The Union
International Union Against Tuberculosis and Lung Disease
Health solutions for the poor

# BEST PRACTICE FOR THE CARE OF PATIENTS WITH TUBERCULOSIS

*A guide for low-income countries*

**Second Edition**
**2017**

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## Abbreviations

| | |
|---|---|
| AFB | acid-fast bacilli |
| ART | antiretroviral treatment |
| ARV | antiretrovirals |
| BMU | basic management unit |
| CDC | United States Centers for Disease Control and Prevention |
| CPT | co-trimoxazole preventive therapy |
| DM | diabetes mellitus |
| DOT | directly observed treatment |
| DOTS | directly observed treatment, short-course |
| DR-TB | drug-resistant tuberculosis |
| DS-TB | drug-susceptible tuberculosis |
| DST | drug-susceptibility testing |
| HCW | healthcare worker |
| HIV | human immunodeficiency virus |
| ICN | International Council of Nurses |
| IMAI | integrated management of adolescent and adult illness |
| IPT | isoniazid preventive therapy |
| IRIS | immune reconstitution inflammatory syndrome |
| LPA | line probe assay |
| LTBI | latent tuberculosis infection |
| MDR-TB | multidrug-resistant tuberculosis |
| NTP | national tuberculosis programme |
| NAP | national AIDS programme |
| PICT | provider-initiated HIV counselling and testing |
| PLWHA | people living with HIV/AIDS |
| PPE | personal protective equipment |
| RR-TB | rifampicin-resistant tuberculosis |
| TB | tuberculosis |
| The Union | The International Union Against Tuberculosis and Lung Disease |
| WHO | World Health Organization |
| XDR-TB | extensively drug-resistant tuberculosis |

# 1

## Introduction

This guide has been developed for healthcare workers who are involved in detecting and caring for patients with *Mycobacterium tuberculosis* (TB) in primary, community and acute (hospital) healthcare settings. It is rooted in the idea that high-quality patient care is the key to improving programme outcomes, and this now extends to meeting the new people-centred targets as set out in the *Global Plan to End TB: The Paradigm Shift 2016-2020*[1] to "reach 90% of all people who need TB treatment, including 90% of people in key populations, and achieve at least 90% treatment success."[1] This guide supports the *Global Plan's* emphasis on patient-centred, human-rights based care and offers a practical way of achieving this.

Detailed guidance is provided regarding good practice for the care and support of people presenting to health services with suggestive symptoms through the different stages of diagnosis up until the end of treatment, if they are found to have active disease. The term TB refers to all types of TB including all forms of resistance unless otherwise specified. There is more information in this second edition about drug-resistant TB (DR-TB), but the underlying patient-centred principles of care remain. Whatever the duration or severity of the disease, each patient needs to be assessed individually.

The guidance is based on existing good practice and has been developed in collaboration with nurses working in a wide variety of settings, but focused mainly on areas where resources are limited. It represents the point of view of the technical staff of The Union and the network of Nurses and Allied Professionals among the members of The Union. Best practice is presented in a series of standards, which are adaptable to local services in low- and middle-income countries and which encourage evaluation through the use of measurable outcomes. Each standard corresponds with a significant point in a TB patient's diagnosis or treatment based on the TB management strategies recommended by The Union[2, 3] and treatment regimens recommended by the World Health Organization (WHO) for drug-susceptible TB and drug-resistant TB.[4, 5] Throughout this guide, readers will be directed to the relevant information published in two other Union guides: *Management of Tuberculosis: A Guide to the Essentials of Good Practice 6th Edition, 2010 (*referred to as the "Orange Guide")[2] and *Guidelines for Clinical and Operational Management of Drug-Resistant Tuberculosis*, *2013* (referred to as "*DR-TB guide*").[3] Other key reference material is listed at the end, and all are consistent with internationally recommended strategies.

