USAID
FROM THE AMERICAN PEOPLE

TB CARE II

TOOLKIT FOR DELIVERY MODELS TO IMPROVE ISONIAZID PREVENTIVE THERAPY FOR CHILDREN AND PEOPLE LIVING WITH HIV

URC
UNIVERSITY RESEARCH CO., LLC

1797 Dartmouth
GEISEL SCHOOL OF MEDICINE

Table of Contents

ACKNOWLEDGEMENTS

Support for this work was provided by the TB CARE II project, which is funded by the United States Agency for International Development (USAID) under Cooperative Agreement Number AID-OAA-A-10-00021. The project's prime recipient is the University Research Co, LLC (URC), Chevy Chase, MD, USA, and the Section of Infectious Disease and International Health at the Geisel School of Medicine at Dartmouth, Hanover, NH, USA, is a sub-recipient.

This toolkit was developed as a joint project of the University Research Co. LLC (URC), Dartmouth College and The Ministry of Health of the Kingdom of Swaziland. The research supporting this toolkit was made possible by the tireless work of URC staff, staff at various HIV clinics in Swaziland and many partners, patients and participants.

The following individuals, listed in alphabetical order, were part of the writing group for this toolkit: Lisa V. Adams, Nicole Beaudoin, Stuart Grande, David de Gijsel, Hala Jassim AlMossawi, Elizabeth Talbot and Maseko Thokozani.

I. OVERVIEW

1. BACKGROUND

THE BURDEN OF MYCOBACTERIUM TUBERCILOSIS

Tuberculosis (TB) is a common, and often fatal, infectious disease caused by the bacteria Mycobacterium tuberculosis (MTB). In 2016, there were about 10.4 million new cases of TB and 1.7 million deaths globally[1]. MTB normally attacks the lungs but can also cause extrapulmonary disease. Most MTB infections remain latent and asymptomatic (i.e., latent TB infection, or LTBI); however, approximately 10% of persons with normal immune systems with LTBI will develop TB disease, which kills 50% of untreated patients[2]. LTBI is particularly dangerous in persons with weak immune systems, such as children under five or persons living with HIV (PLWH). In these populations, the risk of progression from LTBI to TB disease is much higher than 10%[2,3].

ISONIAZID PREVENTIVE THERAPY

Isoniazid Preventive Therapy (IPT) uses the single drug isoniazid (INH) to prevent progression of LTBI to TB disease. INH inhibits the synthesis of mycolic acid, a vital fatty acid needed for cell wall construction in MTB, and is one of the frontline TB treatment drugs utilized worldwide. Previous studies on IPT demonstrate effectiveness preventing initial TB infection and progression of LTBI to TB disease for PLWH as well as for young children who are TB contacts[4].

Due to the low likelihood of drug-drug interactions, low cost, and evidence supporting its effectiveness, the WHO recommends six to nine months of IPT to prevent the development of TB disease for children younger than five years, who are unlikely to have TB disease, and are close contacts to an adult with infectious sputum smear-positive TB; and for HIV-infected adults and children older than 12 months unlikely to have TB disease[5].

IPT PROGRAM IMPLEMENTATION

There is growing need for informed integration of global IPT delivery and implementation since the WHO recommendation was announced. Part of the widespread integration of IPT programs for TB prevention, numerous monitoring and evaluation projects have been undertaken in high TB-burden populations globally, such as in India and South Africa[6]. IPT initiation in child contacts has been shown to be poor in South Africa[7]. Focused efforts to launch IPT[8] and guideline availability[9] have led to increased uptake of IPT in South Africa, but total enrollment is still suboptimal at 46% of eligible patients initiated on IPT. Furthermore, these programs consistently show disappointing IPT completion rates. One recent study found that only 36% of patients took more than four of the six recommended months of INH[10] while another study found that only 12% of patients completed all six months[11].

