Republic of Zambia

Ministry of Health

Managing Tuberculosis in the HIV Setting in Zambia

July 2014

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All Patients with HIV Infection should undergo routine TB symptom screening to determine whether they may have active TB infection.

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Foreword

Learning to recognize the signs and symptoms of tuberculosis in the HIV infected patient is the most important first step to reducing HIV/AIDs related mortality and morbidity. Zambia has the double epidemic of HIV and TB. TB is curable and HIV is now a manageable disease. However TB continues to be the number one cause of illness and death in HIV infected patients. All Zambian health professionals and health care workers must have confidence and competence to manage both these diseases singularly and in patients with co-infection.

Zambia has committed a lot of resources to curb the effects of TB/HIV co-infection. These guidelines have been developed to provide a clear guidance on how to apply the available resources. All stakeholders and patients must recognize these guidelines *"Managing Tuberculosis in the HIV Setting in Zambia"* as the key to reducing TB/HIV co- infection. These guidelines are also a demonstration of the joint energies required to combat the TB/HIV challenges. These guidelines were developed through the joint collaborative innovations of the National Tuberculosis Control Program and National Antiretroviral Program. It is expected that during the implementation this partnership will also be exhibited.

It is the hope of the Ministry of Health and the Ministry of Community Development, Mother and Child Health that through the efficient use of these guidelines all eligible Zambians will have access to TB preventive services and have timely and efficient treatment for HIV and Tuberculosis.

Dr. Davy Chikamata
Permanent Secretary
Ministry of Health

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Abbreviations

3Is	ICF-IPT-ICT interventions
AAFB	Alcohol acid fast Bacilli
ART	Antiretroviral Therapy
ATT	Anti-tuberculosis Therapy
CI	Confidence Interval
CPT	Co-trimoxazole Preventive Therapy
DNA	Deoxyribonucleaic Acid
DOTS	Directly Observed Therapy Strategy
DST	Drug Sensitivity Test
IC	Infection Control
ICF	Intensified Case Finding
ICT	Infection control for TB
IEC	Information Education Communication Materials
INH	Isoniazid
IPT	Isoniazid Preventive Therapy
LOP	Life of project
LTBI	Latent TB infection
M&E	Monitoring and Evaluation
MDR-TB	Multi-Drug Resistant -TB
MOH	Ministry of Health
MTB	Mycobacteria TB
PLHIV	People Living With HIV
QA/QI	Quality assurance /Quality Improvement
RIF	Rifampicin (Resistance)
SOP	Standard Operating Procedures
TAT	Turn Around Time
TB-QUAL	TB Quality Checks
TST	Tuberculin Skin Test
WHO	World Health Organization
Xpert	Genexpert

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Introduction

Tuberculosis is the most common presenting illness among people living with HIV, including those who are taking antiretroviral therapy. Almost one in four deaths among people living with HIV is due to TB.[1]

Tuberculosis around the World

According to the World Health Organization (WHO), the global burden of Tuberculosis remains high. In 2011, an estimated 8.7 million new cases of TB were reported, of which 13% were co-infected with HIV.[1,2] In addition, 1.4 million people died from TB in 2011, with 400,000 deaths occurring in HIV positive individuals.[1,2]

HIV is the strongest risk factor for developing TB in those with latent or new *Mycobacterium tuberculosis* infection.[3] The relative risk of TB among people living with HIV, compared with that among HIV-uninfected persons, ranges from 21 to 34 fold, depending on the state of the HIV epidemic.[1] The WHO has issued the TB/HIV policy recommending twelve collaborative activities as part of the core HIV and TB prevention, care and treatment services (Box 1).[4]

Box 1 WHO recommended collaborative TB/HIV activities

Establish mechanisms for communication

1. Set up a coordinating body for TB/HIV activities effective at all levels
2. Conduct surveillance of HIV prevalence among TB patients
3. Carry out joint TB/HIV planning
4. Conduct monitoring and evaluation (M&E)

Decrease the burden of TB in people living with HIV (the Three I's for HIV/TB)

5. Establish Intensified TB case-finding
6. Introduce Isoniazid prevention therapy (IPT)
7. Ensure TB Infection control in health care and congregate settings

Decrease the burden of HIV in TB patients

8. Provide HIV testing and counseling
9. Introduce HIV prevention methods
10. Introduce co-trimoxazole preventive therapy (CPT)
11. Ensure HIV care and support
12. Introduce antiretroviral therapy (ART)

Scope of guidelines

These clinical guidelines focus on key interventions branded as the Three I's for HIV/TB activities which reduce TB morbidity and mortality in people living with HIV, in addition to the provision of ART (Box 2):

- Intensified Case Finding of TB (ICF)
- Isoniazid Preventive Therapy (IPT)
- Infection Control for TB (ICT)

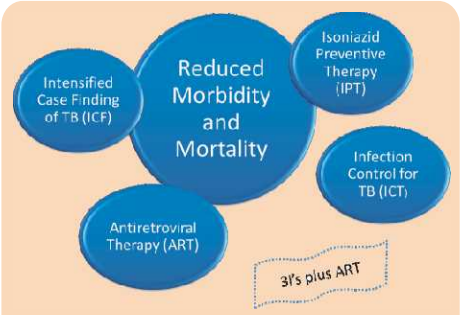
These should be the primary responsibilities of National Antiretroviral Program and HIV stakeholders. These guidelines are intended for care providers and all stakeholders involved in caring for TB and HIV patients.

Tuberculosis in Zambia

The burden of Tuberculosis is high in Zambia and TB is still a major public health challenge ranked among the top 5 causes of morbidity and mortality especially among the young and economically productive adults aged 15-49 years.

In Zambia, the number of TB cases has steadily increased from 4,572 cases in 1964 to 58,070 by 2004, representing a more than ten-fold increment in TB cases. Factors contributing to rapid increase in TB cases since 1985 are:

- HIV epidemic
- Population growth
- Urban overcrowding



Box 2: 3Is plus ART

TB notification in Zambia

Tuberculosis

- TB case notifications has been declining since 2005
- All forms of TB notification: 45,793 [a rate of 349/100,000 population (2013)]
- Treatment success rate for new TB smear positive cases has also improved from 77% in the 2002 cohort to 88% for the 2012 cohort

Tuberculosis /HIV

- In 2013, About 90% of all the notified TB patients were tested for HIV (2013)
- Of the TB patients tested for HIV, 62% were found to be HIV positive
- Of the positive patients 93% (52% of notified TB patients) initiated on co-trimoxazole preventive therapy (CPT) and 66% (52% of notified TB patients) initiated antiretroviral therapy (ART) (figure 1)

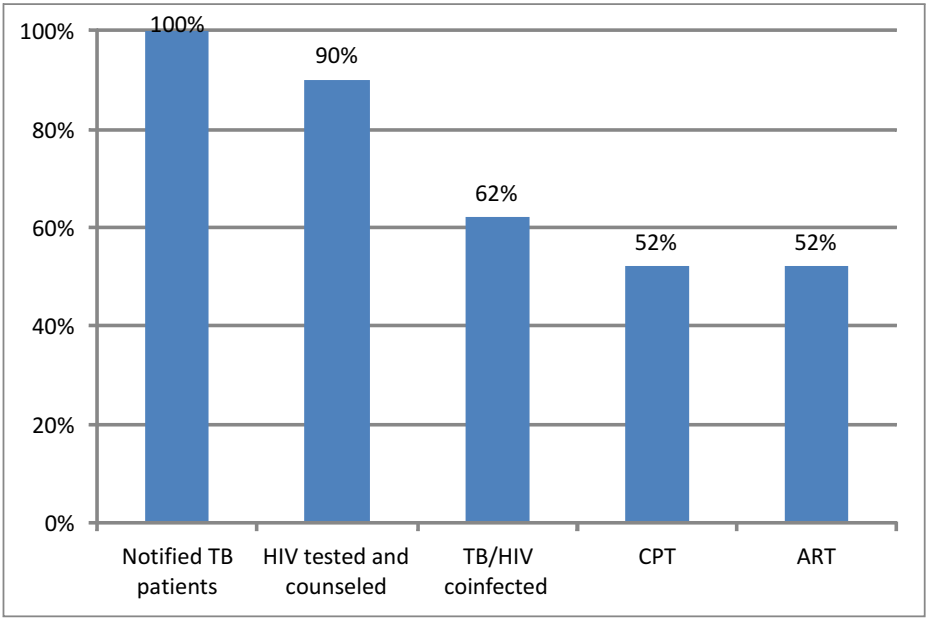


Figure 1 Cascade of services received by TB/HIV patients in Zambia (2013)
Percentages represent portion of total notified TB patients

