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# TB and HIV Care and Management Course for Health Care Workers

*Trainer Guide*

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# Table of Contents

<i>Training Programme</i> .....	i
<i>Abbreviations</i> .....	ii
<i>About this course</i> .....	iii
<i>Session 1. Course Introduction and TB and HIV Review</i> .....	1
Worksheet 1.1. TB and HIV Statistics.....	5
Worksheet 1.2. TB and HIV Review.....	9
Handout 1.3. HIV and the Immune System .....	11
Trainer Tool 1.4. Statements for Review Activity .....	12
<i>Session 2. Diagnosis of HIV in Adults and Children</i> .....	15
Handout 2.1. Overview of Provider-Initiated Counselling and Testing in Context of PMTCT.....	17
Handout 2.2. HIV Testing for Pregnant Women .....	18
Worksheet 2.3. Case Studies – Pregnant Women .....	19
Handout 2.4. Children who Should be Offered HIV Testing.....	22
Handout 2.5. Recommended Testing Algorithm for Abandoned Children .....	23
Worksheet 2.6. Using South Africa’s Algorithm for Children less than 18 Months .....	24
Handout 2.7. Legal Issues Related to HIV Testing of Children.....	27
<i>Session 3. Diagnosis of TB and DR-TB in Adults and Children</i> .....	28
Handout 3.1. TB Definitions .....	36
Handout 3.2. Algorithm for TB diagnosis in a new case using smear microscopy and culture.....	38
Handout 3.3. Algorithm for TB diagnosis in TB suspects using the Line Probe Assay (LPA).....	39
Handout 3.4. Algorithm for TB diagnosis in TB suspects using the GeneXpert .....	40
Handout 3.5. Algorithm for TB diagnosis in re-treatment cases and MDR-TB contacts using smear microscopy, culture and DST.....	41
Handout 3.6. Preventive TB Therapy in Adults.....	42
Worksheet 3.7. Algorithm Practice .....	44
Handout 3.8. Effect of HIV on TB Signs and Symptoms.....	48
Handout 3.9. Diagnosing TB in Children.....	51
Handout 3.10. Algorithm for Screening a Child with Documented TB Exposure.....	54
Worksheet 3.11. Diagnosing TB in Children .....	55
Handout 3.12. Extra-pulmonary Tuberculosis.....	58
<i>Session 4. Management of Patients with Pulmonary and Extra-Pulmonary Tuberculosis</i> .....	65
Handout 4.1. First-Line TB Drugs.....	70
Handout 4.2. Standard Treatment Regimens for Adults (8 years and older) .....	71
Handout 4.3. Treatment for Children.....	73
Worksheet 4.4. Case Studies - Drug Regimens in Adults and Children .....	75
Handout 4.5. Symptom-Based Approach to Management of Drug Side Effects .....	82
Handout 4.6. Management of Treatment Interruption .....	84
Worksheet 4.7. Case Studies for Treatment Interruption.....	86
Worksheet 4.8. Case Studies. Managing Adults & Children with TB .....	88
Handout 4.9. Monitoring Algorithm for New PTB Adults.....	100

<i>Session 5. Drug Resistance, Multidrug-Resistant TB and Adherence</i> .....	101
Handout 5.1. Overview of MDR/XDR-TB .....	104
Handout 5.2. Risk Factors for Drug Resistance .....	105
Worksheet 5.3. MDR/XDR-TB .....	106
Handout 5.4. Decentralised Management of DR-TB.....	108
Handout 5.5. Classification of TB Drugs.....	111
Handout 5.6. Dosing of Standard Regimen for MDR/XDR-TB .....	113
Handout 5.7. Referrals at Primary Health Facilities .....	116
Worksheet 5.8. Calculating Resistance.....	118
Handout 5.9. Common Side Effects During MDR-TB Treatment.....	121
Worksheet 5.10. Cases in the Management of DR-TB .....	126
Worksheet 5.11. Addressing Factors Affecting Adherence.....	133
Handout 5.12. Strategies to Improve Adherence.....	134
Handout 5.13. The Role of Counselling to Ensure Adherence .....	136
<i>Session 6. Management of TB in an HIV-infected Person</i> .....	138
Handout 6.1. HIV and Tuberculosis Co-Infection .....	140
Handout 6.2. Management of HIV and DR-TB Co-Infection .....	142
Handout 6.3. Managing Adverse Reactions to TB and HIV Treatment.....	147
Worksheet 6.4. TB and HIV Co-Infection Case Studies.....	150
<i>Session 7. Infection Control and Prevention</i> .....	161
Handout 7.1. Overview of TB Prevention and Infection Prevention and Control Practices.....	167
Handout 7.2. N95 Respirators.....	169
Handout 7.3. Sample Infection Control Plan .....	171
Handout 7.4. Sample Infection Control Officer Job Description.....	174
Handout 7.5. TB Infection Control Assessment Tool.....	176
Worksheet 7.6. TB Risk Assessment Case Study .....	178
Handout 7.7. Home Isolation .....	179
Handout 7.8. Post-Exposure Prophylaxis .....	181
Worksheet 7.9. Post-Exposure Prophylaxis Case.....	183
<i>Session 8. Putting it all Together</i> .....	185
Handout 8.1. Overview of the Simulated Patient Station Model .....	187
Handout 8.2. Demonstration Patient Scenario .....	189
Handout 8.3a. Patient Scenario and Checklist .....	191
Handout 8.3b. Patient Scenario and Checklist .....	192
Handout 8.3c. Patient Scenario and Checklist.....	193
Handout 8.3d. Patient Scenario and Checklist .....	194
Handout 8.3e. Patient Scenario and Checklist .....	195

# Training Programme

## Day 1

Time	Item	Duration	Presenter
08:00 - 08:15	Welcome and introductions	15 min	
08:15 – 08:30	<i>Pre-test</i>	15 min	
08:30 – 10:30	<i>Session 1</i> <ul style="list-style-type: none"> <li>• Course introductions</li> <li>• TB/HIV review</li> <li>• Orientation to the NSP and the MDGs</li> </ul>	2 hours	
10:30 – 10:45	<i>Tea Break</i>		
10:45 – 12:15	<i>Session 2</i> <ul style="list-style-type: none"> <li>• Diagnosis of HIV in adults and children</li> </ul>	1 hour 30 min	
12:15 – 13:15	<i>Session 3</i> <ul style="list-style-type: none"> <li>• Diagnosis of TB and DR-TB in adults and children</li> </ul>	3 hours	
13:15 – 14:00	<i>Lunch Break</i>		
14:00 – 16:00	<i>Session 3 (cont.)</i> <ul style="list-style-type: none"> <li>• Diagnosis of TB and DR-TB in adults and children</li> </ul>		

## Day 2

Time	Item	Duration	Presenter
08:00 – 08:30	Review of Day 1	15 min	
08:30 – 10:30	<i>Session 4</i> <ul style="list-style-type: none"> <li>• Management of patients with Pulmonary and Extra-Pulmonary TB</li> </ul>	3 hours 45 min	
10:30 – 10:45	<i>Tea Break</i>		
10:45 – 12:30	<i>Session 4 (cont.)</i> <ul style="list-style-type: none"> <li>• Management of patients with Pulmonary and Extra-Pulmonary TB</li> </ul>	1 hour 30 min	
12:30 – 13:15	<i>Lunch Break</i>		
13:15 – 16:15	<i>Session 5</i> <ul style="list-style-type: none"> <li>• Drug Resistant TB</li> </ul>	3 hours	

## Day 3

Time	Item	Duration	Presenter
08:30 – 10:15	<i>Session 6</i> <ul style="list-style-type: none"> <li>• Management of TB in HIV-infected persons</li> <li>• Adherence to Medications</li> </ul>	1 hour 45 min	
10:15 – 10:30	<i>Tea Break</i>		
10:30 – 12:30	<i>Session 7</i> <ul style="list-style-type: none"> <li>• TB Infection Prevention and Control</li> </ul>	2 hours	
12:30 – 14:00	<i>Session 8</i> <ul style="list-style-type: none"> <li>• Putting it All Together</li> <li>• Post-Test</li> <li>• Course Evaluation</li> </ul>	1 hour 30 min	
	<i>Lunch Break</i>		

# *Abbreviations*

ABC	Abacavir	HPV	Human papillomavirus infection
ADS	AIDS dementia complex	IDU	Injection-drug use(r)
AEB	Accidental exposure to blood	IFN	Interferon
AFB	Acid-fast bacilli	IND	Indinavir
AIDS	Acquired immunodeficiency syndrome	INH	Isoniazid
ALT	Alanine aminotransferase	IP	Intensive phase
ART	Antiretroviral treatment/therapy	IPC	Infection prevention and control
AST	Aspartate aminotransferase	IPT	Isoniazid preventive treatment
ATT	Anti-TB therapy	IPV	Intimate partner violence
ATV	Atazanavir	IRIS	Immune reconstitution inflammatory syndrome
AZT	Zidovudine (also known as ZDV)	KS	Kaposi sarcoma
bid	Twice daily	MC	Male circumcision
BCC	Behaviour change communication	MDR-TB	Multidrug-resistant tuberculosis
CBO	Community based organisations	MO	Medical officer
CDC	Centres for Disease Control and Prevention	MSM	Men who have sex with men
CMV	Cytomegalovirus	NFV	Nelfinavir
CNS	Central nervous system	NGO	Non-governmental organisation(s)
CP	Continuation phase	NNRTI	Non-nucleoside reverse transcriptase inhibitor
CRG	Clinical resource guide	NRTI	Nucleoside reverse transcriptase inhibitor
CPK	Creatinine phosphokinase	NVP	Nevirapine
CSF	Cerebrospinal fluid	OHL	Oral hairy leukoplakia
CTC	Care and treatment clinics	OIs	Opportunistic infections
CPT	Cotrimoxazole preventive therapy	PCP	Pneumocystis Jiroveci (Carinii) pneumonia
CTX	Cotrimoxazole	PCR	Polymerase chain reaction
CXR	Chest x-ray	PGL	Persistent generalised lymphadenopathy
d4T	Stavudine	PHCs	Primary health care centres
ddl	Didanosine	PEP	Post-exposure prophylaxis
DMO	District Medical Officer	PI	Protease inhibitor
DNA	Deoxyribonucleic acid	PICT	Provider-initiated testing and counselling
DOTS	Directly observed treatment, short-course	PLHA/s	Person/people living with HIV and AIDS
EBV	Epstein Barr virus	PMTCT	Prevention of mother-to-child transmission of HIV
EFV	Efavirenz	PTB	Pulmonary tuberculosis
EPTB	Extrapulmonary tuberculosis	qd	Once daily
FBC	Full blood count	RNA	Ribonucleic acid
FDC	Fixed-dose combinations	RNTCP	Revised National TB Control Programme
FTC	Emtricitabine	RT	Reverse transcriptase
GDP	Gross domestic product	RTIs	Respiratory tract infections
GI	Gastrointestinal	SQV	Saquinavir
GNP	Gross national product	STIs	Sexually transmitted infections
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria	tid	Three times daily
HAART	Highly active antiretroviral therapy	TB	Tuberculosis
HB	Haemoglobin	TDF	Tenofovir disoproxil fumarate
HBC	Home-based care	TLC	Total lymphocyte count
HBV	Hepatitis B virus	TMP	Trimethoprim
HCV	Hepatitis C virus	UTI	Urinary tract infection
HCW	Health care worker	VZV	Varicella zoster virus
HIV	Human immunodeficiency virus	WBC	White blood cells
		WHO	World Health Organisation

# About This Course

The five-day TB and HIV Care and Management Course for Health Care Workers is designed to prepare health care workers plan and deliver HIV and AIDS and TB (including drug-resistant TB) care. The interactive didactic curriculum includes 8 sessions, focusing on how to diagnose, care, manage and treat HIV, AIDS, TB, including drug resistant TB. The objective of the training is to enhance and strengthen the role of health care professionals in providing quality care to patients infected with HIV and TB.

The course is conducted using the following teaching and learning methods:

- Lecture;
- Case studies;
- Role plays;
- Large- and small-group work and discussions;
- Individual work;
- Demonstration and practice; and
- Application of course content using simulated patients.

This course is designed to support and strengthen TB and HIV management in the health facilities.

## Selection Criteria

This course is considered an advanced training programme. The intended audience for this course is for professional nurses or doctors who have been:

- Palsa Plus-trained,
- IMCI-trained,
- Attended a foundational HIV, AIDS, and TB training, and
- Currently managing HIV, TB and/or Drug-Resistant TB in clinical practice.

This course includes numerous clinical resources to support the health care worker in the clinic or hospital setting. The training will orient participants to the resources, and reference them throughout the activities.

## Course Competencies

At the end of the course, it is expected that participants will be able to:

- Describe the epidemiology of HIV and TB.
- Diagnose HIV infection accurately.
- Manage HIV infection in children and adults, including pregnant women.
- Identify correct treatment regimens for HIV management.
- Identify signs and symptoms of TB infection.
- Detect and manage drug-resistant TB cases.

- Manage clients presenting with all forms of TB including those co-infected with HIV.
- Identify and manage patients and clients eligible for TB Preventative Therapy.
- Identify correct treatment regimens for TB management.
- Recognise and manage all adverse reaction associated with antiretroviral and TB treatment.
- Recognise possible treatment failure based on clinical symptoms.
- Explain the criteria for TB community-based care.
- Identify strategies to assist clients and patients in improving treatment adherence.
- Identify infection control strategies to prevent the transmission of TB in healthcare settings.
- Identify the recording and reporting systems necessary in HIV and TB management.

## Recommendations for Adaptation of Course

### *Target Audience's needs*

The course can be adapted to meet learning needs of different target groups and different levels and categories of health care practitioners. Sessions are developed according to topics, to enable facilitators or trainers to either offer all the 10 sessions the course or to focus on a particular section to meet the needs of the target group, for example, where the need is to learn more about Drug Resistant TB or Infection control, the facilitator can choose and only concentrate on those sessions, making training more meaningful and needs – focused.

### *Facility-Based Training*

The course can easily be adapted for facility-based training. The course content is largely case-based. This content can be broken up and presented in shorter sessions, for example over lunch times or during designated times at the facility. This can be done by identifying a topic area and then presenting the cases, handouts, discussion and/or activities related to the topic during designated times. The course includes many clinical cases that can be conducted one-on-one or as group training. The Clinical Resource Guide can be used as a reference and training tool to support facility-based training. The guide can be utilised by participants to conduct cases (one-on-one, individually or group training). Additionally, the PALSA Plus and IMCI Guidelines can be used to augment course content, with participants utilising the guidelines to conduct case studies as well to further practice with the guidelines for those that are NIMART trained.

To conduct topic-specific, shorter training sessions at the facility level, identify the needs from your participants at the facility and then match content from the course to those needs by selecting relevant topics.

## Course Evaluation

This course will be evaluated based on a pre- and post-training assessment of participants. Allow 45 minutes at the start of day one for the participants to take the pre-test and 45 minutes on the last day for participants to take the post-test. Participants will also complete daily written assessments.

## Course Materials

Course materials include a participant handbook, trainer guide, PowerPoint slide sets, Clinical Resource Guide and numerous job aids. The trainer guide contains instructions for conducting the training and answers to any activities found on worksheets. It references handouts and job aids (such as drug cards or other clinical references), and includes symbols throughout to help organise the trainer. The trainer guide is designed sequentially. For example, slides immediately follow the step in the session. Handouts immediately follow the slide where referenced. Any reference to a Trainer Tool is found at the end of the session materials.

The participant handbook includes course handouts, worksheets, and activities that correspond to the course content. Job aids may be included in the participant handout or as stand-alone documents. Trainers should familiarise themselves with the guides and job aids prior to the start of the course.

Necessary Materials for Trainer to Bring:

- Registers and Recording tools for HIV and TB specific to provinces
- N95 masks (one per participant)
- Incense or smoke stick to demonstrate air flow
- Copies of national guidelines relevant to training: MDR-TB, TB, HIV in adults and paediatrics, IPT, Circulars, TB and HIV stationary to have on hand as reference

## How to Use the Trainer Guide

The trainer guide provides all of the tools and instructions needed for a trainer to conduct the course. Symbols are found throughout the trainer guide and will prompt the trainer to do specific things, such as summarise a discussion. Review the trainer guide carefully and in advance of the training. Table 1 provides an explanation of the symbols used throughout the guide. Look for these symbols to help guide your preparation.

The session overview table found at the start of each session in the trainer guide provides critical information for the trainer. Each session is divided into steps. For each step, the overview table identifies the suggested time, activities or methods, content covered including slide numbers (if there are any), and the resources needed for that step. Resources include handouts, worksheets, or cards/job aids. It is important for the trainer to try to adhere to these time estimates. This will ensure that he or she is able to get through the entire course content in the time allotted. Table 2 is an excerpt from a session overview.

## Tips for the Trainer

Imagine that you are a student back in your first year of study. You are taking a course for the first time, and the subject matter is completely new. Think about how challenging it was for you as a learner. Now think about the participants who are going to attend this training. For some of them, the content may be relatively new and very challenging. For others, the content may be very familiar. Your task is to adjust your training techniques so that you reach as many participants as possible. This is no easy task! There are four important things you can do as a trainer to help align yourself with your participants and the content on the path to learning.

### 1. Establish a Rapport with Participants

Think about a good trainer you have had in the past. What made that person stand out? The qualities that made the trainer effective were not just the ability to present content, right? It was how they presented content and how they communicated with you as the learner. While good trainers are knowledgeable about the content, they also create an atmosphere of trust and support in the learning process. Part of this is done by establishing a good rapport with learners.

What is rapport? Rapport is a style of interpersonal communication that creates a respectful working relationship between the trainer and participant. Trainers establish good rapport with participants by acknowledging the experience the participants bring to the learning process and by demonstrating respect for them as individuals.

Rapport is maintained by using open communication that invites participants to contribute and learn from each other and by using non-verbal communication that expresses warmth and openness. Use body postures, gestures, and facial expressions that communicate approachability. Remember, how you say something is as important as what you say!

**Table 2.** Excerpt from a Session Overview

Step	Time	Activity/Method	Content	Resources Needed
1	5 min	Group Discussion	WHO Staging Quick Review	WHO Staging Cards
2	10 min	Group Work	WHO Staging Practice	WHO Staging Cards Worksheet 2.1

**Table 1.** Symbols in Trainer Guide

Symbol	Name	Description
	Time	At the start of the session, indicates the amount of time that trainers have for the full session. It is important to try to stay within this time frame in order to cover the full course in the allotted time. If found with other symbols in individual activities, indicates a time check to remind trainers to keep activities.
	Resources Needed	Outlines the resources trainers will need for each session. Includes handouts, worksheets, and other resources such as flipcharts, markers, videos, projectors, etc.
	Advance Preparation	Alerts trainer to any actions they need to do in advance of starting the session, for example cutting out pieces of paper, copying certain sessions, or other preparation directly related to activities in that session.
	Trainer Instructions	Corresponds to the step outlined in the session overview. It is always followed by the slides, handouts, and worksheets that accompany that step.
	Handout	Indicates a handout. Participants will have a copy of most handouts in the participant manual.
	Exercise/Activity	Indicates a worksheet. Participants will have a copy of worksheets in the participant manual, but they will not include solutions. The trainer guides includes answers.
	Question	Indicates when the trainer is instructed to ask participants a specific question.
	Card	Indicates when the trainer should reference the set of cards that accompany this course.
	Summarise Activity	Indicates when and what the trainer needs to summarise at the end of an activity.
	Trainer Tip	This indicates a variation that can be done on the activity to make it more appropriate to your audience.
	Trainer Tool	Indicates something that the trainer will need to facilitate a specific activity.
	Rapid Assessment	Indicates a place where you can do a quick assessment to help organise the activity.
	Slides	Indicates when the trainer needs to use a slide set.

#### Tips for Establishing Rapport with Learners:

- Introduce yourself thoughtfully, offering people some information about your professional and personal qualifications.
- Use people's names.
- Be friendly and helpful always, but especially during the first interactions.
- Maintain a positive attitude.
- Create opportunities for participants to feel comfortable interacting with each other.
- Make a positive first impression by arriving early and being prepared.
- Look at individuals as they are speaking.
- Use facial expressions that indicate "I'm listening."
- Be nice!

### 2. Practise Good Organisation

Good organisation is important to the success of the course. Trainers that have organised themselves and the materials in advance are much more likely to succeed than those who have not.

The course materials are structured to help you. They include a timetable and comprehensive trainer instructions to guide discussions and activities. Familiarise yourself with the materials prior to the start of the course. During the course, end each day by asking yourself: "What worked well today? Where did I seem to lose people?" Use this self reflection to adjust the structure for the next day.

#### Tips for Being Organised:

- Familiarise yourself with course goals and learning objectives.
- Review course materials in advance.
- Review daily schedule at the start of each day with participants so they know what to expect.
- Identify ice breakers and energisers to use in advance.
- Practice good time management.
- Encourage feedback to adjust your teaching style.

### 3. Engage Participants in the Learning Process

Participants are the most valuable resource in an adult training course. They help each other learn through sharing relevant work experiences and providing different perspectives. Ask participants questions, engage them in conversations, and encourage them to share their own work experience. Consider fellow trainers and participants as resources, and the learning experience will be enriched for all involved.

The materials in this guide have been structured to include various activities and exercises to engage participants in the content. However, this alone is not enough! You can further this process by taking time to adapt some of these materials to your participants. Think about examples that

are appropriate for your audience and highlight key concepts that you want them to take away from each session. Be sure that your examples are specific to the context of the course and are in line with the course goals and objectives! Remember, the more participants identify with the content, the more they will be motivated to learn.

#### Tips to Engage Participants:

- Adapt materials to your audience.
- Develop additional questions or activities that address the issues and challenges your participants may face at their work sites.
- Use "real life" examples to make the content more interesting and relevant.
- Frequently ask questions of participants to check their understanding and to keep them actively thinking and participating. Questions that begin with "what", "why", or "how" require more than just a few words to answer and can thus help promote rich discussion. Avoid questions that can be answered with a simple "yes" or "no".
- After asking a question, pause. Give participants time to think and volunteer a response. A common mistake is to ask a question and then answer it yourself. Some silence is productive. If no one answers your question, rephrasing it can help to break the tension of silence, but do not do this repeatedly.
- Take advantage of more experienced participants who can help you train those with less knowledge and experience.
- Be available to talk with participants as needed.

### 4. Encourage Interaction with and Among Participants

Integrate participants into the learning process as much as possible by involving them with questions, handouts, and exercises.

#### Tips to Encourage Participant Interaction:

- Ask questions that engage participants in conversations.
- Encourage participants to share relevant work experiences.
- Encourage participants to ask questions.
- Do not feel compelled to answer every question yourself. Depending on the situation, you may turn the question back to the participant or invite other participants to respond. You may need to discuss the question with the course director or another trainer before answering. Be prepared to say "I don't know, but I'll try to find out."
- Listen carefully to participants and respond with sincerity.
- Ask participants to lead energisers.

By exercising these basic training principles, you are on your way to becoming a successful trainer.

**Good luck!**

# *Handouts and Materials Needed*

## **Physical Space:**

- One large training room set up with small tables

## **Materials Needed for each Participant:**

- N95 masks
- Pre-/Post-Tests
- Laminated paediatric dosing chart
- Clinical Resource Guide
- Participant Manual
- Daily Evaluations
- Summary Course Evaluation
- Notebooks
- Pens
- Candy
- Certificates of Completion or Attendance

## **Trainer Needs:**

- Pre-printed sign-in sheet
- Registers and reporting tools for HIV and TB specific to province
- N95 mask for demonstration
- Incense or smoke stick to demonstrate air flow
- Copies of national guidelines relevant to training: MDR-TB, TB, HIV in adults and paediatrics, IPT, Circulars, TB and HIV stationary to have on hand as reference
- Training Workshop Sign
- Signs: Time's Up, 1 minute, 5 minutes, 10 minutes
- Trainer Guide
- Flipchart stands with flipchart paper
- Flipchart markers
- Laptop and LCD
- Slides
- Extension cords; appropriate adapter plugs
- Extra blank paper
- Tape
- Scissors
- Small clocks for timekeeping
- Hole punch
- Name tags
- Rubber bands
- Stapler and staples



# Session 1. Course Introduction and TB and HIV Review



**Total Session Time: 2 hours**

## Learning Objectives:

By the end of this session, participants will have:

- Completed the pre-test.
- Introduced themselves to other participants and the trainers.
- Reviewed course core competencies.
- Reviewed participant training material, the schedule, and logistics for the training.
- Set ground rules to be followed during the length of the course.
- Described the epidemiology of TB and HIV.
- Explained the relationship between TB and HIV.
- Explained the importance of addressing both TB and HIV as health care workers.

## Session Overview

Step	Time	Activity/Method	Content	Resources Needed
1	60 minutes	Trainer Discussion Pre-test	Course Introduction and Pre-test	Flipchart and markers Pre-test
2	60 minutes	Group Activity	Review Activity	Worksheets 1.1, 1.2 Handout 1.3 Trainer Tool 1.4



## Advance Preparation

Step 1: Write the following on a piece of flipchart:

- Name
- Where you work
- Three things you expect to learn from this course

Step 2: Print and cut out statements in Trainer Tool 1.4. Fold statements in half and put in a box or basket. Bring an apple or rock for activity.



## Resources Needed

- Pre-test
- Flipchart and markers
- Worksheet 1.1. HIV and TB Statistics
- Worksheet 1.2. HIV and TB Review
- Handout 1.3. HIV and the Immune System
- Trainer Tool 1.4. Statements for Review Activity



## Trainer Instructions: Step 1 (60 minutes) Course Introduction and Pre-test

### Step 1 Learning Objectives:

- Welcome participants to the course.
- Complete the pre-test.
- Introduce participants to each other and the trainer.
- Review course core competencies.
- Review participant training material, the schedule and logistics of the training.
- Set ground rules to be followed during the length of the course.

### Step 1 Resources Needed:

- Pre-test
- Flipchart and markers

### Step 1 Trainer Instructions:

	1.1. Welcome participants and conduct the opening. Start the group with the pre-test after opening words have concluded. Allow 45 minutes to complete the pre-test.
	1.2. Divide participants into groups of six. Assign the person who traveled the farthest to the training as the group leader. Ask each group to share the following information about themselves, and ask the group leader to record the information on a piece of paper: <ul style="list-style-type: none"> <li>• Name</li> <li>• Where they work</li> <li>• Three things they expect to learn in this course</li> </ul> Refer participants to the prepared flipchart if they have questions.
	1.3. Allow five minutes to complete. Reconvene group and ask each group leader to share: <ul style="list-style-type: none"> <li>• Name of each individual in their group</li> <li>• List of group expectations for the course</li> </ul> Record the expectations on the flip chart.
	1.4. After all groups have presented their information, summarise the expectations for the course.
	1.5. Provide participants with course and training overview: <ul style="list-style-type: none"> <li>• Review training schedule, including when breaks and lunch will occur during the day</li> <li>• Review participant material (including the participant handbook) and how they will be expected to use them</li> <li>• Point out that the participant handbook contains slides, worksheets, and handouts</li> <li>• Tell participants where the washrooms/restrooms are located</li> <li>• Discuss logistics related to per diem or travel costs (if needed)</li> <li>• Review logistics (transportation, accommodations, tea time, lunch breaks, time keeper, etc.)</li> </ul>
	1.6. Explain to participants that the training methodology used in this course is designed to appeal to a variety of learning styles. Methods include many interactive activities designed to build skills in the care and treatment of persons living with HIV. Teaching methodology that will be used in the course includes: <ol style="list-style-type: none"> <li>1. Lectures/discussions</li> <li>2. Group discussions and activities</li> <li>3. Case studies</li> <li>4. Role plays</li> <li>5. Demonstrations</li> <li>6. Simulated Patient Stations</li> </ol>
	1.7. Set ground rules to be followed during the length of the course and record on flipchart paper
	1.8. Ask participants to open the participant manual to course competencies. Ask for a volunteer to review the course competencies. Explain that the course is designed to meet these competencies



## Trainer Instructions: Step 2 (60 minutes) Review Activity

### Step 2 Learning Objectives:

- Describe the epidemiology of TB and HIV.
- Explain the relationship between TB and HIV.
- Explain the importance of addressing both TB and HIV as health care workers.
- Describe how HIV affects the immune system and the course of HIV progression in adults and children.
- Discuss the goals and benefits of antiretrovirals.

### Step 2 Resources Needed:

- Worksheet 1.1. TB and HIV Statistics
- Worksheet 1.2. TB and HIV Review
- Handout 1.3. HIV and the Immune System
- Trainer Tool 1.4. Statements for Review Activity



### Step Rapid Assessment:

If your training is comprised of multiple cadres of healthcare workers, divide them up across all groups. For example, ask the doctors in the room to raise their hand and count of from one to five. Repeat this with other cadres present. Alternatively, if you have all one cadre of HCWs such as nurses, ask those who routinely work in HIV care and treatment to raise their hands and count to one to five. Repeat this question for those that work in TB care and management and then have them count of one to five. Repeat with PMTCT, coordinators, etc. This will ensure a varied level of experience of each group.

### Step 2 Trainer Instructions:

	2.1. Explain that the purpose of this activity is to review some of the key content related to TB, HIV and TB/HIV Co-Infection.
	2.2. Divide participants into groups of five using instructions outlined in the Rapid Assessment above. Explain that groups will remain in these groups for the remaining days of the training.
	2.3. Refer participants to Worksheet 1.1. TB and HIV Statistics. Explain that each group will have 10 minutes to complete the worksheet.
	2.4. Reconvene group and ask for answers to the questions listed in the worksheet.
	2.5. Ask participants, “Why is this data important to you in your practice?” Facilitate a brief discussion. Possible answers: <ul style="list-style-type: none"> <li>• To identify areas of greatest need</li> <li>• Identify gaps, especially related to outcomes</li> <li>• Stress importance of using registers and track data</li> </ul>
	2.6. Explain that Sub-Saharan Africa has the world’s highest rates of HIV and AIDS. South Africa has 5,600,000 million adults and children that have HIV and AIDS, the largest number of people infected in the world.
	2.7. Ask participants to get up and stand in a circle.
	2.8. Explain that participants will play a game. Start by passing the apple or rock that you brought to a participant. That participant will select a statement from the box or basket. The participant will read the question aloud to the group.
	2.9. The participant can either answer the question himself/herself or ask the group for help. Once the question is answered, the participant throws the apple or rock to another participant, repeating the process until all of the questions are read and answered or you run out of time.

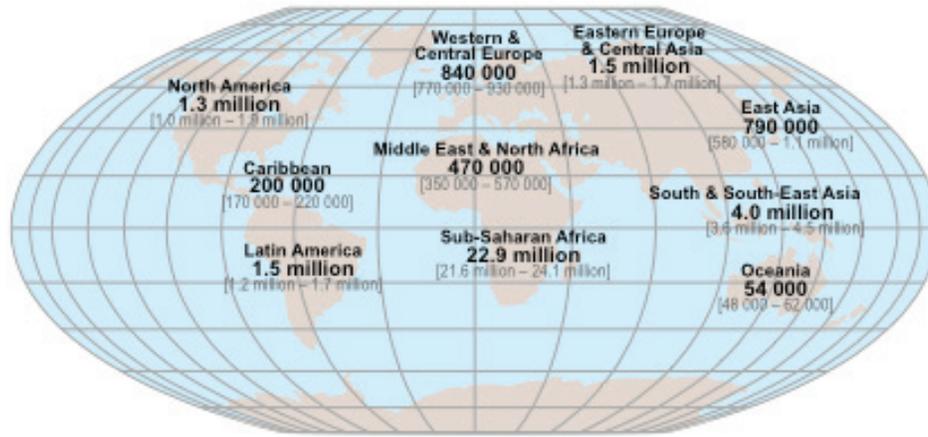
	<p>2.10. Refer to Worksheet 1.2. TB and HIV Review for a complete list of questions and answers to guide this activity. Be sure to repeat the right answers to each question before moving on to the next.</p>
	<p>2.11. Once you have completed this activity, ask participants to return to their seats.</p>
	<p>2.12. Explain that it is important to realise that we must begin thinking of both HIV and TB at the same time and stop referring out for one or the other. As health care workers, we cannot continue to send patients back and forth between TB and HIV providers. We must consider and treat them both simultaneously rather than having people fall out of care from being referred for</p>
	<p>2.13. Refer participants to Handout 1.3. HIV and the Immune System.</p>
	<p>2.14. Review the content in the handout with participants.</p>
	<p>2.15. Explain that the immune system plays a very important role in the progression of HIV in both adults and children.</p>



# Worksheet 1.1. TB and HIV Statistics

**Instructions:** Review the maps, tables and diagrams below and answer the questions associated with them.

## Adults and children estimated to be living with HIV | 2010



**Total: 34.0 million** [31.6 million – 35.2 million]



### Women Aged 15 and over living with HIV:

Rank	Country	Number	Year
	Global	15,900,000	2009
	Sub-Saharan Africa	12,100,000	2009
1	South Africa	3,300,000	2009
2	Nigeria	1,700,000	2009
3	India	880,000	2009
4/5	Mozambique	760,000	2009
4/5	Kenya	760,000	2009
6	Tanzania (United Rep. of)	730,000	2009
7	Zimbabwe	620,000	2009
8	Uganda	610,000	2009
9	Zambia	490,000	2009
10	Russian Federation	480,000	2009
11	Malawi	470,000	2009

1. Which country has the highest number of women living with HIV and AIDS in the world?

*South Africa 3,300,000*

2. South African women represent what percentage of all women living with HIV globally?

*20,8%*

.....

**Children Aged <15 years and Older Living with HIV:**

Rank	Country	Number	Year
	Global	2,500,000	2009
1	Nigeria	360,000	2009
2	South Africa	330,000	2009
3	Kenya	180,000	2009
4	Tanzania (United Rep. of)	160,000	2009
5/6	Uganda	150,000	2009
5/6	Zimbabwe	150,000	2009
7	Mozambique	130,000	2009
8/9	Zambia	120,000	2009
8/9	Malawi	120,000	2009
10	Cote d'Ivoire	63,000	2009

3. How many children are living with HIV and AIDS in South Africa in 2009?

*333,000*

4. What percentage of children living with HIV and AIDS globally does this represent?

*13%*

**Estimated HIV Prevalence among Women attending Antenatal Clinics by South African Province, (2001-2009)**

Province	Prevalence Rate (%)							
	2003	2004	2005	2006	2007	2008	2009	2010
Eastern Cape	27.1	28.0	29.5	28.6	28.8	27.6	28.1	29.9
Free State	30.1	29.5	30.3	31.1	31.5	32.9	30.1	30.6
Gauteng	29.6	33.1	32.4	30.8	30.5	29.9	29.8	30.4
KwaZulu-Natal	37.5	40.7	39.1	39.1	38.7	38.7	39.5	39.5
Limpopo	17.5	19.3	21.5	20.6	20.4	20.7	21.4	21.9
Mpumalanga	32.6	30.8	34.8	32.1	34.6	35.5	34.7	35.1
North West	29.9	26.7	31.8	29.0	30.6	29.0	30.0	29.6
Northern Cape	16.7	17.6	18.5	15.6	16.5	16.2	17.2	18.4
Western Cape	13.1	15.4	15.7	15.1	15.3	16.1	16.9	18.5
<b>South Africa</b>	<b>27.9</b>	<b>29.5</b>	<b>30.2</b>	<b>29.1</b>	<b>29.4</b>	<b>29.3</b>	<b>29.4</b>	<b>30.2</b>

5. Which province had the highest prevalence among antenatal clinics of HIV in 2010?

*KwaZulu-Natal 39.5%*

6. Which province has shown the biggest increase in percentage of HIV prevalence from 2003 to 2010?

*Western Cape 5.4% increase between 2003 and 2010*

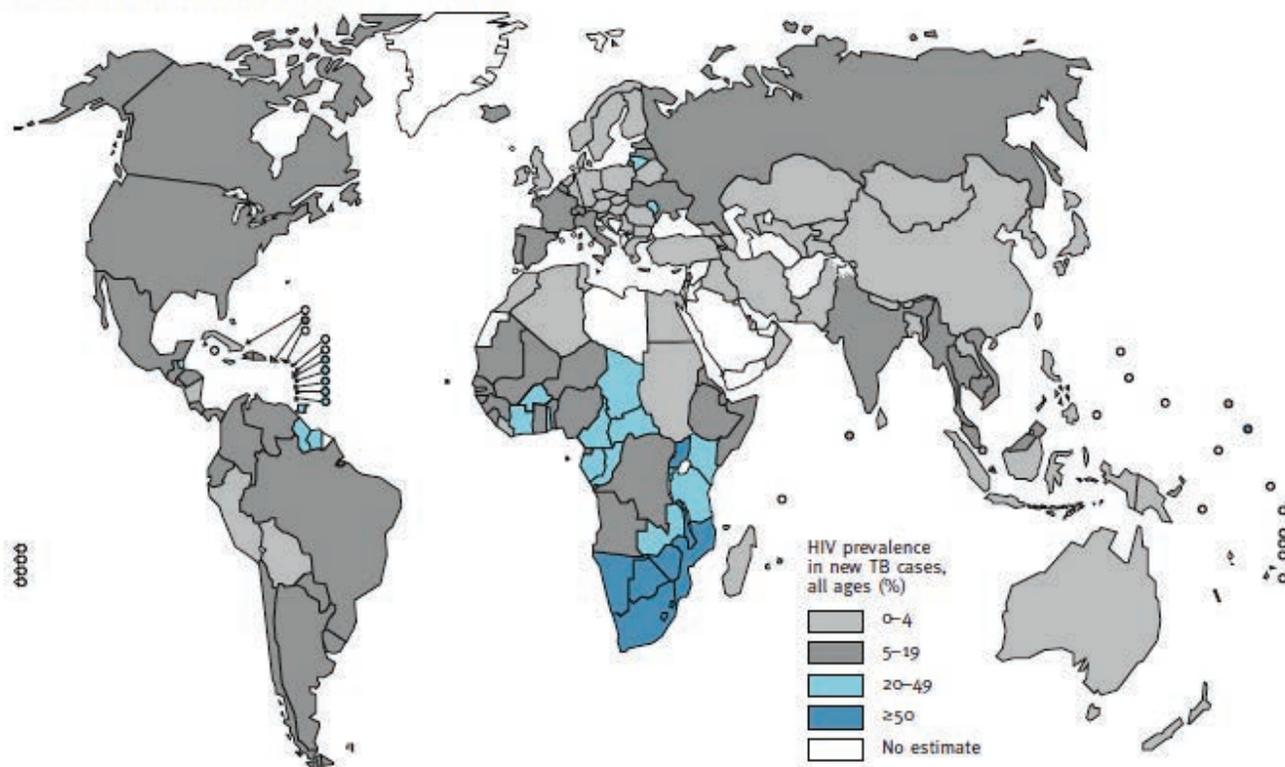
7. What has been the National trend for antenatal prevalence (i.e. increase, decrease, etc) between 2003-2009? Why do you think this may be?

*The National HIV prevalence has increased steadily, with a slight decrease between 2006-2009.*

**Tuberculosis in South Africa\***

Estimates of burden * 2009	Number (thousands)	Rate (per 100 000 pop)
Mortality (excluding HIV)	26 (14–42)	52 (29–85)
Prevalence (incl HIV)	400 (180–650)	808 (362–1 288)
Incidence (incl HIV)	490 (400–590)	971 (791–1 169)
Incidence (HIV-positive)	280 (230–340)	563 (461–675)
Case detection, all forms (%)	74 (61–91)	

**Estimated HIV prevalence in new TB cases, 2009**



TB/HIV 2009	
TB patients with known HIV status	197 448
% of TB patients with known HIV status	49
TB patients that are HIV-positive	114 523
% of tested TB patients that are HIV-positive	58
% HIV-positive TB patients started on CPT	71
% HIV-positive TB patients started on ART	42
HIV-positive people screened for TB	433 662
HIV-positive people provided with IPT	23 583

\*Source: WHO 2010 Global Report on TB Control. WHO TB Country Profiles, 2011.

**Number of MDR-TB Patients, 2004-2010 (Laboratory Diagnosis from NHLS)**

Province	2004	2005	2006	2007	2008	2009	2010	TOTAL
Eastern Cape	379	949	830	1092	1501	1858	1782	<b>7993</b>
Free State	116	151	198	179	181	253	267	<b>1545</b>
Gauteng	537	676	732	986	1028	1307	934	<b>6200</b>
KwaZulu-Natal	583	1024	2200	2208	1573	1773	2032	<b>11393</b>
Limpopo	59	40	77	91	185	204	126	<b>782</b>
Mpumalanga	162	134	139	506	657	446	312	<b>2356</b>
Northern Cape	168	155	188	199	290	631	353	<b>1984</b>
North West	130	203	225	397	363	520	158	<b>1196</b>
Western Cape	1085	1192	1179	1771	2220	2078	1422	<b>10947</b>
<b>South Africa</b>	<b>3219</b>	<b>4120</b>	<b>5774</b>	<b>7429</b>	<b>8198</b>	<b>9070</b>	<b>7386</b>	<b>45196</b>

**Number of MDR-TB and XDR-TB Patients Started on Treatment, 2007-2010**

Province	2007		2008		2009		2010	
	MDR	XDR	MDR	XDR	MDR	XDR	MDR	XDR
Eastern Cape	932	171	772	135	847	135	927	224
Free State	158	7	233	7	148	6	167	5
Gauteng	497	45	414	40	512	25	607	30
KwaZulu-Natal	788	170	1039	163	927	177	1788	235
Limpopo	71	2	104	0	88	3	119	3
Mpumalanga	148	0	727	3	198	5	298	6
Northern Cape	145	11	148	8	253	13	230	37
North West	156	4	189	1	175	9	143	14
Western Cape	439	64	890	34	995	58	1034	61
<b>South Africa</b>	<b>3334</b>	<b>474</b>	<b>4031</b>	<b>391</b>	<b>4143</b>	<b>431</b>	<b>5313</b>	615

*\*\* Source: Management of Drug Resistant Tuberculosis Policy Guidelines. South Africa Department of Health. 2011*

Study the data above and answer the following questions:

8. What is the incidence of all forms of TB in South Africa?

*971/ 100,000 people*

9. What percentage of persons screened for TB were HIV-positive?

*58%*

10. What percentage of TB patients know their HIV status?

*49%*

11. Which province has the most number of MDR-TB cases in 2010?

*KwaZulu-Natal*

12. How many registered people with MDR-TB were NOT started on Treatment in South Africa in 2010?

*2073*

13. How many people died with all forms of TB (deaths per 100,000 population/2009)?

*52/100,000*



## Worksheet 1.2. TB and HIV Review

### HIV and AIDS

- What is the difference between HIV and AIDS?  
*HIV is the virus that causes immunodeficiency, AIDS is the progression of HIV infection that results from the destruction of the immune system leading to the occurrence of diseases. HIV is the infection, AIDS is the disease. Everyone with HIV does not have AIDS; however, everyone with AIDS does have HIV infection. AIDS represents the end-stage disease that generally results from untreated HIV infection.*
- Do ELISA and Rapid HIV tests test for antibodies or antigens?  
*Antibodies*
- What is the window period (also called primary HIV infection?)  
*Period between infection and when first detection of HIV antibody is possible by lab test and rapid test*

### HIV Transmission

1. Name the three primary ways HIV is transmitted.
  1. *Unprotected sexual contact with infected partner(s)*
  2. *Contact with HIV-infected blood products*
  3. *Mother-to-child transmission*

*HIV cannot be transmitted by casual contact, surface contact, hugging, breathing, insect bites, sharing water for drinking or bathing, or sharing a toilet.*
2. What biological factors increase the risk of HIV transmission?
  - *The amount of the HIV virus in blood is a risk factor. The more HIV virus in the blood, the higher the greater the risk.*
  - *Recipient's age, health and/or immune status, and also whether or not the recipient already has a sexually transmitted infection can increase susceptibility. The presence of other sexually transmitted infections increase susceptibility of acquiring and transmitting HIV two- to five-fold. The age of the recipient is important because the vaginal mucosa and cervical tissue in young women is immature, which makes them more vulnerable to STIs than older women.*
3. What behavioural factors decrease the risk of HIV transmission?  
*Delay of sexual debut; abstinence; being faithful; correct and consistent use of condoms; reduction in the number of sexual partners; and the use of ART (which may decrease, but not eliminate, risk).*
4. Which populations are at increased risk for HIV?  
*Persons with more sex partners, migrant/immigrant populations, men who have sex with men, intra-genders/trans-genders, unborn children individuals who use drugs, orphans and vulnerable children, migrants (other responses also possible)*

### Immune System

1. What are the major steps of the life cycle of HIV?  
*Attachment through the interaction between viral glycoprotein and the CD4 receptor and co-receptors; fusion and release of RNA into the cytoplasm of the cell; reverse transcription (RT) to produce proviral DNA; integration of proviral DNA to host DNA (integrase); synthesis of viral proteins (protease); assembly and release of a complete virion.*
2. How does HIV cause AIDS?  
*HIV uses CD4 cells for reproduction. Once infected, T-cells are destroyed; the immune system deteriorates, making it vulnerable to infections.*

## ART

1. How do ARVs work?
  - *Antiretrovirals interrupt the replication of HIV within the CD4 cell.*
  - *Different antiretrovirals keep HIV from being replicated along different points in this cycle.*
  - *With the assistance of several antiretrovirals, it is more likely that HIV will not be able to multiply.*
  - *If HIV does not multiply, then CD4 cells are allowed to replicate and increase as they normally would.*
  - *This allows the immune system to function better, decreasing the number of HIV-related infections and conditions.*
2. At what CD4 count is ARV start recommended (for persons without TB and not pregnant)?
  - *After April 2012, anticipate all pregnant women*
  - *Until new guidelines  $\leq 350$  cells/uL for lifelong ART*
  - *All eligible for PMTCT*

## TB

1. How is TB transmitted?

*TB transmission occurs from persons with active pulmonary TB. When a person with infectious pulmonary TB (PTB) coughs, laughs, sneezes, or speaks, tiny droplets are released into the air. TB droplets remain suspended in the air for hours, making TB more infectious than many other respiratory pathogens. TB can be transmitted when another person inhales these tiny droplets of airborne bacteria. A person must inhale the air containing the droplet nuclei in order for transmission to occur.*
2. Which populations are at increased risk for TB?

*Persons working/living in the mines, close contacts of persons infected with TB, health care workers, incarcerated persons, migrants/immigrants, anyone that has a suppressed immune system*
3. If a pregnant woman has both TB and HIV, when is she eligible for ART start?

*She is eligible for ART regardless of CD4 count and will likely start as soon as TB meds stabilised (2 weeks or more after start of TB treatment)*
4. Where is M(X)DR-TB to be treated?

*At all levels of the health care system*
5. What is the difference between TB infection and TB disease?

*People can be exposed to and infected with TB, but some may not immediately develop the disease. Those with strong immune systems may be able to control the infection and keep it from becoming a disease. This is called TB infection. TB infection means that there is no active multiplication, there are no signs and symptoms, and the person is not infectious. Over time, or with risk factors such as HIV and AIDS, the immune system fails to control infection and TB disease prevails. In the case of TB disease, bacilli actively multiply, the person has signs and symptoms of TB, multiple organs can be involved (e.g., lungs, lymphatic system, glands), and the person is infectious (pulmonary TB).*
6. How do TB and HIV interact?

*HIV complicates the diagnosis of TB. The presentation of TB is altered by HIV, and TB complicates the treatment of HIV due to drug interactions. A joint strategy for HIV and AIDS, STI and TB control in South Africa was developed in 2001. The package of TB/HIV care developed for HIV-infected patients includes routine screening for TB and the offer of treatment to those with TB.*



## *Handout 1.3. HIV and the Immune System*

### **Role of the Immune System**

The immune system protects the body from disease and injury by recognising and destroying:

- Infectious organisms such as viruses, bacteria, fungi, and parasites
- Abnormal cells
- Foreign objects (anything from splinters to transplanted organs)

The immune system consists of both innate immunity (skin, mucous membranes) and acquired/adaptive immunity (T-cells, B-cells).

Innate immunity refers to non-specific defences, meaning these systems recognise and respond to pathogens in a generic way and do not confer long-lasting immunity against a pathogen. Examples of innate immunity include inflammation, which is the first response to the immune system, and cellular barriers, which identify and eliminate pathogens.

Acquired/adaptive immunity allows for a stronger immune response, which is antigen-specific. Part of this system allows for immunological memory, where each pathogen is remembered by a signature antigen, thereby allowing the body to mount specific responses when presented with an antigen. Lymphocytes, including T- and B-cells, are examples of this type of immunity.

### **Cells of the Immune System**

The main cells of the immune system are lymphocytes and macrophages. Lymphocytes include T-lymphocytes, which cover the cell-mediated immune response, CD4 receptors, which are found on a variety of cells but mainly on T4-lymphocytes (T-helper cells), and B-lymphocytes, which make antibodies. Macrophages consist of antigen presenters and engulfing cells (phagocytes).

### **The Effect of HIV on the Immune System**

HIV uses CD4 cells for reproduction. CD4 cells are cells that carry CD4 receptors on their surface. CD4 receptors are protein molecules and are found on the surface of a variety of cells of the immune system. CD4 receptors are found on a variety of cells but mainly on T4-lymphocytes (T-helper cells). Once infected T-cells are destroyed, the immune system deteriorates, making it vulnerable to infections.

### **The Effect of TB on the Immune System**

TB is transmitted through droplets, such as when someone coughs. TB infection occurs when exposure has taken place but the immune system has not cleared the infection. In cases when an individual has a healthy immune system, the immune system will build a wall around the infection, preventing active TB disease. However, if at some point in time the immune system becomes weaker, the TB infection can affect the lungs or other organs and become active TB disease. Some types of TB, such as lymphatic TB, directly affect the immune system. Lymphatic TB is a form of extra-pulmonary TB which affects the lymph nodes, a gland of the immune system.

### **The Effect of HIV and TB on the Immune System**

As the immune system attempts to rid itself of TB, it becomes weaker. Thus, TB can cause the CD4 count to be further depleted. If an individual is HIV infected, the immune system may already be weak, leading to a much greater chance of developing active TB disease. Individuals with low CD4 counts as a result of HIV, are also much less likely to be cured of TB, even with TB treatment and are more likely to be re-infected if re-exposed.



## *Trainer Tool 1.4. Statements for Review Activity*

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What is the difference between HIV and AIDS?

-----

How does HIV cause AIDS?

-----

What are the major steps of the life cycle of HIV?

-----

How do ARVs Work?

-----

How do TB and HIV interact?

-----

At what CD4 count is ARV start recommended  
(for persons without TB and not pregnant)?

-----

-----  
Which population is at increased risk for HIV transmission?  
-----

Name the three primary ways HIV is transmitted.  
-----

What biological factors *increase* the risk of HIV transmission?  
-----

Where is M(X)DR-TB to be treated?  
-----

What is the window period?  
-----

Do ELISA and Rapid Tests test for antibodies or antigens?  
-----

What behavioural factors *decrease* the risk of HIV transmission?  
-----

-----  
How is TB transmitted?  
-----

What is the difference between TB infection and TB disease?  
-----

Which populations are at increased risk for TB?  
-----

If a pregnant woman has both TB and HIV,  
when is she eligible to start ART?  
-----

## Session 2. Diagnosis of HIV in Adults and Children



**Total Session Time: 1 hours and 20 minutes**

### Learning Objectives:

By the end of this session, participants will have:

- Identify key components in HIV diagnosis and testing in children and adults, including pregnant women.
- Demonstrate effective clinical application of algorithms for HIV diagnosis.
- Demonstrate accurate recording and reporting, using correct tools.

### Session Overview

Step	Time	Activity/Method	Content	Resources Needed
1	40 minutes	Group Discussion Case Studies	HIV Testing in Pregnancy	Handout 2.1, 2.2 Worksheet 2.3
2	40 minutes	Group Activity	Using SA HIV Diagnostic Algorithm for Children under 18 months	Handouts 2.4, 2.5, 2.7 Worksheet 2.6 PMTCT Cards Paediatric Algorithm Card



### Resources Needed

- Handout 2.1. Overview of Provider-initiated Counselling and Testing in the Context of PMTCT
- Handout 2.2. HIV Testing for Pregnant Women
- Worksheet 2.3. Case Studies – Pregnant Women
- Handout 2.4. Children who Should be Offered HIV Testing
- Handout 2.5. Recommended Testing Algorithm for Abandoned Children
- Worksheet 2.6. Using South Africa’s Diagnostic Algorithm for Children under 18 Months
- Handout 2.7. Legal Issues Related to HIV Testing in Children
- PMTCT Cards (pages 74 - 83 CRG)
- HIV Testing Algorithm Card (page 9 CRG)
- Paediatric Algorithm Card (page 11 CRG)
- Patient History of TB Suspect Card (page 85 CRG)
- IPT Screening Algorithm Card (page 96 CRG)
- Smear Reporting Card (page 86 CRG)
- Isoniazid Preventative Therapy in Children Card (page 97 CRG)
- Computer and LCD Projector
- Flipchart and markers
- HIV Registers



## Trainer Instructions: Step 1 (40 minutes) HIV Testing in Adults and Pregnant Woman

### Step 1 Learning Objectives:

- Describe the South Africa HIV testing algorithm.
- Explain the difference between provider-initiated counselling and testing and client-initiated counselling and testing.
- Identify key components in HIV testing in pregnant women.

### Step 1 Resources Needed:

- HIV Testing Algorithm Card (page 9 CRG)
- Handout 2.1. Overview of Provider-initiated Counselling and Testing in the Context of PMTCT
- Handout 2.2. HIV Testing for Pregnant Women
- Worksheet 2.3. Case Studies – Pregnant Women
- Flipchart and markers

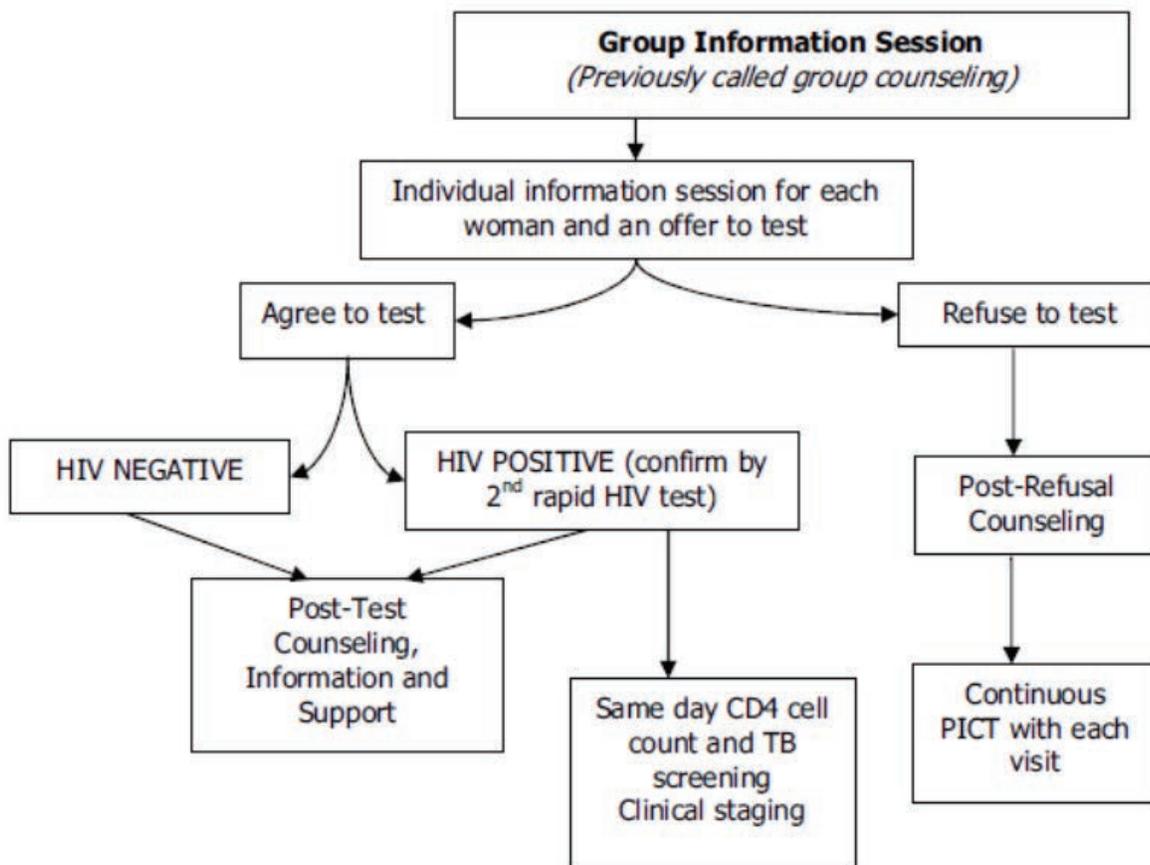
### Step 1 Trainer Instructions:

	<p>1.1. Explain that various methods are used to diagnose HIV infection. They include:</p> <ul style="list-style-type: none"> <li>• Antibody Testing: Rapid Tests, Enzyme-Linked Immunosorbent Assays (ELISA), Western Blot</li> <li>• Antigen detection – most often p24</li> <li>• DNA/RNA Detection</li> </ul>
	1.1. Refer participants to the HIV Testing Algorithm Card in the Clinical Resource Guide (page 9). Review the algorithm aloud with participants.
	1.3. Ask participants, “What is the difference between provider-initiated counselling and testing and client-initiated counselling and testing?” Record responses on a flipchart.
	1.4. Refer participants to Handout 1.1. Overview of Provider-Initiated Counselling and Testing in the Context PMTCT. Review handout with participants. Highlight when participant’s responses are the same or different from the content listed.
	1.5. Ask participants, “What are the differences in HIV testing for pregnant women versus non-pregnant women?” Possible Answers: <i>Repeat test after 2 weeks</i>
	1.6. Refer participants to Handout 1.2. HIV Testing for Pregnant Women. Review handout with participants.
	1.7. Refer participants to Worksheet 1.3. Case Studies – Pregnant Women. Ask each group to complete the worksheet. Allow 10 minutes to complete worksheet.
	1.8. Reconvene groups and ask for a group to give their answers to the first case study.
	1.9. Repeat the correct answers before moving on.
	1.10. Repeat for remaining case studies, asking for different groups to give answers for the other two case studies.