The *Global Plan*[1] sets out a five-year costed plan to support the implementation of the WHO *End TB Strategy 2016 – 2035.*[6] The first edition of this guide was based on the TB management strategy, which was developed by The Union and officially adopted by the WHO as directly observed treatment, short-course (DOTS). This edition is in line with the *End TB Strategy*[6] which was endorsed at the World Health Assembly in 2014, and, while the main principles of the *DOTS Strategy* (1994-2005) and the *Stop TB Strategy* (2006-2015)[7] are maintained, a broader view is taken regarding what is required to achieve lasting control of TB.

The three pillars which make up the *End TB strategy* are:[6]

1. Integrated, patient-centred care and prevention

2. Bold policies and supportive systems

3. Intensified research and innovation.

As this guide is about direct patient care from before diagnosis to the end of treatment, the main focus will be on the practical implementation of the first three elements of pillar one (Table 1). The first edition already emphasised the need for a patient-centred approach to care, so much of the content remains relevant today and therefore has not been changed. Most of the changes are related to updates required to take account of new advances in diagnostics and treatment, the new epidemiological picture of the disease and, in particular, the increases seen in DR-TB. More attention is also paid to infection prevention at all stages.

**Table 1: The End-TB Strategy – Pillar 1: Integrated, patient-centred care and prevention and its four components[6]**

| |
|---|
| A. Early diagnosis of tuberculosis, including universal drug-susceptibility testing, and systematic screening of contacts and high-risk groups |
| B. Treatment of all people with tuberculosis, including drug-resistant tuberculosis, and patient support |
| C. Collaborative tuberculosis/HIV activities, and management of co-morbidities |
| D. Preventive treatment of persons at high risk and vaccination against tuberculosis |

**Quality Assurance**

This guide aims to use a recognised system of quality assurance; that is, standard setting based on the available evidence and existing good practice to offer more definitive guidance regarding patient care in the context of the DOTS strategy in low-income countries. **It is based largely on evidence gathered from experts in the field and has been developed in partnership with healthcare providers who will use the guide in practice.** Those working in better resourced areas may wish to adapt the standards to include the wider diagnostic and treatment facilities that are available to them.

The process of improving quality of care through standard setting and clinical audit is described in Chapter 2, where guidance is also offered on how to implement best practice on the ground. This guide takes account of the feedback received from the first edition at annual meetings of The Union's Nurses and Allied Professionals sub-section Best Practice Implementation Working Group held during The Union's annual World Conference on Lung Health and from the use of the guide as a key part of the International Council of Nurses (ICN) TB/MDR-TB Project courses on Training for Transformation of the Care of Patients with TB and MDR-TB which has been run in 17 different countries.

# 2

## Implementation of best practice: How to use this guide

This guide is intended to be used as a tool for practice development, education and research, which will in turn lead to the development of evidence-based practice in relation to the care of people affected by TB. The aim is to improve the quality of care through a recognised system of standard setting and clinical audit which is well-established in the nursing profession. These standards are rooted in the practice of those providing face-to-face care on a daily basis and can be used directly by individual healthcare providers. As such they are distinct from the International Standards of TB Care,[9] which are more theoretical and consist mainly of standard statements and associated rationales.

### 2.1 Standard setting

Within a nursing context, it is useful to set standards for best practice to clarify what is to be achieved with regard to care being delivered to patients and those closest to them. Standard setting provides the opportunity to plan patient care based on available information (including research and guidelines), the local environment and available resources. It also offers an objective way of finding out whether measurable outcomes have been achieved.

It is essential that 'levels of excellence' are defined locally, and it is intended that these standards should both be used as a guide and adapted to the local setting. This is essential to foster a sense of ownership and promote professional credibility.[10] The standards described in this guide are intended to be adaptable to low-income countries, but the same principles can be used to develop additional standards to reflect more extensive services offered in places where resources are available to offer a wider range of diagnostic and treatment options.

The Marsden approach to standard setting[10] which is used in this guide, provides a framework which consists of the standard statement, rationale, resources, professional practice and outcomes (Table 2.1). This in turn allows standards to be based on available evidence while being appropriate to the local environment.

