



Ministry of health
Kingdom of Swaziland

NATIONAL GUIDELINES For Implementing Tuberculosis

*Intensified Case Finding
Isoniazid Preventive Therapy
and Infection Control in health
care and congregate settings*



Strengthening
Pharmaceutical
Systems



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JANUARY 2012



Swaziland National Tuberculosis
Control Programme



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NATIONAL GUIDELINES

For Implementing Tuberculosis

Intensified Case Finding Isoniazid Preventive Therapy and Infection Control in health care and congregate settings



Swaziland National Tuberculosis
Control Programme

JANUARY 2012



SWAZIS AND AMERICANS
IN PARTNERSHIP TO FIGHT HIV/AIDS

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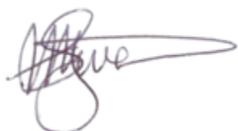
FOREWORD

Swaziland is burdened with the world's highest prevalence of HIV and one of the world's highest rates of Tuberculosis. On average, there is a 78% chance of an HIV infected person developing active Tuberculosis from a previously latent infection. Global evidence has shown that this can be prevented by prophylactic Isoniazid therapy. However, prior to starting preventive therapy with Isoniazid, patients should be screened for active tuberculosis.

Swaziland's team, comprised of the Swaziland National AIDS program (SNAP), Swaziland National Tuberculosis Control Program (SNTCP) and Development Partners, have over the last four years gathered evidence supporting the implementation of Tuberculosis Screening and Isoniazid Preventive Therapy for people living with HIV & AIDS (PLWHA). In addition to these evidence-supported measures, infection control practice must be followed consistently to stop the spread of Tuberculosis. These three countermeasures - Intensive Case Finding using the screening tool, Isoniazid Preventive Therapy, and Infection control - comprise the "Three I's" of tuberculosis control. The Ministry of Health is glad to produce these guidelines for the "Three I's" that will serve as guidance for all healthcare workers involved in the delivery of care to PLWHA. We would like to congratulate the team.

The Ministry is keen to ensure the delivery of quality, evidence based healthcare to all Swazis and recommend this document be used by all healthcare workers.

These guidelines supercede any previous guidance on the subject of Intensified Case Finding (ICF), Isoniazid Preventive Therapy (IPT). They make reference to the National Guidelines on TB Infection Control.



Dr Simon Mfanzile Zwane
Director Clinical Services
Ministry of Health

APPENDIX 3: INFECTION CONTROL RISK ASSESSMENT TOOL

INFECTION CONTROL RISK ASSESSMENT TOOL				
		Likelihood of event occurring. 0= not likely, 1=remotely possible, 2=likely, 3= highly likely	Total = a+b	Assessment 4-6=Very high risk; 2-3= High risk; 1= Low risk; 0=No risk
DATE: ____/____/____	Risk for TB in the setting (0=negligible, 1=Low, 2=High, 3= Very High)			
Exposure of HCW to a potentially infectious TB case				
Exposure of other patients to a potentially infectious TB case				
Inadequacy of ventilation				
Duration of exposure to a potentially infectious case				
Exposure of a person living with HIV (PLHIV) to a potentially infectious TB case				
Contamination of the environment with infectious material from a TB case				
Generation of infectious aerosol containing <i>M. tuberculosis</i>				
Accumulation of potentially hazardous infectious waste material				

Supervision and Monitoring	Availability of supervising, mentoring and support for health care workers			
Data Management	IPT log book available at the clinic			
	Clinic staff trained in data collection and reporting of IPT indicators (M&E monthly report)			
	Recommendations and list of points that still need to be implemented:			

ACKNOWLEDGEMENTS

The development of these guidelines would not have been made possible without the dedication of the team comprised of the Swaziland National AIDS Program, the Swaziland National Tuberculosis Control Program and the Development partners under the umbrella of Swaziland National TB/HIV Coordinating Committee.

We would like to thank in particular the Chairs of the Committee: Dr Velephi Okello (SNAP), Mr Themba Dlamini (SNTCP), the chair of the guideline development committee Dr Samson Haumba (URC).

In addition, we would like to thank the members of the writing team:

Dr Sithembile Dlamini- Nqeketo (SNAP), Dr Charles Azih (SNAP), Dr Hloniphile Mabuza (SNAP), Dr Marianne Calnan (SNAP), Mrs Gugu Mchunu (SNTCP), Mrs Sphiwe Ngwenya (SNTCP), Mrs Lindiwe Mdluli (SNTCP), Dr Yohannes Ghebrenegus (URC), Mr Garrett Young (CHAI), Mr Samuel Porter (CHAI), Ms Thamsanqa Mavuso, Mr Kidwell Matshotyana (MSH), Dr Piluca Ustero (Baylor COE), Dr Canaan Mamvura (GSH), Dr Natalia Tamayo (MSF) Dr Hayk Karakozian (MSF), Dr Peter Ehrenkranz (PEPFAR) and Dr Peter Preko (PEPFAR).

We would also like to thank the consultant, Dr Eunice Nyesigire who assisted with the editing and putting together of the document.

The effort and dedication put into developing these guidelines is highly appreciated.

ABBREVIATIONS AND ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral (drug)
ATT	Anti Tuberculosis Treatment
CDC	Centers for Disease Control and Prevention
CPT	Co-trimoxazole Preventive Therapy
HIV	Human Immunodeficiency Virus
ICF	Intensified Case-Finding
INH	Isonicotinic acid hydrazide (isoniazid)
IPT	Isoniazid Preventive Therapy
LTBI	Latent Tuberculosis Infection
MDR	Multi-Drug-Resistant TB, (resistant to at least isoniazid and rifampicin)
M&E	Monitoring and Evaluation
NTCP	National Tuberculosis Control Program
PEPFAR	US President's Emergency Plan for AIDS Relief
PLWHA	People Living With HIV & AIDS
SNAP	Swaziland National AIDS Program
TB	Tuberculosis
TST	Tuberculin Skin Test
URC	University Research Co.,LLC

APPENDIX 2: ACCREDITATION TOOL FOR HEALTH-CARE SETTINGS THAT WILL OFFER ISONIAZID PREVENTIVE THERAPY

Date of Assessment:				
Facility Name:				
		Yes	No	Comments
General services	HIV counseling and testing?			
	Pre ART and ART services			
	Existing filing system			
	Capacity for patients follow up and adherence counseling			
HIV/TB Care	Existing default tracing system			
	Cough triage at waiting areas			
	Access to microscopy or other TB diagnostic tools			
	Effective TB screening for active TB before initiating TB preventive therapy (ICF)			
Dissemination of guidelines	IPT Guidelines available at the facility			
	Job Aids in consultation rooms (Algorithm for TB screening and dosing schedule for adults and children)			
	IEC material for patient education available at the facility			
Training of Health care providers	Trained Health workers on IPT (to fill the check list of trained staff for details)			
	On site training done (Comments: date and who did the training)			
Drug supply chain	Existing ARV supply and storage system			
	Staff trained in ordering system and reporting to CMS / Mother facility			
	Start stock of INH and pyridoxine (vitamin B6) available at the clinic			