## Handout 2.1. Overview of Provider-Initiated Counselling and Testing in Context of PMTCT

- All women attending antenatal care (both first-time attendees and women attending \*follow up visits) should be given routine information about HIV testing and the PMTCT programme.
- The initial information on HIV and its transmission should be given in a group information session.
- Thereafter, all women who have not previously been tested or those who require repeat testing should meet with a counsellor, nurse, or midwife for a one-on-one individual information session.
- At the individual information session, each woman should be informed of the routine HIV testing procedure and should be given the opportunity to ask further questions. The woman should then be offered an HIV test and asked to provide consent to the testing. A woman may refuse an HIV test (“opt-out”).
- Women who opt-out of HIV testing should be offered post-refusal counselling to explore the reasons for this choice, address any misunderstandings, and encourage her to reconsider her decision not to test, but without applying undue pressure. These women should be offered routine HIV testing at each subsequent clinic visit.
- Information should be offered before the testing procedure and counselling should occur after the test results are provided.
- All women who test HIV positive should have their HIV status confirmed using a second rapid HIV test.
- Post-test counselling should be offered to both HIV positive and HIV negative women; HIV positive women should only be counselled after a second rapid HIV test has been performed to confirm a positive HIV status.





## *Handout 2.2. HIV Testing for Pregnant Women*

Testing must be seen as a key entry point to accessing HIV care and PMTCT service:

- Ensure that the testing algorithm outlined in the HCT Policy is followed.
- HIV testing of women should occur as part of the first antenatal encounter.
- At the time this routine blood sample is drawn, a rapid HIV test should be done using either a drop of blood from the venepuncture site or a finger prick.
- If the test is negative and the woman is asymptomatic, she is considered to be HIV negative
- Women who test HIV negative should be offered a repeat HIV test from 32 weeks gestation to detect late sero-conversion or late infection.
- If the rapid HIV test is positive, a confirmatory HIV test should be done utilising blood from a second finger prick and another rapid HIV test kit (from a different supplier). The woman should be present when this confirmatory test is done.
- A client is HIV positive only if the confirmatory rapid test is also positive.
- If the results are discordant (i.e., the first rapid HIV test is positive and the second rapid HIV test is negative), a specimen of blood should be collected and a laboratory ELISA test conducted. The woman must be asked to return for the HIV ELISA test results urgently (ideally within a week).
- The healthcare provider should explain the reason for the laboratory test to the client.
- For women who missed the opportunity to be tested at the first antenatal visit, the testing algorithm should be followed whenever consent is given and testing occurs.
- The CD4 cell count and TB screening should follow the positive HIV test and should be done at the same visit.
- Antenatal screenings should also be conducted – including haemoglobin, Rhesus factor and syphilis tests.

Nursing staff and lay counsellors/community health workers (CHWs) in facilities should be trained to perform the rapid HIV tests, following specific manufacturer's instructions and quality control protocols.



## Worksheet 2.3. Case Studies – Pregnant Women

*Case Study #1:* 21 year-old Thandi, presents at the antenatal clinic. This is her first visit. On examination, she is estimated to be 20 weeks pregnant. The health care worker initiates a discussion about HIV counselling and testing. Thandi expresses some interest to counselling and testing but mentions that she requires more information.

1. What steps should be taken?
  - *Thandi should attend a group information session, where routine information about HIV and its transmission will be given. Information will include the HIV testing process, ART prophylaxis and therapy, PMTCT, keeping HIV – exposed infants healthy, the importance of couple counselling and the importance of adherence to prophylaxis and treatment.*
  - *Following the group information session, Thandi should be offered an individual information session, to instil a positive focus and acceptance. The HCW should determine if Thandi understood the information given during the group information session, answer any questions Thandi might have, clarify any uncertainties, discuss the way forward, as well as PMTCT treatment options. The HCW must then obtain verbal consent for HIV testing.*
2. Thandi gives consent for HIV testing. What should now happen?
  - *Except for HIV testing, blood should be drawn for routine antenatal tests, including haemoglobin, Rhesus factor and syphilis tests.*
  - *A rapid HIV test should be done, using either a drop of blood from the venepuncture site or a finger prick.*
3. Thandi's screening HIV rapid test is positive. What should be done?
  - *A confirmatory HIV test should be done utilising blood from a second finger prick and another rapid HIV test kit from a different supplier.*
4. The confirmatory test result is positive. What should be done?
  - *Thandi should receive post- test counselling, information and support. Information should include antiretroviral therapy, the side effects of medication, counselling on safe infant feeding, contraception, family planning, stigma, disclosure, safe sexual practice and positive living.*
  - *CD4 cell count, WHO clinical staging and TB screening should all be done at the same visit as the HIV test confirmation. If screening is negative, Thandi should start IPT.*
  - *Post- test counselling at every subsequent antenatal visit and as necessary.*
  - *Ask Thandi regarding partner(s) and encourage her to invite them for partner testing*
  - *Referral to other professionals such as social workers and psychologists should be considered if Thandi requires additional support or expresses complex issues that she is unable to handle. Start AZT until CD4 count result, then add others ARVs if needed*
  - *Discuss feeding options*
5. What registers should be completed in this case?
  - *ANC register, ANC card and or Pre-ART register.*
  - *Screen for TB and complete TB suspect register or IPT register.*
  - *HCT register/Antenatal HCT register*

*Case Study #2: Abigail reports to the ANC clinic and states that she is about 3 months pregnant. During her consultation, Abigail requests to be tested for HIV.*

1. What steps will be followed up to when Abigail gets tested?
  - *Group information session*
  - *Group or Individual information session*
  - *Obtaining consent*
  - *HIV testing*
2. Abigail's HIV test result is negative. What needs is to happen?
  - *Post-test counselling, information and support including: prevention and risk reduction behaviour, risk of transmission from mother-to-child if infected during pregnancy, safe sexual practices, the high risk of transmission of HIV to her infant, if newly infected during pregnancy or breastfeeding, the benefits of exclusive breastfeeding for the first 6 months and continued breastfeeding thereafter and introduction of complementary foods.*
  - *Discuss partner(s) and encourage partner testing*
  - *If Abigail is asymptomatic, she is considered to be HIV negative.*
  - *Abigail should be offered a repeat HIV test at 32 weeks gestation.*
  - *Explain to Abigail that the HIV test at 32 weeks gestation is done to exclude late sero – conversion or late infection.*
3. What registers should be completed in this case?
  - *ANC register and her ANC card*
  - *HCT register/antenatal HCT register*



## Trainer Instructions: Step 2 (40 minutes) Using South Africa’s HIV Diagnostic Algorithm for Children less than 18 months

### Step 2 Learning Objectives:

- Demonstrate effective clinical application of the South African Algorithms for HIV diagnosis in Children less than 18 months.

### Step 2 Resources Needed:

- Handout 2.4. Children Who Should be Offered HIV Testing
- Handout 2.5. Recommended Testing Algorithm for Abandoned Children
- Worksheet 2.6. Using South Africa’s Diagnostic Algorithm for Children less than 18 Months
- Handout 2.7. Legal Issues Related to HIV Testing of Children
- Paediatric Guideline Algorithm Card (page 10 CRG)
- PMTCT Cards (pages 74 - 83 CRG)

### Step 2 Trainer Instructions:

	2.1. Refer participants to the Paediatric Guideline Algorithm Card, page 10 in CRG. Review card with participants.
	2.2. Refer participants to Handouts 2.4. Children Who Should be Offered HIV Testing and 2.5. Recommended Testing Algorithm for Abandoned Children and the PMTCT cards, pages 74 - 83 in CRG.
	2.3. Remind participants that DNA PCR testing is done for all infants <18 months of age with known HIV exposure.
	2.4. Explain that these handouts describe HIV testing in infants. Review each handout with participants.
	2.5. Refer participants to Worksheet 2.6. Using South Africa’s Diagnostic Algorithm for Children less than 18 Months.
	2.6. Explain that each group should use the algorithm to answer the case study questions.
	2.7. Allow 15 minutes for activity.
	2.8. Reconvene the groups and discuss their answers to the case studies.
	2.9. Clarify any outstanding questions related to the algorithm.
	2.10. Ask participants, “What legal issues exist for HIV testing of children?” Facilitate a brief discussion.
	2.11. Refer participants to Handout 2.7. Legal Issues Related to HIV Testing of Children. Review handout with participants. Clarify any questions related to the handout.



## *Handout 2.4. Children who Should be Offered HIV Testing*

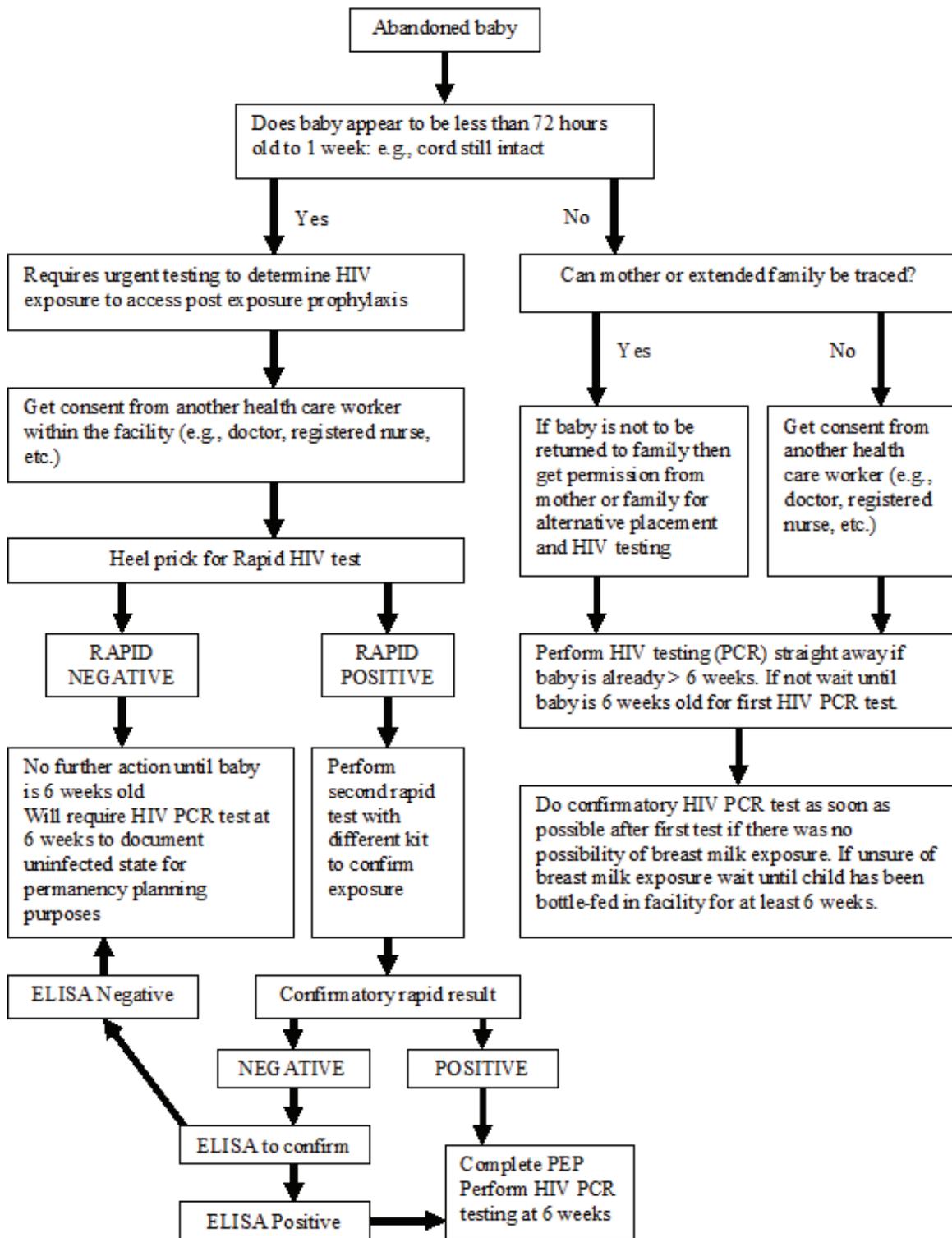
### **Children who should be offered HIV Testing:**

- All HIV-exposed infants
- Children with:
  - Clinical features suggestive of HIV infection
  - Acute illnesses, especially if severe
  - Failure to thrive
  - Un-resolving illnesses
- All children with the following IMCI classifications: Suspected symptomatic HIV infection or possible HIV infection
- All children diagnosed with TB or who have a history of TB treatment
- Family and social history:
  - Parental request to test the child
  - Mother or father or sibling on ART treatment
  - Family member with HIV infection
  - Death of mother, father or sibling
  - When the mother's HIV status is unknown and her whereabouts are unknown
  - Offer PICT to all healthy children
- When the child may have been wet-nursed or breastfed by a woman of unknown or positive HIV status
- When the child may have experienced or been at risk of sexual assault
- When it is in the best interest of the child where the child is being considered for foster or adoption placement

*Source: Clinical Guidelines: Prevention of Mother-to-Child Transmission. NDoH, South African AIDS Council. 2010.*



## Handout 2.5. Recommended Testing Algorithm for Abandoned Children



Source: South Africa National Department of Health. Policy Guideline for HIV Counselling and Testing (HCT). 2010.



## Worksheet 2.6. Using South Africa's Algorithm for Children less than 18 Months

*Case Study #1:* An HIV-exposed baby with a suspected HIV-related disease aged 12 weeks comes in for testing at your health facility. Use the algorithms for early infant diagnosis of HIV using Diagnostic PCR to determine which test to use.

The baby's information is:

Six-week PCR test was negative

Breastfed for the two months prior to the test and continued breastfeeding

Baby's mother is NOT on lifelong ART

1. What is the status of the baby?
  - *Baby is HIV-negative, but at risk. Possible the infant has a low positivity*
2. What are the next steps for working with this infant?
  - *Retest for HIV*
  - *Investigate for other causes of illness*
  - *Continue infant nevirapine until breastfeeding stops*
  - *Continue cotrimoxazole until breastfeeding has stopped and infant negative*
  - *Continue exclusive breastfeeding with mother on ART as eligible*
3. What are the next steps for working with this infant?
  - *Investigate for other causes of illness*
  - *Perform HIV Diagnostic PCR*
  - *Continue with cotrimoxazole*
  - *Refer for expedited ART if PCR is positive*
  - *Continue with nevirapine (NVP) if PCR is negative*
4. When would you retest after the last time the mother breastfeeds?
  - *6 weeks after the cessation of breastfeeding if all prior tests have been negative.*
5. What registers would be completed in this case?
  - *Registers not yet available*

*Case Study #2: An HIV-exposed baby with a suspected HIV-related disease aged 8 weeks comes in for testing using diagnostic PCR at your facility.*

The baby's information is:  
Initial PCR test is positive  
Mother is on lifelong ART  
Currently breastfed

1. What is the status of the baby?
  - *Baby is HIV-exposed with initial test indicating HIV-positive.*
  - *Since the baby is less than 1 year old, confirm status with viral load (expect viral load less than 10,000)*
2. What are the next steps for working with this infant?
  - *Stop Nevirapine*
  - *Referral for expedited ART*
  - *Continue cotrimoxazole prophylaxis and evaluate for opportunistic infection.*
  - *Recommend to continue exclusive breastfeeding for 2 years*
3. What registers would be completed in this case?
  - *Pre ART registers*
  - *ART registers when ART is commenced*

*Case Study #3: An HIV-exposed baby aged 8-months comes in for testing at your health facility. The baby appears well. Use the algorithms for early infant diagnosis of HIV using Diagnostic PCR to determine which test to use.*

The baby's information is:  
Six week PCR test was negative  
Stopped breastfeeding two months ago

1. What is the status of the baby?
  - *Baby is HIV-negative, and at risk*
2. What are the next steps for working with this infant?
  - *Initiate cotrimoxazole prophylaxis (discontinue once repeat PCR is negative)*
  - *Routine follow-up*
  - *Nutritional counselling and support and immunisations*
  - *Repeat HIV DNA PCR*
3. When should the child be retested? Which test should be conducted?
  - *Another rapid test should be obtained at 18 months of age to confirm HIV-negative status (also known as sero-conversion)*
  - *Child should be retested if he/she presents with signs and symptoms of HIV and IMCI classification of suspected HIV infection*
4. What registers should be completed in this case?
  - *HCT register*
  - *Immunisation tracking*
  - *PMTCT register*

*Case Study #4:* A recently abandoned 8 week-old infant is brought in to your health facility for testing. He is malnourished but does not otherwise appear ill. The maternal history is unknown. Use the algorithms for early infant diagnosis of HIV using Diagnostic PCR to determine which test to use.

The baby's information is:  
Baby's ELISA test is positive.

1. What is the status of the baby?
  - *The baby is HIV-exposed*
2. What are the next steps for working with this infant?
  - *Send HIV Diagnostic PCR*
  - *Start cotrimoxazole prophylaxis*
  - *Nutritional support and monitor weight and progress*
3. The PCR returns negative. What are the next steps for working with the infant?
  - *Discontinue cotrimoxazole prophylaxis since the child is HIV-negative*
4. When should the child be retested? What test should be reordered?
  - *An antibody test (rapid or ELISA) should be obtained at 18 months of age to confirm HIV negative status (also known as sero-conversion)*
  - *Child should be retested if he/she presents with signs and symptoms of HIV and IMCI classification of suspected HIV infection*
5. What registers should be completed in this case?
  - *HCT register*



## *Handout 2.7. Legal Issues Related to HIV Testing of Children*

HIV testing of any child may take place if it is in the best interest of the child and if a person legally capable of providing informed consent provides such consent. The primary caregiver of the child is able to give consent for testing regardless of parental whereabouts.

### **Subject to Section 132 of the Children’s Act, children may be tested for HIV except when:**

- It is not in the best interest of the child and no caregiver consent has been given.
- HIV testing without consent may occur when the test is necessary in order to establish whether:
  - A health worker may have contracted HIV due to contact in the course of a medical procedure involving contact with any substance from the child’s body that may transmit HIV; OR,
  - Any other person may have contracted HIV due to contact with any substance from the child’s body that may transmit HIV, provided the test has been authorised by a court.

### **Consent for HIV-test on a child may be given by:**

- The child, if the child is:
  - 12 years of age or older; OR
  - Under the age of 12 years and is of sufficient maturity to understand the benefits, risks and social implications of such a test.
- The parent or caregiver, if the child is under the age of 12 years and is not of sufficient maturity to understand the benefits, risks and social implications of such a test.
- The provincial head of social development, if the child is under the age of 12 years and is not of sufficient maturity to understand the benefits, risks and social implications of such a test.
- A designated child protection organisation arranging the placement of the child, if the child is under the age of 12 years and is not of sufficient maturity to understand the benefits, risks and social implications of such a test.
- The superintendent or person in charge of a hospital, if:
  - The child is under the age of 12 years and is not of sufficient maturity to understand the benefits, risks and social implications of such a test; AND
  - The child has no parent or caregiver and there is no designated child protection organisation arranging the placement of the child.
- A children’s court, if:
  - Consent in terms of paragraph (a), (b), (c) or (d) is unreasonably withheld; OR
  - The child or the parent or caregiver of the child is incapable of giving consent.

### **HIV-testing for foster care or adoption purpose**

If HIV-testing of a child is done for foster care or adoption purpose, the state must pay the cost of such tests where circumstances permit.

### **Section 129(9) of the Children’s Act**

A High Court or Children’s Court may consent to the medical treatment or a surgical operation on a child in all instances where another person that may give consent refuses or is unable to give such consent.

### **Confidentiality**

Children above the age of 12 and who are legally able to provide informed consent to an HIV test are entitled to maintain the confidentiality of their HIV status. Consent to disclose the HIV status of such a child must be given by the child.

The same principle should apply to children below the age of 12, who are of sufficient maturity to understand the benefits, risks, social and other implications of the test. However, a strict interpretation of the law concludes that the parents and legal guardians of children below the age of 12 may have a legal right to have access to the results of the HIV test.

In the case of children below the age of 12 and who cannot consent to HIV testing, consent to disclosure must be given by the persons referred to above.”

*Source: South Africa National Department of Health. Guidelines for the Management of HIV in Children. 2nd. Edition. 2010.*

## Session 3. Diagnosis of TB and DR-TB in Adults and Children



**Total Session Time: 3 hours and 5 minutes**

### Learning Objectives:

By the end of this session, participants will be able to:

- Describe the signs and symptom of TB.
- Differentiate between drug resistant-TB and other forms of TB.
- Demonstrate effective clinical application of algorithms for TB diagnosis.
- Demonstrate accurate recording and reporting, using correct tools.

### Session Overview

Step	Time	Activity/Method	Content	Resources Needed
1	90 minutes	Group Work	TB Diagnosis in Adults	Handouts 3.1, 3.2, 3.3, 3.4, 3.5, 3.8 Worksheet 3.7 Patient History of TB Suspect Card Clinical Resource Guide LCD Projector, computer Slides: Sputum Collection and Reporting TB Case Identification and Follow-up Sputum Register (GW20/13) Laboratory Specimen Request Form Summary of Suspect Register (GW20/13b) TB Register Patient Clinic/Hospital Card Patient Treatment Card DR-TB Register DR-TB Treatment Card DR-TB Patient Follow-Up Card Request for Sputum Examination – for second sputum specimen for culture and DST/LPA Referral Form
2	45 minutes	Group Activity	TB Diagnosis in Children	Handouts 3.9 and 3.10 Worksheet 3.11 Clinical Resource Guide Flipchart and markers
3	50 minutes	Group Discussion	Signs and Symptoms of TB in Children and Adults	Handout 3.12 Flipchart and markers Clinical Resource Guide LCD projector and computer Slides S2: Symptoms of TB



## Advance Preparation

Step 3: Write the following, each on a separate piece of flipchart paper, leaving room for participants to write the definitions:

- “Definite TB Case”
- TB Suspects
- Drug Resistant TB Suspects
- Health Systems Related Drug Resistance Risk Factors
- Patient Related Drug Resistance Risk Factors



## Resources Needed

- Handout 3.1. TB Definitions
- Handout 3.2. Algorithm for TB Diagnosis in a New Case Using Smear Microscopy and Culture
- Handout 3.3. Algorithm for TB Diagnosis in TB Suspects Using the Line Probe Assay (LPA)
- Handout 3.4. Algorithm for TB Diagnosis in TB Suspects Using the GeneXpert
- Handout 3.5. Algorithm for TB Diagnosis in High Risk TB Suspects and Re-treatment Cases
- Handout 3.6. Preventative TB Therapy in Adults
- Worksheet 3.7. Algorithm Practice
- Handout 3.8. Effects of HIV on TB Signs and Symptoms
- Handout 3.9. Diagnosing TB in Children
- Handout 3.10. Algorithm for Screening a Child with Documented TB Exposure
- Worksheet 3.11. Diagnosing TB in Children
- Handout 3.12. Extra-pulmonary Tuberculosis
- Patient History of TB Suspect Card (page 85 CRG)
- IPT Screening Algorithm Card (page 96 CRG)
- Smear Reporting Card (page 86 CRG)
- Isoniazid Preventative Therapy in Children Card (page 97 CRG)
- Computer and LCD Projector
- Slides: Symptoms of TB
- Slides: Sputum Collection and Reporting
- Flipchart and markers
- TB Case Identification and Follow-up Sputum Register (GW20/13)
- Laboratory Specimen Request Form
- Summary of Suspect Register (GW20/13b)
- TB Register
- Patient Clinic/Hospital Card
- Patient Treatment Card
- DR-TB Register
- DR-TB Patient Follow-Up Card
- Request for Sputum Examination – for second sputum specimen for culture and DST/LPA
- Referral Form



## **Trainer Instructions: Step 1 (90 Minutes)** **Pulmonary TB Diagnosis in Adults**

### *Step 1 Learning Objectives:*

- Explain how pulmonary TB disease is diagnosed using sputum smears.
- Explain diagnostic procedures for smear negative pulmonary TB disease.
- Identify who is eligible for Isoniazid Preventative Therapy.

### *Step 1 Resources Needed:*

- Handout 3.1. TB Definitions
- Handout 3.2. Algorithm for TB Diagnosis in a New Case Using Smear Microscopy and Culture
- Handout 3.3. Algorithm for TB Diagnosis in TB Suspects Using the Line Probe Assay (LPA)
- Handout 3.4. Algorithm for TB Diagnosis in TB Suspects Using the GeneXpert
- Handout 3.5. Algorithm for TB Diagnosis in High Risk TB Suspects and Re-treatment Cases
- Handout 3.6. Preventative TB Therapy in Adults
- Worksheet 3.7. Algorithm Practice
- Handout 3.8. Effect of HIV on TB Signs and Symptoms
- Patient History of TB Suspect Card (page 85 CRG)
- IPT Screening Algorithm Card (page 9 CRG)
- Clinical Resource Guide
- Computer and LCD Projector
- Sputum Collection and Reporting Slides
- TB Case Identification and Follow-up Sputum Register (GW20/13)
- Laboratory Specimen Request Form
- Summary of Suspect Register (GW20/13b)
- TB Register
- Patient Clinic/Hospital Card
- Patient Treatment Card
- DR-TB Register
- DR-TB Treatment Card
- DR-TB Patient Follow-Up Card
- Request for Sputum Examination – for second sputum specimen for culture and DST/LPA
- Referral Form

Step 1 Trainer Instructions:

	<p>1.1. Ask participants, “What are the 3 Is?”            Answer: The 3 Is are a World Health Organization (WHO) initiative to help reduce TB infection on a global scale. The 3 Is are: Intensified case finding, Isoniazid preventative therapy and TB infection control. These, combined with early initiation of ART, when appropriate, will help reduce the rates of TB infection and disease.</p>
	<p>1.2. Post the previously prepared flipchart papers around the room. Assign each group a flipchart to write the response to each of the statements on the flipchart pages. After several minutes ask each group to rotate to the flipchart paper on their right – and make any additions or corrections as they see fit.</p>
	<p>1.3. Ask each group to read the response on the flip chart paper they are standing next to. Ask if anyone else has anything they wish to add. Continue until all pages have been read aloud.            Anticipate the following responses:            Definite TB Case: A client with Mycobacterium tuberculosis complex identified from a clinical specimen, either by smear microscopy, culture or molecular line probe assays            TB Case: A definite case (as defined above) or a client has been diagnosed with TB by a health care worker based on clinical picture, x-rays or other tests and started on a full course of TB treatment            TB Suspects: Any person who presents with symptoms or signs suggestive of TB: cough, night sweats, fever and weight loss is a TB suspect. Additionally, anyone with history of exposure to TB or who is HIV-infected.            DR Suspects: Failures of new patient            Failures of Re treatment cases            Relapse and defaulters who are smear positive at 3 months of re-treatment            Symptomatic contacts of known MDR TB cases            TB Patients that remains positive at 3 months of treatment            Patients that has exposure to MDR TB Outbreaks            Health-Systems Related DR Risk Factors: Inadequate treatment regimens            Inadequate dosage            Poor quality drugs            No DOT system            Poor infection control practices            Poor patient treatment adherence counseling            Poor case-finding            Patient Related DR Risk Factors: Poor adherence to TB treatment            History of previous TB treatment            Adverse effects to TB treatment            MDR-TB close contact            Malabsorption            HIV</p>
	<p>1.4. Refer participants to Handout 3.1. TB Definitions. Quickly review definitions with participants.</p>
	<p>1.5. Stress the need for case finding, reflecting on the risk factors for drug resistance. Explain that there the tools for case finding include:</p> <ul style="list-style-type: none"> <li>• Subjective: History Taking, the ASK</li> <li>• Objective: Physical exam, the LOOK, LISTEN and FEEL</li> <li>• Assessment: Sputum examination</li> <li>• Assessment: X-ray exam</li> <li>• Assessment: Tuberculin skin testing (in children)</li> </ul>
	<p>1.6. Refer participants to Patient History of TB Suspect Card, page 83 in CRG.</p>
	<p>1.7. Explain the importance of taking a thorough and specific history of a patient and focusing on all of the signs and symptoms outlined in the previous activity when conducting a physical exam.</p>

	<p>1.8. Ask participants, “Why the emphasis on sputum samples?”</p> <ul style="list-style-type: none"> <li>• The South African TB Diagnosis Algorithm uses sputum samples as a basis for treatment.</li> <li>• Even some of the newer tests – which include drug resistance testing – rely on sputum samples</li> </ul>
	<p>1.9. Remind participants that sputum collection technique is very important. Present slides S2: Sputum Collection and Reporting with participants using trainer notes and referencing recording and reporting registers.</p>
	<p>1.10. Refer participants to Handouts 3.2. Algorithm for TB Diagnosis in a New Case Using Smear Microscopy and Culture, Handout 3.3. Algorithm for TB Diagnosis in TB Suspects Using the Line Probe Assay (LPA), Handout 3.4. Algorithm for TB Diagnosis in TB Suspects Using the GeneXpert and Handout 3.5. Algorithm for TB Diagnosis in High Risk TB Suspects and Re-treatment Cases. Explain that the algorithms come from the TB national guidelines and are the foundation for diagnosing TB in new and re-treatment cases.</p>
	<p>1.11. Review each algorithm with participants. Explain the differences between algorithms based on availability of different laboratory tests, including Line Probe Assay and GeneXpert? Ask participants, “What is the benefit of using LPA or GeneXpert?” Explain that both of these allow for diagnosis of drug resistant TB earlier, thus avoiding more infections and improving the chances of patient survival.</p>
	<p>1.12. Remind participants that one of the 3 I’s is Isoniazid preventative therapy. Ask, “Who is eligible for Isoniazid preventive therapy?”</p>
	<p>1.13. Refer participants to Handout 3.6. Preventative TB Therapy in Adults. Read aloud as a large group.</p>
	<p>1.14. Divide participants into groups of five. Refer participants to Worksheet 3.7. Algorithm Practice. Explain that each group will have 10 minutes to complete case questions in the worksheet and complete appropriate recording registers.</p>
	<p>1.15. Reconvene participants and ask for a group to give their answer to Case 1.</p>
	<p>1.16. To save time, ask if any groups came to a different conclusion and if so, why.</p>
	<p>1.17. Repeat the correct answer before moving on.</p>
	<p>1.18. Repeat this for each of the Cases, asking for a different group to report out.</p>
	<p>1.19. Ask participants “Are there any special challenges in diagnosing pulmonary TB among persons with HIV?” Answer: Yes! HIV-positive patients with pulmonary TB often have negative sputum smears even though TB is more common in HIV-positive persons. It is important to recognise the clinical and chest radiographic characteristics of HIV-TB so that patients who are smear-negative can be recognised and treated appropriately. In adults, refer to the algorithms for TB diagnosis.</p>
	<p>1.20. Ask participants, “What is the effect of HIV infection on TB signs and symptoms?”</p>
	<p>1.21. Refer participants to Handout 3.7. Ask for a participant to read the handout aloud. Highlight where participant responses were the same and different.</p>
	<p>1.22. Remind participants that it is important to always screen for both HIV and TB. If someone has TB or HIV, it is essential to screen for the other infection!</p>
	<p>1.23. Summarise Activity: Explain that key and important changes in the 2011 algorithms include clarification of diagnosing smear negative TB and emphasising getting drug susceptibility testing earlier on in retreatment cases. Also, the algorithm in known HIV-positive patient calls for providing antibiotics, conducting a chest x-ray and sending a third specimen all at the same time rather than waiting to see if the patient improves on antibiotics.</p>

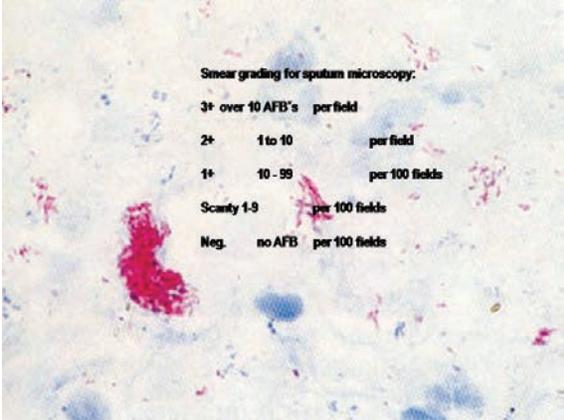
Slide 1

## Diagnostic Tests

- Sputum specimens are essential to diagnosis
- Various diagnostic tests now available
  - Smear microscopy
  - Culture – MGIT (liquid medium)
  - DST
    - 1st Line
    - 2nd Line
  - Line Probe Assay
  - GeneXpert
- Don't forget to include the forms!
- Sputum specimen must be:
  - Adequate
  - Good quality




Slide 2



**Smear grading for sputum microscopy:**

3+	over 10 AFB's	per field
2+	1 to 10	per field
1+	10 - 99	per 100 fields
Scanty 1-9		per 100 fields
Neg.	no AFB	per 100 fields



Slide 3

## GeneXpert Test

- Nucleic Acid Amplification Test – identifies targeted nucleic acid sequences in the TB genome
- Detects TB and Rifampicin resistance within < 2 hours – called “rapid TB Test”
- Better sensitivity than microscopy and culture
- Requires little hands-on or trained laboratory time



Slide 4

## Line Probe Assays

- DNA PCR is used to identify *MTB* resistance
- Used to detect Rifampicin and Isoniazid Resistance sooner
- Cultures still necessary for definitive diagnosis of smear-negative TB
- DST still required to diagnose XDR-TB
- Requires trained and skilled laboratory staff



Slide 5

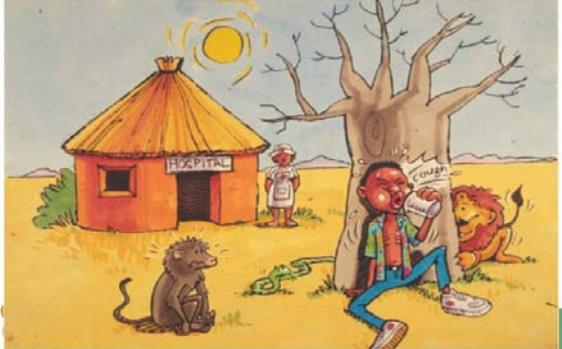
## Culture and Drug-Sensitivity Testing

- Culture takes approximately 28-42 days, DST an additional 28-42 days
- Culture and DST are still indicated for ALL patients with multi-drug resistant TB in order to exclude XDR-TB or confirm a previous diagnosis



Slide 6

## Sputum Collection Procedure




Slide 7

## Sputum investigation

- PRE -TREATMENT
  - One or two specimens to diagnose (depending on sputum testing availability)
  - Re-treatment cases TB culture & susceptibility
- END OF INTENSIVE PHASE
  - Two specimens to monitor progress & To monitor smear conversion
- AT END OF TREATMENT
  - To prove cure
  - Identify treatment failure



Slide 8

## Sputum Collection & Labeling

- 1 or 2 specimens to be collected
  - 1st specimen – “on the spot”
  - 2nd specimen – early morning the following day (or do second supervised sputum 2-3 hours later)
  - Extra 1 for TB culture & sensitivity for re-treatment patients
- Correct labeling is essential to save time and prevent errors



Slide 9

## Steps in Sputum Collection

1. Let person rinse mouth with water
2. Ask patient to direct sputum into container without contaminating outside of container
3. Give patient container without the lid
4. Hold lid yourself
5. Demonstrate deep cough from bottom of chest
6. Encourage person to produce specimen after deep coughing
7. Replace lid immediately
8. Secure lid press on centre till click is heard
9. Wash hands after collection
10. Label properly



Slide 13

## Safe Sputum Collection (2)

- Collect samples outdoors (best option) or in a well ventilated room
- Use sterile rigid containers, properly closed, apply standard precautions
- Accurate labeling, prompt transport is necessary
- Wash your hands



Slide 10

## Storage & Transport

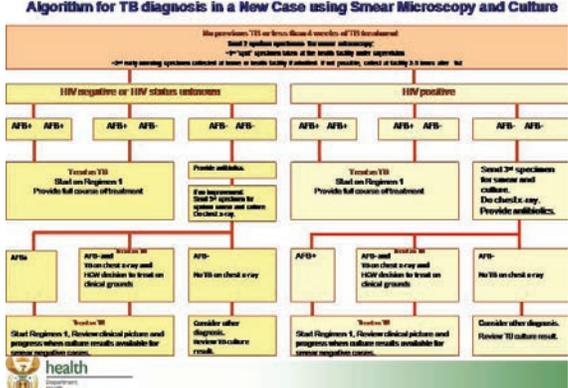


- **STORAGE**
  - Store in fridge/cooler box (do NOT freeze)
  - Protect against heat and sunlight
  - Place in plastic bag to prevent contamination
- **TRANSPORT**
  - Transport to laboratory as soon as possible
  - Prevent spillage!
  - Educate the driver of the vehicle



Slide 14

## Algorithm for TB diagnosis in a New Case using Smear Microscopy and Culture



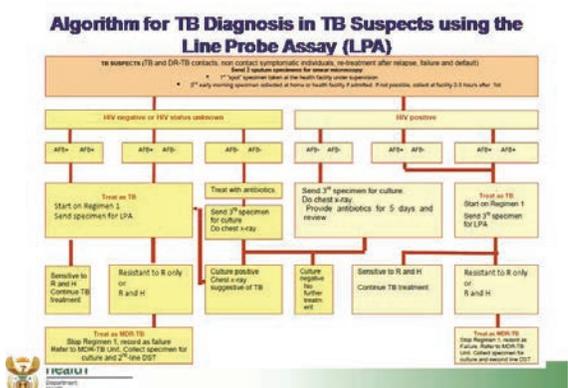

Slide 11

## How can the spread of TB infection be prevented during sputum collection?



Slide 15

## Algorithm for TB Diagnosis in TB Suspects using the Line Probe Assay (LPA)




Slide 12

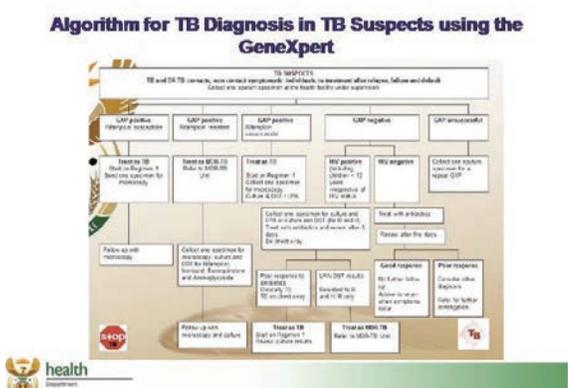
## Safe Sputum Collection

- Remember - TB is spread by infected droplets
- All health care workers must protect themselves when supervising sputum collection
  - Do not stand directly in line of air flow
  - Use N95 mask



Slide 16

## Algorithm for TB Diagnosis in TB Suspects using the GeneXpert




Slide 17

### Algorithm for TB Diagnosis in Re-treatment Cases and MDR-TB Contacts using Smear

Previous TB (1 or more weeks of TB treatment) and return to TB treatment after failure, default and relapse, contacts of MDR-TB cases

Send 2 sputum specimens:  
 • 1st sputum specimen at the health facility for sputum smear microscopy  
 • 2nd sputum specimen for sputum smear microscopy, culture and drug susceptibility testing (DST), collected at home or health facility if within 2-3 days after the first.

Flowchart steps:  
 - HIV negative on HIV status unknown: AFB+ AFB+, AFB- AFB-, AFB+ AFB-, AFB- AFB-  
 - HIV positive: AFB+ AFB+, AFB- AFB-, AFB+ AFB-, AFB- AFB-  
 - AFB+ AFB+ (HIV neg/unk): Treat as TB. Start on Regimen 2. Provide full course of treatment. Review drug sensitivity.  
 - AFB- AFB- (HIV neg/unk): Provide antibiotics. If no improvement, send 2<sup>nd</sup> specimen for culture and drug sensitivity.  
 - AFB+ AFB- (HIV pos): Treat as TB. Start on Regimen 2. Provide full course of treatment. Review drug sensitivity.  
 - AFB- AFB- (HIV pos): Send 2<sup>nd</sup> specimen for smear. Do when +ve. Provide antibiotics.  
 - AFB+ AFB- (HIV neg/unk): AFB and TB on Chest x-ray and HCGI decide to treat on clinical grounds. Start on Regimen 2. Review clinical picture and progress after culture and DST analysis.  
 - AFB- AFB- (HIV neg/unk): No TB on Chest x-ray. Consider other diagnosis. Review TB culture result.  
 - AFB+ AFB- (HIV pos): AFB and TB on Chest x-ray and HCGI decide to treat on clinical grounds. Start on Regimen 2. Review clinical picture and progress after culture and DST analysis.  
 - AFB- AFB- (HIV pos): No TB on Chest x-ray. Consider other diagnosis. Review TB culture result.

Slide 21

### Summary of the Suspect Register

Slide 18

### NATIONAL HEALTH LABORATORY SERVICE

PATIENT DETAILS	CLINIC DETAILS	CLINICAL DETAILS
Patient ID: AAAAA027 PLEASE PRINT CLEARLY Surname: _____ First Name: _____ File Number: _____ Identity Number: _____ Date of Birth: _____ Age: _____ Patient's Physical Address: _____ Postal Code: _____ Gender: <input type="checkbox"/> MALE <input type="checkbox"/> FEMALE	Clinic Name: _____ Sister's Name: _____ Clinic (Responsibility) Code: _____ Telephone Number: _____ File Number: _____ Health District: _____ District Code: _____ Date Collected: _____ Time Collected: _____ Specimen Type: _____	Diagnosis: _____ Current Treatment: _____ TB Sputum Specimen (✓ Tick) Sputum: At 2-3 mlts _____ At 5-7 mlts _____ Other: _____ <b>TEST INVESTIGATION</b> <b>TICK TESTS REQUIRED</b> <input checked="" type="checkbox"/> AFB Smear AFB _____ TB Culture for Mycobacterium TB tests _____ TB Sensitivity (9H + E) _____ TB Sensitivity: other specify _____ HIV Antibody _____ HB _____ RPR _____ IR _____ Glucose _____ MCS (not TB) _____ Other tests: _____

SEE OVERLAP FOR: GYN/OB/GYN CYTOLOGY REQUEST

Slide 22

### TB Register (GW20/11)

Slide 19

### Case Identification and Sputum Follow-up Register (GW 20/13) & Summary

- **When:** Use for all suspects
- **Purpose:**
  - Improve 'Index of suspicion'
  - Diagnose TB cases early
  - Commence positive TB cases on treatment
  - Identify primary defaulters and trace immediately
  - Measure Turn-Around-Time (TAT)
    - In a hospital, anticipate 24 hours
    - If longer than 48, then investigate

Slide 20

### Case Identification and Sputum Follow-up Register (GW20/13)



## *Handout 3.1. TB Definitions*

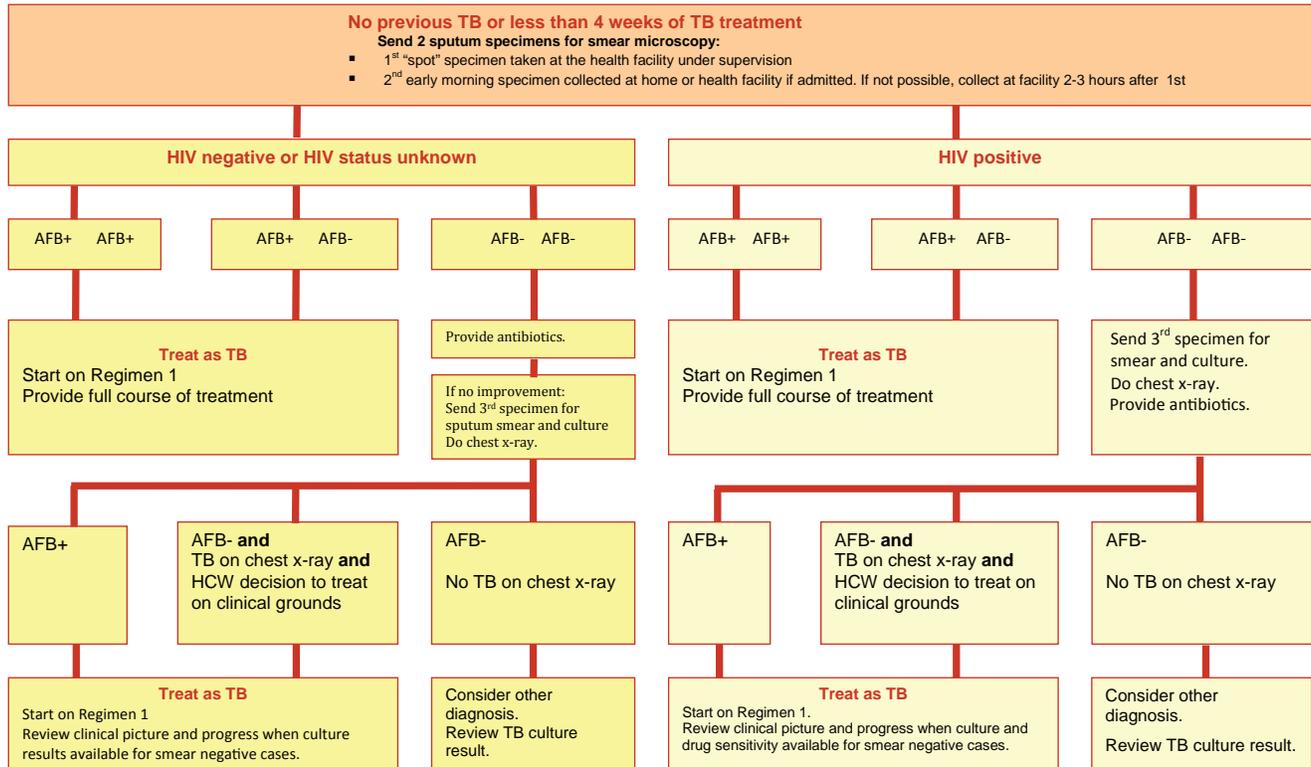
1. Tuberculosis Suspect: Any person who presents with symptoms or signs suggestive of TB. The most common being a cough of 2 weeks or more, drenching night sweats, loss of weight and fever.
2. Definite TB Case: A client with Mycobacterium tuberculosis complex identified from a clinical specimen, either by smear microscopy, culture or nucleic acid amplification tests (LPA, GeneXpert).
3. Tuberculosis Case: A definite case (as defined above) or a client that has been diagnosed with TB by a health care worker based on clinical picture, x-rays or other tests and started on a full course of TB treatment.
4. New Case: A client who has never had treatment for TB or who has taken anti-tuberculosis drugs for less than 4 weeks previously. New patients may have positive or negative bacteriology and may have disease at any anatomical site.
5. Previously Treated: A client who has taken treatment for TB for four weeks or more in the past and either relapsed, defaulted or had treatment failure. They may have positive or negative bacteriology and may have diseases at any anatomical site.
6. Relapse: A sputum smear or culture-positive pulmonary TB client who received treatment and was declared cured or treatment completed at the end of the treatment period and has now developed sputum smear or culture positive pulmonary TB again.
7. Re-infection: Newly acquired infection. May be drug-sensitive or drug resistant (primary resistance)
8. Failure of treatment regimen for new patients (Regimen 1 or 3): Failures of Regimen 1 or Regimen 3 are patients who remain positive at the end of the intensive phase or become sputum smear or culture positive 5 months or later during the course of treatment.
9. Failure of retreatment regimen (Regimen 2): Failures of Regimen 2 are defined as patients who remain sputum positive at the end of the intensive phase or become sputum smear or culture positive 7 months or later during the course of treatment.
10. Treatment after Default: A client who completed at least one month of treatment and returns after having interrupted treatment for two consecutive months or more, and is still smear or culture positive.
11. Transfer Out: A client already registered for treatment that has been transferred to continue treatment in another district and his/her treatment outcome is not known.
12. Transfer In: A client already registered for treatment that has been transferred from another district to continue treatment.
13. Cure: Client whose sputum smear/culture result was positive at the beginning of treatment but who was smear/culture negative in the last month of treatment and on at least one previous occasion.
14. Treatment Completed: Client who completed treatment but who does not have a smear/culture result in the last month of treatment and on at least one previous occasion. The sputum examination may not have been done or results may not be available.
15. Treatment Failure: A client whose sputum smear or culture is positive in the last month of treatment and on at least one previous occasion. Patients found to have multi-drug resistant TB at any point during the treatment are also included in this definition.
16. Died: Client who dies for any reason during the course of TB treatment.
17. Treatment Default: Client whose treatment was interrupted for two or more consecutive months before the end of the treatment period.
18. Moved: Client who is referred to another facility within the same district to continue treatment.
19. Pulmonary TB: Refers to TB disease that involves the lung parenchyma. A client with both extra pulmonary and pulmonary TB is classified as pulmonary TB.

20. Extra-Pulmonary TB: TB of organs other than the lungs (for example, pleura, lymph nodes, abdomen, genito-urinary track, skins, joints and bones and meninges).
21. Smear-Positive Case: A tuberculosis suspect with at least 1+ acid-fast bacilli in at least 1 sputum sample.
22. Smear Negative Case:
  - a. A tuberculosis suspect with at least one sputum smear negative for AFBs and sputum culture is positive for mycobacterium TB; or
  - b. GeneXpert is positive for mycobacterium TB; or
  - c. Chest x-ray abnormalities are consistent with active TB, there has been no response to broad-spectrum antibiotics and the decision to treat with a full course of TB treatment.
23. Tuberculosis Disease (Latent TB): A person has been infected with Mycobacterium tuberculosis but the infection has been contained by the immune system. The Mycobacteria remain dormant in the body and do not cause disease. Therefore they remain asymptomatic, do not transmit infection and the only evidence of infection is a positive tuberculin skin test 4-6 weeks after infection.
24. Tuberculosis Infection (Active TB): Disease (as manifested by fever, loss of weight, night sweats and cough, if pulmonary TB) due to tuberculosis infection.
25. Drug Resistance in New Patients (previously 'primary resistance'): Resistant strains detected in cultures from patients with no history of previous TB treatment or patients who have received TB treatment for less than one month previously.
26. Resistance in Previously Treated Patients (previously 'acquired resistance'): Resistant strains detected in cultures from patients who have had one or more TB treatment episodes previously, of more than one month each.
27. Drug Resistant TB: A disease (usually pulmonary) caused by M.tuberculosis strains resistant to one or more anti-TB drugs.
28. Multidrug Resistant TB: Resistance to rifampicin and isoniazid, with or without resistance to other first-line anti-TB drugs.
29. Extensively Drug Resistant TB: resistance to rifampicin, isoniazid, any fluoroquinolone and one or more of the following injectable anti-TB drugs(kanamycin, amikacin, capreomycin).
30. Intensive Phase: Phase in TB treatment when there is rapid killing of TB bacilli. Patients mostly become non-infectious after about two weeks.
31. Continuation Phase: Phase in TB treatment when drugs kill the persisters and prevent relapse after completion of treatment.
32. Contact: Any person who has been exposed to an index patient
33. Household contact: A person who shared the same enclosed living space for at least eight continuous hours or for frequent prolonged periods with the index case during the 3 months before commencement of the current treatment episode.
34. Index patient: The first patient to be diagnosed with new or recurrent TB in a specific household or other comparable setting in which others may have been exposed, irrespective of age.
35. Laboratory turnaround time (TAT): The time taken from receipt of the specimen in the laboratory to results being dispatched from the laboratory to the facility.
36. Sputum result turnaround time (TAT): Time taken from sputum specimen collection to receiving the results back in the facility.
37. Time to treatment initiation: The time taken from specimen collection to starting the patient on treatment.

*Source: Adapted from SA National TB Guidelines, 2009/2011 and National TB Management Guidelines; 2014.*

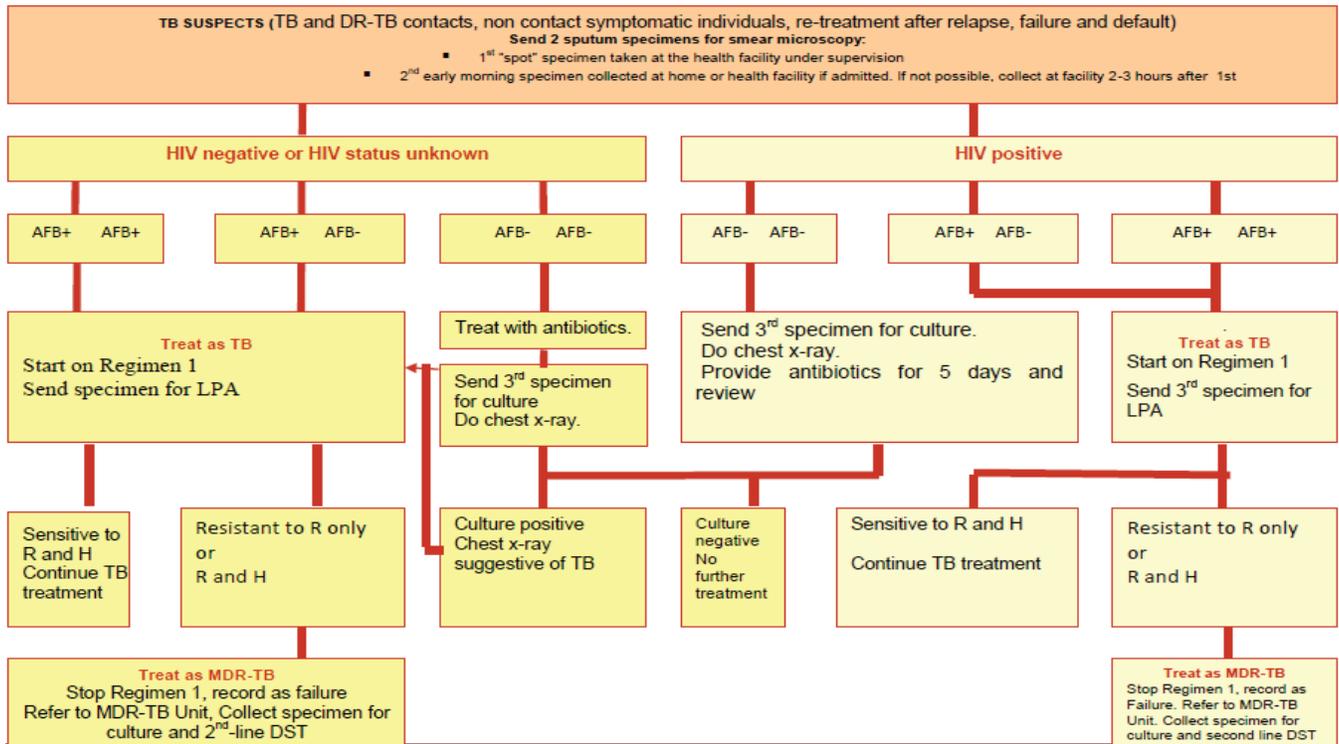


## Handout 3.2. Algorithm for TB diagnosis in a new case using smear microscopy and culture



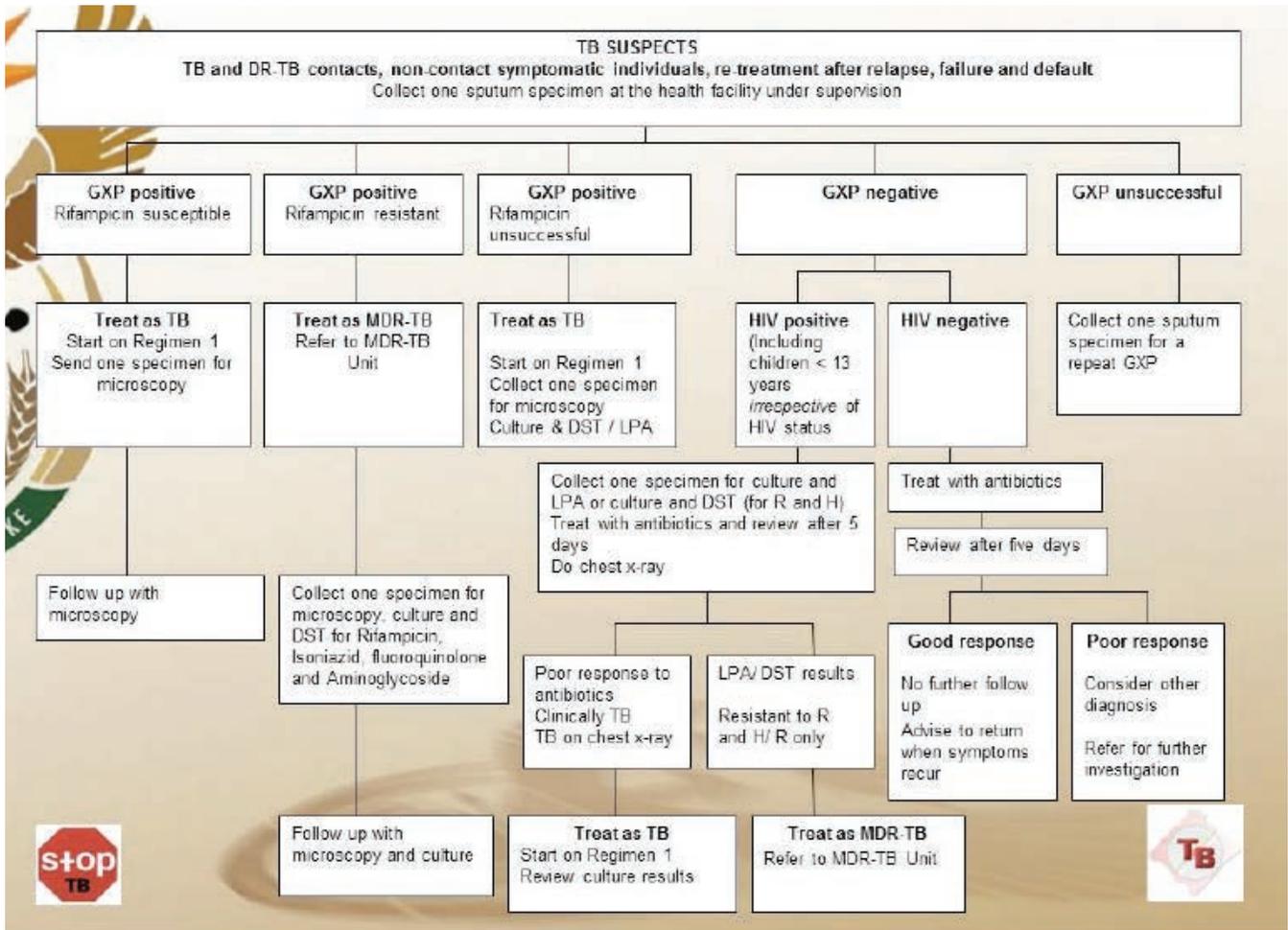


### Handout 3.3. Algorithm for TB diagnosis in TB suspects using the Line Probe Assay (LPA)



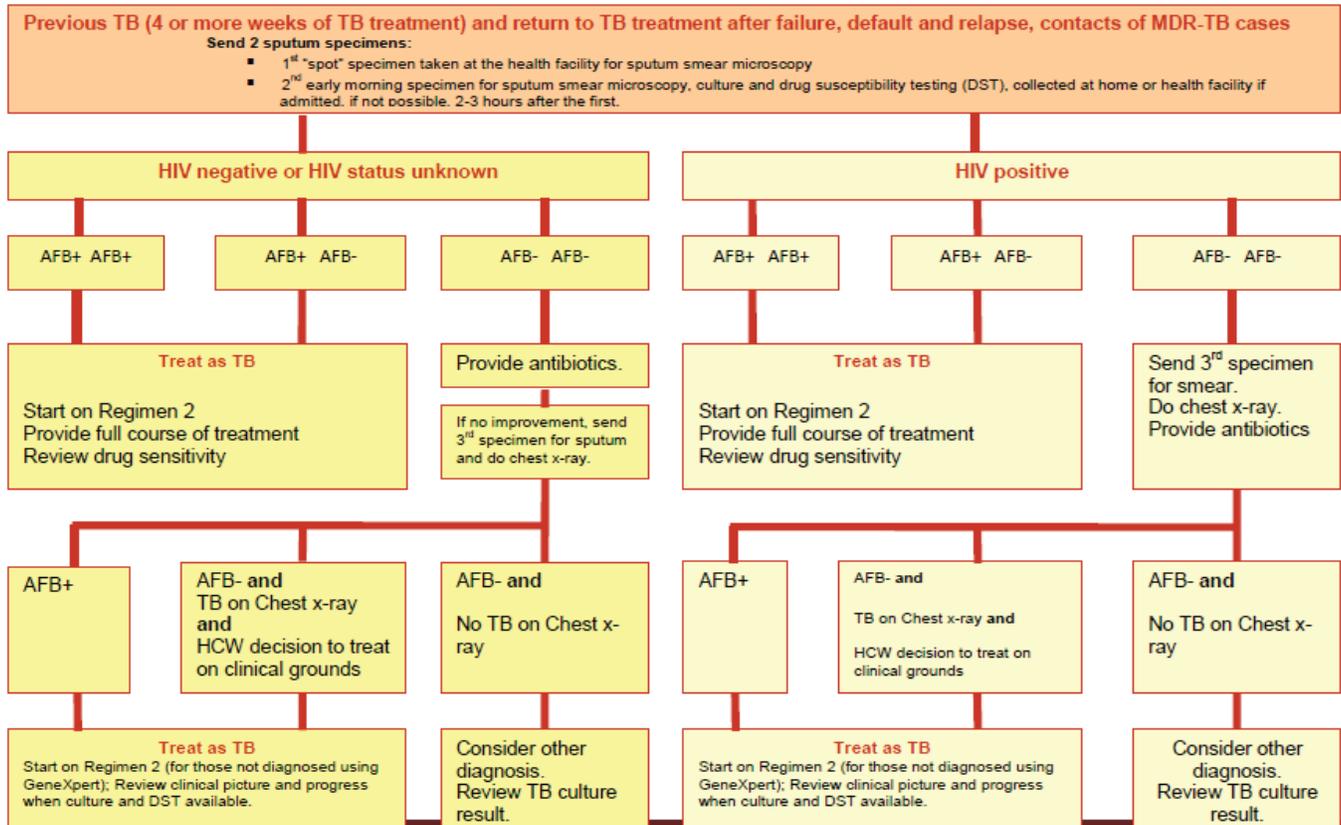


## Handout 3.4. Algorithm for TB diagnosis in TB suspects using the GeneXpert





## Handout 3.5. Algorithm for TB diagnosis in re-treatment cases and MDR-TB contacts using smear microscopy, culture and DST





## *Handout 3.6. Preventive TB Therapy in Adults*

### **WHY:**

70% of new adult TB in South Africa occurs among those living with HIV. TB can also accelerate HIV infection. IPT has been shown to decrease the risk of TB disease in HIV-infected persons by 60%. It provides protection for approximately 18 months (after that recontracting TB infection may have occurred).