### 2.2 Developing best practice standards in the field of TB Care

The standards described in this guide are based on best practice in areas of high TB prevalence. They have been developed in collaboration with experienced nurses who are involved in caring for patients with TB and coordinating TB care and control measures on the ground. The aim is to provide realistic guidance for those involved in providing care to people affected by TB in low-income countries and other poorly resourced settings.

Special attention is paid to the need for accurate documentation, which is as essential to good patient care as it is to performance management through quarterly reporting. Each standard has a measurable outcome, which should be made specific to the local setting and audited regularly for quality assurance purposes.

**Table 2.1: The Marsden framework for standard setting**[10]

| *Component* | *Definition* |
|---|---|
| Standard statement | A clear and concise statement outlining the level of care to be reached for patients with a defined problem or need. |
| Rationale | Support needed based on available evidence regarding the problem in question and the level of care to be achieved. |
| Resources | What is required to meet the defined level of care:<br>People<br>• Knowledge and skills required by healthcare professionals<br>• Availability of relevant training and education<br>• Engagement of family members, patient support groups, and civil society organisations according to patient's individual needs and preferences<br>• Required members of the multidisciplinary team<br>• Role and function of the management in relation to meeting the requirements.<br>Equipment and supplies<br>• Availability of specialist and non-specialist items required<br>• Availability of written materials for patients and the people supporting them<br>• Protective equipment<br>• Policies and procedures available to staff.<br>Environment<br>• Patient environment (e.g., privacy, possibility for isolation, etc.)<br>• Staff environment (e.g., space for both clinical and administrative work; storage, etc.). |
| Professional practice | • Critical elements of assessment, planning, implementation and evaluation<br>• Highlighting specific aspects of professional practice relevant to the patient's problem/need<br>• Suggestions regarding to the identification of and referral to the appropriate care providers including family members, local NGOs and civil society organisations<br>• Documentation required in terms of patient records and for evaluation purposes. |
| Outcome | Expected results of the planned intervention which can be assessed through:<br>• Patient satisfaction<br>• Staff satisfaction<br>• Documentary evidence (e.g., patient records, registers). |

### 2.3 Clinical audit

The first step to improving the overall quality of patient care is to look at the strengths and weaknesses of the existing service. A clinical audit provides a systematic approach to evaluating current practice against agreed standards and making changes with a built-in process for evaluation. Healthcare workers using this guide will discover that much of their practice reflects what is described in the standards and find it helpful to think of it as akin to the nursing process which nurses are trained to use for **assessing** patients' individual needs, **planning** care, **implementing** the plan and **evaluating** the outcome. The idea is to identify areas that could be improved and ask:

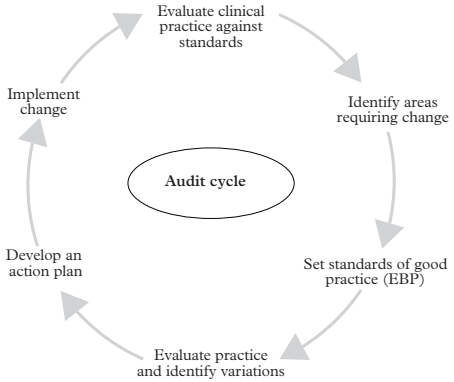
*What are the priorities for improvement?*

Which priorities present the best possibility for practice development under current circumstances, e.g., what capacity is there for change?

*What motivation is there to make a change?*

The key components of clinical audit are: the setting of evidence-based standards; assessment of current practice against these standards; identification of shortfalls; development of practice to address these shortfalls; and evaluation of changes made against set standards (Figure 2.1). It is seen as a cyclical process to emphasise the fact that practice development is a dynamic process and progress needs to be constantly re-evaluated.