A systematic overview of reviews that examined factors affecting IPT uptake showed consistently poor rates of IPT completion[12]. Only integration of TB and HIV services yielded high IPT completion rates in select settings, such as community-based HIV care. None of the other - even intuitive - interventions (e.g., changes in the setting/site of IPT delivery, use of quality monitoring mechanisms such as directly observed therapy (DOT) and use of lay health workers) consistently improved IPT adherence. A recent cohort study performed in Swaziland under the USAID-funded TB CARE II project[13] demonstrated that high rates of IPT adherence and treatment completion among HIV-infected adults and children can be achieved through implementation of models of self-selected IPT

delivery, coordinated with antiretroviral therapy (ART) refills. This model may improve outcomes by simplifying clinic visits and conferring agency to the patient, and may be readily implemented in similar high TB/HIV burden settings.

2. PURPOSE

The purpose of this toolkit is to assist National Tuberculosis Programs (NTPs) in the planning and implementation of the integration of IPT with their HIV services. It is meant to be a comprehensive resource aiding a context-driven, step-by-step process from planning to implementation and evaluation. Program managers can choose to use parts of the toolkit, or apply it in its entirety, depending on local expertise, feasibility, and available resources.

This document provides guidance on the various stages of the implementation process. Packaged with this document are practical tools and files, which can be adapted to a local context: training guides, a stakeholder analysis tool, patient education material, a costing tool and slide decks for various presentations.

3. AUDIENCE

This toolkit is designed for use by stakeholders at any point in the TB care continuum in high TB burden countries. This includes National TB Program staff, non-governmental TB program managers, facility directors, HIV clinics, TB clinics, and patient advocacy groups.

II. INTRODUCTION

Successful implementation of IPT on a national scale requires careful planning and preparation. This toolkit aims to provide a knowledge base, planning and training materials, costing tools, handouts, and monitoring and evaluation tools. All materials are intended as blueprints and should be customized to the local context.

The content of this toolkit is built on the following standard practices, current as of the writing of this toolkit:

1. A 6-month course of INH should be offered as a comprehensive package of HIV care and combined with ART services for PLWH and to children who were in contact with an infectious TB patient.
2. **Patient friendly**, service-oriented environments that allow patients to choose their medication delivery model – and change models if necessary – should be offered to patients without compromising their healthcare.
3. Better sensitization and **in-service training** to motivate healthcare workers to promote IPT uptake to patients and to scale up IPT uptake should be implemented.
4. IPT delivery models may be readily implemented in high TB/HIV burden settings to prevent TB.
5. The NTP and National HIV/AIDS Control Program (NACP) should be equipped to expand its programs. It should have the necessary financial and human resources, the ability to record and report IPT specific data and a sound supply chain.
6. The NTP, NACP, and other relevant government agencies should actively support IPT integration into existing HIV care delivery.

The term "Patient-friendly" can also mean patient-centered approaches to healthcare delivery. We define the patient-centered approach as one which adopts methods of health promotion and preventive care that best fit the patient and is in accordance with what matters most to them. Patient-centered approaches assume that the patient world is meaningfully different from the world of the clinician; therefore, a doctor or nurse (clinician) who adopts a patient-centered approach makes an effort to design, deliver, or modify a health promotion intervention to match what matters most to patients based on the patients' world. In this case, a patient-centered approach means providing patients with options for receiving treatment that fit best with their day-to-day experiences.

The following sections expand on these general principles. The text refers to documents such as handouts, presentations, and budgeting tools which are included with the digital distribution of this toolkit. The accompanying documents are provided in two formats: portable document format (PDF) of presentations given in the setting of a study in Swaziland[13], and unformatted power point slides that can be adapted to a local context.

III. PLANNING

1. PERFORM A READINESS ASSESSMENT

Before setting off to plan and implement an IPT program, a readiness assessment is necessary to assure the success of the program and to minimize unintended consequences. This assessment should be performed on the national, regional and local level and **respect local administrative** structures. Appendix 1 contains a checklist to assess readiness. The criteria are prioritized into Essential and Recommended categories.

There are two main areas of readiness. First, the NTP and NACP have to be functional and effective, as IPT implementation relies on existing infrastructure, human resources and organization. Second, there has to be a firm dedication to education and engagement of staff and patients, with dedicated resources to train and support clinic directors, nurses, medical providers, community health workers and patients.

