National Guidelines for the Three I’s (ISONIAZID PREVENTIVE THERAPY (IPT) INTENSIFIED CASE FINDING (ICF) INFECTION CONTROL (IC)) (FIRST EDITION)
FOREWORD

TB and HIV constitute major public health problems in Lesotho. Undoubtedly, one of the major factors fuelling the TB epidemic in Lesotho is the high HIV prevalence at 23.6% (LDHS 2009). There is clear evidence of increasing morbidity and mortality from this devastating dual epidemic.

Lesotho has one of the highest annual TB incidence of 635/100,000 according WHO 2010 Global Tuberculosis Report. Based on the 2010 surveillance data, the proportion of TB patients that tested positive for HIV was 76.9% compared to 76% in 2009.

It has therefore become imperative to address the two diseases, which are mostly suffered concurrently by one patient, in a comprehensive manner using sound strategies and approaches. The need for such approaches is strong and urgent as most TB/HIV cases occur among the poor segments of our population; and about 70% are young adults in their most productive years.

The goal of these guidelines for Intensified Case Finding (ICF) and Isoniazid Preventive Therapy (IPT) for People Living with HIV (PLHIV) will contribute immensely towards reduction of morbidity and mortality from tuberculosis (TB) as one of key strategies of TB/HIV collaborative activities for this vulnerable segment of our population. Release of World Health Organizations (WHO) guidelines came at an opportune time for Lesotho, as we prepare to kick start the implementation of IPT as part of the three I’s and we were overjoyed to make use of them as baseline as we develop country specific guidelines.

The NTP and HIV/AIDS program strongly feel that implementation of ICF/IPT guidelines will come as a breakthrough for the PLHIV and for the Health System of Lesotho as the country advances towards achieving the health related MDGs.

DR. MPHU RAMATLAPENG

HONOURABLE MINISTER OF HEALTH & SOCIAL WELFARE
REFERENCES


Acknowledgements

The Ministry of Health and Social Welfare appreciates the efforts of the National TB/HIV Technical Advisory Committee, particularly the team responsible for developing the TB/HIV (Three Is) guidelines. We congratulate the National Tuberculosis and the HIV and AIDS Programmes for taking a leading role in the guidelines development process, which will hopefully guarantee sustainability of our programmes and interventions.

The Ministry expresses its sincere thanks to International Center for AIDS Care and Treatment Programs (ICAP), Baylor Center of Excellence, Elizabeth Glaser Paediatrics AIDS Foundation (EGPAF), World Health Organization (WHO), Médecins Sans Frontières (MSF), Solidarmed, Partners In Health (PIH), Johns Hopkins University and The U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) for support.

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When to offer ICF and IPT

ICF: Screening for TB and excluding active TB

Initiation of IPT

Contraindications to IPT

Recommended Regimen, Dose, and Duration

When to stop IPT

Frequently Asked Questions about IPT in Adults and Adolescents

Where should ICF and IPT be provided?

ICF: Screening for TB and excluding active TB

Eligibility for IPT

Contraindications to IPT

Recommended Regimen, Dose, and Duration

Monitoring

When to stop IPT

Frequently Asked Questions about IPT in Infants and Children

Monitoring and Evaluation Tools

What information should be recorded, where, when and by whom?

What information/data should be reported?

Importance of data collection

Flow of information

HIV counseling and testing / ART Centres

TB/HIV Activities

Infection Control Measures on the Wards

Operating Theatres

Laboratories

Intensive Care Areas

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<table>
<thead>
<tr>
<th>UNIT/LOCATION</th>
<th>CONTROL TYPE</th>
<th>NUMBER ON SITE</th>
<th>NUMBER OPEN/IN USE</th>
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<table>
<thead>
<tr>
<th>Low Risk</th>
<th>Medium Risk</th>
<th>High Risk: Potential Ongoing Transmission</th>
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<tr>
<td>Clerical Staff</td>
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<td>Dental Staff</td>
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<td>Dietician</td>
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<td>Drivers</td>
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<td>Food Service Staff</td>
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<tr>
<td>Groundsman</td>
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<td>Health and Safety Staff</td>
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<tr>
<td>Housekeeping Staff</td>
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<tr>
<td>Infection Control Staff</td>
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<td>Laundry Staff</td>
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<tr>
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<td>Paeds.</td>
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<td>Health Educators.</td>
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<td>Radiologists</td>
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<td>Social Workers</td>
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<td>Students</td>
<td>*</td>
<td></td>
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<tr>
<td>Volunteers.</td>
<td>*</td>
<td></td>
</tr>
</tbody>
</table>

**Low Risk** = Baseline medical assessment.

**Intermediate Risk** = Baseline medical assessment and annual TB review.

**High Risk** = Baseline medical assessment and quarterly TB review.

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Instructions: How to Use the Triage Form

1. The Triage Form will be used by designated persons in all of the High Risk Waiting Areas (e.g. Wellness Clinics, OPD (Primary Health Clinics), etc).
2. The Triage Tick sheet will “lead” the Designated Triage Person to take the necessary steps.
3. Each Designated Triage Person will receive necessary training on:
   - How to fill in the Triage Form
   - Importance thereof
4. This will be done by either making use of the Professional and Non-Professional TBIC Training slides and Cough Etiquette and triage Posters (or other training materials if applicable).
5. The Designated Triage Person gives informal TBIC Health Educational talks throughout the day, so that other clients understand why certain clients are given preference in the waiting area and also to take the Triage and Cough Etiquette message home.
6. Time Evaluation:
   - Designated Triage Person signs for time patient arrives at clinic
   - Sister or Doctor signs for time of patient consultation
   - Pharmacist signs for time patient leaves clinic
   - Pharmacist detaches the document from the patient file and keeps the document behind for the TBIC coordinator or TB/HIV officer.
ANNEX 6.3. TB INFECTION CONTROL TRIAGE FORM

TB INFECTION CONTROL PATIENT TRIAGE FORM
(for monitoring and evaluation during period of observation)

Date (dd/mm/yy): ____________________________
Queue number: ____________________________

-------------------------------------------------------------------------------------------------------------

1. Health Service that patient requires today (Tick all that apply by indicating with a √):
   - Medical Clinic
   - HIV Care and Treatment
   - Pharmacy/Medication Refill only
   - TB Clinic
   - Family Planning/Contraception
   - Antenatal Care Clinic
   - Other: Specify

2. Ask the patient the following questions, indicating the patient’s response with a √
   YES NO
   1. Have you had a cough for more than 2 weeks? __________
   2. Are you currently under investigation for TB? __________
   3. Are you currently receiving treatment for TB? __________

   If the patient answers “Yes” to ANY question:
   - Give patient a tissue
   - Instruct on Cough Etiquette
   - Direct patient to separate waiting area (if available)
   - Direct patient to front of the queue

   Time Signature
   Patient arrival (Triage staff) __________
   Patient consultation (Doctor/Sister) __________
   Patient departure (Pharmacist) __________

CHAPTER 1: INTENSIFIED CASE-FINDING FOR TUBERCULOSIS AND ISONIAZID PREVENTIVE THERAPY TO REDUCE THE BURDEN OF TB AMONG PERSONS LIVING WITH HIV

BACKGROUND

Lesotho has the 7th highest incidence of tuberculosis (TB) in the world.[1] In 2009 it was estimated that the incidence of TB was 634 per 100,000.[1] Of new TB cases notified, 34% were sputum smear-positive, 28% were sputum smear-negative, and 22% were extrapulmonary.[1] 73% of new sputum smear-positive, 66% of new sputum smear-negative, and 62% of retreatment TB cases were successfully treated in 2008.[1] It is estimated that 0.9% of new TB cases and 5.7% of retreatment TB cases are multi-drug resistant (i.e. resistant to both isoniazid and rifampin).[1]

TB cases are routinely detected through passive case-finding, when symptomatic patients present to health services for diagnosis and treatment. Unfortunately symptomatic patients not uncommonly have to present multiple times before they are appropriately investigated for TB.[2, 3] Intensified case-finding for TB (ICF) differs from passive case-finding in that screening and the diagnostic work up for TB is initiated by the provider among persons living with HIV/AIDS (PLWHA). ICF benefits the individual patient by detecting TB earlier.[4-6] Morbidity and mortality due to TB is reduced with initiation of treatment earlier in the course of the disease.[4-6] The benefits of ICF at a population level include: (1) detection of undiagnosed active TB cases, which will result in a progressive decline in the prevalence of undiagnosed active TB and an increase in the TB case detection rate; (2) reduction in TB transmission through earlier detection and treatment of TB cases, resulting in a reduction in the prevalence of TB (a key driver of TB transmission at a population level) and subsequently a decline in the incidence of TB; and (3) improved infection control within health facilities.

Isoniazid preventive therapy (IPT) is used to treat latent TB infection and reduce the risk of progression from latent to active TB disease. IPT was first studied by Dr. George Comstock in Bethel, Alaska in the United States, where it was used to control an epidemic of TB in the 1950s and 1960s.[7] IPT and other preventive regimens for TB have been studied in numerous settings since that time. A Cochrane systematic review of 12 trials including 8,578 randomized HIV-infected participants found that TB preventive therapy reduced the risk of active TB by 32%.[8] Although all TB preventive regimens studied had similar efficacy, IPT was less likely than other regimens to require discontinuation due to adverse reactions.[8] Antiretroviral therapy (ART) has also been shown to reduce the risk of progression from latent to active TB through reconstitution of the immune system, but HIV-infected patients on ART are still at higher risk for active TB than are HIV-uninfected persons. The risk of TB is particularly high during the first 6 months after ART initiation.[9, 10] IPT has been shown to have an added benefit on top of ART for preventing active TB.[11, 12] IPT is also effective as
secondary prevention for preventing recurrent TB among patients with a prior history of TB.[13] Isoniazid is safe in pregnancy and is not teratogenic.[14][15]

Although Lesotho has been successful in integrating HIV-related services into TB care, it is only now beginning to integrate TB-related services into HIV care. 78% of TB patients knew their HIV status in 2009, 77% of whom were HIV-infected. 96% of HIV-infected TB patients received co-trimoxazole prophylaxis, and 28% were started on antiretroviral therapy.[1] In contrast, Lesotho did not report any data on ICF or IPT among HIV-infected persons in 2009.[1]

Lesotho’s ICF and IPT guidelines are based on the World Health Organization (WHO) guidelines, which recommend screening for TB and excluding TB using the following symptoms: cough of any duration, fever, night sweats and weight loss.[16] Sputum should be collected from symptomatic PLHIV for sputum smear microscopy and mycobacterial culture, or for GeneXpert rapid testing.[17] TB is the most common opportunistic infection and a leading cause of death in PLHIV. The risk of an HIV positive person to develop TB disease is ten times more than that of a person who is HIV negative.

Persons without TB disease at the time of HIV diagnosis may still develop TB in later years, and will then be at risk of spreading M. Tuberculosis in the community as well as to fellow patients, Health Care Workers, and staff at their ART clinics and in community programs. Health Care Workers and other staff are particularly at high risk of infection with TB because of frequent exposure to TB patients and immuno-suppressed due to HIV infection.

The goal of the TB Infection Control (IC) section, is to help management and staff to minimize the risk of TB transmission at facilities and communities. This guideline document is for policy makers, health care workers, administrators, and stakeholders in the public, private, and non-governmental health sector involved in providing care and treatment to persons with TB. It can also be helpful for persons or institutions responsible for the health and well-being of large numbers of persons living with HIV / AIDS (PLHIV) and to the general public as a whole. Settings include HTC centres, community-based outreach centres, health centres, clinics, correctional institutions including detention centres.

The WHO guidelines thus recommend screening for TB using symptoms of cough of any duration, fever, night sweats and weight loss, and collecting sputum for testing from symptomatic persons.[16]

**DELIVERY OF ICF/IPT BY LESOTHO’S HEALTH SERVICES**

ICF and IPT are interventions that should be part of a comprehensive package of care provided to all PLHIV who present for HIV/AIDS-related care in Lesotho.
ICF AND IPT AMONG HIV-INFECTED ADULTS AND ADOLESCENTS

When to offer ICF and IPT

Patients with an CD4 count of less than 350 or WHO stage III/IV should be offered ICF and IPT. In addition, patients who present with symptoms of TB, or patients who are judged to be at high risk of TB, should be offered ICF and IPT. Patients should be counseled about the benefits of taking IPT, including the potential for reduced morbidity and mortality, and the need for adherence to IPT.

