB clinics.

Responsible persons: Pharmacists, pharmaceutical technologists and other health professionals.

Procedure

1. Submit monthly reports and orders for resupply from all CCCs and TB clinics offering IPT to KEMSA or central sites (as the case may apply).
2. Follow same timelines for reporting and ordering for ARVs and INH monthly reports.
3. Apply same formula for determining quantity for resupply of INH as that for ARVs i.e. [(AMC X 3)-SOH for central and standalone sites and [(AMC X 2)-SOH for satellite sites].
4. Use revised ART LMIS tools(2014) i.e. D/F-CDRR and D/F-MAPS (manual or electronic) for reporting and ordering for INH and Pyridoxine.
5. Submit filled D/F-CDRR and D/F-MAPS as per normal ARV reporting channels i.e. to KEMSA or central site.

12. Monitoring and Evaluation

i) Facilities implementing IPT should have the following tools

a) Recording tool

| Tool | Use | Location CCC | Location MCH (PMTCT) | Location TB clinic |
|--|--|-----------------|----------------------------|-----------------------|
| Adult and Pediatric ICF/IPT tool | At each visit and for any child contact for intensive case finding and IPT patient follow up | √ | √ | √ |
| IPT register | A record of all patients on IPT in the facility and their outcomes | √ | √ | √ |
| Presumptive TB/ Contact tracing register | For contacts of bacteriologically confirmed TB patients | √ | √ | √ |
| Daily activity register for CCC | A record of daily patient visits and services offered | √ | √ | √ |
| Pharmacovigilance tools | Record patients with ADR | √ | √ | √ |

b) Reporting tools

| Tool | Use | Location CCC | Location MCH (PMTCT) | Location TB clinic |
|---|---|-----------------|----------------------------|-----------------------|
| MOH 731 | Comprehensive HIV/AIDS facility form | √ | √ | |
| MOH 711 | National Integrated form- RH/ HIV/TB/Malaria | √ | √ | √ |
| FCDRR | Facility consumption data report and request | √ | | √ |
| Daily activity register for TB and OI drugs | A record of daily patient visits and services offered | √ | | √ |
| Pharmacovigilance tools | Report patients with ADRs | √ | | √ |

ii) SOP on use of IPT Monitoring and Evaluation (M&E) tools

Procedure for documenting and Reporting Number of clients screened for TB and uptake of IPT among eligible clients

| 1. Documentation | |
|-----------------------|--|
| Screening | <p>All PLHIV, children <5years exposed to smear positive TB and prisoners shall be screened for TB as per the National guidelines using ICF/IPT tool. Record those screened in the following registers</p> <ol style="list-style-type: none"> Daily Activity Register (DAR) for PLHIV. (Use the appropriate column against the patients CCC number at each visit when they are screened) Combined presumptive TB/contact register at the TB clinic for children < 5 exposed to smear positive TB. The TB screening registers for prisoners. |
| IPT Initiation | <ol style="list-style-type: none"> Clinicians should fully update the patient IPT /ICF card at the start of IPT and at every visit made for IPT refills. The facility M&E staff (data clerk) will record all PLHIVs started on IPT in the CCC IPT register, and at every subsequent visit made for IPT refills. The TB clinician/nurse will record all children under the age of 5 started on IPT in the TB clinic's IPT register, and at every subsequent visit made for IPT refills. <p>The IPT registers will be recorded such;</p> <ul style="list-style-type: none"> Serially record all patients in the IPT register beginning each calendar year, <i>(the number should indicate a serial number and year e.g. 1/15).</i> Indicate the IPT serial number in the ICF/IPT tool and the MOH 258(appointment card) for PLHIV and ICF/IPT card for children < 5 exposed to smear positive TB. At the end of every month, draw a line to close the month and summarize the month as per criteria provided at the bottom of the IPT register <i>(Total started on IPT during the month disaggregated by age < 15 and 15+).</i> The Facility serial numbers in the IPT register shall be continued in the following month. For Each Month, Identify the cohort that has 12 months since the IPT start date and Indicate their 12 months outcomes. New serial numbers shall be initiated in the beginning of the following calendar year. <i>(Use the codes provided at the bottom of the register)</i> |