If important gaps and shortcomings are identified during the readiness assessment, IPT implementation should be deferred until these deficits have been addressed. The necessary guidance to improve an NTP is beyond the scope of this toolkit, but can be found in several WHO Guidelines[14–16].

2. CONVENE A STAKEHOLDER MEETING

Utilizing current systems and relationships will help guide implementation of IPT. Most countries have an established system and infrastructure for the prevention, detection and treatment of TB. National HIV programs have varying degrees of centralization and integration with TB programs. The introduction of new interventions such as IPT therefore, requires engagement of all stakeholders. These usually include the Ministry of Health, the NTP, the NACP, public health organizations, public and private healthcare providers, pharmaceutical committees, national and international NGOs, and patient advocacy organizations.

The Stop TB Partnership has published a guide in 2008 called 'Engaging Stakeholders for Retooling TB Control,' which we have included in this toolkit. It contains detailed instructions on how to identify and engage stakeholders and how to perform a stakeholder analysis. Its annex provides sample forms, which are very applicable to the implementation of IPT delivery models. Below are three questions posed in the guide and adapted to IPT.

1. **Who are the stakeholders?** It is critical to understand:
   - who or which organizations will implement IPT?
   - who or which organizations will have influence and resources to support IPT?
   - who or which organizations will be directly or indirectly affected by IPT?
   - who or which organizations will support IPT; who will resist it and why; and how can resistance to change be addressed?
   - what can these organizations and individuals contribute to IPT?
   - what is the best ways to leverage insights or assuage objections and concerns?

2. **Why are stakeholders engaged?** Engagement aims to:
   - obtain political support
   - mobilize participation in advocacy for IPT
   - leverage financial and/or technical resources across the public and private sectors

- obtain broader insights for designing appropriate ways to introduce IPT
- provide opportunities for community participation in pilot and feasibility studies, determining acceptability of IPT; and contribute to monitoring and evaluation activities, including reporting of adverse drug events
- build relationships and trust
- establish partnerships to work together to achieve integration of IPT into the TB control and prevention program and effective implementation

3. How are stakeholders engaged? The process includes:

- establishing or identifying an existing working or advisory group
- defining clear objectives for engaging the various stakeholders
- conducting a stakeholder analysis
- developing and implementing a plan for engaging each type of stakeholder
- providing timely feedback to all participants

3. IDENTIFY RESOURCES AND TECHNOLOGIES

The readiness assessment should have ensured that the basic structure of the NTP is working effectively. IPT implementation requires specific resources, the availability of which has to be carefully planned. The exact quantity of goods and services, logistics, and organizational structure depend on the local context. The following list serves as a general guide, but details should be made explicit in the planning process.

1. **Drug availability**
    a. INH as a single drug, not in combination with other TB drugs
    b. sufficient quantity of INH to assure continuous supply for the anticipated number of patients
    c. quality assurance of INH in accordance with local pharmaceutical supply procedures
    d. delivery to local clinics or storage at local/regional facilities
2. **Human resources**
    a. national lead or point person
    b. dedicated committee or bureau
    c. regional lead
    d. local lead
    e. local clinical staff
    f. IPT pharmacist
    g. trainers
    h. data collectors
    i. data analyst
3. **Facilities**
    a. clinic space to enroll patients
    b. clinic space to perform exam to rule out TB disease