APPENDICES

APPENDIX 1A: TB SYMPTOM SCREENING TOOL FOR ADULTS

TB Screening						
Facility name: _____						
Patient Data	Question 1	Question 2	Question 3	Question 4	Question 5	000002 Serial Number
Date / /	Cough of any duration?	Fever for 2 weeks or more?	Night sweats for 2 weeks or more?	Weight loss in the last 4 weeks?	Any Chest pain?	
Identifier	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Age	a) If Yes to one or more of the 5 questions, investigate further for TB (Sputum for smear microscopy or refer to the Doctor for CXR) b) If No to all questions, repeat screening at next visit (in 1 month time) c) Record patient's weight at every visit					
Sex M F						
Weight (in Kgs)						
ACTION TAKEN →	Sputum ordered <input type="checkbox"/>	Result:.....	Referred to Doctor for CXR <input type="checkbox"/>	Result:.....		

APPENDIX 1B: TB SYMPTOM SCREENING TOOL FOR CHILDREN

TB Screening						
Facility name: _____						
Patient Data	Question 1	Question 2	Question 3	Question 4	Question 5	000002 Serial Number
Date / /	History of TB contact?	Cough of any duration?	Night sweats for 2 weeks or more?	Failure to gain weight or Failure to thrive?	Fever for 2 weeks or more?	
Identifier	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Age	a) If Yes to one or more of the 5 questions, investigate further for TB (Sputum for smear microscopy or refer to the Doctor for CXR) b) If No to all questions, repeat screening at next visit (in 1 month time) c) Record patient's weight at every visit					
Sex M F						
Weight (in Kgs)						
ACTION TAKEN →	Sputum ordered <input type="checkbox"/>	Result:.....	Referred to Doctor for CXR <input type="checkbox"/>	Result:.....		

USAID

United States Agency for International Development

WHO

World Health Organization

XDR

Extensively Drug-Resistant TB

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Figure 7: Log Book

IPT N ^o	Date	T/I	Pre -ART or ART N ^o	Name & Surname	Sex M/F	Age	IHN start date	INH completion date	Outcome	Reason for interruption	Comments

<p><u>Treatment outcomes</u></p> <ul style="list-style-type: none"> ➤ Completed ➤ Failed ➤ Defaulted ➤ Died ➤ IPT discontinued at Health Facility 	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 5px;">COMPLETED</td> <td style="width: 50%; padding: 5px;">INTERRUPTED</td> </tr> <tr> <td> </td> <td> </td> </tr> </table>	COMPLETED	INTERRUPTED			<p><u>Reason for interruption</u></p> <ul style="list-style-type: none"> Active TB Lost to follow up Side effect Poor adherence
COMPLETED	INTERRUPTED					

5.5 REPORTING FORM

IPT reporting will be done on a 3 monthly basis using the IPT reporting form.

Figure 8: Reporting Form

IPT SITE	Cumulative total # of patients put on IPT	Total # of persons currently taking IPT	Total # of new persons started on IPT	Total # of new persons Transferred in on IPT	Total # of new persons Transferred out on IPT	Total # of persons completed full IPT	Total # of persons discontinued on IPT	Total # of persons defaulted treatment	Total # of patients having major side effects	Total # of IPT Failures (developed active TB)	Total # of deaths receiving IPT

- Proportion of health-care workers employed in facilities providing care for people living with HIV, who developed TB during the reporting period

5.3 PATIENT AND FILE CARD

Every patient will have the section in their chronic care cards completed once initiate INH. The file card (see figure 6) will be filled once the patient initiated on INH therapy and at every subsequent visit. For those facilities that have the electronic patient information system, the data entry must reflect the INH start date and the clinic visits updated to reflect the INH refill date.

Figure 6: Filecard

IPT PATIENT TREATMENT CARD			
PATIENT INFORMATION:			
Name			
Surname			
Date of Birth:	Age:		
Gender	M	F	
Region			
Facility Name			
Physical Address			
Telephone Number	Cell phone		
	Home		
	Work		
	Next of Kin		
Initial Weight		Kg	
Pregnant	YES	NO	
HIV Sero Status	R	NR	
EXCLUSION CRITERIA AT BASELINE			
Active Hepatitis (Acute or Chronic)	Y	N	
Excessive Alcohol Consumption	Y	N	
Current diagnosed TB	Y	N	
Peripheral neuropathy > grade 2	Y	N	
MONITORING (6 months)			
Date IPT Started:			Date IPT Completed:
	Month	Date	Side Effects
			TB Symptoms
			wt
1			Y N Y N
2			Y N Y N
3			Y N Y N
4			Y N Y N
5			Y N Y N
6			N Y N
7			Y N Y N
8			Y N Y N
9			Y N Y N
List side effects			
IPT OUTCOME			
Completed			
Defaulted			
Failed (developed TB)			
Died			
Transferred Out			
Treatment Discontinued			
REASON FOR IPT DISCONTINUATION			
Side effects			
TB Disease			
Other Reasons			

5.4 LOG BOOK

At every facility, all patients who start on IPT will be recorded in a logbook (see figure 7). At initiation of the INH, the columns from IPT No to INH start date should be populated and when the patient stops/ interrupts or completes treatment, the last 4 columns must be completed.

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CHAPTER 5. MONITORING AND EVALUATION OF THE THREE I'S

Monitoring and evaluation serves to provide the means to assess the quality, effectiveness, coverage and delivery of services. It also promotes a learning culture within programs to ensure continual health improvement. The major challenge is to ensure that patients are screened at every contact with a health facility and that patients receive optimal care. More to the challenge is to ensure that data are collected to determine whether this is the case and that corrective measures are implemented if it is not.

5.1.1 CASE REGISTRATION

A case "on IPT" is a patient who has accepted IPT and has received a dose of at least one month of isoniazid.