**Figure 2.1: Audit cycle**[11]




**Source:** Adapted from Bryar, R. M. & Griffiths, J. M. (eds.) 2003. *Practice development in community nursing: Principles and processes.*

**It is important to assess a service's strengths and build on these to motivate staff and support small changes, which are likely to show improvements within a short period of time.** This is an important way to achieve successful change in the first instance and give staff confidence and enthusiasm to look at other areas which need to be improved. Failure is more likely if expectations are unrealistic or the challenge is too great, and failure can lead to poor motivation and demoralisation.

The scale of the task will depend on:

- strong leadership
- local support
- staff capacity and
- motivation.

Before starting to implement any of the standards, it is necessary to identify which elements need to be adapted so that the standard in question is relevant and understandable within the local context (e.g., ensure that terminology reflects what is commonly used). Tools to help guide this step of the clinical audit are outlined in Box 2.1. Consider the organisation's supervisory structure and ensure the appropriate authorities (managers) are involved in recruiting someone to lead and coordinate the team who will contribute to the audit. Ideally, the clinical audit team would involve representatives from various disciplines including a patient representative if appropriate.

**Box 2.1: Sample tools for practice assessment, planning and implementation**

| *Sample Tools* | *Purpose* | |
|---|---|---|
| **STEP 1: Assessment and pre-planning** | To help the user systematically assess current practice, the impact of current practice on service delivery, identification of resource gaps and practice changes needed. | Appendix 1 |
| **STEP 2: Planning and implementation** | To help guide the planning process ensuring sufficient detail is included in the plan regarding resources required, specific actions to be taken to improve current practice, who is responsible and target dates for accomplishing actions. | Appendix 1 |

Training will inevitably form an important part of this process if gaps in essential knowledge and skills are identified. This holistic approach to practice development, however, looks at the practice environment and resources available, as well as the training needs. It is often assumed that a training event will change practice without any real consideration being paid to the trainees' situation or barriers that may be faced when trying to implement recommended practices.

Participatory education including group work and discussion with regular follow up may be more effective than a traditional classroom approach, which simply focuses on the dissemination of information.[11] Healthcare providers caring for TB patients will know that simply telling a patient how to take their medication without taking into account any barriers they may face to doing so and without offering any support will often lead to poor adherence. It is just as difficult for healthcare workers to change their practice without taking into account the conditions under which they have to work.

### 2.4 Evaluation of the care given to people affected by TB

Evaluation can often be challenging, especially if the outcome is different from what was predicted, but it is vital that it is carried out to see what works and what does not, and to identify possible problems that need to be addressed. Sometimes an unpredicted outcome can lead to a stronger intervention or service than initially expected. It may be tempting to introduce a particular intervention without planning to evaluate it because there is good evidence that it has been effective elsewhere. The problem with this is that the process of developing good practice through standard setting is context specific, and the intervention may need to be altered to become effective in a different setting.[12]

- In TB programmes and service delivery, nurses routinely collect data relating to case finding and treatment outcomes. This routine data could be useful in evaluating a number of different practices, for example:
  - Quarterly cohort analysis gives regular feedback about overall programme performance and can highlight problems regarding rates of sputum conversion, loss to follow-up, etc. The Unit Coordinator responsible for undertaking the analysis can work through the outcome data with the relevant healthcare workers in order provide a clearer picture about what is happening locally, including signs of service strengths and weaknesses
  - Laboratory registers compared with TB registers can evaluate how many sputum smear-positive cases actually started treatment and within what time period and/or how many with a risk factor for drug resistance (e.g., prior treatment) had a specimen sent for Xpert® MTB/RIF (or culture) at the time of treatment initiation
  - Treatment outcome data can be tracked pre- and post-intervention to evaluate for effectiveness of the intervention. They can also highlight and help monitor rates of loss to follow-up, failure or death
  - Patient record / treatment cards can show treatment adherence patterns.

Basically, if a problem is identified, a change in practice can be implemented and its impact measured using the same data as well as considering other means of evaluation, such as patient experience and/or staff reaction, depending on who is involved in the change.