| 2. Reporting for IPT | |
|----------------------------|--|
| Various populations | <p>PLHIV</p> <ol style="list-style-type: none"> Use the MOH C&T Tally sheet to tally and count the persons started on IPT during the month. Transfer the Totals from tallying to MOH 731 departmental form and the Monthly summary form. <p>Children under 5 exposed to smear +ve TB</p> <ol style="list-style-type: none"> The SCTLC shall document all < 5 in TIBU. The health care worker at the TB clinic shall summarize the total number of exposed children under 5 years started on IPT. Transfer the totals number of children <5 years to relevant section of MOH 711. <p>Prisoners</p> <p>The health care worker at the prison shall make a monthly summary on the IPT register and transfer the totals to MOH 711.</p> |
| Data Flow | <ol style="list-style-type: none"> The Sub County HRIO shall report the number of clients started on IPT and the number screened for TB into DHIS using MOH 731summary sheet. The HRIO shall enter the MOH 731 and MOH 711 to DHIS. The Sub County Tb Coordinator shall report the monthly totals using TIBU. |
| Data Use | <p>DQA</p> <p>The SCASCOs and SCTLC shall conduct Data Quality Assessments (DQA) at least once in a quarter. They will check on data completeness, accuracy and validity.</p> <p>CQI</p> <p>The CQI team at the health facility will check their performance every quarter and identify areas of improvement.</p> <p>NB: <i>There will be instructions at the beginning of all tools to aid in proper use of each of the registers.</i></p> |

Annex 1

[illegible]

Annex 2: Editorial Team

| | |
|----------------------------|------------------------------------|
| Caroline Olwande | NASCOP |
| Christine Wambugu | NTLD Program |
| Immaculate A. Kathure | NTLD Program |
| Irene Mukui | NASCOP |
| Jacob Odhiambo | NASCOP |
| Lorraine Mugambi – Nyaboga | CHS |
| Shobha N. Vakil | NASCOP/HRH Capacity Bridge Project |
| Susan Njogu | NASCOP |
| Ruth Wanjala | CHS-TB ARC |

Annex 3: List of Contributors

Brenda Mungai, CHS- TB ARC
 Caroline Olwande, NASCOP
 Carolly Migwambo, Homabay District Hospital
 Christine Wambugu, NTLD Program
 Daniel Maina – NASCOP
 Elizabeth Mueni, CHMT-Nairobi
 Enos Masini, NTLD Program
 Eunice Mailu, NTLD Program
 Eunice Omany, Aphia Plus
 Hellen Kalili, CHS
 Hiram Mathenge, CHMT-Nyeri
 Immaculate A. Kathure, NTLD Program
 Irene Mukui, NASCOP
 Jack Kioko, NTLD Program
 Jennifer Kiruri, CHMT-Nyeri

Jeremiah Okari, NTLD Program
John Ndegwa, CHMT-Nyeri
John Njenga, CHS-TB ARC
Kadondi Kasera, NTLD Program
Kamene Kimenya, NTLD Program
Kennedy Chepkonga, APHIA Plus
Lorraine Mugambi-Nyaboga, CHS
Magdalene Ongas, CHMT-Homabay
Mary Mugambi, CHMT-Nairobi
Maureen Kimani, NASCOP
Micah Anyona, MOH
Mohamud Mohamed, NASCOP
Mutungi Muriithi, FHI 360
Nelius Njeri Mwangi, NASCOP
Newton Ang'wa, NTLD Program
Philip Owiti, AMPATH
Rebecca Wangusi, ICAP
Richard Muthoka, NTLD Program
Ruth Kamau, CHS
Shobha N. Vakil, NASCOP/HRH CBP
Willis Omwoyo, CHMT-Homabay



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