Data collection

Data on the number of patients screened for TB, the number found to be TB suspects, and the number referred for TB investigations should be collected as a part of the routine data collection process. This information can be used to monitor the implementation of the ICF and IPT program and to assess the impact of the program on TB control.

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The following pre-conditions are in line with the Lesotho Ministry of Health and Social Welfare (MoHSW) guidelines and policies and must be met in order to assure proper implementation:

- High quality voluntary counseling and rapid testing for HIV is available.
- There is strong collaboration between HIV/AIDS and TB services.
- HIV/AIDS services – including pre-ART, ART and MCH/ANC – take responsibility for implementing ICF and IPT.
- TB Infection Control (IC) is also an essential component of TB prevention among PLHIV.
- All PLHIV that attend HIV/AIDS services should be screened for TB, including the number of people screened for TB, number found to be TB suspects, and the number referred for TB investigations.
- Early initiation of ART is an essential component of TB prevention among eligible HIV-infected persons. Eligibility criteria for ART include:
  - CD4 <350 or WHO stage III/IV
  - Any CD if the patient has TB

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- All PLHIV that attend HIV/AIDS services should be screened for TB, including the number of people screened for TB, number found to be TB suspects, and the number referred for TB investigations.
- Early initiation of ART is an essential component of TB prevention among eligible HIV-infected persons. Eligibility criteria for ART include:
  - CD4 <350 or WHO stage III/IV
  - Any CD if the patient has TB

The following pre-conditions are in line with the Lesotho Ministry of Health and Social Welfare (MoHSW) guidelines and policies and must be met in order to assure proper implementation:

- High quality voluntary counseling and rapid testing for HIV is available.
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  - CD4 <350 or WHO stage III/IV
  - Any CD if the patient has TB
HIV-infected patients should be screened for signs and symptoms of active TB at every clinical encounter, including when he/she is first diagnosed with HIV. ICF is essential to exclude active tuberculosis, which requires treatment with a multi-drug TB treatment regimen.

Eligible HIV-infected adults and adolescents should be initiated on IPT irrespective of the CD4 count and WHO stage. Adults and adolescents who are already on ART and in whom active TB has been excluded should be initiated on IPT.

Where should ICF and IPT be provided?
ICF and IPT should be offered to all HIV-infected adults and adolescents presenting to health care facilities in Lesotho (e.g. hospitals, filter clinics, health centres, specialized centers and private clinics).

IPT needs to be integrated within the HIV services provided by the pre-ART clinics, HIV/ART clinics, MCH/ANC clinics and pediatric clinics.

Who can provide ICF and IPT?
All health care providers are expected to provide TB symptom screening according to national guidelines to HIV-infected adults and adolescents.

All doctors, clinical officers, nurse clinicians and nurses who have been trained and mentored can initiate IPT.

ICF: Screening for TB and excluding of active TB
It is essential to exclude active tuberculosis in HIV-infected adults and adolescents prior to starting IPT in order to avoid giving a single anti-tuberculosis drug to patients with TB disease who require a multi-drug treatment regimen.

At every clinical encounter, HIV-infected adults and adolescents should be screened for signs and symptoms of TB using the Lesotho TB Screening Tool (see TB Screening Tool in Annex 1).

All HIV-infected adults and adolescents should be screened for active TB at every clinical encounter using the following screening questionnaire (see TB screening tool in Annex 1):

- Cough of any duration
- Fever
- Weight loss
- Night sweats

<table>
<thead>
<tr>
<th>Objective</th>
<th>Data Source of Information</th>
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<tbody>
<tr>
<td>Indicator</td>
<td>Direct observation; triage form</td>
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<thead>
<tr>
<th>Indicator</th>
<th>Source of Information</th>
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<tbody>
<tr>
<td>#1 Number of patients who entered the facility during the period of observation</td>
<td>Direct observation; triage form</td>
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<tr>
<td>#2 Number of patients with chronic cough identified upon entry</td>
<td>Direct observation; triage form</td>
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<tr>
<td>#3 Number of patients with chronic cough identified upon entry screened for chronic cough</td>
<td>Direct observation; triage form</td>
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<tr>
<td>#4 Number of patients identified as having a chronic cough when screened for chronic cough</td>
<td>Direct observation; triage form</td>
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<tr>
<td>#5 Proportion of patients identified as having a chronic cough</td>
<td>Direct observation; triage form</td>
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<tr>
<td>#6 Average time from facility entry to health service delivery for patients identified as having a chronic cough</td>
<td>Direct observation; triage form</td>
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<tr>
<td>#7 Average time from facility entry to health service delivery for patients NOT identified as having a chronic cough</td>
<td>Direct observation; triage form</td>
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<tr>
<td>#8 Difference in average time from facility entry to health service delivery for patients identified as having a chronic cough and patients NOT identified as having a chronic cough</td>
<td>Direct observation; triage form</td>
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</tbody>
</table>

ANNEX 6.2: M&E MATRIX: INDICATORS FOR MONITORING & EVALUATION OF THE IMPLEMENTATION OF THE TB IC PLAN
All HIV-infected adults and adolescents who do not report any symptoms of active TB are highly unlikely to have active TB and should be offered IPT if they have no contraindications to IPT.

HIV-infected adults and adolescents with one or more sign or symptom of active TB are considered to be TB suspects, and must undergo further investigations for active TB disease as per national TB guidelines. TB suspects are not eligible for IPT until active TB has been excluded on the basis of sputum smear microscopy in line with NTP guidelines. Additional investigation such culture or GenXpert may be carried on case to case basis. Once TB has been excluded in accordance with national guidelines, IPT should be initiated and the patient should be followed up closely.

Initiation of IPT

All HIV-infected adults and adolescents should be screened for TB using the national TB screening tool as described above, and should be initiated on IPT (see Annex 2 for clinical algorithm) after:

- Active TB has been excluded.
- Contraindications to IPT (i.e. active TB disease, active hepatitis, alcoholism, severe peripheral neuropathy, epilepsy, or kidney failure) have been excluded.
- They have been counselled on the benefits of IPT, the importance of adherence to IPT, and on the need to return should possible side-effects or signs/symptoms of TB develop.

Given the high prevalence of latent TB infection in Lesotho, all HIV-infected adults and adolescents who have no signs or symptoms of TB at the time of HIV testing and/or entry into care and who do not have contraindications to IPT should be started on IPT as soon as possible.

A tuberculin skin test and chest x-ray is not required to identify HIV-infected adults and adolescents eligible for IPT.

Contraindications to IPT

HIV-infected adults and adolescents with signs and/or symptoms of TB, or with signs and/or symptoms of active liver disease should not be offered IPT.

HIV-infected adults and adolescents should not be offered IPT if they report:

- Acute or chronic liver disease. Signs and symptoms suggestive of active hepatitis are: nausea, vomiting, right upper quadrant pain, jaundice, dark urine.
- Regular and heavy alcohol consumption.
- Symptoms of severe peripheral neuropathy (grade III and IV, see annex 10 ART guidelines).
- History of epilepsy or convulsions.
- Kidney failure.

Patients who were unable to tolerate isoniazid on previous occasions for various reasons (e.g. nausea, vomiting, neuropathy, rash or symptoms/signs of hepatitis) should not be offered IPT.

Laboratory investigations, including liver function tests (e.g. ALT), are not required prior to initiation of IPT.

The absence of baseline liver function tests should not preclude the initiation of IPT. However, as all HIV-infected patients have a baseline lab assessment, the most recent ALT result should be reviewed if available, and if available, the following recommendations apply:

Table 1: Interpretation of ALT levels in the context of initiating IPT

<table>
<thead>
<tr>
<th>Baseline Liver Function Tests</th>
<th>Course of action</th>
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<tbody>
<tr>
<td>Normal up to 2x the upper limit of normal (ULN) in the absence of symptoms of hepatitis</td>
<td>Initiate IPT, no further testing required.</td>
</tr>
<tr>
<td>2-5x the ULN in the absence of symptoms of hepatitis</td>
<td>Initiate IPT. Check ALT monthly.</td>
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<tr>
<td>Greater than 5x the ULN and/or symptoms of hepatitis</td>
<td>Do not initiate IPT.</td>
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</table>

Recommended Regimen, Dose, and Duration

The standard IPT regimen for HIV-infected adults and adolescents is:

- Isoniazid (INH): 300 mg/day x 6 months
- Pyridoxine (Vitamin B6): 25 mg/day x 6 months

Pyridoxine should be given concomitantly with isoniazid to prevent the occurrence of peripheral neuropathy.

Strict adherence to IPT is essential. If a patient has an interruption in IPT for no more than three months, he/she can be restarted if still asymptomatic. Thus in case of interruption of less than 3 months, the treatment can be completed over 9 months.

Isoniazid preventive therapy should be given once daily for 6 months followed by a period of 18 months not on IPT. This cycle should be repeated every 24 months.
<table>
<thead>
<tr>
<th>Objective 1.4: Effective triaging of TB suspects to the front of the queue</th>
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<tbody>
<tr>
<td><strong>Identification of staff member(s) responsible for daily triaging of TB suspects in all units and implementation of daily triaging</strong></td>
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<tr>
<td><strong>Explanation of triaging to other patients</strong></td>
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<td><strong>Q1</strong></td>
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**Objective 1.5: To ensure prompt (referral for) investigations of TB suspects**

- Separation of coughers/putting coughers ahead of queue in place
- Explanation of triaging to other patients

**Objective 1.6:**

- **Prompt (immediately after identification as TB suspect) sputum specimen taking for all TB suspects identified**
- **Use of designated well-ventilated area for sputum collection**
- **Ensure sputum is sent to laboratory according to policy**
- **Ensure patients have sputum taken at TB suspect register**
- **Obtain sputum for culture and DST when indicated (see indications for culture)**
- **Ensure efficient specimen transfer (not patient driven) between OPD/MCH/ART clinic and lab**
- **Implement a system for tracking laboratory results**

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<th>Responsible</th>
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**Objective 1.7:**

- **Ensure adequate clinical management of patients with confirmed TB**

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<th>Responsible</th>
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**Objective 1.8:**

- **Provision of confidential TB and HIV services to staff**

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<th>Responsible</th>
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**Monitoring**

- **Clinical monitoring**
  - **Adults and adolescents on IPT** should be monitored through monthly clinical assessment to include:
    - **Screening for symptoms and signs of active TB using the TB Screening Questionnaire**: (e.g. cough of any duration, fever, night sweats or weight loss)
    - **Screening for possible side-effects of isoniazid**: (e.g. nerves, joint pain, and feeling sick)
- **Laboratory monitoring**
  - Routine laboratory monitoring of liver function tests (e.g. ALT) is no longer required during IPT.
  - **If an adult and adolescent on IPT develops a possible side-effect of isoniazid**:
    - **Discourage IPT immediately**.
    - **Refer for possible side-effects of isoniazid**.
    - **Investigate if active TB is confirmed**: (e.g. send three sputum (spot-morning-spot) for smear microscopy or Xpert if available).
    - **If active TB is confirmed**:
      - **Discontinue IPT immediately**.
      - **Send sputum specimen(s) for culture and DST (if possible)**
      - **Refer if needed to ensure that investigations are completed**.
    - **If an adult and adolescent on IPT develops symptoms of active TB**:
      - **Refer to initial investigations**.
      - **Investigate if active TB is confirmed**: (e.g. send sputum specimen(s) for culture and DST if possible).
However, if an adult or adolescent is known to have an elevated ALT at baseline (2-5x ULN), then monthly monitoring of the ALT is indicated (see also ART guidelines page 76). An ALT should also be ordered if an adult or adolescent develops symptomatic hepatitis while on IPT. If the ALT is greater than 5x the ULN, then IPT should not be restarted and the patient should be referred for further investigations.

All other laboratory tests should be ordered as clinically indicated.