### 2.5 Practice development as a means of carrying out operational research

The process of undertaking the initial assessment, planning changes, implementing those changes and carrying out an evaluation can be approached as a pilot project and written up as a research paper. Research projects tend to follow a similar format: identify the problem or question; review the relevant literature (books and articles) which has something to say on the subject; explain what you plan to do, how you are going to do it and why; record and analyse results/findings and discuss what happened. This in turn will begin to inform evidence-based practice and encourage others to use similar processes.

If this is the intention, then the collection of baseline data is essential to evaluate any changes seen following the intervention. TB programmes routinely collect data on all aspects of care which could be used to guide and answer research questions. If possible and feasible, it might be helpful to link with a local nursing or social research department. With clear and rigorous planning, it might even be possible to apply for grants, which are sometimes made available through NGOs or government departments.

# 3

## Identifying an active case of TB

The diagnostic phase is critical to effective case finding. By the time someone with symptoms arrives at a health facility, he or she has already realised that something is not right and decided to seek help. If that person is given confusing advice or not treated well, he or she may never return or follow any instructions given. The two standards in this section focus on obtaining an accurate diagnosis while maintaining the cooperation of the patient. It should be remembered that the accuracy of the diagnosis relies on the quality of the sputum sample and the approved first-line diagnostic test. This will in most cases be acid-fast bacilli (AFB) smear microscopy, but in many countries, will be an approved rapid molecular test such as Xpert MTB/RIF. Regardless of the diagnostic test used, identifying a case of TB will rely on the HCW's knowledge of TB and the care and information provided to the patient and his or her family members. The capacity of lab staff and the quality of lab processes also play an important role in identifying case of TB.

### 3.1 Standard: Assessment of a patient who might have TB

#### 3.1.1 Standard statement

A good relationship is developed with the patient while symptoms, signs and risk factors consistent with TB are assessed and investigated appropriately.

#### 3.1.2 Rationale

*The importance of early diagnosis*

One of the key ways of controlling TB is to identify and treat the disease in its early stages. This prevents the spread of TB bacilli because the sooner someone is diagnosed and started on appropriate treatment the shorter the time they remain infectious. It also benefits the patient physically because organ damage may increase the longer the disease remains untreated.

*Maintaining a safe environment*

People are most infectious before they are started on treatment, and staff, patients, family members, and other visitors all require protection from exposure to disease. This can best be achieved through different measures:

- Triage and fast-track coughing patients entering health facilities
- In high-burden TB settings, screen all patients entering health facilities for common symptoms of TB: cough of any duration (for patients living with HIV) or cough of more than two weeks (for individuals not living with HIV), fever, night sweats, loss of weight and haemoptysis (coughing up blood) using a simple screening tool (see Appendix 2). Patients with any of the above symptoms should be asked to produce a sputum sample to test for active TB[13]
- Reducing the number of TB bacilli people are exposed to overall by ensuring proper ventilation in waiting areas and consulting rooms

- Reducing the risk of transmission by asking patients who are coughing to cover their mouths when they cough and to safely dispose of sputum and/or by asking people who may have TB or are known to have TB to wear a surgical mask while actively coughing and not on treatment or early in their course of TB treatment
- Reducing the length of time spent in general waiting areas through cough triage where people who are coughing are shown to a well-ventilated designated waiting area and seen promptly
- Protecting healthcare providers who are routinely in contact with patients with N95 or FFP2 respirators
- Providing antiretroviral therapy (ART) and isoniazid preventive therapy (IPT) for healthcare workers (HCWs) living with HIV.14

*Identifying someone who may have TB*

**Special groups at risk for TB**

WHO has identified several key populations that are at an increased risk of developing TB disease. Some of these key groups include, but are not limited to, individuals with HIV or diabetes mellitus (DM), people who use tobacco products, children, the elderly, miners, prisoners, mobile populations, healthcare workers, etc.[13] More detailed information can be found on the StopTB Partnership website at http://stopb.org/resources/publications/.