Latent TB Infection & Active TB Disease

TB is a bacterial disease caused by Mycobacterium tuberculosis. TB usually affects the lungs, but can affect other parts of the body. Infection with MTB does not necessarily lead to being sick as person may have either latent TB or active TB disease.[1]

Latent TB Infection

Latent TB infection (LTBI) occurs when a person carries the TB mycobacteria, but the mycobacteria kept under control by immune system thereby unable to cause disease. People with LTBI are usually asymptomatic. They are also not infectious.[2]

Most people with latent TB never develop active TB disease and never become sick. Overall about 5 to 10% of people with latent TB who do not receive treatment will develop active TB disease at some time in their lives.[3] Some people have a higher risk of progressing from latent TB to active TB disease.[4]

These include:

- Infants and children aged less than 4 years
- People infected within the previous two years
- People infected with HIV
- People who have certain conditions which compromise their immune system, such as diabetics, and patients with chronic renal failure

TB Disease

Active TB or TB disease occurs when the TB mycobacteria overcomes the body's immune system. Active TB disease usually causes a person to show symptoms, and in certain circumstances they are able to pass the TB mycobacteria on to other people.[5]

Some people develop active TB disease soon after they become infected, before the immune system can fight the TB bacteria. Other people don't develop disease but have active TB disease years later when their immune system becomes weak for another reason, such as infection with HIV, or some other health problem.

The main steps of intensified case finding (ICF) include:

- Performing a TB symptom screen at every visit.
- Performing appropriate diagnostic evaluation for all patients with a positive symptom screen.
- Performing TB symptom screen for household contacts of all index patients.

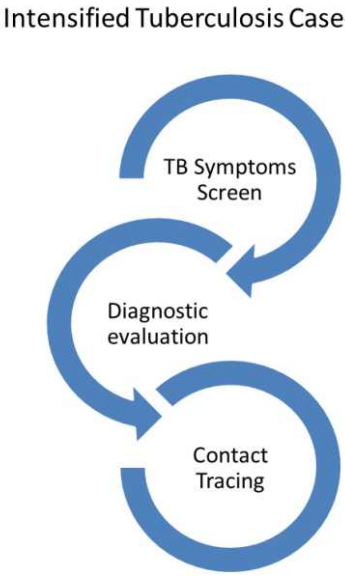


Figure 2 Intensified case finding components

Symptom Screen at Points of Care

High rates of previously undiagnosed TB is common among people living with HIV.

- At all points of care, all people living with HIV, should be regularly screened for TB.
- Screening should be done in all HIV patients including those who have previously received or currently receiving IPT or ART.

Points of care where screening should be done include the following:

- HIV/ART clinics
- STI clinics
- General health care settings including in-patient departments, admission wards, out-patient departments.
- HIV Testing and counseling corners/rooms and centers.
- PMTCT/MNCH centers
- Community-based outreach centers and activities.
- Hospices
- Home Based Care centers.
- Prisons and other congregate settings.

Symptom Screening in Adults and Adolescents (>10 years)

All patients with HIV infection should undergo routine TB symptom screening to determine whether they may have active TB disease (figure 4). The symptom screening process is incorporated in the routine review of systems whenever a patient presents for a clinical review in any health setting. In settings where a review of systems is not routinely done, the symptom screening checklist (annex 2) will be applied. The screening should be applied to ALL HIV clients.

All HIV infected patients who report **any of the symptoms*** below may have active TB and should be evaluated for TB and other diseases:

- current cough
- fever
- weight loss
- night sweats

The duration of symptom(s) is not taken into consideration: it does not matter whether a client has symptoms for less than 2 weeks

Symptom Screening in Children (≤10 years)

Children living with HIV may have active tuberculosis and should be evaluated for TB and other diseases if they present with any one of the following:

- current cough
- fever
- poor weight gain*
- contact history with a TB case

All children living with HIV should routinely be screened for TB, including those who previously

***Poor weight gain is defined as:**

Children (≤5 years):

- Reported weight-for-age of -2 z-score or less, OR
- Growth curve flattening

Children (>5yrs - <15yrs):

- Weight loss of ≥5% since last visit, OR
- Any weight loss recorded at follow up visit in the absence of any other possible explanation

received or are currently receiving TB prophylaxis/treatment or ART. However, the diagnosis of TB in children, with or without HIV, is difficult and clinicians need a high index of suspicion at all times and follow national guidelines. History of contact of the infant or child with someone with TB within the home is particularly important and should motivate the health care worker to screen for TB in the child and among other family members. TB screening should be carried out at each contact of the child with a health care provider regardless of history of TB treatment.

In order to increase the likelihood of identifying children without active TB for IPT, it is recommended that any child with a current cough of any duration should be considered to have presumptive diagnosis of TB in line with the recommendation for adolescents and adults. Unlike the screening rule for adults and adolescents, this recommendation requires that the differential diagnosis should be broadened to include other diseases that may cause children with HIV to present with current cough, fever and poor weight gain. Contact history with a known TB case should raise the clinical suspicion of TB in children with HIV.

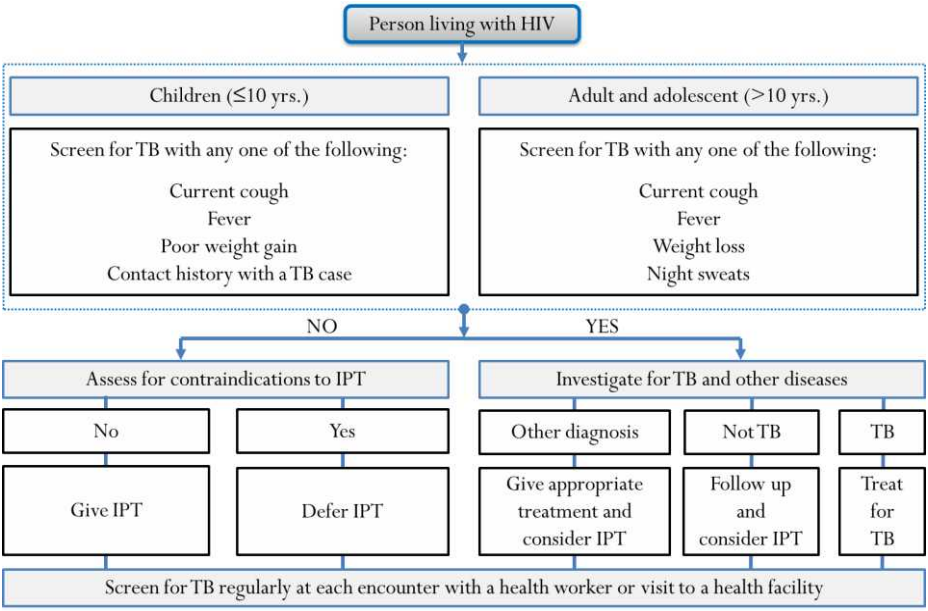


Figure 4: TB screening algorithm

Appropriate Diagnostics Evaluation of Patient with a Positive Symptom Screen

Among adults and adolescents living with HIV, a patient with presumptive TB is defined as a person who reports any one of the following: current cough, fever, weight loss or night sweats. Among children living with HIV, a patient with presumptive TB is defined as a person who reports one of the following symptoms: poor weight gain, fever, current cough, or history of contact with a TB case. In addition, all persons newly diagnosed with HIV will be treated as presumptive TB cases under this guideline.

Patients having a presumptive diagnosis of TB should be promptly evaluated for TB disease. This should be done in accordance with the current national guideline protocols (figure 5). This evaluation will include collection of one (1) spot sputum specimen if the method for analysis is Xpert, or two (2) sputum specimens (spot and early morning) if smear microscopy is used following the current national TB guidelines.