### **WHO:**

- HIV positive with NO symptoms of TB disease: cough (24 hours or longer), fever, weight loss, drenching night sweats
- Exclude TB with sputum microscopy/culture
- If TST available, offer only to patients TST positive (induration  $\geq$  5 mm)
- TST not required, if no TST or patient is high risk (miners, prisoners, TB contacts, health care workers, and children)
- NO active liver disease or alcohol abuse

\*Critical to exclude active TB in order to prevent INH monotherapy

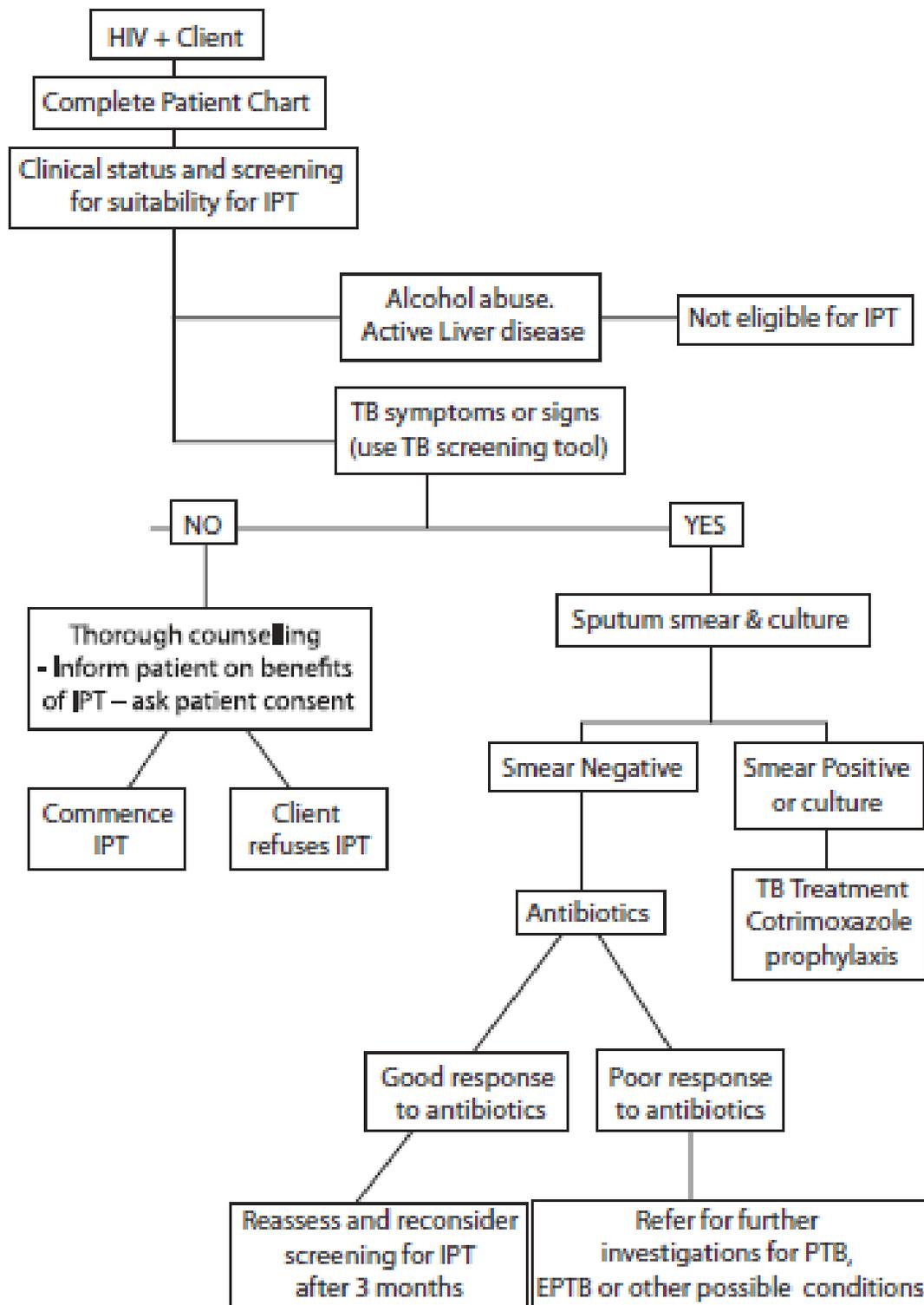
### **WHAT:**

- Screen for active TB BEFORE initiating TB preventive therapy
- Isoniazid (INH) 5mg/kg daily (max 300mg/day) for 6 months of continuous treatment (may be completed over 9 months)
- Vitamin B6 (pyridoxine) 25 mg daily to prevent peripheral neuropathy
- If interruption of no more than 3 months can be restarted if asymptomatic
- Advisable to take IPT if pregnant and to continue if ART started
- Give IPT once only
- Monitor monthly to obtain weight, counsel regarding adherence, side effects (hepatitis, peripheral neuropathy), and importance of seeking care if develop any symptoms of side effects or active TB

### **REGISTER:**

- Number of people started on IPT
- Number of people completing 6 months of IPT
- Number of people developing active TB when on IPT

Screening Algorithm for TB Prophylactic Therapy (PT)



**SCREEN FOR TB REGULARLY AT ALL SUBSEQUENT VISITS**

Source: Adapted from South Africa Department of Health. Guidelines for Tuberculosis Preventive Therapy Among HIV Infected Individuals in South Africa. May 2010.



## Worksheet 3.7. Algorithm Practice

*Case Study #1:* Kopano is a 43 year-old man complaining of a productive cough and fatigue for 2 months. There is a history of TB. He also has 5kg weight loss. He is evaluated for pulmonary TB. An HIV test is negative. 2 sputum specimens are collected and are both negative.

Physical Exam: Temperature: 38.0C, Heart Rate: 100, Respiratory rate: 18, Blood Pressure: 119/63, Weight: 70kg

He is thin and breathing comfortably. Kopano's exam is unremarkable and his lungs are clear.

1. What would be the next steps in evaluating this patient?
  - *He is HIV-negative and has no danger signs (unable to walk unaided, respiratory rate 30 or more, T>39.0, Pulse>120)*
  - *He should be treated with Amoxicillin for 5 days to see if he improves. This would suggest that he has bacterial pneumonia though would not rule out TB. It is important that the patient is closely monitored and returns to the clinic to be re-evaluated after antibiotics.*

*Case continued:* Kopano takes a 5 day course of amoxicillin and returns to your clinic. He still is having cough and fatigue. The exam is unchanged.

2. What is the next step in evaluating this patient?
  - *Send a 3rd sputum for smear AND culture. Check chest x-ray.*
3. If Kopano's results indicate TB disease what else will you do as part of follow-up for this patient's family?
  - *Contact screening for all family members*
  - *Treat any family members who show evidence of TB disease*
  - *Offer IPT to any HIV-infected adults who are contacts without evidence of TB disease or to any TB-exposed children < 5 years old or HIV-positive children without evidence of TB disease.*
  - *Counsel regarding TB prevention*
4. Indicate recording registers to complete in this case. Complete as best as possible (you may provide information not present in the case).
  - *TB Case Identification and Follow-up Sputum Register (GW20/13)*
  - *Laboratory Specimen Request Form*
  - *Summary of Suspect Register (GW20/13b) – he will be tallied as one case when this is completed at the end of the month.*
  - *HCT if HIV testing*

*Case Study #2:* Mandgakazi is a 59 year-old woman who complains of productive cough and night sweats for 3 weeks. She has no history of TB. Her husband died from TB two years ago. She is evaluated for pulmonary TB. HIV test is positive and 2 sputum specimens sent for smear microscopy and both are negative.

Physical Exam: Temperature: 37.8, Pulse: 80, Respiratory Rate: 18, Blood Pressure: 110/70, Weight 50 kg. Mandlakazi is able to walk unaided and exam reveals right-sided crackles.

1. What should be next in the management of Mandlakazi?
  - *She is HIV positive. There are no danger signs. She should have, a 3rd sputum sample sent for culture and chest x-ray (if available), and should start Amoxicillin.*
2. What reporting registers should be completed at this point?
  - *TB Case Identification and Follow-up Sputum Register (GW20/13)*
  - *Laboratory Specimen Request Form*

*Case continued:* Mandlakazi's sputum culture is pending. Chest x-ray is suspicious for TB.

3. What should be done next?
  - *The chest x-ray could be TB, she should be started on Regimen 1 TB treatment and await culture results. In an HIV-negative patient, you should wait to see if the patient gets better with antibiotics before diagnosing smear negative TB and starting TB treatment. In an HIV-positive patient it is important to start TB treatment early if it is suspected. Do not wait to see if there is a response to antibiotics. Start on cotrimoxazole.*
  - *If confirmation is done earlier before the course of antibiotics is finished, she should still finish the Amoxicillin (up to five days). Even if she improves after the Amoxicillin she should continue TB treatment.*
  - *Follow-up on sputum culture results and monitor closely for response to treatment. If no improvement after 1 month, she should be re-evaluated for other causes of her symptoms.*
  - *Consider ART start pending CD4 count*
4. What else will you do as part of follow-up for this patient and her family?
  - *Contact screening for all family members*
  - *Treat any family members who show evidence of TB disease*
  - *Offer IPT to any HIV-infected adults who are contacts without evidence of TB disease or to any TB-exposed children < 5 years old or HIV-positive children without evidence of TB disease.*
  - *HIV screening for the family*
  - *Counsel regarding TB and HIV prevention*
5. Indicate recording registers to complete in this case. Complete as best as possible (you may provide information not present in the case).
  - *TB Case Identification and Follow-up Sputum Register (GW20/13) – with results and follow-up*
  - *Laboratory Specimen Request Form – as additional laboratory requests are being made*
  - *TB Register – As started on treatment*
  - *Patient Clinic/Hospital Card – As started on treatment*
  - *Patient Treatment Card – As started on treatment*

*Case Study #3:* Letsego is a 36 year-old man who is seen at clinic complaining of a non-productive cough for 2-3 weeks, pleuritic chest pain, and breathlessness. He is HIV positive, last CD4 count 200 cells/mm<sup>3</sup> approximately 6 months ago. He has no history of TB. He is not taking any medications.

Physical exam: Temperature: 38.3, Pulse: 109, Respiratory Rate: 20, Blood Pressure: 109/64

Letsego appears a little short of breath but is able to walk unaided. Exam reveals fine crackles in all lung fields. Rest of exam is normal. He has sputum sent for GeneXpert and results reveal GXP+, Rifampicin resistant.

1. What would you do next?
  - *Treat as MDR-TB*
  - *Send specimen for smear, culture and DST/LPA (Fluoroquinolone, Aminoglycoside)*
  - *Cotrimoxazole initiation and refer for ART, initiation to begin as soon as possible after DR-TB treatment is tolerated, preferably within 1st month of treatment.*
2. If Letsego has active TB, what else will you do as part of follow-up for this patient and his family?
  - *Contact screening for all family members*
  - *Treat any family members who show evidence of TB disease*
  - *Offer IPT to any HIV-infected adults who are contacts without evidence of TB disease or to any TB-exposed children < 5 years old or HIV-positive children without evidence of TB disease.*
  - *HIV screening*
  - *Counsel regarding TB and HIV prevention*
3. If Letsego's GeneXpert results had instead returned GXP-, what would you do next for this case?
  - *Send sputum specimen for culture and DST/LPA, obtain a chest x-ray, provide antibiotics. If no TB on chest x-ray, consider other diagnosis while awaiting TB culture and DST/LPA results.*
4. Indicate recording registers to complete in this case. Complete as best as possible (you may provide information not present in the case).
  - *TB Case Identification and Follow-up Sputum Register (GW20/13) – with results and follow-up*
  - *Laboratory Specimen Request Form – as laboratory requests are being made*
  - *Patient Clinic/Hospital Card – As started on treatment*
  - *DR-TB Register*
  - *DR-TB Treatment Card*
  - *DR-TB Patient Follow-Up Card*
  - *Request for Sputum Examination – for second sputum specimen for culture and DST/LPA –same as first one but second form for culture/DST*
  - *Referral Form (as likely referring)*

*Case Study #4:* Daniel is a 17 year-old HIV-negative male. He received treatment for TB with Regimen 1 for 8 weeks. Following that, he has not been to the clinic and has not taken his medication for the past 8 weeks. He returns today with a cough and fevers. He lives with his family.

Physical exam: Temperature: 38.0, Pulse: 109, Respiratory Rate: 24, Blood Pressure: 112/68

Daniel has a productive cough in clinic. Rest of exam is normal

1. If smear microscopy is available, what would you do next?
  - *This is a default case and the appropriate algorithm should be utilised. 1 spot sputum specimen and a 2nd early am specimen should be sent for smear microscopy, culture and DST/LPA.*
2. What is recommended if the results of two separate smear samples are AFB+ and AFB-?
  - *Treat for TB using Regimen 2 (until streptomycin is phased out, then base on GXP or LPA results). Await culture and DST results. Treat as appropriate once those results are available.*
3. If GeneXpert testing had been available for the above case, what would you have done?
  - *Collect 1 spot sputum specimen. Point out that this algorithm is also for individuals who have previously received treatment.*
4. What is recommended if the GeneXpert results are MTB+ and Rif sensitive?
  - *Start on Regimen 1, send specimen for microscopy and follow-up with results*
5. What is recommended if the GeneXpert results are MTB+ and Rif resistant?
  - *Treat as MDR-TB and send specimen for microscopy, culture, and DST/LPA. If resistant to R or R and H, continue to treat as MDR-TB.*
6. What if Line Probe Assay testing had been available for the above case, what would you have done?
  - *Collect two specimens for smear microscopy. You can collect on spot an hour apart or two (on spot and early morning). Point out that this algorithm is also for individuals who have previously received treatment.*
7. Indicate recording registers to complete in this case. Complete as best as possible (you may provide information not present in the case).
  - *TB Case Identification and Follow-up Sputum Register (GW20/13) – with results and follow-up*
  - *Laboratory Specimen Request Form – as additional laboratory requests are being made*
  - *TB Register – As started on treatment*
  - *Patient Clinic/Hospital Card – As started on treatment*
  - *Patient Treatment Card – As started on treatment*
  - *If MDR-TB (DR-TB Register, DR-TB Treatment Card, DR-TB Patient Follow-Up Card, Request for Sputum Examination – Referral Form as likely referring)*

*Case Study #5:* Priscilla is a 24 year old HIV-infected female. During her initial HIV visit she was screened for TB and found to live with her mother, who is currently receiving treatment for pulmonary TB. She denies any symptoms of TB and has no history of prior TB treatment.

Her current CD4 count is 675 cells/mm<sup>3</sup>. Her current weight is 72kg. Her last menses was 1 week ago.

1. Is Priscilla eligible for IPT? If yes, what would you prescribe and for how long?
  - *Screen for TB and if all sputa are negative, she would meet criteria for IPT. The dose would be INH 300mg daily x 6 months with Vitamin B6 25mg daily.*



## *Handout 3.8. Effect of HIV on TB Signs and Symptoms*

1. HIV-positive persons have higher rates of pulmonary and extrapulmonary TB than HIV-negative persons.
2. Persons with clinically significant immunosuppression from HIV can have primary progressive pulmonary and extrapulmonary TB, reactivation pulmonary and extrapulmonary TB and a high risk of disseminated and meningeal TB (especially children).
3. HIV-related immunosuppression doesn't always allow the body to contain TB disease to a single organ system.
4. Must look for signs and symptoms of both pulmonary and extrapulmonary TB
5. HIV-positive persons more likely to develop primary progressive TB (ie, develop TB after exposure to person with infectious TB) without the classic chest x-rays that are associated with reactivated pulmonary TB.
6. HIV-positive persons more likely to have extrapulmonary TB, especially with lower CD4 counts (HIV-related immunosuppression doesn't always allow the body to contain TB disease to a single organ system).
7. The diagnosis of drug-resistant TB in HIV-positive persons is more difficult and may be confused with other pulmonary or systemic infections.
8. DR-TB treatment is the same for HIV-positive and HIV-negative patients. However, MDR-TB and XDR-TB treatment is much more difficult and adverse events are much more common in HIV-positive patients.
9. Mortality is high during treatment particularly in the advanced stages of immunodeficiency mainly due to advanced MDR- or XDR-TB disease and other HIV-related opportunistic infections.
10. All patients must be started on ART irrespective of CD4 cell count. Moreover the initiation of ART must be fast tracked as soon the DR-TB treatment is tolerated.



## Trainer Instructions: Step 2 (45 minutes) TB Diagnosis in Children

### Step 2 Learning Objectives:

- Explain diagnostic procedures for TB in children.
- Discuss the use of the tuberculin skin test (TST).
- Explain the importance of INH preventive therapy in all children.
- Describe the role of BCG vaccination and when it should be used.

### Step 2 Resources Needed:

- Handout 3.9. Diagnosing TB in Children
- Handout 3.10. Algorithm for Screening a Child with Documented TB Exposure
- Worksheet 3.11. Diagnosing TB in Children
- Isoniazid Preventative Therapy in Children Card (page 109 CRG)
- Clinical Resource Guide
- Flipchart and markers

### Step 2 Trainer Instructions:

	<p>2.1. Ask participants, “What are key risk factors for TB in children?” <i>Answers: Household contact with newly diagnosed smear-positive cases, children less than five years old, HIV infection, severe malnutrition.</i></p>
	<p>2.2. Record responses on flipchart.</p>
	<p>2.3. Explain that the recommended approach to diagnosis in children is done through assessment including:</p> <ul style="list-style-type: none"> <li>• Patient history (contact to PTB+, symptoms consistent with TB); Clinical exam; TST; Chest X-ray</li> </ul>
	<p>2.4. Refer participants to Handout 3.9. Diagnosing TB in Children. Ask for a participant to read the handout aloud.</p>
	<p>2.5. Refer participants to Handout 3.10. Algorithm for Screening a Child with Documented TB Exposure. Review algorithm with participants.</p>
	<p>2.6. Remind participants that all children under 5 years of age and all HIV-infected children in close contact with an infectious case of TB, but who are asymptomatic for TB, should receive Isoniazid prophylaxis to prevent developing TB disease.</p>
	<p>2.7. Ask participants, “Are there ways to prevent TB in children?” <i>Answer: Yes, the BCG vaccine prevents severe forms of TB including TB meningitis and Miliary TB in infants by up to 85% in HIV-negative children.</i> <i>Isoniazid prophylaxis can also help prevent TB disease in children who have already been infected with TB, but who do not have active disease.</i></p>
	<p>2.8. Refer participants to the Isoniazid Preventative Therapy in Children Card. Review card with participants.</p>
	<p>2.9. Remind participants that universal BCG use is part of the South African plan for protecting children against TB, except in the case where children are HIV-positive.</p>
	<p>2.10. Refer participants to Worksheet 3.11. Diagnosing TB in Children. Explain each participant will have 10 minutes to complete the case study.</p>

	2.11. Ask for a participant to give their answers to question 1.
	2.12. To save time, ask if anyone else came to a different conclusion and if so, why.
	2.13. Repeat the correct answer before moving on.
	2.14. Repeat this for each of the questions, asking for a different person to report out.
	2.15. Remind participants that a negative PPD and/or negative sputum smear/culture does not rule out TB!



## *Handout 3.9. Diagnosing TB in Children*

The diagnosis of TB is based on a combination of history of exposure, clinical presentation, Mantoux test and chest x-ray. The approach to the diagnosis of TB in children depends on the resources that are available. In areas where Mantoux skin test and chest x-ray are limited, the diagnosis can still be made through taking a good history and doing a thorough clinical examination.

### **SIGNS AND SYMPTOMS OF TB DISEASE IN CHILDREN:**

History of exposure, especially a close family member. Remember to inquire whether or not the family member has been treated and assess for the possibility of a drug resistant strain. The most common symptoms are:

- Chronic cough is a cough (>14 days) that is not improving
- Fever of greater than 38°C for 14 days, after excluding common causes
- Weight Loss
- Unusual fatigue in a child that is not playing or very tired

### **Signs suggestive of TB disease:**

- Fever of greater than 38°C for 14 days, after excluding common causes
- Painless enlarged lymph nodes (most commonly in neck)
- Night sweats
- Breathlessness (due to pleural effusion)
- Peripheral Oedema (due to pericardial effusion)
- Painful limbs and joints (due to erythema nodosum or dactylitis/inflammation of digits)

### **DANGER SIGNS of TB in Children Requiring Urgent Referral:**

- Headache (especially if accompanied by vomiting), irritability, drowsiness, neck stiffness and convulsions (signs of TB meningitis)
- Meningitis not responding to treatment, with a sub-acute onset or raised intracranial pressure
- Big liver and spleen (signs of disseminated TB)
- Distended abdomen with ascites
- Breathlessness and peripheral oedema (signs of pericardial effusion)
- Severe wheezing not responding to bronchodilators (signs of severe bronchial compression)
- Acute onset of angulation (bending) of the spine.

### **Indications for the evaluation of children as TB suspects include:**

- Exposure to a smear or culture positive case of PTB.
- Indication of TB infection (Mantoux 10mm or more in HIV-negative or 5mm or more in HIV positive children).
- Symptoms suggestive of TB.
- HIV positive children should be screened for TB exposure and symptoms at each clinical visit.

SCENARIO	REGARD AS TB CASE IF THE FOLLOWING EXIST
History of exposure to infectious TB case WITH Confirmed infection (positive Mantoux)	There are symptoms of TB (e.g. increased temperature for 3 weeks, progressive weight loss on the road to health chart) AND An abnormal chest x-ray suggestive of TB
Symptoms of TB	History of exposure to infectious TB case OR Confirmed infection (positive Mantoux) AND –An abnormal chest x-ray suggestive of TB –The diagnosis can be confirmed by collecting a gastric aspirate or sputum for smear and culture.
No Chest X-ray available	Symptoms of TB AND History of exposure to infectious TB case OR Confirmed infection (positive Mantoux)

\* Note: Whenever possible encourage child to produce sputum for diagnostic confirmation. Preferred method via gastric aspirate or induction.

### Contact screening

All children in close contact (same household) with an infectious case of TB (smear and/or culture positive) must be screened to exclude TB disease. Screening should include a thorough history and clinical examination. Children who have symptoms suspicious of TB disease require a Mantoux test and chest x-ray, if available, to aid the diagnosis of TB.

Close child contacts of MDR-TB cases should be rapidly identified and screened. These children should ideally be referred to the expert MDR centre in the Province for evaluation. Asymptomatic contacts should receive careful clinical follow-up for a period of at least two years. If active MDR-TB develops, prompt initiation of treatment with a regimen designed to treat MDR-TB is essential.

### INH Prophylaxis in Children

After exclusion of TB disease, INH prophylaxis should be given to:

- All children under 5 years of age in contact with an infectious case of TB (drug susceptible TB and MDR-TB), and HIV-infected children (irrespective of age)

Dosage recommendations for INH preventive therapy in children 10 (10-15) mg/kg/day x 6months	
<i>Body weight</i>	<i>Daily isoniazid (INH)</i>
2 - 3.4 kg	1/4 tab
3.5 - 6.9 kg	½ tab
7 - 9.9 kg	1 tab
10 –14.9 kg	1 1/4 tabs
15 – 19.9 kg	1 ½ tabs
20 – 24.9 kg	2 tabs
25 – 29.9 kg	2 ½ tabs
≥ 30 kg	3 tabs

\*Isoniazid may be dissolved in water or multivitamin syrup. To be administered concomitantly with Vitamin B6.

### Infants exposed to TB disease:

- Congenital TB is rare!
- The baby should not receive BCG at birth.

- If the baby is symptomatic:
  - Refer to a hospital for evaluation to exclude TB
  - If the baby has TB, the baby should receive a full course of TB treatment (regimen 3)
  - TB treatment should be started in a referral centre to ensure correct dosages.
- If the baby is asymptomatic:
  - The baby needs preventive therapy (isoniazid 10 mg/kg/day) for 6 months.
  - The baby should not initially receive BCG vaccination.
  - If the baby continues to be asymptomatic the BCG is administered after completion of the preventive treatment (unless the child is HIV infected or has symptoms suggestive of HIV infection).

Breastfeeding - Although low doses of anti-TB drugs are secreted in the breastmilk, the concentrations should not affect the baby. A mother on anti-TB drugs does have the option of breastfeeding and should be counselled about feeding options based on her HIV-status.

### **HIV testing in childhood TB suspects:**

A HIV test is important in the diagnosis of childhood TB. As with adults, the standard of care is to provide HIV counselling and testing to all child TB suspects and their parents/caregivers. Families should be given the necessary information about HIV to help make an informed choice about an HIV test. The HIV test should be strongly recommended and consent for testing sought (from parents or the legal guardian of children if younger than 12 years of age).

In children younger than 18 months – An HIV ELISA or HIV rapid test is used for screening. A positive test could be due to maternal antibodies and an HIV DNA PCR test is used to confirm the diagnosis.

In children over 18 months of age – HIV ELISA or HIV rapid tests are used both for screening and confirmation of the diagnosis.

The diagnosis of TB disease in HIV-infected children is exactly the same as for HIV-uninfected children except that there is greater uncertainty because:

- The symptoms of TB can be confused with the symptoms of HIV disease.
- The chest x-ray is more difficult to interpret.

Important things to do in a child diagnosed with TB:

- Exclude HIV infection
- Refer HIV-infected children to the local HIV clinic
- Consider referral for nutritional support
- Complete the TB Register
- Make a note in the Road to Health Card
- Ask about other children or adults in the household and screen them for TB

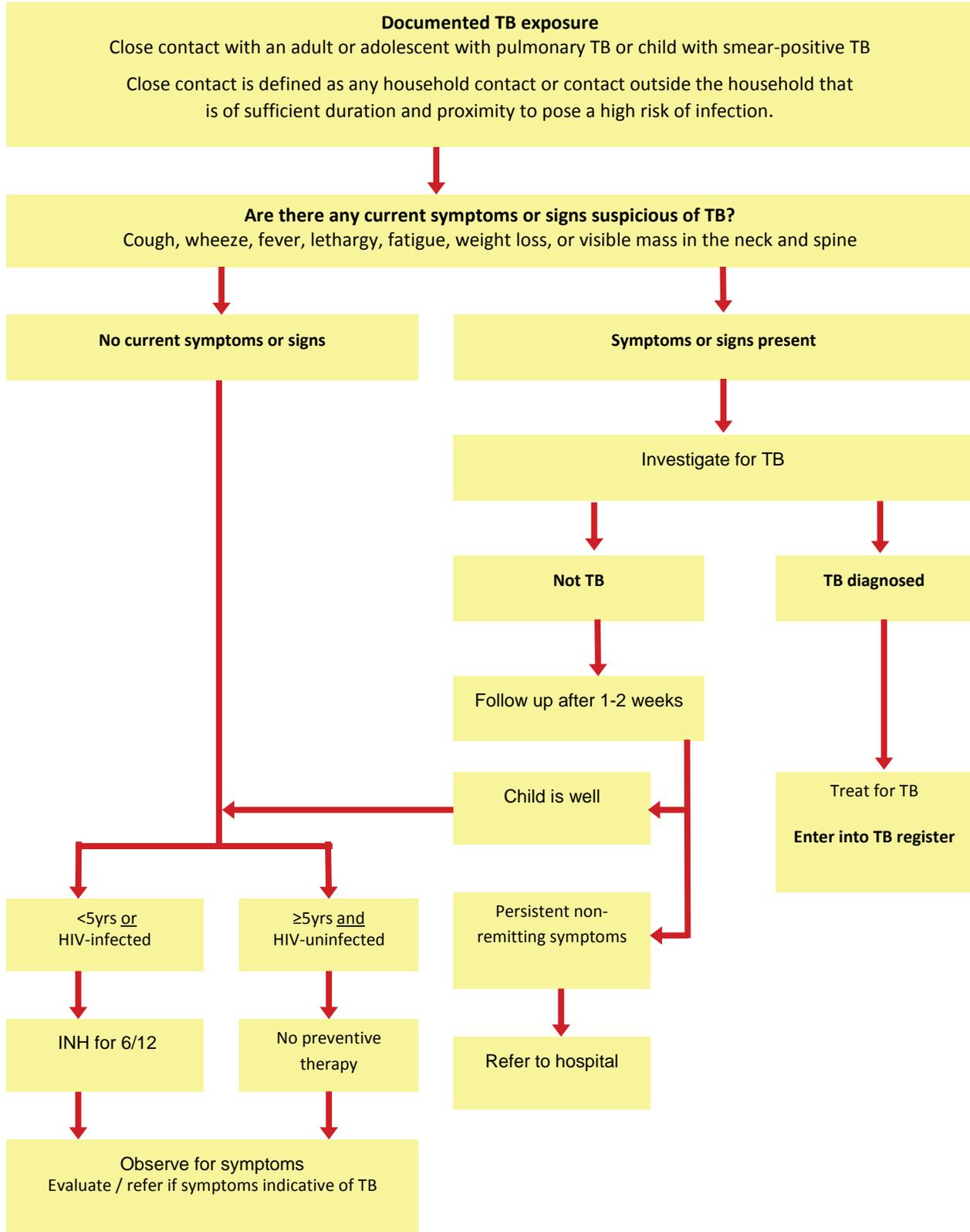
### **Diagnosing TB in HIV-infected children:**

- The symptoms and signs of tuberculosis and those of other HIV related lung diseases could be indistinguishable. Symptoms such as chronic cough, weight loss and persistent fever are common to both HIV-related lung disease and TB.
- The Mantoux skin test is frequently negative even though the child may be infected with TB or has TB disease.
- Although the radiological features are usually similar to that found in HIV-negative children, the picture could also be atypical. Radiological changes of HIV related lung diseases are confused with those caused by tuberculosis e.g. LIP may look very similar to miliary TB.
- The differential diagnosis of pulmonary TB in HIV-infected children is much broader and includes: bacterial pneumonia, viral pneumonia, fungal lung disease, pneumocystis jiroveci pneumonia (previously known as PCP), pulmonary lymphoma and Kaposi's sarcoma.
- It is for these reasons that an HIV test is included as the standard of care in all child TB suspects.
- If there is uncertainty of the TB diagnosis, the child should be treated with antibiotics for 5-7 days and the chest x-ray repeated after two weeks depending on the clinical picture of the child.

*Source: Adapted from SA National TB Guidelines, 2009.*



## Handout 3.10. Algorithm for Screening a Child with Documented TB Exposure



Source: SA National TB Guidelines, 2009.



## Worksheet 3.11. Diagnosing TB in Children

*Case Study #1:* Ntombi is 2 years-old. Her mother was just diagnosed with smear-positive pulmonary TB. Ntombi is brought to the hospital by her parents. Ntombi's father says she has been ill for 3 weeks. She eats poorly, is losing weight, doesn't play, and feels hot most days.

Her physical exam shows Temperature: 39°C, Weight: 70% of the expected weight for her age, enlarged lymph nodes in the neck, axilla, and inguinal areas, swollen parotid glands and an enlarged liver and spleen. A malaria smear is negative. Her case is managed by prescribing ampicillin, educating the parents and asking the parents to return in 3 days.

1. What are common signs and symptoms of TB in small children?
  - *Night sweats*
  - *Fever of >38 degrees for 2 weeks*
  - *Weight loss or failure to thrive*
  - *Fatigue*
  - *Chronic cough*
2. What tests provide a confirmed diagnosis of tuberculosis disease in small children?
  - *Positive TST*
    - *Do not treat active TB in children based only on positive TST*
  - *Suggestive x-ray images (very important)*
    - *Widened mediastinum from hilar or mediastinal lymphadenopathy*
    - *Miliary pattern*
    - *Pleural effusion*
  - *Road to health card – monitor weight for age changes, document BCG immunisations*
  - *Positive gastric aspirate or induced sputum smear or culture*
  - *Other positive culture (for example: bone marrow, CSF, pleural, etc.)*
  - *Positive acid-fast stain on lymph node aspirate*
  - *Caseous material on biopsy*
    - *Cheesy material on visual inspection of biopsied lymph node*
3. How would you induce sputum in a child?
  - *By administering 3% nebulised saline for 5 minutes followed by collection of posterior pharyngeal secretions via suction catheter is effective and easier to obtain, or*
  - *Nasal gastric aspirate*
4. What will make you suspicious of TB if microbiologic or radiologic testing is not possible?
  - *History of exposure*
  - *Fatigue*
  - *No response to broad spectrum antibiotic*
  - *Fever*
  - *Weight loss*
  - *Positive TST, though a negative TST and/or negative sputum smear/culture does not rule out TB in children*

*Case Study #2:* Thomas is Ntombi's 4 year-old brother. Their mother was recently diagnosed with pulmonary TB and their father has been ill for three weeks. He does not currently have any symptoms, appears healthy and is active. He is afebrile and weighs 18 kg.

1. Since Thomas has been exposed to TB, what should be part of Thomas's screening process for TB?
  - *A thorough history. Screen specifically for any symptoms including: history of a cough, weight loss, fevers or night sweats.*
  - *A thorough physical examination for symptoms of pulmonary or extrapulmonary TB*
  - *If no signs and symptoms, give IPT.*
  - *If signs and symptoms, collect sputums, consider chest x-ray and TST*
  - *Screen for HIV if status is unknown*
  
2. If Thomas continues to have no evidence of TB disease, what will you do next ?
  - *Recommend IPT: 1 and a ½ tabs of Isoniazid (100mg) dissolved in water daily for 6 months. Thomas is eligible due to age < 5 years of age with history of exposure and no active disease, regardless of HIV status.*
  - *Emphasise the importance of adherence*
  - *Screen any other family members who are TB contacts*
  - *Monitor at future visits for any signs or symptoms of TB disease and side effects of isoniazid*



## Trainer Instructions: Step 3 (50 minutes) Signs and Symptoms of TB in Children and Adults

### *Step 3 Learning Objectives:*

- Identify and explain the signs and symptoms of TB in children and adults.
- Recognise the clinical features of TB and disease progression.
- Explain diagnostic procedures in extra-pulmonary TB in adults and children.

### *Step 3 Resources Needed:*

- Handout 5.12. Extra-pulmonary Tuberculosis
- Clinical Resource Guide
- Flipchart and markers
- LCD projector and computer
- Slides 1-9

### *Step 3 Trainer Instructions:*

	<p>3.1. Assign each group one or two of the following:</p> <ul style="list-style-type: none"><li>• TB Lymphadenitis</li><li>• TB Pleural Effusion</li><li>• TB of the Bones and Joints</li><li>• TB Pericardial Effusion</li><li>• TB Peritonitis</li><li>• TB Meningitis</li><li>• Disseminated /miliary TB</li></ul>
	<p>3.2. Give each group two pieces of flipchart paper. Explain that each group will have 15 minutes needs to identify the signs, symptoms and diagnostic procedures of their specific TB in both adults and children and write them on the flipchart paper. Each group will present when asked by the trainer.</p>
	<p>3.3. Refer participants to the clinical resource guide and Handout 5.12. Extra-pulmonary Tuberculosis for this activity.</p>
	<p>3.4. Present Slides 1-9 using trainer notes.</p>



## Handout 3.12. Extra-pulmonary Tuberculosis

### TB Meningitis

Before the advent of effective anti-tuberculosis chemotherapy, TB meningitis was uniformly fatal. TB meningitis remains a potentially devastating disease that is associated with a high morbidity and mortality. HIV positive clients appear to be at increased risk for developing TB meningitis but the clinical features and outcome of the disease are similar to that in HIV-negative clients.

#### *Clinical Presentation and Management*

- Clients present with gradual onset of headache, malaise, confusion, decreased consciousness and sometimes vomiting.
- Examination reveals neck stiffness and a positive Kernig's sign (flex one of the client's legs at hip and knee with the client lying on back, and then straighten the knee; resistance to straightening the knee and pain in the low back and posterior thigh suggest meningeal inflammation).
- Diagnosis rests on clinical presentation and a lumbar puncture examination of cerebrospinal fluid (CSF). The following CSF features are highly suggestive of TB meningitis:
  - Clear CSF
  - Elevated pressure
  - High levels of protein (>1g/l)
  - High lymphocyte count (30-300/mm<sup>3</sup>)
  - Low glucose
  - Negative Indian ink stain for cryptococcus
- Clients with suspected TB meningitis should be referred to hospital without delay as TB meningitis is life threatening, with serious complications if not treated promptly.
- Those presenting with more severe neurological impairment such as drowsiness or coma have a greater risk of neurological sequelae and a higher mortality.

CSF Differential Diagnosis for TB Meningitis				
Disease	White Cell Count	Protein	Glucose	Microscopy
<b>Tuberculous meningitis</b>	Elevated L > PMN	Increased	Decreased	Presence of AFB (rare)
<b>Bacterial meningitis</b>	Elevated PMN > L (L increases with partial treatment)	Increased	Decreased	Presence of bacteria after gram staining (rare)
<b>Viral meningitis</b>	Elevated L > PMN	Moderately increased	Normal	Negative
<b>Cryptococcal meningitis</b>	Elevated L > PMN	Increased	Decreased	Presence of parasites shown by Indian ink stain

### Disseminated/Miliary TB

Disseminated or miliary TB results from widespread blood borne dissemination of TB bacilli. This is either the consequence of a recent primary infection or the erosion of a tuberculosis lesion into a blood vessel. It occurs most often in children and young adults. Unlike pulmonary tuberculosis, acute disseminated TB is highly fatal. Disseminated TB is an under-diagnosed cause of end-stage wasting in HIV positive individuals and should be considered in all febrile clients presenting with HIV wasting syndrome.

#### *Clinical features*

- The client presents with a general deterioration in health and constitutional symptoms such as high fever, night sweats, weight loss and shortness of breath.

- Clinical signs may reflect the involvement of other organs: pleural effusion, digestive problems, hepatosplenomegaly and meningeal signs.
- There may be choroidal tubercles on fundoscopy.
- Other conditions that may present in a similar way need to be excluded, including: acute viral infections, staphylococcus, salmonella, cryptococcus and malaria.

### *Diagnosis*

- Chest X-ray shows diffuse, uniformly distributed, small miliary (“like small millet seeds”) nodules.
- Full blood count may show pancytopenia (anaemia, thrombocytopaenia, neutropaenia), however, this may also be seen as a result of HIV.
- Liver function tests may be abnormal.
- Bacteriological confirmation is sometimes possible from sputum, C.S.F., or bone marrow.
- Smear microscopy of sputum from cases with disseminated (miliary) tuberculosis is usually negative, as the disease is paucibacillary.

**When disseminated TB is suspected, treatment should be commenced immediately without waiting for bacteriological proof of diagnosis.**

## **Tuberculous Lymphadenopathy**

TB lymphadenopathy, caused by lymphatic spread of the organism, is one of the commonest forms of extra-pulmonary TB. Involvement of the lymph nodes is usually a complication of primary TB and is commoner in children. It tends to also be found in the later stages of HIV infection.

### *Clinical features*

- Large mediastinal lymph nodes can compress the airways leading to an audible wheeze or typical brassy cough.
- Peripheral TB lymphadenopathy most commonly occurs in the neck and armpits. Typically lymph nodes are large (>2 cm), tender, non-symmetrical, matted, firm to fluctuant and rapidly growing.
- Associated systemic features include fever, night sweats and weight loss.
- As nodes increase in size and become fluctuant, they may suppurate and drain via a chronic fistula, resulting ultimately in scarring.
- TB lymphadenopathy needs to be differentiated from persistent generalized lymphadenopathy (PGL). PGL develops in up to 80% of HIV-infected individuals during the early stages of infection. These lymph nodes are typically non-tender, <2 cm in size and symmetrical. PGL requires no treatment.
- TB infected lymph nodes decrease extremely slowly in size (over weeks or months) on treatment, and in a few cases, are still the same size after the treatment has finished. This does not mean that the treatment was not successful.

### *Diagnosis*

- If a lymph node is exuding caseous material through a fistula, this can sent to the laboratory for microscopy.
- Otherwise, refer the client to a doctor to do a needle (18G or 19G) aspirate of the lymph node. TB is diagnosed if a smear of the aspirated material reveals acid-fast bacilli.
- If no diagnosis is made after a needle aspirate, a lymph node biopsy should be done.
- Mediastinal lymph nodes can be diagnosed through chest x-rays.
- Intra-abdominal lymphadenopathy is more readily detected by ultrasound or computerised axial tomography (CT scan). These cases are treated empirically, unless the nodes can be readily aspirated at a tertiary health facility.

## **Tuberculous Serous Effusions**

Inflammatory tuberculous effusions may occur in any of the serous cavities of the body, i.e. pleural, pericardial or peritoneal cavities. They are a common form of TB in HIV positive clients. In populations with a high prevalence of HIV, TB is the commonest cause of a serous exudate.

Clients usually have systemic and local features. Microscopic examination of the aspirate rarely shows AFBs because the fluid forms as an inflammatory reaction to TB lesions in the serous membrane. TB culture is of no immediate help because a culture result takes up to six weeks or more. The aspirate is an exudate with a protein content of more than 30g/l. A biochemical test is not required to diagnose an exudate: let the aspirated fluid stand for a while - if it clots, it is an exudate. However, failure of the aspirate to clot does not exclude TB as it may indicate a low protein content, found for example in wasted clients.

## **Tuberculous Pleural Effusion**

Tuberculous pleural effusion is the commonest cause of a unilateral pleural effusion in countries with a high TB burden. It is also the commonest form of HIV-related extra-pulmonary disease, with a mortality of about 20% in the first 2 months on treatment. Management of tuberculous pleural effusion should aim at starting TB treatment promptly and determining the HIV-status of the client.

### *Clinical features*

- Presentation is most often acute with a non-productive cough, chest pain, shortness of breath and high temperature.
- The chronic form is found predominantly in the elderly and presents with systemic symptoms such as weakness, anorexia, weight loss, slight fever, cough, and chest pain.
- Clinical examination shows:
  - Tracheal and mediastinal shift away from the side of the effusion
  - Decreased chest movement
  - Stony dullness on percussion on the side of the effusion.

### *Diagnosis*

- Suspected pleural effusions should be confirmed by immediate chest x-ray. This will show unilateral, uniform white opacity, often with a concave upper border.
- Pleural aspiration should be undertaken wherever possible: the fluid is a straw coloured exudate and has a protein content >30g/l. The white cell count is high (1000-2500 per mm<sup>3</sup>) with predominantly lymphocytes. The adenosine deaminase (ADA), which is a measure of the lymphocyte count, is raised >30 IU.
- Failure of the aspirate to clot does not exclude TB as it may indicate lower protein content in wasted clients; the predominance of lymphocytes (>50%) confirms a TB diagnosis.
- Since the number of bacilli present is relatively small, AFB are not usually seen on microscopy of centrifuged specimens of pleural fluid, however, culture may be positive.
- If aspiration is not possible, commence TB treatment unless the chest x-ray suggests a different diagnosis.
- Differential diagnosis of a pleural exudate includes malignancy, a post-pneumonia effusion and pulmonary embolism.
- Bilateral effusions or those with cloudy or bloody aspirates should be investigated further.
- Pleural biopsy is not recommended, as it is unnecessarily invasive.

## **Tuberculous Pericardial Effusion**

Tuberculosis accounts for about 90% of pericardial effusions in HIV positive clients and for about half of those who are HIV-negative.

### *Clinical features*

- Cardiovascular symptoms include: chest pain, shortness of breath, cough, dizziness and weakness due to low cardiac output.
- Symptoms of right-sided heart failure include leg swelling, right hypochondrial pain (liver congestion), abdominal swelling (ascites).
- Signs include: tachycardia, low blood pressure, pulsus paradoxus (fall in systolic pressure >10mmHg on inspiration), raised jugular venous pressure, impalpable apex beat, distant heart sounds and a pericardial friction rub.
- Signs of right-sided heart failure include hepatosplenomegaly, ascites, and peripheral oedema.

### *Diagnosis*

Diagnosis usually rests on suggestive systemic features and ultrasound:

- Chest X-ray may show a large globular heart, clear lung fields and bilateral pleural effusions.
- ECG may show tachycardia, flattening of ST and T waves, low voltage QRS complexes.
- In cases of cardiac tamponade the client should be referred to a specialist for aspiration of the effusion.
- Treatment without pericardiocentesis usually results in resolution of a tuberculous pericardial effusion.

**In high TB and HIV prevalent populations, TB is the most likely treatable cause of a pericardial effusion. It may be safer for the client to start presumptive TB treatment than to undergo diagnostic pericardiocentesis. Treatment is the same as for all types of TB, but a specialist may decide to add corticosteroids if required. If not properly treated, TB pericarditis may evolve towards constriction over the following months.**

## Peritoneal Tuberculosis

Peritoneal TB is the commonest type of abdominal TB.

### *Clinical features*

- Clinical features include systemic features and ascites with no signs of portal hypertension.
- There may be palpable abdominal masses (mesenteric lymph nodes).
- Bowel obstruction may develop from adhesion of caseous nodules to bowel.

### *Diagnosis*

- Always do a diagnostic ascitic tap - the aspirated fluid is usually straw coloured, but is occasionally turbid or blood stained. The fluid is an exudate, usually with more than 300 white cells per mm<sup>3</sup> with lymphocytes predominating (in spontaneous bacterial peritonitis which is a common complication of cirrhosis, polymorphonuclear leucocytes predominate).
- Investigate for pulmonary TB
- Abdominal ultrasound may show retroperitoneal or mesenteric lymph node enlargement •
- Diagnosis is usually presumptive - in doubtful cases, a macroscopic examination and bacteriological or histological examination of the samples may be considered in a hospital where exploratory surgery or laparoscopy can be performed.

## Tuberculous Empyema

- This usually arises when a tuberculous cavity in the lung ruptures into the pleural space.
- The physical signs are similar to a pleural effusion, but aspiration reveals thick pus. Send the pus to the laboratory for examination for TB, gram stain and bacterial culture. The main differential diagnosis is bacterial empyema.
- A succussion splash is a splashing sound heard with the stethoscope while shaking the client's chest. It indicates a pyopneumothorax (pus and air in the pleural space). After chest x-ray confirmation of a pyopneumothorax, insert a chest drain with underwater seal to remove fluid and air.

## Tuberculosis of the Spine

TB can affect any bone but most commonly affects the vertebral column. It is seen both in children and adults and can be severe, with neurological sequelae.

Involvement of the intervertebral disc occurs by spread of a lesion from the vertebral body. In many cases more than one intervertebral disc is involved. It is characterised by loss of bone density and slow bone erosion, with the disc space being maintained for a long time (differentiating it from pyogenic infections). In children, an acute form may develop with vertebral osteomyelitis, collapse of the vertebral body and neurological involvement. Collapse of adjacent vertebral bodies may lead to angulated kyphosis. Thrombosis of the anterior spinal artery caused by the inflammation causes transverse myelitis and paralysis.

Spread may occur into the soft paravertebral tissue to form a so-called "cold abscess". These form symmetrical masses; they may spread further and end up calcifying.

### *Clinical features*

- Features include back pain, stiff back, reluctance to bend the back
- There may be referred pain radiating out from the site of origin
- Localised swelling, sometimes with an obvious lump or abnormal curvature of the spine
- A child that refuses to walk or has weakness or paralysis of the lower limbs.
- Involvement of cervical vertebrae may cause pain in the neck and shoulders and rigidity of the neck. A cold abscess can develop behind the sternocleidomastoid muscle. More rarely, neurological involvement leads to progressive tetraplegia.

- Involvement of the thoracic vertebrae causes localized back pain, deformity of the spine, and in extreme cases an angulated kyphosis (gibbus). The chief risk is spinal cord compression and paraplegia.
- Involvement of the lumbar vertebrae results in lower back pain. A “cold abscess” from here can drain along the psoas muscle towards the inguinal area.
- In the early stages the physical examination can be non-specific.
- Clients with weakness or paraplegia should be referred to a specialist urgently.

### *Diagnosis*

- X-rays of the spine show disc space narrowing and erosion of the adjacent vertebral bodies, wedge shaped collapse and angulation.
- Biopsy of cold abscess for microscopy and culture if possible, can confirm the diagnosis.
- Differential diagnosis includes degenerative disc disease, infectious spondylitis and cancerous vertebral metastases.

**The principles of treatment for clients with EPTB are the same as for PTB:**

- **Regimen 1 for new cases**
- **Regimen 2 for retreatment cases**
- **A specialist may decide to extend the treatment of severe forms of extra-pulmonary TB from 6 to 9 months and to provide corticosteroids.**

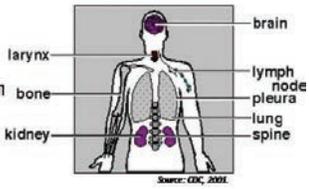
**The response to treatment is assessed clinically. Weight loss may occur as large effusions/ascites resolves and does not necessarily indicate failure to respond.**

*Source: National Tuberculosis Management Guidelines. Department of Health.2009.*

Slide 1

### Sites of TB Disease

- Lungs (most common - 88%)
- Pleura
- Lymphatic system
- Central nervous system
- Genitourinary systems
- Bones and joints
- Disseminated (miliary TB)
- Pericardial disease



Source: CDC, 2001.



Slide 5

### TB of Bones and Joints



© Slides of TB and Sumner S. Strassman  
Courtesy of © F-TEOL, 2003.



Slide 2

### Pulmonary TB

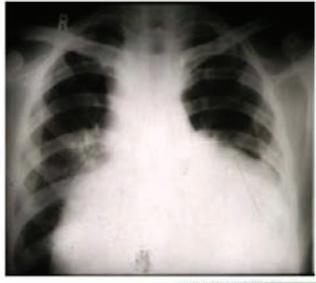


Courtesy of: San Francisco City and County Dept. of Public Health, TB Division



Slide 6

### TB Pericardial



Courtesy of: © F-TEOL, 2003.



Slide 3

### TB Lymphadenitis



Courtesy of: © F-TEOL, 2003.



Slide 7

### TB Peritonitis



Courtesy of: © F-TEOL, 2003.



Slide 4

### TB Pleural Effusion

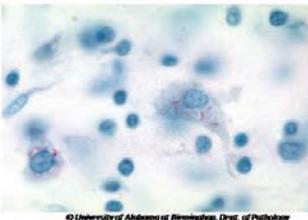


Courtesy of: © F-TEOL, 2003.



Slide 8

### TB Meningitis



© University of Alabama at Birmingham, Dept. of Pathology



## Disseminated TB



Courtesy of: © I TECH, 2001.  
**MILIARY / NODULAR TB**



Courtesy of: © I TECH, 2001.  
**DISSEMINATED TB**



## Session 4. Management of Patients with Pulmonary and Extra-Pulmonary Tuberculosis



**Total Session Time: 3 hours and 50 minutes**

### Learning Objectives:

By the end of this session, participants will be able to:

- Explain the standardised tuberculosis case definitions and treatment categories.
- List the principles of anti-TB drug treatment.
- Explain the modes of action of anti-TB drugs.
- Recognise the indications for first line TB treatment.
- Assess for second line TB treatment or MDR TB.
- Describe the first line regimen for pulmonary TB.
- Recognise and manage the side effects of TB medications.
- Describe when to start TB treatment in children.
- Properly monitor response to treatment.

### Session Overview

Step	Time	Activity/Method	Content	Resources Needed
1	75 minutes	Group Work	Overview of Anti-TB Drug Treatment in Adults	Handouts 4.1, 4.2,4.3 Worksheet 4.4 Standard treatment Regimen Dosages Card Fixed Dose Combination Tablets Available for Adults Card Regimen 1: Treatment in New Cases Card Regimen 2: Treatment in Re-Treatment Cases Card Regimen 3: Dosages for the Treatment of Uncomplicated TB in Children <8 years of age Card Recommended Doses for First-Line: TB Drugs in Children Card Flipchart and markers
2	30 minutes	Group Work	Side Effects of Anti-TB Drug Treatment	Handout 4.5 TB drug cards Flipchart and markers Clinical Reference Manual
3	20 minutes	Group Work	Treatment Interruption	Handout 4.6 Worksheet 4.7 Clinical Reference Manual

Step	Time	Activity/Method	Content	Resources Needed
4	75 minutes	Group Work	Management of Adults and Children on Anti-TB Drug Treatment	Worksheet 4.8 TB drug Cards Clinical Reference Manual
5	30 minutes	Group Discussion Group Presentation	Monitoring Therapy	LCD projector and computer S6: Monitoring Handout 4.9



## Resources Needed

- Handout 4.1. First Line TB Drugs
- Handout 4.2. Standard Treatment Regimens for Adults (8 years and Older)
- Handout 4.3. Treatment for Children
- Worksheet 4.4. Case Studies – Drug Regimens in Adults and Children
- Handout 4.5. Symptom-Based Approach to Management of Drug Side Effects
- Handout 4.6. Management of Treatment Interruption
- Worksheet 4.7. Case Studies for Treatment Interruption
- Worksheet 4.8. Case Studies - Management of Adults and Children with TB
- Handout 4.9. Monitoring Algorithm for New PTB Adults
- Standard treatment Regimen Dosages Card
- Regimen 1: Treatment in New Cases Card
- Regimen 2: Treatment in Re-Treatment Cases Card
- Regimen 3: Dosages for the Treatment of Uncomplicated TB in Children <8 years of age or <35 kg Card
- Recommended Doses for First-Line: TB Drugs in Children Card
- TB drug cards
- Clinical Reference Manual
- Flipchart and markers
- LCD projector and computer
- PowerPoint Slides – Monitoring New and Re-Treatment Cases and Recording



## Trainer Instructions: Step 1 (75 Minutes) Overview of anti-TB Drug Treatment in Adults and Children

### Step 1 Learning Objectives:

- List the principles of anti-TB drug treatment.
- Explain the modes of action of anti-TB treatment.
- List the drugs in regimen 1 and 2 for TB.
- Explain when to use regimen 1 and regimen 2 in TB patients.
- Explain dosing guidelines for regimens 1 and 2.
- Discuss what the appropriate treatment to start in children diagnosed with TB.