**When to stop IPT**

IPT should be discontinued if an adult or adolescent develops any of the following:

- Symptoms of TB (i.e. cough of any duration, fever, weight loss, night sweats).
- Symptoms of active hepatitis (i.e. nausea, vomiting, jaundice, right upper quadrant pain, or dark urine).
- ALT levels increase to greater than 5x ULN.
- Severe rash (grade III and IV; see ART guidelines, Annex 10, page 133).
- Symptoms of severe peripheral neuropathy (grade III and IV; see ART guidelines, Annex 10).
- Convulsions.

**Frequently Asked Questions about IPT in Adults and Adolescents**

**IPT during Pregnancy and Breastfeeding:** Yes

10% of maternal deaths in Africa occur among women with HIV/TB co-infection. Active TB during pregnancy is associated with an increased risk of premature birth, intrapartum growth retardation, low birth weight, mother-to-child transmission of HIV and perinatal mortality for mother and baby. Thus it is especially important to prevent HIV-infected pregnant women from developing active TB disease.

Isoniazid (INH) is safe in pregnancy and during breastfeeding.

- IPT should be offered to all eligible HIV-infected pregnant and breastfeeding women.
- IPT should be initiated after TB screening and exclusion of active TB.
- IPT can be started at any time during pregnancy.
- In the event that a woman on IPT becomes pregnant, IPT should be continued.
- Following delivery, IPT should be continued during breastfeeding to complete the 6 month course of therapy.

**IPT and ART:** Yes

HIV-infected patients on ART remain at increased risk of developing TB compared to HIV-uninfected persons.

**ANNEX 6.1: WORK-PLAN**

This work-plan contains suggested activities for the implementation of the different TB Infection Control policies. Sections that are not relevant for the facility can be deleted, and other activities can be included if necessary.

<table>
<thead>
<tr>
<th>Overall aim: Reduction of nosocomial transmission of M. tuberculosis to PLWHA and HCWs through TB and HIV services integration</th>
<th>Responsible</th>
<th>Timeframe</th>
<th>Indicator</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Goal 1: Implement policy on occupational and nosocomial transmission of TB among health care workers and PLWHA</td>
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<tr>
<td>Identification of staff members who will perform screening on arrival</td>
<td>IC coordinator</td>
<td></td>
<td>Screening staff member allocated</td>
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<tr>
<td>Training of identified staff members on TBIC and screening</td>
<td>TBIC team</td>
<td></td>
<td>Number of staff trained</td>
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<tr>
<td>Implementation of chronic cough screening on arrival</td>
<td>IC coordinator</td>
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<tr>
<td>Objective 1.2: To ensure cough etiquette is implemented</td>
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<tr>
<td>Education of staff and patients on cough etiquette and general principles of TBIC</td>
<td>Number of education sessions conducted</td>
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<tr>
<td>Availability of tissues, cloths or face masks for TB suspects</td>
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<tr>
<td>Availability of waste bins for safe disposal of tissues, cloths and face masks</td>
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<tr>
<td>Availability of IEC material including posters on cough hygiene</td>
<td>Number of posters displayed in facility</td>
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<tr>
<td>Administration of tissues or surgical masks to patients with prolonged cough and TB cases on identification</td>
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<tr>
<td>Objective 1.3: Provision of separate waiting areas for TB suspects</td>
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<tr>
<td>Construction or identification of well-ventilated waiting areas to be used by TB suspects</td>
<td>Availability of separate waiting area</td>
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<tr>
<td>Education of patients on triaging and need for separate waiting area</td>
<td></td>
<td>Number of education sessions conducted</td>
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</tbody>
</table>

An ALT should also be ordered if an adult or adolescent develops symptomatic hepatitis while on IPT. If the ALT is greater than 5x the ULN, then IPT should not be restarted and the patient should be referred for further investigations.
g. Spirometry rooms
h. Surgery on potentially infectious TB patients
x. Staff will wear the respirators for no longer than seven (7) days/nights.
xi. Respirators are not to be worn or carried outside of patient care areas, i.e. corridors, unless the staff member is transporting a patient elsewhere.
 xii. Respirators should not be shared between staff.
 xiii. The use of respirators will be included in the Infection Control In-service Programme for General Hospital Staff orientation as a component of Transmission precautions.
 xiv. The appropriate use of respirators will be included as an item for audit in the Infection Control TB compliance monitoring programme.

There is an additional protective benefit of concomitant use of IPT and ART.

IPT should be initiated once active TB has been excluded, irrespective of immune status and whether or not a patient is on ART.

It is safe to co-administer ART and IPT.

Patients who are receiving IPT and who are eligible for ART should continue IPT while initiating ART. Being on IPT should not delay ART initiation among eligible PLWHA.

Among PLWHA already on ART, IPT should be offered once TB has been excluded.

Generally speaking, IPT is well tolerated by patients on ART.

IPT is associated with a low risk of hepatotoxicity.

IPT is also associated with a risk of peripheral neuropathy. This risk can be decreased by providing daily pyridoxine (Vitamin B6) to all patients on IPT. In addition, if a patient develops peripheral neuropathy while receiving d4T, they should be switched from d4T to another antiretroviral medication (e.g. ZDV or TDF).

Patients on IPT should be monitored clinically for side-effects, and if evidence of hepatotoxicity occurs, should have liver function tests checked.

IPT and co-trimoxazole: Yes

It is safe to co-administer co-trimoxazole (CTX) and IPT.

Patients already on CTX should be initiated on IPT once active TB is excluded.

IPT initiation or completion should not be the cause for any delay in starting CTX among eligible PLWHA.

IPT in PLWHA previously treated for TB: Yes

IPT provides protective benefit to patients who have successfully completed TB treatment.

All HIV-infected adults and adolescents should take IPT for 6 months immediately after completion of TB treatment.

Special high-risk populations
PLWHA who live or work in congregate settings (e.g. hostels, prisons, mines) and health care facilities are at greater risk for TB.
ICF and IPT should be offered to PLWHA who live or work in congregate settings (e.g., hostels, prisons, mines) or health care facilities.

How should TB cases that occur after starting IPT be treated?

Persons with active TB should be started on the standard TB treatment regimen as per national guidelines. It is generally safe to continue to use isoniazid as one of the treatment drugs as studies show that isoniazid resistance after monotherapy is uncommon, and that if isoniazid monotherapy is present, the treatment outcomes with standard therapy are similar to those for drug-susceptible TB.

ICF and IPT among Infants and Children

When to offer ICF and IPT

Information about tuberculosis, including ICF and IPT, should be made available to all HIV-exposed and -infected infants and children who present for health services. Clinicians should also counsel patients and their families about the benefits of taking IPT, side-effects associated with IPT and need for adherence to IPT.

HIV-exposed and -infected infants and children should be screened for signs and symptoms of active TB at every clinical encounter, including when he/she is first diagnosed with HIV. ICF is essential to exclude active tuberculosis, which requires treatment with a multi-drug TB treatment regimen.

Eligible HIV-exposed or -infected infants and children should be initiated on IPT irrespective of the CD4 count and WHO stage. Infants and children who are already on ART and in whom active TB has been excluded should be initiated on IPT.

Where should ICF and IPT be provided?

ICF and IPT should be offered to all HIV-exposed or -infected infants and children presenting to health care facilities in Lesotho (e.g., hospitals, filter clinics, health centres, specialized centers and private clinics).

IPT needs to be integrated within the HIV services provided by pre-ART clinics, HIV/ART clinics, MCH/ANC clinics and pediatric clinics.

Who can provide ICF and IPT?

All health care providers are expected to provide TB symptom screening according to national guidelines to HIV-exposed and -infected infants and children.

All doctors, clinical officers, nurse clinicians and nurses who have been trained and mentored can initiate IPT.

c. The Infection Control Practitioner is the designated person to check that environmental control measures are in place and maintain a log of monitoring and maintenance. (See Environmental Control Evaluation Record.)

d. Consultation areas where TB patients may be seen, which may not be adequately controlled by natural ventilation should contain a propeller fan. In considering the direction of airflow, Health care staff must be positioned closest to the clean air source, and the patient nearest to where the air is being blown out.

iii. Isolation:

a. All patients with a diagnosis of TB are to be admitted to the designated TB wards.

b. MDR/XDR patients pending transfer to another facility will remain in the designated isolation areas for MDR/XDR patients until transferred or discharged.

c. Patients in the MDR/XDR units are to remain in the units where possible. If they require transfer to another area they are to wear surgical masks at all times until they return to their isolation area.

iv. Filtration: If applicable, see policy/procedures section B

Using personal respiratory protective equipment

| Implementing respiratory protection for all HCW and patients (for more details see also Policy and Procedure Section D) |
| Purpose: to define the use of particulate respirators and masks in conjunction with administrative and environmental control measures to stop transmission of M.Tuberculosis to health care workers and patients |
| Procedures: |
| viii. Health care workers involved in high-risk procedures or situations should have access to and correctly use N95 respirators |
| ix. High risk procedures and situations include (delete those not applicable): |
| a. Sputum induction or other cough-inducing procedures |
| b. Observing sputum collection |
| c. Close proximity to a patient with MDR or XDR TB |
| d. Isolation rooms for patients with TB, especially M(X)DR-TB |
| e. Bronchoscopy suites |
| f. Autopsy areas |
b. Evaluate the training process
   i. Number of staff who attend TB IC training at all levels

c. Evaluate protection of HCW:
   i. Number of staff screened at baseline, quarterly or annual medicals

d. Evaluate compliance with environmental measures
   i. Use environmental Control evaluation Record (see Annex 3)

iv. The Infection Control Coordinator, will co-ordinate the monitoring and evaluation and provide all reports as defined in point 1, to the committee and management, on a monthly basis.

v. The Infection Control coordinator, in collaboration with supervisors and staff will develop a plan for correcting inappropriate practices or failure to comply with the policies.

vi. The Infection Control Committee will review the above data on a monthly/quarterly basis in order to evaluate frequency and efficacy of the TB plan and make recommendations for change if indicated.

vii. The Infection Control TB management plan will be revised by all key members of staff on an annual basis to reflect updates and changes in staff responsibilities, policies and procedures.

Using and maintaining environmental control measures

Implementing Environmental Control: See also Policy and Procedures Section B

Purpose: The implementation and continuous monitoring of appropriate environmental controls in combination with work practices and administrative measures in order to reduce the spread of TB.

Procedures:

i. ____________________ (name), ________________ (designation), is the designated staff person to check on environmental control measures and maintain a log of monitoring and maintenance.

ii. Ventilation:
   a. In all units where TB patients are admitted or managed for diagnostic services, doors and windows are to be kept open.
   b. The unit managers are responsible for ensuring that the windows and doors are kept open at all times, day or night.

ICF: Screening for TB and excluding active TB

It is essential to exclude active tuberculosis in HIV-exposed and -infected infants and children prior to starting IPT in order to avoid giving a single anti-tuberculosis drug to patients with TB disease who require a multi-drug treatment regimen.

All HIV-exposed and -infected infants and children up to 14 years of age should be screened for active TB at every clinical encounter using the following screening questionnaire (see TB screening tool in Annex 1):

- Cough of any duration
- Fever
- Poor weight gain
- Contact with a TB case

HIV-exposed and -infected infants and children with any signs or symptoms of active TB are considered to be TB suspects, and must undergo further investigations for active TB disease as per national TB guidelines. TB suspects are not eligible for IPT until active TB has been excluded. Once TB has been excluded in accordance with national guidelines, IPT should be initiated and the patient should be followed up closely.

Eligibility for IPT

HIV-exposed or -infected infants and children

All HIV-exposed or -infected infants less than 12 months of age with a known household TB exposure should be offered IPT as part of a comprehensive package of HIV care if (see Annex 1):

- Active TB has been excluded using the national TB screening tool.
- All laboratory and radiological tests for TB are negative.
- Contraindications to IPT (i.e. active TB disease, active hepatitis, epilepsy, or kidney failure) have been excluded.
- They and their families have been counselled on the benefits of IPT, the importance of adherence to IPT, and on the need to return should possible side-effects or signs/symptoms of TB develop.