5.1.2 CASE OUTCOMES

Defaulted: If patient has taken INH for one or more months, then interrupted for 60 days or more

Completed: A person who received a full course INH (6 months/180 doses) in a period of 6-9 months

Died: A person on IPT who is reported to have died of any cause during the course of treatment (based on information gathered and recorded by a responsible health worker)

Failed: If a person while on IPT develops Active TB disease

Transferred out: A person who has been transferred to another ART Site or region to continue treatment

Treatment Discontinued: A person for whom the IPT has been discontinued by a health care worker due to adverse effects or any other reason

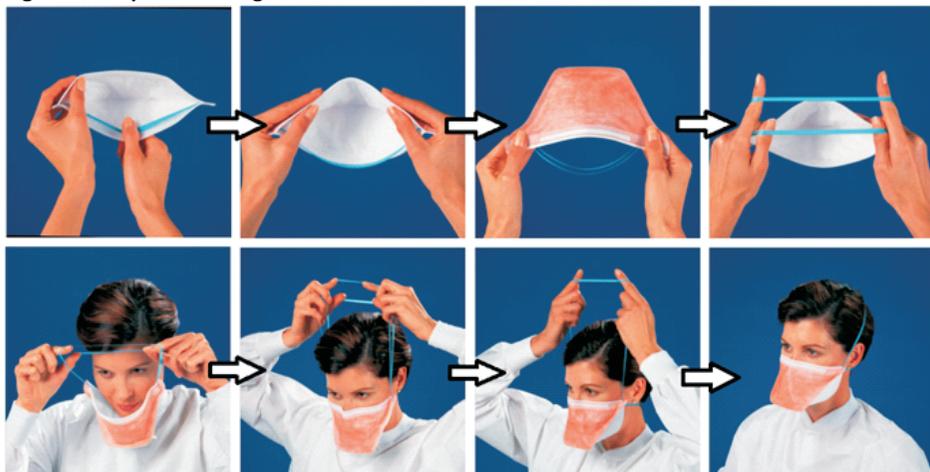
5.2 INDICATORS

- Percentage of HIV + patients who were screened for TB in HIV care or treatment settings
- Percentage of children exposed to TB contact screened for TB
- Percentage of people at high risk such as prisoners and miners screened for TB
- Percentage of HIV + patients who received TB treatment
- Percentage of estimated HIV + incident TB cases that received treatment for TB and HIV
- Percentage of new HIV + patients starting IPT during the reporting period
- Poportion of health-care facilities providing services for people living with HIV that have infection control practices that include TB control

4. 3 PERSONAL RESPIRATORY PROTECTION

- TB patients with explosive cough should wear a surgical mask when being transferred to other health care setting areas.
- N95 masks should be used by health workers supervising a cough-inducing procedure e.g. bronchoscopy or sputum induction for specimen collection.
- Respirators should be properly fitted. See diagram below for proper fitting methods.

Figure 5: Respirator fitting



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1.1 THE TB AND HIV LANDSCAPE AND RESPONSE IN SWAZILAND

Swaziland, with a national population of 1.1 million, has the highest prevalence of HIV in the world at 26% among people aged 15 to 49 years [1] and a high HIV incidence rate of 3% [2]. TB incidence in the country has also increased 6 fold over the last 20 years, making Swaziland the country with the highest TB incidence rate in the world at 1,257 cases per 100,000 population [3]. The government recently declared TB a national emergency, having declared HIV an emergency about one decade previously.

The high prevalence of HIV demands urgent action against TB because HIV increases the risk for both reactivation of latent M. tuberculosis infection (LTBI) and progression to active TB following new infection. HIV is the strongest risk factor for developing tuberculosis (TB) disease in those with latent or new Mycobacterium tuberculosis infection.

In response to the dual epidemics of HIV and TB, Swaziland is implementing a National Multi sectorial Strategic Framework (NMSF: 2009-2014) for HIV and AIDS to expand HIV and TB interventions. In addition, through the TB/HIV National Coordination Committee (TB/HIV NCC) formed in 2007 by SNAP, NTCP and the health sector development partners, the country is implementing the 12 Swaziland Collaborative TB/HIV activities adopted from the WHO recommendations (Table 1). The section relevant to these guidelines is shaded.

Since a major goal of the National Multi sectorial Strategic Framework for HIV and AIDS is to improve the diagnosis and management of TB/HIV co-infection among patients, one of its nine core strategies is to strengthen active and passive TB case detection, whereby all individuals who test positive for HIV or TB or both should be linked to treatment, care and support. Management centers include the HIV treatment centers, TB clinics and prisons health facilities.

At these facilities, it is paramount to provide detection, treatment, and prevention services to control the national TB emergency. Three key interventions addressing each of these fronts comprise the "Three I's" of TB Control:

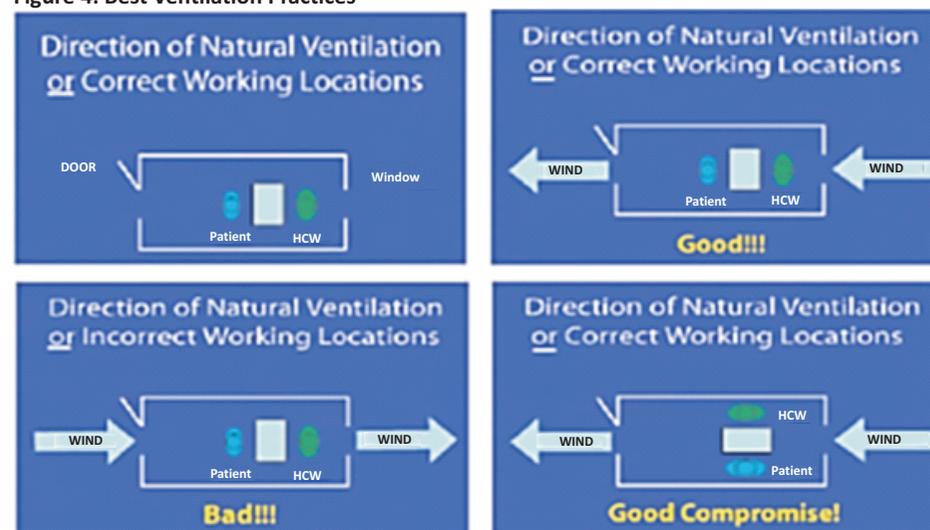
1. Intensified Case Finding
2. Isoniazid Preventive Therapy; and
3. Infection Control

In general, the number of visitors per patient at one time should be restricted to two. All visitors, relations, or lodgers are to carry out hand hygiene before and after the visit. Children should not be allowed in, unless given special permission by the nurse in charge. Adequate N95 respirators should be provided to those visiting an infectious case, or the patient should be provided with a surgical mask that should be worn for the duration of the visit.

4.2 ENVIRONMENTAL CONTROLS TO REDUCE TB TRANSMISSION

- Ensure all windows are open for the duration of the working day.
- All TB wards and clinics should be well lit, because sunlight has a sterilizing effect on mycobacterium tuberculosis.
- Where possible, ceiling extractor fans should be installed in wards, out-patient consultation, and waiting areas in health centers that admit TB patients.
- Wards and TB clinics should be well ventilated and exposed to as much sunlight as possible. See the diagram below for proper ventilation methods and seating arrangement in consultation rooms. If possible the HCW should be positioned such that the natural airflow carries the patients' exhalations away from him/her.