### Step 1 Resources Needed:

- Handout 4.1. First Line TB Drugs
- Handout 4.2. Standard Treatment Regimens for Adults (8 years and Older)
- Handout 4.3. Treatment for Children
- Worksheet 4.4. Case Studies – Drug Regimens in Adults and Children
- TB Drug Cards
- Recommended Doses for First-Line: TB Drugs in Children Card
- Standard treatment Regimen Dosages Card
- Fixed Dose Combination Tablets Available for Adults Card
- Regimen 1: Treatment in New Cases Card
- Regimen 2: Treatment in Re-Treatment Cases Card
- Regimen 3: Dosages for the Treatment of Uncomplicated TB in Children < 8 Years
- Flipchart and markers

### Step 1 Trainer Instructions:

	<p>1.1. Ask participants, “What is the aim of TB treatment?” Record responses on flipchart.</p> <p>Answers:</p> <ul style="list-style-type: none"> <li>• Cure patient of TB</li> <li>• Prevent death from TB or complications from TB</li> <li>• Decrease transmission of TB to others</li> <li>• Prevent the development of acquired drug resistance.</li> <li>• Economic reasons</li> </ul>
	<p>1.2. Ask participants, “What does TB treatment include?” Record responses on flipchart paper.</p> <p>Answers:</p> <ul style="list-style-type: none"> <li>• Anti-TB drugs</li> <li>• On-going management</li> <li>• Recognising signs of urgent care</li> <li>• Infection control practices</li> <li>• Patient Education/psychosocial support</li> <li>• Family involvement</li> <li>• DOTS and supporting adherence</li> <li>• Contract tracing and treatment</li> <li>• Recording and reporting</li> <li>• Financial management</li> </ul>

	1.3. Explain that the key to stopping the spread of TB in a community is to start treating clients who are coughing up live TB bacilli (smear or culture positive) as soon as possible.
	1.4. Refer participants to the TB drug cards. Explain that these cards are similar to the ARV cards. They outline the medications used in South Africa for treatment of TB including dosage, drug information, contraindications, and patient education.
	1.5. Refer participants to Handout 4.1. First Line TB Drugs. Ask a participant to read the information aloud.
	1.6. Write 2(HRZE)/4(HR)3 on a piece of flipchart paper.
	1.7. Explain that in treatment regimens, medications are abbreviated as indicated on the flipchart for the initiation phase and the continuation phase: <ul style="list-style-type: none"> <li>• 2 (HRZE): Refers to the initiation phase. “2” is the duration of the phase in months</li> <li>• “(HRZE)”: Refers to the drugs to be taken daily. (HRZE) is a fixed dose combination.</li> <li>• “4(HR)3” Refers to the continuation phase. “4” Refers to the duration of the phase in months</li> <li>• “(HR)3”: Refers to the drugs to be taken. The subscript “3” refers to how often to take the drugs. In this instance, “3” denotes three times per week. If there is no number, then that assumes daily administration.</li> </ul>
	1.8. Refer participants to Handout 4.2. Standard Treatment Regimens for Adults (8 years and Older). Explain that this handout provides more information on the standard treatment regimens for adults (8 years and older).
	1.9. Explain that there are several different regimens: <ul style="list-style-type: none"> <li>• Regimen 1 for New Cases: 2(HRZE)/4(HR) <ul style="list-style-type: none"> <li>– Intensive Phase 2(HRZE): Fixed Dose Combination with isoniazid, rifampicin, pyrazinamide and ethambutol given 7 days a week for 2 months</li> <li>– Continuation Phase 4(HR): Fixed dose combination with isoniazid and rifampicin given 7 days a week for 4 months</li> </ul> </li> <li>• Regimen 2 for Retreatment Cases (Relapse, Treatment, after Failure, Treatment after Default): 2(HRZES)/1(HRZE)/5(HRE) <p>Stress that this is used in people NOT diagnosed with GeneXpert.</p> <ul style="list-style-type: none"> <li>– Intensive Phase 2(HRZES)/1(HRZE): Fixed dose combination with isoniazid, rifampicin, pyrazinamide, and ethambutol given 7 days a week for 2 months and streptomycin injections given 7 days a week (or a minimum 5 times a week if daily injections are not possible) for 2 months. In the third month, fixed dose combination with isoniazid, rifampicin, pyrazinamide and ethambutol given 7 days a week</li> <li>– Continuation Phase 5(HR): Fixed dose combination with isoniazid, rifampicin and ethambutol given 7 days a week for 5 months</li> </ul> </li> <li>• Treatment for MDR-TB and XDR-TB cases – discussed in Session 6</li> </ul>
	1.10. Ask participants, “Why are retreatment cases treated differently and for a longer duration than new cases?” Answers: <ul style="list-style-type: none"> <li>• Higher likelihood of resistance that may have been acquired through inadequate prior chemotherapy</li> <li>• This regimen can cure clients excreting bacilli still fully sensitive to drugs as well as those excreting bacilli resistant to isoniazid and/or streptomycin.</li> </ul>
	1.11. Refer participants to the following cards: <ul style="list-style-type: none"> <li>• Standard treatment Regimen Dosages</li> <li>• Regimen 1: Treatment in New Cases</li> <li>• Regimen 2: Treatment in Re-Treatment Cases</li> </ul> <p>Explain that cards are an overview of dosage for different regimens.</p>
	1.12. Ask participants, “What is the difference between treating adults versus children?” Facilitate a brief discussion.

	<p>1.13. Refer participants to Handout 4.3. Treatment for Children. Review handout aloud.</p>
	<p>1.14. Refer participants to the following cards:</p> <ul style="list-style-type: none"> <li>• Regimen 3A: Treatment of Uncomplicated TB in Children &lt;8 years of age or &lt; 35kg</li> <li>• Regimen 3B: Treatment of Complicated TB in Children &lt;8 years of age or &lt; 35kg</li> <li>• Regimen for the Treatment of Meningitis for Children &lt;8 years of age or &lt; 35kg</li> </ul> <p>Review Regimen 3 in detail. Emphasise the importance of monthly weighing of the child to monitor clinical response and readjust dose at end of two months of treatment.</p>
	<p>1.15. Divide participants up into pairs. Refer participants to Worksheet 4.4. Case Studies – Drug Regimens in Adults and Children. Allow participants to 30 minutes to complete the case studies.</p>
	<p>1.16. Reconvene participants and ask for a group to give their answer to Case 1. To save time, ask if any groups came to a different conclusion and if so, why. Repeat the correct answer before moving on. Repeat this for each of the other case, asking a different pair to report out.</p>



## Handout 4.1. First-Line TB Drugs

TB drugs have varying properties:

- They may be bactericidal, bacteriostatic (sterilising) or have the ability to prevent resistance.
- They differ in the ability to act against the various populations of bacilli found in a tuberculosis lesion:
  - Metabolically active bacilli, intermediately active bacilli, semi-dormant bacilli (persisters), which undergo occasional spurts of metabolism and dormant bacilli (that may become active).
- Some TB drugs act best in an acid environment; others better at a more alkaline pH
  - Bacilli occur both in extracellular spaces where the pH is usually neutral or alkaline and in intracellular spaces where it is acidic.

<b>Properties of TB Drugs</b>				
<b>Drug</b>	<b>Drug Property</b>	<b>Target Bacilli</b>	<b>pH</b>	<b>Site of Action</b>
<b>Isoniazid (H)</b>	Bactericidal after 24 hours. High potency: kills >90% bacilli in first few days of treatment.	Rapid and intermediate growing bacilli	Alkaline and acid media.	Intracellular and extracellular.
<b>Rifampicin (R)</b>	Bactericidal within 1 hour. High potency. Most effective sterilising agent.	All populations including dormant bacilli.	Alkaline and acid media.	Intracellular and extracellular.
<b>Pyrazinamide (Z)</b>	Bactericidal with a low potency. Achieves its sterilising action within 2-3 months.	Slow growing bacilli.	Acid medium.	Intracellular bacilli only (macrophages).
<b>Ethambutol (E)</b>	Bacteriostatic. Low potency. Minimises the emergence of drug resistance.	All bacterial populations.	Alkaline and acid media.	Intracellular and extracellular.
<b>Streptomycin (S)</b>	Bactericidal with a low potency.	Rapidly growing bacilli.	Alkaline medium.	Extracellular bacilli

### *Fixed dose combination tablets*

The use of fixed dose combinations (FDCs) has several advantages over individual drugs:

- Prescription errors are less likely as dosage recommendations are more straightforward and adjustment of doses according to client weight is easier.
- The number of tablets to be ingested is fewer and this may encourage client adherence.
- If treatment is not observed, clients cannot be selective in the choice of drugs ingested.



## Handout 4.2. Standard Treatment Regimens for Adults (8 years and older)

Standardised treatment regimens have several advantages over individualised treatment:

- Reducing prescription errors
- Facilitating estimates of drug requirements and procurement
- Reducing cost
- Facilitating regular drug supply when clients move from one facility to another
- Simplifying training

A standard code is used to describe treatment regimens. It describes the duration of both the intensive and continuation phases, the fixed drug combinations used in each of the phases and the number of doses of the drugs per week.

Each antituberculosis drug has an abbreviation: R (Rifampicin), H (Isoniazid), Z (Pyrazinamide), E (Ethambutol) and S (Streptomycin).

The number before a phase is the duration of that phase in months: 2 months for the intensive phase and 4 months for the continuation phase.

Letters in brackets indicate fixed dose combinations of drugs in that phase.

A subscript after the letters in brackets indicates the number of doses of that drug per week. If there is no subscript treatment is taken daily. The subscript of 5 here indicates treatment taken 5 days a week, as in the old treatment regimens.

**New recommendations are that treatment is given daily. The exception is where Streptomycin injections may be given a minimum of 5 times per week where health services are unavailable on weekends and no alternative plan for daily injections is possible.**

### New Cases

**A new case is a client who has never been treated for TB in the past or who has taken TB treatment for less than four weeks.**

The standard treatment regimen for new cases has an initial (or intensive) phase lasting 2 months and a continuation phase lasting 4 months. Treatment with 4 drugs (isoniazid, rifampicin, pyrazinamide, and ethambutol) in the intensive phase results in rapid killing of tubercle bacilli. Infectious clients become non-infectious within approximately 2 weeks. Symptoms abate. The vast majority of clients with sputum smear-positive TB become smear-negative within 2 months. In the continuation phase, 2 drugs (isoniazid, rifampicin) are used, but for a longer period of time. The sterilizing effect of the drugs eliminates the remaining bacilli and prevents subsequent relapse.

**The standard treatment regimen for new cases is regimen 1: 2(HRZE)/4(HR)**

- **The intensive phase is 2(HRZE). Treatment is with isoniazid, rifampicin, pyrazinamide and ethambutol in fixed dose combinations given 7 days a week for 2 months.**
- **The continuation phase is 4(HR). Treatment is with isoniazid and rifampicin in fixed dose combinations given 7 days a week for 4 months.**

## Retreatment cases (will be phased out once GXP roll-out is complete)

**Retreatment clients include all TB clients who were treated for 4 weeks or more in the past and who are now smear or culture positive or who have clinically been diagnosed with TB (failure, relapse, treatment after default).**

These cases have a higher likelihood of resistance that may have been acquired through inadequate prior chemotherapy. The retreatment regimen has an intensive phase lasting 3 months. For the first 2 months, treatment includes 5 drugs: isoniazid, rifampicin, pyrazinamide, ethambutol and streptomycin. In the 3rd month, treatment is with 4 drugs: isoniazid, rifampicin, pyrazinamide, ethambutol. The continuation phase with 3 drugs (isoniazid, rifampicin, ethambutol) lasts 5 months.

This regimen can cure clients excreting bacilli still fully sensitive to the drugs as well as those excreting bacilli resistant to isoniazid and or streptomycin.

**The standard regimen for retreatment cases is regimen 2: 2(HRZES)/1(HRZE)/5(HRE)**

- **The intensive phase is 2(HRZES)/ 1(HRZE). It lasts 3 months in total. For the first two months treatment is with isoniazid, rifampicin, pyrazinamide and ethambutol in fixed dose combinations given 7 days a week and streptomycin injections given 7 days a week (or a minimum of 5 times a week if daily injections are not possible). In the third month only isoniazid, rifampicin, pyrazinamide and ethambutol in fixed dose combinations is given 7 days a week.**
- **The continuation phase is 5(HR)E. Treatment is with isoniazid, rifampicin in fixed dose combinations given 7 days a week plus ethambutol given 7 days a week.**

*Source: SA National TB Guidelines, 2009.*



## Handout 4.3. Treatment for Children

### TB Treatment Aim:

The aim of TB treatment in children is to:

1. Identify children with TB infection at risk of developing disease (young children and HIV-infected children)
2. Diagnose and treat children with TB disease to prevent the development of more serious TB or death.
3. Protect children from developing TB, especially serious forms of TB by implementing a combination of three strategies:
  - a. The early detection and treatment of adult infectious cases
  - b. Universal use of BCG
  - c. TB preventative therapy to children under 5 years of age and HIV-infected children in contact with cases of infectious tuberculosis

### TB Treatment in Children

Children with TB usually have paucibacillary disease and are not a risk to other children or adults. However, some children, mainly school-aged children and adolescents, have smear-positive TB with cavities on chest x-ray. These children are as infectious as smear-positive adults and other children in contact with them must be investigated as if they were in contact with an adult infectious case.

High success rates are achievable in children with uncomplicated TB and less severe forms of EPTB such as TB lymphadenopathy and pleural effusion. Like adults, children also receive 2 phases of treatment: an intensive phase of 2 months and a continuation phase of 4 months. Fewer drugs are required to treat paucibacillary TB because the risk of resistance is much lower due to the low numbers of bacilli. These children receive a regimen with 3 three drugs during the intensive phase (HRZ) and 2 drugs in the continuation phase (HR).

Children who are sputum smear-positive or have a cavity visible on chest x-ray have a high bacillary load and should be treated in the same way as newly diagnosed smear-positive adult clients on regimen 1. They are treated with 4 drugs (HRZE) in the intensive phase and 2 drugs (HR) in the continuation phase.

### Referrals

**To Specialist:** All children with severe forms of tuberculosis (meningitis, spine, peritonitis, miliary, skeletal) and those suspected of having MDR-TB (in contact with MDR case or not responding to first line therapy) should be referred for management. In these children the drug therapy may be given for a longer time but still through directly observed therapy (DOT). Children with severe disease are also treated with 4 drug regimens. It is important that on discharge from the hospital, the treatment is continued at the primary health facility at the drug dosages recommended by the referral centre.

**To Hospital:** Indicated in the evaluation of the child with suspected TB, especially in the presence of danger signs including:

- Headache (especially if accompanied by vomiting), irritability, drowsiness, neck stiffness and convulsions (signs of TB meningitis)
- Meningitis not responding to treatment, with a sub-acute onset or raised intracranial pressure
- Big liver and spleen (signs of disseminated TB)
- Distended abdomen with ascites
- Breathlessness and peripheral oedema (signs of pericardial effusion)
- Severe wheezing not responding to bronchodilators (signs of severe bronchial compression)
- Acute onset of angulation (bending) of the spine.

### Drug Dosages

Over dosage may lead to increased toxicity and under dosage can lead to treatment failure.

- The drug dosages depend on the body weight of the child
- Adjust dosage as weight changes during the course of treatment. Children should be weighed monthly to monitor response to treatment and the drug doses adjusted according to the weight of the child at the time.

## Regimen 3A: 2(RHZ)/4 (RH)

Regimen 3A the Treatment of Children < 8 years of Age or < 35kg:

- Regimen 3 is indicated for the treatment of children < 8 years of age or < 35kg
- Most children have paucibacillary TB
- Fewer drugs are required to treat TB in paucibacillary TB because the risk of resistance is much lower due to the low numbers of bacilli
- Children who are sputum smear-positive or have a cavity visible on chest x-ray have a high bacillary load and should be treated in the same way as newly diagnosed smear-positive adult clients on regimen 3B.

2(RHZ)/4(RH) given 7 days a week is the recommended regimen for treatment of uncomplicated TB and EPTB such as lymph node TB and TB pleural effusion in children. Children should receive regimen 3A for 6 months and there should be direct observation of the treatment.

Regimen 3A is not used in children above the age of 8 years of age or weighing >35 kg and adolescents.

## Regimens 3B

Children with smear positive or cavitory pulmonary TB disease, extrapulmonary disease (excluding miliary TB and meningitis) or with severe immunosuppression should be treated with Regimen 3B, using 4 drugs (RHZE) in the intensive phase and 2 drugs (RH) in the continuation phase.

Children above 8-years of age or who weigh more than 35kg and adolescents should be treated like adults with Regimen 1 for newly diagnosed.

Dosages for all regimens are calculated based on the child's weight.

## Use of steroids in children with TB

Indications for oral steroids in children with TB include:

- TB meningitis
- TB pericarditis
- Mediastinal lymph glands obstructing the airways.
- Severely ill children with disseminated TB (miliary)

Children with these forms of TB should be referred to the hospital for management. The dosage is prednisone 1-2 mg/kg daily orally for 4-6 weeks added to the TB drugs. The dose can be tapered to stop over 2 weeks.

Recommended Treatment Regimens for Children < 8 years of Age or <35 kg			
Regimen	Definition	Initial phase Daily treatment	Continuation phase Daily treatment
<b>Regimen 3A</b>	New smear negative PTB without parenchymal involvement, less severe forms of extrapulmonary TB	RHZ for 2 months + Isoniazid Booster	RH for 4 months + Isoniazid Booster
<b>Regimen 3B</b>	New smear positive PTB, smear negative with extensive parenchymal involvement, severe forms of extrapulmonary TB	HRZE for 2 months + Isoniazid Booster	HR for 4 months + Isoniazid Booster
<b>Regimen 3C</b>	TB Meningitis	HRZ + Isoniazid Booster + Ethionamide for 9 months only	

Source: Adapted from SA National TB Guidelines, 2009/2012.



## Worksheet 4.4. Case Studies – Drug Regimens in Adults and Children

*Case Study #1:* Devide is a 32 year-old man from Nelspruit. He reports 4 weeks of productive cough with fever, sweats and weight loss. He is HIV-infected.

1. What additional subjective information would you like to obtain from Devide?
  - Any additional symptoms, length of symptoms, history of TB exposure or exposure to other infectious illness
  - Any current medications, history of TB infection or treatment, any known drug allergies
  - Is he on any ARVs or cotrimoxazole, recent CD4 or Viral Load results, history of any opportunistic infections, prevention, disclosure, HIV and TB contact status and testing
2. What objective information (physical exam and laboratories) do you plan to obtain?
  - Assess for urgent signs and symptoms: Airway/Breathing, Circulation, Consciousness, Fever
  - Sputum microscopies x 2 (or specimen x1 if GXP), consider chest xray depending on subjective information
  - CD4 if not recently obtained, consider viral load and other laboratories if on ARVs
  - Vital signs and physical exam – specifically including weight, heart rate, respiratory rate, blood pressure, examine mouth, lungs and for any extrapulmonary TB
  - Too little subjective or objective information to determine the need for additional information.

*Case continued:* Subjective: Devide also complains of some fatigue. He denies any other symptoms at present. He has never been diagnosed or treated for TB before. He does not know of any TB exposure and as far as he is aware, no family or friends have similar symptoms. He has no known drug allergies and is not currently on medications. He had a CD4 obtained when he was first diagnosed with HIV one year ago and the result was 750 cells/mm<sup>3</sup>.

Objective: Weight 53 kg, Respiratory Rate 18 breaths/minute, Heart rate 65 beats/minute, Blood Pressure 112/78. HEENT: Mouth without thrush, no erythema. Lungs: Minimal crackles anteriorly, bilaterally. Otherwise clear to auscultation. Heart: Regular rate and rhythm. Abdomen: No hepatosplenomegaly, No abdominal masses or tenderness. Skin: No rashes/lesions appreciated. Lymphadenopathy: Shotty anterior cervical lymphadenopathy bilaterally. No other lymph appreciated.

Sputum Smears positive x2 by microscopy. No chest x-ray obtained at this time. CD4 cell count 468 cells/mm<sup>3</sup>.

3. How do you classify this patient?
  - Definite TB case with concomitant HIV
  - Smear positive pulmonary TB
  - New
4. What medications including dosage and number of tabs do you start with for the initial phase?
  - FDC: Rifampicin (150 mg), Isoniazid (75 mg), Pyrazinamide (400 mg), Ethambutol(275 mg) – 3 tabs for 2 months
  - Cotrimoxazole prophylaxis (Stage III due to TB infection)
5. What medications including dosage and number of tabs would you start in the continuation phase?
  - Fixed Dose Combination: Rifampicin (150 mg), Isoniazid (75 mg) – 3 tabs, 7 days per week for 4 months

6. What counselling will you provide regarding TB?
  - *Adherence*
  - *Prevention*
  - *Screening for other family members and close contacts*
7. How will you address his HIV status?
  - *Assuming patient has already had post test counselling, discuss the implications of his HIV status*
  - *Address the need to treat TB first (curable)*
  - *Discuss ARV not currently recommended at his CD4 count but importance of repeating labs regularly*
  - *Schedule follow-up*
  - *Discuss disclosure and prevention*
  - *Repeat CD4 monitoring at appropriate time*
8. What recording and reporting tools/registers to complete in this case?
  - *TB Case Identification and Follow-up Sputum Register (GW20/13) – with results and follow-up*
  - *Laboratory Specimen Request Form – as laboratory requests are being made*
  - *TB Register – As started on treatment*
  - *Patient Clinic/Hospital Card – As started on treatment*
  - *Patient Treatment Card – As started on treatment*
  - *Pre-ART*

*Case Study #2: Ntombi is a 44 year-old woman with a chronic cough, fever, and weight loss. She recently moved. Her HIV status is unknown.*

1. What additional subjective information would you like to obtain from Ntombi?
  - *Any urgent signs and symptoms or additional symptoms, length of symptoms, history of TB exposure or exposure to other infectious illness*
  - *Any current medications, history of TB infection or treatment, any known drug allergies*
  - *Any symptoms of pregnancy, current family planning*
2. What objective information (physical exam and laboratories) do you plan to obtain?
  - *Assess for urgent signs and symptoms: Airway/Breathing, Circulation, Consciousness, Fever*
  - *Sputum microscopies x 2 (or sputum specimen x1 if GXP available), consider chest x-ray depending on subjective information*
  - *Send 2nd sputum for culture and drug susceptibility testing*
  - *HIV test*
  - *Vital signs and physical exam – specifically including weight, heart rate, respiratory rate, blood pressure, examine mouth, lungs and for any extrapulmonary TB*
  - *Last menses and symptoms of pregnancy*
  - *Too little subjective or objective information to determine the need for additional information.*

*Case continued:* Ntombi informs you that she was started on TB treatment after experiencing similar symptoms approximately eight months ago. You are able to assess that it was likely Regimen 1. She completed the initial phase six months ago but moved and did not return to start the continuation phase of treatment. She denies any other significant signs or symptoms. She recently moved in with several family members. She is not married and has no children. She denies recent sexual activity. She has no known drug allergies and is not currently taking any medications or herbal remedies.

Objective: Weight 48 kg, Respiratory Rate 20 breaths/minute, Heart Rate 72 beats/minute, Blood Pressure 169/76. Menses was two weeks ago. HEENT: Posterior pharynx mildly erythematous, no exudate. Lungs: Difficult to auscultate due to continuous coughing with exhalation. Heart: Regular rate and rhythm. Exam is otherwise normal.

Laboratories: HIV test negative. 2 sputum smears positive for acid fast bacilli on direct microscopy. Chest X-ray not obtained. DST pending. (GeneXpert not available)

3. How do you classify this patient and why?

- *Re-treatment case*
- *Return after default on regimen 1 because she took 4 weeks of TB therapy and discontinued treatment for 2 months*
- *Sputum smear positive*
- *Important to exclude M(X)DR-TB*

4. What medications including dosage and number of tabs do you start with for the initial phase?

- *FDC: Rifampicin (150 mg), Isoniazid (75 mg), Pyrazinamide (400 mg), Ethambutol (275 mg) – 3 tabs and streptomycin injections (0.75 g) for 2 months then 1 month FDC: Rifampicin (150 mg), Isoniazid (75 mg), Pyrazinamide (400 mg), Ethambutol (275 mg) without streptomycin. This is regimen 2. Once regimen 2 phased out, treatment with Regimen 1 or MDR-TB regimen depending on GXP results.*

5. What medications including dosage and number of tabs would you start in the continuation phase?

- *Fixed Dose Combination: Rifampicin (150 mg), Isoniazid (75 mg) – 3 tabs, and ethambutol (400mg) – 2 tabs, 7 days per week for 5 months*

6. What recording and reporting tools/registers to complete in this case?

- *TB Case Identification and Follow-up Sputum Register (GW20/13) – with results and follow-up*
- *Laboratory Specimen Request Form – as laboratory requests are being made*
- *TB Register – As started on treatment*
- *Patient Clinic/Hospital Card – As started on treatment*
- *Patient Treatment Card – As started on treatment*
- *HCT Register*

*Case Study #3:* A 4 year-old girl named Tumi is brought to the clinic by her father who reports that she has had cough and fevers for several weeks. She was given amoxicillin last month for the swollen glands and had no improvement.

1. What additional subjective information would you like to obtain from Tumi's father?
  - *Any urgent signs and symptoms or additional symptoms, length of symptoms, history of TB exposure or exposure to other infectious illness*
  - *Any other current medications, history of TB infection or treatment, any known drug allergies, did she complete the amoxicillin treatment*
  - *HIV status or history of exposure*
2. What objective information (physical exam and laboratories) do you plan to obtain?
  - *Assess for urgent signs and symptoms: Airway/Breathing, Circulation, Consciousness, Fever*
  - *Sputum microscopy, consider chest x-ray and/or TST*
  - *HIV test*
  - *Vital signs and physical exam – specifically including weight, heart rate, respiratory rate, blood pressure, examine mouth, lungs and for any extrapulmonary TB*
  - *Too little subjective or objective information to determine the need for additional information.*

*Case continued:* Subjective: The girl had pulmonary TB treated one year ago. In addition, her grandmother who cares for her during the day was treated for smear-positive pulmonary TB last year.

Objective: Weight 10kg, Respiratory Rate 25 breaths/minute. Heart rate 102 beats/minute. On exam she has an enlarged lymph node on the left side of her neck. A chest x-ray shows enlarged hilar lymph nodes with normal lung fields. A gastric aspirate and fine needle aspiration of her lymph node are performed. The smears are negative.

3. Should this child be started on TB treatment? Why or why not?
  - *The child should be started on TB treatment because she has symptoms of TB and abnormal chest x-ray which is suggestive of TB and because she had a trial with antibiotics with no response.*
4. How do you classify this patient and why?
  - *Re-treatment case due to previous TB treatment one year ago*
  - *Smear negative with normal lung fields and emphasise that she has extrapulmonary TB (TB lymphadenitis)*
5. What type of tuberculosis does this girl presumptively have?
  - *Extrapulmonary TB Lymphadenitis*
6. Based on her symptoms, does she require referral?
  - *No, there is no evidence of danger signs that require referral (severe wheezing or respiratory distress, breathlessness and peripheral oedema)*
7. What regimen should she be started on? Why?
  - *She should be treated with regimen 3A, as she has uncomplicated or less severe form of EPTB.*
8. What medications including dosage and number of tabs do you start with for the initial phase and continuation phase?
  - *Children less than 8 usually will receive RHZ in a fixed dose tablet with rifampicin 60mg, isoniazid 30mg, and pyrazinamide 150mg. Using the weight band tables, this child (at 10 kg) should receive 2 tabs of RHZ as a fixed drug combination and an additional ½ tablet of Isoniazid 100mg tablet*
  - *Continuation phase will depend on her weight. RH is given 7 days a week for 7 months.*
9. What recording registers to complete in this case?
  - *TB Case Identification and Follow-up Sputum Register (GW20/13) – with results and follow-up*
  - *Laboratory Specimen Request Form – as laboratory requests are being made*
  - *TB Register – As started on treatment*
  - *Patient Clinic/Hospital Card – As started on treatment*
  - *Patient Treatment Card – As started on treatment*

*Case Study #4:* A 6 year-old boy named Rodney is brought to clinic by his mother. She reports the boy has not been feeling well for approximately 1 month. His symptoms started with fatigue and night sweats.

1. What additional subjective information would you like to obtain from Rodney's mother?
  - *Any additional symptoms, length of symptoms*
  - *History of TB exposure or exposure to other infectious illness*
  - *Any other current medications, history of TB treatment, any known drug allergies*
  - *HIV status or history of exposure*
2. What objective information (physical exam and laboratories) do you plan to obtain?
  - *Assess for urgent signs and symptoms: Airway/Breathing, Circulation, Consciousness, Fever*
  - *Vital signs and physical exam – specifically including weight, heart rate, respiratory rate, blood pressure, examine mouth, lungs and for any signs of extrapulmonary TB*
  - *Chest x-ray, consider TST and/or sputum microscopies*
  - *HIV test*
  - *Too little subjective or objective information to determine the need for additional information.*

*Case continued:* Subjective: He recently has complained of headaches and for the past several days has been sleeping much more than usual. There are no known TB exposures. He had been seen in the clinic 1 week ago and had a Mantoux and chest x-ray that was negative. He is not known to be HIV exposed or infected. But the mother and child have not previously been tested.

Objective: Weight 20 kg, Temperature 39 C, Respiratory Rate 26 breaths/minute, Heart rate 99 beats/minute.

On exam he appears drowsy. His neck is stiff; the neurologic exam shows no focal neurologic deficits and the rest of the exam is otherwise normal.

3. How should this child be managed?
  - *Patient should be stabilised in the clinic and then urgently referred to hospital for management for an LP and evaluation for TB.*
  - *History is suspicious for TB meningitis or other meningitis, but should get a lumbar puncture prior to make the diagnosis.*
  - *Chest x-ray*
  - *Test for HIV*
4. What are your differential diagnoses (possible reasons for his symptoms)?
  - *The stiff neck, fever, lethargy, headache and fatigue increase suspicion of meningitis.*
  - *Meningitis could be Bacterial or Viral*
  - *TB meningitis*
  - *If HIV infected, cryptococcal meningitis*
5. If the diagnosis is confirmed as TB meningitis, what regimen should he be started on? Why?
  - *Regimen 3C because he has severe disease (meningitis). The therapy may be given for a longer time and through DOT.*
  - *The specialist will start the patient on HRZ + Ethionamide for a period of 9 months*
  - *Steroids should be considered for treatment of TB meningitis (prednisone 1-2 mg/kg daily orally for 4-6 weeks and tapered to stop over 2 weeks).*
6. What recording registers to complete in this case?
  - *TB Case Identification and Follow-up Sputum Register (GW20/13) – with results and follow-up*
  - *Laboratory Specimen Request Form – as laboratory requests are being made*
  - *TB Register – As started on treatment*
  - *Patient Clinic/Hospital Card – As started on treatment*
  - *Patient Treatment Card – As started on treatment*
  - *Referral Forms – as likely referred to the hospital*

*Case Study #5:* A 2 year-old girl is brought to your rural clinic by her mother who reports that she has been losing weight for approximately two months.

1. What additional subjective information would you like to obtain from Thembi's mother?
  - *Any additional symptoms, length of symptoms*
  - *History of TB exposure or exposure to other infectious illness*
  - *Any other current medications, history of TB infection or treatment, any known drug allergies*
  - *HIV status or history of exposure*
2. What objective information (physical exam and laboratories) do you plan to obtain?
  - *Assess for urgent signs and symptoms: Airway/Breathing, Circulation, Consciousness, Fever*
  - *Vital signs and physical exam – specifically including weight, heart rate, respiratory rate, blood pressure, examine mouth, lungs and for any signs of extrapulmonary TB*
  - *Chest x-ray, consider TST and/or sputum microscopies*
  - *HIV test*
  - *Too little subjective or objective information to determine the need for additional information.*

*Case continued:* Subjective: The child has also had drenching night sweats for several weeks and fevers. There is no known exposure to a TB case. The mother has not noticed any cough or breathlessness. Objective: On exam the child has a temperature of 39 C, heart rate 120, respiratory rate 20, BP 117/82, weight 12kg. The child is thin but not in any acute distress. The exam does not reveal any enlarged lymph nodes and is otherwise within normal limits.

No chest x-ray is available. A Mantoux test if performed and two days later the Mantoux is 14 mm. An HIV test is negative.

3. Should this child be started on TB treatment? Why or why not? If not, what should be done next?
  - *The child should be referred to the hospital for further evaluation.*
  - *According to new guidelines she meets criteria for TB due to symptoms suggestive of TB and positive TST if no chest X-ray is available.*
  - *Ideally, she would receive further work-up right away. Children 2 years and younger under often present with EPTB and therefore are less likely to have pulmonary symptoms than their older peers.*
  - *She should be evaluated for extrapulmonary TB and non-TB causes with a chest x-ray, full blood count, blood chemistries and liver function tests and blood cultures.*
4. What recording registers to complete in this case?
  - *TB Case Identification and Follow-up Sputum Register (GW20/13) – with results and follow-up*
  - *Laboratory Specimen Request Form – as laboratory requests are being made*
  - *TB Register – As started on treatment*
  - *Patient Clinic/Hospital Card – As started on treatment*
  - *Patient Treatment Card – As started on treatment*



## Trainer Instructions: Step 2 (30 Minutes) Side Effects of Anti-TB Drug Treatment

### Step 2 Learning Objectives:

- Describe common side effects related to taking anti-TB drugs.
- Identify potential adverse drug interactions while on anti-TB medications.

### Step 2 Resources Needed:

- Handout 4.5. Symptom-Based Approach to Management of Drug Side Effects
- TB drug cards
- Flipchart and markers
- Clinical Reference Manual

### Step 2 Trainer Instructions:

	2.1. Assign each group one of the following: <ul style="list-style-type: none"> <li>• Isoniazid</li> <li>• Rifampicin</li> <li>• Pyrazinamide</li> <li>• Ethambutol</li> <li>• Streptomycin</li> </ul>
	2.2. Give each group two pieces of flipchart paper.
	2.3. Explain that participants are to record potential side effects, contraindications, drug interactions and management of their specific anti-TB drug on the flipchart paper and select one person to present their group's findings to the larger group.
	2.4. Refer participants to the clinical reference manual and the TB drug cards for this activity.
	2.5. Allow 10 minutes for this activity
	2.6. Reconvene group.
	2.7. Ask group 1 to present the side effects, contraindications, drug interactions and management of side effects associated with their medication.
	2.8. Repeat this for each of the other medications.
	2.9. Ask participants, "What is the healthcare workers' role in assessing side effects?" Record responses on a flipchart. <i>Possible Answers: Asking whether patients have them, educating on potential side effects, identifying and treating side effects, monitoring to assess adherence and identifying side effects.</i>
	2.10. Refer participants to Handout 4.5. Symptom-Based Approach to Management of Drug Side Effects. Review table with participants, highlighting the management of each of the symptoms presented.



## *Handout 4.5. Symptom-Based Approach to Management of Drug Side Effects*

<b>Minor Symptoms</b>	<b>Drug(s) responsible</b>	<b>Management</b>
Anorexia, nausea, abdominal pain	Rifampicin	Continue TB drugs. Give tablets last thing at night.
Joint pains	Pyrazinamide	Continue TB drugs. Aspirin.
Burning sensation in feet	Isoniazid	Continue TB drugs. Pyridoxine 25mg daily.
Orange/red urine	Rifampicin	Continue TB drugs. Reassurance.

<b>Major Symptoms</b>	<b>Drug(s) responsible</b>	<b>Management</b>
Skin itching/rash (anaphylactic reaction)	Streptomycin	Stop streptomycin. Treat as for hypersensitivity reaction.
Deafness (no wax on auroscopy)	Streptomycin	Stop streptomycin.
Dizziness (vertigo and nystagmus)	Streptomycin	Stop streptomycin if severe.
Jaundice (other causes excluded)	Most TB drugs	Stop TB drugs until jaundice resolves, then re-introduce one by one
Vomiting and confusion (suspected drug-induced pre-icteric hepatitis)	Most TB drugs	Stop TB drugs, urgent liver function tests.
Visual impairment	Ethambutol	Stop ethambutol.
Generalised reaction, including shock and purpura	Rifampicin	Stop rifampicin.



## Trainer Instructions: Step 3 (20 Minutes) Treatment Interruption

### *Step 3 Learning Objectives:*

- Discuss the management of tuberculosis treatment interrupters.

### *Step 3 Resources Needed:*

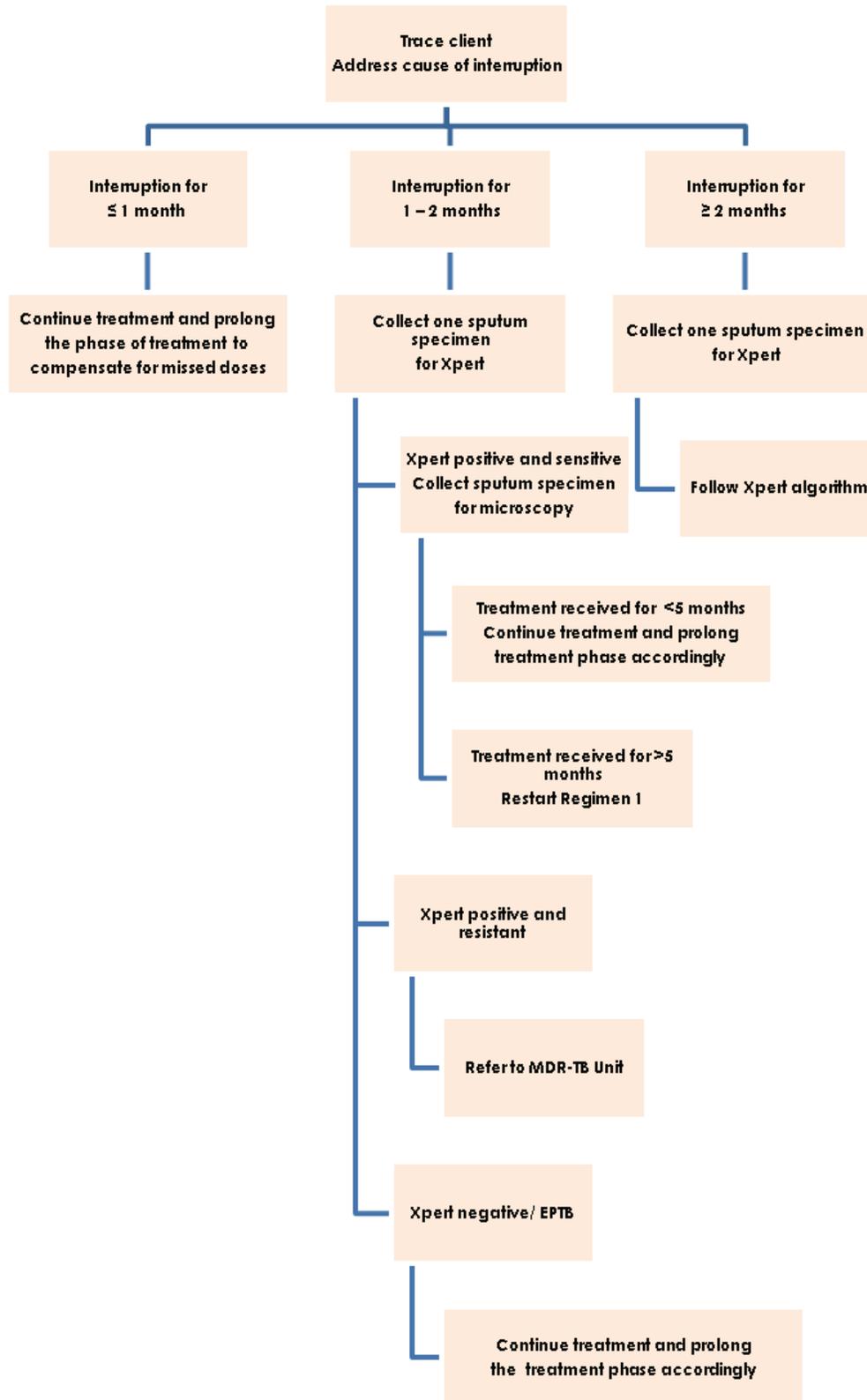
- Handout 4.6. Management of Treatment Interruption
- Worksheet 4.7. Case Studies for Treatment Interruption
- Clinical Reference Manual

### *Step 3 Trainer Instructions:*

	3.1. Explain that the management of clients who have interrupted treatment is complex and takes into consideration multiple variables including their immune status, degree of remission of the disease with the previous treatment and drug susceptibility.
	3.2. Refer participants to Handout 4.6. Management of Treatment Interruption. Explain that this handout shows actions to take when TB treatment is interrupted for less than 1 month, 1-2 months, and more than 2 months. Review the algorithm with participants.
	3.3. Divide participants into pairs. Refer participants to Worksheet 4.7. Case Studies for Treatment Interruption. Allow each pair 10 minutes to complete the worksheet using the algorithm presented in Handout 4.6.
	3.4. Reconvene pairs and ask for volunteers to present answers.
	3.5. Clarify correct answer before moving on.



## Handout 4.6. Management of Treatment Interruption



## Management of Treatment (No GXP)

### I. Interruption for less than one month

- Trace client
- Address the cause of interruption

- Continue treatment and prolong it to compensate for missed doses:
  - Add the number of days of missed doses at the end of either the intensive or

### II. Interruption for one to two months

- Trace client
- Address the cause of interruption
- Collect 1 sputum specimen for smear microscopy
- Continue treatment while waiting for results

Smear negative or  
EPTB

Continue treatment  
and prolong it to  
compensate for missed  
doses as above.

Smear positive:  
Send sputum for culture and drug susceptibility testing/ LPA

Treatment received:  
Less than 5 months

Continue treatment and  
prolong phase to  
compensate for missed  
doses  
Review drug susceptibility  
testing

Treatment received:  
More than 5 months

Regimen 1:  
Start Regimen 2  
Review drug  
susceptibility  
testing

Regimen 2:  
Review the DST  
results and  
manage  
appropriately

### III. Interruption for two months or more (defaulter)

- Trace client
- Address the cause of interruption
- Collect 2 sputum specimen for smear microscopy, culture and DST/ LPA
- No treatment while waiting for results

Smears negative or  
EPTB

Do Chest x-ray  
Clinical decision on  
treatment. Review  
culture results

One or more smears positive:

If patient was on Regimen 1:  
Start Regimen 2  
Review DST results

If patient was on Regimen 2:  
Review DST results and manage  
appropriately



## Worksheet 4.7. Case Studies for Treatment Interruption

*Case Study #1:* Lesetho is a 38 year-old man with smear positive pulmonary TB presents to the clinic complaining of cough and breathlessness. He is HIV negative. Lesetho quit taking his TB medication approximately three months ago after he moved from East London to Mpumalanga. He received three months of TB treatment before he defaulted. He was a new case and was on regimen 1.

1. What is the approach to managing this patient's treatment interruption?
  - *The patient has defaulted from treatment as he has interrupted treatment for more than two months. The cause of his treatment interruption should be addressed (ie, why he did not follow-up with TB program after moving) through education and counselling.*
  - *Two sputum specimen should be collected for smears, culture and DST/ LPA should be performed and no treatment given while waiting for results.*
  - *If GXP is available, collect one specimen and follow algorithm.*

*Case continued:* The patient in the previous case had one positive smear (If GXP is available, rifampicin susceptible.)

2. What should be done next?
  - *Since his sputa are positive he should be started on regimen 2 since he was on regimen 1 and DRUG SUSCEPTIBILITY TESTING results reviewed when they are available. If sensitive to the first line drugs – treatment continued and if resistant to Rifampicin and or Isoniazid – recorded as failure and started on MDR-TB treatment.*
  - *If GXP is available, treat as regimen 1. Send one specimen for microscopy and then follow-up with microscopy.*

*Case Study #2:* Lakisha is a 40 year-old woman with smear positive pulmonary TB who comes to clinic after missing 3 weeks of TB treatment while she was visiting family in a different city. She had completed 3 months of Regimen 1.

1. What is the approach to managing this patient's treatment interruption?
  - *The client had a treatment interruption of less than one month. The cause of her treatment interruption should be addressed through education and counselling and she should continue continuation phase of regimen 1 and prolong it by 3 additional weeks to make up for missed doses.*
  - *If GXP is available, continue treatment and prolong phase of treatment to compensate for missed doses.*

*Case Study #3:* Lesego is a 59 year-old man who comes to clinic after a treatment interruption of 6 weeks. He has smear positive pulmonary TB and is on regimen 1. After just over 5 months of treatment he was feeling better so he stopped the treatment. Sputa are sent and are positive.

1. What is the approach to managing this patient's treatment interruption?
  - *The client has a treatment interruption of less than two months, therefore not a defaulter. Since his sputum are smear positive he should have sputum sent for culture and DRUG SUSCEPTIBILITY TESTING/ LPA. Since he received more than 5 months of treatment he should be started on Regimen 2 while awaiting DRUG SUSCEPTIBILITY TESTING results. If sensitive to the first line drugs – treatment continued and if resistant to Rifampicin and or Isoniazid – recorded as failure and started on MDR-TB treatment.*
  - *Also educate and counsel the patient to address reason for interrupting treatment.*
  - *If GXP is available, if sensitive, collect sputum for microscopy and restart regimen 1. If resistant, refer.*
2. What would have been done if Lesego's sputa were negative when he returned to the clinic after the treatment interruption?
  - *The continuation phase of regimen 1 would have been continued and prolonged by an additional 6 weeks to compensate for missed doses.*



## Trainer Instructions: Step 4 (75 Minutes) Management of Adults and Children on Anti-TB Drug Treatment

### Step 4 Learning Objectives:

- Manage adults and children with tuberculosis.
- Identify when children should be referred for assessment.

### Step 4 Resources Needed:

- Worksheet 4.8. Case Studies - Management of Adults and Children with TB
- TB drug cards
- Clinical Reference Manual

### Step 4 Trainer Instructions:

	4.1. Refer participants to the Worksheet 4.8. Case Studies – Management of Adults and Children with TB. Allow participants up to 40 minutes to complete the case studies.
	4.2. Reconvene participants and ask for a group to give their answer to Case 1.
	4.3. To save time, ask if any groups came to a different conclusion and if so, why. Repeat the correct answer before moving on. Repeat this for each of the other case, asking a different pair to report out.
	4.4. Ask participants, “Should patients typically have significant improvement in the signs and symptoms of TB within 2-4 weeks. What should you do if a child doesn’t respond to treatment in this time frame?”  <i>Answer: Those with prolonged signs and symptoms of TB should be referred for assessment.</i>
	4.5. Ask participants, “What questions do you ask if a child experiences a worsening of symptoms despite adequate therapy?”  <i>Answers:</i> <ul style="list-style-type: none"> <li>• <i>Is the drug dosage correct?</i></li> <li>• <i>Is the child taking the drugs as prescribed (good adherence)?</i></li> <li>• <i>Is the child HIV-infected?</i></li> <li>• <i>Was the child severely malnourished?</i></li> <li>• <i>Is there a reason to suspect drug-resistant TB?</i></li> <li>• <i>Has the child developed IRIS?</i></li> <li>• <i>Is there another reason for the child’s illness, other than or in addition to TB?</i></li> </ul>
	4.6. Summarise Activity: Any child with persistent symptoms or who deteriorates on TB treatment should be referred for assessment.



## Worksheet 4.8. Case Studies: Managing Adults & Children with TB

*Case Study #1:* Rose, a 59 year-old female, comes to clinic complaining of abdominal pain and swelling.

1. What subjective information would you like to know?

- *Previous active TB infection?*
- *HIV infection?*
- *Length of symptoms?*
- *Additional symptoms – night sweats? Cough? Fever? Vomiting? Diarrhoea? Where is her abdominal pain?*
- *Hepatitis?*
- *Substance use?*
- *Social/economic history?*
- *What medications is she taking*

2. Is this an urgent patient?

- *She is stable but should be evaluated immediately. Although she does not fit the criteria for seriously ill patient, there is a high suspicion for TB peritonitis which is a severe form of extrapulmonary TB and she should be referred to the hospital.*

*Case continued:* Subjective Component: Her symptoms have been getting worse for 2-3 months. She reports severe weight loss and night sweats. She denies any cough. She denies any significant past medical history. She reports no alcohol use. Her son lives with her and was treated for TB last year. She has no prior history of TB.

Objective Component:

On exam: temperature: 38.7, pulse: 115, Blood Pressure: 104/83, Respiratory Rate: 22, Weight: 50kg

She is very thin and her abdomen is distended, diffusely tender, dull to percussion with a fluid wave. Her lungs are clear and the exam is otherwise normal. HIV test is negative.

3. What are your differentials?

- *peritoneal tuberculosis*
- *hepatitis*
- *pancreatitis*
- *viral or bacterial gastritis*

4. Discuss how this patient should be managed?

- *The patient has signs and symptoms suggestive of peritoneal tuberculosis. She has ascites on physical exam with weight loss and sweats. The appropriate evaluation should include checking sputum specimen for AFB smear as patients with extrapulmonary TB may also have pulmonary TB as well. A chest x-ray is important for evaluating extrapulmonary TB for the same reason and if abnormal will raise the suspicion of extrapulmonary TB.*
- *Most importantly, a diagnostic tap of the ascites is important and in TB is usually >300 white cells with predominantly lymphocytes. The fluid can be sent for routine bacterial culture and also for TB smear and culture. Finally, an ultrasound of the abdomen that showed enlarged lymph nodes would also support a diagnosis of TB.*
- *HIV test should be performed as well.*

*Case continued:* The patient is referred to the hospital and undergoes a diagnostic ascites tap. The fluid is straw colored with more than 300 white cells per mm<sup>3</sup> with predominantly lymphocytes. Chest x-ray is normal and sputum sample are negative. HIV test is negative.

5. What should you do now?

- *The patient should be started presumptively on TB treatment regimen 1 for TB peritonitis. Usually the fluid is smear and culture negative but the high white cell count with mostly lymphocytes supports the diagnosis.*
- *Negative sputum smears should not change your decision to start TB treatment.*
- *Her weight is 50kg so should be started on FDC RHZE 3 tabs daily.*

6. What recording and reporting tools/registers to complete in this case?

- *TB Case Identification and Follow-up Sputum Register (GW20/13) – with results and follow-up*
- *Laboratory Specimen Request Form – as laboratory requests are being made*
- *TB Register – As started on treatment*
- *Patient Clinic/Hospital Card – As started on treatment*
- *Patient Treatment Card – As started on treatment*
- *Referral Cards – If referred*
- *HCT register*

*Case continued:* Rose has shown slow improvement to the treatment started in the hospital and is discharged to home after three weeks. She develops an itchy rash over her arms and comes to the clinic. She denies fever but still has some night sweats.

On exam: Temperature: 37.0, Pulse: 89, Respiratory Rate: 12, BP: 120/90, Weight: 50kg

Her HEENT exam is normal and abdomen is less distended and tenderness is improved.

She has a faint macular rash over her arms.

7. How would you manage her rash? What information should be obtained in order to decide whether to stop her TB medications?

- *Rashes are common and are usually mild and can be managed with antihistamines. Calamine lotion may also help.*
- *TB medications should be stopped immediately if the rash is generalized especially with fevers and mucous membrane involvement.*
- *This patient has no signs of a serious rash so she can continue her TB medications and given antihistamines and calamine lotion.*

*Case continued:* The rash and itching resolve with the use of antihistamines. After two months of therapy she returns to the clinic. Her abdominal pain, although initially improved, has been worsening, and night sweats are worsening in addition to weight loss.

8. What do you think is going on and how should she be evaluated?

- *The patient appears to be having a poor response to treatment. Her abdominal pain in addition to night sweats and weight loss have been getting worse.*
- *The main reasons that should be considered in this patient include poor adherence, drug resistant TB, side effects of drugs, and alternative diagnosis such as cirrhosis or cancer.*
- *You should assess her adherence and check liver function tests. She should be referred for further evaluation with ultrasound of the abdomen and repeat diagnostic ascites tap.*
- *Monitoring extrapulmonary TB and assessing for drug resistant TB is difficult in patients with extrapulmonary TB. If she has good adherence and her symptoms are not attributed to side effects or alternative diagnosis then treatment with regimen 2 should be considered. This should be decided by a specialist.*

*Case Study #2:* David is a 29 year-old man who reports left sided chest pain with shortness of breath.

1. What additional subjective information would you like to know?
  - *HIV status*
  - *History of TB/contacts*
  - *Current medications/previous medications or drug allergies?*
  - *Length of symptoms?*
  - *Additional symptoms? Cough, abdominal symptoms, weight loss, fever, night sweats?*

*Case continued:* Subjective Component: David's chest pain has occurred for the past 3 weeks with worsening shortness of breath. The pain is worse when he takes a deep breath. He also reports weight loss and night sweats. He denies having any cough. There is no prior history of TB.

Objective: On physical exam his vital signs are Temperature: 39C, Heart rate 110, Respiratory Rate 22, Blood Pressure: 106/67, Weight: 70kg

He has decreased breath sounds at his left lower lung fields with dullness on percussion. His lungs are clear and the exam is otherwise unremarkable.

2. Is this an urgent patient?
  - *No, but patient should be thoroughly evaluated immediately considering his shortness of breath.*
3. What are your differentials?
  - *Pulmonary TB*
  - *PCP*
  - *Other bacterial pneumonia*
  - *MOTT*
  - *Pleural effusion*
4. Discuss how David should be evaluated.
  - *He has signs and symptoms of TB so should be evaluated for pulmonary TB*
  - *HOWEVER, his exam is suspicious for a pleural effusion.*
  - *He should have a chest x-ray to evaluate further for a pleural effusion.*
  - *Remember that he should also have an HIV test performed.*
  - *Sputum should be sent for smear microscopy.*

*Case continued:* An HIV test is negative. Sputa are sent and GXP is positive and rifampicin sensitive. A chest x-ray shows a left-sided pleural effusion. Because of the pleural effusion, a pleural aspiration is performed to assess for TB. Straw coloured fluid is removed. Fluid analysis shows a protein count of 35g/l, white cell count of 1500 with predominantly lymphocytes and an adenosine deaminase of 39IU. Smear microscopy of the fluid is negative for TB.

Signs of TB in pleural aspirate include: straw coloured exudate with a high protein content >30g/l. The white cell count is high (1000-2500 cells per mm<sup>3</sup>) with predominantly lymphocytes. A high adenosine deaminase (ADA) >30IU.

5. What would be the appropriate treatment (specific drugs and dosages) for this patient at this time?
  - *Start patient on Regimen 1 for treatment as a new case with the diagnosis of TB pleural effusion. He weighs 70 kg so should be started on fixed drug combination of RHZE and take 5 tabs daily because he is a borderline case, so round up.*

*Case continued:* David is started on the FDC RHZE tablet - 5 tabs daily.

6. How should this patient's response to treatment be monitored?
- *Extrapulmonary TB in general is monitored clinically. He should have significant improvement in his symptoms within a month. If he does not, alternative diagnoses should be considered in addition to other causes of poor response to treatment. Chest x-ray at 7 weeks and repeat blood count.*
7. What recording registers to complete in this case?
- *TB Case Identification and Follow-up Sputum Register (GW20/13) – with results and follow-up*
  - *Laboratory Specimen Request Form –laboratory requests are being made*
  - *TB Register – As started on treatment*
  - *Patient Clinic/Hospital Card – As started on treatment*
  - *Patient Treatment Card – As started on treatment*
  - *Referral Card – If referred*

*Case continued:* David returns to the clinic in two weeks with multiple complaints including orange-red urine, joint pains, and nausea with the medications.

8. What drugs could be causing each problem.
- *Reassure patient that orange-red body fluids including urine are normal and are not harmful with rifampicin.*
  - *Arthralgias (body pains) can be caused by several of the medications for TB including isoniazid, rifampicin and pyrazinamide.*
  - *Pyrazinamide can cause gout with elevations of uric acid which may require treatment with allopurinol if severe. Joint pains can often be managed with aspirin or NSAIDS.*
  - *Nausea is a common problem and is often from rifampicin but can be from any of the TB medications. Taking the medication with food or at night before bed can often be helpful.*

*Case continued:* David does not return to clinic further for DOT. He is traced by a community health worker who convinces the patient to return to the clinic after a total of six weeks of missing treatment. He reports that the night sweats and shortness of breath have been worsening since stopping treatment.

9. How should his treatment interruption be managed?
- *Importantly, the patient was successfully traced and brought back to clinic.*
  - *Address the cause of the treatment interruption. It was likely from the side effects. Educate the patient about the side effects and how they will be managed.*
  - *Do 1 sputum smear and continue his treatment as before.*

*Case continued:* His sputum is negative. He is restarted on medications and tolerates them better with food and by taking them at night. Nausea and arthralgias do not return.

10. How long should he be treated?
- *He should be treated for 6 months. He should have the treatment prolonged to compensate for missed doses. Therefore he should have his initial phase of Regimen 1 (RHZE) extended for 6 weeks so a total of 6 months.*

*Case Study #3:* Thaba is a 5 year-old boy who complains of pain in his back.

1. What additional Subjective information would you like to know?

- *Length of symptoms?*
- *HIV status?*
- *TB status?*
- *Exposure to either TB or HIV?*
- *Other symptoms: Fever, Headaches, Meningeal S&S, neural S&S, weight loss, night sweats, cough?*
- *Any medications or drug allergies?*

*Case continued:* Subjective Component: His mother reports that he has been unwell for several months with weight loss, fevers, and night sweats. She has not noticed a cough and he denies any trouble breathing. The father is on treatment for pulmonary TB. Child's HIV status is unknown, as is the family's.

Objective Component: On exam he is febrile (38.1 Celsius) and thin (15kg). He has pain over his T5 and T6 vertebrae with mild swelling. The rest of his exam is normal.

2. Is this an urgent patient?

- *Because he is a child, he should be referred for immediate evaluation.*

3. What are your differentials?

- *TB of the spine*
- *Meningitis (less likely)*

4. How should Thaba be evaluated?

- *Thaba should be evaluated for TB given his symptoms of weight loss, fevers, and night sweats, the history of exposure from the father. The back pain is concerning for possible TB of his spine (Pott's Disease).*
- *He requires referral to a hospital for diagnosis and initiation of treatment.*
- *Clinic TB evaluation should include:*
  - *HIV test*
- *Hospital TB evaluation should include:*
  - *Mantoux skin test*
  - *Sputum collection or gastric aspirate if possible*
  - *Chest x-ray*
  - *X-ray of his spine*

*Case continued:* Thaba is referred to the hospital. His HIV test is negative. A chest x-ray is normal. Sputum/gastric aspirated could not be collected. The x-ray of his spine shows bony erosion, disc space narrowing suggestive of an infection. The Mantoux skin test is 15mm.