All HIV-exposed or -infected infants and children greater than 12 months of age and less than 14 years should be offered IPT as part of a comprehensive package of HIV care if (see Annex 2):

- Active TB has been excluded using the national TB screening tool.
- All laboratory and radiological tests for TB are negative.
- Contraindications to IPT (i.e. active TB disease, active hepatitis, new seizure while on IPT or kidney failure) have been excluded.
They and their families have been counseled on the benefits of IPT, the importance of adherence to IPT, and on the need to return should possible side-effects or signs/symptoms of TB develop.

HIV-uninfected infants and children with history of household TB contact

All HIV-uninfected children less than 5 years of age with a known household TB exposure in the last 2 years should be offered IPT if (see Annexes 1 and 2):

- Active TB has been excluded using the national TB screening tool.
- All laboratory and radiological tests for TB are negative.
- Contraindications to IPT (i.e. active TB disease, active hepatitis, epilepsy, or kidney failure) have been excluded.
- They and their families have been counseled on the benefits of IPT, the importance of adherence to IPT, and on the need to return should possible side-effects or signs/symptoms of TB develop.

If tuberculin skin test or chest x-ray are unavailable, initiation of IPT to eligible HIV-exposed and -infected infants and children should not be delayed.

Contraindications to IPT

HIV-exposed or -infected infants and children, and HIV-uninfected infants and children should not be offered IPT if they have:

- Active TB disease
- Acute or chronic liver disease. Signs and symptoms suggestive of active hepatitis are: nausea, vomiting, right upper quadrant pain, jaundice, dark urine.
- Symptoms of severe peripheral neuropathy (grade III and IV, see annex 10 ART guidelines).
- Kidney failure.

Infants and children who were unable to tolerate isoniazid on previous occasions for various reasons (e.g. nausea, vomiting, neuropathy, rash or symptoms/signs of hepatitis) should not be offered IPT. INH should be stopped in a child who develops new onset of convulsions while on the drug.

Laboratory investigations, including liver function tests (e.g. ALT), are not required prior to initiation of IPT.

The absence of baseline liver function tests should not preclude the initiation of IPT.

Procedures:

i. All HIV-infected clients consulted by medical officers, professional or staff nurses, nursing assistants or (lay) counselors should be screened for TB, by using the TB screening questionnaire. Results of the symptom screen should be recorded in the appointment book (without seeing clinician) and/or ART treatment card (if seeing clinician) at every visit.

iii. Relevant investigations should be requested for all patients having any one of the four (4) signs or symptoms, including investigations to rule out extra-pulmonary tuberculosis (such as fine needle aspirate, chest X-ray, abdominal ultrasound etc.).

iv. All TB patients who do not know their HIV status should be offered HIV counseling and testing.

v. All HIV positive TB patients should receive co-trimoxazole (CPT) prophylaxis.

vi. All HIV positive TB patients should have access to HAART.

Monitoring and evaluating the TB infection control plan’s implementation

**Monitoring TB IC management (see also Policy and procedures Section F)**

Purpose: To establish appropriate indicators and mechanisms to monitor and evaluate the efficacy of the Tuberculosis Infection Control Management plan.

**Procedures:**

**Monitoring**

i. Develop monitoring plan by choosing indicators from the provided list in annex 4.

**Evaluation**

ii. Determine the frequency of the infection control plan evaluation

   a. During initiation of procedures, monitoring and evaluation should be done frequently, perhaps monthly or bi-monthly.

   b. When procedures are running well, less frequent evaluation will be necessary – at a minimum, annually.

iii. Evaluate whether procedures have been applied according to plan

   a. Evaluate adherence to clinical pathway including routine screening, cough hygiene, triage and referral

      i. by using Clinical pathway Audit Tool (see annex …)

      ii. by using TB IC Patient Triage Form during certain period of observation (see annex 2)
viii. Immuno-compromised HCW’s will be given the option to work in areas with a lower risk of exposure to TB.

ix. Non discriminative provision of PEP assured:
   a. _____________________ is responsible for provision, documentation and reporting of PEP
   b. Protocol available and known to all staff
   c. 2-3 drug regimen available

x. _____________________ is responsible to maintain all documentation and records pertaining to TB and HIV screening, therapy and surveillance for all HCW’s with the utmost confidentiality.

Training of staff on all aspects of TB and the TB infection control plan

Implementing staff training and development (see also Policy and Procedure Section E)
Purpose: To ensure that all Health Care Workers are provided with information regarding M. Tuberculosis. That they understand the importance of the TB infection control policies and what their role will be in implementing them.

Procedures:

i. All staff (professional and non-professional) should receive training on TB transmission, TB/HIV co-infection, and TB infection control at the time of hire and on an annual basis thereafter.

ii. _____________________ is the designated staff person to provide training to new staff as they are hired and to maintain a log indicating who has had initial training.

iii. _____________________ is the designated staff person to provide annual training to all staff and to maintain a log indicating who has attended training. This may be incorporated into a broader training topic or be stand alone TB infection control training.

Strengthen TB/HIV service integration

Implementing TB/HIV integration (see also New Referral Guidelines for TB/HIV co-management)
Purpose: to ensure continuum of care for TB/HIV co-infected patients in the most cost-effective and patient-friendly way.

However, as all HIV-infected patients have a baseline lab assessment, the most recent ALT result should be reviewed if available, and the following recommendations apply:

Table 2: Interpretation of ALT levels in the context of initiating IPT

<table>
<thead>
<tr>
<th>Baseline Liver Function Tests</th>
<th>Course of action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal up to 2x the upper limit of normal (ULN) in the absence of symptoms of hepatitis</td>
<td>Initiate IPT, no further testing required.</td>
</tr>
<tr>
<td>2-5x the ULN in the absence of symptoms of hepatitis</td>
<td>Initiate IPT. Check ALT monthly.</td>
</tr>
<tr>
<td>Greater than 5x the ULN and/or symptoms of hepatitis</td>
<td>Do not initiate IPT.</td>
</tr>
</tbody>
</table>

Recommended Regimen, Dose and Duration
The standard IPT regimen for HIV-exposed or -infected infants and children under 14 years of age, and HIV-uninfected infants and children with history of a household TB contact is:

- Isoniazid (INH): 10 mg/kg/day x 6 months (up to a maximum of 300 mg/day)
- Pyridoxine (Vitamin B6): 12.5-25 mg per day x 6 months

Pyridoxine should be given concomitantly with isoniazid to prevent the occurrence of peripheral neuropathy.

A guide to isoniazid and pyridoxine doses in infants and children is provided in Tables 3 and 4 below.

Table 3: Simplified weight-based dosing for isoniazid 10mg/kg/day

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>Number of 100 mg tablets of isoniazid (INH) to be administered per day</th>
<th>Dosage given (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 5 kg</td>
<td>½ tablet</td>
<td>50</td>
</tr>
<tr>
<td>5.1 – 9.9 kg</td>
<td>1 tablet</td>
<td>100</td>
</tr>
<tr>
<td>10 – 13.9 kg</td>
<td>1½ tablets</td>
<td>150</td>
</tr>
<tr>
<td>14 – 19.9 kg</td>
<td>2 tablets</td>
<td>200</td>
</tr>
<tr>
<td>20 – 24.9 kg</td>
<td>2 ½ tablets</td>
<td>250</td>
</tr>
<tr>
<td>≥ 25 kg</td>
<td>3 tablets</td>
<td>300</td>
</tr>
</tbody>
</table>

19
Table 4: Simplified pyridoxine (Vitamin B6) dosing

<table>
<thead>
<tr>
<th>Age</th>
<th>Pyridoxine dose per day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 3 years of age</td>
<td>12.5 mg</td>
</tr>
<tr>
<td>3-14 years of age</td>
<td>25 mg</td>
</tr>
</tbody>
</table>

Strict adherence to IPT is essential. If a patient has an interruption in IPT for no more than three months, he/she can be restarted if still asymptomatic. Thus in case of interruption of less than 3 months, the treatment can be completed over 9 months.

Unlike adults and adolescents, repeated courses of IPT are not necessary unless infants or children have a new documented exposure to a TB case.

Monitoring

Clinical monitoring

Although infants and children are less likely to develop isoniazid-related toxicities than are adults and adolescents, they should nevertheless be monitored through monthly clinical assessment to include:

- Screening for symptoms and signs of active TB using the TB Screening Questionnaire (i.e. cough of any duration, fever, poor weight gain, new documented contact with a known active TB case).
- Screening for possible side-effects of isoniazid (e.g. rash, peripheral neuropathy, convulsions, or any signs/symptoms of hepatitis including nausea and vomiting, loss of appetite, jaundice, right upper quadrant pain, abdominal pain, and dark urine).
- Adherence to isoniazid.

Patients starting IPT may be given a 1 to 3 month supply at a time, but should be monitored monthly as above.

If an infant or child on IPT develops symptoms of active TB:

- Discontinue IPT immediately.
- Investigate for active TB disease:
  - Send gastric aspirates or sputum specimens for mycobacterial culture or GeneXpert testing.
  - Chest x-ray
- Refer if needed to ensure that investigations are completed.
- If active TB is confirmed, a full TB treatment regimen should be started according to national guidelines.

viii. TB treatment should be initiated as soon as possible after the diagnosis of TB has been made
ix. Adherence to treatment should be ensured (elaborate on local methods to ensure adherence)
x. The national TB control program register (ETR: Electronic TB Register) should be completed for all patients with confirmed TB who were started on TB treatment at the facility or who were moved or transferred in to the facility

Providing confidential TB and HIV services to health care workers and staff

Implementing protection of HCW (see also Policy and Procedure Section C)

Purpose: to define a comprehensive TB screening and surveillance program for all HCW in order to reduce the risk of TB as a Health Care Associated Infection (HCAI)

Procedures:

i. All HCW’s deployed within the hospital are required to have a baseline medical assessment upon hire. The infection control coordinator will ensure that all new staff undergo the baseline medical which includes the TB screening component. (Baseline Health Assessment).

ii. The screening component will establish whether the HCW has been allocated to High, Intermediate or Low risk activity area for TB. (See also annex 4 for Staff Risk Assessment Review.)

iii. Contract workers assigned to the defined high risk areas will be required to submit documentation of baseline and quarterly TB screening to the infection control coordinator.

iv. Staff will be encouraged to seek investigations promptly, if they develop any signs and symptoms suggestive of TB.

v. Employees who are diagnosed with Tuberculosis will be assessed by the TB Physician and managed by the Occupational Health service in order to maintain confidentiality.

vi. _____________________ is responsible to determine when a staff member, who has developed TB, may return to work.

vii. _____________________ is responsible to encourage and counsel HCW’s to undergo VCT and provide information on relevant HIV care resources.
Moving TB suspects and cases to the head of the queue to receive services in the facility

Procedures:

i. TB suspects and cases should be moved to the head of the queue for whatever services they want or need, e.g., VCT, medication refills, medical investigation. This reduces the duration of potential exposure while they wait in the facility and may be an incentive to disclose information during screening.

ii. All clients should be educated about the purpose of triage, which is to make the facility safer for everyone by minimizing the risk of exposure to TB.

Assure clinical management of TB suspects and confirmed TB cases: TB diagnostic services and TB treatment

Procedures:

i. Clients should submit three (3) specimens for TB microscopy (preferably one specimen on the spot, a second early morning specimen and a third once more on the spot) in adherence with the National TB Control (NTP) guidelines.

ii. Sputum collection should be done safely in a separate, well ventilated area, preferably outdoors, under supervision by a staff member (standing behind the patient).

iii. Staff should ensure that the quality of sputum specimens is adequate.

iv. Efficient sputum specimen transfer to the laboratory should be ensured.

v. A tracking system for sputum results should be implemented.

a. Sputum turn-around time (TAT) should be monitored.

vi. A TB suspect register should be kept for all patients identified as TB suspects who have sputum investigations done.

vii. Clients should be given a return date as soon as possible, based on the average sputum specimen turn-around time in the facility.

Sputum for culture should be submitted in case of:

- High risk of MDR-TB, including Contacts of known MDR-TB case and probable treatment failure (Smear + after 5 months of TB treatment; HIV (+) and clinically worsening or History of previous treatment for cat II).
- Moderate risk for MDR-TB, including treatment after defaulting or relapse; migrant worker with new TB and HCW with new TB.

If an infant or child on IPT develops a possible side-effect of isoniazid:

- Discontinue IPT immediately.
- If hepatotoxicity is suspected, order an ALT.