In patients with Xpert MTB+/RIF+, MDR-TB should be ruled out by performing TB culture/DST or line probe assays. Xpert MTB-/RIF- should be further evaluated to rule out differential diagnoses for TB. A chest X-ray, where available, could also be included as part of the work up for TB diagnosis.

If diagnostic services are not available on-site, the facility should have an established link with a TB diagnostic centre to which symptomatic patients can be referred. Each facility should also have a linkage with a TB treatment centre to which HIV patients diagnosed with TB can be referred.

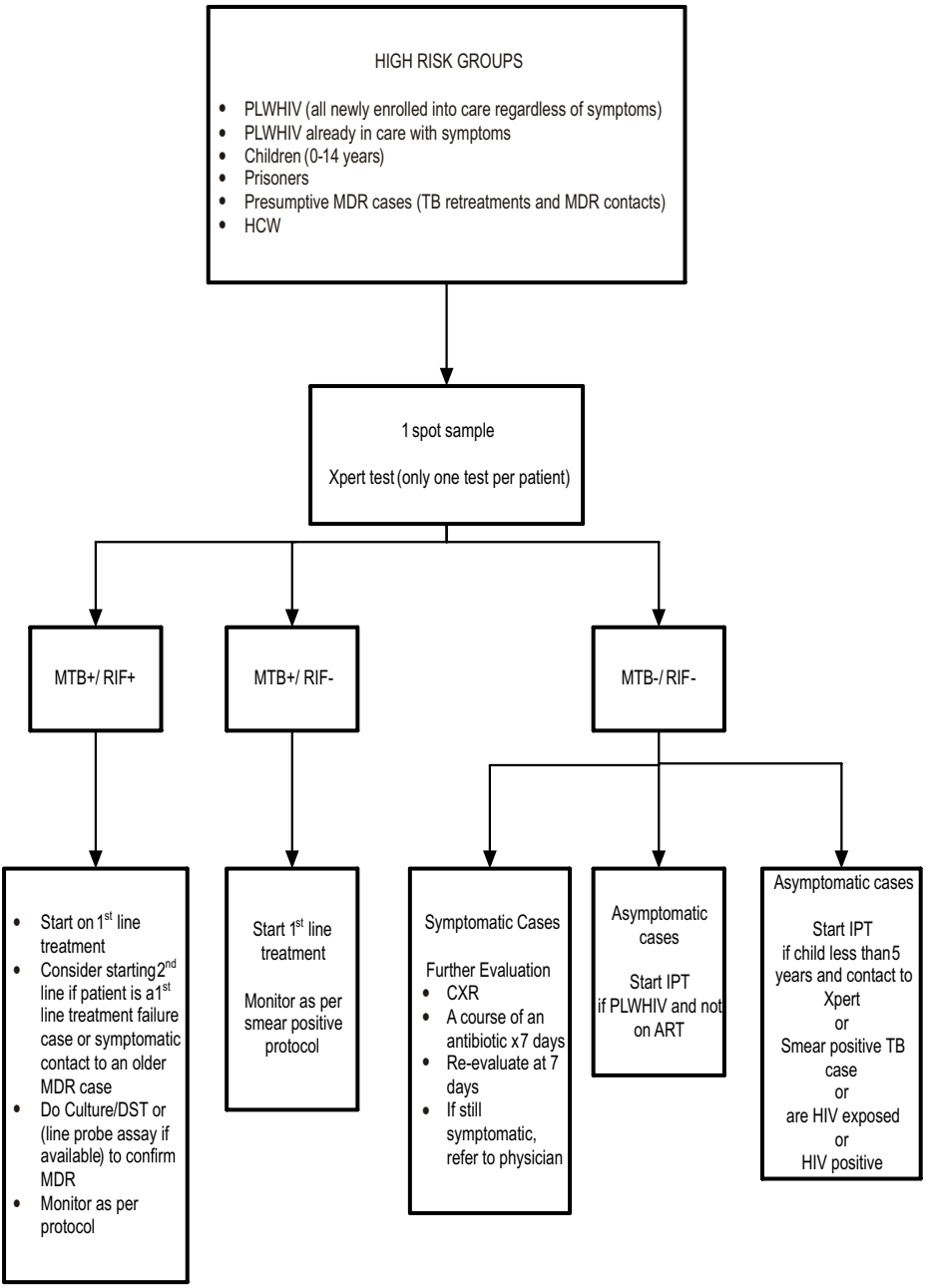


Figure 5: Algorithm for Evaluation of Patients with Presumptive TB Diagnosis

What is Xpert MTB/RIF?

People living with HIV (PLHIV) have more than a 20-fold increased risk of TB compared to HIV-uninfected people.[5] Diagnosing TB is a particular challenge among HIV patients who are more likely to have smear-negative pulmonary TB. This results in a delay in the detection of TB and subsequent start of treatment. As a result, HIV-related TB deaths become a significant public health problem.

Xpert MTB/RIF is a molecular test which detects the DNA in TB mycobacteria. It uses a sputum specimen and can give a result in less than 2 hours. It can also detect the genetic mutations associated with resistance to the drug Rifampicin. Xpert MTB/RIF is a self-contained cartridge based technology platform that integrates sputum processing, DNA extraction and amplification, TB diagnosis and Rifampicin resistance determination. It has similar sensitivity to culture. Compared to sputum smear microscopy, which has limited utility among PLHIV, Xpert MTB/RIF is able to detect more TB cases regardless of HIV status. For this reason Xpert MTB/RIF is now the recommended primary diagnostic test for TB in PLHIV.

According to the findings of recent research on the use of Xpert MTB/RIF for detecting TB in people living with HIV:

- Xpert MTB/RIF is sensitive and specific for detection of TB when it is used as an initial diagnostic test in patients suspected of having HIV-associated TB. Xpert MTB/RIF detected 80% (95% CI: 67% - 88%) of pulmonary TB cases in people living with HIV.[6]
- Xpert MTB/RIF increased case detection of TB by 45% compared with microscopy among people living with HIV enrolling in ART in South Africa.[7]
- Xpert MTB/RIF improved the quality of rapid TB diagnosis among PLHIV by increasing significantly the proportion of TB patients with a bacteriologically confirmed diagnosis compared to smear microscopy. In areas of high HIV prevalence, Xpert MTB/RIF confirmed diagnosis in 36 - 75% of pulmonary TB patients who were smear-negative.[8-11]
- Xpert MTB/RIF facilitated earlier diagnosis and reduced time-to-initiation of TB treatment, especially for smear-negative pulmonary TB and at the decentralized clinics in areas of high HIV prevalence.[11,12]
  Xpert MTB/RIF, therefore, enables decentralization of TB diagnosis from hospitals to peripheral health care facilities in HIV-prevalent settings.
- Xpert MTB/RIF was shown to be a sensitive and specific test for rapid diagnosis of pulmonary TB in children, including in HIV infected children, in settings with high HIV and TB prevalence. Xpert MTB/RIF performed well in two induced sputum specimens for detecting TB in children.[13, 14]

Xpert MTB/RIF - A New Diagnostic Test for Detection of TB among People Living With HIV

Sputum smear microscopy has a particularly low sensitivity for detecting TB among HIV patients. This is because people in later stages of HIV infection and with compromised immune systems often release fewer organisms into their sputum, at concentrations below the threshold for visual detection under a microscope. For HIV patients with a negative smear microscopy result but who are still presumed to have TB, bacterial culture has been the other option. However, culture can only be undertaken at central level laboratories, and results are normally only available after a number of weeks or months. Culture is therefore not good enough for patients with HIV, who need a speedy TB diagnosis and prompt treatment.

What Are The Strengths of Xpert MTB/RIF?

Xpert MTB/RIF has the following advantages over smear microscopy:

- it can detect as few as 50-150 MTB organisms/ml
- false negative and false positive results are uncommon with Xpert
- turnaround time (TAT) is 2 hours
- detects susceptibility to rifampicin

What Are The Weaknesses of Xpert MTB/RIF?