Figure 4: Best Ventilation Practices



Important managerial measures include:

- Convening an infection control committee (or strengthening, refocusing and coordinating existing ones, which are often focused on different diseases or topics, such as surgical infections or hepatitis prevention).
- Conducting annual assessments of the risk of transmission in the facility.
- Developing an IPC plan that details in writing the measures that should be taken in a given facility.
- Providing adequate training of HCWs to implement the plan.
- Assigning one individual to be responsible and to be given sufficient authority and resources for monitoring the implementation of the IPC plan.
- Admitted smear-positive TB patients should be isolated from other non-TB patients until they are expected to have become non-infectious, usually two weeks after the commencement of treatment.

4.1.2 Patient Isolation and Separation Measures

- Ideally, patients infected with TB should be isolated from all other patients in a well-ventilated room.
- A second, less satisfactory but practical solution is to separate rather than isolate patients.
- If airborne precaution rooms are not available, the patient should be placed in a single room that is well ventilated.
If individual rooms are not available, it is preferable to identify two separate wards.
- In health facilities with only one ward available, a separate compartment within the ward can be established for patients with TB, preferably in a better-ventilated portion of the ward. There should be a special area where bedridden patients can collect sputum. The room should ideally have plastic curtains.
- In ongregate settings such as prisons, people suspected or known to have infectious TB (including MDR-TB) should always be separated and, if possible, isolated in an adequately ventilated area, until sputum smear conversion.
- Ambulatory patients should use an outside sputum collection area.

All of these interventions are based on evidence. In 2008, the TB/HIV NCC commissioned an operational research project to validate a TB screening tool which was then piloted at a national level in 2009-2010 among PLWHA. The TB/HIV NCC also commissioned a pilot on feasibility and safety of Isoniazid Preventive Therapy, conducted from 2009-2011. Based on the evidence from these commissioned studies, further recommendations from the WHO [4], and information on best infection control practices, the Ministry of Health has developed the "Three I's" Guidelines to support the scale up of TB/HIV control interventions.

Table 1: Recommended collaborative TB/HIV activities [5,6]

Establish mechanisms for collaboration	
<ul style="list-style-type: none"> • Set up a coordination body for TB/HIV activities • Conduct surveillance of HIV prevalence among TB patients • Carry out joint TB/HIV planning • Conduct monitoring and evaluation. 	Jointly by SNAP, NTCP and partners
Reduce the burden of TB in people living with HIV: the "Three I's"	
Establish Intensified case-finding: TB screening and diagnosis	SNAP and Partners
Introduce Isoniazid preventive therapy	
Ensure TB infection control in health care and congregate settings	
Reduce the burden of HIV in people living with TB	
<ul style="list-style-type: none"> • Provide HIV testing and counseling • Introduce HIV prevention methods • Introduce co-trimoxazole preventive therapy • Ensure HIV care and support • Introduce antiretroviral therapy. 	NTCP and Partners

1.2 THE THREE I'S

Pilot studies in Swaziland and international protocol recommend the adoption of the "Three I's" as a critical interventions to reduce the burden of TB among PLWHA.

Intensified case finding (ICF) actively identifies those who have contracted or are at risk of contracting TB disease. ICF among populations at risk of TB helps to urgently and promptly identify cases of active TB so that such cases are evaluated for treatment. ICF in high HIV and TB prevalence settings will also help quickly identify cases with latent TB to maximize interventions that prevent progression to active TB.

A TB symptom screening tool (Appendix 1) was piloted in Swaziland with the following aims:

1. To assess the feasibility of the application of the screening tool in HIV health care settings in Swaziland
2. To validate that the tool is sensitive enough to consistently detect TB disease among PLWHA
3. To demonstrate the ease of administration of the tool by lay health care workers.

The tool was administered to a sample of nearly 4000 PLWHA attending HIV clinics in three pilot sites. Over 19.6% of the patients screening positive on the tool were confirmed by sputum culture as true cases on tuberculosis. The study provided evidence that the TB screening tool was easy to administer, feasible, and sensitive to TB. It is recommended for use to exclude active TB.

Isoniazid Preventive Therapy (IPT) is a course of prophylactic antibiotics (Isoniazid) to prevent the progression from latent TB to active TB. Although IPT is a therapy for individuals, it is important as a preventive measure for communities affected by HIV. Preventing active TB in one individual can prevent thousands of people from being infected in the community and in health care services.

A pilot study of IPT implementation was undertaken in the Lubombo region, Shiselweni region and Baylor Clinic. Both Pre-ART and ART patients were included in the pilot. The pilot study demonstrated that IPT is feasible and safe and suggests that a nationwide implementation of IPT will benefit all PLWHA at risk of developing active TB.

Infection Control (IC) is the establishment of administrative and environmental measures to prevent the spread of TB in health facilities and congregate settings. The country's approach is an adaptation of the WHO 2010 guidelines for prevention and control of Tuberculosis infection in Health care, congregate and community settings. A task team conducted a review of the related literature and evidence, the existing National IC Policy and guidelines as well as the generic guidance from WHO, CDC and other partners. This was followed by setting priorities for infection control for the country, development of key context-specific IC policy objectives and relevant interventions. The guidelines were reviewed by a larger group of stakeholders and shared for peer review before undergoing final validation and approval by the Ministry of Health.

In line with the above evidence, and the WHO guidelines on Intensified Case Finding and Isoniazid Preventive Therapy of 2011, these new guidelines recommend the use of a simplified screening algorithm that relies on five clinical symptoms to identify those eligible for either IPT or further diagnostic work-up for TB. (see figure 2 & 3). Additionally, the guidelines recommend ongoing implementation and monitoring of TB infection control in accordance with recommendations from the WHO.

CHAPTER 4. INFECTION CONTROL

Three levels of infection control measures are recognized in these guidelines for implementation in health care settings, congregate settings, and households depending on the circumstances. These are:

- Administrative.
- Environmental.
- Personal respiratory protection.

Administrative controls should be considered most important because environmental controls and personal protective equipment will not work in the absence of reliable administrative control measures. For full details on all control procedures, please refer to the National TB Infection Control Guidelines.

4.1 ADMINISTRATIVE INFECTION CONTROL

Important administrative controls include:

- Prompt identification of people with TB symptoms.
- Prompt diagnosis and timely treatment of TB patients (use rapid diagnostic methods where available, and use appropriate diagnostic algorithms). High priority should be given to triage patients coughing or showing any other signs of TB infection in the waiting areas.
- Measures to reduce turnaround time for sputum testing and culture (as much as possible, carry out clinical laboratory investigations in parallel rather than in sequence).
- Prompt separation or isolation of infectious TB patients.
- Education on hygiene and cough etiquette.
- Minimization of patient's time in the facility.
- Provision of high-quality clinical care to infectious patients and minimization of time spent with such patients in areas that are overcrowded or poorly ventilated.
- Use of clear and simple rules to govern visitors' contact with infectious TB cases (at given time, in open spaces, etc.).
- HIV/AIDS patients should not be admitted to TB wards, until the diagnosis of TB has been confirmed and treatment has been initiated.
- Health workers who are HIV positive should not work in TB wards.
- Health workers should be screened annually for TB (either by the ICF tool or chest x-ray), and should be investigated if any symptoms suggestive of TB develop.