4. DEVELOP POLICIES AND PROTOCOLS

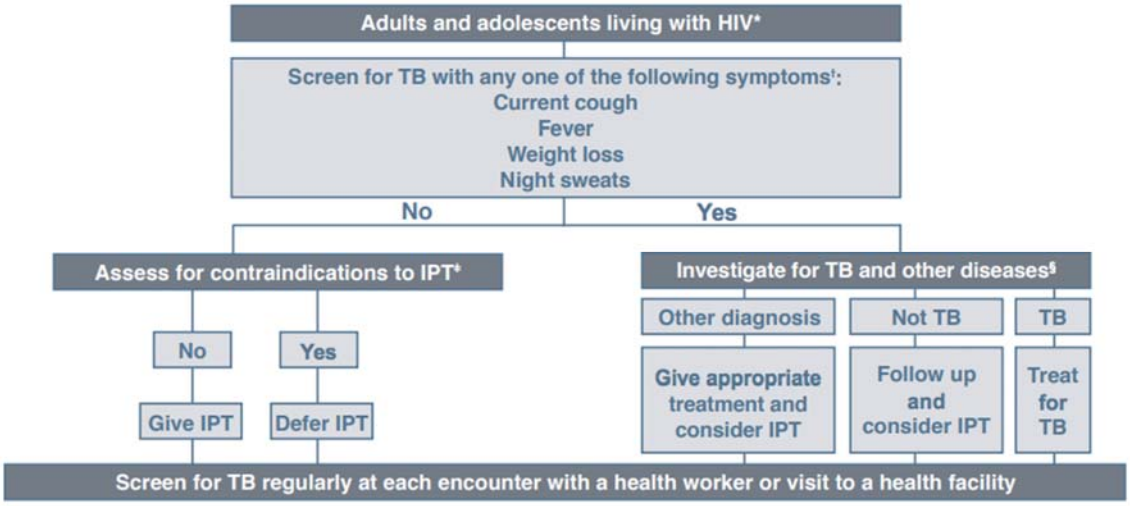
One of the first decisions in the implementation process should be optimizing plans for program roll-out. For example, will the implementation of IPT be country-wide at once or through a phased

roll-out. This decision will be greatly aided by a thorough assessment of available resources and capacity and should be clearly communicated to all stakeholders.

Next, it should be decided who will perform the implementation. Will this be a government effort, from leadership to delivery? Or will the government partner with local and/or international non-governmental organizations (NGOs)?

Prior to launch, a target population has to be clearly defined. Based on WHO recommendations, all PLWH over the age of 12 months should receive IPT. Ideally, children under 5 with infectious pulmonary TB contacts should receive IPT, but they have to be explicitly included in the target population, if feasible. Depending on the local context, special attention should be given to vulnerable groups such as migrant workers, refugees, commercial sex workers, injecting-drug users, and men who have sex with men.

Below is an algorithm for TB screening in adults and adolescents living with HIV in HIV-prevalent and resource-constrained settings, taken from the WHO *Guidelines for intensified tuberculosis case-finding and isoniazid preventive therapy for people living with HIV in resource-constrained settings*.[5] This should be adapted to the local clinic context and should be clearly posted and distributed amongst staff.



* Every adult and adolescent should be evaluated for eligibility to receive ART. Infection control measures should be prioritized to reduce M. tuberculosis transmission in all settings that provide care.
☐ 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.
☐ Contraindications 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. Although not a requirement for initiating IPT, TST may be done as a part of eligibility screening in some settings.
§ Investigations for TB should be done in accordance with existing national guidelines.

5. MODELS OF IPT DELIVERY

In accordance with a patient-centered approach, different ways to deliver IPT should be considered when developing or optimizing current treatment strategies. As described earlier, working with stakeholders (which includes patient representatives) is helpful when seeking a mode of delivery that works best for patients. To help inform delivery options, we have outlined three scripts for clinicians to describe the following modes of delivery (Traditional, CHW, Peer-support):

1. Routine clinic-based delivery (traditional approach) *One way is that you come into this clinic each month for 6 months so that we can check to see if you are having any symptoms and then we will provide your INH refill. This is the traditional method.*
2. Use of community health workers for home or community-based delivery (A Community Health Worker (CHW) approach) *Another way is that you review any symptoms you are having with your community healthcare worker and then that person will give you your INH at your home or another public place you agree to. The public place might be a shop, a school, a church or an outdoor location.*
3. Use of a community-based treatment group with rotating medication pick-ups. (Peer support approach) *You can pick a friend, neighbor, or family member who is also taking IPT and you can alternate picking up each other's INH from the clinic.*

6. TRAIN STAFF

Training materials should be developed in collaboration with representatives from the key stakeholder groups. The working group should develop training materials to educate and/or update clinicians at each implementation site. Through didactic lectures, role play, and discussion, these trainings will transfer pertinent information to the IPT enrolling clinicians, including:

- Review of the national IPT policy
- Review of the proven benefits of IPT
- Review of effective educational materials and approaches for patients and their families about TB
- Results from the IPT program evaluation
- Patient motivational interviewing techniques and ensuring shared decision making
- Overview of the project, using the approved SOPs
- Transfer of data collection tools

The importance of training and engagement of staff to the success of IPT implementation cannot be overstated. Knowledgeable and motivated providers are the key players in this effort.