5. How should Thaba be managed?

- *Thaba should be treated for TB of the spine. The x-ray of his spine is consistent with an infection which in this setting is most likely from tuberculosis. He has a positive TST, systemic symptoms with weight loss, fevers, and night sweats, and TB exposure.*
- *Treatment should be managed with a specialist and 4 drugs are generally recommended as TB of the spine is a severe form of extrapulmonary TB.*
- *Thaba is started on RHZE (Regimen 3C).*
- *With a weight of 15kg he should be started on approximately rifampicin 150mg, isoniazid 75mg, pyrazinamide 375mg, ethambutol 225mg daily.*
- *This could be approximated with 3 and ½ tabs of fixed drug combination RHZ (60,30,150) and 300mg ethambutol tablets and ½ tablet of isoniazid booster.*

6. What recording registers to complete in this case?

- *TB Case Identification and Follow-up Sputum Register (GW20/13) – with results and follow-up*
- *Laboratory Specimen Request Form – as laboratory requests are being made*
- *TB Register – As started on treatment*
- *Patient Clinic/Hospital Card – As started on treatment*
- *Patient Treatment Card – As started on treatment*
- *Referral Card – If referred out*

*Case continued:* Thaba is discharged from the hospital after 1 month. At that time he appeared to be improving with resolution of fevers, improvement in his back pain, and was starting to gain weight. However, when he comes to the clinic for a 2 month visit he is feeling worse. Fevers and night sweats have returned and his back pain has returned.

7. What are the possible reasons for his deterioration on treatment?

- *Thaba is having a poor response to therapy although he initially seemed to be responding to TB treatment. Important questions to answer are:*
  - *Is the drug dosage correct?*
  - *Is the child taking the drugs as prescribed (good adherence)?*
  - *Was the child severely malnourished?*
  - *Is there a reason to suspect drug-resistant TB (index case has drug resistant TB, is a re-treatment case or is also not responding to therapy)?*
  - *Is there another reason for the child's illness, other than or in addition to TB?*

*Case continued:* Thaba's mother is asked about her husband's treatment for pulmonary TB and she reports that he was recently admitted to an MDR-TB hospital.

8. How should Thaba be managed now?

- He should be referred for further assessment and treatment of likely MDR-TB.

*Case Study #4:* Zamile is a 7 year-old girl with a cough.

1. *What additional subjective information would you like to obtain?*

- *TB exposure*
- *TB status*
- *HIV status*
- *Length of symptoms*
- *Additional symptoms: fever, headaches, dry versus productive cough, night sweats, blood tinged sputum?*

*Case continued:* Subjective Component: She has had a poor appetite, and fevers for 1 week. Her mother reports that she has been tired and sleeping more than usual. There is no known TB exposure.

Objective Component: Physical Exam: Temperature 38.2C, Pulse:110, Blood Pressure: 110/69, Respiratory Rate: 18, Weight: 22kg

She is well nourished and not ill-appearing. There are no enlarged lymph nodes and her lungs are clear. The exam is otherwise unremarkable.

2. Is this an urgent case?
  - *This is not an urgent case, but the child does need to be evaluated.*
3. What are your differentials?
  - *Bacterial or viral pneumonia*
  - *Pulmonary tuberculosis*

*Case continued:* Zamile is given a course of amoxicillin but has no improvement. She returns to the clinic in two weeks with progressive cough, shortness of breath, fevers, and weight loss.

On exam she is febrile (38.5) and has lost 2kg of weight. She appears fatigued and mildly ill. Her lungs are clear and the rest of the exam is unchanged from prior.

4. How should Zamile be managed?
  - *Zamile has only had a cough for 1 week and does not appear seriously ill. There is no known TB exposure. TB should not be highly suspected at this point. It would be reasonable to start with a trial of antibiotics and see if she improves. Neither a chest x-ray or Mantoux skin test is indicated at this point. Inquire regarding HIV exposure and consider HIV test.*
5. How should Zamile be evaluated?
  - *Zamile has not improved after antibiotics and has been having symptoms including cough for 3 weeks. There should be a higher suspicion for TB at this point and investigations for TB should include:*
    - *Mantoux skin test*
    - *Sputum collection or gastric aspirate if possible*
    - *Chest x-ray*
    - *HIV test*
  - *She does not require referral for evaluation at this point as there are no signs suggestive of severe TB disease.*

*Case continued:* A chest x-ray is performed and shows a widened mediastinum and a right lower lobe infiltrate. An HIV test is negative and a Mantoux test is 11mm. Zamile is able to produce two sputum samples and they are both smear negative.

6. How should Zamile be treated now?
  - *She should be started on TB treatment for uncomplicated pulmonary TB which is smear negative. Since she can be started on Regimen 3A with the fixed drug combination of RHZ (60, 30, 150). Her weight is 20kg so she should receive 4 tabs daily.*
  - *Pyridoxine can be considered and for children is recommended in malnourished children, HIV-infected, and pregnant adolescents.*
7. What recording registers to complete in this case?
  - *TB Case Identification and Follow-up Sputum Register (GW20/13) – with results and follow-up*
  - *Laboratory Specimen Request Form – as laboratory requests are being made*
  - *TB Register – As started on treatment*
  - *Patient Clinic/Hospital Card – As started on treatment*
  - *Patient Treatment Card – As started on treatment*
  - *Referral Card – if referred*

*Case continued:* A chest x-ray is performed and shows a widened mediastinum and a right lower lobe infiltrate. An HIV test is negative and a Mantoux test is 11mm. Zamile is able to produce two sputum samples and they are both smear negative.

8. What should you do now?

- *She has signs and symptoms of hepatitis likely from the TB treatment. All her medications should be stopped and referred to hospital for further investigation and management. She should have urgent liver function tests performed and a hepatitis screen (A,B,C) conducted.*

*Case continued:* Her liver function tests show AST 450, ALT 400, with a normal bilirubin and alkaline phosphatase. Hepatitis A and B are sent and are negative.

9. Discuss how this patient should be managed further.

- *The hepatitis is likely from the TB medications. She should not have her TB medications re-started until her liver function tests have normalized. An expert should be involved in the further management of such cases. She does not have a severe form of TB she will likely not have significant deterioration of her TB while her medications are withheld.*
- *She should be restarted on the TB drugs starting with the least likely to cause hepatotoxicity (Rifampicin), followed by Isoniazid. These should be introduced one week apart and LFT monitored weekly. If at any time symptoms recur or liver enzymes increase, the last drug added should be stopped.*
- *Patients with severe forms of TB should be continued with non-hepatotoxic TB drugs such as ethambutol, streptomycin, amikacin, kanamycin, capreomycin, ofloxacin , levofloxacin.*

*Case continued:* Under the management of an expert she is restarted on her TB drugs one at a time after her liver function tests normalised, after two weeks. She is on RH daily

10. How will you follow-up?

- *She must be monitored monthly for side effects*
- *As for any interruption the continuation phase must be extended by two weeks as treatment was interrupted for two weeks.*
- *Sputum smear examination must be done at 25 weeks (23+2), if still negative treatment continued for another week and stopped. She should be registered as having completed treatment.*



## Trainer Instructions: Step 5 (30 Minutes) Monitoring Therapy

### *Step 5 Learning Objectives:*

- Explain how to properly manage response to therapy.

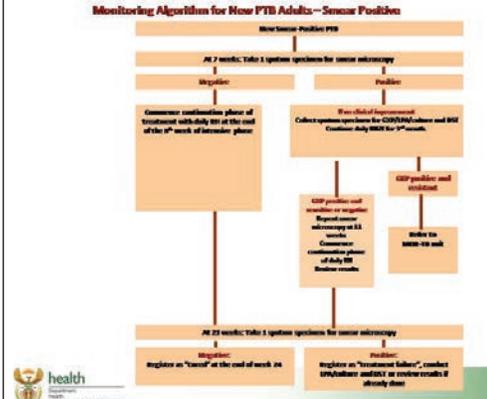
### *Step 5 Resources Needed:*

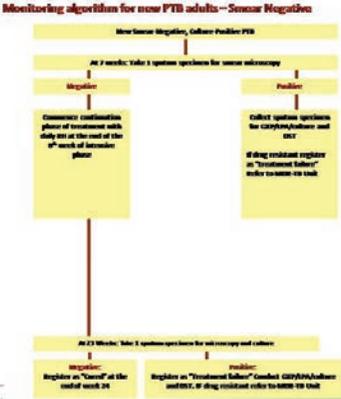
- Clinical Reference Manual
- LCD projector and computer
- Slides 1-18

### *Step 5 Trainer Instructions:*

	<p>5.1. Explain that appropriately monitoring the response to treatment is important for the clinical care of all categories of TB clients. Clients with bacteriological confirmation of pulmonary tuberculosis should have bacteriological as well clinical monitoring to assess their response to treatment:</p> <ul style="list-style-type: none"><li>• Clients with smear-positive PTB and smear-negative, culture positive PTB are monitored by sputum smear examination</li><li>• Clients with EPTB and those in whom there has been no confirmed bacteriological diagnosis are assessed through clinical monitoring.</li></ul>
	<p>5.2. Present Slides 1-18 using trainer notes.</p>

Slide 1	 <h2 style="margin-top: 100px;">Monitoring New and Re-Treatment Cases &amp; Recording</h2>
Slide 2	<h3 style="text-align: center;">Monitoring the Response to New Cases – Smear Positive</h3> <ul style="list-style-type: none"> <li>▪ Response to treatment should be monitored by sputum smear examination</li> <li>▪ Two sputum specimens should be collected for smear examination at each time point (one if using GXP):             <ul style="list-style-type: none"> <li>• One week before the end of the 2 month intensive phase of treatment (i.e. at 7 weeks), to evaluate smear conversion</li> <li>• At the end of 23 weeks of treatment, to evaluate treatment outcome</li> </ul> </li> </ul>
Slide 3	<h3 style="text-align: center;">Monitoring the Response to New Cases – Smear Positive (2)</h3> <ul style="list-style-type: none"> <li>▪ If a client has a positive smear at this time, it indicates one of the following:             <ul style="list-style-type: none"> <li>• Initial phase of therapy was poorly supervised and that client's adherence to treatment was poor (most common)</li> <li>• Slow rate of progress with smear conversion. For example, when a client has extensive cavitations and a heavy initial bacillary load (sometimes)</li> <li>• Client may have drug resistant TB that does not respond to first line drugs (rare)</li> </ul> </li> </ul>
Slide 4	<h3 style="text-align: center;">Monitoring the Response to New Cases – Smear Positive (3)</h3> <ul style="list-style-type: none"> <li>▪ If a client is smear positive at 7 weeks             <ul style="list-style-type: none"> <li>• Collect sputum specimen for GXP/LPA/Culture (as available) and DST</li> <li>• Continue intensive phase for a 3rd month                 <ul style="list-style-type: none"> <li>• If results positive/resistant refer to MDR-TB unit</li> <li>• If sensitive or negative, repeat smears at 11 weeks and commence continuation phase, reviewing results when available</li> </ul> </li> </ul> </li> </ul>

Slide 5	<h3 style="text-align: center;">Monitoring the Response to New Cases – Treatment Outcomes</h3> <ul style="list-style-type: none"> <li>▪ If client has negative smears at 23 weeks and had negative smears on at least one previous occasion at least 30 days prior:             <ul style="list-style-type: none"> <li>• Discharged as cured after 24 weeks of treatment (accounting for any missed doses, if necessary)</li> </ul> </li> </ul>
Slide 6	<h3 style="text-align: center;">Monitoring the Response to New Cases – Treatment Outcomes (2)</h3> <ul style="list-style-type: none"> <li>▪ If the sputum is still positive at 23 weeks, the client is categorised as a treatment failure</li> <li>▪ GXP/LPA/culture should be obtained             <ul style="list-style-type: none"> <li>• If sensitive use the standard retreatment regimen</li> <li>• if MDR refer/start appropriate MDR treatment</li> </ul> </li> </ul>
Slide 7	<h4 style="text-align: center;">Monitoring Algorithm for New PTB Adults – Smear Positive</h4>  <pre> graph TD     Start[New Smear Positive PTB] --&gt; Step1[At 7 weeks, Table 1 sputum specimens for smear microscopy]     Step1 --&gt; Neg1[Negative]     Step1 --&gt; Pos1[Positive]     Neg1 --&gt; Step2[Commence continuation phase of treatment with daily 8H at the end of 8th week of intensive phase]     Pos1 --&gt; Step3[Two clinical specimens: Culture sputum specimen for GXP/LPA/culture and DST. Continue daily 8H for 12 weeks]     Step3 --&gt; GXP1[GXP positive and resistant or negative]     Step3 --&gt; GXP2[GXP positive and resistant]     GXP1 --&gt; Step4[Repeat sputum microscopy at 11 weeks. Commence continuation phase of daily 8H. Review results]     GXP2 --&gt; Step5[Refer to MDR-TB unit]     Step4 --&gt; Step6[At 23 weeks, Table 1 sputum specimens for smear microscopy]     Step6 --&gt; Neg2[Negative]     Step6 --&gt; Pos2[Positive]     Neg2 --&gt; Step7[Register as "cured" at the end of week 24]     Pos2 --&gt; Step8[Register as "treatment failure", repeat LPA/culture analysis at end of week 24 if already done]     </pre>
Slide 8	<h3 style="text-align: center;">Monitoring the Response to New Cases – Smear Negative</h3> <ul style="list-style-type: none"> <li>▪ Response to treatment should be monitored by 1 sputum specimen at 7 weeks</li> <li>▪ If remains negative, commence continuation phase at the end of 8<sup>th</sup> week of intensive phase</li> <li>▪ If positive, collect sputum specimen for GXP/LPA/culture and DST             <ul style="list-style-type: none"> <li>• If resistant register as "treatment failure" refer to MDR-TB Unit</li> </ul> </li> </ul>

Slide 9	<p><b>Monitoring the Response to New Cases – Smear Negative (2)</b></p> <ul style="list-style-type: none"> <li>• If negative at end of intensive phase, commence continuation phase and obtain sputum specimen for microscopy and culture at 23 weeks</li> <li>• If Negative, register as “cured” at end of 24 weeks</li> <li>• If Positive, register as “treatment failure” <ul style="list-style-type: none"> <li>• Obtain GXP/LPA/culture and DST</li> <li>• If drug resistant refer to MDR-TB Unit</li> </ul> </li> </ul> 	<p><b>Monitoring the Response to Retreatment Cases – Treatment Outcomes</b></p> <ul style="list-style-type: none"> <li>• If client has negative smears at 7 months (180 days or later) and had negative smears on at least one previous occasion 30 days prior: <ul style="list-style-type: none"> <li>• Client is discharged as cured after 8 months of treatment (treatment end date at least 210 days after treatment started)</li> </ul> </li> <li>• If the client has shown susceptibility to the first line drugs and the sputum smear is still or becomes positive at 7 months: <ul style="list-style-type: none"> <li>• Client is categorised as a treatment failure and referred for the management of chronic TB</li> </ul> </li> </ul> 
Slide 10	<p><b>Monitoring algorithm for new PTB adults – Smear Negative</b></p>  	<p><b>Monitoring the Response to Retreatment Cases – Smear Negative, Culture Positive</b></p> <ul style="list-style-type: none"> <li>• Response to treatment should be monitored both clinically and by sputum smear and culture examination: <ul style="list-style-type: none"> <li>• Two sputum smears should be evaluated one week before the end of the 3 month intensive phase of treatment (i.e. at 11 weeks), to evaluate non-response to treatment (disease progression)</li> <li>• Two sputum samples should be evaluated at the end of 7 months of treatment – 1 for smear and 1 for culture, to evaluate treatment outcome</li> </ul> </li> </ul> 
Slide 11	<p><b>Monitoring the Response to Retreatment Cases – Smear Positive</b></p> <ul style="list-style-type: none"> <li>• Similar to new cases, response to treatment should be monitored by sputum smear examination</li> <li>• Sputum specimens should be collected for smear examination at each time point: <ul style="list-style-type: none"> <li>• One week before the end of the 3 month intensive phase of treatment (i.e. at 11 weeks), to evaluate smear conversion</li> <li>• At the end of 7 months of treatment, to evaluate treatment outcome</li> </ul> </li> </ul> 	<p><b>Monitoring the Response to Retreatment Cases – Smear Negative, Culture Positive (2)</b></p> <ul style="list-style-type: none"> <li>• When the client has completed the 3-month intensive phase: <ul style="list-style-type: none"> <li>• If both sputum smears are negative, start the continuation phase of treatment</li> <li>• If both the sputum smears have become positive at the end of the 3 months: <ul style="list-style-type: none"> <li>• Register the client as a treatment failure and refer for management of chronic TB</li> </ul> </li> <li>• If only one smear is positive, a third smear should be taken as two positive smears are required to confirm diagnosis of treatment failure to avoid errors</li> </ul> </li> </ul> 
Slide 12	<p><b>Monitoring the Response to Retreatment Cases – Smear Positive (2)</b></p> <ul style="list-style-type: none"> <li>• If the client is smear-positive at 11 weeks, the four drugs used in the 3<sup>rd</sup> month of treatment are extended by another month and sputum GXP/LPA/culture and DST is repeated; at the end of the 4<sup>th</sup> month change to continuation phase whilst awaiting results: <ul style="list-style-type: none"> <li>• If sensitive, repeat smear and continue treatment</li> <li>• If resistant to two of the three drugs used in the continuation phase (RHE), record as treatment failure and refer to MDR unit for evaluation and treatment</li> </ul> </li> </ul> 	<p><b>Monitoring the Response to Retreatment Cases – Treatment Outcomes</b></p> <ul style="list-style-type: none"> <li>• If the client has negative smears and culture at 7 months, the client is discharged as cured after 8 months of treatment</li> <li>• If client has shown susceptibility to the first line drugs and the sputum smear or culture is positive at 7 months, the client is registered as a treatment failure and referred for management of chronic TB</li> </ul> 

Slide 17

### **Monitoring the Response to Retreatment Cases – EPTB and Smear-Negative, Culture-Negative Cases**

- Extra-pulmonary TB or cases that have been diagnosed on clinical grounds without bacteriological confirmation of TB should be monitored clinically over the duration of treatment
- Weight is a useful indicator of clinical improvement



Slide 18

### **Conclusion**

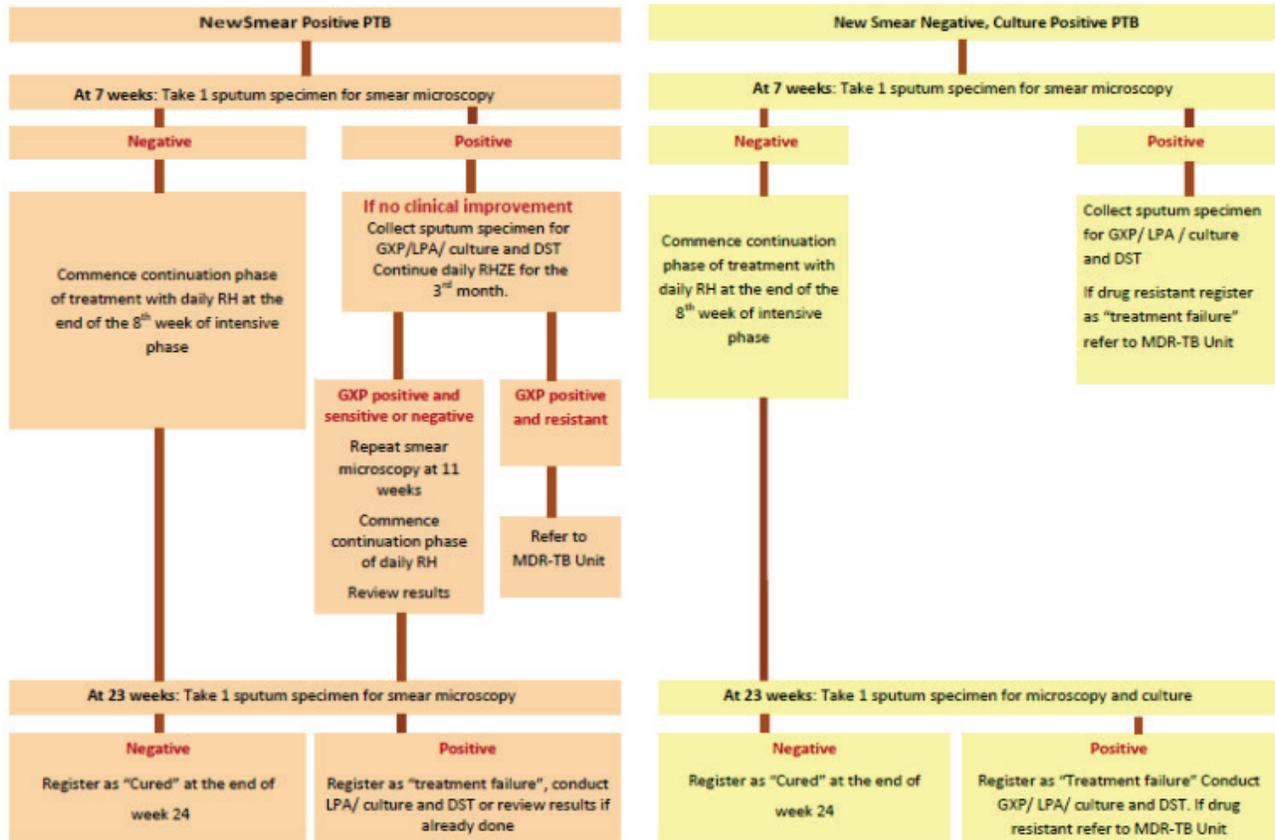
- Currently main problem is "smear not done"
- Focus for diagnosis is still reliant on bacteriological testing.
- Sputum specimen must be:
  - Adequate
  - Good quality
- Recommended measures to obtain specimen
  - Induction
  - Gastric aspiration





## Handout 4.9. Monitoring Algorithm for New PTB Adults

### MONITORING ALGORITHM FOR NEW PTB ADULTS



## Session 5. Drug Resistance, Multidrug-Resistant TB and Adherence



**Total Session Time: 3 hours and 30 minutes**

### Learning Objectives:

By the end of this session, participants will be able to:

- Describe drug-resistant TB (MDR/XDR TB).
- Identify risk factors for resistance and barriers to treatment adherence.
- Assist clients in developing strategies to improve treatment adherence.
- Effectively manage Drug Resistant TB and related activities at the provincial and district TB programme level.
- Recognise treatment and management of drug-resistant tuberculosis from the TB programme perspective.
- Highlight new developments in the management of DR-TB.
- Detect and treat MDR TB Cases.
- Manage 1st and 2nd line drugs.
- Monitor the success of DR TB Treatment.
- Monitor the detection and treatment data for their local facility.

### Session Overview

Step	Time	Activity/Method	Content	Resources Needed
1	20 minutes	Group Discussion Group Work	Overview of Drug Resistance and MDR-TB	Handout 5.1 Worksheet 5.2
2	160 minutes	Group Presentation Group Work	Management and Care of MDR/XDR-TB	Handouts 5.3, 5.4, 5.5, 5.6, 5.8 Worksheets 5.7, 5.9 Slides 1-26 Computer/LCD Projector
3	30 minutes	Group Discussion Group Work	Overcoming Barriers to Adherence	Worksheet 5.10 Handouts 5.11 and 5.12



## Advance Preparation

Step 1: Write the following on 4-5 pieces of flipchart paper (one per every 4-5 participants). Leave room below each heading for participants to write the definition:

- Mono-Resistance:
- Poly-Resistance:
- Multi-Drug Resistant TB (MDR-TB)
- Extensively Drug Resistant TB (XDR-TB)



## Resources Needed

- Handout 5.1. Overview of MDR/XDR-TB
- Handout 5.2. Risk Factors for Drug Resistance
- Worksheet 5.3. MDR/XDR TB
- Handout 5.4. Decentralised Management of DR-TB
- Handout 5.5. Classification of TB Drugs
- Handout 5.6. Dosing of Standardised MDR and XDR-TB Regimens
- Handout 5.7. Referrals at Primary Health Facilities
- Worksheet 5.8. Calculating Resistance
- Handout 5.9. Common Side Effects During MDR-TB Treatment
- Worksheet 5.10. Cases in the Management of DR-TB
- Worksheet 5.11. Addressing Factors Affecting Adherence
- Handout 5.12. Strategies to Improve Adherence
- Handout 5.13. The Role of Counselling to Ensure Adherence
- DR-TB Patient Follow-Up Card
- LCD projector and computer
- Slides 1-29
- Flip Chart and Markers



## Trainer Instructions: Step 1 (20 minutes) Overview of Drug Resistance and MDR-TB

### Step 1 Learning Objectives:

- Describe the development of drug resistance and how to prevent it.
- Recognise signs of drug resistance TB.

### Step 1 Resources Needed:

- Handout 5.1. Risk Factors for Drug Resistance
- Worksheet 5.2. MDR/XDR TB
- Flipchart and markers

### Step 1 Trainer Instructions:

	1.1. Post several previously prepared flipcharts around the room. Divide participants into groups of 4-5 persons and ask each group to complete the flipchart.
	1.2. As a large group review the responses. <i>Answers: Mono-Resistance: If resistance to ONE first-line drug (Rifampicin, Isoniazid, Pyrazinamide or Ethambutol)</i> <i>Poly-Resistance: If resistance to TWO or more first-line drugs but NOT both Isoniazid and Rifampicin</i> <i>Multi-Drug Resistant TB (MDR-TB): Caused by a bacteria that is resistant to both isoniazid and rifampicin</i> <i>Extensively Drug Resistant TB (XDR-TB): Caused by a bacteria that is resistant to INH &amp; rifampicin + A fluoroquinolone (ciprofloxacin, ofloxacin) + 1&gt; of the second line injectable ATT drugs: kanamycin OR amikacin OR capreomycin</i>
	1.3. Refer participants to Handout 5.1. Overview of MDR/XDR-TB. Review Handout 5.1 aloud. Highlight where participant responses were the same or different as group report backs.
	1.4. Ask participants, “How does drug resistance happen?” Facilitate a brief discussion.
	1.5. Refer participants to Handout 5.2. Risk Factors for Drug Resistance. Review handout with participants.
	1.6. Ask participants, “Why should we care about MDR/XDR TB?” Facilitate a brief discussion. Explain that MDR poses a serious threat to the gains made in TB and HIV control. HIV-infected persons progress more rapidly to TB disease. Resistance to both isoniazid and rifampicin is disastrous for patient and community. Treatment is less effective, for longer duration, with more side-effects, more expensive and has a much lower chance of cure.
	1.7. Remind participants of epidemiologic data from Session 1: <ul style="list-style-type: none"> <li>• South Africa has the largest number of incident cases in the world (0.40-0.59 million)</li> <li>• In South Africa, an estimated 58% of tested TB cases are co-infected with HIV</li> </ul>
	1.8. Divide participants into groups of five. Refer participants to Worksheet 5.3. MDR/XDR TB. Explain that each group will have 5 minutes to study the data presented and answer the questions.
	1.9. Reconvene participants and ask for each group’s answers to the questions listed. Ask participants, “What could be done to improve MDR/XDR-TB outcomes?” Facilitate a brief discussion.
	1.10. Summarise Activity: MDR/XDR-TB are present in the community. Health care workers need to do their best to stop the spread of TB overall, including MDR and XDR-TB.



## *Handout 5.1. Overview of MDR/XDR-TB*

### **What is Drug Resistant TB?**

Drug resistance refers to the ability of an organism (such as TB) to withstand and no longer respond to a drug that could previously have been used to treat or reduce the symptoms of a disease.

### **Categories of Drug Resistant TB**

New: A patient that has never received anti Tuberculosis, MDR TB or XDR TB drugs for less than one month

Previously treated with first line drugs only: Patient that has been treated for one month and more for TB with first line drugs

Previously treated with second line drugs only: Patient that has been treated for one month and more for TB or DR TB with one or more first and second line drugs

### **Causes of Resistance**

1. Inadequate regimens
2. Drug supply issues
3. Poor adherence

Failure to recognise and treat drug-resistant TB and case contacts in a timely and appropriate manner, also contributes to the spread of resistant TB.

### **Types of Drug Resistant TB – Diagnosed by Drug Susceptibility Testing**

Mono-resistance: If resistance to ONE first-line drug (Rifampicin, Isoniazid, Pyrazinamide or Ethambutol)

Poly-resistance: If resistance to TWO or more first-line drugs but NOT both Isoniazid and Rifampicin

Multi-Drug resistance (MDR): If resistance to BOTH Isoniazid and Rifampicin

Extensive-Drug resistance (XDR): If multi-drug resistance PLUS a fluoroquinolone (ciprofloxacin, ofloxacin) PLUS one or more 2nd line injectable drugs (kanamycin, amikacin or capreomycin). XDR-TB is very difficult to treat, with high rates of mortality.



## *Handout 5.2. Risk Factors for Drug Resistance*

### **1. Any patient with prior history of TB**

- a. Failure of first-line regimen
  - i. First-line regimen failure: these are patients who are sputum smear-positive at 5 months or later during the course of treatment.
- b. Failure of re-treatment regimen and chronic TB cases
  - i. Patients with re-treatment failure and/or chronic TB have the highest number of MDR-TB rates of any group, often exceeding 80%.
- c. Patients who remain sputum smear-positive at two or three months of short course chemotherapy
- d. Patients who revert from smear-negative to smear-positive at the end of the intensive phase

### **2. Exposure to a known MDR-TB case**

- a. Close contacts of MDR-TB patients have high rates of MDR-TB
- b. Exposure to MDR-TB in institutions is a serious public health risk

### **3. Poor adherence, malabsorption**

### **4. Cavitory disease (high burden of organisms)**

### **5. Inadequate treatment regimen**

- a. Under dosing
- b. Giving anti-TB treatment without regard to patient's weight
- c. Administering fewer than the recommended number of drugs (e.g., INH/RIF only during intensive phase)

### **6. Poor monitoring**

### **7. Poorly organised TB programme and drug supply**

### **8. Barriers to treatment (social, adverse effects, transportation)**



## Worksheet 5.3. MDR/XDR-TB

### MDR

- New TB cases that are MDR-TB: 1.8%
- Previously treated TB Cases that are MDR-TB: 6.7%
- Incident Cases of MDR-TB per year in South Africa: approx. 10,000
- In 2009, fewer than 5,000 MDR-TB cases were started on treatment
- MDR-TB beds in South Africa: approx. 2000

### XDR-TB

Study in 2006, Kwazulu-Natal:

- 544 TB patients suspected to have resistance: 221 had MDR-TB
- 53 of the 221 (24%) met criteria for XDR-TB
  - 44 of the 53 were tested for HIV
  - All were positive; 15 on ARVs
  - 55% had no previous TB treatment
- 100% mortality average of 16 days from TB diagnosis
- Provinces with confirmed XDR-TB Cases: 9

### Questions

1. What is the significance of the data presented above?
  - Not enough beds for treatment in-hospital, half diagnosed are not started on treatment
  - Increased exposure of MDR/XDR to patients
  - Increased exposure of MDR/XDR to health care workers
  - Increased exposure of MDR/XDR to community due to long waits for treatment
  - Poor outcomes of Dr-TB cases, increased mortality of PLWHA and TB
2. What does this data mean for you as a health care worker?
  - Importance of diagnosing and treating right away
  - Importance of screening contacts right away
  - Importance of patient prevention measures (separate waiting area, masks, UV lights)
  - Important to wear appropriate masks when dealing with all TB patients



## Trainer Instructions: Step 2 (160 minutes) Management and Care of MDR/XDR-TB

### Step 2 Learning Objectives:

- Explain how to monitor patients with mono-, multi- and poly-drug resistant TB.
- Recognise side effect of drugs used in treatment of MDR-TB and when to refer.

### Step 2 Resources Needed:

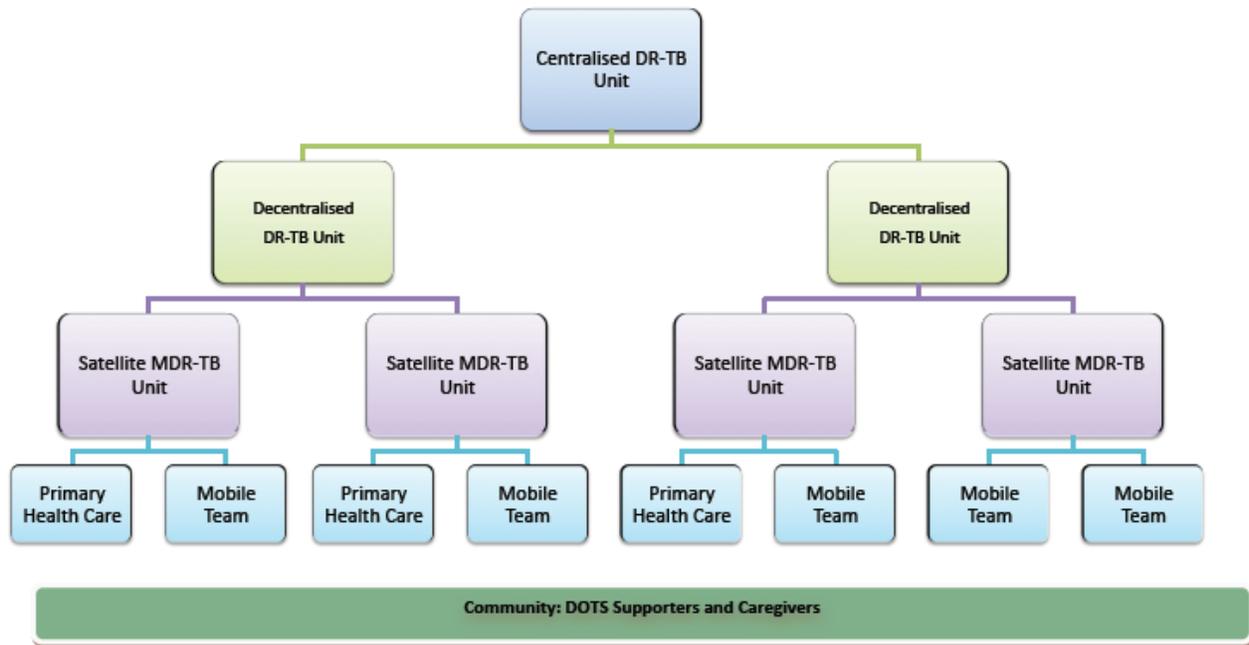
- Handout 5.4. Decentralised Management of DR-TB
- Handout 5.5. Classification of TB Drugs
- Handout 5.6. Dosing of Standardised MDR and XDR-TB Regimens
- Handout 5.7. Referrals at Primary Health Facilities
- Worksheet 5.8. Calculating Resistance
- Handout 5.9. Common Side Effects During MDR-TB Treatment
- Worksheet 5.10. Cases in the Management of DR-TB
- LCD projector and computer
- Slides 1-29

### Step 2 Trainer Instructions:

	2.1. Refer participants to Handout 5.4. Decentralised Management of DR-TB. Ask participants to volunteer to read Handout 5.3 aloud. Discuss the changes in policy regarding flow of DR-TB patients. Stress that this will mean an increased roll of many additional sites in the care of DR-TB.
	2.2. Refer participants to Handout 5.5. Classification of TB Drugs. Review Handout 7.5 aloud. Ask participants if this is new information. Tell participants the information will be further discussed through a slide set
	2.3. Indicate that Handout 5.6. Dosing of Standardised MDR and XDR-TB Regimens is a reference useful in treatment and will be utilized during the case-based activity that follows.
	2.4. Present slides 1-29 using trainer notes.
	2.5. Ask participants, “What are common side-effects of DR-TB treatment?” Facilitate a brief discussion.
	2.6. Ask participants, “How do you currently assess for side effects?” Discuss importance of asking about specific side effects related to their medications and not making patients feel bad for expressing their symptoms. Appropriate side effect management can greatly improve adherence.
	2.7. Refer participants to Handout 5.9. Common Side Effects During MDR-TB Treatment. Allow 5-10 minutes for individuals to review with a partner. Stress that the interventions listed are in order – one should be attempted first, and if no resolution, the next. Lowering the dose of drugs or stopping drugs should only be reserved for severe cases.
	2.8. Refer participants to Worksheet 5.10. Cases of MDR-TB Management. Ask participants to work through both cases in small groups. Regroup and discuss the responses as a larger group.
	2.9. Summarise Activity: by stressing the importance of early identification and appropriate management of DR-TB.



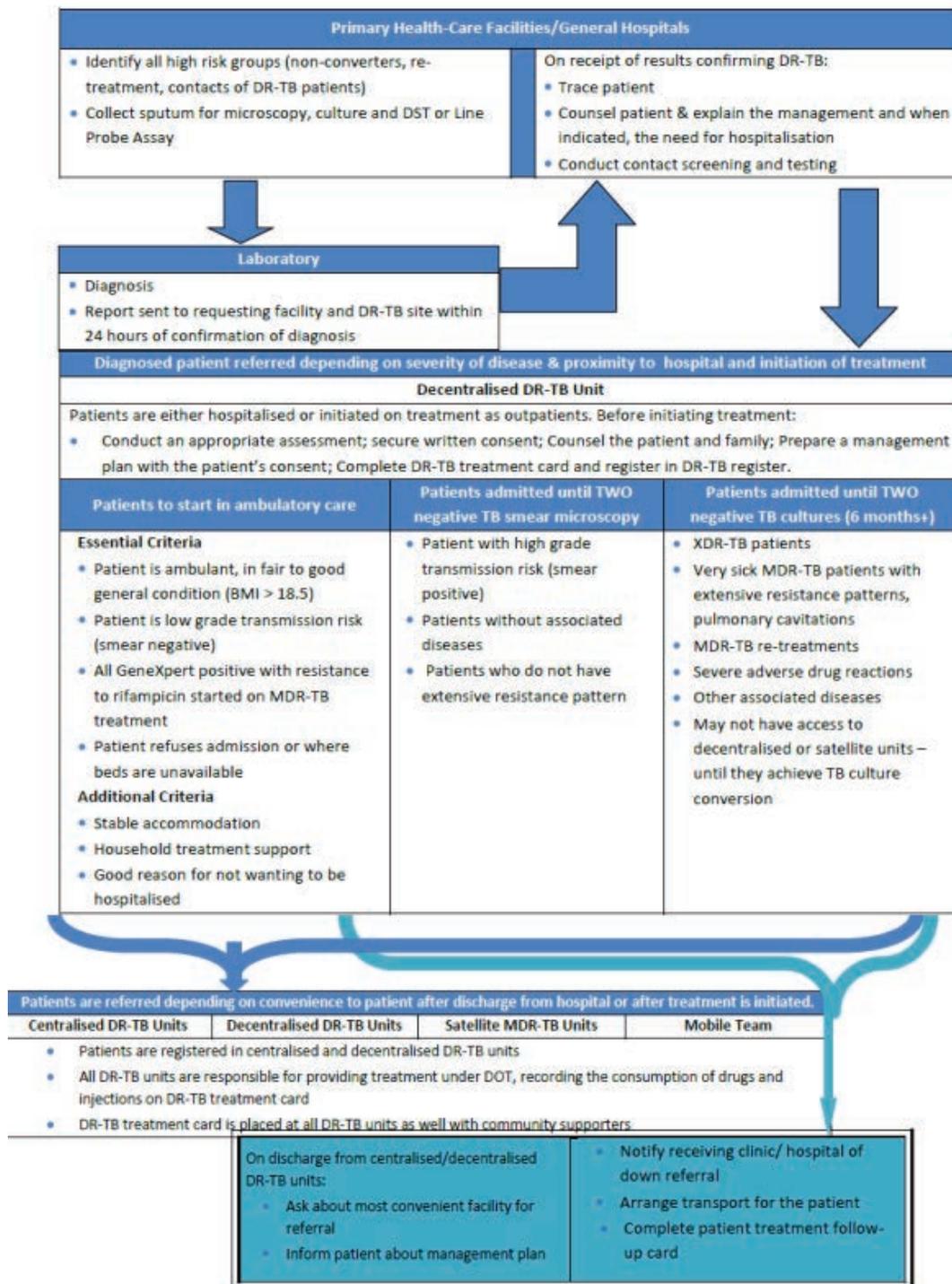
## Handout 5.4. Decentralised Management of DR-TB



Levels of Care	Roles
Centralised DR-TB Unit (Provincial)	<ul style="list-style-type: none"> <li>• Initiate treatment of DR-TB cases</li> <li>• Admission of DR-TB cases from geographical area</li> <li>• Ensure hospitalisation all XDR-TB cases until 2 successive negative cultures</li> <li>• Assessing all DR-TB patients attending clinic each month</li> <li>• Providing DOT to all DR-TB patients attending unit daily</li> <li>• Recording and reporting to provincial Department of Health</li> <li>• Providing ongoing training, support and supervision to all facilities in province</li> <li>• Providing social support, rehabilitation, educational and skills building programmes for patients</li> <li>• Providing education and counselling to all patients admitted</li> <li>• Preparing discharge plan for all patients and ensuring effective down referrals</li> <li>• Monitoring DR-TB patients post-discharge until completion of treatment and two years post treatment completion</li> <li>• Monitoring rational usage of second-line drugs and ancillary drugs for side effects management</li> <li>• Establishing and maintaining functional clinical management teams</li> <li>• Compiling monthly, quarterly, six-monthly and annual reports</li> <li>• Providing technical assistance and capacity building</li> <li>• Arranging patients' evaluations at provincial patient review committees</li> </ul>

Levels of Care	Roles
Districts or Sub-Districts	<ul style="list-style-type: none"> <li>• Trace all confirmed DR-TB patients and refer to DR-TB hospital</li> <li>• Ensure availability of drugs for patients at clinic and district hospitals</li> <li>• Establish efficient patient retrieval system for patients who default DR-TB treatment</li> <li>• Arrange transportation for patient evaluation and follow-up at DR-TB hospital</li> <li>• Appoint disease outbreak teams to conduct contact screening programmes for all close contacts of confirmed DR-TB cases six monthly for two years</li> <li>• Conduct household assessments prior to patient discharge from DR-TB units</li> <li>• Monitor and evaluate DR-TB programme performance</li> <li>• Ensure continuum of care for patients post discharge</li> <li>• Ensure ongoing psychosocial support for patients</li> <li>• Increase awareness and education about DR-TB among communities</li> </ul>
Decentralised DR-TB Units	<ul style="list-style-type: none"> <li>• Initiate treatment of all MDR-TB cases after appropriate assessment</li> <li>• Admit DR-TB cases when indicated</li> <li>• Provide transport for patient evaluation and monthly follow up of all DR-TB cases attending clinic</li> <li>• Trace confirmed DR-TB patients and refer to DR-TB hospital</li> <li>• Provide DOT to all DR-TB patients attending unit daily</li> <li>• Provide social support, rehabilitation, educational and skills building programmes for patients</li> <li>• Provide education and counselling to all admitted patients</li> <li>• Prepare a discharge plan for all patients ensuring effective down referrals</li> <li>• Monitor DR-TB patients post discharge until completion of treatment and two years post treatment completion</li> <li>• Ensure availability of drugs and monitoring rational usage of second-line drugs</li> <li>• Establish and maintain functional clinical management teams</li> <li>• Record and report to provincial Department of Health</li> <li>• Compile monthly, quarterly, six monthly and annual reports of DR-TB patients started on treatment, culture conversion and outcomes</li> <li>• Monitor and evaluate DR-TB programme performance</li> <li>• Provide technical assistance and capacity building to satellite MDR-TB units and feeder clinics</li> <li>• Monitor treatment side effects</li> <li>• Ensure referral of patients with XDR-TB, severe adverse events and complicated disease to the centralized DR-TB unit</li> <li>• Trace all confirmed cases</li> </ul>
Satellite DR-TB Units (PHC clinic, Isolation ward, Mines & Prisons)	<ul style="list-style-type: none"> <li>• Admit all MDR-TB cases referred from centralized or decentralised units</li> <li>• Ensure monthly follow-up of all DR-TB patients attending daily</li> <li>• Educate and counsel all patients admitted to hospital</li> <li>• Prepare a discharge plan for all patients and ensure effective down referrals</li> <li>• Monitor treatment side effects</li> <li>• Ensure referral of patients with XDR-TB, severe adverse events, and complicated disease to the centralised DR-TB site</li> </ul>
Primary Health Care Facilities	<ul style="list-style-type: none"> <li>• Identify high risk groups</li> <li>• Screen and test symptomatic high-risk groups</li> <li>• Trace patients with confirmed diagnosis of DR-TB</li> <li>• Notify the district TB coordinator</li> <li>• Provide initial counselling and education of the patient and family</li> <li>• Prepare patient for hospital admission when indicated</li> <li>• Coordinate referral to centralised and decentralised DR-TB units</li> <li>• Ensure monthly follow up of all DR-TB cases attending clinic</li> <li>• Provide DOT to all DR-TB patients attending daily</li> <li>• Conduct contact screening of all close contacts</li> <li>• Follow patients initiated to start community-based treatment or patients who are post discharge from hospital</li> <li>• Coordinate follow up visits in hospital</li> <li>• Trace treatment interrupters</li> <li>• Collect monthly sputum and other routine tests</li> <li>• Monitor treatment side effects</li> <li>• Ensure referral of patients with XDR-TB, severe adverse events, and complicated disease to the centralised DR-TB unit</li> </ul>

Levels of Care	Roles
Mobile Teams	<ul style="list-style-type: none"> <li>• Provide DOT to all DR-TB cases in the area</li> <li>• Provide patient family and community education on TB</li> <li>• Monitor treatment side effects and refer to the nearest health-care facility when necessary</li> <li>• Maintain appropriate records</li> </ul>
Community Supporters (community levels close to the patient)	<ul style="list-style-type: none"> <li>• Provide DOT to all DR-TB cases in the area</li> <li>• Provide patient family and community education on TB</li> <li>• Monitor treatment side effects and refer to the nearest health-care facility when necessary</li> <li>• Maintain appropriate records</li> </ul>





## Handout 5.5. Classification of TB Drugs

CLASSIFICATION OF TB DRUGS		
Group	Anti-TB agents	Drugs
1	First-line oral	Isoniazid (H), Rifampicin (R), Ethambutol (E) and Pyrazinamide (Z)
2	Injectables	Streptomycin (S), Kanamycin (Km), Amikacin (Am), Capreomycin (Cm) and Viomycin (Vi)
3	Fluoroquinolones	Ofloxacin (Ofx), Levofloxacin (Lfx), Moxifloxacin (Mfx)
4	Second-line oral bacteriostatic	Ethionamide (Eto), Protionamide (Pto), Cycloserine (Cs), Terizidone (T) p-aminosalicylic acid (PAS)
5	Antituberculosis agents with unclear efficacy	Clofazimine (Cfz), Amoxicillin/Clavulanate (Amx/Clv), Thioacetazone, Imipenem, High-dose INH, Clarithromycin (Clr), Linezolid (Lzd)

TREATMENT OF MONO/POLY-RESISTANCE			
Drug resistance pattern	Suggested regimen	Minimum duration	Comments
H (+/-S or +/- Z or +/- E)	Regimen I or II intensive phase for full duration (except for H)	6 – 9 months	If patient on Regimen II, stop streptomycin after 6 months. If resistant to streptomycin, discontinue immediately
R (+/- any other 1st line drug)	Standardised MDR-TB regimen	18 months	Notion of potential over treatment. Use of terizidone in the MDR regimen
HEZ (+/- S)	Rifampicin, Moxifloxacin, Ethionamide, + kanamycin for first 2-3 months	18 months	6 months of kanamycin may strengthen regimen in patients with extensive disease

### PRINCIPLES OF MDR/XDR-TB TREATMENT

- Choose treatment based on drug history and DST results
- Avoid drugs that are not safe
- Avoid drugs with cross-resistance
- Include drugs from Groups 1-4 in a hierarchical order based on potency
- Step 1: use any first-line drug still susceptible
- Step 2: add an injectable agent
- Step 3: add a fluoroquinolone
- Step 4: use the remaining group IV drugs to make a regimen with at least 4 effective drugs
- “More is better than less”
- Dose 6 days a week
- Give each dose with strict supervision

**MDR-TB Standardised Regimen in Adults and Children > 8 years (switch to individualized, if necessary, based on DST results):**

6 Km(Am)-Mfx-Eto-Trd - Z/18 Mfx-Eto- Trd - Z

Intensive Phase for at least 6 month, taken 6 times per week.

Kanamycin or amikacin, moxifloxacin, ethionamide, terizidone and pyrazinamide

Continuation Phase with 4 drugs for 18 months, taken 6 times per week:

moxifloxacin, ethionamide, terizidone and pyrazinamide

**XDR-TB Standardised Regimen in Adults and Children > 8 years (switch to individualized, if necessary, based on DST results):**

6 Cm-Mfx-Eto-Trd -Z-PAS-Clofazimine/ 18 Mfx-Eto-Trd or Cs-Z -PAS/Clofazimine

Duration of MDR/XDR treatment:

The intensive phase of 5 drugs should last at least 6 months.

- A sputum should be collected monthly for smear microscopy and culture
- The culture conversion date is when 2 negative sputum culture results, each 30 days apart, have been collected
- Continue intensive (injectable) phase for 4 months following culture conversion date

The continuation phase should last until 18 months following the culture conversion date. Treatment may last up to 24 months for chronic cases with extensive pulmonary damage.

*References: South Africa NDOH. Management of Drug Resistant Tuberculosis. 2011. WHO. Treatment of Tuberculosis Guidelines. 4th edition. 2010.*



## Handout 5.6. Dosing of Standard Regimen for MDR/XDR-TB

<b>MDR-TB Standardized Treatment Regimen</b>				
<i>Intensive Phase: Treatment taken six times weekly for at least 6 months, guided by TB culture conversion</i>				
<b>Drug</b>	<b>Dose (&lt;33kg)</b>	<b>Dose (33-50kg)</b>	<b>Dose (51-70 kg)</b>	<b>Dose &gt; 70kg</b>
Kanamycin	15-20mg/kg	500-750mg	1000mg	1000mg
Moxifloxacin	400mg	400mg	400mg	400mg
Ethionamide	15-20mg/kg	500mg	750mg	750-1000mg
Pyrazinamide	30-40mg/kg	1000-1750mg	1750-2000mg	2000-2500mg
Terizidone	15-20mg/kg	750mg	750mg	750-1000mg

<b>MDR-TB Standardized Treatment Regimen</b>				
<i>Continuation Phase: Treatment taken six times weekly, for at least 18 months following culture conversion</i>				
<b>Drug</b>	<b>Dose (&lt;33kg)</b>	<b>Dose (33-50kg)</b>	<b>Dose (51-70 kg)</b>	<b>Dose &gt; 70kg</b>
Ethionamide	15-20mg/kg	500mg	750mg	750-1000mg
Pyrazinamide	30-40mg/kg	1000-1750mg	1750-2000mg	2000-2500mg
Moxifloxacin	400mg	400mg	400mg	400mg
Terizidone	15-20mg/kg	750mg	750mg	750-1000mg

<b>XDR-TB Standardized Treatment Regimen</b>				
<i>Intensive Phase: Treatment taken daily for at least 6 months, guided by TB culture conversion</i>				
<b>Drug</b>	<b>Dose (&lt;33kg)</b>	<b>Dose (33-50kg)</b>	<b>Dose (51-70 kg)</b>	<b>Dose &gt; 70kg</b>
Capreomycin	15-20mg/kg	500-750mg	1000mg	1000mg
Moxifloxacin	400 mg	400mg	400mg	400mg
Ethionamide	15-20 mg/kg	500mg	750mg	750-1000mg
Terizidone	15-20 mg/kg	500mg	750mg	1000mg
Pyrazinamide	30-40 mg/kg	1000-1750mg	1750-2000mg	2000-2500mg
PAS	150 mg/kg	8000mg	8000mg	8000mg
Clofazimine	3-5 mg/kg	200mg	300mg	300mg

<b>XDR-TB Standardized Treatment Regimen</b>				
<i>Continuation Phase: Treatment taken daily for at least 18 months following culture conversion</i>				
<b>Drug</b>	<b>Dose (&lt;33kg)</b>	<b>Dose (33-50kg)</b>	<b>Dose (51-70 kg)</b>	<b>Dose &gt; 70kg</b>
Moxifloxacin	400 mg	400mg	400mg	400mg
Ethionamide	15-20 mg/kg	500mg	750mg	750-1000mg
Terizidone	15-20 mg/kg	500mg	750mg	1000mg
Pyrazinamide	30-40 mg/kg	1000-1750mg	1750-2000mg	2000-2500mg
PAS	150 mg/kg	8000mg	8000mg	8000mg
Clofazimine	3-5 mg/kg	200mg	300mg	300mg

<b>Dosing of Standard MDR-TB Drugs in Paediatrics</b>				
<b>Drug</b>	<b>Formulation</b>	<b>Daily dose mg/kg/day</b>	<b>Frequency</b>	<b>Maximum daily dose</b>
Amikacin	Vials: 500 mg, 1 g	15 – 22.5	Once Daily	1g
Levofloxacin (for children under 8 years)	Tablets: 250, 500, 750 mg	<5 yrs: 10	Divided Twice Daily	1 g
		> 5 yrs: 10	Once Daily	
Ethionamide	Tablets: 250 mg	15 – 20	2x daily initially aim for 1x daily	1g
Terizidone	Capsules: 250 mg	10 – 20	Once daily	1g
Pyrazinamide		30-40		

<b>Dosing of Additional Second-Line TB Drugs in Paediatrics</b>				
<b>Drug</b>	<b>Formulation</b>	<b>Daily dose mg/kg/day</b>	<b>Frequency</b>	<b>Maximum daily dose</b>
Streptomycin	Vials: 500 mg, 1 g	15-30	Once Daily	1g
Kanamycin	Vials: 500 mg, 1g	15 – 30	Once Daily	1g
Capreomycin	Vials: 1g	15 – 30	Once Daily	1g
Moxifloxacin (for children older than 8 years and adult)	Tablets: 400 mg	7.5 – 10	Once Daily	400 mg
Prothionamide	Tablets: 250 mg	15 – 20	Twice daily	1g
PAS	PAS granules 4 g packets	150	Twice daily	12 g

*NB: Ethambutol may be given at the dosage of 20-25mg/kg.*

*Adapted from: SA NDOH MDR Guidelines August 2011.*

Slide 1

## Strategies to Reduce DR-TB

- Intensified Case Finding
- Isoniazid Prophylaxis
- Infection Control
- Integration of TB/HIV Care

**The best anti-TB drug for patients with MDR-TB and HIV is ART!**

- Anti-TB Drugs
- Rapid and early diagnosis and treatment



Slide 2

## Treatment

- How infectious are persons with DR-TB on treatment?
  - Prompt, effective treatment stops transmission!
  - Persons with unsuspected or inadequately treated drug resistant TB cause most transmission
- It is critical to get any and all persons presenting with signs and symptoms of TB on effective treatment as soon as possible!