3.8.6 QUALITY ASSURANCE FOR ISONIAZID PREVENTIVE THERAPY SERVICES

Delivery of IPT in both public and health sector should be guided by quality standards. Thus facilities planning to offer IPT should be accredited before initiating services and thereafter required to maintain the accreditation status. (See accreditation tool in appendix2)

It is recommended that Adults and adolescents living with HIV should be screened for TB with a clinical algorithm and those who do not report any one of the symptoms of **current cough, fever, weight loss or night sweats** are unlikely to have active TB and should be offered IPT.

And that Children living with HIV who have any one of the symptoms of **poor weight gain/ failure to thrive, fever, lethargy or decreased playfulness, current cough or contact history with a TB case** may have TB and should be screened for TB using a clinical algorithm. Children should be initiated on IPT if the evaluation is negative for TB.

1.3 GOALS AND OBJECTIVES OF THE "THREE I'S" POLICY AND GUIDELINES

The purpose of the ICF/IPT/IC policy guidelines is to provide a consistent framework for implementers to use in expanding and providing ICF/IPT/IC services to eligible adults and children. The policy and guidelines for ICF promote early diagnosis and treatment, increase number of TB cases detected, increase number of TB cases on treatment and increase number of TB cases cured. While maximum benefit is for those at risk of developing a new TB infection, developing a TB re-infection, or developing active TB from latent TB, contacts of people living with HIV, people living in congregate settings e.g. prisons, mines and the community also benefit. The success of ICF requires a strong collaboration between SNAP and NTCP, particularly in the development, implementation and monitoring & evaluation of protocols and activities.

The goal for IPT is to prevent patients who screen negative for active TB from developing TB. Such Patients are initiated on Isoniazid preventive therapy (IPT), a 6 month course of medication that accomplishes three goals:

- (1) decreasing the risk of occurrence of new TB infection
- (2) decreasing the risk of occurrence of re-infection among patients who have had TB in the past
- (3) decreasing the risk of latent TB progressing to active TB

The goal of infection control (IC) in health facilities and congregate settings is to ensure the safety of health care workers and patients in facilities that treat Tuberculosis. In order to stop the spread of *Mycobacterium tuberculosis*, facilities must put into practice administrative, managerial, environmental, and personal protection respiratory controls. These guidelines establish a general framework for establishing these controls.

These guidelines supercede any previous guidance on IPT in the national comprehensive

package of care (2010) and pediatric HIV/AIDS Treatment guidelines (2011). Laboratory monitoring is not a prerequisite for initiating patients on IPT. However, close clinical monitoring of signs and symptoms is important as is documentation on adverse events. Where indicated, laboratory tests can be done for patients with previous liver disease or

1.4 BARRIERS AND CHALLENGES TO THE THREE I'S

The major barrier to ICF has been lack of a sensitive, easy to use symptom screening algorithm. Furthermore, most health units have a high patient load with disproportionately few health workers rendering them unable to incorporate the activity into their routine.

Lack of IPT implementation was driven by concerns about the challenges of ensuring treatment completion and excluding active TB. While many claim that it is too hard to rule out active TB among HIV+ persons, it is believed that intensified case finding and the new WHO diagnostic algorithm for smear-negative and extrapulmonary TB will be able to consistently identify these cases. Another concern is that if active TB is not excluded, IPT may lead to INH resistance. In fact, studies have shown no statistically significant increased risk of developing INH resistant TB among those who were taking INH [14,15]. Furthermore, regular screening for those taking IPT will help identify early those who could develop TB. Early identification leads to prompt diagnosis and treatment which should help to prevent the development of drug-resistant TB.

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

On the question of safety, some concerns were raised with regards to IPT. It has been claimed that IPT is too toxic for HIV-positive patients and has greater toxicity when they are on ART. However, the literature indicates that IPT is far less toxic [16,17] than HRZE and has far fewer interactions with ART than Rifampicin. In addition to being rare, IPT toxicity can be successfully managed. Others argue itself is enough to reduce TB incidence. However, IPT and ART are synergistic in reducing TB incidence among people with HIV taking both [18].

3.8. INSTITUTIONAL RESPONSIBILITIES

3.8.1 CENTRAL LEVEL

The provision of INH in the country will be the responsibility of Central Medical Stores (CMS) in conjunction with SNAP and NTCP. The CMS will coordinate procurement and distribution alongside distribution of cotrimoxazole and ART.

SNAP will be responsible for projections of patients to be initiated on IPT. SNAP, NTCP and CMS will be responsible for projection of IPT needs in the country. An IPT implementation sub team responsible for projection for INH needs and the roll out and monitoring of implementation will be formed from SNAP, NTCP and implementing partners.

3.8.2 OVER SIGHT AND COORDINATION

The expansion of public IPT provision will be guided by the TB/HIV NCC and TB/HIV-IPT/ICF sub-committee. The national oversight for IPT implementation will be the responsibility of SNAP.

3.8.3 REGIONAL LEVEL COORDINATION

The regional TB/HIV coordination committees will be responsible for monitoring and harmonizing implementation of IPT and other HIV and care interventions at regional level. The regional TB coordinators, the regional AIDS coordinators and the regional focal persons for TB and HIV will address IPT issues in program implementation.