Xpert MTB/RIF some limitations including:

- cannot be used to monitor TB patients
- not validated on extra-pulmonary specimens yet
- cannot detect INH resistance - therefore it is a screening (not diagnostic) test for MDR-TB

How is sputum processed for Xpert MTB/RIF?

Steps in processing samples for Xpert (figure 6)

1. The required test kit is available
2. A good 1st sputum specimen is collected from patient
3. The sputum specimen is prepared appropriately inactivating agent added
   - kills MTB if present
   - releases TB DNA
4. Two (2) ml is added to the cartridge
5. Cartridge inserted into the GeneXpert machine

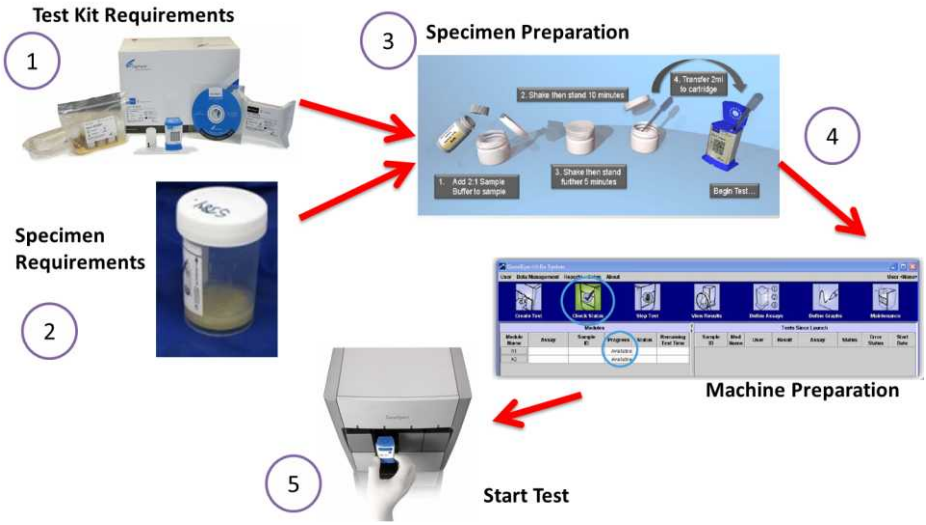


Figure 6: Steps for Processing a Sputum Specimen using Xpert MTB/RIF

The Sputum Specimen

A patient is required to submit one spot sputum specimen for Xpert MTB RIF testing:

The specimen must be of good quality and meet the following requirement:

- Minimum 1 ml of sputum, not saliva
  - Collect specimen on the spot to reduce time to diagnosis!
- No food particles
- Storage of specimen:
  - at <35°C maximum storage up to 3 days
  - at 4 °C maximum storage up to 10 days

Directly Observed Therapy

HIV clients who are found to have TB should begin anti-tuberculosis therapy (ATT) via Directly Observed Therapy Strategy (DOTS) as recommended by the National TB guidelines. DOTS has been shown to improve the chances for cure compared to self-administered ATT.

Screening Health Care Workers for Tuberculosis

Health care providers and volunteers working in the TB care settings should also be screened for TB every six months using the screening tool and applicable tests if necessary.

Tuberculin Skin Test

Tuberculin Skin Test (TST) relies on a competent immune response to identify patients with latent *M. tuberculosis* infection. In patients with a compromised immunity, the TST result can be falsely negative due to anergy therefore; in Zambia TST is not a pre-requisite for IPT.

Isoniazid Preventive Therapy

Isoniazid preventive therapy (IPT), refers to the use of isoniazid to treat patients who are infected with MTB but do not have active disease, a condition known as latent TB infection (LTBI). For these patients, a six month course of INH significantly reduces the risk of progression from LTBI to active TB. Providing IPT for HIV patients does not only reduce the individual patient's risk but also helps to lessen TB transmission to others. These guidelines recommend provision of IPT to HIV-infected adults and children who are unlikely to have active TB based on simple symptom screening.

Providing IPT to people living with HIV does not increase the risk of developing isoniazid-resistant TB. Therefore, concerns regarding the development of INH resistance should not be a barrier to providing IPT.

IPT in Adults and Adolescents

All adults and adolescents, irrespective of CD4 count who do not have current cough, fever, weight loss or night sweats are unlikely to have active TB. These are patients who can reliably start Isoniazid Preventive Therapy (IPT). This recommendation includes patients on ART, those who have previously been treated for TB and HIV infected pregnant women.

Using the symptom screening algorithm (figure 4) it is estimated that 90.4% of the patients that DO NOT have any of the four symptoms (current cough, fever, weight loss or night sweats) are unlikely to have active TB. Augmenting the symptom-based screening with abnormal findings on chest radiography increases the sensitivity only marginally to 94.3%. For this reason these guidelines recommend use of symptoms only to screen patients for active TB.

IPT Regimen and Duration in Adults and adolescents

Adults and adolescents who are eligible for IPT should receive as part of a comprehensive package of HIV care for at least **6 months**:

- INH 300mg/day (5mg/kg/day) with
- Pyridoxine (vitamin B6) 25mg/day

IPT should be dispensed as follows:

1. Monthly for the first 2 months,
2. As close to the ART pharmacy pick-up schedule, as possible or
3. Every two months thereafter

IPT should be given for 6 months, however if treatment is interrupted it can be given for 9 months:

- If a patient does not complete IPT within 9 months the cycle must be re-started.
- If a patient discontinues IPT for more than 3 months, screen for TB before continuing

IPT in Children

In HIV infected children less than 12 months, only those exposed to a TB case and are found to be TB negative on evaluation (using investigations) must receive IPT.

In HIV infected children above 12 months, children who are unlikely to have active TB based on symptom screening algorithm must receive IPT.

In circumstances where HIV-exposed infants (less than 12 months of age) and children receiving HIV care are pending a result of a virological HIV test, they should be considered as children living with HIV and get the appropriate services until their results are known. In children, INH should be given 10mg/kg of body weight and vitamin B6 be supplied with INH at 25 mg daily. All available data to date suggest that INH is not toxic for children, even in those receiving ART. The following table shows simplified dosing for INH 10mg/kg/day.

Table 1 Simplified INH dosing

Weight Ranges (kg)	Number of 100 mg tablets of INH to be administered per dose	Dose given (mg)
< 5	½ tablet	50
5.1-9.9	1 tablet	100
10-13.9	1 ½ tablet	150
14 -19.9	2 tablets	200
20 -24.9	2 ½ tablets	250
>25	3 tablets or one adult tablet	300

Secondary prophylaxis and IPT with ART in children

There is no evidence about the use of IPT in children after successful completion of TB treatment. Like adults, children living with HIV are exposed to re-infection and recurrence of TB; therefore, all children who have been successfully treated for TB and living in settings with high TB transmission like Zambia, should receive IPT for an additional 6 months. IPT should be started immediately following the last doses of anti-tuberculosis therapy or at the earliest contact with a health worker. TB screening should be carried out regardless of history of TB treatment during each contact of the child with a health care worker.

IPT Contra-indications

IPT is contraindicated in patients with:

- Active or suspected Tuberculosis
- Known or suspected hypersensitivity to INH
- Active hepatitis (jaundice, nausea, vomiting, right upper quadrant pain, dark urine, pale stools)
- Chronic hepatitis
- Peripheral neuropathy
- Above recommended Alcohol consumption (see annex 1)
- History of convulsions
- History of Psychosis
- Concomitant medication: phenytoin, carbamazepine, warfarin, theophylline, disulfiram, selective serotonin re-uptake inhibitor antidepressants (e.g. italopram, fluoxetine, paroxetine, sertraline), oral ketoconazole or itraconazole.

Side effects of IPT

Patients taking IPT commonly report minor side effects, mostly in the first month of treatment, which include:

- increased appetite
- headache
- itchy skin
- joint pains
- diarrhoea
- nausea
- stomach pains
- decreased libido or energy

The following are uncommon but may potentially be serious:
- hepatitis
- hypersensitivity rash
- psychosis and
- convulsions

Severe hepatotoxicity and death are rare if INH is stopped immediately when patients develop symptoms suggestive of hepatitis.