Slide 3

## Confirmed Drug Resistance

- Confirmed by culture and drug sensitivity testing (C/DST)
  - Culture takes approximately 28-42 days; DST an additional 28-42
  - Culture and DST are indicated for ALL patients with suspected drug resistance
- DR-TB is a laboratory diagnosis

**All patients started on category II regimen must have culture and DST obtained**



Slide 4

## Mono Resistance - Regimen 2

- TB patients with a strain that is mono-resistant to INH will respond to drug-susceptible TB treatment
- Patient who are found to have mono-resistance to INH after regimen 1 treatment should be put on regimen 2
- The following treatment refers to NEW patients who will show the described resistance patterns at the beginning of their TB treatment



Slide 5

## Treating Mono- and Poly-Resistant TB

Drug Resistance Pattern	Suggested Regimen	Minimum Duration (months)	Comments
H (+/- S or +/- Z or +/- E)	Regimen I or II intensive phase for full duration (except for H)	6-9 months	If patient on Regimen II, stop streptomycin after 6 months. If resistant to streptomycin, discontinue immediately
R (+/- any other 1 <sup>st</sup> line drug)	Standardized MDR-TB regimen	18 months	Notion of potential over treatment. Use of terizidone in the MDR regimen
HEZ (+/- S)	Rifampicin, Moxifloxacin, Ethionamide, + kanamycin for first 2-3 months	18 months	6 months of kanamycin may strengthen regimen in patients with extensive disease



Slide 6

## Treat Mono and Poly Resistance Appropriately

- Mono- and poly- resistance are often unrecorded, unreported
- These are conditions that will become MDR-TB if neglected
- Pay close attention to mono- and poly-resistance TB and treat appropriately to improve outcomes and prevent MDR-TB



Slide 7

## Follow-Up Mono/Poly DR-TB

- TB microscopy and culture every 2 months until TB culture conversion
- TB microscopy and culture every 2 months during continuation phase
- DST repeated if unsatisfactory clinical and biological progress after 3-4 months of treatment



Slide 8

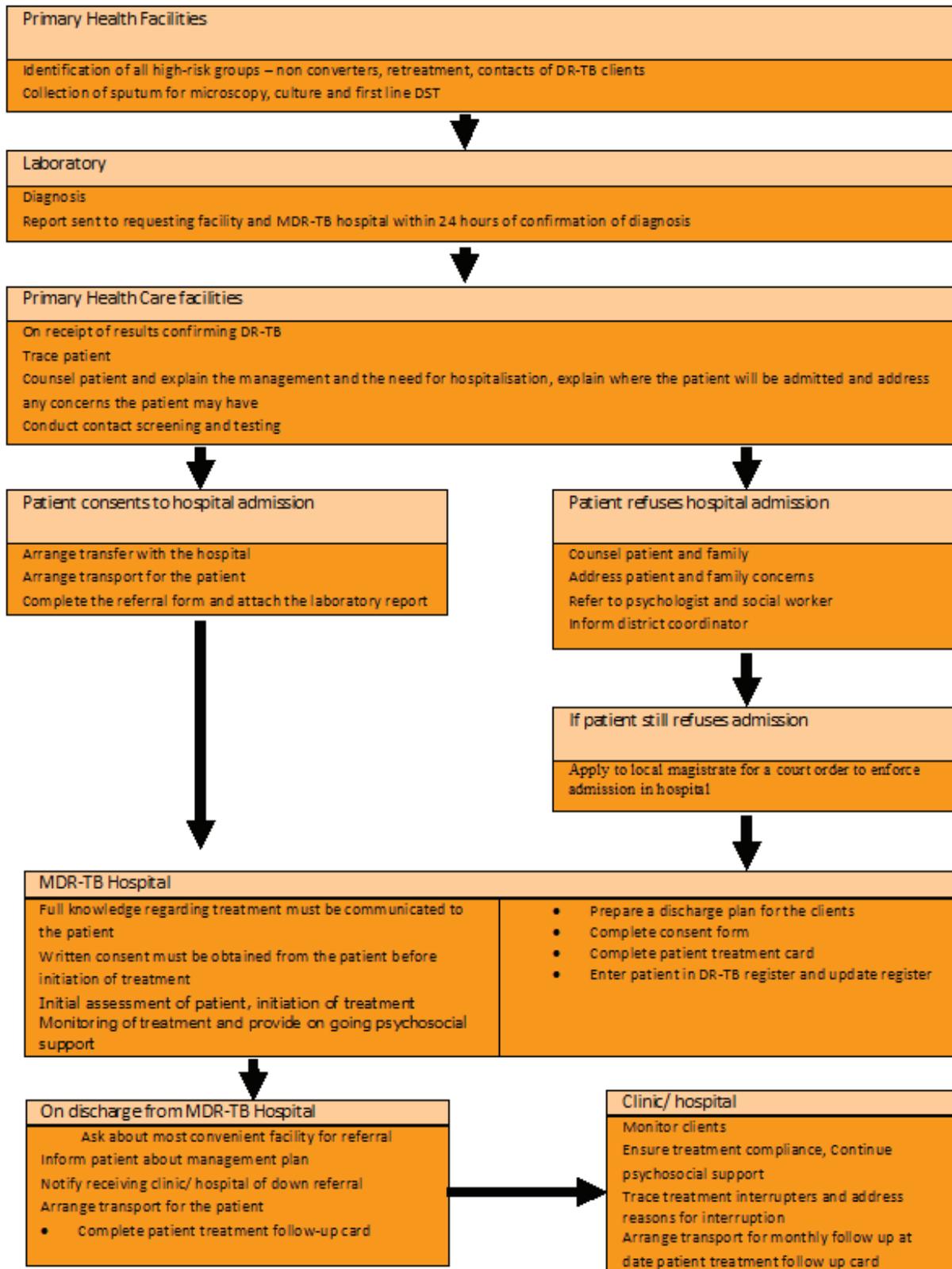
## Pre-treatment Evaluation and Care for MDR-TB Patients

- Initial labs include:
  - HIV test, sputum smear microscopy, culture & DST, chest x-ray, pregnancy test
  - Baseline renal, thyroid, and liver function tests
- Care can be hospital-based, clinic-based, or community-based, but MUST have uninterrupted quality drug supply
- Care should be given through multidisciplinary team of providers





## Handout 5.7. Referrals at Primary Health Facilities



Slide 9

## General Principles

- Regimens to be based on the history of drugs taken by the patient
- Drugs commonly used in the country and prevalence of resistance to 1st and 2nd line drugs are to be considered
- Give at least 4 drugs with either certain, or almost certain effectiveness
- Use 5 drugs in intensive phase and 4 drugs in continuation phase (stop injectable) as per standard regimen



Slide 10

## General Principles (2)

- Do not use drugs for which there is possibility of cross-resistance
- Avoid drugs that are not safe for the patient
- DST of drugs with high reproducibility and reliability (from a dependable laboratory) should be used to guide therapy



Slide 11

## General Principles (3)

- DST of ethambutol, streptomycin and group 4 and 5 drugs do not have high reproducibility and reliability
- WHO guidelines strongly caution against basing individual regimens on DST of these drugs
- PZA can be used during the entire duration of treatment if it is judged to be effective. Many MDR-TB patients have chronically inflamed lungs, which theoretically produce the acidic environment in which PZA is active. If patients are doing well PZA may be stopped in continuation phase.



Slide 12

## MDR-TB Regimen

**6Km(Am)-Mfx-Eto-Trd-Z/18 Mfx-Eto- Trd-Z**



MINIMUM NUMBER OF MONTHS OF TREATMENT



Slide 13

## Treatment Administration

- Number of days of administration: At least 6-7 in intensive phase and at least 5-6 days in continuation phase
- Use DOT for the whole duration of treatment
- Duration of the injectable phase **IS GUIDED BY CULTURE CONVERSION**
- TB culture Conversion is achieved when patient gets a 2nd negative TB culture (specimens taken 30 days apart)
- Conversion date is date of collection of the 1st specimen that turned to be TB culture negative



Slide 14

## Duration of Treatment

- Determine conversion date (if patient converted)
- Duration of injectable phase:
  - Add 4 months to conversion date to calculate the last day of the injectable phase
  - Calculate duration from treatment initiation to the last day of injectable phase
  - If the above is 6 months or more: it is acceptable and must be followed
  - If it is less than 6 months, it must be brought to six months
- Total duration of treatment:
  - Check treatment initiation date
  - Total duration of treatment: add 18 months to date of TB culture conversion



Slide 15

## Calculating Duration of Treatment

MONTH	DATE	AFB (Microscopy)	TB CULTURE	REMARK
RX-start (baseline)	04/08/2011	+++	Pos	
1	04/09/2011	+	Pos	
2	04/10/2011	-	Neg	Conversion date: 04/10/2011
3	04/11/2011	-	Neg	



Slide 16

## Calculating Duration of Treatment

MONTH	DATE	AFB (Microscopy)	TB CULTURE	REMARK
RX-start (baseline)	02/05/2011	+++	Pos	
1	02/06/2011	-	Neg	Conversion date: 2nd June 2011
2	02/07/2011	-	Neg	





## Worksheet 5.8. Calculating Resistance

MONTH	DATE	AFB (Microscopy)	TB CULTURE	REMARK
RX-start (baseline)	02/05/2011	+++ 03/05/2011	Pos 07/06/2011	
1	02/06/2011	- 03/06/2011	Neg 15/07/2011	Conversion date: 2nd June 2011
2	02/07/2011	- 03/07/2011	Neg 15/08/2011	

### Questions

1. When is the injectable agent going to be stopped?
  - November 2nd 2011, 6 months after initiating injectable phase
2. Determine the duration of the injectable phase.
  - 6 months
3. When is the treatment going to be stopped?
  - To calculate add 18 months to the end of the TB culture conversion date (02/06/2011). The continuation phase will end on 2/12/2012.
4. Calculate the duration of treatment.
  - In this case total duration of treatment will be 19 months

Slide 17

### Calculating Duration of Treatment (2)

DATE OF INITIATION OF TREATMENT	02/05/2011
TB CULTURE CONVERSION DATE	02/06/2011
ADD 4 MONTHS TO CONV. DATE	02/10/2011
INJECTABLE PHASE	2 <sup>ND</sup> MAY TO 2 <sup>ND</sup> OCT. 2011: 5 MONTHS
DECISION	ADD one month to make a total of 6 months; Stop injectable on 2 <sup>nd</sup> NOV. 2011
TOTAL DURATION OF TREATMENT (END OF CONTINUATION PHASE): Add 18 months to conversion date	02/06/2011 PLUS 18 MONTHS: 02/12/2012 (last day cont. phase)
CONTINUATION PHASE	3 <sup>RD</sup> NOV. 2011 to 2 <sup>nd</sup> DEC. 2012



Slide 18

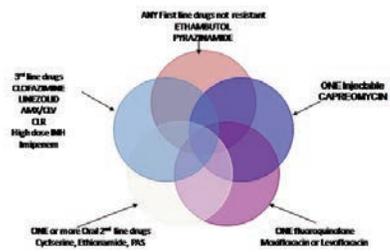
### XDR-TB: General principles and Drug selection

- Use at least 4 (ideally 6-7) drugs with expected or known susceptibility
- Do not use drugs with cross-resistance
- Eliminate drugs that are not safe
- Include drugs from groups 1-5, starting with group 1
  - Add any first-line agents to which the TB strains are susceptible (Pyrazinamide and/or Ethambutol) but remember these DST are not reliable. History of use of these drugs need to be considered.
  - Use an effective injectable (Capreomycin)
  - Add a fluoroquinolone (Moxifloxacin or Levofloxacin)
  - Add one or more of the following oral second-line drugs: Cycloserine, Ethionamide and PAS
  - Use group 5 only if needed
- Prevent, monitor and manage any side effects



Slide 19

### Designing an XDR-TB Regimen




Slide 20

### XDR-TB Standardised Regimen

- Intensive phase:  
6 Cm-Mfx-Eto-Trd-Z-PAS-Clofazimine
- Continuation phase:  
18 Mfx-Eto-Trd or Cs-Z- PAS/Clofazimine



Slide 21

### XDR-TB General Principles and Drug Selection (2)

- Number of days of administration: At least 6-7 in intensive phase and at least 5-6 days in continuation phase
- Injectable to be given 3x/week if ototoxicity
- Use DOT
- Duration of injectable phase and total duration of treatment guided by TB culture conversion (calculated same way as MDR-TB)



Slide 22

### Role of Surgery in MDR/XDR-TB Treatment

Major indications for surgery:

- When following adequate treatment and adherence:
  - Cultures continue to be positive after 6 months
  - Relapse in the same site
- Minor indications:
  - When risk for relapse after sputum conversion
    - Drug resistance so severe AND/OR
    - Residual cavitation or gross lobe or lung destruction



Slide 23

### Clinical Follow-up during Treatment

- Evaluation by clinician
- Weight and BMI
- Height
- Side effect monitoring
- Signs and symptoms of hypothyroidism
- Audiometry/eye tests



Slide 24

### Monitoring during Treatment

- Sputum smear at baseline and monthly
- TB culture monthly until conversion, then every other month
- DST on admission and if no improvement
- Liver function tests
- Serum creatinine
- Serum potassium
- Thyroid stimulating hormone
- HIV and pregnancy test
- Chest x-ray baseline and every 6 months
- Lung CT when indicated



## Case Management

- Provide DOT for all doses
- Educate patient and family
- Prevent, monitor and manage minor adverse effects for each of the drugs selected
- Refer major adverse events to medical officer
- Collect one smear and culture every month throughout treatment to detect treatment failure as soon as possible
- Conduct contact tracing





## Handout 5.9. Common Side Effects During MDR-TB Treatment

Drug	Complaint/Side Effect
Aminoglycoside	Hearing loss, vestibular toxicity, hypokalemia, hypomagnesemia, rash
Amikacin (Amk)	Ototoxicity*: dizziness and hearing loss, renal failure*
Capreomycin (Cm)	Hearing loss, vestibular toxicity, Hypokalemia, hypomagnesemia, Rash
Clofazimine	GI complaints, rash
Cycloserine (Cs)	GI complaints, behavioural changes including depression and anxiety*, rash, peripheral neuropathy, seizures*, headache*, psychosis
Ethambutol (E)	Visual changes, rash, headache
Ethionamide (Eto)	GI complaints (nausea, anorexia)*, hypothyroidism*, hepatotoxicity*, behavioural changes, rash, peripheral neuropathy*, headache
Fluoroquinolones (FQs)	Seizures, headache, GI complaints, rash
Isoniazid (H)	Hepatotoxicity, behavioural changes, visual changes, rash, bone marrow suppression, peripheral neuropathy, seizures, headache
Linezolid (L)	Visual changes, rash, bone marrow suppression, peripheral neuropathy
Para-Aminosalicylic Acid (PAS)	GI complaints, hyperthyroidism, hepatotoxicity, rash
Pyrazinamide (Z)	Hepatotoxicity, rash
Rifampicin (R)	Hepatotoxicity, rash, bone marrow suppression
Rifabutin	Visual changes, rash
Terizidone (Trd)	

Adverse Reaction	Responsible Agent	Management
<p>Seizures</p> <ul style="list-style-type: none"> <li>– Generally not permanent sequelae and history of seizure not a contraindication</li> </ul>	<p>Cs Trd FQs</p>	<p>Rule out other likely causes (Clinical evaluation generally sufficient unless high suspicion of infectious, malignant, vascular or metabolic cause)</p> <p>Treat any suspected causes</p> <p>Initiate anticonvulsant treatment phenytoin 3-5 mg/kg/day; valproic acid 750-1250 g/kg/day; carbamazepine 600-1200 mg/day; phenobarbital 60-120 mg/kg/day</p> <p>Continue anticonvulsant through MDR-TB treatment</p> <p>Increase pyridoxine to 200 mg daily</p> <p>Lower dose/discontinue offending drug</p>
<p>Peripheral neuropathy</p> <ul style="list-style-type: none"> <li>– Generally not reversible but unlikely to require continued intervention following MDR-TB treatment</li> </ul>	<p>Cs, Trd S Km, Amk Cm Eto/Pto, FQs</p>	<p>Increase pyridoxine to 200 mg daily</p> <p>Begin exercise regimen, focusing on affected regions</p> <p>Initiate therapy with tricyclic antidepressant drugs</p> <p>Lower dose/discontinue suspected drug</p> <p>Initiate therapy with gabapentin 300mg qid initially, and increase by 600mg every 3-7 days; max dose 1200mg tds</p>
<p>Hypothyroidism</p> <ul style="list-style-type: none"> <li>– Completely reversible upon discontinuation</li> </ul>	<p>PAS Eto/Pto</p>	<p>Initiate thyroxine</p>
<p>Hearing loss</p> <ul style="list-style-type: none"> <li>– Generally not reversible</li> </ul>	<p>S Km Amk Cm</p>	<p>Conduct audiometry and compare with baseline</p> <p>Consider reducing the frequency of the drug administration to 5 times or even 3 times per week</p> <p>Lower dose/discontinue suspected drug if this will not compromise the regimen</p>
<p>Psychosis</p> <ul style="list-style-type: none"> <li>– Generally reversible</li> <li>– History of psychiatric disease not a contraindication</li> </ul>	<p>Cs Tdr FQs Eto/Pto</p>	<p>Refer to a psychiatrist for assessment</p> <p>Hold suspected agent for short period of time (1-4 weeks) while psychotic symptoms brought under control</p> <p>Initiate anti-psychotic drugs (eg. risperidone 0.5-2 mg po bd; Haloperidol 1-5mg po or IV or IM repeated every hour as needed)</p> <p>Some will need to continue anti-psychotic treatment throughout MDR-TB treatment</p> <p>Lower dose of suspected agent/discontinue if this will not compromise the regimen</p>

Adverse Reaction	Responsible Agent	Management
<p>Depression</p> <ul style="list-style-type: none"> <li>- History of depression is not a contraindication</li> </ul>	<p>Cs Trd FQs Cm Eto/Pto</p>	<p>Rule out side effects of concomitant medications, eg. amoxicillin-clavulanate, penicillin, benzodiazepines</p> <p>Refer to psychologist/ psychiatrist for assessment</p> <p>Initiate group or individual psychological therapy</p> <p>Initiate anti-depressant drugs (eg. amitriptyline, nortriptyline, fluoxetine, sertraline), but use with caution when there is a history of convulsions</p> <p>Increase pyridoxine to 200 mg daily</p> <p>Lower dose of the offending drug/ discontinue if this will not compromise the regimen</p>
<p>Nausea and vomiting</p> <ul style="list-style-type: none"> <li>- Most common in early weeks of treatment and reversible</li> </ul>	<p>Eto/Pto PAS Cm E Z</p>	<p>Assess for dehydration and rehydrate if indicated</p> <p>Initiate anti-emetics 30 min prior to administering MDR-TB drugs</p> <p>Administer ethionamide in 3 separate doses</p> <p>Administer ethionamide at night with short-acting benzodiazepine</p> <p>Lower dose/Discontinue offending drug agent</p>
<p>Gastritis</p> <ul style="list-style-type: none"> <li>- Reversible</li> </ul>	<p>PAS Eto/Pto E Z</p>	<p>Administer MDR-TB drugs with a small amount of food</p> <p>Caffeine, cigarettes should be avoided</p> <p>Consider use of Antacids (eg. calcium carbonate, aluminium hydroxide, magnesium-hydroxide). Carefully time (2 hours before or 3 hours after TB medication) so as not to interfere with absorption.</p> <p>H2-blockers (eg. cimetidine, ranitidine), proton-pump inhibitors (eg. omeprazole)</p> <p>Withhold offending drug (s) for short periods of time (eg. 1-7 days)</p> <p>Lower dose/Discontinue offending drug</p>
<p>Hepatitis</p> <ul style="list-style-type: none"> <li>- Generally reversible</li> </ul>	<p>Z FQs Eto/Pto PAS E</p>	<p>Stop treatment pending resolution of the hepatitis</p> <p>Rule out other potential causes of hepatitis</p> <p>Consider suspending the causative drug permanently</p> <p>Re-introduce drugs individually while monitoring liver function, with the most likely drug introduced first</p> <p>Monitor liver function every 1-2 months</p>

Adverse Reaction	Responsible Agent	Management
Renal failure and nephrotoxicity – Renal impairment may be permanent – History of DM or renal disease not a contraindication	S Km Amk Cm	Discontinue causative drug Consider dosing 3 times per week and monitor creatinine clearance Adjust dose of all the drugs according to creatinine clearance Consider use of capreomycin if patient was on aminoglycoside
Optic neuritis – Usually reversible	E	Stop agent Refer patient to an ophthalmologist
Arthralgia/Arthritis – Symptoms generally diminish over time	Z FQs	Initiate therapy with non-steroidal anti-inflammatory drugs Initiate exercise regimen/physiotherapy where necessary Lower dose/discontinue offending drug, if this will not compromise the regimen
Electrolyte disturbances (hypokalemia, hypomagnesemia) – Hypokalemia may be lifethreatening	Cm Km Am S	Replenish potassium po or IV Treat associated vomiting or diarrhoea Check magnesium levels if potassium levels do not improve Discontinue arrhythmogenic drugs (eg. digoxin, amyltriptyline, cisapride, haloperidol) if patient is taking them Amiloride 5-10mg qid or spironolactone 25mg qid may decrease the potassium and magnesium wasting and is useful in refractory cases. Discontinue aminoglycosides if condition is severe

Slide 26	<h3 style="text-align: center;">Special Situations</h3> <ul style="list-style-type: none"><li>• <b>Fertile women</b><ul style="list-style-type: none"><li>– Avoid pregnancy: use injectable medroxy-progesterone (Depo-Provera) and/or condoms</li><li>– Oral contraceptives may have decreased efficacy</li></ul></li><li>• <b>Pregnancy</b><ul style="list-style-type: none"><li>– Some 2nd line drugs have teratogenic effects<ul style="list-style-type: none"><li>– Aminoglycosides</li><li>– Ethionamide</li></ul></li><li>– Delay injectable agent until 2nd trimester/immediately postpartum if possible</li></ul></li></ul> 
Slide 27	<h3 style="text-align: center;">Special Situations – Breastfeeding/Diabetes</h3> <ul style="list-style-type: none"><li>• <b>Breast-feeding</b><ul style="list-style-type: none"><li>– Full course of treatment of mother is essential to prevent transmission to baby</li><li>– Minute amounts of drug passed through breastmilk, risks of long-term exposure unknown</li><li>– If safe and sustainable, formula feeding would avoid risk of infant toxicity</li><li>– If mother is smear-positive she should not be forced to stay apart from her infant. She should wear a mask and follow infection control practices</li></ul></li><li>• <b>Diabetes</b><ul style="list-style-type: none"><li>– Poor outcomes without good glucose control!</li><li>– Help keep glucose levels controlled</li></ul></li></ul> 
Slide 28	<h3 style="text-align: center;">Special Situations - Children</h3> <ul style="list-style-type: none"><li>• Seldom culture +, make every effort to obtain good sputum specimen</li><li>• If culture – with symptoms and exposure, guide treatment based on DST results and TB drug exposure of contact</li><li>• Limited experience with 2nd line drugs</li><li>• Base all drug doses on weight, dose at higher end of recommended ranges</li></ul> 
Slide 29	<h3 style="text-align: center;">Chain of Survival</h3> <ul style="list-style-type: none"><li>• EARLY AWARENESS</li><li>• EARLY SUSPICION</li><li>• EARLY DIAGNOSIS</li><li>• EARLY TREATMENT</li></ul> 



## Worksheet 5.10. Cases in the Management of DR-TB

*Case Study #1:* Mr. Vuyo presents to the Clinic for cough and night sweats on 24/03/2011. He worked at the mines and has had TB before.

Investigations done: AFB: ++

DST showed resistance to rifampicin and isoniazid

He is referred to MDR-TB Unit for admission and started on treatment on 2nd May 2011.

1. What do you plan to do on admission/treatment initiation day, including laboratory tests?
  - Obtain thorough history
  - Smears for microscopy culture
  - Evaluation by clinician, weight, BMI & height
  - Audiometry and eye tests
  - HIV test, serum creatinine, chest x-ray
  - Liver function tests, FBC with differential
  - Counsel regarding adherence, length of treatment, side effects
  - Contact tracing/screening and treatment
2. What treatment regimen is he likely to commence (weight 65kg at admission visit)?
  - 6Kanamycin(Km) or Amikacin–Moxifloxacin-Ethionamide- Terizidone and Pyrazinamide/18 Moxifloxacin - ethionamide-terizidone-pyrazinamide
  - 1000mg Km(injected), Moxifloxacin 400 mg,750mg Eto, 750mg Trd, 1750-2000mg pyrazinamide all taken daily (at least 6x/week x 6 months). For continuation phase, re-weigh patient and dose accordingly.
3. What is your plan for clinical/laboratory follow-up monitoring?
  - Evaluation by clinician monthly until culture conversion, then every 2-3 months. Weight and BMI monthly. Assess for signs and symptoms of side effects. Monthly sputum smears. TB culture monthly until conversion, then bimonthly. LFTs every 1-3 months if on pyrazinamide or if symptoms of liver problems. Serum creatinine and potassium monthly while receiving injectable agent. TSH every 6 months. Chest x-ray every 6 months. (DST if no improvement)
  - Daily DOT
4. What recording and reporting tools/registers will you complete in this case?
  - TB Case Identification and Follow-up Sputum Register (GW20/13) – with results and follow-up
  - Patient Clinic/Hospital Card
  - DR-TB Register
  - DR-TB Patient follow-up card
  - Request for Sputum Examination baseline (smear, culture, DST/LPA), monthly sputum (culture and smear)
  - Referral Form (as likely referring at some point)

5. Below are his records, using this information please answer the questions that follow:

Month	Date	Gene Xpert	AFB (microscopy)	TB Culture	Remark
RX-start (baseline)	02/05/2011	Positive	+++ 03/05/2011	Pos 07/06/2011	
1	02/06/2011		+ 03/06/2011	Pos 07/07/2011	
2	02/07/2011		- 03/07/2011	Pos 07/08/2011	
3	02/08/2011		- 03/08/2011	Neg 15/09/2011	Conversion 02/08/2011
4	02/09/2011		- 03/09/2011	Neg 15/09/2011	

- a. When will the injectable agent be stopped?
  - 2nd December 2011. Use the date of the TB culture conversion (02/08/2011- date sample provided) and add 4 months (making sure it is at least 6 months in duration)
- b. Determine the duration of the injectable phase?
  - 7 months. Use the date of the initiation of treatment (02/05/2011) until calculated end of injectable phase (02/12/2011).
- c. When is the treatment (end of continuation phase) going to be stopped?
  - 02/02/2013. Add 18 months to conversion date (02/08/2011).
- d. Calculate the duration of the treatment?
  - Total duration of treatment is 21 months.

6. At his 6 month visit Mr. Vuyo complains of feeling very unmotivated about life, the things that used to bring him joy no longer interest him and he sleeps all the time. What may be occurring and what would be the next step?
- Depression is a likely cause. Physical causes should be excluded through physical examination and laboratory exams. Drugs most likely to cause depression include Cs, Trd, FQs, Cm, Eto or Pto. Potential side-effects due to other medications should be excluded, he should be referred to a psychologist/psychiatrist and started on group or individual therapy. An anti-depressant drug, such as amitriptyline, nortriptyline, fluoxetine or sertraline may be beneficial. His pyridoxine could be increased to 200mg daily. Consider the psychosocial issues he may currently be encountering and discuss potential solutions. If all else fails consider lowering or discontinuing the offending drug if it will not compromise the regimen. Note that depression is a strong indicator of poor adherence and the depressive symptoms should be taken seriously and addressed appropriately. Adherence should also be discussed extensively. If this patient has HIV consider as potential synergistic side effect associated with efavirenz.

Case Study #2: Mrs. Vivian had TB a year ago and started Regimen 1, but did not return after the first 2 months. She presents today with a cough, fevers and weight loss. One sputum was submitted for GXP and returned GXP positive, rifampicin resistant. After culture and DST were submitted, results were resistant for rifampicin and isoniazid.

1. What do you plan to do on admission/treatment initiation day, including laboratory tests?
  - Evaluation by clinician, weight, BMI & height, pregnancy test, Audiometry and eye tests, HIV test, serum creatinine, chest x-ray. Begin on birth control.
2. What treatment regimen is she likely to commence (weight 45kg at admission visit)?
  - 6Kanamycin(Km) or Amikacin-Moxifloxacin-Ethionamide-Terizidone and Pyrazinamide/ 18 Moxifloxacin- ethionamide-terizidone-pyrazinamide
  - 500-750mg Km(injected), Mfx 400mg, Eto 500mg, Trd 750 mg, 1000-1750 mg pyrazinamide all taken daily (at least 6x/ week x 6 months). Dosing unknown for continuation phase due to potential weight change.

3. What is your plan for clinical/laboratory follow-up monitoring?
  - *Evaluation by clinician monthly until culture conversion, then monthly.*
  - *Weight and BMI monthly. Assess for signs and symptoms of side effects.*
  - *Monthly sputum smear. TB culture monthly until conversion, then bimonthly. LFTs every 1-3 months if on pyrazinamide or if symptoms of liver problems. Serum creatinine and potassium monthly while receiving injectable agent. TSH every 6 months. Chest X-ray every 6 months. (DST if no improvement) CD4 and Viral load as routine. Assess for pregnancy routinely.*
4. What recording and reporting tools/registers will you complete in this case?
  - *TB Case Identification and Follow-up Sputum Register (GW20/13) – with results and follow-up*
  - *Patient Clinic/Hospital Card (??) – As started on treatment*
  - *DR-TB Register*
  - *DR-TB Patient Follow-up Card*
  - *Request for Sputum Examination baseline (smear, culture, DST/LPA), monthly sputum (culture and smear)*
  - *Referral Form (as likely referring at some point)*
5. Below are her records, using this information please answer the questions that follow:

Month	Date	Gene Xpert	AFB (microscopy)	TB Culture	Remark
RX-start (baseline)	15/1/2011	Positive	++ 16/01/2011	Pos 19/02/2011	
1	15/02/2011		+ 16/02/2011	Pos 19/03/2011	
2	15/03/2011		+ 16/03/2011	Pos 19/04/2011	
3	15/04/2011		– 16/04/2011	Neg 19/05/2011	Conversion 15/04/2011
4	15/05/2011		– 16/05/2011	Neg 19/06/2011	
5	15/06/2011		– 16/06/2011	Neg 19/07/2011	

- a. *When will the injectable agent be stopped?*
    - *15th August 2011. Use the date of the TB culture conversion (15/04/2011- date sample provided) and add 4 months (making sure it is at least 6 months in duration)*
  - b. *Determine the duration of the injectable phase?*
    - *7 months. Use the date of the initiation of treatment (15/01/2011) until calculated end of injectable phase (15/08/2011).*
  - c. *When is the treatment (end of continuation phase) going to be stopped?*
    - *15/10/2012. Add 18 months to conversion date (15/04/2011).*
  - d. *Calculate the duration of the treatment?*
    - *Total duration of treatment is 21 months.*
6. During the first month of therapy Vivian complains of nausea and vomiting. Which medications are likely to cause this side effect and what can you do?
    - *Likely medications are Eto/Pto, PAS, CM, E or Z. Assess for dehydration and rehydrate if necessary. Initiate anti-emetics 30 minutes prior to administering MDR-TB, ethionamide can be administered in 3 separate doses and can also be administered at night with short acting benzodiazepines. Or in severe cases can consider lowering dose or discontinue of offending drug. Generally it is common in the first several weeks of therapy and then resolves.*
  7. At her 6 month visit, you assess Vivian's thyroid levels by obtaining a TSH. It returns elevated. What do you think may be occurring and what do you suggest?
    - *She is likely to have hypothyroidism. Note that in hypothyroidism the TSH is elevated (the thyroid levels (T3 or T4 would be low, causing Thyroid Stimulating Hormone – TSH- to produce higher amounts in order to attempt to help the body produce more thyroid hormone). Hypothyroidism is usually caused by PAS or Eto/Pto. She should start thyroxin and complete the therapy. Her levels should resolve once she completes the therapy and stops the offending drug. Recheck thyroid levels shortly after initiating thyroxin.*

*Case Study #3:* Francois is a 3 year-old boy, his dad is currently on MDR treatment. He has not been gaining weight and has had a cough for several months.

Investigations done: AFB: + by gastric aspirate

Father's DST showed resistance to rifampicin and isoniazid; DST pending

He is referred to MDR-TB Unit for admission and started on treatment on 13nd August 2011.

1. What do you plan to do on admission/treatment initiation day, including laboratory tests?
  - *Evaluation by clinician, weight, BMI & height*
  - *Audiometry and eye tests*
  - *HIV test, serum creatinine, chest x-ray*
2. What treatment regimen is he likely to commence (weight 10.7kg at admission visit)?
  - *Amikacin-Levofloxacin -Terizidone -Ethionamide-Pyrazinamide*
  - *Approximately Amikacin (approximately 140mg daily), Levofloxacin (approximately 107 mg divided into two daily doses), Ethionamide (approximately 200 mg daily), Terizidone (approximately 250 mg once daily) and Pyrazinamide (approximately 300-400 mg daily). All should be administered at least 6x/week for 6 months. Dosing unknown for continuation phase due to potential weight change.*
3. What is your plan for clinical/laboratory follow-up monitoring?
  - *Evaluation by clinician monthly until culture conversion, then every 2-3 months. Weight and BMI monthly. Assess for signs and symptoms of side effects and hypothyroidism monthly. Monthly sputum smears. TB culture by gastric aspirate or induced monthly until conversion, then bimonthly. LFTs every 1-3 months if on pyrazinamide or if symptoms of liver problems. Serum creatinine and potassium monthly while receiving injectable agent. TSH every 6 months. Chest X-ray every 6 months. (DST if no improvement)*
4. What recording and reporting tools/registers will you complete in this case?
  - *TB Case Identification and Follow-up Sputum Register (GW20/13) – with results and follow-up*
  - *Patient Clinic/Hospital Card (??) – As started on treatment*
  - *DR-TB Register*
  - *DR-TB Patient Follow-up Card*
  - *Request for Sputum Examination baseline (smear, culture, DST/LPA), monthly sputum (culture and smear)*
  - *Referral Form (as likely referring at some point)*
5. Below are his records, using this information please answer the questions that follow:

Month	Date	Gene Xpert	AFB (microscopy)	TB Culture	Remark
RX-start (baseline)	13/08/2011	Positive	+ 14/08/2011	Pos 16/09/2011	
1	13/09/2011		- 14/09/2011	Pos 16/10/2011	
2	13/10/2011		- 14/10/2011	Neg 16/11/2011	
3	13/11/2011		- 14/11/2011	Neg 16/12/2011	Conversion 13/10/2011
4	13/12/2011		- 14/12/2011	Neg 16/01/2012	

- a. *When will the injectable agent be stopped?*
    - *13th February 2012. Use the date of the TB culture conversion (13/10/2011- date sample provided) and add 4 months (making sure it is at least 6 months in duration)*
  - b. *Determine the duration of the injectable phase?*
    - *6 months. Use the date of the initiation of treatment (13/10/2011) until calculated end of injectable phase (13/2/2012).*
  - c. *When is the treatment (end of continuation phase) going to be stopped?*
    - *13/4/2013. Add 18 months to conversion date (13/10/2011).*
  - d. *Calculate the duration of the treatment?*
    - *Total duration of treatment is 20 months.*
6. At his 6 month you note that Francois's weight appears to not be increasing. At his 4 month visit he weighed 12 kg, but has not gained any more weight since then. What is your concern and your plan?
- *You are concerned of relapse or treatment failure. Adherence should be assessed and discussed extensively. A repeat sputum and culture should be obtained to assess for infection, A Chest X-ray may be merited. Assessment of close contact's TB status, particularly MDR should be assessed. Since his father was known to have MDR to begin with, you may be concerned of either the father or Francois having developed additional resistance.*



## Trainer Instructions: Step 3 (30 minutes) Overcoming Barriers to Adherence

### Step 3 Learning Objectives:

- Discuss the barriers clients face in adhering to treatments.
- Assist clients in developing strategies to improve treatment adherence.

### Step 3 Resources Needed:

- Worksheet 5.11. Addressing Factors Affecting Adherence
- Handout 5.12. Strategies to Improve Adherence
- Handout 5.13. The Role of Counselling to Ensure Adherence

### Step 3 Trainer Instructions:

	3.1. Ask all trainees to stand and to think about times in their lives when they have been prescribed medication and inform them that they can sit down only if they have always taken medication exactly as prescribed.
	3.2. Ask those who remain standing to consider the occasion when they failed to comply with instruction or complete a course, and to think about why this happened.
	3.3. Ask each person to give their reasons for non-adherence. Record their responses on a flipchart.
	3.4. Try to group these experiences into the following headings: <ul style="list-style-type: none"> <li>• Beliefs about medication, e.g. “It is better I stop because the drugs are toxic”</li> <li>• Practical difficulty, e.g. “I had to have the tablet within two hours of eating”</li> <li>• Memory, e.g. “I just forgot to take it”</li> <li>• Social, e.g. “I didn’t want anyone to know I wasn’t well and see me”</li> <li>• Misinformation, e.g. “My symptoms went so I thought I was cured”</li> </ul>
	3.5. Remark that clients have the same difficulties. Note that there are many reasons that contribute to non-adherence. Information provision clearly is not enough—they are health workers and had information but still did not adhere to their prescription. Remind participants that ARVs and TB treatment can be extremely challenging to adhere to given the length and pill burden of TB treatment. ARV treatment is for life!
	3.6. Stress that adherence is a crucial factor in determining the effectiveness of the treatment. For the patient, poor adherence can lead to virological failure, the evolution of drug resistance and subsequent immunological and clinical failure. From a public health perspective, the development of drug resistance, which causes the medications to become less effective, or stop working all together means that the range of treatments becomes increasingly limited and resistant infections can then be very difficult to treat.
	3.7. Divide participants into groups of 5. Refer participants to Worksheet 5.11. Addressing Factors Affecting Adherence. Assign each group one factor listed. Explain that groups will have 15 minutes to complete the worksheet. Reconvene participants and ask for each group to share responses.
	3.8. Tell participants that the three main reasons people give for TB and MDR-TB treatment defaulting are: <ul style="list-style-type: none"> <li>• Patients’ perceptions to negative attitudes among health care workers</li> <li>• Substance abuse</li> <li>• Employment concerns</li> </ul>
	3.9. Direct participants to the Handout 5.12. Strategies to Improve Adherence. Ask participants to read these. Then ask, “What other strategies have you used in you work to help patients adhere to their treatment?” Record these on the flipchart.

	<p>3.10. Ask participants, “What is the role of the healthcare worker in supporting adherence?”</p> <p><i>Possible Answers:</i></p> <ul style="list-style-type: none"> <li>• <i>Prescribe an appropriate regimen</i></li> <li>• <i>Assess the adherence of the patient to the regimen</i></li> <li>• <i>Address poor adherence when it occurs</i></li> <li>• <i>Ensure adherence to the regimen until treatment is completed</i></li> <li>• <i>Ensuring a positive attitude and establishing rapport with patients</i></li> </ul>
	<p>3.11. Ask participants, “What is the role of counselling in adherence?” Refer participants to Handout 5.13. The Role of Counselling to Ensure Adherence. Quickly review handout with participants.</p>
	<p>3.12. Summarise Discussion: Adherence in prevention of drug resistant TB is critical!</p>



## Worksheet 5.11. Addressing Factors Affecting Adherence

<b>Factors that Influence Person's Adherence</b>	<b>Strategies to Overcome Factors</b>
<b>Patient factors</b>	
<b>Regimen factors</b>	
<b>Patient-provider relationship factors</b>	
<b>Psychosocial factors</b>	
<b>Health services related factors</b>	



## *Handout 5.12. Strategies to Improve Adherence*

- Communication difficulties (language, cultural differences, patient attitudes regarding treatment efficacy, lack of comprehension about treatment plan or regimen)
  - Discuss in an open and non-judgmental way
  - Provide patients with scientific basis for treatment
  - Repeat and paraphrase
  - Use counsellors who speak the same language and understand the cultural context of the patient
- Establish a Rapport
  - Build a trusting relationship with patients and his/her family
  - Involve patients in the decision making process about adherence
  - Demonstrate supportive and non-judgmental attitudes and behaviours: This will encourage patients to be honest about adherence and about problems they have with adherence
  - Monitor and encourage adherence at every clinical encounter as motivation fluctuates over time
  - Prepare patients on adherence for several sessions before starting ART
  - Communicate effectively between clinical team and home-based care providers
- Literacy levels
  - Verbal repetition of adherence message, treatment plan and regimen
  - Use patient literacy materials
  - Use dummy pills for demonstration
  - Review information with patient
- Inadequate knowledge or awareness about HIV and TB disease
  - Provide patients with scientific information about HIV and TB disease
  - Review information with patient
  - Use examples to which the patient can relate
- Inadequate understanding about effectiveness of medications
  - Inform patient and bring change in attitudes and understanding of effectiveness of medications
- Forgetting medications:
  - Drawing up a medications schedule. Use a calendar or diary to help keep track of medications that are due to be taken and when they have been taken, e.g. at the start of each week write down when the doses are due and then tick off each time they are taken
  - Dividing up the correct amounts at the start of each day or each week. They could divide the doses into separate containers, e.g. cups or plastic bags, and label them. It may be helpful for a health care worker to help the first time this is done
  - Taking the medication at the same time of day each day (depending on the instructions about when the medications need to be taken)
  - Incorporating taking medications into other activities that are part of the daily routine, e.g. with a meal or before going to work (depending on the instructions about when the medications need to be taken)
  - Planning ahead for when more medication is needed so that the person taking medications does not miss doses because they have run out
  - When travelling, taking medications along too and taking extra in case some are lost
  - Make taking medication a priority in the day
- Lack of social support
  - Establish contact with PLHA support groups
  - Link with community health workers and home-based care services
  - Link with charitable institutions, Faith Based Organisations

- Discomfort with disclosure of HIV status
  - Counselling patient to support disclosure
  - Identify other support persons like friends or peers if patient unable to disclose to the family
- Difficult life conditions (lack of income, housing and food; lack of support for childcare)
  - Establish contact with PLHA support groups
  - Link with community health workers and home-based care services
  - Link with charitable institutions, church programs
- Alcohol and drug use
  - Counselling—emphasize link between alcohol, ARV medications and liver damage
  - Family support
  - Peer group support programs, church programs
  - Medical consultation—de-addiction programs
- Depression and other psychiatric problems
  - Don't hesitate to ask about these symptoms or possible adverse effects of medications
  - Refer to physician for treatment
- Negative or judgmental attitude of providers
  - Training of providers

*Source: Adapted from Horizons/Population Council, International Centre for Reproductive Health and Coast Province General Hospital, Mombasa–Kenya, 2004. Adherence to Antiretroviral Therapy in Adults: A Guide for Trainers. Nairobi: Population Council*



## *Handout 5.13. The Role of Counselling to Ensure Adherence*

### **Goals**

- Help patients develop an understanding of their treatment and its challenges.
- Prepare the patient to initiate treatment.
- Provide ongoing support for clients to adhere to treatment over the long term.
- Help clients develop good treatment taking behaviour.
- Help patients in setting goals for their treatment.

### **Assessment**

- Involves assessment of an individual's capacity to adhere to treatment, and screening for mental or substance use disorder, which may impact on HIV. This includes:
  - Learning about the patient's health through a detailed medical history.
  - Learning about the prior use of antiretrovirals and other medications.
  - Learning about the patient's beliefs and attitudes about HIV and treatment.
  - Learning about the sources of social support.
  - Learning about the socio-economic situation of the patient.
  - Identifying barriers to adherence

### **Preparation**

- Describe the treatment and adherence program.
- Discuss the layout of the health facility including the laboratory and pharmacy.
- Discuss the system for treatment and follow-up:
  - Three counselling sessions prior to starting ART.
  - After starting ART the first two follow-up visits to be every two weeks followed by monthly doctor consultations.
  - Laboratory tests. Some tests to be done every month, others every 2–6 months. The doctor will inform the patient about required investigations.
- It is important that the patient fully understands
  - The type of the medication
  - The purpose of the medication
  - The duration
  - Potential side effects and that there are potential solutions (many patients cease medication because of unanticipated side effects.)
  - How to take the medications correctly
- The person taking the medication should have an understanding about taking:
  - The right medicines – that they are taking the right medicines for the illness. If the person taking the medications is going to put all the medications together for each dose into bags or pill boxes (e.g., morning doses, afternoon doses), then make sure that a record is kept about what the medication is called, what it is for and what it looks like so that there is no confusion if medications run out
  - The right way – that they are using the correct route of administration of the medication, whether the medication should be chewed, swallowed, sucked, rubbed onto the skin, injected, etc. Some medications need to be taken on an empty stomach. This means up to 30 minutes before food or one hour after food. Others should be taken with food, which may be during a meal, or with a snack

- The right amount – that they are taking the correct dosage, and not to take more than the amount prescribed (mistakenly believing that this will increase effectiveness) or less than the amount prescribed (mistakenly believing this may make the tablets last longer)
- At the right time – that they are taking the medications at the correct times during the day, e.g., every 4 hours. It may help to write the times down so that it is less confusing, e.g. 8.00 am, 12.00 pm, 4.00 pm, 8.00 pm, etc.

## Monitoring adherence

- Assist the individual in resolving any difficulties that may arise during treatment that impact on adherence—side effects, barriers, etc.

### *References:*

Gandhi N, Moll A, Sturm A, et al. Extensively drug-resistant tuberculosis as a cause of death in patients co-infected with tuberculosis and HIV in a rural area of South Africa. *The Lancet*, Volume 368, Issue 9547, Pages 1575-1580, 4 November 2006.

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Republic of South Africa. Management of Drug Resistant Tuberculosis. 2011.

Weyer, Karin : Case study : Round Table Discussion. Bulletin of the World Health Organization. May 2007, 85 (5)

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## Session 6. Management of TB in an HIV-infected Person



**Total Session Time: 1 hour and 50 minutes**

### Learning Objectives:

By the end of this session, participants will be able to:

- Describe and recognise atypical presentations of TB in HIV-infected persons.
- Discuss how to manage HIV-positive patients with TB.
- Explain the use of ART for HIV-TB co-infection, including DR-TB.
- Discuss the indications of ART in TB patients.
- Identify the most common side effects of anti-TB and ARV drugs.
- Define overlapping side effects of Anti-TB and ARV drugs.

### Session Overview

Step	Time	Activity/Method	Content	Resources Needed
1	20 min	Group Discussion	Overview of TB and HIV Co-Infection	Flipchart and markers Handout 6.1
2	90 min	Presentation Group Work	Co-infection of TB and HIV	Handout 6.2 and 6.3 Worksheet 6.4 Antiretroviral Treatment for Adults with Concomitant TB Card LCD projector and computer Slides 1-23



### Advance Preparation

Step 1: Write the following statistics on a flipchart:

- 112,000 people died from Tuberculosis in 2007 – 94,000 of those who died were co-infected with HIV
- Highest incidence of TB is in patients age 20 – 35, leading to increased childhood exposure
- Case fatality rate for HIV infected TB patients is high, 25-50% die during six months of TB treatment



### Resources Needed

- Handout 6.1. HIV and TB Co-Infection
- Handout 6.2. Management of HIV and DR-TB Co-Infection
- Handout 6.3. Managing Adverse Reactions to HIV and TB Treatment
- Worksheet 6.4. TB and HIV Co-Infection Case Studies
- Antiretroviral Treatment for Adults with Concomitant TB Card
- Flipchart paper and markers
- LCD projector and computer
- Slides 1-23



## Trainer Instructions: Step 1 (20 minutes) Overview of TB and HIV Co-Infection

### *Step 1 Learning Objectives:*

- Cite South Africa's TB epidemiology rates.
- Explain the effects of TB on HIV progression.
- Explain the effects of HIV on TB Progression.

### *Step 1 Resources Needed:*

- Handout 6.1. HIV and TB Co-Infection
- Flip chart and markers

### *Step 1 Trainer Instructions:*

	1.1. Show participants statistics you wrote on the flipchart. Ask participants, "What do the statistics tell you?" Facilitate a brief discussion. Highlight: <ul style="list-style-type: none"><li>• Importance of case finding</li><li>• Importance of prevention, including IPT</li><li>• Importance of TB treatment</li><li>• Importance of HIV treatment</li></ul>
	1.2. Explain that HIV and AIDS is the number one infectious cause of death in the world, but many people with HIV and AIDS become ill with TB and die with TB.
	1.3. Refer participants to Handout 6.1. HIV and TB Co-Infection. Ask for a participant to read the points listed in the handout and explain the diagram.
	1.4. Answer any questions related to HIV and TB Co-Infection.



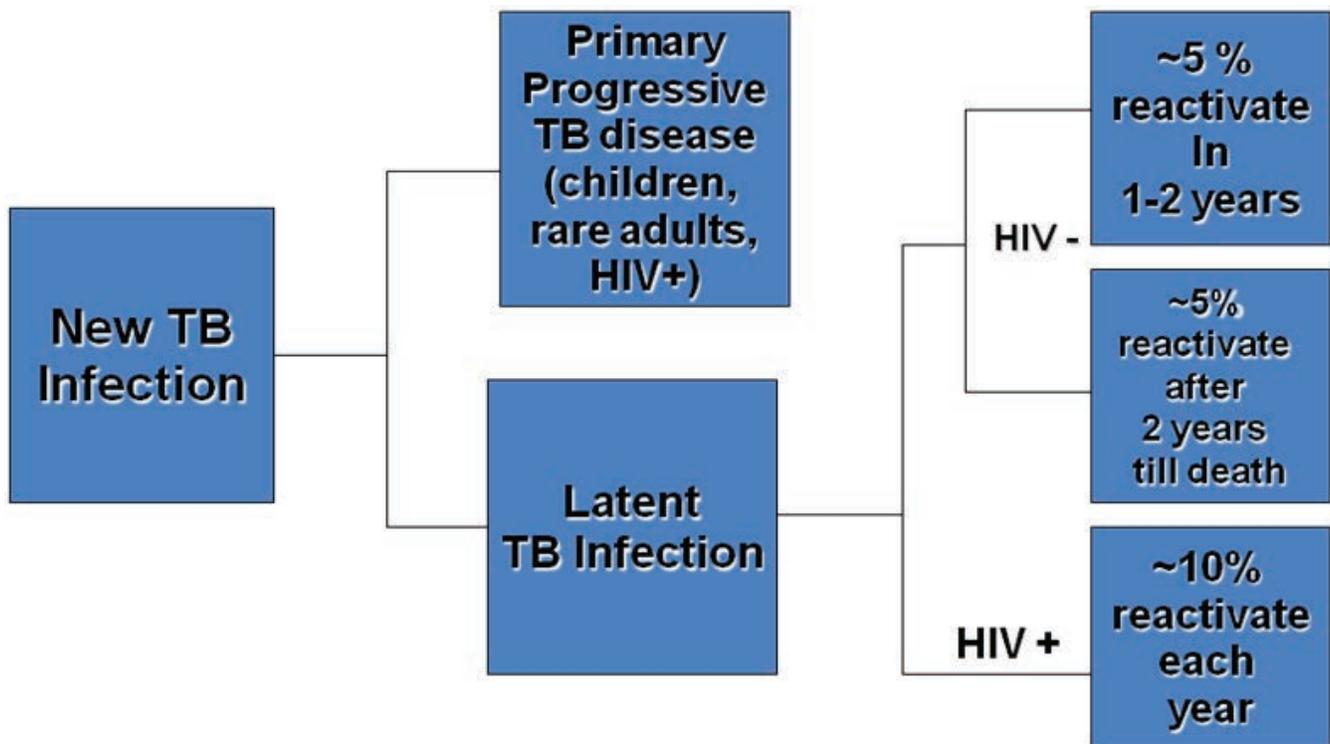
## Handout 6.1. HIV and Tuberculosis Co-Infection

### Effects of TB on HIV Progression

1. Individuals with active TB often have very high HIV viral loads: immune system activation increases the rate of HIV growth. Activation of the immune system CD4 lymphocytes and macrophages increases the growth of HIV. This leads to more rapid development of immunosuppression than with HIV alone. In other words, active TB has been shown to induce HIV virus-replication, thus accelerating the progression of AIDS.
2. Immunosuppression progresses more quickly and survival may be shorter despite successful treatment of TB
3. Individuals with TB/HIV have a shorter life expectancy than persons with HIV who never had TB
4. ART reduces mortality in patients with TB/HIV by reducing the risk of progression to active TB in latently infected individuals by as much as 80-92%

### Effects of HIV on Tuberculosis Progression

1. HIV-positive person is more likely to progress rapidly to active TB disease following HIV-infection
2. Greater risk of reactivation of latent TB infection if HIV-infected
3. High risk of becoming re-infected with Mycobacterium tuberculosis (even after prior treatment) if HIV-positive
4. If HIV-positive, latent TB infection: 5–10% annual risk of developing active TB (Compared with a 2-10% lifetime risk of active TB in an HIV-negative person.)
5. Greater risk of mortality within the first 6 months of TB diagnosis if HIV-positive, risk of mortality with DR-TB and HIV is exceedingly high





## Trainer Instructions: Step 2 (90 minutes) Co-infection of TB and HIV

### Step 2 Learning Objectives:

- Describe and recognise atypical presentations of TB in HIV-infected persons.
- Discuss how to manage HIV-positive patients with TB.
- Explain the use of ART for HIV-TB co-infection.
- Discuss the indications of ART in TB patients.
- Identify the most common side effects of anti-TB and ARV drugs.
- Define overlapping side effects of Anti-TB and ARV drugs.

### Step 2 Resources Needed:

- Handout 6.2. Management of HIV and DR-TB Co-Infection
- Handout 6.3. Managing Adverse Reactions to HIV and TB Treatment
- Worksheet 6.4. TB and HIV Co-Infection Case Studies
- Antiretroviral Treatment for Adults with Concomitant TB Card
- LCD projector and computer
- Slides 1-23

### Step 2 Trainer Instructions:

	2.1. Present Slides 1- 23 using trainer notes.
	2.2. Refer participants to Handout 6.2. Management of HIV and DR-TB Co-Infection. Ask participants to review as small groups.
	2.3. Ask participants, “What differences exist between HIV and TB co-infection management in cases where DR-TB is present?” <i>Answers should include: All patients eligible for ART regardless of CD4 cell count, risk of side effects is higher, consider start cotrimoxazole two weeks before ART due to increased risk of side effects, and efavirenz is an acceptable regimen in cases where rifampicin is not utilised and other drug/drug interactions are not present.</i>
	2.4. Refer participants to Worksheet 6.4. TB and HIV Co-Infection Case Studies.
	2.5. Explain that groups will have 30 minutes to complete the case studies in the worksheet. They should use Handout 6.2 and 6.3 as a reference.
	2.6. At the end of 30 minutes, reconvene groups and ask for volunteers to present answers. To save time, ask if any groups came to a different conclusion and if so, why. Repeat the correct answer before moving on.
	2.7. Answer any questions that remain.



## *Handout 6.2. Management of HIV and DR-TB Co-Infection*

DR-TB treatment is the same for both HIV negative and HIV-infected persons.

Persons living with HIV are more difficult to treat due to:

- Increased mortality
- Increased risk of other opportunistic infections
- Increased risk of side effects

### **Timing of treatment:**

**If already on ART: Stay on ART and begin DR-TB treatment immediately.**

**Development of DR-TB does not indicate ART failure and is not a reason to stop or change regimens!**

**If not already on ART: All HIV-infected MDR/XDR-TB patients (including pregnant women) are eligible to start ART regardless of CD4 cell count and should be fast tracked as soon as DR-TB treatment is tolerated.**

### *Advantages of starting ART early:*

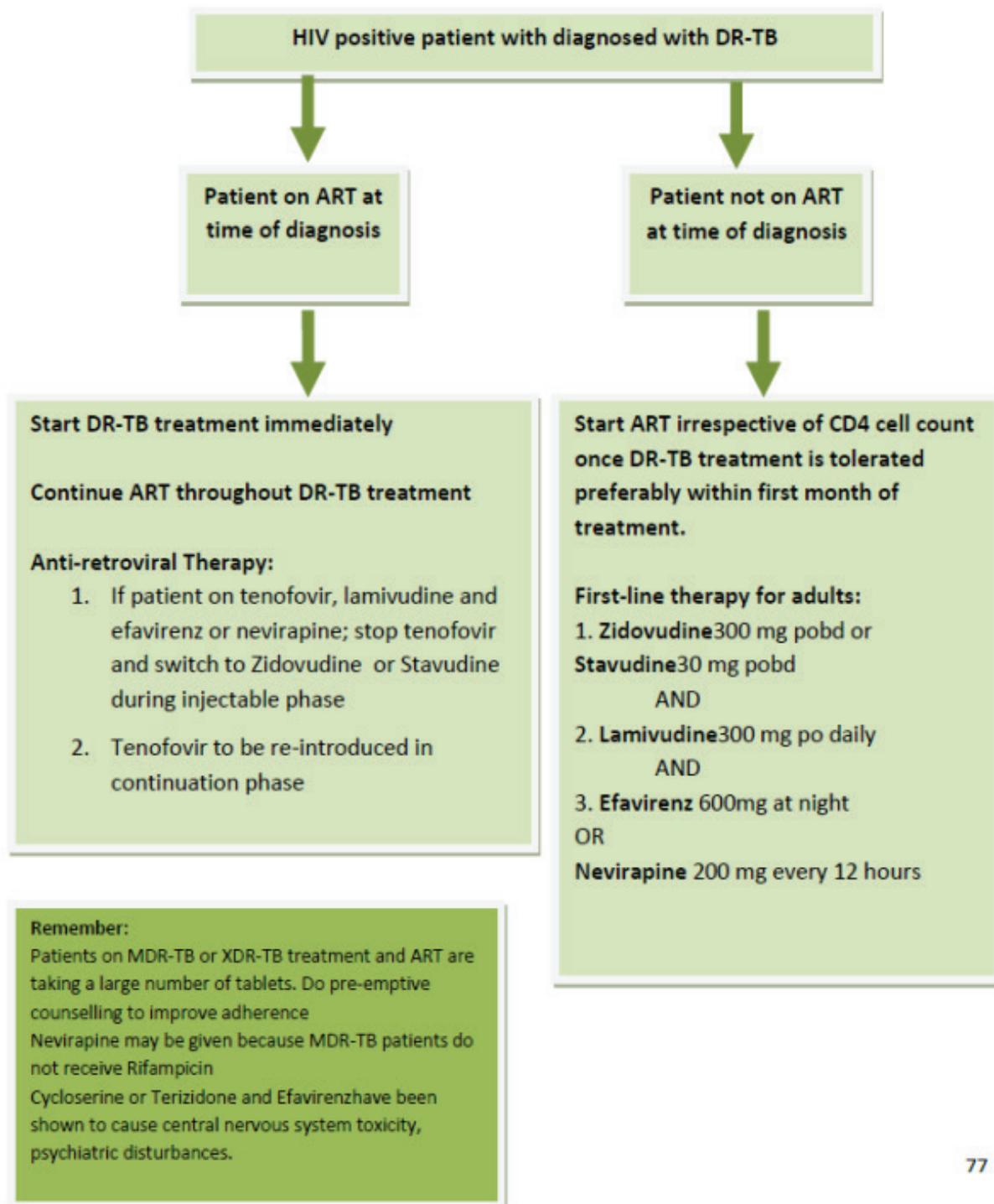
- Reduction of HIV-related morbidity and mortality
- Increased survival of co-infected DR-TB patients
- Slow progression to AIDS

### *Issues to consider when initiating ART:*

- Overlapping adverse effects from ART and second line drugs
- Complex drug-drug interactions
- Occurrence of immune reconstitution syndrome
- Poor adherence due to high pill burden

Cotrimoxazole Prophylaxis: Decreases hospitalizations and mortality. Should be dispensed for WHO Stage 2, 3 or 4. There is a higher likelihood of sulfa-related adverse reactions in HIV-positive patients (6-8 times greater than in the general population) so ideally sulfa-based prophylaxis should be started at least two weeks apart from MDR or XDR-TB treatment and/or ART.

## Flow Chart: Adult MDR-TB patient with HIV



77

Source: Management of Drug Resistant TB Policy Guidelines. August 2011. National Department of Health.