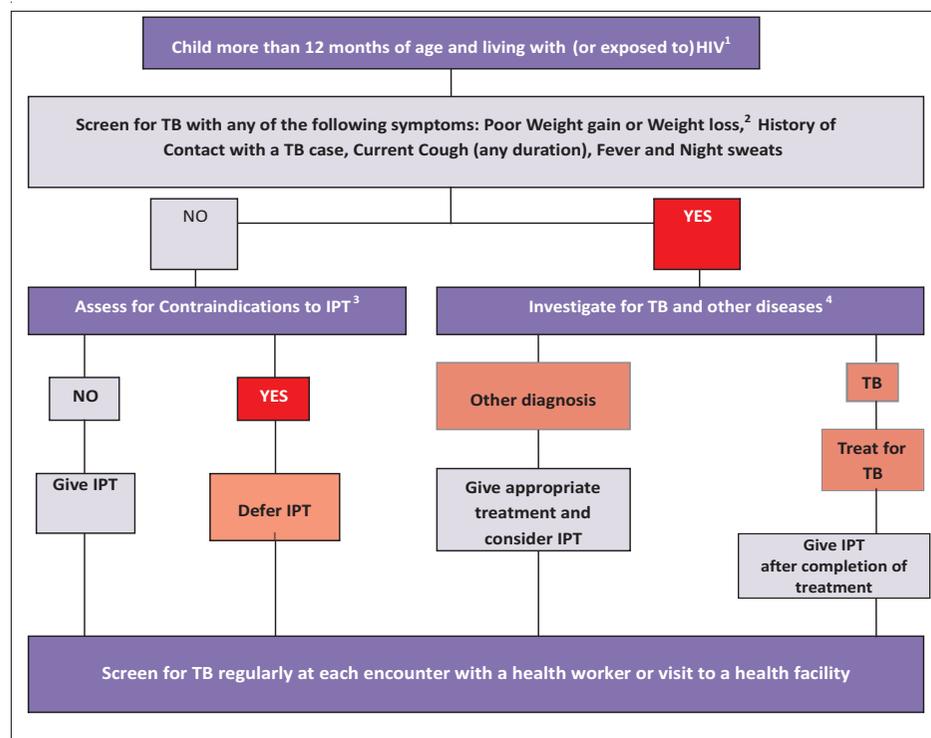
3.8.4 HEALTH FACILITIES COORDINATION

IPT service delivery at facility level will be the responsibility of the facility team. A multi disciplinary team consisting of health workers in the ART clinic, TB clinic, laboratory and pharmacy will be responsible for IPT implementation.

3.8.5 EXPANSION OF ISONIAZID PREVENTIVE THERAPY SERVICE

The expansion of IPT services will be built on the existing implementation arrangements starting with the sites already implementing, and scaled up as per the roll out plan.

Figure 3: Algorithm for TB screening in children more than one year of age and living with HIV



Footnotes to algorithm for children

1. All children and infants less than one year of age should be provided with IPT if they have a history of household contact with a TB case and active TB is ruled out.
2. 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.
3. Contraindications include: active hepatitis (acute or chronic) and symptoms of peripheral neuropathy. Past history of TB should not be a contraindication for starting IPT. Although not a requirement for initiating IPT, TST may be done as a part of eligibility screening in some settings.
4. Investigations for TB must be done in accordance with existing national guidelines (National TB Control Guidelines, 2006).

CHAPTER 2. INTENSIFIED CASE FINDING IMPLEMENTATION STRATEGY

2.1 INTENSIFIED CASE FINDING RECOMMENDATIONS

ICF in Swaziland is recommended for all people living with HIV to rule out new TB infection, re-infection and those with latent TB at risk of progression to TB disease. It is also recommended for contacts of PLWHA who have active TB disease. These are the priority groups. The other groups include people living in congregate centers like prisons and mines, people from any general population with known high TB prevalence, and people of unknown HIV status.

Table 2: Patients Recommended for TB Screening

Recommended for TB Screening				
All people living with HIV	Contacts of TB-infected PLWHA	People living in congregate centers	People in a High-TB-Prevalence area	People of unknown HIV status

2.2 ENTRY POINTS FOR INTENSIFIED CASE FINDING

All entry points in the health facilities should screen patients for TB. However, HIV treatment and care centers are priority entry points for TB screening. TB screening services should be arranged in such a manner that the screening will be conducted each time a patient comes in contact with the health facility.

2.3 ELIGIBILITY FOR INTENSIFIED CASE FINDING

2.3.1 ELIGIBILITY

All patients are eligible for TB screening, but may only be screened passively. ICF is intended to detect TB cases among people living with HIV as early as possible.

For adults and adolescents, the following symptoms can be used to screen for TB:

- **Current cough (Any duration)**
- **Weight loss**
- **Night sweats**
- **Fever**
- **Chest pain**

Any one of these symptoms is sufficient to return a positive TB screen. Refer to Figure 1 below (after section 4) for a complete algorithm.

Adults and adolescents living with HIV should be screened for TB with a clinical algorithm and those who do not report any of the symptoms of **current cough, fever, weight loss, or night sweats** are unlikely to have active TB and should be offered IPT.

Adults and adolescents living with HIV and screened with a clinical algorithm for TB who report any of the symptoms of **current cough, fever, weight loss, or night sweats** may have active TB and should be evaluated for TB and other diseases.

Any one of these symptoms is sufficient to return a positive TB screen. Refer to Figure 1 below (after section 4) for a complete algorithm

For **children more than 12 months of age and living with (or exposed to) HIV**, the following symptoms can be used to screen for TB:

- **Poor weight gain or weight loss**
- **Current cough (any duration)**
- **Night sweats**
- **Fever**
- **Contact history with a TB case.**

Children living with HIV who **do not have** poor weight gain, fever or current cough are **unlikely to have active TB**.

Children living with HIV **who have** any one of the symptoms of poor weight gain, fever, current cough or contact history with a TB case **may have TB** and should be evaluated for TB and other conditions.

If the evaluation shows no TB, such children should be offered IPT regardless of their age.

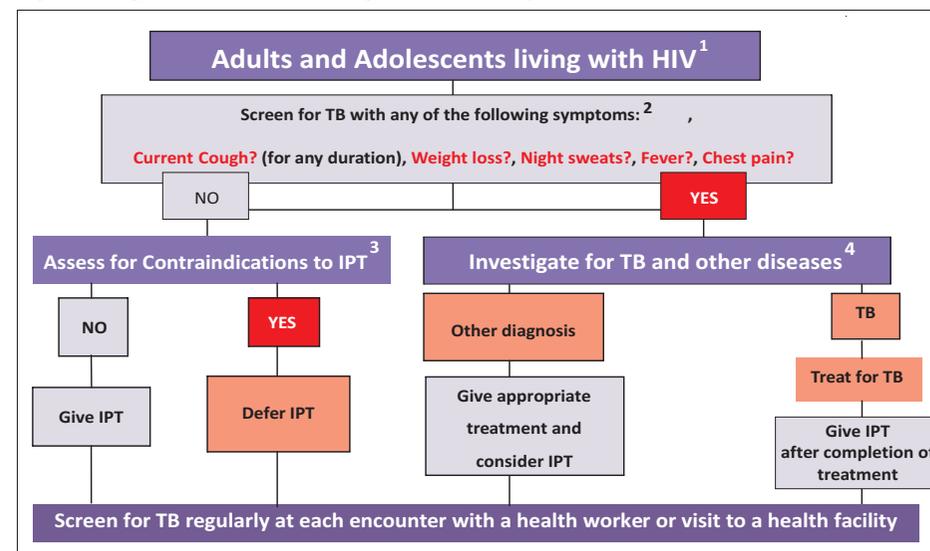
Any one of these symptoms is sufficient for a positive TB screen. Refer to Figure 2 below (after section 4) for a complete algorithm.

Note: Children less than 12 months should only be screened if there is a TB contact.

- If interruption is less than 60 days complete the course.
- If interruption is more than 60 days restart the therapy after ensuring that obstacles to adherence have been addressed.

If interruption is due to drug toxicity, manage toxicity as suggested in table 3 above and restart therapy when toxicity has resolved.