Monitoring of IPT in Adults and Adolescents

At each visit the following should be assessed:
- Symptom screening using the algorithm
- Monitor for side effects particularly acute hepatitis
- Assess for adherence
- Provide HIV/ART and TB counselling

IPT and CPT
INH and CTX may be safely co-administered

Symptoms of TB whilst on IPT
Stop IPT until results of investigations are obtained. Investigate for TB using the algorithm for evaluating patients with presumptive Tuberculosis diagnosis (Figure 5).

TB Infection Control

TB infection control (TBIC) refers to the development and implementation of basic infection control practices in facilities and communities where individuals are at risk of transmitting or contracting TB. TBIC protects the health of patients and health facility staff. TBIC practices can be categorized into four:

- Managerial activities
- Administrative controls
- Environmental controls
- Utilization of personal protective equipment

Implementing Managerial Controls

- Each facility should Identify or strengthen its infection control coordinating committee and focal person to lead the TBIC activities in the facility.
- The facility must adopt all national recommended policies, standards and technical guidelines that minimize transmission of TB including ICF and IPT.
- Facilities Infection Control (IC) coordinating committees must ensure the assessments of their facility are conducted periodically to determine the risk for TB transmission and to monitor the status of implementation of control measures.
- Every facility should have an integrated comprehensive budgeted IC plan
- Every facility should develop its human resources and build capacity.
- Health Care Workers will need to know when and how to protect themselves against health hazards at their place of work. They should also know how to minimize the transmission of TB between patients.

Implementing administrative controls

This begins with the easiest to institute. These include:

- Developing a standard triage procedure or checklist to identify potentially infectious patients as they enter the facility.
- Assigning responsible persons for triaging.
- Finding outdoor waiting areas for coughing patients to achieve separation where possible.
- Promoting cough etiquette with posting of appropriate signage, which should be posted in wards and in all outpatient waiting areas
- Training staff in ways to courteously instruct coughing patients in cough etiquette
- Making tissues and covered waste containers available in all waiting areas and inpatient units

- Minimizing time TB suspects and confirmed TB patients spend in the facility by:
  - Minimizing waiting time.
  - Minimizing delays in ordering, obtaining, and processing sputum samples; and reporting results.
  - Introducing new diagnostic tests e.g. GeneXpert, whenever possible to improve turnaround time
  - Routinely caring for patients with TB at home unless the patient has other medical conditions warranting hospitalization (exception: cases involving documented or suspected MDR TB should optimally be cared for in specialized facilities with isolation rooms)
- Ensuring prevention and care interventions for health care workers

Implementing environmental controls

- Adopt an open windows policy
- Redesigning consultation room setting and inpatient areas to assure that health care workers and asymptomatic patients are positioned upwind from coughing patients
- Including other control measures to be implemented as resources permit

Providing personal protective equipment

The personal protective equipment should be used to prevent and/or minimize exposure.

All facilities should have personal protective equipment including;

- Eye protection such as goggles or face shield.
- Full face respirators or N-95 respirators should be used when an employee enters an isolation room for a patient with active TB.

TBIC Measures in Prisons

Preventing the spread of infection from community to prison

- Using intensified TB screening for new or transferred prisoners.
- Preparing adaptation blocks or rooms (to be used for two to four weeks) for new or transferred prisoners.

Preventing TB infection among prisoners (from one TB prisoner to other prisoners or to prison's staff)

- Conducting a contact investigation for Presumptive TB cases

- Improving infection control (i.e. implementing managerial, administrative, and environmental interventions) in prisons
- Using IEC for prisoners

Preventing infection of family members and the community by released prisoners or prison staff

- Examining prisoners before release
- Examining prison staff regularly

TBIC in Households

- Houses should be adequately ventilated, particularly rooms where people with infectious TB spend considerable time (natural ventilation may be sufficient to provide adequate ventilation).
- Anyone who coughs should be educated on cough etiquette and should follow such practices at all times.
- While smear/ Xpert positive, TB patients should spend as much time as possible outdoors, sleep alone in a separate, adequately ventilated room. and spend as little time as possible in public places or in public transport.
- While smear/ Xpert or culture positive, MDR-TB patients who cough should always practice cough etiquette (including use of face masks) when in contact with people.
- Ideally, health service providers should wear respirators when attending to MDR-TB patients in enclosed spaces.
- Ideally, family members living with HIV, or family members with strong clinical evidence of HIV infection, should not provide care for infectious MDR-TB patients. If there is no alternative, HIV positive family members should wear respirators.
- Children below five years of age should spend as little time as possible in same living spaces as culture-positive MDR-TB patients. Such children should be followed up regularly with TB screening and, if positive, drug-susceptibility testing
- When conditions do not exist to minimize risk of TB infection in a household, XDR-TB patients should be admitted to a specialized healthcare facility
- Household members of any TB patients should be encouraged to get screened for HIV and TB and be given appropriate (preventive) therapy
- If possible, HIV-positive family members, or family members with a strong clinical evidence of HIV infection, should not share a household with culture positive XDR-TB patients.

Monitoring and Evaluation

Introduction
Diagnosis of TB in HIV infected people in the country has been a challenge. This is partly due to low sensitivity attributable to smear microscopy method that is predominantly used. Furthermore, the true rate of co-infection from the HIV setting is not known while the same is known in the TB treatment settings. The above situation has partly been due to poor integration of TB/HIV services.

M & E Plan Goal and Objectives
The overall goal of the 3Is program in Zambia is to strengthen the integration of TB and HIV services, with improved co-infection surveillance. The following are the specific objectives and program outcomes expected by the end of 2015:

- To increase bacteriologically confirmed TB case detection by 40% through intensified case finding by using Xpert MTB/RIF in specified populations
- To implement IPT for HIV patients in HIV Care and prison facilities to cover 30% of those eligible
- To Implement TB Infection control measures in 100% of the ART and non-ART facilities
- To Improve treatment success rate to at least 90% among TB/HIV co infected patients in HIV settings
- To increase uptake of ART to 80% in TB/HIV co-infection through improved linkages for ART provision for TB patients

Descriptions of specific interventions to be implemented

- Implement IPT in HIV care setting and strengthen the already existing IPT program in children.
- Implement Xpert MTB/RIF testing for HIV patients with TB symptoms and all newly enrolled into HIV care regardless of TB symptoms.
- Strengthen TB infection control measures in health care settings and prisons.
- Introduce proven referral mechanism in facilities to increase ART uptake in the TB HIV co-infected persons.

Program Indicators
The outcome indicators that will be used to monitor this program are provided for in annex 1. Routine program registers and reports will form part of the data sources. These include the Pre- & ART, TB Treatment, Presumptive TB, IPT, and Community Referral registers, and quarterly TB reports. Patients' treatment records such as Smart Care and TB treatment cards will form part of the verification tools.

Reporting
The National ARV and TB programs will produce one national report annually representing the TB/HIV collaborative activity report.

Zambia will implement quality improvement programs in all ART facilities targeting the TB and HIV services integration using a score card for the 3Is program (see annex 4). District HIV and TB focal persons will carry out quality checks at least biannually. Appropriate compilation methods will be used by the national surveillance office to collect this information.