Laboratory monitoring

As the risk for hepatotoxicity is low in infants and children, routine laboratory monitoring of liver function tests (e.g., ALT) is not required during IPT.

However, if an infant or child is known to have an elevated ALT at baseline (2-5x ULN), then monthly monitoring of the ALT is indicated (see also ART guidelines page 76).

An ALT should also be ordered if an infant or child develops symptomatic hepatitis while on IPT. If the ALT is greater than 5x the ULN, then IPT should not be restarted and the patient should be referred for further investigations.

All other laboratory tests should be ordered as clinically indicated.

When to stop IPT

IPT should be discontinued if the infant or child develops any of the following:

- Symptoms of TB (i.e. cough of any duration, fever, poor weight gain).
- Symptoms of active hepatitis (i.e. nausea, vomiting, jaundice, loss of appetite, right upper quadrant pain, abdominal pain, or dark urine).
- ALT levels increase to greater than 5x ULN.
- Severe rash (grade III and IV; see ART guidelines Annex 10, page 133).
- Symptoms of severe peripheral neuropathy (grade III and IV; see ART guidelines, Annex 10).
- Convulsions.

Frequently Asked Questions about IPT in Infants and Children

IPT and ART in infants/children: yes

HIV-exposed or -infected infants and children on ART remain at increased risk of developing TB compared to HIV-uninfected infants and children.

- There is an additional protective benefit of concomitant use of IPT and ART, and they are safe to co-administer.

IPT should be initiated once active TB has been excluded, irrespective of immune status and whether or not an infant or child is on ART.
Additionally, infants and children who are receiving IPT and who are eligible for ART should continue IPT while initiating ART. Being on IPT should not delay ART initiation among eligible infants and children.

Generally speaking, IPT is well tolerated by infants and children on ART. There is a low risk of hepatotoxicity and peripheral neuropathy.

**IPT and co-trimoxazole in infants/children: Yes**

It is safe to co-administer co-trimoxazole (CTX) and IPT.

Patients already on CTX should be initiated on IPT once active TB is excluded.

IPT initiation or completion should not be the cause for any delay in starting CTX among eligible HIV-exposed or -infected infants and children.

**IPT in HIV-exposed or -infected infants/children previously treated for TB: Yes**

- IPT provides protective benefit to patients who have successfully completed TB treatment.

All HIV-exposed or -infected infants and children should take IPT for 6 months immediately after completion of TB treatment.

**How should TB cases that occur after starting IPT be treated?**

Infants and children with active TB should be started on the standard TB treatment regimen as per national guidelines. It is generally safe to continue to use isoniazid as one of the treatment drugs as studies show that isoniazid resistance after monotherapy is uncommon, and that if isoniazid monotherapy is present, the treatment outcomes with standard therapy are similar to those for drug-susceptible TB.

**Monitoring and Evaluation of ICF/IPT**

**Introduction**

Monitoring and evaluation (M&E) provides data on program progress and effectiveness; improves program management and decision-making; allows accountability to stakeholders, including funders; provides data to plan future resource needs; and provides data useful for policy-making and advocacy.

**Monitoring** is the routine tracking of the key elements of program performance, including inputs and outputs, through record-keeping, regular reporting and surveillance systems as well as health facility observation and client surveys.

who are being investigated or treated for TB should be managed as described before: they should be handed a tissue or surgical mask, should be moved to the head of the queue to receive different services within the facility, and should receive instructions for submitting sputum specimen. The patient details should be entered in the TB Suspect Register. (See also procedures b to e)

**iii. Staff seeing clients in examination rooms should report clients they find to have a prolonged cough or to be a case that were not identified at triage to the infection control coordinator in a timely manner so that factors contributing to the potential exposure (e.g., an emergency or short staffing interfered with the designated person screening all clients) can be documented and corrected.**

**Instructions on cough etiquette/respiratory hygiene**

**Procedures:**

- Clients who are found to be TB suspects or cases should immediately be advised of the importance of cough hygiene and be handed tissues (or pieces of cloth) and instructed to cover their mouth and nose when they cough. Alternatively, clients should be given a face mask, and asked to wear it while in the facility. Clients should also be instructed to dispose of used tissues or masks in identified no-touch receptacles and not on the ground.
- No-touch receptacles for disposal of used tissues, cloths and masks should be available in the waiting areas.
- Tissue disposal bins should have lids and plastic bags.

**Placing TB suspects and cases in a separate waiting area (if applicable)**

**Procedures:**

- A staff person should direct or escort the client to a separate waiting area in ________________. This special waiting area should have the highest natural ventilation possible or be outside the building. Clients need to be assured of their place in the queue for registration and/or services.
Purpose: To ensure early identification, separation, receipt of services and referral of clients with TB disease in order to reduce risk of transmission of TB

Screening (adult) clients to identify persons with prolonged cough and those under investigation or treatment for TB disease

**Procedures:**

i. Before clients enter an enclosed part of the facility, a designated staff person (______________________________, __________________) should ask each adult (aged 15 years or more) about prolonged cough and whether they are being investigated for or receiving treatment for TB. The questioning should occur before clients queue for long periods to register or obtain services.

ii. Screening questions to be asked on arrival at the facility:
   - "Do you have a cough?" If client answers yes, ask
     - "For how long have you been coughing?"
   - An adult who has coughed for 2 weeks or more may be considered a "TB suspect" for pulmonary (infectious) TB.

   To determine whether a client may be under investigation for TB or a diagnosed case of TB, who may still be infectious, ask:
   - "Are you being investigated or treated for TB?"

   If the answer to either is yes, the screen classifies the client as a TB suspect or case, and he/she should be separated from the other patients, should be handed a tissue or surgical mask, should be moved to the head of the queue (fast track to see clinician ASAP) and should receive instructions for submitting sputum specimen. (see also procedures below). The patient details should be entered in the TB Suspect Register.

As clients who are not identified as a TB suspect or case at triage enter an examination room with the medical officer, nurse, or counselor, they should be screened for TB (including Extra-pulmonary TB) using the standardized TB-screening tool with 4 screening questions. Those clients who answer or report any one symptom of: cough, weight loss, night-sweats or fever or those

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**Evaluation** is the episodic assessment of the change in targeted results that can be attributed to the program. Evaluation attempts to link a particular output or outcome directly to an intervention after a period of time has passed.

An indicator is a measurable characteristic or variable, which represent program progress. Indicators are necessary in order to analyze the present situation; to make comparisons; and to measure changes over time. Good indicators should be SMART: specific, measurable, achievable, relevant and time-bound.

A target is an objective that is time-limited and can be measured.

M&E of ICF/IPT will allow the MoHSW to assess scale up and quality of ICF and IPT services, to refine ICF/IPT guidelines and reporting and recording tools; and to project future resource and training needs.

**Monitoring and Evaluation Tools**

The measuring tools include any of the following depending on the service delivery area where ICF and IPT are being provided:

- Patient’s “Bukana”
- HIV Chronic Care/ART card
- ART register
- Pre-ART card
- Pre-ART register
- ANC register
- Delivery register
- IPT register (see Annex 5)
- TB suspect register
- TB treatment register
- TB treatment card
- Under-five register
- Appointment book (see Annex 6)

The HIV Chronic Care/ART card is the primary facility-based record for PLWHA in care, and at a minimum must be opened for all patients enrolled in HIV care.

What information should be recorded, where, when and by whom?
All patients enrolled in HIV care and treatment should have the HIV Chronic Care/ART Card opened. At each patient encounter information on ICF/IPT must be recorded on the HIV Chronic Care/ART Card and in the patient’s “Bukana.”
A patient may present to the health facility at OPD, ART clinic, MCH and adolescent health corner for any of the following: initial enrolment visit, follow up consultation, adherence counselling, laboratory testing, drug refills, Pap smear, family planning, sexually transmitted infections (STIs), antenatal care, postnatal care, prevention of mother-to-child transmission of HIV (PMTCT) services, or immunizations/growth monitoring. All relevant registers should be updated at each patient encounter, including the HIV Chronic Care/ART card.

The table below summarizes what information must be recorded in relation to ICF/IPT.

<table>
<thead>
<tr>
<th>Information</th>
<th>Where to record or update</th>
<th>When to record or update</th>
<th>Responsible person(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TB symptom screening</td>
<td>Bukana, HIV Chronic Care/ART card, ART register, Pre-ART card, ANC register, Delivery register, Under-five register, IPT register, Appointment book</td>
<td>At each clinical encounter with an HIV-infected patient</td>
<td>Any care provider (i.e. medical officer, nurse, lay counselor, pharmacy personnel) that the patient meets during his/her visit.</td>
</tr>
<tr>
<td>Referral and investigation of TB suspects</td>
<td>Bukana, HIV Chronic Care/ART card, ART register, Pre-ART card, ANC register, Delivery register, Under-five register, IPT register, TB suspect register, Appointment book</td>
<td>When TB is suspected</td>
<td></td>
</tr>
<tr>
<td>TB diagnosis</td>
<td>Bukana, HIV Chronic Care/ART card, ART register, Pre-ART card, ANC register, Delivery register, Under-five register, IPT register, TB suspect register, TB treatment register, TB treatment card, Appointment book</td>
<td>When TB is diagnosed</td>
<td>Medical officers and nurses are responsible for recording the TB diagnosis, TB treatment start date/end dates and IPT start/end dates.</td>
</tr>
<tr>
<td>TB treatment start date</td>
<td>Bukana, HIV Chronic Care/ART card, ART register, Pre-ART card, TB suspect register, TB treatment register, TB treatment card, Appointment book</td>
<td>When TB treatment is started</td>
<td></td>
</tr>
</tbody>
</table>
6.3: Establishing an TB Infection Control Team

The TB Infection Control (TBIC) team is integrated in the general Infection Control Committee (delete if not applicable). The team is comprised of the following members:

<table>
<thead>
<tr>
<th>Name</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>(Chair)</td>
</tr>
<tr>
<td>2</td>
<td>(Vice chair)</td>
</tr>
<tr>
<td>3</td>
<td>(Scribe)</td>
</tr>
<tr>
<td>4</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td></td>
</tr>
</tbody>
</table>

The (TB) Infection Control team will meet monthly on the _______ (first, second, etc.) _______ day of the month.

Roles and Responsibility

Lead: ______________________ (name), __________________ (designation) has the responsibility for overseeing the implementation of these policies and its procedures, calling Infection Control meetings, and reports to ______________________ (name), __________________ (designation).

The roles of the (TB) Infection Control team include (elaborate):

- Development of policies on TB Infection Control
- Development and implementation of TB Infection Control plan
- Coordination of activities around TB Infection Control
- Monitoring of implementation of TB Infection Control plan through periodic supervision of the measures as outlined in the TB IC plan
- Evaluation and revision of TB Infection Control plan

What information/data should be reported?

The facility’s head clinician – either the Medical Officer or Nurse-in-charge – will report HIV care and treatment data every month to the national level using the ART monthly report form. This ART monthly report should contain consolidated information for all department or sections where HIV care and/or treatment are provided.

Absolute numbers of patients who received services are obtained by careful counting of patients as captured in the appointment books or the updated registers. Care must be taken to ensure that each patient is counted only once particularly for those patients who made more than one visit during the month.

Below is a summary of the data that should be reported in relation to ICF and IPT.

Table 6: Monthly data reporting for ICF/IPT

<table>
<thead>
<tr>
<th>Data to be reported every month</th>
<th>Data sources*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of persons seen at least once for HIV care during the reporting period (will also serve as denominator for the other indicators below)</td>
<td>Appointment book, ART register, Pre-Art register, ANC register in MCH and AHC, Under-five register</td>
</tr>
</tbody>
</table>
To be useful, the data should be accurate and complete, and must be communicated in a health facility level. The overall goal of this information is to improve on service delivery meaningfully used for evidence-based decision-making at all levels, including district and The collected and reported data will be only meaningful and worthwhile if it can be

Importance of data collection

The collected and reported data will be only meaningful and worthwhile if it can be meaningfully used for evidence-based decision-making at all levels, including district and health facility level. The overall goal of this information is to improve on service delivery.