Enclosed with this toolkit are slides that can be used for training of staff.

IV. LAUNCH AND ADJUST

Once the planning is wrapped up, it is time to launch! To boost IPT implementation, the start of the program should be a public celebration. This is a good opportunity to acknowledge and celebrate stakeholders and to assure commitment for the long term. A successful launch requires planning and deliberate decisions:

- Can the launch be on a meaningful date, for example World TB Day?
- Which dignitaries should be invited?
- Can you identify a patient spokesperson to share his or her story?
- Should there be a press conference? If so, make sure to prepare a press statement with a focused message, which should be sent to news organizations.
- What promotional material can be provided? T-shirts, posters, stickers, mobile phone cases, etc.

The enrollment of the first patients should be closely observed. Initially, daily or weekly meetings of the staff with a local lead should be scheduled. In these meetings, staff should share obstacles, questions, problems and successes. The local team might find fixes for problems, but these should be communicated with the appropriate regional and national leads, so they can be incorporated into the program or substituted with programmatic adjustments. The exact reporting lines will depend on the local administrative structure.

As more and more patients are enrolled, it is essential to actively monitor the local, regional and national INH supply in cooperation with the NTP.

V. MONITORING, EVALUATION AND CONTINUOUS IMPROVEMENT

The Monitoring and Evaluation (M&E) of IPT delivery must ensure that patients are receiving their treatment as prescribed by national guidelines. Process and outcome measures should be adopted to account for changes in processes and outcomes. Process measures should be collected routinely and should inform new processes when indicated by data. Outcome measures should be collected to assess success of delivery methods and where gaps in service delivery occur. We encourage all stakeholders involved in the dissemination of IPT to share input around accepted measures for process and outcomes. Stakeholders must be in charge of setting up timelines for deliverables and identifying personnel and consumable resources.

I. PROCESS EVALUATION

a. Monitor IPT adherence

- Conduct pill counts at visits
- Record number of patients being treated each week
- Make routine home visits to follow patients who selected community-based care

b. Monitor TB and HIV case load weekly or monthly

- Record number of new HIV patients at treatment site
- Record number of patients who started IPT
- Record number of patients who discontinued IPT and the reason
- Record number of patients on IPT who died
- Record number of patients on IPT who were lost to follow up or moved
- Record number of patients on IPT who screened positive for TB disease
    1. The number of cases with confirmed TB
    2. The number of cases with ruled out TB

c. Monitor educational activities

- Record the number of staff trained
- Record where trainings were conducted, which ones, and how many
- Record the number of patients who received counseling or education
- Record the number of information flyers handed out

d. Monitor selected delivery models

- Record the number of patients opting for facility-based care?
- Record the number of patients opting for community-based delivery
- Record the number of patients being offered treatment delivery options
    1. How many received a choice
    2. Which treatment delivery choices were made by the patients and why

e. Troubleshooting

II. OUTCOME EVALUATION

a. Record final treatment outcomes

- Record number of patients who started IPT
- Record number of patients who completed IPT
- Record number of patients who stopped IPT
- Record number of patients on IPT who died

- Record number of patients on IPT who were lost to follow up or moved
- Record number of patients on IPT who screened positive for active TB
    1. The number of cases with confirmed TB
    2. The number of cases with ruled out TB

b. Number of new TB cases at the end of year 1

To ensure complete and timely reporting, a defined reporting structure has to be in place. Depending on the existing administrative structures, clinics might report to regional or national authorities. The established policies should explicitly state who is responsible for reporting at each level, at what time interval and in which format.

VI. REFERENCES

1. World Health Organization. *Global Tuberculosis Report*. Geneva; 2017.

2. Vynnycky E, Fine PE. The natural history of tuberculosis: the implications of age-dependent risks of disease and the role of reinfection. *Epidemiol Infect*. 1997;119(2):183-201.