HIV: HIV is a leading risk factor for developing active TB, and TB is the most common opportunistic infection among people living with HIV. Those living with HIV are 26 times more likely to develop TB than those who are HIV negative.[15] TB is a leading cause of mortality among people living with HIV and more die from TB than any other condition, accounting for about 24% of all HIV-related mortality.[16]

Diabetes: Patients with diabetes have a three-fold increased risk of developing TB if exposed, and WHO estimates that 15% of patients with TB also have diabetes. Moreover, the WHO estimates the global prevalence of diabetes among adults to be more than 8%.[17]

People who smoke tobacco: Those who smoke tobacco are estimated to have a more than two-fold increased risk developing and dying from TB. It is estimated that approximately 20% of the global incidence of TB may be linked with smoking tobacco even in the absence of drinking alcohol or other risk factors like socioeconomic risk factors. In addition, among patients with TB who smoke tobacco there may be a two-fold risk of having recurrent TB. WHO and The Union recommend screening TB patients for smoking behaviors and to include smoking cessation counseling.[18, 19]

Miners: Miners are at an increased risk of respiratory illnesses including tuberculosis due to what is being mined and airborne particles/pollutants, poor ventilation in the mines and living quarters, cramped working conditions and length of exposure. Miners are exposed to many airborne particles like silica dust which has been known to increase the risk of developing TB and other lung diseases.[20]

Prisoners: Prisons around the world are often overcrowded which greatly increases the risk for prisoners to develop TB. Some estimates indicate that prisoners have more than a twenty-fold increased risk of developing TB infection and disease than the general population. This increased risk is due to overcrowding, poor ventilation (due to security reasons there is little natural ventilation), poor nutrition and HIV. In some studies, the rate of TB in prisoners has been estimated to be nearly 1,000 times greater than the rate in the general population.[21]

Healthcare workers: HCWs have a two- to three-fold increased risk of developing TB compared with the general population due to frequent and prolonged exposure to undiagnosed persons with TB or DR-TB in the workplace. It is also estimated that in some sub-Saharan countries the rate of HIV in HCWs is approximate to the rate in the general population, placing these HCWs at an even greater risk of developing TB. In many low-resourced settings, there are limited infection control measures in place to protect HCWs in the workplace. HCWS should know their HIV status and be provided ART and IPT to prevent TB, and all HCWs should be screened regularly for TB and adhere to infection prevention and control measures.[22-24]

In high-burden settings it is recommended to screen individuals presenting at health facilities, especially individuals with any of the risk factors listed above.[13]

It is recommended that any person with one or more of the following symptoms be evaluated for TB:

- persistent cough for two or more weeks (or cough of any duration in those living with HIV)
- loss of appetite
- weight loss
- fatigue, a general feeling of illness (malaise)
- night sweats
- fever
- sputum which may contain blood (haemoptysis)
- shortness of breath or
- chest pain.

These symptoms are even more indicative of TB if the person has had contact with someone known to have the disease. Ensuring healthcare workers have an adequate level of awareness about TB symptoms will help prevent cases being missed. Extra-pulmonary TB may or may not be accompanied by a cough, and other symptoms may be present as well including pain and swelling or deformation of the site affected. Special care should be taken when assessing children as symptoms vary and they seldom produce sputum, which means TB can be more difficult to diagnose in children.[2]

*Assessing risk of drug resistance*

The development of drug resistance is often a result of mismanagement of drug-susceptible TB (often called acquired drug resistance or amplified drug resistance) by healthcare workers, due to health system issues (lack of appropriate diagnostics, drug stock outs, etc.) or poor adherence by patients due to cost or adverse drug effects, to name a few. These factors have severe consequences to both the patient and the community. The prevention of DR-TB must have the highest priority in the care of every patient with TB. The most important first step in preventing drug resistance is the correct diagnosis and treatment of the patient when they first present to the health service. Before ordering any tests it is essential to find out:

- if the patient has previously taken any treatment for TB, and if so, what medications and for how long and
- if he or she has any knowledge of being in contact with someone who has DR-TB either at home, at work, or in a social setting.