To be useful, the data should be accurate and complete, and must be communicated in a timely fashion to the program managers who are responsible for providing feedback to the different facilities.

Flow of information

Routine clinical staff working in the health facilities will enter the information in the registers and cards for all persons receiving HIV/AIDS-related services, and will subsequently submit monthly reports to the district HIV/AIDS Officer. The facility’s head clinician should ensure accurate and complete recording and compilation of data at the facility level.

<table>
<thead>
<tr>
<th>Data to be reported every month</th>
<th>Data sources*</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Number of persons screened for TB during the reporting month</td>
<td>Appointment book, ART register, Pre-ART register, ANC register in MCH and AHC, Delivery register, Under-five register, IPT register</td>
</tr>
<tr>
<td>3 Number of TB suspects identified during the reporting month</td>
<td>TB suspect registers in the ART clinic, pre-ART clinic, and MCH/ANC</td>
</tr>
<tr>
<td>4 Number of TB suspects diagnosed with TB during the reporting month</td>
<td>TB suspect registers in the ART clinic, pre-ART clinic, and MCH/ANC</td>
</tr>
<tr>
<td>5 Number of persons diagnosed with TB and started on TB treatment during the reporting month</td>
<td>TB suspect registers in the ART clinic, pre-ART clinic, and MCH/ANC, TB treatment register</td>
</tr>
<tr>
<td>6 Number of persons on ART started during the reporting month</td>
<td>ART Register, Appointment book, ART register, ANC register</td>
</tr>
<tr>
<td>7 Number of TB suspects on ART identified during the reporting month</td>
<td>TB suspect registers in the ART clinic and MCH/ANC</td>
</tr>
<tr>
<td>8 Number of TB suspects on ART identified during the reporting month</td>
<td>TB suspect registers in the ART clinic and MCH/ANC</td>
</tr>
<tr>
<td>9 Number of TB suspects on ART started during the reporting month</td>
<td>TB suspect registers in the ART clinic and MCH/ANC</td>
</tr>
<tr>
<td>10 Number of persons on ART started during the reporting month</td>
<td>TB suspect registers in the ART clinic and MCH/ANC, TB treatment register</td>
</tr>
<tr>
<td>11 Number of persons started on IPT during the reporting month</td>
<td>IPT register</td>
</tr>
<tr>
<td>12 Number of persons who collected IPT refill during the reporting month</td>
<td>IPT Register, Pharmacy dispensing registers in the ART clinic, pre-ART clinic and MCH/ANC</td>
</tr>
<tr>
<td>13 Cumulative number of persons who started IPT during the reporting month</td>
<td>IPT Register, Pharmacy dispensing registers in the ART clinic, pre-ART clinic and MCH/ANC</td>
</tr>
<tr>
<td>14 Number of persons who developed TB during the reporting month</td>
<td>IPT Register</td>
</tr>
<tr>
<td>15 Number of persons who completed their IPT course during the reporting month</td>
<td>IPT Register</td>
</tr>
</tbody>
</table>

*Data source refers to sources of information used to collect the data needed to calculate the indicators.

**Aspect** | **Findings (Example for Motherwell CHC – replace with local info)**
--- | ---
MCH?, other places?) | TB symptom checklist in place and used consistently
Coughers put in front of queue? | TB suspect register in place (at OPD? HIV clinic, MCH, TB clinic …)
Cough etiquette/respiratory hygiene | Surgical masks available for high-risk patients
Tissues available for out-patients? For coughers? | Waste baskets for disposal of tissues available?
Investigations | Sputum specimens collected safely (separate place, outdoor?)
Sputum Turn-Around Time (TAT) <72 hours? |
TB treatment and referrals | Formal referral system in place to refer TB suspects? (between OPD and TB clinic, between HIV clinic and TB clinic ) How to ensure actual enrollment in TB treatment?
Refer to HC: how to ensure actual enrollment at HC level? | Feedback on progress of patients treated off-site?
Tracing system for defaulters in place? |
Environmental control measures | Written environmental control measures in place? Policy for natural mechanical ventilation?
Patient education and awareness | Patient education materials available (MOHSW material – other partners) and presented to patients?
Staff capacity building | Training on TB Infection Control for staff?
(number? When?) |
Staff protection | Regular screening of staff for TB? (Uptake?)
Confidential HIV C&T available (Uptake?) | IPT for staff?
TB data | % of TB suspects with confirmed smear results?
Proportion of TB suspects with smear positive?
Smear Conversion Rate?
Treatment Outcomes (cure rate %, default rate %) | TB screening among HIV patients (% of patients enrolled into HIV care were screened)
Recording of TB screening in HIV registers?
professional and non-professional health care workers in ________________ (name of health care facility).

The first section of this document summarizes the findings of the baseline assessment conducted in ______________ (month, year) and thereafter describes the different policies regarding TB infection control applicable in this facility. A detailed work-plan is included in annex 1, followed by tools (triage form and indicators) for monitoring and evaluation of the implementation of the plan.


6.2: TB INFECTION CONTROL BASELINE ASSESSMENT FINDINGS

A baseline assessment was conducted in ___________200__ (month, year), assessing TB infection control practices as well as Knowledge, Attitudes and Beliefs (KAB) of clinical and non-clinical staff.

A summary of the findings is provided in the table below:

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Findings (Example for Motherwell CHC – replace with local info)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge, Attitudes, Beliefs</td>
<td>Basic knowledge about TB transmission? (clinicians versus non-clinicians) – risk of transmission- factors affecting risk - ways to prevent TB transmission</td>
</tr>
<tr>
<td></td>
<td>Infection control coordinator in place?</td>
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<tr>
<td></td>
<td>Infection Control Committee in place?</td>
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<td></td>
<td>Infection Control Plan in place?</td>
</tr>
<tr>
<td>Infrastructure</td>
<td>Separate waiting area for TB suspects?</td>
</tr>
<tr>
<td></td>
<td>Sufficient waiting area at OPD? At TB clinic?</td>
</tr>
<tr>
<td></td>
<td>Sufficient space for HIV clinic?</td>
</tr>
<tr>
<td></td>
<td>Location TB clinic? (within OPD? Within TB ward? Separate place?)</td>
</tr>
<tr>
<td>Patient triage</td>
<td>Routine Screening takes place for all out-patients ? (at OPD? HIV clinic?)</td>
</tr>
</tbody>
</table>
CHAPTER 2: TB INFECTION CONTROL

DELIVERY OF TB IC BY LESOTHO HEALTH SERVICES

There are three main ways to reduce the chances to spread TB in the health care settings: administrative (managerial), environmental, and personal respiratory protection.

First priority is the administrative control measures:
They prevent production of infectious droplet nuclei in the air leading to reduction of exposure to the HCWs and patients.

Second priority is the environmental control measures; they reduce concentration of the droplet nuclei in high-risk areas.

Third priority is the personal respiratory protection measures:
They prevent health worker from inhaling infectious droplets in areas where the concentration of droplet nuclei cannot be adequately reduced by administrative and environmental controls.

The administrative (managerial) control measures include:
- Proper patient flow (triage) in OPD.
- Patient education and community awareness.
- Coordination and communication between TB and ART Centres leading to proper and timely referrals.
- Health workers exposed to TB to have TB screening yearly and be encouraged to test for HIV.

The environmental control methods:
- Encourage natural ventilation by opening windows, and the use fans to control the direction of airflow.
- Mechanical ventilation by use of window fans, mechanical exhaust systems (outside air in, inside air out e.g. by laboratory hoods, sputum collection booths) or the use of a closed recirculation system.
- Ultraviolet germicidal irradiation (UVGI ) with shielding for protection of HCWs and the patients from adverse effects (coetaneous and ocular changes). the UVGI can be used in the TB clinic waiting areas, in patient areas e.g. TV rooms and recreation rooms.

6.1: BACKGROUND AND PURPOSE

Persons with undiagnosed, untreated and potentially infectious (contagious) tuberculosis (TB) are often seen in healthcare facilities, particularly in HIV care settings. TB is the most common opportunistic infection and a leading cause of death in persons with HIV infection or AIDS.

In high TB burden settings surveys have shown that up to 10% of persons with HIV infection may have previously undiagnosed TB at the time of HIV voluntary counseling and testing (VCT). Up to half of these may be infectious TB cases.

Thirty to 40% of HIV-infected persons living in high burden TB settings will develop TB in their lifetime, in the absence of isoniazid preventive therapy (IPT) or antiretroviral therapy (HAART). The risk of developing TB disease doubles in the first year after becoming HIV-infected and gets progressively higher from then onwards. Thus persons without TB disease at the time of HIV diagnosis may still develop TB in later years, and will then be at risk of spreading M. tuberculosis in the community as well as to fellow clients, healthcare workers, and staff at their HIV care clinics and in community programs.

Persons with HIV-associated immunosuppression may become infected or re-infected with TB if they are exposed to someone with infectious TB disease. They can progress rapidly from TB infection to disease – over a period of months rather than the usual period of years for persons with a normal immune system.

Given this burden of unrecognized disease, coupled with an increased prevalence of multidrug- (MDR-) and extremely drug-resistant (XDR-)TB, nosocomial transmission of M. tuberculosis at outpatient HIV care and treatment facilities is of concern.

Health care workers and other staff are at particularly high risk of infection with TB because of frequent exposure to patients with infectious TB disease. Health care workers and staff may themselves be immuno-suppressed due to HIV infection and thus be at higher risk of developing TB disease once infected.

The purpose of this document is to assist health care managers and workers to minimize the risk of TB transmission to patients, people living with HIV and AIDS,
The personal respiratory protection:
- The use of surgical masks worn by patients reduces transmission of infection from the patients. They must be used when transporting a patient from one unit to elsewhere e.g. to x-ray unit.
- Respirators (N 95 masks) should be used in high-risk isolation units in health facilities and in referral hospital settings e.g. for drug resistant TB (MDR TB and XDR TB). They have tiny pores block droplet nuclei and have airtight seal around the edges. HCWs should follow the enclosed instructions in order to use them properly.

Work practice, administrative control measures and environmental control measures are the focus of this document. Other issues addressed are HIV and TB in health care workers and staff and protecting their health, MDR TB and XDR TB.

INFECTION CONTROL MEASURES IN AREAS OF HIGH INFECTION RISK IN HEALTH FACILITIES

Out-Patient Department (OPD)
1. Each health facility should have a protocol for TB suspect/patient flow in the OPD.
2. A triage/cough officer should assist in promptly detecting TB suspects/patients by screening patients for a history of cough for 2 weeks or more and or being on TB treatment when patients arrive at the health facility. Patients should be screened before they wait in line to register or obtain services.
3. A triage/cough officer should instruct TB suspects/patients on cough hygiene. TB suspects/patients should specifically be instructed to cover their nose and mouth with their arm, tissues, cloth or a surgical mask. Patients should be instructed to dispose of used tissue or masks in no-touch waste bins and not on the ground.
4. No-touch waste bins for disposal of used tissues and masks should be available in waiting areas at all health facilities.
5. TB suspects/patients should be triaged to a separate waiting room. When a separate room is not available, TB suspects/patients should be triaged to the TB Clinic waiting room. When a room is not available, TB suspects/patients should wait outside and at least 3 feet away from other patients or visitors.
6. Good ventilation is essential. Windows and doors should be kept open to maximize natural ventilation.
7. TB suspects/cases should be fast-tracked for care and seen as soon as they arrive. TB suspects/cases should be seen in a well-ventilated consultation room, preferably with windows and doors open to reduce concentration of infectious droplet nuclei in the environment.
8. Transport of TB suspects/cases from the room should be kept to a minimum. If movement of TB suspect/cases is necessary, patient dispersal of infectious droplets should be minimized by having the patient wear a surgical face mask.

9. Sputum should be expectorated and collected outside in an open space or at home.

10. All TB suspects must provide sputum for smear microscopy and other laboratory testing as a matter of urgency. Sputum is most easily collected in the OPD, TB Clinics and HIV Clinics.

11. Disposable non-transparent sputum cups with lids should be used.

12. Reusable sputum cups should be avoided wherever possible. Sputum cups may be reused if first disinfected with 1% hypochlorite and sodium dichloroisocynurate.