Annex #1 Program Outcome Indicators

N	Indicator	Definition	Numerator	Denominator	Target or Program benchmark	Data source	Data collection method	Frequency	Staff resources & Responsible person
Objective 1: Increase TB detection through intensified case finding using Xpert MTB/RIF in health care and prison facilities, and through community and household case finding									
1.1	Bacteriologically confirmed PTB case notification rate (**outcome**)	Number of pulmonary TB cases notified out of the facility catchment area population	Number of reported PTB by facility	Facility catchment area population	20% LOP	Facility TB Register; Facility census data	Quarterly Facility TB Report or Review of TB data from Facility TB Registers	Quarterly	MOH M&E Officer
1.2	TB symptom screening rate	Proportion of persons undergoing symptom screening for TB on their last clinic visit or when newly enrolled in HIV care	Number of persons screened with the WHO 4 questions at most recent visit (including enrollment) among the patients records reviewed)	Number of patient records reviewed in the HIV clinic for the TB QUAL	100%	Smart care records and all TB related registers.	TB-QUAL: Review the smart care records, presumptive TB register, Laboratory register and TB treatment register in that order for each sample (minimum 30 records with a presumptive case)	Baseline Follow-up: ~quarterly (more if necessary)	MOH M&E Officer
1.3. A	Presumptive TB case registration rate- screened positive	Proportion of patients who screened positive who are registered as presumptive TB	The number of patients who screened positive among all eligible patients found in the TB suspect register (in record review)	The number of persons with a positive symptom screen at last visit (in record review) in HIV care	100%	Smart care records and Presumptive TB register	TB QUAL-Review the smart care records and Presumptive TB register for the sampled patients' records.	Baseline Follow-up: ~quarterly (more if necessary)	MOH M&E Officer
1.3. B	Presumptive TB case registration rate- newly enrolled	Proportion of patients who were newly enrolled who are registered as presumptive TB	Number of patients newly enrolled among all eligible patients found in the TB suspect register (in record review)	Number of persons newly enrolled at last visit (in record review) in HIV care	100%	Pre ART and Presumptive TB suspect registers	TB-QUAL-New HIV patients enrolments in that quarter in Pre-ART register compared with those registered in presumptive TB Register	Baseline Follow-up: ~quarterly (more if necessary)	MOH M&E Officer
1.4	TB diagnostic testing referral rate	Proportion of eligible presumptive TB cases who submitted samples for TB evaluation	Number of presumptive TB cases recorded in the TB laboratory register within a specified period.	Total number of presumptive TB cases within the same period.	100%	Presumptive TB register and TB lab register	TB-QUAL-Compare the records in the presumptive TB register against those found in the TB lab register for a specific period	Baseline Follow-up: ~quarterly (more if necessary)	MOH M&E Officer

1.5	Compliance with diagnostic algorithm	Proportion of newly enrolled patients [or proportion of Xpert eligible patients] who are tested using Xpert MTB/RIF.	Number of newly enrolled HIV patients [or number of Xpert eligible patients] who are tested using Xpert MTB/RIF	Total number of newly enrolled patients [or total number of Xpert eligible patients]	100%	Review; Presumptive TB Register, Lab Register)	TB QUAL Review; Compare the number tested on Xpert in the lab register with that in the Presumptive TB register for all newly enrolled HIV patients for that period	Quarterly (more if necessary	MOH M&E Officer
1.6	Compliance with turnaround time from identification of presumptive TB case to TB diagnostic results	Proportion of presumptive TB cases with a TB diagnostic test result recorded within 2 working days of TB screening	Number of presumptive TB cases with a TB diagnostic test result recorded in the Lab Register within 2 working days of TB screening	Total number of presumptive TB cases reviewed	100%	Presumptive TB Register, Lab Register	TB QUAL Review; Compare the dates of registration in the Presumptive TB register to that in the TB register under results column for each case in the sampled records	Baseline Follow-up: ~quarterly (more if necessary)	MOH M&E Officer

No.	Indicator	Definition	Numerator	Denominator	Target or Program benchmark	Data source	Data collection method	Frequency	Staff resources & Responsible person
Objective 2: Improve treatment success rate among TB patients diagnosed in HIV settings by improving DOTS coverage									
2.1	TB treatment success rate among PLHIV (**outcome**)	Proportion of HIV patients diagnosed with TB who have a recorded TB treatment success outcome (cure, completion of treatment)	Total number HIV+ TB cases with a recorded treatment success outcome	Total number HIV+ TB cases started on treatment	90% treatment success	Facility Quarterly Notification Report	Review the report for each facility. compare the data to that in the TB treatment registers	Quarterly-- cohort analysis	MOH M&E Officer
2.2	TB treatment outcomes in HIV care settings (**outcome**)	Proportion of TB patients with recorded TB treatment outcome diagnosed in HIV care setting (cure, completion of treatment, mortality, failure, default, transfer out)	Number of HIV cases with a TB treatment outcome	Total number HIV+ TB cases notified during the quarter in HIV care settings	100%	Facility Quarterly Notification Report or facility TB Register	Review the report for each facility. compare the data to that in the TB treatment registers	Quarterly	MOH M&E Officer
2.3	Anti-TB treatment (ATT) initiation rate by bacteriological diagnosis	Proportion of diagnosed TB patients initiated on ATT who were bacteriologically confirmed	The number of TB patients with a bacteriological confirmation (Xpert/Smear positive) who were initiated on ATT	Total number of TB patients who were initiated on ATT	80%	Lab register; TB register OR Quarterly Notification Report	TB-QUAL- For a sample of patient during reviews, check the diagnostic information Or review the facility quality report	Baseline Follow-up: ~quarterly (more if necessary)	MOH M&E Officer

2.4	ATT initiation among clinically diagnosed	The proportion of diagnosed TB patients initiated on ATT who were treated based on clinical diagnosis	Number of patients clinically diagnosed with TB (Xpert/Smear negative) who were initiated on ATT	Total number of TB patients initiated on ATT	20%	Lab register; TB register	TB-QUAL- The difference between the total number initiated on treated and those found in 1.3.1	Baseline Follow-up: ~quarterly (more if necessary)	MOH M&E Officer
2.5	Time from bacteriologically confirmed TB diagnosis to ATT initiation	Proportion of bacteriologically confirmed (Xpert/Smear positive) TB tested patients initiated on ATT within 3 days	Number of patients with bacteriologically confirmed (Xpert/Smear) TB who were initiated on ATT within 3 days following their TB diagnosis (in record review)	Total number of TB patients in TB treatment register with bacteriologically confirmed TB.	100%	Lab register; TB register)	TB-QUAL- Comparison of dates between lab test result record and TB treatment initiation for a sample of patients during the TB QUAL review	Baseline Follow-up: ~quarterly (more if necessary)	MOH M&E Officer
2.6	Time from non-bacteriologically confirmed TB diagnosis to ATT initiation	Proportion of non-bacteriologically confirmed (Xpert/Smear negative) diagnosed TB patients initiated on ATT within 14 days	Number of patients with a negative Xpert/Smear-negative TB test who were on ATT within 14 days following their TB diagnosis (in record review)	Total number of patients in TB treatment who tested negative on Xpert/ smear tests but were initiated on TB treatment.	100%	Lab register; TB register	TB-QUAL- Comparison of dates between lab test result record and TB treatment initiation for a sample of patients during the TB QUAL review	Baseline Follow-up: ~quarterly (more if necessary)	MOH M&E Officer

No.	**Indicator**	**Definition**	**Numerator**	**Denominator**	**Target or Program benchmark**	**Data source**	**Data collection method**	**Frequency**	**Staff resources & Responsible person**
Objective 3: Implementation of IPT for PLHIV in HIV Care and at prison facilities									
3.1	IPT Coverage among the newly enrolled into Care	Proportion of patients known to be HIV-positive, and with no bacteriologically or clinically confirmed active TB , who were initiated on IPT or have received IPT within the last three months from enrolled facilities". TB	Number of patients known to be HIV-positive and without active TB, who were initiated on IPT or had previously received IPT within the last three months from enrolled facilities	Number of patients known to be HIV-positive and without active TB, who were seen within the last 3 months in enrolled facilities	60%	IPT register; Smart Care (facility); Prison screening register	Secondary review and analysis of IPT data from IPT register and Prison screening register compared with the data from the HIV clinic visit statistics in that quarter	Quarterly	MOH M&E Officer
3.2	IPT Completion rate (**outcome**)	The proportion of patients completing recommended (6 or 9 months) IPT	Total number of patients who complete recommended months of IPT	Total number of patients initiated on IPT, 9-12 months prior to the assessment period	80%	IPT register	Secondary review and analysis of IPT data from IPT register	Quarterly	MOH M&E Officer
3.3	Active TB rate in persons who completed IPT (**outcome)**	Proportion of patients who completed IPT, who subsequently develop active TB within 24 months of IPT completion.	Number of patients who develop active TB within 24 months of IPT completion	Number of patients who completed IPT, up to 12-24 months prior to assessment period	0%	IPT register (once updated	Secondary review and analysis of IPT and TB outcome data from IPT register	Annually	MOH M&E Officer
3.4	Known IPT outcome	The number of patients with a recorded IPT outcome (completed, death, stopped, defaulted etc)	Total number of patients with an IPT outcome	Total number of patients initiated on IPT and expected to have an outcome during that period	100%	IPT register	Secondary review and analysis of IPT data from IPT register	Quarterly	MOH M&E Officer