3. Selwyn PA, Hartel D, Lewis VA, et al. A prospective study of the risk of tuberculosis among intravenous drug users with human immunodeficiency virus infection. *N Engl J Med*. 1989;320(9):545-550. doi:10.1056/NEJM198903023200901.

4. Akolo C, Adetifa I, Shepperd S, Volmink J. Treatment of latent tuberculosis infection in HIV infected persons. Akolo C, ed. *Cochrane Database Syst Rev*. 2010;(1):CD000171. doi:10.1002/14651858.CD000171.pub3.

5. World Health Organization. *Guidelines for Intensified Tuberculosis Case-Finding and Isoniazid Preventive Therapy for People Living with HIV in Resource Constrained Setting*. Geneva; 2011.

6. Pothukuchi M, Nagaraja SB, Kelamane S, et al. Tuberculosis Contact Screening and Isoniazid Preventive Therapy in a South Indian District: Operational Issues for Programmatic Consideration. Marais BJ, ed. *PLoS One*. 2011;6(7):e22500. doi:10.1371/journal.pone.0022500.

7. van Wyk SS, Reid AJ, Mandalakas AM, et al. Operational challenges in managing Isoniazid Preventive Therapy in child contacts: a high-burden setting perspective. *BMC Public Health*. 2011;11(1):544. doi:10.1186/1471-2458-11-544.

8. Bristow CC, Larson E, Vilakazi-Nhlapo AK, Wilson M, Klausner JD. Scale-up of isoniazid preventive therapy in PEPFAR-assisted clinical sites in South Africa. *Int J Tuberc Lung Dis*. 2012;16(8):1020-1022. doi:10.5588/ijtld.11.0744.

9. Chehab JC, Vilakazi-Nhlapo K, Vranken P, Peters A, Klausner JD. Survey of isoniazid preventive therapy in South Africa, 2011. *Int J Tuberc Lung Dis*. 2012;16(7):903-907. doi:10.5588/ijtld.11.0722.

10. Mohamed AM. Adherence to and outcome of isoniazid chemoprophylaxis among household contact children of adults having pulmonary tuberculosis in Alexandria, Egypt. *J Egypt Public Health Assoc*. 2012;87(3-4):71-78. doi:10.1097/01.EPX.0000417999.05730.32.

11. Garie KT, Yassin MA, Cuevas LE. Lack of adherence to isoniazid chemoprophylaxis in children in contact with adults with tuberculosis in Southern Ethiopia. Pai M, ed. *PLoS One*. 2011;6(11):e26452. doi:10.1371/journal.pone.0026452.

12. Adams L V, Talbot EA, Odato K, Blunt H, Steingart KR. Interventions to improve delivery of isoniazid preventive therapy: an overview of systematic reviews. *BMC Infect Dis*. 2014;14(1):281. doi:10.1186/1471-2334-14-281.

13. Adams L V, Mahlalela N, Talbot EA, et al. High completion rates of isoniazid preventive therapy among persons living with HIV in Swaziland. *Int J Tuberc Lung Dis*. 2017;21(10):1127-1132. doi:10.5588/ijtld.16.0946.

14. World Health Organization. *The Stop TB Strategy*. Geneva; 2006. doi:10.2165/00128413-200615310-00002.

15. World Health Organization. *Implementing the Stop TB Strategy*. Geneva; 2008. doi:WHO/HTM/TB/2008.401.

16. World Health Organization. *Framework for Conducting Reviews of Tuberculosis Programmes*. Geneva; 2014. http://www.ncbi.nlm.nih.gov/books/NBK258647/pdf/TOC.pdf.