13. If a TB case is diagnosed by a positive sputum smear, positive mycobacterial culture or positive GeneXpert test, he/she should be referred to the TB Clinic (or the HIV Care/ART Clinic) for initiation of TB treatment as soon as possible.

14. TB suspects who have a negative sputum smear, negative mycobacterial culture and negative GeneXpert test, or who are unable to expectorate sputum for testing should be referred to a clinician for further assessment. The clinician may elect to refer the TB suspect to the TB Clinic (or HIV Care/ART Clinic) for TB treatment on the basis of clinical suspicion.

15. Every form of TB case diagnosed should be recorded in the district TB register.
**IPT register, page 2**

<table>
<thead>
<tr>
<th>Name of Health Facility/Clinic:</th>
</tr>
</thead>
</table>

### Procedure for TB screening AT ANY Out-patient department (OPD, MCH, ART clinic)

**PATIENT IS SCREENED FOR TB, ON ARRIVAL AT THE FACILITY, BY A TRIAGE / COUGH OFFICER**

**ARE YOU BEING INVESTIGATED OR TREATED FOR TB?**

**DO YOU HAVE A COUGH?**

**MORE THAN TWO WEEKS?**

**HOW LONG HAVE YOU BEEN COUGHING?**

**NO**

**YES**

**DO YOU HAVE A COUGH?**

**NO**

**YES**

**ARE YOU INVESTIGATED OR TREATED FOR TB?**

**NO**

**YES**

**PATIENT IS SCREENED FOR TB ON ARRIVAL AT THE FACILITY BY A COUGH OFFICER**

---

### Table: Baseline/Month 0

<table>
<thead>
<tr>
<th>Date</th>
<th>Weight (kg)</th>
<th>Dose (mg/d)</th>
<th>TB Symptom Screen*</th>
<th>Side-effects**</th>
<th>Dose (mg/d)</th>
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<tbody>
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### Table: Month 1

<table>
<thead>
<tr>
<th>Date</th>
<th>Weight (kg)</th>
<th>Dose (mg/d)</th>
<th>TB Symptom Screen*</th>
<th>Side-effects**</th>
<th>Dose (mg/d)</th>
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### Table: Month 2

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<th>Date</th>
<th>Weight (kg)</th>
<th>Dose (mg/d)</th>
<th>TB Symptom Screen*</th>
<th>Side-effects**</th>
<th>Dose (mg/d)</th>
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### Table: Month 3

<table>
<thead>
<tr>
<th>Date</th>
<th>Weight (kg)</th>
<th>Dose (mg/d)</th>
<th>TB Symptom Screen*</th>
<th>Side-effects**</th>
<th>Dose (mg/d)</th>
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</table>
Procedure for cough hygiene, triage and referral AT ANY Out-patient department (OPD, MCH, ART clinic)

PATIENT ARRIVES AT COUGH OFFICER STATION.
COUGH OFFICER OFFERS PATIENT A MASK.
COUGH OFFICER COUNSELS THE PATIENT ON THE NEED FOR TB DIAGNOSTIC SERVICE.
COUGH OFFICER GIVES THE PATIENT COUGH HYGIENE EDUCATION.
PATIENT'S DETAILS ARE ENTERED IN THE TB SUSPECT REGISTER.

SPUTUM SMEAR RESULTS?

NEGATIVE?
PATIENT IS SENT TO THE COUGH BOOTH TO PRODUCE A SPUTUM SPECIMEN.
PATIENT IS SENT TO LAB FOR SMEAR.

POSITIVE?
COUGH OFFICER COUNSELS THE PATIENT ON THE NEED FOR TB DIAGNOSTIC SERVICE.
COUGH OFFICER GIVES THE PATIENT COUGH HYGIENE EDUCATION.
PATIENT COMPLETES COUGH HYGIENE.

UNABLE TO PROVIDE SPUTUM?
PATIENT MUST PRODUCE SPUTUM.
PATIENT ACCOMPANY THE PATIENT TO THE DOCTOR.
ACCOMPANY THE PATIENT TO DOTS CLINIC FOR FURTHER TB MANAGEMENT.

PATIENT REJOINS THE QUEUE FOR CONSULTATION.

ANNEX 5: IPT REGISTER

<table>
<thead>
<tr>
<th>IPT No.</th>
<th>Unique ART No.</th>
<th>Name</th>
<th>Contact of (Eng no.)</th>
<th>Age</th>
<th>Sex (M/F)</th>
<th>TB Symptom Screen*</th>
<th>ART Status (y/n)</th>
<th>Sputum AFB Results</th>
<th>Sputum GXP Results</th>
<th>CXR</th>
</tr>
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* Symptom screen for TB: cough (C), fever (F), night sweats (NS), weight loss (W). A patient is a TB suspect if he/she reports any symptom of TB for any duration.

** Side effects: jaundice (J), nausea/vomiting (NV), peripheral neuropathy (PN), severe rash (R), convulsions (C).

*** Final outcome: treatment completed (TC), defaulted (DT), transferred out (TO), died (D), IPT discontinued because patient developed active TB (TB), IPT discontinued because patient developed IPT-related side-effects (SE).
**ANNEX 4: CLINICAL ALGORITHM FOR IPT THERAPY IN HIV-EXPOSED/INFECTED CHILDREN >12 MONTH UP TO 14 YEARS**

**HIV-Exposed/Infected Child > 12 Months**

- Screen for TB Disease
  - Poor weight gain* or Severe Malnutrition (wasting or swollen feet)
  - Fever
  - Current Cough
  - Contact history with a TB case

**Screen for TB Disease**

- **Positive**
  - Assess for contraindications to IPT
  - Symptomatic Hepatitis
  - Symptomatic Peripheral Neuropathy
  - LFTs > 5 times upper limit of normal (if results available)

- **Negative**
  - Investigate for TB Disease according to National Guidelines (including CXR)

- **Not Tuberculosis**
  - Give IPT
  - Defer IPT if contraindications present

- **Possible Tuberculosis**
  - Evaluate for other possible diagnoses
  - Expand Search for TB

- **Tuberculosis Disease**
  - Treat for TB

- Continue to Screen for TB Disease at every visit**

**Defer IPT if contraindications present**

- **Give IPT**
  - Continue to Screen for TB Disease at every visit**

**Treat for TB**

---

* Poor weight gain is defined as reported weight loss, or very low weight (weight-for-age less than –3 z-score), or underweight (weight-for-age less than –2 z-score), or confirmed weight loss (>5%) since the last visit, or growth curve flattening.

** Symptoms of TB disease during IPT treatment should prompt discontinuation of INH and a complete evaluation.

---

**TB Diagnostic Centers**

1. A triage/cough officer should instruct TB suspects/patients on cough hygiene. TB suspects/patients should specifically be instructed to cover their nose and mouth with their arm, tissues, cloth or a surgical mask. Patients should be instructed to dispose of used tissue or masks in no-touch waste bins and not on the ground.

2. No-touch waste bins for disposal of used tissues and masks should be available in waiting areas at all health facilities.

3. Good ventilation is essential. Windows and doors should be kept open to maximize natural ventilation.

4. TB patients should be counseled to bring their TB contacts for screening, especially children below 5 years of age who have been in contact with smear positive TB patients, and all contacts above 5 years of age with a chronic cough that has not responded to broad-spectrum antibiotics.

5. District TB Coordinators and health assistants should conduct contact tracing using the notification forms.

6. Care of sputum specimens:
   - Sputum specimens should be transported to the laboratory as soon as possible after collection, or kept refrigerated but not frozen until transportation can be arranged.
   - Sputum specimens should be packed in a carrier bag with absorbent packing prior to transport.

7. TB patients/contacts/suspects and patients receiving isoniazid preventive therapy (IPT) should be fast-tracked for care and seen as soon as they arrive.

8. All suspected or confirmed cases of M/XDR-TB should be referred to the Botšabelo MDR-TB Hospital in Maseru. Health care workers should wear N95 respirators when caring for these patients.

---

**HIV counseling and testing / ART Centres**

1. All the infection control measures recommended for OPDs should be implemented.

2. HIV counseling and testing and ART centres should have a separate office or space for seeing patients referred from TB Clinics to speed up management and discharge home; alternatively HIV counseling and testing and ART should be provided by the TB clinics.

3. Ideally TB patients receive both TB treatment and ART in the TB clinics to prevent transmission of TB.

4. Health care workers should provide isoniazid preventive therapy (IPT) to HIV positive persons in whom active TB has been ruled out:
5. Health care workers should also provide IPT to the following high-risk groups if active TB has been ruled out:
   - Household’s contacts of TB patients
   - Miners
   - Health care workers
   - Factory workers (e.g. textile factories)
   - Staff and inmates of correctional facilities

TB/HIV Activities
1. A referral protocol for TB/HIV co-infected patients should be available and followed in the facilities.
2. A TB/HIV collaborating committee or focal person should assist in coordinating TB/HIV activities in all the hospitals and health centres.

Infection Control Measures on the Wards
1. Patients should only be admitted to the hospital when they cannot be managed and treated as out-patients.
2. Patients should be discharged as early as is safe.
3. All hospitalized patients should be screened for symptoms of TB (i.e. cough of any duration, fever, night sweats, weight loss) at the time of admission. Any patient reporting one or more symptom of TB is a TB suspect.
4. Sputum should be collected from all TB suspects at the time of hospital admission.
5. TB suspects and TB patients who are sputum smear positive, mycobacterial culture positive or GeneXpert rapid test positive should be isolated from other hospitalized patients. Patients suspected of having M/XDR-TB should be cohorted separately from other TB patients and other hospitalized patients. TB suspects/patients should be kept in well-lit and well ventilated rooms and wards. When possible, TB suspects/patients should be placed in private rooms. When cohorting is not feasible, TB suspects/patients should be kept at least 3 feet away from other patients or visitors.
6. TB Officers and other health care workers will be responsible for sputum collection, transportation of sputum to the lab, and delivery of results from the lab to the medical team on the wards. TB Officers and other health care workers will also be responsible for overseeing the implementation of TB infection control policies.
7. Transport of TB suspects/patients from the room should be kept to a minimum. If movement of TB suspect/patient is necessary, minimize patient dispersal of infectious droplets by providing the patient with a surgical face mask.
8. Health care workers and staff should wear gloves when caring care for patients, and change gloves after having contact with bodily fluids that are potentially infectious.

ANNEX 3: CLINICAL ALGORITHM FOR IPT THERAPY IN HIV-INFECTED AND EXPOSED INFANTS < 12 MONTHS

HIV-Exposed or Infected Infant < 12 months

Has the child had a close contact with TB or with chronic cough?

No

Yes

Screen for TB and continue to screen for TB disease and close contacts at every visit

Screen for TB Disease:
1) Poor Weight Gain* or Severe Malnutrition (wasting or swollen feet)
2) Fever
3) Current Cough

Positive

Investigate for TB Disease according to National Guidelines (including CXR)

No contraindications

Continue to Screen for TB Disease and Close Contacts. Repeat IPT for new TB contacts.

Not Tuberculosis

Give IPT

Tuberculosis

Assess for Isoniazid Contraindication
1) Symptomatic Hepatitis
2) Symptomatic Peripheral Neuropathy
3) LFTs > 5 times upper limit of normal

Investigate for TB according to national TB guidelines (Chest X-ray and/or sputum sample via gastric lavage, if available)***

No close contact has chronic cough. Investigate for TB

If close contact has chronic cough. Investigate for TB

* Poor weight gain is defined as reported weight loss, or very low weight (weight for age less than –3 z-score), or underweight (weight-for-age less than –2 z-score), or confirmed weight loss (>5%) since the last visit, or growth curve flattening.
** Symptoms of TB disease during IPT treatment should prompt discontinuation of INH and a complete evaluation.
*** Unavailability of chest X-ray or gastric lavage should not delay IPT
ANNEX 2: TB SCREENING AND INH PREVENTIVE THERAPY INITIATION AMONG ADULTS AND ADOLESCENTS LIVING WITH HIV

Adults living with HIV*

Screen for TB: Any of the following symptoms/signs present?
• Any Cough
• Weight loss in past 4 weeks
• Fever

No

Assess for contraindications to IPT**

No

Give IPT
INH 300mg daily + pyridoxine 25mg daily for 6 months
Monitoring***
Discontinue INH if necessary

Yes

Investigate for TB according to the National Guidelines

Not TB

Defer IPT

Follow up and consider IPT

TB

Treat for TB*****

Screen for TB at every follow-up visit******

If a patient develops active TB:
Stop IPT immediately, initiate TB treatment, and send culture and drug susceptibility testing.