Objective 4: Improve infection control work practices in HIV care and treatment and prison settings									
No.	**Indicator**	**Definition**	**Numerator**	**Denominator**	**Target or Program benchmark**	**Data source**	**Data collection method**	**Frequency**	**Staff resources & Responsible person**
4.1	IC compliance rate **(outcome)**	Proportion of facilities meeting at least 80% of infection control requirements as detailed in the TB Infection Control Assessment	Number of enrolled facilities achieving at least 80% of infection of infection control requirements	Total number of 'facilities enrolled	100%	TB Infection Control Assessment Tool (Edited	Facility-based TB ICP assessments conducted each quarter, using the TB IC Facility assessment report	Quarterly	MOH M&E Officer
4.2	TB among HCW **(outcome)**	Number and proportion of HCWs who develop active TB each year	Number of HCWs who develop active TB within 12 months at all enrolled facilities	Total number of HCW employed in the enrolled facilities over the same period	0%	HCW TB/HIV log	Secondary review and analysis of TB outcome data from HCW TB/HIV log	Annually	MOH M&E Officer
4.3	Up-to-date TB Infection Control plan in place	Proportion of facilities which have a budgeted infection control plan in place at the facility, that has been updated within the past year	Number of facilities with a budgeted IC plan that has been updated within the past year	Total number of facilities enrolled	100%	Facility budget and planning documents; interview notes	Site visit; review of facility plans and records; interview of facility manager	Quarterly	MOH M&E Officer
4.4	IPC focal person assigned	IPC focal person assigned to each health care facility	Number of facilities with an assigned IPC focal person	Total number of health care facilities enrolled	100%	TB Infection Control Facility Assessment Tool	Facility-based TB ICP assessments conducted each quarter, using the TB IC Facility assessment tool	Quarterly	MOH M&E Officer
4.5	Annual participation rate of HCWs in the screening program	Proportion of healthcare workers screened for TB in the previous year	Number of HCWs screened for TB in the previous year at enrolled facilities	Total number of HCWs employed in the enrolled facilities during the same period	90%	HCW TB/HIV log	Secondary review and analysis of TB screening data from HCW TB/HIV log or data from the laboratory register on Xpert testing	Annually	MOH M&E Officer
4.6	IPT Use by HCWs **(outcome)**	Proportion of healthcare workers with known HIV positive status and no active TB, who received or were initiated on IPT	Number of healthcare workers seen within the previous quarter with known HIV positive status and with negative TB symptom screen, who either previously received IPT or are initiated on IPT	Number of healthcare workers seen within the previous quarter with known HIV positive status and with negative TB symptom screen	90%	HCW TB/HIV log	Secondary review and analysis of IPT coverage data from HCW TB/HIV log	Quarterly	MOH M&E Officer

No.	Indicator	Definition	Numerator	Denominator	Target or Program benchmark	Data source	Data collection method	Frequency	Staff resources & Responsible person
Objective 5: Improved linkages for ART provision for TB patients diagnosed with HIV in TB care settings									
5.1	HIV status rate among TB patients **(outcome)**	The proportion of TB patients with known HIV status	Number of TB patients with a recorded HIV test result	Number of TB patients	100%	TB treatment register Of facility quarterly notification report	Review of the TB treatment register or review of the facility quarterly TB notification report	Quarterly	MOH M&E Officer
5.1.a	Provision Of Antiretroviral Treatment For TB Patients During TB Treatment	Number of HIV-positive registered TB patients who are started on or continue previously initiated ART during TB treatment as a proportion of all HIV- positive TB patients for a specified period (cumulative proportion).	Number of HIV-positive registered TB patients who are started on or continue previously initiated ART during TB treatment in that quarter.	Total number of HIV positive TB patients reported in the same quarter	70%	TB treatment register.	Review of the TB treatment register	Quarterly	MOH M&E Officer
5.1b	Provision Of Antiretroviral Treatment For HIV-positive TB Patients During TB Treatment	The cumulative proportion of HIV-positive registered TB patients who are started on or continue previously initiated ART during TB treatment for the previous two quarters.	Total number of HIV-positive registered TB patients who are started on or continue previously initiated ART during TB treatment for the last six months.	Total number of HIV-positive TB patients recorded during the same period (last six months)	90%	TB treatment registers	Review of the register for the previous two quarters	Quarterly	MOH M&E Officer
5.2	Early ART initiation among TB patients newly diagnosed as TB/HIV co-infected	The proportion of TB patients receiving TB treatment that initiate ART within 8 weeks of TB treatment initiations	Number of TB patients receiving TB treatment that initiate ART within 8 weeks of TB treatment initiation	Total number of TB patients diagnosed with HIV from the TB clinic	80%	Tb Treatment register and ART register	Review of the two registers with emphasis on time of dual infection establishmen t in TB register, then each patient checked for date of ART initiation in ART register	biannually	MOH M&E Officer

Annex #2. Recommended Alcohol Consumption Limits

Daily alcohol consumption of men should not regularly exceed 3-4 units, for women this limit is 2-3 units. Persons below the age of 18 years should not be offered, sold or consume alcohol.

1 UNIT	1.5 UNITS	2 UNITS	3 UNITS	9 UNITS	30 UNITS
 Normal beer half pint (284ml) 4%	 Small glass of wine (125ml) 12.5%	 Strong beer half pint (284ml) 6.5%	 Strong beer Large bottle/can (440ml) 6.5%	 Bottle of wine (750ml) 12.5%	 Bottle of spirits (750ml) 40%
 Single spirit shot (25ml) 40%	 Alcopops bottle (275ml) 5.5%	 Normal beer Large bottle/can (440ml) 4.5%	 Large glass of wine (250ml) 12.5%	Government advises alcohol consumption should not regularly exceed:  Men 3-4 units daily	 Women 2-3 units daily
Source: ONS, NHS		 Medium glass of wine (175ml) 12.5%			

Annex #3 TB ICF Symptom screening checklist

TUBERCULOSIS

Ministry of Health
Republic of Zambia

Symptom Checklist

Name:

Community:

Adult Classic Symptoms	Children Classic Symptoms
☐ Cough	☐ Cough
☐ Fever	☐ Fever
☐ Weight loss	☐ Weight loss
☐ Night Sweats	☐ Failure to thrive

Refer all patients with any one of these symptoms to be nearest health care facility. Any patient with any of these symptoms should be ***presumed to be with Active Tuberculosis*** unless laboratory evaluation proves otherwise.

Infants and the elderly may not always present with the classic signs and symptoms of active tuberculosis (TB). It is important to consider other symptoms as possible signs of disease. If you notice any suspicious symptoms, further investigation may be warranted. It is also important to consider individual risk factors when assessing for the possibility of TB disease.

Individuals at higher risk for developing TB disease:

- Infected with TB bacteria within the last two years
- X-ray suggesting previous TB, and no adequate treatment received
- Treatment with steroids (glucocorticoids)
- Diabetes
- Smoking
- Certain lung disease called silicosis
- Chronic kidney failure requiring dialysis
- Cancer of the head and neck
- HIV/AIDS

MINISTRY OF HEALTH June 2014

Annex #4 Zambia 3Is Program TB-HIV Facility Report Card

Facility Code: __ __ __ __ Facility Name:_____

Date of Review: __ __/__ __/__ __ Review No: ___ (0=baseline, 1=1st qtr follow-up, etc.)

Fill in the far right column with score (0-3) that best fits the assessed standard. For services or standards that do not apply, place an "N/A" in the far right column. Write any comments or issues explaining the score. Items in red are for standards requiring data from chart review, facility assessment or register review.