VII. APPENDICES

1. Readiness assessment tool
2. Patient Handout - Choice of Delivery of IPT
3. Patient Handout - Information on TB and INH
4. Sample script for patient enrollment

VIII. ATTACHMENTS

1. GUIDES

- Motivational Interviewing Training New Trainers Manual.pdf
- WHO 2004 Interim Policy TB HIV.pdf
- WHO 2006 The Stop TB Strategy.pdf
- WHO 2008 Implementing the Stop TB Strategy – handbook for NTCPs.pdf
- WHO 2011 Intensified TB case finding.pdf
- WHO 2014 Framework for conducting reviews of tuberculous programmes.pdf
- WHO 2017 TB Report.pdf

2. HANDOUTS

- Patient Education on INH by CDC.pdf
- Patient Education on IPT Delivery Choices.docx
- Patient Education on TB and INH.docx

3. MONITORING AND EVALUATION (M&E)

- MEASURE – Getting to an Evaluation Plan.pdf
- MEASURE – Health Systems Strengthening – M_E.pdf
- IPT Patient Data Collection Form.xlsx

4. PLANNING

- Costing Calculator.xlsx
- Readiness Assessment Tool.docx
- Stakeholder toolkit – Stop TB Partnership.pdf

5. TRAINING

- EXAMPLES: IPT AND TB BACKGROUND
  - IPT Evidence Review – Swazi IPT Indaba.pdf
  - IPT Evidence Review 1 – Basics.pdf
  - IPT Evidence Review 2 – TB CARE II.pdf

- EXAMPLES: MOTIVATIONAL INTERVIEWING
  - Motivational Interviewing – Alan Forrest.pdf

- Motivational Interviewing – Prantik Saha.pdf
- Motivational Interviewing and IPT – Nan Cochran.pdf

- TEMPLATES: IPT AND TB BACKGROUND
  - IPT Evidence Review 1 – Basics.pptx
  - IPT Evidence Review 2 – Challenges.pptx
  - IPT Patient Education Materials.pptx

- TEMPLATES: MOTIVATIONAL INTERVIEWING
  - Medication Adherence.doc
  - MI Reminder Card.pdf
  - Motivational Interviewing and IPT with mov.pptx
  - Motivational Interviewing and IPT.pptx
  - Teach Back.mov

APPENDIX 1. READINESS ASSESSMENT TOOL: IS YOUR SITE READY FOR IMPLEMENTATION OF PATIENT-SELECTED ISONIAZID PREVENTIVE THERAPY (IPT) DELIVERY?

ESSENTIAL CRITERIA FOR IPT DELIVERY READINESS

- ❑ Does your facility provide antiretroviral therapy (ART) and monitor patient adherence?
- ❑ Has your country (or district) achieved a TB treatment success rate of 85% or higher?
- ❑ Does your facility currently provide community-based or home-based care?
    - ❑ If not, does it have the capacity to offer community-based or home-based care?
- ❑ Do your national TB and HIV guidelines include instructions on providing IPT?
- ❑ Does your facility have adequate staff (clinicians, nurses, pharmacists etc.) to assess eligibility and provide IPT in accordance with national guidelines using a patient-selected model?
- ❑ Does your facility have sufficient resources and the ability to purchase single isoniazid tablets (apart from fixed-dose combination tablets)?

RECOMMENDED CRITERIA FOR IPT DELIVERY READINESS

- ❑ Is your facility already providing IPT to HIV-infected patients and child contacts?
    - ❑ If so, is the treatment completion rate below desired national targets?
- ❑ Do your TB and/or HIV control programs have a TB/HIV director/focal person?
- ❑ Does your HIV surveillance systems have a mechanism for capturing IPT administration, adherence, adverse reactions, and treatment outcomes?
    - ❑ If not, could this be added?
    - ❑ If not, some means of capturing these data will need to be created.
- ❑ Does your facility have monitoring and evaluation staff to assess IPT treatment outcomes?
    - ❑ If not, is there someone that can be assigned this responsibility?
- ❑ Does your facility have the capacity to train healthcare workers on IPT and the patient-selected model?
- ❑ Does your facility have the capacity to do patient education on IPT?
- ❑ Does your facility have the capacity to produce job aids to support a patient-selected model of IPT delivery?

APPENDIX 2. PATIENT HANDOUT: CHOICE OF DELIVERY OF IPT

You (or your child) and your healthcare provider have decided to start treatment with medicines for latent TB infection. This treatment is called IPT and will last for 6 months. You can choose among different options for picking up your medicines to make it more convenient for you. We want your treatment to fit well with your life and other commitments you have outside of receiving medical care.