Figure 2: Algorithm for TB Screening and IPT Prescription for Adults & Adolescents



Footnotes to the algorithm for adults and adolescents

1. Every adult and adolescent should be evaluated for eligibility to receive ART at every visit. Wearing face masks and hand washing should be emphasized to reduce M. tuberculosis transmission in all settings that provide care.
2. Chest radiography can be done if available, but is not required to classify patients into TB and non-TB groups. In high HIV prevalence settings with a high TB prevalence among people living with HIV (e.g. greater than 10%), strong consideration must be given to adding other sensitive investigations.
3. Contraindications for IPT include: active hepatitis (acute or chronic), regular and heavy alcohol consumption, and symptoms of peripheral neuropathy. Past history of TB and current pregnancy should not be contraindications for starting IPT.
4. Investigations for TB should be done in accordance with existing national guidelines (National TB Control Guidelines, 2006).

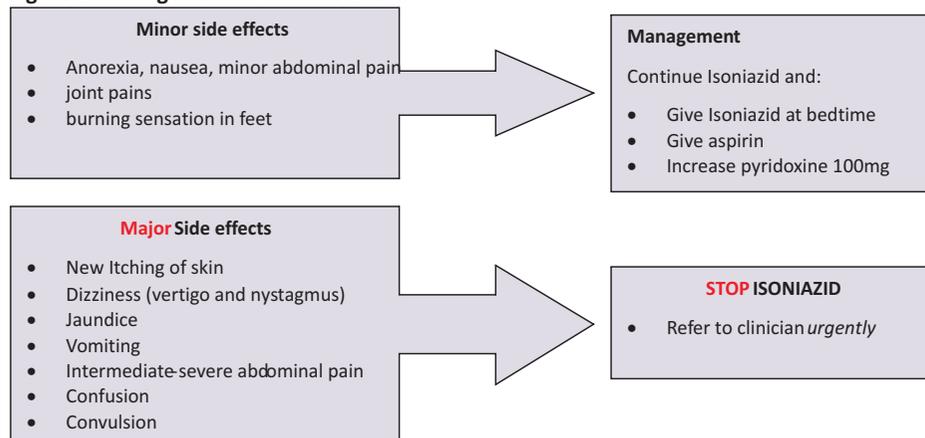
3.5.3 MANAGEMENT OF SIDE EFFECTS

In case of peripheral neuropathy of grade 2 or less: prescribe 100 mg pyridoxine (vitamin B6) daily until IPT is completed. Patients with a neuropathy of grade 3 or more should not be given INH and referred for further assessment. Neuropathy should be assessed at every visit.

If the patient develops signs and symptoms suggestive of hepatitis (nausea, vomiting, jaundice), stop INH preventive therapy immediately and refer to a medical officer.

If the patient develops active TB, stop the preventive therapy, start the full TB treatment regimen and do culture and drug sensitivity.

Figure 1: Management of IPT Side Effects



3.6 THE ISONIAZID PREVENTIVE THERAPY CYCLE

Patients who have completed a course of IPT should repeat the course every two years after TB screening based on the algorithm for adults and children.

6 months of IPT is repeated every two years

3.7. MANAGEMENT OF TREATMENT INTERRUPTION

Patient should take one dose daily for 6 months. For those interrupting treatment, ensure completion of the 180 doses within a maximum period of 9 months.

If the patient interrupts therapy, enquire about the possible reasons for interrupting and counsel on the importance of adherence appropriately.

2.3.2 WHO CAN ADMINISTER INTENSIFIED CASE FINDING?

The TB screening tool may be administered by the following members of staff:

- Doctors
- Nurses
- Trained lay counselors or TB screening officers

2.4 POST INTENSIFIED CASE FINDING SERVICES.

These include:

- Assess patients who screened negative for TB for eligibility for IPT
- Refer those who screen positive for full evaluation for active TB
- Link those diagnosed with TB to care and management
- Ensure those co infected with TB and HIV receive both ART and anti-tuberculosis treatment

2.5 RE-SCREENING

All HIV + patients should be re-screened at every clinic visit irrespective of whether they are on ART. In each case, the post screening services should be implemented as described in section 3.4 above.

2.6 PATIENT, FAMILY AND COMMUNITY CENTERED APPROACH

Community and patient education

- Empower PLWHA to understand symptoms of TB and ask for care/screening
- Address TB stigma through: education and awareness, community and national leaders and role models, simple clear positive messages, "best care possible"

Identify interventions to reach family members (high risk group)

- Use "Think of the Family" educational/motivational approach
- Health providers should inquire whether their patients' family members have been screened for TB
- School education

2.7 TUBERCULIN SKIN TEST REQUIREMENTS

Multiple studies of people living with HIV demonstrated that IPT is associated with lower TB incidence in people with a positive TST than in those with a negative test [10]. In addition, the use of TST could reduce the number of patients receiving IPT and the numbers needed to treat to prevent one case of active TB. However, in resource-constrained settings, operational challenges to the implementation of TST are significant impediments for access to IPT. Such challenges include the costs of procuring tuberculin and administering the test, maintaining an effective supply chain, training staff in administering and accurately reading the test, and the need for the patient to attend the clinic at least twice over 48-72 hours with its associated inconvenience and cost [11]. In addition, the immunological status of the patient and the negative results in anergic patients or those with a long lapse between infection and the TST may affect its interpretation [12,13]. This means that a negative TST does not rule out TB infection. Therefore, tuberculin skin test (TST) is not a mandatory investigation before starting IPT for people living with HIV. However, in some settings where it is feasible, it can help to identify those who would benefit most from IPT.

TST is not a requirement for initiating IPT in people living with HIV in Swaziland.

People living with HIV who have a positive TST have a lower TB incidence when they take IPT compared to those with a negative TST; TST can be used where feasible to identify such individuals.

- Disuss side-effects (such as peripheral neuropathy, hepatotoxicity, etc) and support patient by problem solving ways to manage minor side effects.
- Encourage questions

3.5.2 CLINICAL MONITORING AND PATIENT FOLLOW UP

Regular IPT refills are recommended for both ART and pre-ART patients. Efforts should be made to harmonize IPT review dates with ART review dates. IPT should be harmonized as follows:

- for Pre-ART patients, at Co-trimoxazole refill appointments
- for ART patients, at ART refill appointments

NOTE: For patients who are to be initiated on ARVs within 4 weeks, delay IPT initiation until the patient has been on ARVs for at least 3 months

At every visit:

- Provide adherence support for both isoniazid and pyridoxine
- Routine laboratory monitoring as Pre-ART or ART
- Look for side effects (next page)

Table 5: Side Effects of IPT

Side Effects					
Minor	peripheral neuropathy	Nausea	rash	fever	dizziness
Major	jaundice	Vomiting	confusion due to hepatitis		

Grading of peripheral neuropathy:

Grade 1: Symptoms of tingling but no neurological deficits

Grade 2: Some sensory alteration or weakness

Grade 3: Interfering with the activities of daily living

Grade 4: Life threatening and disabling (paralysis)

Children:

In children, INH should be given at a dose of **10 mg/kg** body weight and it is required that pyridoxine be supplied with INH at a dose of **1.2 mg/kg daily**. All available data to date suggest that INH is not toxic for children, even in those receiving ART. The following table shows a simplified dosing schedule for children.