Health care workers and staff should remove their gloves before leaving a patient’s room and wash his/her hands immediately with an antimicrobial agent or waterless antiseptic agent.

9. When possible non-critical patient care equipment should be used only on a single patient to avoid transmission of infections between patients.

Operating Theatres
1. Elective operative procedures should be delayed until the TB suspect/patient is no longer infectious (i.e. two to four weeks following initiation of TB treatment).
2. When surgery cannot be delayed, a negative pressure theatre should be used where available. If a negative pressure theatre is not available, then adequate environmental controls should be established and the TB suspect/patient should be put at the end of the operation list.
3. Personal respiratory protection (i.e. N95 masks) should be worn by all personnel working in the operating room.

Intensive Care Areas
1. TB suspects/patients should not be intubated unless absolutely necessary.
2. Natural ventilation and mechanical ventilation should be implemented in intensive care areas. When possible, TB suspects/cases should be placed in negative pressure isolation rooms.
3. Intensive care staff should wear personal respiratory protection (i.e. N95 masks) for procedures that are likely to create aerosols (e.g. bronchoscopy or sputum induction) in potentially infectious TB suspects/cases.

Laboratories
1. Entry into the laboratory should be restricted to only laboratory health care workers.
2. Sputum should not be collected in the laboratory.
3. Sputum samples should be delivered through a window to the lab.
4. Laboratory health care workers should decontaminate used specimen cups with 0.25% hypochlorite or 2% phenol solution as appropriate prior to disposal or incineration.
5. Laboratory health care workers should also autoclave specimen cups prior to disposal or incineration.

Radiology Units
1. Health care workers should schedule radiologic testing on TB suspects/cases at the least busy times of day (e.g. end of the afternoons).
2. TB suspects/cases should wear surgical masks when transported to and from the Radiology Unit.
3. Once TB suspects/cases have been transported to the Radiology Unit, they should be given priority to minimize how long they are in the Radiology Unit.
4. TB suspects/cases should undergo imaging in the best ventilated room of the Radiology Unit.
5. Entry into the Radiology Unit should be restricted to essential personnel and patients.

**Sputum Induction and Cough-Inducing Procedures**

1. Cough-inducing procedures (e.g. sputum induction or bronchoscopy) should only be done when absolutely necessary if a TB suspect/patient is unable to spontaneously expectorate sputum.
2. Bronchoscopy on patients with a known diagnosis of TB should be avoided.
3. Where cough-inducing procedures are performed, it is essential that environmental control measures be in place and that health care workers wear personal respiratory protection (i.e. N95 masks).

**Multidrug Resistant TB and Extensively Drug Resistant TB**

1. Patients with multidrug resistant TB (MDR-TB) or extensively drug resistant TB (XDR-TB) have prolonged periods of infectiousness, and therefore should be managed in a separate clinic or ward, and preferably in a separate hospital if feasible.
2. All M/XDR-TB suspects/cases should be referred to the Botsabelo MDR-TB Hospital in Maseru.
3. Details of TB infection control in an M/XDR-TB unit will be dealt with in the M/XDR-TB Management Guidelines.

**Improvement of the General Environment in the Health Facilities**

1. All visitors to health facilities should be protected through:
   - Posters and messaging to educate visitors about infection control.
   - Signage and banners to warn visitors against entering high-risk areas (e.g. no children under the age of 5 should be restricted from entering TB wards).
   - Restrictions on the number of visitors to TB wards, and how long visitors may stay in the TB wards.
2. Health care workers should be protected through:

**ANNEX 1: TB SCREENING TOOL**

| Screening date (day / month / year) |  /   /  
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>District __________________________</td>
<td>Health Facility __________________________</td>
</tr>
<tr>
<td>Client Name ________________________</td>
<td>Sex (circle)</td>
</tr>
</tbody>
</table>
| Age ______________________________| DOB   /   /  
| Pregnant (circle) | No | Yes | Gestational age ____ weeks |
| HIV status (circle) | Positive | Negative | Indeterminate | Unknown |

**Adults / Adolescents**

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Are you coughing?</td>
<td></td>
</tr>
<tr>
<td>2. Have you lost weight (without trying)?</td>
<td></td>
</tr>
<tr>
<td>3. Do you have drenching/soaking sweats at night?</td>
<td></td>
</tr>
<tr>
<td>4. Do you have fevers?</td>
<td></td>
</tr>
</tbody>
</table>

**Infants / Children**

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. Has the child been coughing?</td>
<td></td>
</tr>
<tr>
<td>6. Has the child had a fever?</td>
<td></td>
</tr>
<tr>
<td>7. Failure to thrive / faltering growth² or signs of severe malnutrition²?</td>
<td></td>
</tr>
<tr>
<td>8. Has the child been in contact with someone with TB disease?</td>
<td></td>
</tr>
</tbody>
</table>

[ ] If “Yes” to any question above, then the patient is a TB suspect. Record patient details in the TB suspect register, record TB suspect ID number below, and collect 3 sputum specimen for smear examination ± TB culture or GeneXpert testing.

TB suspect ID number: __________________________

Sputum collected for smear microscopy x 3 [ ] Yes [ ] No
Sputum sent for TB culture [ ] Yes [ ] No
Sputum sent for GeneXpert testing [ ] Yes [ ] No

[ ] If “No” to all questions above, then the patient is not a TB suspect. Educate HIV-infected patients and child contacts under the age of 5 years about the benefits of IPT.

IPT ID number: __________________________

---

1 Is the child not gaining weight as expected?
2 Severe malnutrition as noted by signs of severe wasting, bilateral foot edema, bloated stomach, etc.
What changes should be made to the referral or screening process?

7. Evaluate the training process
   - Did all new staff receive training on TB infection control during their induction?
   - Did all staff receive annual re-training on TB infection control?

8. Evaluate the implementation of environmental control measures
   - Periodical evaluation by using environmental control evaluation record (see annex 5 in IC plan)

9. Evaluate the protection of HCW:
   - Are all HCW offered TB and HIV screening?
   - Is TB screening offered on a regular basis according to their risk? (annually for low risk, quarterly for high risk like all staff from out-patient departments, wards, lab etc)
   - Is related information managed with the utmost confidentiality?
   - Do all staff wear N95 mask when in direct contact with TB patients?

10. It is the responsibility of the IC committee to:
    - Revise the facility’s infection control plan as needed to reflect changes in staff responsibilities, policies and procedures.
    - Develop a plan for correcting inappropriate practices or failure to adhere to institutional guidelines and policies.
    - Identify incentives to encourage participation and adherence to guidelines and policies.
    - Identify corrective actions if guidelines and policies are not followed.

   • Enforcement of occupational health policies.
   • Encouraging health care workers to undergo yearly medical check-ups, including TB screening and the option of HIV counseling and testing.
   • Providing Wellness Centre services for HIV positive health care workers, which should include IPT.
   • Health facility managers should respect and maintain the confidentiality of their staff’s individual health status.
   • Health care workers should be informed that if they are HIV positive, they should avoid working in certain high-risk areas (e.g. TB Clinics, TB wards, HIV Care/ART Clinics, Botsabelo MDR-TB Hospital in Maseru).

Universal Precautions

1. Hand washing procedures:
   - Hand washing is the most single important procedure for preventing transmission of infections.
   - Hand washing with plain soap is effective for removing most infectious agents.
   - Components of good hand washing include using an adequate amount of soap, rubbing the hands together to create some friction, and rinsing under running water.
   - Health care workers should wash their hands properly and thoroughly between patient contacts and after contact with bodily fluids and/or surfaces, equipment or items that may be contaminated with bodily fluids.

2. Gloves and hand washing:
   - Health care workers and staff should put on gloves after washing their hands and before entering a patient’s room.
   - Health care workers and staff should wear gloves during the course of providing care to a patient or while in a patient’s room.
   - Health care workers and staff should remove their gloves and wash their hands after caring for a patient and prior to moving on to another patient or other tasks.

3. Use of gowns:
   - Health care workers and staff should wear a gown when entering a room if there will be contact with the patient, environment surfaces or other items in the room.

TB Infection Control in the Community

Following measures should be put in place to reduce risk of TB transmission within the community:

- • Hand washing procedures:
- • Hand washing with plain soap is effective for removing most infectious agents.
- • Components of good hand washing include using an adequate amount of soap, rubbing the hands together to create some friction, and rinsing under running water.
- • Health care workers should wash their hands properly and thoroughly between patient contacts and after contact with bodily fluids and/or surfaces, equipment or items that may be contaminated with bodily fluids.

- • Gloves and hand washing:
- • Health care workers and staff should put on gloves after washing their hands and before entering a patient’s room.
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- • Use of gowns:
- • Health care workers and staff should wear a gown when entering a room if there will be contact with the patient, environment surfaces or other items in the room.

TB Infection Control in the Community

Following measures should be put in place to reduce risk of TB transmission within the community:
1. Health care workers in health facilities and community health care workers should provide their clients with Information, Education and Communication (IEC) materials on basic hygiene, cough hygiene, overcrowding and natural ventilation in the home.
2. Community health care workers should educate their communities on the need for natural ventilation at community gatherings (e.g. night prayers and funerals).
3. Community health care workers should encourage chronic coughers, TB suspects and contacts to health facilities for TB screening.
4. Community health care workers should screen their clients for symptoms of TB and refer them to health facilities for TB screening.
5. Correctional facilities, factories (e.g. textile factories) and mines should ensure that there is adequate natural and mechanical ventilation in the workplace, and provide workplace DOTS programmes.

DEVELOPMENT OF AN INFECTION CONTROL PLAN FOR EACH HEALTH FACILITY

Each health facility needs to develop an IC plan (see Annex 6 for IC Plan Template) outlining:
1. The people responsible for the implementation of IC activities (or IC control team) and their responsibilities
2. Policy areas involved
3. Description of the different interventions
4. Actual IC work plan with clearly defined activities, responsible concerned and indicators with timeframe
5. M&E matrix with selected indicators to monitor the implementation of the IC plan

MONITORING AND EVALUATION OF TB INFECTION CONTROL

Monitoring
1. In order to monitor the implementation of the TB infection control plan, an monitoring plan need to be developed by using indicators selected from the list as provided in the M&E matrix (see Annex 2 of IC plan: M&E matrix)
2. Processes that need to be monitored are:
   • Patient triage
   • Rapid identification of TB suspects
   • Rapid TB diagnosis
   • Rapid initiation of TB treatment
   • Health staff education

Evaluation
1. Evaluation of TB infection control procedures should be conducted periodically according to the infection control plan at that health facility.
2. Determine the frequency of IC plan evaluation
   • During initiation of procedures, monitoring and evaluation should be done frequently, perhaps monthly or bi-monthly.
   • When procedures are running well, less frequent evaluation will be necessary (annually at a minimum).
3. Processes that need to be evaluated are:
   • Screening clinical pathway including routine screening, cough hygiene , patient triage (ahead of queue or separate waiting area) and
   • Training process
   • Protection of HCW
   • Implementation of environmental control measures
4. Evaluate the screening process (by using patient triage form: see annex 3 of IC plan)
   • Were patients with a cough missed when entering the facility and only detected at a later time or in the examination room?
   • Time interval from suspicion of TB to ordering sputum collection.
   • Time interval from ordering to the collection of sputum.
   • Time interval from sputum testing to reporting of results.
   • Time interval from the return of laboratory results to the initiation of TB treatment.
5. Evaluate the success of TB suspect identification and referral to diagnosis and treatment (use the TB suspect register):
   • Access to TB diagnosis:
     • Did each TB suspects submit sputum?
     • Were results obtained for each TB suspect? Recorded in TB suspect register?
6. Access to treatment:
   • Did all TB suspects, diagnosed with TB (positive sputum or X-ray or clinical decision) actual start TB treatment?
   • Were all TB suspects, diagnosed with TB, actually registered in TB register?