Slide 1

## Diagnosis of TB in HIV

- Cannot rely on "typical" indicators of TB
- Fever and weight loss are important symptoms. May be more prominent at presentation
- Cough and haemoptysis are less common because less cavitation, inflammation and endobronchial irritation in HIV patients
- Chest radiographic pattern more variable
- 50-70% of TB cases in HIV infected patients are extrapulmonary, which can lead to a misdiagnosis of DR-TB
- Patient can present smear-negative
- Differential diagnosis is broader



Slide 2

## Smear-Negative TB

- **Why is smear negative TB of particular importance in HIV?**
  - More common in HIV, especially with lower CD4 counts
  - Smear negative sputa can lead to delayed diagnosis or missing a diagnosis of DR-TB
  - Higher mortality likely related to delayed diagnosis
- **Why are Chest x-rays, GXP and repeat cultures more critical in evaluation?**
  - May shorten delays in diagnosis
  - Should be done early in the work-up
- Difficult to distinguish smear-negative pulmonary TB from other HIV-related pulmonary diseases



Slide 3

## Clinical Presentation of TB in HIV Infection

Features of PTB	Stage of HIV Infection	
	Early (high CD4 count)	Late (low CD4 count)
Clinical Picture	Often resembles post-primary TB	Often resembles primary TB, extrapulmonary
Sputum smear results	Often positive	Often negative
Chest X-ray	Often cavities	Often infiltrates No cavities No abnormalities



Slide 4

## Early Diagnosis: Better Outcomes

- Decrease in mortality for treated patients
- Decrease in period of transmission to others especially family members who may be HIV infected
- Decrease in transmission in the community
- Identification of at-risk contacts in a timely manner



Slide 5

## Treating a Person with HIV and TB

- TB case definitions are the same regardless of HIV status
- TB treatment is the priority - if HIV positive patients are not treated for TB, they will die
- Clinician should decide the optimal timing for initiation of ART during TB treatment guided by National policy



Slide 6

## How To Improve Outcomes of HIV-Related TB?

- Appropriate treatment of TB
  - TB treatment regimens are the same for HIV-infected patients as for non-infected patients
- Assure adherence with TB treatment (DOT)
- Cotrimoxazole preventative treatment (CPT)
- Antiretroviral therapy (ART)



Slide 7

## ART and TB Treatment

- HIV is associated with markedly increased mortality during TB treatment
- Early deaths (< 30 days after TB diagnosis) often due to TB; later deaths - other complications of HIV
- Survival during TB treatment is associated with level of immune function
- ART can substantially reduce mortality among HIV/TB co-infected patients



Slide 8

## Benefits and Risks

- **Benefits:**
  - Strengthen immune system for fighting TB and other infections
  - Avoid deaths due to OIs and AIDS during TB therapy
- **Risks**
  - Drug interactions and side effects limit ART regimens
  - Immune reconstitution inflammatory syndrome
  - Drug toxicity
  - Adherence to complicated treatment regimens



Slide 9

## Timing of ART

- Patients frequently will present with TB prior to commencing ART
- Early ART can be life-saving and help prevent the high risk of mortality present in the first 2 months of TB treatment
- 2010 WHOART Guidelines recommend ART for all patients with TB



Slide 10

## ART and TB Treatment

Current National Guidelines:

- ART if CD4 count of  $\leq 350$  cells/mm<sup>3</sup>
  - Start TB treatment and add ART after completing 2-8 weeks of TB therapy
  - Initiate as soon as tolerating TB therapy, usually within 2-4 weeks
- All DR-TB patients eligible REGARDLESS of CD4 count
  - Fast-track, begin within 2 weeks of eligibility
- All pregnant women with TB and HIV are eligible for ART regardless of CD4 count



Slide 11

## Drug Interactions When Using ART During TB Therapy

- Interaction of rifampicin with NNRTIs and PIs
- Increased drug toxicity and drug-drug interactions
- Overlapping ARV and TB medicine side effect



Slide 12

## Rifampicin Decreases Blood Levels of NVP and EFV

NNRTI	Effect of rifampicin
Nevirapine	↓ 37-58%
Efavirenz	↓ 13-26%



Slide 13

## Use of Efavirenz

- Patients should be started on Efavirenz whenever possible
- If not possible (pregnancy or significant risk of becoming pregnant, intolerance), patient could be started on nevirapine or lopinavir/ritonavir but should discuss with ART expert
- Nevirapine is an option in MDR/XDR-TB as Rifampicin is not utilized (as long as no other interactions/contraindications)



Slide 14

## Rifampicin Markedly Decreases Blood Levels of all PIs

Protease Inhibitor	Rifampicin effect
Ritonavir	↓ by 35%
Lopinavir/ritonavir	↓ by 75%



Slide 15

## Other Treatment Options: ART During Rifampicin-Based TB Therapy

- "Super boosting"
  - Ritonavir boosting of lopinavir may achieve adequate blood levels:
  - Increased risk of gastrointestinal side effects
  - Increased risk of hepatotoxicity



Slide 16

## ART and TB Treatment

- Patients with TB diagnosed before starting ART:
  - Tenofovir 300mg once daily
  - Lamivudine 300mg, once daily
  - Efavirenz 600mg at night
  - AZT if contraindication to TDF (renal disease)
- TB develops while on ART
  - If on nevirapine change to efavirenz recommended wherever possible
  - DO NOT STOP ARVs WHEN STARTING TB TREATMENT



Slide 17

## ART and TB Treatment (2)

- If patient on ART 2<sup>nd</sup> Line:
  - In adults, lopinavir / ritonavir 400/400 twice daily
  - If using lopinavir/ritonavir 400/100mg mg tablets increase to 4 tablets twice daily
  - In paediatrics, a ritonavir booster is added according to weight
  - Monitor closely for GI side effects, hepatotoxicity



Slide 21

## Adverse Events During Combined TB+HIV Treatment

- Some adverse events related to advanced AIDS, some to other infections or malignancies, and some to their treatment
- Few events result in permanent discontinuation of first-line TB drugs, even though therapy may have been temporarily discontinued
- Side effects more common with DR-TB, due to multiple drug-drug interactions

**Do not give up on the first-line TB drugs unless it is clear that one of them is causing a severe side effect!**



Slide 18

## ART and M(X)DR-TB Treatment

- If patient on M(X)DR-TB Treatment:
  - Avoid tenofovir (increased risk of renal toxicity)
  - Can use Nevirapine as Rifampicin is not used



Slide 22

## Overlapping Side Effects of Anti-TB and ARV Drugs

Side Effect	Possible Causes	
	Anti-TB Drugs	ART drugs
Skin rash	S, Z, R, H Most M(X)DR drugs	nevirapine, efavirenz, abacavir
Nausea, vomiting	Z, R, H, E Eto/Pto, PAS, Cm	zidovudine, ritonavir, protease inhibitors
Hepatitis	Z, R, H, E FQs, Eto/Pto, PAS	nevirapine, efavirenz, protease inhibitors
Leukopaenia, anaemia	R	zidovudine
Peripheral Neuropathy	INH	stavudine



Slide 19

## ART and M(X)DR-TB Treatment (2)

- If on ART prior to M(X)DR-TB treatment:
  - Continue ART
  - Substitute Zidovudine or Stavudine for Tenofovir
  - May reintroduce Tenofovir in continuation phase
- If on M(X)DR-TB prior to ART:
  - Start ART irrespective of CD4
  - Begin on 1<sup>st</sup> line ART with Zidovudine or Stavudine + Lamivudine + Efavirenz or Nevirapine



Slide 23

## Monitoring Side Effects

- Monitor patients at least monthly when starting antiretrovirals or TB treatment
  - Assess adherence
  - Identify side effects
- If symptomatic, order appropriate test according to the identified side effect, for example:
  - Renal function
  - Liver function tests-AST, ALT, bilirubin
  - Full Blood Count



Slide 20

## TB/HIV: Treatment Outcomes

- TB treatment regimens are the same in HIV-positive and HIV-negative patients





## *Handout 6.3. Managing Adverse Reactions to TB and HIV Treatment*

### **General principles helpful in managing HIV and TB infection**

1. Do one thing at a time - makes it easier to decide the cause of an event
2. Stop medications for severe adverse events
3. Use sequential re-challenge to decide the cause of an event
4. Don't switch from the first-line TB drugs (especially isoniazid and rifampicin) without evidence of an association with a significant side effect
5. Remember Immune Reconstitution Inflammatory Syndrome as a possible cause of adverse events during treatment
6. REPORT!
7. Remember that early recognition of adverse events – at all levels of the health system (community workers, nurses, etc) – can make a significant difference!

### **Gastrointestinal**

- Encourage patient that gastrointestinal symptoms (nausea, vomiting) are common during the first few weeks of treatment but usually get better
- Evaluate carefully for jaundice, abdominal pain:
  - Check liver function tests, if abnormal stop medications
  - If normal, continue medications
  - Encourage taking medications with food
  - Try an antiemetic 30minutes before medications
- Pancreatitis is an important side effect of stavudine and didanosine
- Typical presentation is abdominal pain, nausea, and vomiting
- Check lipase to ensure no pancreatitis
- Careful physical exam should be performed with a focus on the abdomen
- ART should be stopped and patient admitted to hospital if pancreatitis suspected
- Lactic acidosis should also be considered in patients on stavudine or didanosine with gastrointestinal symptoms, especially if accompanied by weight loss, appetite loss, and abdominal pain. A confirmed serum lactate > 5 in the presence of a symptomatic patient should prompt hospital admission and discontinuation of ART.

### **Rashes**

- Before attributing a skin symptom or rash to TB medications, assess:
  - Was it present before TB therapy began?
  - Is it a condition unrelated to TB treatment?
- Many persons on TB treatment also have HIV
  - Many people with HIV have skin conditions
  - ARVs (especially nevirapine and abacavir), co-trimoxazole, and TB medications (especially rifampicin, streptomycin, and pyrazinamide) can cause skin conditions
- Mild to Moderate rashes
  - Skin rash with mild itching
  - No blisters or mucous membrane involvement
- Management of Mild to Moderate Rashes
  - Consider other causes (scabies, etc.)
  - Aqueous cream, Calamine skin lotion
  - May need to stop TB medications, ART or co-trimoxazole

- Chlorpheniramine 4 mg every 4-6 hours, or
- Promethazine 25-50 mg nocte
- Severe Rashes
  - Stop all drugs together
  - Hospitalise the patient
    - Give IV fluids as required
    - Consider antibiotics for severe desquamation/exfoliation
    - Treat like a burn
    - Consider the use of steroids
    - Prescribe anti-histamines and analgesics as needed
      - ~ No evidence of effectiveness, but may offer symptomatic relief
    - Do not re-start offending drug
  - Most patients can wait for the rash to resolve before resuming TB or ART treatment
  - If the patient has life-threatening TB as well as life-threatening rash, may provide at least 2 TB drugs the patient has not taken before until the rash subsides(3 drugs preferred)
- Treatment after rashes
  - If it is not obvious which caused the reaction, which is often the case, re-introduce TB medications in a step-wise fashion (in consultation with expert)
  - Use in reverse order of likelihood of cause of rash
    1. Rifampicin
    2. Isoniazid
    3. Ethambutol
    4. Pyrazinamide
  - If no reaction, continue the medication and gradually increase the dose of the next medication
  - Treatment after a severe rash should be in consultation with specialist
  - For ART, restart on new regimen
  - For cotrimoxazole, change to dapsone

## Peripheral Neuropathy

- HIV infection, isoniazid, d4T, and ddI can all cause peripheral neuropathy
- Symptoms of peripheral neuropathy are:
  - Nocturnal pain in the toes and feet usually the first symptoms
  - Paraesthesia (burning and tingling)
  - Sensory loss and motor impairment (may occur later)
- All HIV patients on TB treatment should receive pyridoxine 10-25mg daily to prevent isoniazid related peripheral neuropathy
- Treatment of isoniazid related neuropathy:
  - NSAIDS, acetaminophen, amitriptyline,
  - Severe neuropathy may require opiates to manage pain
  - Increase dose of pyridoxine to 100mg daily if patient develops peripheral neuropathy on isoniazid
- Should consider avoiding d4T in patients with pre-existing peripheral neuropathy and substitute with AZT or tenofovir
- If a new neuropathy develops or an existing neuropathy rapidly worsens after d4T or ddI initiation then a d4T/ddI induced neuropathy is likely
- Peripheral neuropathy may herald the development of symptomatic hyperlactataemia in patients on d4T. Patients should be carefully evaluated
- Suspected d4T/ddI peripheral neuropathy:
  - Symptomatic therapy with simple analgesia
  - Amitriptyline 25-75 mg daily
  - Vitamin supplementation (B6 and BCo).
  - Carbamazepine should be avoided with ART because of drug interactions

- If the symptoms progress despite this and particularly if there is any sensory loss or motor deficit the d4T should be switched to tenofovir (TDF) or AZT
- Switch to AZT provided there is no anaemia (Hb below 6.5 g / dl ) or neutropenia (Neutrophil count below 0.5 X 10<sup>9</sup>/ L) and patient cannot tolerate TDF due to reduced renal function
- Use Tenofovir in patients who have severe neuropathy and anaemia or neutropenia.

## Hepatotoxicity

- Similar strategy as in TB treatment
- Stop ART in addition to TB meds for patients with signs and symptoms of hepatotoxicity such as abdominal pain, hepatomegaly, jaundice, nausea, vomiting, and elevated liver function tests (ALT > 5 times upper limit of normal or 200). Patients with symptoms of liver failure (confusion, metabolic flap, elevated INR, or jaundice) should be admitted to the hospital for management.
- First, restart TB medications sequentially, every 3-7 days, once liver function tests have normalized (ALT < 3 times upper limit of normal):
  - Rifampicin (with or without ethambutol)
  - Isoniazid
  - Consider not restarting pyrazinamide and using ethambutol, a fluoroquinolone (moxifloxacin) or cycloserine instead
- If the patient has severe tuberculosis or still sputum smear positive, some form of TB treatment should be given until the liver function is normal (for example, moxifloxacin, streptomycin, and ethambutol)
- Second, restart ART after the patient is stable on TB medications
  - Re-introduce a safe ART regimen (if the patient was on nevirapine, switch to efavirenz or dose adjusted lopinavir/ritonavir); consult with an HIV clinician as needed
  - Monitor the patient and liver function tests closely
- Third, re-challenge with prophylactic medications (co-trimoxazole)



## Worksheet 6.4. TB and HIV Co-Infection Case Studies

*Case Study #1:* Thomas is a 52 year-old man with HIV. He presents with cough and night sweats for 2 weeks.

1. What additional information do you plan to obtain – including questions you will ask and physical exam/laboratory examinations?
  - Ask/examine for urgent signs and symptoms (*Fever  $\geq 38C$ , breathlessness at rest/when talking, respiratory rate  $\geq 30$  breaths/minute, prominent use of breathing muscles, coughing up  $\geq 1$  tsp fresh blood, agitation or confusion, BP  $< 90/60$ )*
  - Ask regarding other related symptoms including: *weight loss, fevers, swelling, coughing up blood, wheezing.*
  - Ask regarding any other symptoms (go through review of systems): *any HEENT, cardiac, abdominal, musculoskeletal, neurologic or dermatologic symptoms (refer back to Session 3, if necessary and physical exam checklists)*
  - Ask regarding known drug allergies
  - Ask regarding history of TB, previous screening of TB, prior TB treatment, exposure
  - Ask regarding HIV – any medications (ART or cotrimoxazole), recent CD4 or other laboratory results
  - Ask regarding prevention behaviours for TB/HIV
  - Ask regarding knowledge of TB/HIV, readiness to start on ART
  - Ask regarding family HIV/TB testing and status
  - Perform physical exam
  - Obtain sputum smears x 2 for microscopy
  - Consider Chest X-ray
  - CD4 if not recently obtained (viral load, if available)
  - If on ART, then appropriate monitoring laboratories
  - Screen for STIs
2. What are various causes for his symptoms that you will consider (differential diagnoses)?
  - TB
  - PCP
  - Bacterial pneumonia
  - Lung Cancer (*increased risk if a smoker*)
  - Heart failure (*symptoms might include leg swelling or wheezing*), increasing risk with age
  - Chronic bronchitis (*increased risk with HIV or smoking*)

*Case continued:* Thomas denies any urgent symptoms. He reports weight loss, no swelling. No other signs and symptoms. He is a non-smoker. He was recently diagnosed with HIV but does not know if a CD4 count was performed. He is not currently on any medications and has no known drug allergies.

His partner was also tested and was negative for HIV. Neither he nor his family members have previously been tested or treated for TB. His partner does have a similar cough.

Physical Exam: Temperature 36C, BP 117/87, Respiratory Rate 16, Heart Rate 82

Physical exam normal other than productive cough without blood. One sputum returned AFB+ and one was AFB-. CD4 count was 198 cells/mm<sup>3</sup>.

3. How do you plan to manage this patient at this point in time?
- *Begin on RHZE once daily for TB treatment*
  - *Test/treat any recent contacts for TB, consider IPT for his children if no evidence of TB disease and < 5yo.*
  - *Provide adherence and prevention counselling*
  - *Provide education regarding HIV/TB disease process*
  - *Begin to prepare for ART start*
  - *Initiate cotrimoxazole*
  - *Discuss potential medication side effects and importance of returning if occur*

*Case continued:* Thomas returns after starting regimen 1 for pulmonary TB (RHZE) 4 weeks ago. His CD4 count was 198 cells/mm<sup>3</sup>. He has been tolerating his medications well, including cotrimoxazole. He is here for a follow-up visit.

4. What questions are important to ask at this visit? What do you plan to examine as part of his physical exam?
- *It is important to ask regarding any urgent signs and symptoms*
  - *Inquire regarding any potential side effects to the TB regimen or cotrimoxazole.*
  - *Inquire regarding any new symptoms that may indicate an opportunistic infection. Remember it is important to screen for OIs prior to initiating ART.*
  - *Assess adherence to the regimen and cotrimoxazole*
  - *Assess ARV readiness*
  - *Assess family HIV/TB status and testing*
  - *Assess preventative measures for him and his family*
  - *A brief complete physical exam would be appropriate to assess for any new opportunistic infections or potential medication side effects such as rash, peripheral neuropathy, etc. If he has any specific complaints, a focused exam for that complaint would be appropriate.*
5. When would you start this patient on ARVs? When started on ARVs, what regimen will you start?
- *Current SA guidelines recommend he start on ARVs between 2-8 weeks after commencing TB treatment and once TB treatment is tolerated. In this case he appears to be tolerating his medication well. If he reports good adherence it would be appropriate to start him on ARVs. An appropriate regimen would be tenofovir, lamivudine and efavirenz.*

*Case continued:* Case 1 continued: He returns 3 weeks later with a rash on his lower extremities.

6. What questions are important to ask in evaluating this rash?
- *Check for any danger signs*
    - *Fever*
    - *Any mucosal involvement (conjunctival, oral and/or genital)*
    - *Any angio-oedema*
    - *systemic symptoms such as myalgia*
    - *Blistering, desquamation or ulceration*
7. If the patient had a petechial rash, what TB medications should you suspect and what tests would you order?
- *Rifampicin can cause a thrombocytopaenia that can be associated with renal failure and hemolytic anaemia.*
  - *Check FBC urgently.*

*Case continued:* Thomas is feeling fine otherwise. He says the rash is non-pruritic and non-painful.

Physical Exam:

Temperature: 36.5, Blood Pressure: 120/60, Pulse:78, Respiratory rate:12

Exam shows no conjunctivitis, oral ulcers, or other mucosal involvement including genital. The exam is otherwise unremarkable.

8. How should Thomas's rash be managed?

- *Thomas can continue with ART and TB treatment. He has no danger signs that require stopping medications.*
- *Antihistamines should be given.*
- *Most importantly, educate patient to stop medications and see doctor urgently if any danger signs develop.*
- *Should be monitored closely, re-evaluate in several days.*

*Case continued:* Thomas is seen back in clinic in 3 days. His rash is worse and now having fevers. On exam, you see:



9. How would you manage Thomas now?

- *Thomas is having severe symptoms and likely Stevens-Johnsons Syndrome.*
- *He should have urgent admission to the hospital.*
- *Stop all drugs immediately.*
- *Once rash is resolved TB drugs and ART should be restarted only with expert consultation.*

*Case Study #2:* Dinda is a 20 year-old male seen in clinic with cough and weight loss for 4 weeks. He has no prior history of TB.

1. What additional information do you plan to obtain – including questions you will ask and physical exam/laboratory examinations?
  - *Ask/examine for urgent signs and symptoms (Fever  $\geq 38C$ , breathlessness at rest/when talking, respiratory rate  $\geq 30$  breaths/minute, prominent use of breathing muscles, coughing up  $\geq 1$  tsp fresh blood, agitation or confusion, BP  $< 90/60$ )*
  - *Ask regarding other related symptoms including: weight loss, fevers, swelling, coughing up blood, wheezing.*
  - *Ask regarding any other symptoms (go through review of systems): any HEENT, cardiac, abdominal, musculoskeletal, neurologic or dermatologic symptoms (refer back to Session 3, if necessary and physical exam checklist cards)*
  - *Ask regarding known drug allergies*
  - *Ask regarding history of TB, previous screening of TB, prior TB treatment, exposure*
  - *Ask regarding HIV testing*
  - *Ask regarding prevention behaviours for TB/HIV*
  - *Ask regarding knowledge of TB/HIV,*
  - *Ask regarding family HIV/TB testing and status*
  - *Perform physical exam*
  - *Obtain sputum smears x 2 for microscopy*
  - *Consider Chest X-ray*
  - *HIV test, CD4 if HIV-infected*
2. What are various causes for his symptoms that you will consider (differential diagnoses)?
  - *TB*
  - *Pneumonia*
  - *PCP if HIV-infected*
  - *Lung Cancer (increased risk if a smoker)*
  - *Heart failure (symptoms might include leg swelling or wheezing), increasing risk with age*
  - *Chronic bronchitis (increased risk with HIV or smoking)*

*Case continued:* Dinda reports he has not previously been tested for HIV. He does report that his Father, who lives with him, is currently on TB treatment. Dinda has not previously been tested or treated for TB. He has no other signs and symptoms other than fatigue. He has a girlfriend, but she does not live with him. No children. He lives with his mother, father and several siblings.

Physical exam:

Temperature 36.3C, Weight 73kg, Respiratory Rate 22 breaths/minute, Heart Rate 82, Blood Pressure 123/78. His physical exam was normal other than right sided anterior crackles.

His HIV test is positive and his sputum are smear positive. His CD4 count is 190 cells/mm<sup>3</sup>.

3. How do you plan to manage his TB disease?
  - *Begin on RHZE once daily for TB treatment*
  - *Discuss potential medication side effects and importance of returning if occur*
  - *Test/treat any recent contacts for TB*
  - *Provide adherence and prevention counselling*
  - *Provide education regarding HIV/TB disease process*

4. How do you plan to manage his HIV infection?

- *Discuss timing of ARVs in patients with TB. CD4 190cells/mm<sup>3</sup> so meets criteria for starting ARVs. Delay ART until TB medications tolerated. Ideally 2 weeks to 4 weeks, no more than 8 weeks.*
- *Discuss readiness to start on ART*
- *Begin to prepare for ART start*
- *Initiate cotrimoxazole as he has pulmonary TB, which is WHO Stage III and his CD4 count is <200.*
- *Recommend HIV testing for partner(s)*
- *Provide adherence and prevention counselling*
- *Provide education regarding HIV/TB disease process*
- *Provide TB screening for close contacts*

*Case continued:* Dinda starts Regimen 1 (HRZE) for TB with pyridoxine 25mg daily. In 2 weeks he returns to clinic complaining of rash and generalized itching. No fevers, mucosal involvement or systemic signs.

Objective Component:

Physical Assessment:

Temperature: 36.0, Heart Rate: 67, Blood Pressure: 120/80, Respiratory Rate: 12

Exam shows diffuse rash on back, chest and thighs and mucosa is normal.

5. How should this patient's rash be managed?

- *He has a severe rash. Although he has no other danger signs, many experts would hold all of his TB meds.*
- *If the patient has severe tuberculosis, three new drugs (e.g., an aminoglycoside and two oral agents) should be started – This decision can only be taken at a TB specialized centre not at PHC level.*
- *Give oral antihistamines*
- *When the rash is substantially improved the medications can be restarted one by one, at intervals of 2–3 days.*
- *Rifampicin should be restarted first (because it is the least likely to cause rash, and it is the most important agent), followed by isoniazid, and then ethambutol or pyrazinamide*
- *If the rash recurs the last drug added should be stopped.*
- *If no rash appears after the first three drugs have been restarted, the fourth drug should not be restarted unless the rash was relatively mild and the fourth drug is considered essential for therapy.*

*Case continued:* Dinda's rash improves once medications are stopped. He is able to restart the medications sequentially without return of the rash. It was decided that pyrazinamide would not be restarted because his rash was severe.

A TB expert consulted for advice as the patient was not able to use pyrazinamide and it was decided that Dinda should be treated for 9 months. He is seen in clinic after 7 weeks of treatment. He is feeling well and denies any signs or symptoms of TB.

6. How should Dinda be managed now? What tests should be ordered?

- *Sputum should be sent for monitoring response to therapy.*
- *Physical exam-normal, weight 50kg*
- *Consider starting ARV*
- *Review baseline labs (FBC, Creatinine, Liver Function Tests)*

*Case continued:* Dinda's physical exam is normal and his weight is 50 kg. His FBC comes back Hb9.0, liver function tests and creatinine are normal.

He was erroneously prescribed the following ART a first line:

Stavudine 30 mg po 12 hourly (remember, 30mg if weight<60 kg)

Lamivudine 150mg 12 hourly

Efavirenz 600mg at night

Dinda is started on ART. He is doing well until 3 months later when he comes to the clinic complaining of abdominal pain and weight loss. He denies any nausea, vomiting, cough, fever or night sweats.

Physical Assessment:

Temperature: 37.0, Pulse: 110, Respiratory Rate: 28, Blood Pressure: 110/70

Dinda is mildly ill-appearing, tachypneic. Lungs are clear to auscultation. Heart is tachycardic. Abdomen is mildly distended, mild generalised tenderness but no rebound/guarding. Liver is not enlarged or tender. Extremities have no clubbing/cyanosis/oedema. Neuro: alert and oriented at time, person and place.

7. What is your differential diagnosis?

- *Lactic Acidosis: Patient on ARVs, especially stavudine, with abdominal pain should be evaluated for lactic acidosis. Tachypnoea also supports this diagnosis especially since lung exam is normal.*
- *Hepatitis: no clear physical exam findings (ie, right upper quadrant pain, hepatomegaly) but still should be considered*
- *Pancreatitis*
- *With these concerns, unless a physician/expert provider you would likely refer to hospital for evaluation*

8. What labs/procedures would you request?

- *FBC*
- *Lactic Acid*
- *Liver function tests*
- *Lipase*

*Case continued:* Dinda's labs come back.

FBC normal

Lactic acid 10 mmol

Liver function tests normal

Lipase normal

9. How should the patient be managed?

- *The lactic acid level is elevated and he has symptoms suggestive of lactic acidosis. He should be hospitalised immediately and stop ARVs. Don't reintroduce ARVs until lactic acid level has returned to normal. Change regimen to avoid offending drug (d4T). Remember this is a case that should be managed at the hospital level by a physician.*

*Case Study #3:* Lebo is a 31 year-old female with HIV-infection. She was diagnosed 5 years ago. Lebo presents with a fever and cough of 2-3 weeks duration.

1. What additional information do you plan to obtain – including questions you will ask and physical exam/laboratory examinations?
  - Ask/examine for urgent signs and symptoms (*Fever  $\geq 38C$ , breathlessness at rest/when talking, respiratory rate  $\geq 30$  breaths/minute, prominent use of breathing muscles, coughing up  $\geq 1$  tsp fresh blood, agitation or confusion, BP  $< 90/60$ )*
  - Ask regarding other related symptoms including: *weight loss, night sweats, swelling, coughing up blood, wheezing, enlarged lymph nodes.*
  - Ask regarding any other symptoms (go through review of systems): *any HEENT, cardiac, abdominal, musculoskeletal, neurologic or dermatologic symptoms (refer back to Session 3, if necessary and physical exam checklists)*
  - Ask regarding known drug allergies
  - Ask regarding history of TB, previous screening of TB, prior TB treatment, exposure
  - Ask regarding HIV – any medications (ART or cotrimoxazole), recent CD4 or other laboratory results
  - Ask regarding prevention behaviours for TB/HIV
  - Ask regarding knowledge of TB and HIV
  - Ask regarding family HIV and TB testing and status
  - Perform physical exam
  - Obtain sputum smears x 2 for microscopy
  - Consider Chest X-ray
  - CD4 if not recently obtained (viral load, if available)
  - If on ART, then appropriate monitoring laboratories
  - Ask regarding last menses, risk of family, family planning
  - Assess substance use, including smoking

*Case continued:* Lebo reports some recent weight loss. She reports otherwise feeling “fairly good” and does not have any other specific complaints. She is not allergic to any medications and is not currently taking any medications. She has never been on ART. She and her partner were both on TB treatment approximately one year ago. They both stopped taking their medications after 2 months. They never returned for follow-up. Her last menses was one week ago. She is not currently using any form of family planning. She and her husband use condoms “occasionally”. She is a non-smoker.

Objective Component:

Weight 65kg, Temperature 37.6C, Respiratory Rate 18 breaths/minute, Pulse 63 beats/minute, Blood pressure 118/76

Exam: Unremarkable other than a small (1 cm) submandibular lymph node was found on the right side.

Lab: CD4 count 26, sputum smears x 2 positive for AFB, you do not currently have GXP available

2. How would you manage this patient?
  - *Started on TB medications (HRZE+S) Regimen 2, plus antiretroviral started as soon as TB therapy is stabilised (at least 2 weeks between starting TB therapy and starting ARVs). Start on cotrimoxazole.*
  - *Counsel regarding prevention of HIV/TB transmission*
  - *Review DST as soon as available (LPA if available)*
  - *Discuss adherence*
  - *Counsel regarding family planning and offer contraceptives*
  - *Counsel regarding testing/treatment for TB/HIV of close contacts/partner(s)*

3. What labs/procedures would you request?

- Repeat CD4 count
- Chest x-ray
- Review cultures/DST
- Aspiration
- FBC

*Case continued:* CD4 count was 120 cells/mm<sup>3</sup> and chest x-ray came back with diffuse nodular infiltrates bilaterally with right pleural effusion:



4. What are your differential diagnoses (what do you think is causing these symptoms)?

- *Early IRIS should be suspected due to increasing CD4 with worsening of symptoms. IRIS may occur with concurrent TB infection. However it is important to evaluate other potential reasons for her deterioration as it is possible there is more than one underlying cause.*
  - *Poor adherence to medications*
  - *Drug resistant TB*
  - *New infection such as PCP*
  - *Fungal infection such as cryptococcus, histoplasmosis*
  - *Malignancies such as lymphoma and Kaposi's*
  - *Mycobacterium other than tuberculosis (MOTT)*

5. What would you do next?

- *Refer for further workup. The workup could include (participants are not expected to provide all of these answers if all nurses):*
  - *Silver stain for PCP if possible*
  - *Consider Cryptococcal antigen and histoplasmosis antigen if available*
  - *FNA of lymph node*
  - *Review previous AFB sputum and DST*
  - *Consider another AFB sputum culture and DST (especially if partner not yet tested as DST results currently available would only show resistance at baseline, not if she has acquired any since she started treatment)*

*Case continued:* Her DST reveals resistance to rifampicin and isoniazid.

6. Should HIV and/or TB medications be stopped?

- *HIV medications should be continued. IRIS is common and usually can be managed without stopping ARVs with anti-inflammatory drugs and steroids in more severe cases. The increasing CD4 indicates the treatment is working and should be continued. Improving her immune system, will improve her outcome. ARVs should only be stopped if life-threatening IRIS is present. Her TB meds should be stopped and she should start on MDR-TB regimen. Her partner needs to be tested and treated. If not previously done, obtain repeat culture and DST.*

*Case Study #4:* Limpho is a 4 month-old HIV-exposed female who is brought to the outpatient paediatric department for cough, intermittent fever, increased work of breathing, and poor feeding.

1. What additional questions do you plan to ask/obtain (Subjective information) and what will you examine (Objective)?
  - Ask regarding any urgent symptoms – high fever, loss of consciousness, seizures, shortness of breath or difficulty breathing, lethargy, severe dehydration
  - Ask regarding any follow-up HIV testing (by PCR at 6 weeks or after) and the results
  - Ask regarding the caregiver's health status and possible exposure to any additional infections, including TB
  - Ask regarding any additional symptoms, length of symptoms
  - Ask regarding any previous examinations or medications for these symptoms
  - Complete physical examination

*Case continued:* The child has been ill for 7 days and is in the care of the grandmother. Her mother died when the baby was three weeks old of a respiratory illness. The road to health card describes her as a graduate of the PMTCT program, but there is no documented HIV status.

On exam she appears to be struggling to breathe.

Temperature 38.C, Pulse: 175, Blood Pressure: 80/40, Respiratory Rate: 60, Weight: 3.9kg

There is extensive oral thrush. The lungs have coarse crepitations with intracostal and subcostal retractions. The liver and spleen are both palpable and feel firm. Lymph nodes are palpable in the axillae and groin. There is a significant nappy rash.

2. What are your differential diagnoses for this child's illness?
  - Possible responses include:
    1. HIV
    2. Bacterial pneumonia
    3. PCP
    4. TB
    5. Bronchiolitis
    6. Congenital heart disease
    7. Herbal medicine intoxication
    8. Nappy rash is likely candidal
  - Important points in the initial presentation are:
    1. The child's HIV status is unknown and therefore the child must be assumed positive until proven otherwise
    2. PCP pneumonia peaks at 4 months of age and results in the majority of deaths in HIV-infected infants under 1 year of age
    3. Untreated PCP is uniformly fatal
    4. TB in infants often presents as an acute, life-threatening pneumonia
    5. Bacterial pneumonia is extremely common in HIV-uninfected as well as HIV-infected infants
    6. This child is very ill

3. Do you believe this child is likely to be HIV infected? Why or why not?

- *Acutely ill and malnourished infants can present similar to infants with HIV. In particular, generalized lymphadenopathy, thrush, hepatosplenomegaly, and wasting are commonly seen in uninfected as well as infected children alike. For this reason it is very important to consider any child such as this HIV infected until proven otherwise. All critically ill infants should be considered HIV infected until they are ruled out by ELISA if mother's status is unknown or by DNA PCR if mother is HIV-positive.*

4. Is this child in need of Urgent Care? Why or why not?

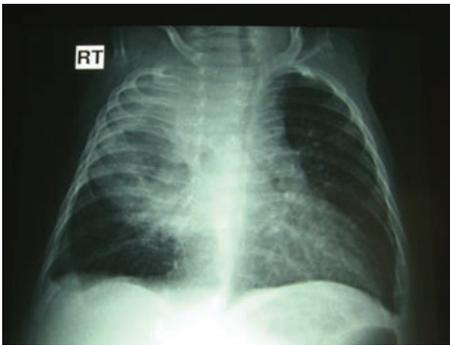
- *Yes! This child has a very high respiratory rate and is struggling to breath. Less urgent need, but child also has a weight below 3rd percentile*

*Case continued: Limpho is admitted to the hospital.*

5. What labs/studies are likely to be request?

- *Chest x-ray*
- *Oxygen saturation*
- *HIV DNA PCR*
- *Full blood count*
- *Blood culture*
- *Liver panel since liver is enlarged*
- *Gastric aspirate or induced sputum for AFB, and silver stain for PCP would be ideal but are technically difficult in a child of this age; therefore, they are not required as this child needs to be treated for both entities until further results are available.*

*Case continued: Limpho's chest x-ray is shown below. It demonstrates a large cavitating RUL infiltrate as well as right-sided paratracheal lymphadenopathy, a small right pleural effusion, and a diffuse nodular pattern throughout the lungs. (Infants with TB often progress rapidly and cavitary lesions can develop in progressive primary TB in this age group. Upper-lobes drain to para-tracheal lymph nodes. This child has right-sided paratracheal lymphadenopathy further supporting a diagnosis of TB. Severe bacterial pneumonia can also cause cavitary pneumonia, but does not usually cause lymphadenopathy. Nodular pattern throughout the lungs is consistent with TB, but PCP can also cause diffuse nodular pneumonia. It does not usually cause lymphadenopathy or pleural effusions.)*



*Case continued: Limpho's oxygen saturation returns at 90%. The rest of her studies are pending.*

6. What medications should Limpho begin while awaiting laboratory results?
- *Limpho meets criteria for treatment for TB; she has an illness consistent with TB, her mother died of a severe respiratory illness suggesting TB exposure, and she has an xray consistent with severe TB. She is very ill so should be started on regimen 3B, RHZE.*
  - *She also should be started on antibiotics to treat bacterial pneumonia, either penicillin AND gentamicin, or cefotaxime.*
  - *Finally, because she is HIV exposed and has severe pneumonia, she should be started on treatment for PCP with cotrimoxazole, 5 mg/kg of trimethoprim component every 6 hours. If her HIV test returns negative the PCP treatment can be stopped. It is very important to understand that when an infant has been exposed to HIV, there is frequently more than one problem causing illness and life-threatening diseases need to be treated empirically until they are ruled-out.*
  - *Some physicians would add prednisone for PCP or for disseminated TB. Reviews suggest the average oxygen saturation in infants presenting to hospital in Africa with PCP is <70%. Most guidelines suggest adding prednisone for PCP if <90%.*
  - *Oxygen*
7. What registers/forms should be completed for this case to-date?
- *TB Case Identification and Follow-up Sputum Register (GW20/13) – with results and follow-up*
  - *Laboratory Specimen Request Form – as additional laboratory requests are being made*
  - *TB Register – As started on treatment*
  - *Patient Clinic/Hospital Card – As started on treatment*
  - *Patient Treatment Card – As started on treatment*
  - *Pre-ART HIV registers*

*Case continued: Limpho's laboratories return with the following:*

WBC 24,000

Haemoglobin 7.4

Platelets 370

ALT 163

Alkaline Phosphate 459

HIV DNA PCR positive

8. What is her WHO clinical stage?
- *She is WHO stage IV given disseminated TB and/or PCP. While we do not have proof by sputum, our clinical diagnosis is sufficient to categorize her in this way.*
9. Would you order any further laboratory studies at this time? Why or why not?
- *This child has several criteria for initiation of ARV in the very near future; she is <1 year of age and is WHO stage IV.*
  - *Therefore a CD4, RNA PCR for viral load, and a lipid panel should be sent in preparation for beginning, 3TC, and kaletra.*
10. When should this child begin ART? What regimen would you select and how will you dose her medications?
- *Ideally she should begin ART 2 weeks after initiation of her TB therapy.*
  - *Dose medications for 4-4.9 kg anticipating weight gain as her TB is treated*
  - *She needs to be treated with ABC, 3TC, and "super-boosted" kaletra with extra ritonavir as follows:*
    - i. abacavir 20mg/mL; 3mL twice daily*
    - ii. lamivudine 10 mg/mL; 3 mL twice daily*
    - iii. lopinavir/ritonavir 80/20 mg/mL; 1.5 mL twice daily*
    - iv. ritonavir 80 mg/mL; 1.2 mL twice daily*

# Session 7. Infection Control and Prevention



**Total Session Time: 2 hours and 45 minutes**

## Learning Objectives:

By the end of this session, participants will be able to:

- Explain why infection prevention and control is important in TB care.
- Identify three levels of tuberculosis prevention.
- Identify infection control strategies to prevent the transmission of TB in the healthcare setting.
- Identify the importance of contact tracing.
- Identify necessary post-exposure prophylaxis for STIs and HIV.

## Session Overview

Step	Time	Activity/Method	Content	Resources Needed
1	60 minutes	Group Discussion	Infection Control and Prevention Overview	Handouts 7.1 and 7.2 Flipchart and markers Slides 1-23
2	30 minutes	Group Work	Developing a Comprehensive TB Infection Control Plan	Handout 7.3, 7.4 Flipchart and markers
3	45 minutes	Group Work	Conducting a Facility Risk Assessment	Handout 7.5, 7.7 Worksheet 7.6 Flipchart paper and Markers
4	30 minutes	Group Discussion	Post-Exposure Prophylaxis	Handout 7.8 Worksheet 7.9 Flipchart paper and Markers



## Advance Preparation

Step 1: Write the following statistics on a flipchart:

- TB risk among health care workers is 742/100,000 person-years at risk – 10 times that of the general population
- TB incidence ratio in health care workers working at TB-inpatient facilities is 17.7 times higher compared to general health workers
- Health care workers are 6 times more likely to be infected with MDR/XDR-TB than community
- Institutional transmission is fueling MDR/XDR-TB epidemic

Step 2:

- Bring incense or candle or match for air flow demonstration
- Bring enough N95 masks for each participant. Try to bring different sizes if possible.

Step 3: Write the following questions on a piece of flipchart paper.

1. What infection control measures in this plan are being carried out currently in your facilities?
2. What are some of the things that need to change?
3. Are there any potential barriers to implementing those changes?



## Resources Needed

- Handout 7.1. Overview of TB Prevention and Infection Prevention and Control Practices
- Handout 7.2. N95 Respirators
- Handout 7.3. Sample Infection Control Plan
- Handout 7.4. Sample Infection Control Officer Job Description
- Handout 7.5. TB Infection Control Assessment
- Worksheet 7.6. Risk Assessment Case Study
- Handout 7.7. Home Isolation
- Handout 7.8. Post-Exposure Prophylaxis
- Worksheet 7.9. Post-Exposure Prophylaxis Case
- Flipchart and markers
- LCD projector and computer
- Slides 1-18



## Trainer Instructions: Step 1 (60 minutes) Infection Control and Prevention Overview

### Step 1 Learning Objectives:

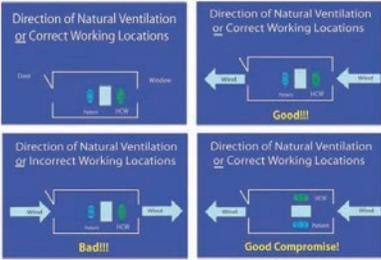
- Explain why infection prevention and control is important in TB Care.
- Identify three levels of prevention.

### Step 1 Resources Needed:

- Handout 9.1. Overview of TB Prevention and Infection Prevention and Control Practices
- Handout 9.2. N95 Respirators
- Flipchart and marker
- LCD projector and computer
- Slides 1-18

### Step 1 Trainer Instructions:

	<p>1.1. Ask participants, “Who is at risk for TB infection?”</p> <p><i>Answer: Everyone exposed to TB bacilli. The closer a person is to someone who has open pulmonary TB disease, the greater the chance that person has to becoming infected with TB. This means health care workers and close contacts are especially at risk as well as HIV-infected persons or other immune compromising diseases.</i></p>
	<p>1.2. Show participants the prepared flipchart. Explain that health care workers need to protect themselves and their patients from nosocomial TB infection.</p>
	<p>1.3. Ask participants, “What are the essential components of TB prevention?”</p> <p><i>Answers should include:</i></p> <p><i>Intensified Case Finding – identification of all infected by increased screening of all persons, especially close contacts</i></p> <p><i>Isoniazid Preventive Therapy</i></p> <p><i>Infection control – provide examples such as wearing respirators, proper airflow, preventing patients from exposure, teaching about proper prevention at home</i></p> <p><i>Complete and appropriate TREATMENT!</i></p>
	<p>1.4. Refer participants to Handout 7.1. Overview of TB Prevention and Infection Prevention and Control Practices. Read the handout aloud.</p>
	<p>1.5. Ask participants, “How many facilities are implementing all of these practices? What has worked well and what does not happen?” Record responses on a flipchart.</p>
	<p>1.6. Present Slides 1-18 using trainer notes.</p>

<p>Slide 1</p>	 <h2 style="text-align: center;">Environmental Controls</h2>	<p>Slide 5</p> <h2 style="text-align: center;">Improving Ventilation Patterns</h2> <ul style="list-style-type: none"> <li>• Waiting areas should be open</li> <li>• Windows should be kept open all the time in every room/ward</li> <li>• Cross ventilation is recommended and can be ensured by keeping windows on opposite sides of the room open at all times</li> <li>• Fans must be kept clean and working properly; their functioning must be checked on a weekly basis             <ul style="list-style-type: none"> <li>– Fans should be cleaned once a month with a damp cloth or vacuum cleaner</li> </ul> </li> </ul> 
<p>Slide 2</p>	<h2 style="text-align: center;">Natural Ventilation</h2>  	<p>Slide 6</p> <h2 style="text-align: center;">Improving Ventilation Patterns (2)</h2> <ul style="list-style-type: none"> <li>• Fans must be kept running as much as possible during any examination and afterwards</li> <li>• Ventilation produced by fans should direct air flow outside the room through the windows and doors             <ul style="list-style-type: none"> <li>• The flow should be from the HCW to the patient to the outside of the room</li> </ul> </li> <li>• Fans should not be cleaned when patients are in the room</li> </ul> 
<p>Slide 3</p>	<h2 style="text-align: center;">Air Mixing</h2> <ul style="list-style-type: none"> <li>• Air mixing increases the effectiveness of other environmental controls</li> <li>• This can be done by using propeller fans that:             <ul style="list-style-type: none"> <li>• Increase the effectiveness of natural ventilation, by increasing the mixing of airborne TB</li> <li>• Assist in directing air movement by pushing or pulling the air</li> </ul> </li> </ul> 	<p>Slide 7</p>  <h2 style="text-align: center;">Demonstration: Determining Airflow Direction</h2>
<p>Slide 4</p>	<h2 style="text-align: center;">Mechanical Ventilation: Fans</h2> <p>Propeller fans include: ceiling fans, small fans that sit on a desk or other surface, fans that stand on the floor, and fans mounted in a window opening</p>  	<p>Slide 8</p> <h2 style="text-align: center;">Personal Respirators</h2> <p>The goal of personal respirators are to protect the health care worker from acquiring TB</p>  

Slide 9

## Personal Respiratory Protection

- Have capacity to protect against smaller particles (e.g. 0.03 micrograms)
- They must be used in conjunction with administrative controls
- Can protect HCWs if used correctly
- They are not universally recommended because they are expensive
- They are therefore used in high-risk settings like MDR/TB, sputum inducing rooms, bronchoscopy rooms
- Important to fit test these respirators
- Can be reused until damaged or contaminated



Slide 10

## Personal Respiratory Protection (2)

- Face/surgical masks
- Act as a barrier to prevent infectious patients from expelling droplets
- Do not protect against inhalation of microscopic TB particles
- Respirators should be used by health workers while masks should be used by patients



Slide 11



## Infection Control can have a significant impact... But not often practiced

Slide 12

## Preventing Nosocomial Infection

- Using mathematical modelling and 2 years of data from Tugela Ferry, KZN

Intervention	Estimated XDR-TB cases averted
Improved natural ventilation, air filtration, UV air disinfection	33%
Enforced use of respirators/masks	33% cases in staff
Reducing length of stay + enforced use of respirators/masks + natural ventilation	26-40%
Reducing length of stay + enforced use of respirators/masks + natural ventilation + DST + Hospital based VCT with ARV + separation of patients in 5 bed units	34-50%



*Source: Baun S et al. Lancet. 2007.*

Slide 13

## South Africa MDR-TB Infection Control Study - 2009

- 24 M(X)DR-TB facilities in South Africa
  - 7 TB specialty hospitals with MDR wards
  - 8 district hospitals with MDR wards
  - 8 MDR facilities with XDR wards
  - 1 non -TB specialty hospital with MDR ward
- Interviews and observation to examine infection control practices, based on IC guidelines



*Source: Farley, J et al. Int J Tuberc Lung Dis 2012*

Slide 14

## Study Outcomes

- HCWs with highest level of clinical training have the greatest IC knowledge and better attitudes toward IC practices
- But, personal IC practices were NOT different!



Slide 15

## Study Outcomes - IC Infrastructure

Measure	Result
No IC officer	21%
IC officers felt no authority to influence change	89%
Annual IC training for all staff	38%
Written IC plan	54%
Infection prevention and control committee	79.2%



Slide 16

## Study Outcomes - Administrative Measures

Measure	Result
Available signage on cough hygiene	100%
Provided surgical masks, tissue and waste bins for patients	25%
Physical separation of smear + patients from patients not on treatment	29%
Outdoor family visit policy	8%
Maximized natural ventilation	67%



Slide 17

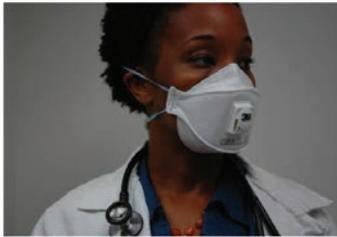
## Study Outcomes - HCW Safety

Measure	Result
Annual HCW TB symptom screening	50%
Personal protective equipment available	100%
HCWs entering drug-resistant wards <b>WITHOUT</b> appropriate protection	88%
Sputum specimens reported collected <b>on ward</b>	100%



Slide 18

## Respirator Fitting Demonstration and Practice





# Handout 7.1. Overview of TB Prevention and Infection Prevention and Control Practices

## Levels of TB Prevention:

1. Primary Prevention: Preventing TB infection:
  - Infection control measures in health care settings to prevent transmission to patients and staff.
2. Secondary Prevention: Preventing TB Disease:
  - Isoniazid therapy to prevent the progression to TB disease
  - Intensified case finding
  - Early diagnosis and treatment
3. Tertiary Prevention: Preventing TB morbidity and mortality:
  - BCG vaccination does not prevent infection with TB, but it does prevent severe forms of childhood TB
  - Diagnosis and treatment before complications develop

## Infection Control Practises (ICP)

ICP are strategies aimed to protect health care workers, patients and the community from acquiring noscomial infections. In health care settings, ICP are intended to help health care managers and health care workers minimise the risk of TB transmission at their facilities where the risk of TB transmission may be high due to high prevalence of both diagnosed and undiagnosed TB, MDR-TB and XDR-TB. The World Health Organisation arranges ICP into Administrative and Work Practice Controls, Environmental Controls and Personal Respiratory Protection.

### 1. Work Practice and Administrative Controls

- First line of defense and specify the appropriate work practices for the setting:
  - Respiratory hygiene/cough etiquette
  - Screening, investigation and referral (This includes screening for HIV/TB and DR-TB)
- Managerial or administrative controls: written policies and practices developed towards reducing the risk of TB transmission by preventing the generation of droplet nuclei or reducing exposure to droplet nuclei
  - Infection Prevention and Control Plan

#### *Main Goal for Work Practice and Administrative Controls*

1. To prevent TB exposure to Health workers and patients
2. To further reduce spread of infection by ensuring:
  - a. Rapid diagnostic investigation of TB suspects including health workers (e.g. considering everyone with cough or fever as a TB suspect and screening everyone, screening all contacts promptly, etc.)
  - b. Prompt commencement of appropriate treatment for those confirmed patients including staff that are suspected or known to have TB. (e.g. improving the turn-around time for obtaining sputum results, ensuring screening for DR-TB, ensuring follow-up sputums collected, etc.)
3. Isolation of patients with PTB:
  - a. Avoid mixing TB suspects with other patients e.g. identifying chronic coughers in the OPD and attend them
  - b. To the extent possible, avoid mixing TB patients and HIV patients in the ward or clinic setting. Plan different days for different patients (i.e. no sharing of space for TB patients and well baby visits)
4. Educate, train, and counsel HCWs about TB
5. Educate patients and community members to increase community awareness on TB transmission
6. Patients should be taught on cough etiquette:
  - a. Using face mask while coughing (face masks can be distributed to all patients if there is a desire to decrease stigma)
7. Sputum collection should always be done in an area with fresh air supply.
  - a. Away from other people
  - b. Not in small rooms such as toilet rooms or other enclosed areas.

- 8. Referral systems for those suspected of TB in centres like VCT
- 9. All these should be written in an infection control plan

<b>Five Steps for Patient Management to Prevent Transmission of TB in Health Care Settings</b>		
<i>Step</i>	<i>Action</i>	<i>Description</i>
1	Screen	Early recognition of patients with suspected or confirmed TB disease is the first step in the protocol. It can be achieved by assigning a staff member to screen patients for prolonged duration of cough immediately after they arrive at the facility. Patients with cough of more than two weeks duration, or who report being under investigation or treatment for TB*, should not be allowed to wait in the line with other patients to enter, register, or get a card. Instead, they should be managed as outlined below.
2	Educate	Educating the above-mentioned persons identified through screening, in cough hygiene. This includes instructing them to cover their noses and mouths when coughing or sneezing, and when possible providing face masks or tissues to assist them in covering their mouths. If resources allow, consider providing surgical masks to all patients irrespective of TB status, to avoid stigma.
3	Special waiting areas and separation of services	Patients who are identified as TB suspects or cases by the screening questions must be moved away from other patients and requested to wait in a separate well-ventilated waiting area, and provided with a surgical mask to tissues to cover their mouths and noses while waiting. Separate services in time and space so that TB clinics and TB suspects are cared for on different days and in separate areas of the facility.
4	Triage	Triaging symptomatic patients to the front of the line for the services they are seeking (e.g. patients for voluntary HIV counselling and testing, and medication refills), to quickly provide care and reduce the amount of time that others are exposed to them, is recommended. In an integrated service delivery setting, if possible, the patient should receive the services they are accessing before the TB investigation.
5	Investigate for TB or Refer	TB diagnostic tests should be done onsite or, if not available onsite, the facility should have an established link with a TB diagnostic and treatment site to which symptomatic patients can be referred. Turn-around-time for diagnostics should be monitored.

## 2. Environmental Controls

Environmental controls are the second line of defense for preventing the spread of TB in health care settings through

- a. Ventilation: Movement of air in a building and replacement of air in a building with air from outside to reduce or remove nuclei droplets from the air. This movement must be done in a controlled manner to ensure directional airflow.
  - i. Natural: refers to open windows and doors to replenish fresh air.
  - ii. Local: refers to a decentralised (independent) air extraction or inlet device
  - iii. General
- b. Filtration – mechanical way of taking out particles:
  - i. Other measures to control concentration of TB droplet nuclei in the air through use of High Efficiency Particulate Air (HEPA) filters which filter out particles
  - ii. These are methods which require ongoing professional maintenance
- c. Ultraviolet Germicidal Irradiation:
  - i. TB bacteria can be killed by ultra violet light – however there is concern that not all have been found to be effective and some may be harmful

## 3. Personal Protective Equipment

- a. Mechanical barriers to help prevent the spread of microorganisms from:
  - i. Person to person
  - ii. From Equipment, instruments and environmental surfaces to people
- b. Examples: Caps, eye ware, masks, respirators, aprons, gowns, gloves

Improving infection control at a facility level involves a continuous process of preparation, implementation and on-going monitoring and evaluation of infection control practises.



## Handout 7.2. N95 Respirators

### Using Respirators

1. Be sure your respirator is properly fitted!
  - a. Should fit snugly at nose
  - b. Respirator should cover chin and create a seal
2. Don't forget to wear it!

### When to Fit Test:

- Before wearing the respirator in the work place
- If person has:
  - Any facial changes
  - Significant weight change
  - Change in respirator size, make, model

### Factors Affecting Respirator Seal

- Facial Hair
- Facial Bone Structure
- Dentures
- Facial Scars
- Eyeglasses
- Excessive make up



### Fitting an N95 Respirator

- Cup the respirator in your hand, with the nosepiece at your fingertips, allowing the headbands to hang freely below your hand
- Position respirator under your chin with the nosepiece up. Pull the top strap over your head so it rests high at the back of your head. Pull the bottom strap over your head and position it around the neck, below the ears.
- Use the fingertips from both hands to mold the metal nosepiece to the shape of your nose by pushing inward down both sides of the nosepiece.
- Prior to each use, perform a user seal check by placing both hands completely over the respirator and exhale. If you feel air leaking around the nose, readjust the nosepiece. If air leaks at the edges of the respirator, work the straps farther back along the sides of your head.

References: <http://www.health.state.mn.us/divs/idepc/dtopics/infectioncontrol/rpp/comp/fittest.html>



## Trainer Instructions: Step 2 (30 minutes) Developing a Comprehensive TB Infection Control Plan

### Step 2 Learning Objectives:

- Identify infection control strategies to prevent the transmission of TB in the healthcare setting.

### Step 2 Resources Needed:

- Handout 7.3. Sample Infection Control Plan
- Handout 7.4. Sample Infection Control Officer Job Description
- Flipchart and markers

### Step 2 Trainer Instructions:

	<p>2.1. Ask participants, “What are key elements to implementing an infection control plan?” Allow participants to respond.</p> <p><i>Discuss: Infection control team/committee, infection control coordinator, risk assessment, development of infection control plan, policies and procedures, staff training, at least annual evaluation of infection control plan</i></p>
	<p>2.2. Explain that the South African National Guidelines mandate having an infection control plan.</p>
	<p>2.3. Refer groups to Handout 7.3. Sample Infection Control Plan. Explain that this infection control plan comes from the national guidelines. Each group will have 30 minutes to review the plan and come up with a list of ideas for adapting and implementing it based on their facility.</p>
	<p>2.4. Show participants the prepared flipchart paper. Explain that each group should answer the 3 questions listed on the flipchart.</p>
	<p>2.5. Reconvene group. Ask for a volunteer group to present their plans including implementation as well as the answers to the questions. Note: To save time, have each group build on what the previous group reported, adding only new information.</p>
	<p>2.6. Discuss that an infection control officer plays an essential role in coordinating infection control efforts and helping bring together the pieces of the infection control plan. This individual needs to be very knowledgeable regarding prevention and management of TB and other infectious processes. The infection control officer helps ensure a risk assessment takes place, infection control plans are developed, staff are trained, evaluations take place, etc.</p>
	<p>2.7. Refer participants to Handout 7.4. Sample Infection Control Officer Job Description. Ask participants to read in small groups.</p>
	<p>2.8. Discuss the role of the infection control officer by asking and processing the following questions with participants, “How many of your sites have an infection control officer?”, “How might it be helpful to have an infection control officer at your facility?” “What could take place at your facility to help bring about someone to fill this job description within your facility?”</p>



## Handout 7.3. Sample Infection Control Plan

- A. The plan will include, but not be limited to, the following areas:
1. Screening patients to identify persons with symptoms of TB disease or who report being under investigation or treatment for TB disease.
  2. Providing face masks or tissues to persons with symptoms of TB disease (“TB suspects”) or who report being under investigation or treatment for TB disease (“TB suspects or cases”), and providing waste containers for disposal of tissues and masks.
  3. Placing TB suspects and cases in a separate waiting area.
  4. Triage TB suspects and cases to the front of the line to expedite their receipt of services in the facility.
  5. Referring TB suspects to TB diagnostic services and confirming that TB cases are adhering with treatment.
  6. Using and maintain environmental control measures.
  7. Educating staff periodically on signs and symptoms of TB disease, specific risks for TB for HIV-infected persons, and need for diagnostic investigation for those with signs of symptoms of TB.
  8. Training and educating staff on TB, TB control, and the TB infection prevention and control plan.
  9. Monitoring the TB infection and control plan’s implementation.
- B. The facility will implement each policy by following the procedure(s) that accompany it.

### Policy and Procedures

Purpose: Early identification, separation, receipt of services, and referral of patients with TB disease is essential in preventing spread of TB.

Lead: \_\_\_\_\_ has the responsibility for overseeing the implementation of these policies and its procedures, and reports to (District health executive committee, etc).