Table 4: IPT Dosing Schedule for Children

IPT Dosing for 6 months		
Weight range (Kg)	Number of 100 mg tablets of INH per dose (10 mg/kg daily max 300 mg)	Dose given (mg)
< 5	½ tablet	50
5.1 - 9.9	1 tablet	100
10 -13.9	1 ½ tablet (or ½ adult tablet)	150
14 - 19.9	2 tablets	200
20 - 24.9	2 ½ tablets	250
> 25	1 adult tablet (300 mg)	300

Pyridoxine 1-2 mg/Kg daily: children 5 to 14.9 kg: 1 tab of 10 mg or ½ tab of 25 mg.
Children > 15 Kg: 1 tab of 25 mg

3.4.3 DISPENSING

Enough medicine to last until the next visit is dispensed in the correct daily dosage to each eligible patient until a full course of 6 months is completed. This can be conveniently scheduled along with ART or with CTX for those not on ART. The first 2 prescriptions for INH should be done on a monthly basis to ensure patient is coping with the medication and thereafter, the schedule for INH should be adjusted to suit either the ARV or CTX refills.

The supply of INH, cotrimoxazole, and ART to credible facilities is the responsibility of the Central Medical Stores.

3.5 POST ELIGIBILITY COUNSELING AND PATIENT SUPPORT

3.5.1 PATIENT INFORMATION

Ensure availability of counseling and patient support services for all patients who are eligible/taking IPT

- Ensure HIV positive patients understand the benefits of IPT
- Reinforce information at each visit
- Assess adherence to therapy, as with TB treatment
- Patients should be taught to recognize signs & symptoms of active TB

CHAPTER 3. ISONIAZID PREVENTIVE THERAPY IMPLEMENTATION STRATEGY

3.1 ISONIAZID PREVENTIVE THERAPY RECOMMENDATIONS

Adults and adolescents living with HIV should receive at least six months of IPT as part of a comprehensive package of HIV care if they:

- have an unknown or positive TST status
- are unlikely to have active TB

IPT should be given to such individuals irrespective of the degree of immune suppression, and also to those on ART, those who have previously been treated for TB, and pregnant women.

Children who are more than 12 months of age and living with HIV should receive six months of IPT (10 mg/kg/day) as part of a comprehensive package of HIV prevention and care services if they:

- are unlikely to have active TB on symptom-based screening
- have no contact with a TB case

Children living with or exposed to HIV who are less than 12 months of age should receive six months of IPT (10 mg/kg/day) as part of a comprehensive package of HIV prevention and care services if they

- have a positive history of TB contact
- are unlikely to have active TB on symptom-based screening

All HIV + patients who screen negative for TB should be offered IPT.

3.2 ENTRY POINTS FOR ISONIAZID PREVENTIVE THERAPY

3.2.1 ELIGIBILITY OF ENTRY POINTS

IPT will be offered in accredited settings as per the accreditation tool (Appendix 2). Such settings include:

- HIV care and treatment centers
- PMTCT centers
- TB clinics
- Prison health facilities

3.2.2 PREREQUISITES FOR ENTRY POINTS

Eligible centers will be assessed for the presence of the following pre-requisites in whose absence the center will not be allowed to offer IPT.

- Availability of quality HIV counselling and rapid testing for HIV
- Effective TB screening for active TB before initiating TB preventive therapy
- Capacity for regular follow up and monitoring of patients to encourage adherence
- Integrated HIV and TB care in the facility
- Health Care Workers trained in IPT
- Availability of mentoring and support for health care workers

3.3 ELIGIBILITY FOR ISONIAZID PREVENTIVE THERAPY

IPT eligibility should be assessed on every visit to a health care worker and IPT should be offered on the same visit that the patient is identified as eligible.

The following groups should be initiated on IPT:

- 1). All HIV Positive patients who screened negative for TB
 - Adults
 - Children 12 months of age and above regardless of history of contact
 - Children less than 12 months with history of TB contact
 - Patients on ART for more than three months fulfilling above age criterion
 - Adults and adolescents who have completed a full course of anti-TB drugs
- 2). High risk groups for TB regardless of HIV status screened negative for TB
 - Children less than 5 years with history of TB contact
 - Individuals in institutionalized congregate settings (prisoners and miners)
 - Health care workers who are in close contact with TB patients.

Patients must consent before starting IPT.

3.3.1 SECONDARY PROPHYLAXIS

Evidence supports IPT as secondary prophylaxis for adults who have previously been successfully treated for TB. These guidelines strongly recommend that adults and adolescents living with HIV who successfully complete their TB treatment should continue receiving INH for another six months. There was no evidence on the potential role of IPT for those who had successfully completed treatment for multidrug-resistant (MDR) or extensively drug-resistant (XDR) TB and hence IPT should not be used after successful treatment for MDR or XDR TB.

All Adults and adolescents living with HIV who have successfully completed treatment for TB disease should receive INH for an additional six months.

3.3.2 CONTRA-INDICATIONS TO ISONIAZID PREVENTIVE THERAPY

- | Absolute | Relative |
|---|---|
| ➤ Active hepatitis (acute or chronic) [Elevated Liver Function Enzymes - absolute levels > 5x the normal limit (except bilirubin)]. | ➤ Patients on work up for ART initiations within the next 4 weeks (delay of IPT initiation is recommended until the patient has been on ARVs for at least 3 months) |
| ➤ Regular and Excessive alcohol consumption. | ➤ HIV negative adults except those living or working in high risk settings |
| ➤ Peripheral neuropathy grade 2 or above. | ➤ Early pregnancy |
| ➤ Patient currently on TB treatment | |

3.4 PRESCRIPTION

3.4.1 WHO CAN INITIATE ISONIAZID PREVENTIVE THERAPY

Health Care Workers who are trained to prescribe ARVs and TB drugs are eligible to prescribe/ initiate IPT including nurses and doctors.

3.4.2 DOSING

IPT intervention makes use of INH: **10 mg/kg/day (maximum 300 mg per day) for 6 months**. In addition, Pyridoxine 25mg per day is given to prevent peripheral neuropathy. Patient has to consent to IPT. Efforts should be made to ensure that IPT is completed within 6 months.

Adults and adolescents:

Isoniazid PO 10 mg/kg/ (max dose 300mg) daily for 6 months and Pyridoxine PO 25mg daily for 6 months.

Table 3: IPT Dosing Schedule for Adults

IPT Dosing for 6 months	
INH 300 mg	1 tablet
Pyridoxine 25 mg	1 tablet