I. TB Intensified Case Finding (TB ICF)

Surpasses standards in this area	Meets standard	Needs improvement	Needs urgent remediation	SCORE
4	3	2	1	
National guidelines for TB ICF are available on site. AND Written standard protocol for TB ICF exists and an algorithm for patient screening is clearly posted or easily accessible. AND Clinic staff has received training on TB intensified case finding and understand the protocol. AND Clinic staff can clearly explain how patients who have TB symptoms are systematically referred and followed to ensure there is no loss to follow-up (e.g., using a referral register, etc.) AND **>90% of charts reviewed showed evidence TB symptom screening and timely referral for diagnostic workup and treatment when this is indicated. Documentation of these processes was excellent.**	A TB ICF protocol exists, but algorithms are not posted or easily accessible. AND The clinic staff appears to have an understanding of how to do TB symptom screening and seem to be doing this consistently. AND Referral and follow-up of patients who need diagnostic work-up seems to be done in most cases. AND **>70-90% of charts reviewed showed evidence TB symptom screening and timely referral for diagnostic workup and treatment when this was indicated. Documentation was good.**	A TB ICF protocol exists, but it is not uniformly understood by staff. AND TB symptom screening may not be implemented systematically. AND Systems to ensure referral and follow-up for TB diagnostic work-up are weak. AND **50-70% of charts reviewed showed evidence TB symptom screening. Referral for diagnostic workup and treatment was done inconsistently and there were instances where patients were loss to follow-up or delays in receipt of these services occurred. Documentation was inconsistent.**	No protocol is in place for TB ICF. TB symptom screening is not done systematically. AND No systems are in place for referral and follow-up of TB suspects. AND **<50% of charts reviewed showed evidence of TB symptom screening. Many patients who were should have been referred for diagnostic work up and treatment services did not receive them. Loss to follow-up was frequent. Documentation was non-existent or poor.**	

Isoniazid Preventive Therapy (IPT)

Surpasses standards in this area	Meets standard	Needs improvement	Needs urgent remediation	Facility score and comments
4	3	2	1	
National guidelines for IPT are available on site. AND Written standard protocol for IPT exists and an algorithm to assist clinic staff in determining eligibility for is clearly posted or easily accessible. AND Clinic staff has received training on determining eligibility for IPT and on how to administer and monitor it. AND Clinic staff can clearly explain how to determine eligibility for IPT and how to administer and monitor it. AND **>90% of charts reviewed showed evidence that TB symptom screening was performed and IPT was appropriately administered to eligible patients.** AND Supply of IPT on site is adequate. AND Adherence supporters and other systems support adherence to IPT.	An IPT protocol exists, but algorithms are not posted or easily accessible. AND The clinic staff appears to have an understanding of how to determine IPT eligibility and to administer and monitor it. AND **>70-90% of charts reviewed showed evidence that TB symptom screening was performed and IPT was appropriately administered to eligible patients.** AND Supply of INH on site is adequate. AND There is a system in place to monitor patient adherence to IPT.	An IPT protocol exists, but it is not uniformly understood by staff. AND TB symptom screening is not implemented systematically and IPT-eligible patients may not be put on it. AND **50-70% of charts reviewed showed evidence that TB symptom screening was performed and IPT was appropriately administered to eligible patients.** AND Supply chain for INH may be inconsistent. AND There is no system in place to monitor patient adherence to IPT.	No protocol is in place for IPT. TB symptom screening is not done systematically. AND IPT has not been implemented or it has been implemented inconsistently. AND **≤50% of charts reviewed showed evidence of TB symptom screening. Patients who screen positive were inconsistently administered to eligible patients. Documentation is non-existent or poor.**	

II. TB Infection Control (TB IC)

Surpasses standards in this area	Meets standard	Needs improvement	Needs urgent remediation	Facility score and comments
4	3	2	1	
National guidelines for TB IC are available on site. AND An infection control focal person has been appointed, and the facility administration provides a budget as well as policy support for infection control. AND A written plan for infection control for the facility exists and includes SOPs for TB IC. AND Clinic staff has received training in TB IC. AND **On the facility TB IC assessment, the clinic received a "green" score at least 9 of the 10 TB IC measures.**	A written plan for TB IC exists either separately or incorporated in to the facility infection control plan. AND Clinic staff has received training in TB IC. AND **On the facility TB IC assessment, the clinic received a "green" score at least 8 of the 10 TB IC measures.**	A written plan for TB IC exists, but many of the clinic staff are not aware of it and have not received training in TB IC. AND **On the facility TB IC assessment, the clinic received a "green" score on at least 6 of the 10 TB IC measures.**	No plan for TB IC is in place, and there is no one on staff who has been trained in TB IC. AND **On the facility TB IC assessment, the clinic received a "green" score on ≤5 of the 10 TB IC measures.** **.**	

III. Early initiation of ART Therapy for HIV-Infected Patients in TB Clinics

Surpasses standards in this area	Meets standard	Needs improvement	Needs urgent remediation	Facility score and comments
4	3	2	1	
National guidelines for provider-initiated HIV testing of TB patients and guidelines for antiretroviral treatment of HIV-infected TB patients are available on site. AND TB clinic staff has received training on the guidelines. AND **Review of the TB clinic treatment register for the most recent quarter showed that >90% of TB patients were offered HIV testing and >90% of HIV-positive patients received ART during TB treatment.** AND Mechanisms (with documentation) are in place to ensure timely referral and linkage to the HIV clinical services (including ART) or ART services are provided in the TB clinic.	TB clinic staff are aware of the current guidelines to offer PITC to all TB patients and to start HIV-infected TB on ART within the first month of TB treatment. AND **Review of the TB clinic treatment register for the most recent quarter showed that 80-90% of TB patients were offered HIV testing and 80-90% of HIV-positive patients received ART during TB treatment.**	TB clinic staff members are aware of the guidelines but have not made efforts to ensure that all HIV-infected TB patients are linked to HIV services and put on ART while they are receiving TB treatment. AND **Review of the TB clinic treatment register for the most recent quarter showed that 70-79% of TB patients were offered HIV testing and 50-70% of HIV-positive patients received ART during TB treatment.**	TB clinic staff members do not appear to know that all HIV-infected TB patients are eligible for ART and should start it early during TB treatment. AND **Review of the TB clinic treatment register for the most recent quarter showed that <70 of TB patients were offered HIV testing and <50% of HIV-positive patients received ART during TB treatment.**	

IV. TB Treatment and Outcomes

Surpasses standards in this area	Meets standard	Needs improvement	Needs urgent remediation	Facility score and comments
4	3	2	1	
National guidelines for TB treatment are available on site. AND TB clinic staff has received training on the guidelines. AND **Review of the TB clinic treatment register for the most completed cohort showed that >90% of TB patients (excluding transfer outs) successfully completed TB treatment. Lost to follow-up or missing outcomes were <5%.** AND Documentation of directly observed therapy (DOT) on TB treatment cards and in the TB register was good, including correct calculation of the DOT score. AND Treatment supporters are available on site to assist with DOT and follow-up of patients who miss scheduled appointments to pick up medication. Documentation is available showing their efforts to find these potential treatment defaulters.	TB clinic staff members are aware of the current TB treatment guidelines and have received at least some on-the-job training in management of TB patients. AND **Review of the TB clinic treatment register for the most completed cohort showed that 80-90% of TB patients (excluding transfer outs) successfully completed TB treatment. Lost to follow-up or missing outcomes were <10%.** AND Documentation of directly observed therapy (DOT) on TB treatment cards and in the TB register was good, including correct calculation of the DOT score.	TB clinic staff turnover is high and there are some members who have not received training in the management of TB patients. AND **Review of the TB clinic treatment register for the most completed cohort showed that 70-79% of TB patients (excluding transfer outs) successfully completed TB treatment. Lost to follow-up or missing outcomes were 10-15%.**	TB clinic staff members do not appear to know how to monitor patients for directly observed therapy. AND **Review of the TB clinic treatment register for the most completed cohort showed that <70% of TB patients (excluding transfer outs) successfully completed TB treatment. Lost to follow-up or missing outcomes were >15%.**	

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National Antiretroviral Program
National Tuberculosis Control Program