#### *Policy 1: Screening patients to identify persons with symptoms or recent history of TB disease.*

Procedures:

- i. Before patients enter an enclosed part of the facility, a designated staff person should ask each adult and any child capable of coughing forcefully (usually age 14 or older) about symptoms or recent history of TB. The questioning should occur before the patients wait in line for long periods to register or obtain services.
- ii. Many combinations of symptoms have been recommended as sensitive and specific for TB. A simple screen is:

“Do you have a cough?” If patient answers “yes,” ask

“For how long have you been coughing?”

An adult who has coughed for two weeks or more may be considered a “TB suspect” for pulmonary TB.

To determine whether a patient may be under investigation or diagnosed case of TB, who may still be infectious, ask-

“Are you being investigated or treated for TB?”

If the answer to either is “yes,” the screen classifies the patient as a TB suspect or case, and he should be managed as described in the procedures under policies 2-5 below.

- iii. As patients who are not identified as a TB suspect or case on the initial symptoms screen enter an examination room with the clinical officer, nurse, or counsellor, they should again be asked the simple screening questions. Those patients who report a cough of two or more weeks or who are being investigated or treated for TB should be managed as follows in the procedures under 2-5 below. Staff seeing patients in examination rooms should report patients they find to be a suspect or case to the infection control officer in a timely manner so that factors contributing to the potential exposure (e.g. an emergency or short staff interfering with the designated person screening all patients) can be documented and corrected.

*Policy 2: Instructions on cough hygiene.*

Procedures:

- i. Patients who are found to be TB suspects or cases should immediately be informed about the importance of cough hygiene and be handed tissues (or pieces of cloth) and instructed to cover their mouths and noses when they cough. Alternatively, patients should be given a facemask, and asked to wear it while in the facility. Patients should also be instructed to dispose of used tissues or masks in identified no-touch receptacles and not on the floor or on the benches.

When tissues, cloths or facemasks are not available, clients should be instructed to lift their arm up and cover their nose and mouth with the inner surface of the arm or forearm when they cough or sneeze. *M. tuberculosis* cannot be spread from the hands, but other serious lung infections can.

- ii. No- touch receptacles for disposal of used tissues and masks should be available in the waiting areas.

*Policy 3: Preventing overcrowding and exposure of other patients and health care workers*

Procedures:

- i. A staff person should direct or escort the patient to a separate waiting area. This special waiting area should have the highest natural ventilation possible. Patients should be assured of their place in the line for registration and/or services.
- ii. Avoid over congestion of waiting areas
- iii. Ensure minimum bed spacing to prevent overcrowding on wards
- iv. Alternate days or times when specific services are provided to prevent at risk populations (immune-deficient, pregnant, children) from exposure
- v. High risk activities, such as sputum collection, should be identified and performed in ways and areas that minimise exposure to others

*Policy 4: Triaging TB suspects and cases to the head of the line to receive services in the facility.*

Procedures:

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

*Policy 5: Referring TB suspects to TB diagnostic services.*

Procedures:

- i. \_\_\_\_\_ is the designated staff person to counsel patients about obtaining TB diagnostic services.

Patients will be referred to \_\_\_\_\_ (a TB diagnostic centre with whom the health care facility has a previously negotiated agreement with).

- ii. Patients should be given a card with the name, location, and operating hours of the TB diagnostic centre. The card should also have the name of the referring facility on it, with date of referral marked. These cards can be collected at the TB centre and used as an anonymous check on number of referrals that successfully obtain TB services. (See also the TB suspect and case form listed in Annex A2 below, which can be used to cross reference referrals that are made/ successful).

*Policy 6: Using and maintaining environmental control measures.*

Procedures:

- i. \_\_\_\_\_ is the designated staff person to check on environmental control measures and maintain a log of monitoring and maintenance.
- ii. Windows and doors should be checked on a daily basis to assure they are in proper position (open or closed as called in the plan). Generally, all windows and doors should be open when natural ventilation is the primary environmental control to allow for the free, unencumbered movement of air (e.g., across room, from window to door or vice versa).
- iii. Fans should be checked on a monthly basis to assure they are clean, are pulling (or pushing) the correct amount of air, and are pulling (or pushing) air in the correct direction.

*Policy 7: Providing confidential TB and HIV services to health care workers and staff.*

Procedures:

- i. Health care workers and all other staff working at the facility should be educated about the signs and symptoms of TB and encouraged to seek investigations promptly if they develop symptoms and signs suggestive of TB.
- ii. Healthcare workers and other staff should be informed about the special specific risk for TB for HIV-infected persons (see selection on Training of staff).

- iii. Health care workers and staff should be encouraged to undergo HIV testing, and given information on relevant HIV care resources.
- iv. Staff training should include reduction of stigma of TB and HIV.
- v. \_\_\_\_\_ is responsible for determining when staff who develop TB disease may return to work.
- vi. Staff who develop TB disease may return to work when determined to be no longer infectious after:
  - a. Having completed at least two weeks of standard anti-TB therapy;
  - b. Exhibiting clinical improvement;
  - c. Having continued medical supervision and monitoring of treatment until cured; and
  - d. Where possible, having had three consecutive negative sputum smears obtained on three different days with at least one morning specimen. (Note: Frequent evaluation of sputum smear status may not be done routinely in resource-limited settings.)

*Policy 8: Training of staff on all aspects of TB and the TB infection prevention and control plan.*

Procedures:

- i. \_\_\_\_\_ is the designated staff person to provide training to new staff as they are employed and to maintain a log indicating who has had the initial training.
- ii. \_\_\_\_\_ is the designating staff person to provide annual training to all staff and to maintain a log indicating who has attended training. This may be incorporated into a broader training topic or it could be a stand-alone TB infection control training.

*Policy 9: Monitoring the TB infection prevention and control plan's implementation*

Procedures:

- i. Determine the frequency of the infection prevention and control plan evaluation.
  - a. During initiation of procedures, monitoring and evaluation should be done frequently, perhaps monthly or bi-monthly.
  - b. When procedures are running well, less frequent evaluation will be necessary- at a minimum, annually.
- ii. Evaluate the screening process.
  - a. Were patients with significant cough missed when entering the facility and only detected at a later time or in the examination room?
  - b. What correctable factors were associated with these potential exposures?
- iii. Evaluate the success of referrals to the TB diagnostic centre.
  - a. Did referred patients access care?
  - b. Did referred patients have TB disease?
  - c. What changes in screening or referral process should be made, if any?
- iv. Evaluate the training process.
  - a. Did all new staff receive training on TB infection prevention and control during their induction?
  - b. Did all staff receive annual re-training on TB infection control?
- v. Revise the infection prevention and control plan to reflect changes in staff responsibilities, policies, and procedures.
- vi. Develop a plan for correcting inappropriate practices or failure to adhere to institutional policies.
  - a. Identify incentives to participate fully and adhere to policies.
  - b. Identify corrective actions if policies are not followed.

*Source: Adapted from National TB Infection Control Guidelines, June 2007*



## *Handout 7.4. Sample Infection Control Officer Job Description*

**TITLE:** Infection Control Officer

**FUNCTION:** The Infection Control Officer is responsible for implementation, monitoring, and evaluation of the Infection Control Plan. The Infection Control Officer will oversee the infection control programme and ensure that all policies are followed and requirements met on a timely basis. All safety and infection control trainings held throughout the year will be documented and maintained at this facility by the Infection Control Officer.

### **ESSENTIAL DUTIES AND RESPONSIBILITIES:**

- Develop and update the facility infection control policy and procedures as part of the facility's infection control plan.
- Maintain up to date copies of the South African Department of Health TB Infection Control Guidelines at the facility; ensure that the facility's infection control plan meets current guideline recommendations.
- Coordinate and participate in infection control team meetings with relevant staff.
- Ensure that all proper forms for documenting TB infection in patients are available including National Department of Health TB registers and patient green cards, sputum collection logbooks, isoniazid preventative therapy (IPT) registers, and TB screening tools and problem lists for patient medical records.
- Collect surveillance data on staff infections from all hospital departments, maintain medical records for every case, and submit staff infections summaries to relevant stakeholders.
- Follow, investigate, and report infection outbreaks; generating reports and analyze trends of infections among patients and employees.
- Identify the staff member(s) responsible for implementation of a cough protocol, and follow up on the triage of patients as they enter the health facility.
- Ensure that the cough protocol is understood by relevant staff including the front desk persons and guards.
- Ensure that patient education materials on infection control and prevention are available and posted throughout the facility.
- Ensure that the proper universal precautions are in place for preventing nosocomial TB transmission, including presence of soap and water, N95 masks for healthcare workers, and surgical masks or tissues for patients.
- Conduct continuous surveillance to ensure prevention of infection among staff and patients.
- Screen staff for TB at regular intervals and record screening results; refer for therapy initiation as needed and follow up on successful therapy completion.
- Work closely with occupational health to ensure that all staff receive recommended preventative adult immunizations at time of employment and annually thereafter.
- Ensure that the high TB transmission risk activities are carried out in the manner described in the infection control plan.
- Schedule and implement educational programmes for the provision of skills and knowledge regarding infection preventive measures and control practices to ensure a safe environment or surroundings to patients, visitors and staff.
- Monitor the execution of preventive measures and provide guidance to staff.
- Participate in unit meetings, in-service education programmes, and quality improvement initiatives as assigned.
- Report any interference for the implementation of infection control practices.
- Facilitate availability HIV testing and confidential care for affected staff.
- Ensure the availability of isoniazid preventive therapy for eligible individuals (including monitoring for stock outs).

### **SKILLS AND SPECIFICATIONS:**

- Commitment to reducing nosocomial TB transmission at health care facility.
- Knowledge of techniques for data collection and analysis.
- Knowledge of infection control practices.
- Able to lead and influence staff.
- Able to work independently.
- Proactive and organised.
- Good training skills.
- Degree in nursing required; work history involving direct patient care preferred.



## Trainer Instructions: Step 3 (45 minutes) Conducting a Facility TB Risk Assessment

### Step 3 Learning Objectives:

- Identify components of a facility TB risk assessment

### Step 3 Resources Needed:

- Handout 7.5. TB Infection Control Assessment
- Worksheet 7.6. Risk Assessment Case Study
- Handout 7.7. Home Isolation
- Flipchart and markers

### Step 3 Trainer Instructions:

	3.1. Tell participants that a risk assessment should be conducted at each facility prior to implementing an infection control plan and routinely thereafter to locate areas where IC can be improved. Similar to the activity conducted with the infection control plans, risk assessments help the facility be aware of gaps where infection control practices need to be improved.
	3.2. Ask participants, “How many of you have been involved in a facility risk assessment?”, “How long ago did the risk assessment take place?” Allow participants time to respond.
	3.3. Ask participants, “What elements should be included in a facility risk assessment?” Record responses on a flipchart.
	3.4. Refer participants to Handout 7.5. TB Infection Control Assessment Tool. Ask participants to review the risk assessment checklist in small groups.
	3.5. Ask participants, “What additional elements were included in the risk assessment that were not previously listed?” Allow participants to respond.
	3.6. Refer participants to Worksheet 7.6. Risk Assessment Case Study. Ask participants to work in small groups to review the case and then score the facility in the case, using the risk assessment tool in Handout 7.5. Review the instructions for the activity. Stress that if an answer is not provided in the case scenario, participants should answer based on their own experiences. Review how to use the assessment tool and how to score.
	3.7. In the large group, ask small groups to report their findings. Compare scores and findings. Ask how they answered the areas for which answers were not supplied.
	3.8. Ask participants, “How do you think your facility would do if this same risk assessment were conducted at your facility today?” Allow participants to respond.
	3.9. Refer participants to Handout 7.7. Home Isolation. Review specifics of home isolation and stress the similar components of a risk assessment prior to and during home isolation.
	3.10. Summarise Activity: Risk assessments help evaluate the status of a facility’s infection control program and assist in the development or revision of the infection control plan.



## Handout 7.5. TB Infection Control Assessment Tool

<b>Administrative</b>	<b>Yes</b>	<b>No</b>
An Infection Control Focal person has been assigned to oversee infection control activities in the facility		
An Infection Control Committee/Team has been designated (see minutes book)		
A written site-specific infection control (IC) plan has been written and is available to staff (must be seen)		
A facility TB IC risk assessment is completed and recorded in the past 6 months (must be seen)		
Patients are routinely asked about cough when entering the facility (must be seen)		
Patients that are coughing are separated from others and "fast tracked" to a HCW. (must be seen)		
A designated person gives cough etiquette guidance and assists with separation and triage (must be documented)		
Signage for cough etiquette is present in the clinic (must be seen)		
Supplies are available to coughing patients (tissues, masks, trash bins, etc) (must be seen)		
Is there medical surveillance for staff in the clinic		
Number of Health Care Workers who contracted TB in the last 12 months		

<b>Environmental</b>	<b>Yes</b>	<b>No</b>
Signage is in place to keep doors and windows open when feasible (must be seen)		
Patient waiting areas are out-of-doors or have good cross-ventilation.		
There is a designated area for producing sputum specimen		

<b>Protective Personal Equipment</b>	<b>Yes</b>	<b>No</b>
Surgical masks are available and worn by coughing patients (must be seen)		
N-95 or FFP2 respirators are available and used by staff (must be seen)		
Staff has been trained on proper fitting of respirators and documentation of training is available.		

<b>Training of Facility Staff</b>			
<i>Staff</i>	<i>Number trained</i>	<i>Trained by</i>	<i>When</i>
Doctors			
Nurses			
Other categories of nurses			
Cleaners			
Community workers			
Other (Specify)			

<b>Training of Partner Staff</b>			
<i>Staff</i>	<i>Number trained</i>	<i>Trained by</i>	<i>When</i>
Doctors			
Nurses			
Other categories of nurses			
Cleaners			
Community workers			
Other (Specify)			

*\*From NDOH, USAD and CDC*



## Worksheet 7.6. TB Risk Assessment Case Study

*Instructions:* Please read through the following facility case scenario. After reading through the case, please complete the risk assessment for the facility, to the best of your ability. If the case does not provide a specific response, please base your scoring on your group's experience within their own facilities.

After completing the risk assessment, please score the facility.

### Case Scenario

During the course of the risk assessment you conduct at XX facility, you find the following. This facility is located in an area of high TB incidence, including DR-TB. Approximately 5 patients were diagnosed with DR-TB in the past year. One of these was a health care worker. 7 other health care workers were diagnosed with TB.

After talking with several individuals, an infection control plan was located. It includes a respiratory protection plan and all disciplines are included. With it are minutes from previous meetings and documentation of staff training. The last staff training took place 7 months ago and the agenda reports information was included on administrative, environmental and personal respiratory protection controls.

The infection control plan specifies an individual who is to be acting in the role of infection control officer. However, upon asking a few more questions, you discover that this individual has since changed jobs and the role has not been filled by another individual. The infection control officer was a nurse who reported to his manager.

The infection diseases physician is technically in charge of the implementation of infection control at the facility. However no infection control committee meetings have taken place in the last 6 months. There was an awareness campaign in the hospital about a year ago and several community members used to be very involved in the infection control process and awareness campaigns. However, 1 of them passed away and the other moved.

You interview several staff members. They indicate that all infection control indicators are monitored and used to make changes except for the following indicators, died and moved out.

The last review of the infection control plan took place slightly over a year ago. At first, everyone was very excited about the infection control plan but in the last year or so, interest has waned and people are more lax about implementing the infection control measures.

When a patient is diagnosed with TB, he or she is provided with information regarding all three levels of controls. But patients with a cough are not always given information regarding prevention.

You proceed to tour the facility and notice many open windows, lots of natural light and several fans. There appears to be good cross ventilation in the appropriate directions. The only area in which you notice very little cross ventilation is in the pediatric wing. You notice obstruction of windows in the hallways and in the staff room. The facility does not have mobile consulting rooms. There are no exhaust ventilation systems and HEPA filters only in isolation rooms. Patients with confirmed MDR-TB were isolated, however, suspected infectious patients remained in the same waiting area with other patients. However, there are only 3 isolation rooms.

Upon speaking with the lab staff, they seem less aware of the respiratory protection plan. You notice that respirators do appear to be available, although you are uncertain if they are available or used by the cleaning staff. You notice they are used primarily in the consulting, procedure and TB rooms. No one is able to find record of the respiratory protection training. One person tells you it took place 2 years ago, and another mentions it was just 11 months ago. No fit testing took place.

The facility sends sputum for culture and microscopy. The microscopy is received within 1 day. DST is available. Once a patient is a suspect, they are generally seen right away in a separate room. The health care workers routinely use respirators when caring for patients who are having sputums collected, are awaiting results, or are known pulmonary TB cases without sputum conversion. Patients who are hospitalized with TB are separated from other patients and those with DR-TB are in a separate area, ideally in an isolation room, when available. Treatment is started as soon as possible following sputum result, generally within 2-5 days.

The last risk assessment took place a year and a half ago. At the time the primary problems were that patients were not being screened during triage for, TB, suspected cases or symptoms of TB. Health care workers were not routinely wearing respirators and windows were often left closed in the exam rooms.



## *Handout 7.7. Home Isolation*

Home isolation occurs once the decision has been made to suspend treatment. This decision is made by the M(X)DR-TB Review Committee.

### **Actions:**

- TB Treatment is suspended
- Patient may receive supportive drugs (ie vitamins)
- Inform: District Staff – PHC manager of the area, Sub district TB and home based care, TB Coordinator, TB Nurse of the Clinic
- Provide Counseling to patient and family at DR TB Unit
- Conduct a Home Assessment

### **Home Assessment:**

- Done before discharge
- Responsibility of a multidisciplinary team
- Maintain strict Infection Control measures during the assessment
- The goal is to help reduce the risk of transmission to the family and general public
- Assessment tool:
- Infection control measures
  - Ventilation and airflow, Open Windows policies
  - Access to masks
  - Cough Hygiene
  - Sleep in different rooms, sleeping area
- Demographic information
- Patient details
- Socio-economic detail
  - Time spent with members of the family (i.e. watch TV together, eat meals together)
- Household members
  - Who lives in the household
  - Number of children
- Education
- Develop an action plan for the household



## Trainer Instructions: Step 4 (30 minutes) Post-Exposure Prophylaxis

### Step 3 Learning Objectives:

- Identify necessary post-exposure prophylaxis for STIs and HIV.

### Step 3 Resources Needed:

- Handout 7.8. STI Post-Exposure Prophylaxis
- Worksheet 7.9. Post-Exposure Prophylaxis Case
- Flipchart and markers

### Step 3 Trainer Instructions:

	<p>4.1. Ask participants, “What is post-exposure prophylaxis?” Answer:</p> <p>PEP is the use of therapeutic agents to prevent infection following exposure to a pathogen. For health care workers, PEP is commonly considered for exposure to HIV and Hepatitis B.</p>
	<p>4.2. Ask participants, “When is post-exposure prophylaxis given?” Record responses on a flipchart. Possible answers:</p> <p>Occupationally – Percutaneous injury (needle-stick or cut through the skin). Contact of mucous membrane or non-intact skin with blood, tissue or other bodily fluids that are potentially infectious.</p> <p>Non-occupational exposure – Rape.</p>
	<p>4.3. Explain that all women and men aged 14 years and older presenting at a health facility after being raped should be counselled about potential risks of HIV transmission post-rape and offered PEP to prevent HIV transmission in the context of using the comprehensive rape protocol.</p>
	<p>4.4. Refer participants to Handout 7.8. Post-Exposure Prophylaxis. Ask for volunteers to read the handouts aloud.</p>
	<p>4.5. Refer participants to Worksheet 7.9. Post-Exposure Prophylaxis Case. Review Case as a large group.</p>
	<p>4.6. Ask participants, “How can services for persons who have experienced sexual assault or coercion be improved in your clinic setting?” Record responses on a flipchart.</p>
	<p>4.7. Summarise Activity: Reiterate the following:</p> <p>It is important to assess for and identify sexual abuse and report any work-related exposures.</p> <p>A confidential approach to care must always be followed.</p> <p>Clients are vulnerable when sexually abused so it is especially important to be non-biased and provide empathetic care.</p> <p>Health care workers should always offer testing and PEP to prevent STIs, including HIV.</p>



## Handout 7.8. Post-Exposure Prophylaxis

### Definition:

“Sexual assault, sexual abuse or rape is considered when a person intentionally and unlawfully commits an act of sexual penetration with another person by force or threat. Sexual penetration is defined broadly and refers to any act which causes penetration to any extent whatsoever by:

- The genital organs of one person into the mouth, anus or genital organs of another person
- Any object, any part of the body of one person into the anus or genital organs of another person in a manner that simulates sexual intercourse

“A person who has sexual intercourse with another person without disclosing that he/she is HIV-positive will be guilty of rape, as the consent given will not be valid due to the fact that it was obtained by false pretences.”

### Lab Analysis:

- Obtain Consent for testing and PEP (if agrees)
- Voluntary rapid HIV testing if status unknown
- Full Blood Count
- RPR/VDRL
- Hepatitis B serology
- Pregnancy Test

### STI PEP:

- Obtain Consent
- Assess for Drug Allergies
- Review importance of completing treatment

### *Non-pregnant women, men:*

- Doxycycline, oral, 100mg 12 hourly for 7 days
- Cefixime, oral, 400mg immediately as a single dose
- Metronidazole, oral, 2g immediately as a single dose

### *Pregnant women:*

- Amoxicillin, oral, 500mg 8 hourly for 7 days
- Cefixime, oral, 400mg immediately as a single dose
- Metronidazole, oral, 2g immediately as a single dose

### Emergency Contraception

- Within 72 hours: Norgestrel/oestradiol 0.5/0.05 mg 2 tablets stat; repeat in 12 hours
- Within 5 days: Intrauterine Device can be inserted
- More than 5 days: check pregnancy test 6-8 weeks after last menstrual period

### HIV PEP (if HIV negative or status unknown):

- Within 72 hours of rape
- Zidovudine (AZT) 300 mg 12 hourly for 1 month
- Lamivudine (3TC) 150 mg 12 hourly for 1 month
- Add Lopinavir/ritonavir (LPV/r) 400/100 mg 12 hourly for 1 month if high risk rape (signs of anal penetration, multiple perpetrators, HIV positive perpetrator or obvious trauma to genital area)

.....

### **Follow-up Testing/Vaccination:**

- Follow-up visit 3 days after PEP initiated, and for testing thereafter
- HIV testing – 4 weeks, 3 months, 6 months
- RPR – 4 weeks if initially negative
- Full Blood Count (if on PEP) – 2 and 4 weeks
- Hepatitis B vaccination

### **Education and Counselling:**

- Importance of starting PEP as soon as possible
- Potential medication side effects
- Window Period for HIV and other STI transmission
- Prevention – Abstinence/condom use until tested negative
- Importance of completing treatment and returning for follow-up testing
- Assess for safety
- Assess for psychological needs – refer as appropriate
- Review symptoms of post traumatic stress disorder

### **Referral:**

- All patients with severe physical or psychological injuries
- Infants with significant evidence of sexual assault need referral after beginning dual therapy as soon as possible
- If there are inadequate resources with regard to: counselling, laboratory for testing, medico-legal examination, drug treatment

*Source: Standard Treatment Guidelines and Essential Drugs List for South Africa: Primary Health Care. Chapter 21: Trauma and ER, p. 361-366. (2008). Accessed at: <http://www.doh.gov.za/docs/factsheets/>*



## Worksheet 7.9. Post-Exposure Prophylaxis Case

*Case Study #1:* Rejoice is a 28 year-old mother of one. Two nights ago, while walking from the taxi rank to her home she was attacked by a man and raped. She pleaded with him to please use a condom and she even lied telling the rapist that she is HIV positive [she's never been tested] but they simply ignored her. As a result of the rape, she was bleeding from her vagina.

1. What signs and symptoms are concerning and why?
  - *Risk for STIs and HIV due to rape*
  - *Bleeding from vagina*
2. What additional questions do you plan to ask the patient?
  - *Although it is important to be sensitive in this scenario, it is critical to ask regarding the possibility of pregnancy – including last menses and contraceptive method*
  - *Is she breastfeeding? Also important to note when prescribing prophylactic medications.*
  - *Any drug allergies?*
  - *Any current medications?*
  - *Has she had any other recent symptoms of which you should be aware?*
  - *Assess psychological status and safety – is she suicidal, does she have a support system, is she safe at home, is there a possibility this may reoccur?*
3. What will you include as part of your physical examination, including laboratory examinations?
  - *Advise to be screened where a rape kit is available, if possible*
  - *Thorough physical exam assessing for fractures, bruising, laceration*
  - *Cursory genital exam – in this case specifically to assess injury, assess for possible STIs – this portion of the exam requires great sensitivity (and is where it is advisable that it be performed by someone trained in assessing rape victims)*
  - *HIV test*
  - *Screen for STIs*
  - *Pregnancy test*
  - *Baseline LFTs and CMP prior to starting ARVs*
4. Assuming Rejoice is HIV negative, not allergic to any medications, not pregnant and is not breastfeeding, what is your management plan for this scenario?
  - *Prophylaxis for STIs:*
    - *Metronidazole 2g stat po*
    - *Cefixime 400mg orally x 1 dose*
    - *Doxycycline 100mg bd po x 7days provided the patient is not pregnant*
    - *If pregnant, give Amoxicillin 500mg 8 hourly x 7 days*
  - *Emergency contraception:*
    - *Ovral 2 tablets stat; repeat in 12 hours*
    - *Nordette 4 tabs stat; repeat in 12 hours*
  - *Prophylaxis for HIV*
    - *3 day PEP starter pack while awaiting ALT and CMP results*
    - *Follow up at three days, if minimal to no side effects, adherence and labs within normal limits, then dispense the rest of the 4 week PEP dose*
    - *Follow up at 6 weeks, 6months and 12 months*

- *If there is significant tearing of vagina,, refer for specialty care*
  - *Referral to mental health care, where available*
5. What counselling will you provide?
- *Benefits of PEP and prophylaxis*
  - *Adherence*
  - *Risks of transmission*
  - *Advise to abstain or use protection with routine partners*
6. What would be a good approach to providing counselling for this patient?
- *Confidentiality, establish rapport, do not pass judgement*
  - *Reassure and praise for seeking care*
  - *Address her biggest concerns*
  - *Provide education, but realise she may be too distraught to retain a great deal of information*
  - *Write down instructions*
  - *Referral to mental health for same day appointment, if possible*

# Session 8. Putting it all Together



**Total Session Time: 3 hours**

## Learning Objectives:

By the end of this session, participants will be able to:

- Conduct skills in simulated patient stations presenting clinical cases.
- Provide feedback to course participants.
- Demonstrate the simulated patient station role play model.

## Session Overview

Step	Time	Activity/Method	Content	Resources Needed
1	180 minutes	Demonstration Group Activity	Simulated Patient Stations	Handouts 8.2 and 8.3a-8.3e Flipchart and markers



## Advance Preparation

Overall: This session involves setting up patient stations for practice of all of the skills learned throughout the training. It requires identifying five participants to play the role of a patient. Each patient should sit in a different part of the room. The participants who will play patients should ideally be your most clinically advanced members, for example, if there are doctors present or if you have noticed over the course of the week that some nurses are particularly advanced. You should select them the day before this session starts. On the day before the session starts, tell the five you have selected to join you for lunch. At lunch, explain the process to them using Handout 8.1.

Make five copies, one for each “patient”.

Step 1: Prepare the room with five patient stations. Set up two chairs facing each other with several chairs surrounding it in different areas of the room, far away from each other. The patient should make sure s/he has enough copies of the case-specific scenario (Handout 8.3a-8.3e) for each rotation. In addition, have enough copies of the case specific checklist that will be handed to the “lead” participant as feedback for the case and that they have any needed materials specific to the case available to the “lead” participant when requested (i.e. medical history, medications, physical exam results, laboratory results). Create a case number sign for each station.

Make enough copies of checklists for all participants.

Step 1: Ask one of the expert patients to participate in the demonstration of the method.



## Resources Needed

- Handout 8.1.Overview of the Simulated Patient Station Model
- Handout 8.2. Demonstration Patient Scenario
- Handout 8.3a – 8.3f: Patient Scenario and Checklist
- Flipchart and markers
- TB and HIV Records and Forms



## Trainer Instructions: Step 1 (180 minutes) Simulated Patient Stations

### Step 1 Learning Objectives:

- Conduct skills in simulated patient stations presenting clinical cases.
- Provide feedback to course participants.
- Demonstrate the simulated patient station role play model.

### Step 1 Resources Needed:

- Handout 8.2. Demonstration Patient Scenario
- Handout 8.3a – 8.3e: Patient Scenario and Checklist

### Step 1 Trainer Instructions:

	<p>1.1. Explain to participants that for the next few hours, participants will utilise skills they have learned in the course on five simulated patient encounters. Explain that five stations have been set up around the room. At each station will be a simulated patient. The patient will role play a clinical case in a comprehensive care of HIV, AIDS and/or TB as taught during the training.</p>
	<p>1.2. Explain that each station will have one of the five different patient scenarios. Participants will be divided into small groups. Each group will cycle through all of the patient stations. Each group should pick one participant to play the role of the nurse/doctor for each patient station. This “lead” person should switch off for every patient station, so that everyone in the group has the opportunity to be the “lead”.</p> <p>The lead participant will:</p> <ul style="list-style-type: none"> <li>• Conduct a patient history, with the simulated patient</li> <li>• State what components of a physical exam they would perform and which laboratories would be requested (but do not actually have to do the physical examination).</li> </ul> <p>After being given the results of the physical exam and laboratories, they will then:</p> <ul style="list-style-type: none"> <li>• Assess the scenario and state the differential diagnoses</li> <li>• Create a plan for the patient case</li> </ul> <p>They can ask their small group for help, as needed. Each person in a group will lead for one patient scenario, but can ask his/her group for help if needed.</p> <p>Participant manuals and Clinical Reference tools may be utilised throughout the cases.</p>
	<p>1.3. Explain that the simulated patient will assess each patient encounter, providing the lead in the group with direct feedback on how well they have done. Tell participants that each person will get their checklist from the simulated patient at the end of the encounter.</p>
	<p>1.4. Explain that you will now conduct a demonstration of this process (10 minutes). Refer participants to Case #1 of Handout 8.2. Ask one of your simulated patients to come to the front with you. Demonstrate the technique using Handout 9.2. Request assistance from participants throughout the demonstration by asking, “Are there any other questions I should ask? Are there any additional laboratories I should order? Do you agree with the differential diagnoses? Should I counsel regarding any additional points? What dose should I give?”</p> <p>At the end of the demonstration, refer participants to the handout to see the checklist. Explain that the patient will now use the checklist to “grade” the encounter. Explain that each of the patient stations will be conducted similarly.</p>
	<p>1.5. Clarify any outstanding questions related to this activity.</p>
	<p>1.6. Divide participants into groups of five. Remind participants that each patient station should have a different lead for their group. Explain that groups will have 30 minutes (20 minutes for the role play and 10 minutes for feedback from the patient) at each station.</p>
	<p>1.7. Debrief the activity (15 minutes) with the following questions:</p> <p>Where there any challenges during this activity?</p> <p>Did you feel prepared or well equipped for these cases?</p> <p>Which cases were the most challenging and why?</p>



## *Handout 8.1. Overview of the Simulated Patient Station Model*

Your primary task as the simulated patient is to provide details about an illness that will help the health care worker in their diagnosis/counselling. You will initially provide the general information provided in the statement. Following the statement is a list of additional information you will provide as asked about it. Don't give away too much information right away, wait for the appropriate questions to be asked.

Remember to be thorough, accurate, and simple in the description of your symptoms.

- Be thorough by describing, explaining, and demonstrating the symptoms you are experiencing.
  - A description provides details about how much pain you are experiencing, whether you have a fever or how long you have been experiencing certain symptoms.
  - An explanation tells a story about when the symptoms began, how they progressed and possible reasons why you experienced certain discomforts, such as indigestion.
  - Give a thorough account of your symptoms by demonstrating the symptoms you are experiencing. Point to where you are feeling pain or show the health care professional how high you can raise your arm if you are experiencing difficulty with motor control.
- Be accurate. It is sometimes easy to provide a description of symptoms and get carried away. Stay with the basic symptoms of the illness and don't stray into other symptoms.
- Be simple. Use language that is basic and natural, as though you are talking with a friend or family member. There is no need to use medical terms or appear knowledgeable about your disease beyond the symptoms experienced.

### **Clarity**

Clear communication includes words and sentences that other people understand. As you carry out your task as the simulated patient, be careful to use language that is specific and vivid. This "paints" a picture of your illness in the mind of the health care worker and allows them to more fully understand the symptoms.

- Specific language. Communication that is specific doesn't leave the listener wondering what you mean. Although patients are often vague in their descriptions of their symptoms, try to avoid words that leave the other person guessing what your symptoms really are. For example, saying, "my stomach hurts" is a good start but be sure to specify the kind of pain you are experiencing (burning, sharp, dull?) and at what intensity and duration (a lot of pain every few hours, a little pain constantly?).
- Vivid language. Language that is vivid provides details that are clear and graphic without exaggerating. Instead of describing your symptoms using a phrase such as "I'm feeling poorly," continue to describe your symptoms with phrases such as, "I've felt weak for several days" or "I've had diarrhoea for almost two weeks."

### **Believability**

Although this is a role-playing situation, you want your descriptions and explanations of your symptoms to be believable. You want to act the way a real patient would. The more believable and credible your descriptions, the easier it will be for the health care worker to analyse your symptoms and properly treat you. Believability is communicated both through your words and your body.

- Believable words. Refrain from over emphasising and exaggerating your symptoms. State them plainly and specifically without using dramatic words.
- Believable body. People experiencing symptoms of any serious or painful illness may slump their shoulders, talk slowly, look away from the healthcare worker while speaking or not smile very much.

## Responsiveness

One of the most common forms of communication patients use during visits to health care workers is answering and asking questions.

- Answering questions. Most often patients will wait for a health care worker to ask them questions during a medical examination. When answering, you want to follow the key rules of being specific, clear and believable. But you also don't want to give too much information at once. Let the health care worker ask a series of questions and then respond to each one in turn. Listen carefully for the kinds of information she or he is requesting. Do they want to know about the pain you are experiencing, or are they asking about your medical history?
- Asking questions. Patients also ask questions of a doctor, nurse or medical assistant. Questions often focus on how long a symptom will last, diagnosis of an illness, or ways of relieving pain and discomfort. Determine what questions would be appropriate given the symptoms you are role-playing and ask them at key points during the role-play.

## Awareness

As the simulated patient, you are a member of a training team. Being aware of what is happening during the role-play and identifying moments when you can change your communication to make the role-play more useful is important. Be aware of when you may need to give more detail, or when you have given enough detail and need to wait for questions. Perhaps a certain detail at a specific time will help your partner just enough to allow him or her to diagnose a symptom correctly. Your thoughtful awareness throughout the role-play can help determine its success as an educational part of the training course.

*Source: Adapted from the Facilitator's Guide to the Preparation of Expert Patient-Trainers for the WHO Basic ART Clinical Training Course and the ART Aid Training Course. Based on the IMCI Chronic HIV Care with ARV Therapy Module. December 2005 Draft.*



## *Handout 8.2. Demonstration Patient Scenario*

### **CASE A**

You are a 23 year-old pregnant female. This is your first pregnancy. You are HIV-infected, but have never been on ART. You have not told your current partner about your HIV infection because you are scared he might leave you. You are at the clinic for your first antenatal visit.

### **IF ASKED**

- Your last CD4 count was 650 cells/mm<sup>3</sup>, 3 months ago
- You are not allergic to any medications
- You are not currently taking any medications
- Last menses was 2 months ago
- Your partner does not have any symptoms
- You have never had any STIs
- You have never been tested or treated for TB
- No symptoms other than some nausea and vomiting. Otherwise feeling well and no significant symptoms in the past.

----- ✂ CUT HERE -----

Medical History: HIV +. No significant past medical history

Medications: None

Physical Exam: Current weight 60kg (no change from previous visit 3 months ago), Temperature and Blood Pressure are normal. Exam is normal.

Laboratory (today): CD4 560 cells/mm<sup>3</sup>, ALT within normal limits, 2 sputum smears AFB negative

<b>Simulated Patient:</b>	<b>Good</b>	<b>Ok</b>	<b>Not Good</b>	<b>Not Done</b>
<b>Health Worker:</b>				
<b>GENERAL</b> <ul style="list-style-type: none"> <li>• Respectful</li> <li>• Simple words</li> <li>• Listened to patient</li> <li>• Made sure patient understood</li> </ul>				
<b>SUBJECTIVE (ASK)</b> <ul style="list-style-type: none"> <li>• Asked why came to the clinic?</li> <li>• Reviewed symptoms</li> <li>• Screened for symptoms of TB and STIs</li> <li>• Asked about partner HIV, TB, STI status</li> <li>• Asked about past medical history and any current or prior medications</li> <li>• Asked about knowledge of HIV and TB</li> <li>• Assessed readiness for PMTCT</li> <li>• Assessed gestational age</li> </ul>				
<b>OBJECTIVE (Look, Listen, Feel)</b> <ul style="list-style-type: none"> <li>• Stated plans to conduct physical exam</li> <li>• Stated plans to obtain prenatal labs (CD4, Sputum x 2, STI screen, ALT)</li> </ul>				
<b>ASSESSMENT</b> <ul style="list-style-type: none"> <li>• Discussed HIV and WHO Clinical Stage 1</li> <li>• Discussed Pregnancy with need for PMTCT</li> </ul>				
<b>PLAN</b> <ul style="list-style-type: none"> <li>• Prenatal vitamin start</li> <li>• Scheduled follow-up visit for 14 weeks gestation for AZT start</li> </ul> <b>Counselling</b> <ul style="list-style-type: none"> <li>• Discussed adherence</li> <li>• Discussed medication side effects</li> <li>• Prepared for PMTCT including (AZT from 14 weeks, sdNVP + AZT 3 hourly in labour, TDF+FTC single dose stat after delivery)</li> <li>• Prepared for infant PMTCT including (NVP at birth and daily for 6 weeks as long as breastfeeding, feeding options, cotrimoxazole prophylaxis, and need for follow-up visits including testing)</li> <li>• Talked about prevention for HIV and TB</li> <li>• Talked about partner testing for HIV and TB</li> <li>• Discussed disclosure tactics</li> <li>• Provided psychological support</li> </ul>				



## *Handout 8.3a. Patient Scenario and Checklist*

### **CASE 1**

You are a 29 year-old diagnosed with HIV-infection 2 weeks ago. You have come to the health centre for a follow-up visit. Last week you had your initial HIV evaluation and several laboratory examinations were obtained. You have had a cough for the past 2 weeks and you intend to ask about it.

### **IF ASKED**

- You also have night sweats and fatigue, no other significant symptoms
- You don't have any family members known to be TB infected, but your husband/wife has a similar cough
- You have not previously been treated for or diagnosed with TB
- Your partner and children have not been tested for HIV or TB
- You are married and practice safer sex
- If female, you do not currently want to conceive and your last menses was 1 week ago
- You are not currently on any medications
- You have no known drug allergies
- Your aunt recently died with HIV and you would like to start on ARVs as soon as possible because you do not want to die

----- ✂ CUT HERE -----

Medical History: HIV + (diagnosed 2 weeks ago), Diagnosed when presented with oral candidiasis. No significant surgeries or other symptoms.

Medications: None

Physical Exam: Weight 70kg, No oral candidiasis noted. Lungs with right sided crackles. Heart has regular rate and rhythm. Soft, mobile, non-tender cervical lymph nodes. Temperature and Blood Pressure are normal

Laboratories (one week ago): CD4 300 cells/mm<sup>3</sup>, FBC normal with Haemoglobin 11g/dL (normal in Women= 12.1-15.1 g/dL; in Men = 13.8-18.2 g/dL), Creatinine clearance within normal limits, Sputum smears: 1st AFB positive, 2nd smear AFB negative.



## Handout 8.3b. Patient Scenario and Checklist

### CASE 2

You are a 34 year-old patient who is HIV infected. You are here because you have tingling and pain in both of your legs. It bothers you the most when you are trying to go to sleep. Your last HIV visit was three months ago and laboratories were obtained at that time.

### IF ASKED

- You are currently on cotrimoxazole, stavudine (d4T), lamivudine (3TC), and efavirenz (EFV).
- You have been on this regimen for a little over one year.
- You missed one dose in the past month, approximately two weeks ago.
- If you are a female, you are currently on an injectable contraceptive and do not have a menses.
- You do not currently have a partner, you were widowed 2 years ago.
- You were diagnosed when you had Pneumocystis Jiroveci pneumonia. You have also had oral thrush.
- You do not have any other symptoms at this time.
- You were screened for TB 3 years ago and had negative sputum smears. You have not had a cough since then.

----- ✂ CUT HERE -----

Medical History: HIV + (diagnosed 3 years ago), History of Pneumocystis Jiroveci Pneumonia and oral candidiasis.

Medications: Cotrimoxazole, stavudine (d4T), lamivudine (3TC), and efavirenz (EFV).

Physical Exam: Weight 69kg, Temperature 37 , Blood Pressure 128/84.

No oral candidiasis noted. Lungs clear to auscultation. Heart has regular rate and rhythm. Full range of motion in upper and lower extremities bilaterally. Decreased sensation on exam of lower extremities below ankles.

Laboratories (3 months ago): CD4 367 cells/mm<sup>3</sup> and viral load <400



## *Handout 8.3c. Patient Scenario and Checklist*

### **CASE 3**

You are a 26 year-old patient who is HIV infected. You were diagnosed with HIV infection two months ago and began on ART 4 weeks ago. You are at the clinic because you are feeling worse. You have fevers and night sweats.

### **IF ASKED**

- You are currently on cotrimoxazole, tenofovir (TDF), lamivudine (3TC), and efavirenz (EFV).
- You missed one dose 2 weeks ago when you felt so sick you fell asleep before you could take it.
- If you are a female, you are currently on an injectable contraceptive and do not have a menses.
- Your partner is also infected and is on the same regimen as you are. You have disclosed. You do not use condoms.
- You do not have any children.
- You have never been diagnosed or treated for TB. You have not been screened for TB since your HIV diagnosis.
- You do have a productive cough and have had a cough for the past several months.
- You do not have any headaches, rashes, blurred vision or other significant symptoms.
- Your partner also has a cough.
- You do not have any other significant medical history.

----- ✂ CUT HERE -----

Medical History: HIV + (diagnosed 2 months ago), no significant medical history

Medications: Cotrimoxazole, tenofovir (TDF), lamivudine (3TC), and efavirenz (EFV).

Physical Exam: Current weight 65kg (down from previous visit), Temperature 37.5 , Blood Pressure 117/78.

No oral candidiasis noted. Productive cough during exam, crackles auscultated anteriorly. Heart has regular rate and rhythm. No rash appreciated.

Non-tender, cervical lymphnode swelling. Normal liver, spleen, abdomen examination.

Laboratories (2 months ago): CD4 198 cells/mm<sup>3</sup>, FBC normal, Haemoglobin 14.2 g/dL (normal in Women= 12.1-15.1 g/dL; in Men = 13.8-18.2 g/dL), creatinine clearance within normal limits



## Handout 8.3d. Patient Scenario and Checklist

### CASE 4

You are the caregiver of a 5 year-old girl with HIV. The child has been on HIV medications for the past two years and is in for a follow-up appointment. The child had labs obtained two weeks prior to this visit. The child is feeling well today but since the last ART visit, the child has been treated twice for bacterial pneumonia at another clinic. You are concerned the child is getting worse.

### IF ASKED

- The child is taking cotrimoxazole daily
- The child has a history of oesophageal candidiasis and recurrent oral candidiasis. There had been no recurrence since starting ART until last month.
- He child has been on stavudine (d4T), lamivudine (3TC) and efavirenz (EFV) for the past two years.
- The last labs were “OK”, you are not aware what the results were from 2 weeks ago. The CD4 cell percentage 6 months ago was 20% with a Viral Load < 400 copies/mL.
- When asked about adherence, you respond that you were busy caring for your other sister, who is ill, for the past 2 months. In the meantime, the child was in the care of another family member. You are not sure whether or not the child was taking her medication appropriately. In the past week since you’ve been back, she has not missed any doses.
- No cough, fevers or night sweats at present. No significant symptoms today other than very little appetite.
- The child has difficulty swallowing.

----- ✂ CUT HERE -----

Medical History: HIV + (diagnosed 3 years ago following the death of her mother), history of recurrent oral candidiasis and oesophageal candidiasis in the past. Case of oral candidiasis last month. Treated for bacterial pneumonia twice in the past several months.

Medications: Cotrimoxazole, stavudine (D4T), lamivudine (3TC), and efavirenz (EFV).

Physical Exam: Weight 15kg, Temperature 37.5, Blood Pressure is normal

Thick white coating present along tongue and rough of mouth. Lungs clear to auscultation bilaterally. No cough during exam. Heart regular rate and rhythm. Abdomen soft and nontender without hepatomegaly. No rashes appreciated.

Laboratories (2 weeks ago): CD4 220 cells/mm<sup>3</sup>, viral load 13500 copies/mL.



## *Handout 8.3e. Patient Scenario and Checklist*

### **CASE 5**

You are 35 year old woman on MDR-TB treatment. You started the treatment four months ago. At the last visit your microscopy was negative but other results were not yet available. You have had strict DOT every day, so you know you have not missed any doses. You are HIV-infected. Last CD4 150 cells/mm<sup>3</sup>. You are hoping you will have negative results so that you can go home.

### **IF ASKED**

- You take cotrimoxazole daily
- You take efavirenz, tenofovir and emtricitabine. You started this 3.5 months ago. You have not missed doses due to the DOT.
- You use condoms, but no other form of birth control. Your last menstrual period was 3 weeks ago.
- Your partner was tested for HIV and screened for TB. He is HIV infected and does not appear to have active TB. Your children have also been screened for HIV and TB.
- You are not really sure about how to keep your family from getting infected if you are at home.
- You don't really have enough space for you to have your own room, unless your partner and youngest child move in to a room with other children.
- Side effects: Nausea and vomiting at the beginning of treatment, you are starting to experience some tingling of your toes.

### **FOR CLINICIAN:**

Medical History: HIV+, MDR-TB on standardized regimen. She has been on DOT for MDR-TB for 4 months. Last microscopy result negative. You have been awaiting culture. Physical Exam: Weight 50kg, Temperature normal. Blood Pressure is normal

Decreased tactile feeling at toes to ankle. Exam otherwise normal.

Laboratories (obtained 1 month ago): Culture negative.

<b>Case #1-Handout 3.1a</b>  <b>Simulated Patient:</b>  <b>Health Worker:</b>	Good	Ok	Not Good	Not Done
GENERAL <ul style="list-style-type: none"> <li>• Respectful</li> <li>• Simple words</li> <li>• Listened to patient</li> <li>• Made sure patient understood</li> </ul>				
SUBJECTIVE (ASK) <ul style="list-style-type: none"> <li>• Asked why came to the clinic?</li> <li>• Reviewed symptoms</li> <li>• Screened for symptoms of TB</li> <li>• Asked about family HIV and TB health status and screening</li> <li>• Asked about past medical history and any current or prior medications</li> <li>• Asked about knowledge of HIV and TB</li> <li>• If female, asked about pregnancy/family planning</li> </ul>				
OBJECTIVE (Look, Listen, Feel) <ul style="list-style-type: none"> <li>• Stated plans to examine vital signs, mouth, heart, lungs and quick physical exam</li> <li>• Stated plans to review current laboratory findings</li> </ul>				
ASSESSMENT <ul style="list-style-type: none"> <li>• Discussed HIV, WHO Stage 3</li> <li>• Discussed Pulmonary TB diagnosis</li> </ul>				
PLAN <ul style="list-style-type: none"> <li>• Start Pulmonary TB treatment - RHZE fixed dose 4 tabs daily for 2 months, then RH (300/150 – if maintains same weight although anticipate increase) 2 tabs once daily for 4 months</li> <li>• Discussed starting ART once TB treatment tolerated (2weeks)               <ul style="list-style-type: none"> <li>– Cotrimoxazole start</li> <li>– INH Prophylaxis for children in household after active TB is ruled out</li> <li>– Schedule follow-up within maximum 2 weeks to assess adherence, side effects, toxicities and tolerance (considering ART start)</li> </ul> </li> </ul> Counselling <ul style="list-style-type: none"> <li>• Discussed adherence</li> <li>• Discussed medication side effects</li> <li>• Prepared for ART start</li> <li>• Talked about prevention for HIV and TB</li> <li>• Talked about family/partner testing for HIV and TB and disclosure</li> <li>• INH Prophylaxis for children in household after active TB is ruled out</li> <li>• Provided psychological support</li> <li>• If female, discussed family planning</li> </ul> Forms <ul style="list-style-type: none"> <li>• Complete appropriate forms, if time allows</li> <li>• Forms anticipated: TB Case Identification and Follow-Up Sputum Register, TB Register, Patient Clinic/Hospital Card, Patient Treatment Card</li> </ul>				

<b>Case #2-Handout 3.1b</b>  <b>Simulated Patient:</b>  <b>Health Worker:</b>	Good	Ok	Not Good	Not Done
GENERAL <ul style="list-style-type: none"> <li>• Respectful</li> <li>• Simple words</li> <li>• Listened to patient</li> <li>• Made sure patient understood</li> </ul>				
SUBJECTIVE (ASK) <ul style="list-style-type: none"> <li>• Asked why came to the clinic?</li> <li>• Reviewed symptoms</li> <li>• Screened for symptoms of TB</li> <li>• Asked about family HIV and TB health status and screening</li> <li>• Asked about past medical history and any current or prior medications</li> <li>• Asked about knowledge of HIV</li> <li>• If female, asked about pregnancy/family planning</li> <li>• Screened for HIV prevention</li> <li>• Assessed adherence</li> </ul>				
OBJECTIVE (Look, Listen, Feel) <ul style="list-style-type: none"> <li>• Stated plans for physical exam</li> <li>• Stated plans to review recent laboratory findings</li> </ul>				
ASSESSMENT <ul style="list-style-type: none"> <li>• Discussed HIV, WHO Stage 4 (history of Pneumocystis pneumonia)</li> <li>• Discussed Peripheral Neuropathy, likely side effect of stavudine (d4T)</li> </ul>				
PLAN <ul style="list-style-type: none"> <li>• Discuss switch from stavudine (d4T) to tenofovir (TDF), if available. All other ART to remain the same</li> <li>• Obtain baseline serum creatinine and clearance</li> <li>• Provide suitable analgesia (for example, amitriptyline)</li> <li>• Schedule return visit for follow-up several weeks after new ART start to assess for side effects, tolerability and adherence</li> <li>• Patient to return in 3 months for repeat labs</li> </ul> Counselling <ul style="list-style-type: none"> <li>• Discussed adherence</li> <li>• Discussed medication side effects</li> <li>• Prepared for ART switch</li> <li>• Talked about prevention for HIV and TB</li> <li>• Provided psychological support</li> <li>• If female, discussed family planning/use of condoms to prevent STI and HIV infection/re-infection</li> </ul>				

<b>Case #3- Handout 3.1c</b>  <b>Simulated Patient:</b>  <b>Health Worker:</b>	Good	Ok	Not Good	Not Done
GENERAL <ul style="list-style-type: none"> <li>• Respectful</li> <li>• Simple words</li> <li>• Listened to patient</li> <li>• Made sure patient understood</li> </ul>				
SUBJECTIVE (ASK) <ul style="list-style-type: none"> <li>• Asked why came to the clinic?</li> <li>• Reviewed symptoms, including of side effects</li> <li>• Assessed adherence and possibility of treatment failure</li> <li>• Screened for symptoms of TB</li> <li>• Asked about family HIV and TB health status and screening</li> <li>• Asked about past medical history and any current or prior medications</li> <li>• Asked about knowledge of HIV</li> <li>• If female, asked about pregnancy/family planning</li> <li>• Screened for HIV prevention</li> </ul>				
OBJECTIVE (Look, Listen, Feel) <ul style="list-style-type: none"> <li>• Stated plans for physical exam</li> <li>• Stated plans to review recent laboratory findings</li> </ul>				
ASSESSMENT <ul style="list-style-type: none"> <li>• Discussed HIV, WHO Stage I (if Pulmonary TB confirmed, Stage 3)</li> <li>• Discussed worsening of symptoms may be IRIS, presumptively due to undiagnosed pulmonary TB</li> </ul>				
PLAN <ul style="list-style-type: none"> <li>• Encourage patient to continue ARVs</li> <li>• Chest x-ray</li> <li>• Obtain sputum smears (GXP or culture/DST) and treat for TB according to result</li> <li>• Encourage partner screening</li> <li>• Patient to return as soon as results are returned</li> </ul> Counselling <ul style="list-style-type: none"> <li>• Discussed adherence</li> <li>• Talked about prevention for HIV and TB</li> <li>• Provided psychological support</li> <li>• If female, discussed family planning</li> </ul> Forms <ul style="list-style-type: none"> <li>• Reviewed forms to complete, if time allows completed actual forms</li> <li>• TB Case ID and Follow-Up Sputum Register, Laboratory Specimen Request Form, Additional forms only if diagnosed with TB</li> </ul>				

<b>Case #4- Handout 3.1d</b>  <b>Simulated Patient:</b>  <b>Health Worker:</b>	Good	Ok	Not Good	Not Done
GENERAL <ul style="list-style-type: none"> <li>• Respectful</li> <li>• Simple words</li> <li>• Listened to patient’s caregiver</li> <li>• Made sure patient’s caregiver understood</li> </ul>				
SUBJECTIVE (ASK) <ul style="list-style-type: none"> <li>• Asked why came to the clinic?</li> <li>• Reviewed symptoms, including side effects</li> <li>• Assessed adherence</li> <li>• Screened for symptoms of TB</li> <li>• Asked about family HIV and TB health status and screening</li> <li>• Asked about past medical history and any current or prior medications</li> <li>• Assessed caregiver knowledge</li> </ul>				
OBJECTIVE (Look, Listen, Feel) <ul style="list-style-type: none"> <li>• Stated plans for physical exam</li> <li>• Stated plans to review recent laboratory findings</li> </ul>				
ASSESSMENT <ul style="list-style-type: none"> <li>• Discussed HIV, WHO Stage 4</li> <li>• Discussed worsening of symptoms and lower CD4 % may be due to repeated poor adherence or treatment failure(Since the caregiver is uncertain of adherence we do not know if all doses were missed or doses were missed sporadically – which would increase likelihood of treatment failure)</li> <li>• Discussed oral candidiasis</li> </ul>				
PLAN <ul style="list-style-type: none"> <li>• Treated for oesophageal candidiasis</li> <li>• Began step-up adherence package and repeat viral load in three months</li> </ul> Counselling <ul style="list-style-type: none"> <li>• Discussed adherence and ways to ensure all caregivers are knowledgeable regarding importance of adherence</li> <li>• Provided HIV education</li> <li>• Talked about prevention for TB</li> <li>• Provided psychological support</li> </ul>				

<b>Case #4- Handout 3.1d</b>  <b>Simulated Patient:</b>  <b>Health Worker:</b>	Good	Ok	Not Good	Not Done
GENERAL <ul style="list-style-type: none"> <li>• Respectful</li> <li>• Simple words</li> <li>• Listened to patient's caregiver</li> <li>• Made sure patient's caregiver understood</li> </ul>				
SUBJECTIVE (ASK) <ul style="list-style-type: none"> <li>• Asked why came to the clinic?</li> <li>• Reviewed symptoms, including side effects</li> <li>• Assessed adherence</li> <li>• Screened for symptoms of TB</li> <li>• Asked about family HIV and TB health status and screening</li> <li>• Asked about past medical history and any current or prior medications</li> <li>• Assessed caregiver knowledge</li> </ul>				
OBJECTIVE (Look, Listen, Feel) <ul style="list-style-type: none"> <li>• Stated plans for physical exam</li> <li>• Stated plans to review recent laboratory findings</li> </ul>				
ASSESSMENT <ul style="list-style-type: none"> <li>• Discussed HIV, WHO Stage 4</li> <li>• Discussed worsening of symptoms and lower CD4 % may be due to repeated poor adherence or treatment failure(Since the caregiver is uncertain of adherence we do not know if all doses were missed or doses were missed sporadically – which would increase likelihood of treatment failure)</li> <li>• Discussed oral candidiasis</li> </ul>				
PLAN <ul style="list-style-type: none"> <li>• Treated for oesophageal candidiasis</li> <li>• Began step-up adherence package and repeat viral load in three months</li> </ul> Counselling <ul style="list-style-type: none"> <li>• Discussed adherence and ways to ensure all caregivers are knowledgeable regarding importance of adherence</li> <li>• Provided HIV education</li> <li>• Talked about prevention for TB</li> <li>• Provided psychological support</li> </ul>				

<b>Case #5- Handout 3.1e</b>  <b>Simulated Patient:</b>  <b>Health Worker:</b>	Good	Ok	Not Good	Not Done
GENERAL <ul style="list-style-type: none"> <li>• Respectful</li> <li>• Simple words</li> <li>• Listened to patient</li> <li>• Made sure patient understood</li> </ul>				
SUBJECTIVE (ASK) <ul style="list-style-type: none"> <li>• Asked why came to the clinic?</li> <li>• Reviewed symptoms, including side effects</li> <li>• Assessed adherence</li> <li>• Screened for side effects and new symptoms</li> <li>• Asked about family HIV and TB health status and screening</li> <li>• Asked about past medical history and any current or prior medications</li> <li>• Assessed knowledge regarding infection and infection control</li> </ul>				
OBJECTIVE (Look, Listen, Feel) <ul style="list-style-type: none"> <li>• Stated plans for physical exam</li> <li>• Stated plans to review recent laboratory findings</li> </ul>				
ASSESSMENT <ul style="list-style-type: none"> <li>• Discussed MDR-TB and negative culture</li> <li>• Reviewed length of time of intensive phase based on current culture</li> <li>• Discussed peripheral neuropathy</li> </ul>				
PLAN <ul style="list-style-type: none"> <li>• Suggestions for treating peripheral neuropathy</li> <li>• Stress continued adherence DOT</li> <li>• Encourage and praise</li> <li>• Discuss possibility of discharge from hospital and what that would require</li> </ul> Counselling <ul style="list-style-type: none"> <li>• Adherence</li> <li>• Provided HIV and MDR-TB education</li> <li>• Talked about infection control measures and home risk assessment</li> <li>• Provided psychological support</li> </ul> Forms <ul style="list-style-type: none"> <li>• Reviewed forms to complete, completed if time allows</li> <li>• Forms include: DR-TB Register, DR-TB Treatment Card, Request for Sputum Examination</li> </ul>				