You have three options for picking up your IPT medicine refills and you can switch between the three options at any time you want.

OPTION 1: You will pick up your IPT medicine at the same place as you pick up your ART refills and return to the clinic every two or three months to check in with a doctor about any problems or symptoms you are having.

OPTION 2: A community nurse will deliver the IPT refills to your house, or meet you to give you your refills at a public place near your house that you choose. This could be at church, a nearby market, a school or grocery store. You can review any symptoms or questions you have with the community nurse.

OPTION 3: You will be a part of a group care model with approximately five other people in your community who also take IPT. Each month one person in the group will go to the clinic and pick up everyone's IPT refill. You will all take turns going to pick up each other's medicine refills. You will also have an expert client assigned to your group who will help to make sure you are taking your medicine. You can also ask the expert client any questions about the medicine or any symptoms or problems you may be having.

IMPORTANT: If you have questions about your IPT medicine or this program at any time or would like to change between options of receiving you IPT refills please discuss this with your healthcare provider.

APPENDIX 3. PATIENT HANDOUT: INFORMATION ON TUBERCULOSIS (TB) AND ISONIAZID (INH)

WHAT IS TUBERCULOSIS OR TB?

TB is a disease spread through the air from one person to another. Anyone near a sick person who coughs, speaks or sneezes can breathe TB germs into their lungs.

TB germs can live in your body without making you or anyone else sick. This is called latent TB infection and means you have only inactive (sleeping) TB germs in your body. However, if these germs become active, you will get sick with TB disease and can spread the germs to other people around you. Taking medicine given to you by your doctor or healthcare worker (HCW) can stop you from getting sick, or spreading TB germs to family, friends and others around you.

TREATMENT FOR LATENT TB INFECTION

You have been given pills called isoniazid to treat your latent TB infection. You do not have TB disease and cannot spread TB to others. This medicine will help you prevent getting TB disease.

WHILE ON THIS MEDICATION

- Tell your doctor or nurse if you have any questions or concerns with the medicine.
- Go to your planned clinic visits.
- Discuss any alcohol use with your doctor. Alcohol use may cause side effects.
- Tell your doctor about all the medications you are taking.
- Be sure to tell your other doctors that you are being treated for latent TB infection.
- Take all of your medicine as the TB doctor or nurse instructed you to.
- Some people find that the medicine affects them less while taken with food.

WATCH FOR THESE POSSIBLE PROBLEMS

STOP taking your medicine right away and call your TB doctor or nurse if you have any of the following:

- Less or No Appetite for Food
- Upset stomach or stomach cramps
- Nausea or vomiting
- Brown urine or light-colored stools
- Rash or itching
- Yellowing skin or eyes
- Tingling or numbness in your hands or feet

TIPS TO HELP YOU TAKE YOUR MEDICINE

- Take your medicine at the same time every day.
- Set an alarm reminder for the time you should take your medicine.
- Ask a family member or friend to remind you.
- Use a pillbox.
- Put a reminder note on your mirror.
- Use a calendar to tick off the day when you take your medicine.

MEDICINE SCHEDULE

Take _1_ pill each day (for example, with breakfast or dinner) for the next six months.

IF YOUR FORGET TO TAKE YOUR MEDICINE

If it is still the same day, take your medicine as soon as you remember. If the day has passed, skip the missed medicine dose and take your next scheduled medicine. DO NOT take two doses at the same time.

APPENDIX 4. SAMPLE SCRIPT FOR PATIENT ENROLLMENT

At this clinic, we have three ways that our patients can choose from to receive their isoniazid preventive therapy (IPT).

One way is that you pick up your INH refill when you come to get your ART. You will only need to take INH for 6 months. At every clinic visit, we will check to see if you are having any symptoms and if not, then we will provide your next INH refill. This is the traditional method.

The second way you can choose is that you review any symptoms you are having with your community healthcare worker and then that person will give you your INH at your home or another public place you agree to. The public place might be a shop, a school, a church or an outdoor location.

Third, you can pick a friend, neighbor, or family member who is also taking IPT and you can alternate picking up each other's INH from the clinic.