Individuals at highest risk for DR-TB are those who have previously been treated for TB. It is critical that these patients be correctly diagnosed prior to being given treatment and that they are prescribed an appropriate second-line regimen if found to have rifampicin-resistant TB (RR-TB), multidrug-resistant TB (MDR-TB) or extensively drug-resistant TB (XDR-TB).

**Please note:** In resource-limited settings, the regular directly observed treatment (DOT) facilities where patients presumed to have MDR-TB are identified may not be able to provide the care needed for the management of MDR-TB. There is a need in such situations to establish a referral system between the DOT facilities and specialized facilities for MDR-TB.

*Ordering the appropriate tests*

It is important to order the appropriate tests as soon as possible to prevent delays in diagnosis, and to use resources appropriately, particularly in low-resource settings. The most widely used test for identifying active TB is sputum smear microscopy for AFB, as this will identify the people with the highest levels of TB bacilli in their sputum. A rapid molecular test, such as Xpert MTB/RIF, has been approved by WHO and adopted as the first-line test in many countries with a high incidence of HIV and/or MDR-TB which is effective at detecting TB in immunocompromised patients as well as rifampicin resistance.[25] Chest radiographs may be useful in diagnosing the disease in the smear-negative patient, but their interpretation can be unreliable in identifying active TB, particularly in the immunocompromised patient.[26] If there is a risk that a person may have DR-TB, in particular for anyone who has been previously treated for TB or has risk factors for DR-TB, the sample should be sent for rapid molecular testing such as Xpert MTB/RIF and/or culture or line probe assay (LPA) for drug-susceptibility testing (DST), if it is available.[5] WHO also recommends a new second-line LPA to detect second-line drug susceptibility. This test will be required to enrol patients on the new short-course treatment for DR-TB.[27]

*Assessing the patient's thoughts and feelings about TB*

TB can be a stigmatising disease, even in the absence of HIV, and it is essential to assess the patient's attitudes and feelings towards the fact that he or she may have the disease to respond appropriately. Various factors may affect the patient's response to the possibility that he or she may have TB including:

- his or her knowledge and understanding of the disease
- any experience he or she has either personally or through family or friends who may have suffered from it
- how he or she thinks family or community members might react
- how the patient is treated by the healthcare workers.

**Please note:** if a rapid TB diagnostic test is being used, it is important to prepare the patient for the possibility of a diagnosis of DR-TB. This will require extra counselling in order to ensure the patient is confident to return for results.

*Building trust*

A good relationship needs to be developed at the earliest contact with the patient so he or she has confidence in the service and trusts the information given. This is always essential. The patient who does not believe that TB can be treated may see no reason to come back for further appointments. In areas where the patient has to pay for investigations it is essential that he or she understands the need for the tests – especially the need for more than one sputum test, HIV testing, etc. ***As with any other condition, the patient's confidentiality must be maintained throughout and the patient should be reassured that this will be the case. If a patient feels that people may find out what they are being tested for, they may feel nervous about coming back for results.***

### 3.1.3 Resources

- Staff in healthcare facilities, where people are most likely to present with symptoms, are alert to TB and levels of the disease in the local community regarding:
  - drug-sensitive TB
  - drug-resistant TB
  - extra-pulmonary TB
  - HIV
  - diabetes mellitus.
- The healthcare provider assessing the symptomatic patient:
  - has been given the responsibility and appropriate training to do so
  - is familiar with the signs and symptoms of TB
  - is aware of what tests are available and is able to order the correct tests or refer the patient to an appropriate facility
  - is familiar with the treatment available for TB and DR-TB
  - can assess each patient's response to the fact that he or she may have TB and react accordingly.
- Can assess each patient for comorbidities (HIV, DM, etc.) and treat or refer to an appropriate provider or facility.
- The patient, who is very sick, can be referred to an appropriate medical officer.
- If the facility cannot provide care for people who may have DR-TB, a system is in place to assess and coordinate support for those who need to be referred to a specialist facility *and weekly checks are made to ensure that those referred have arrived.*
- A safe environment is maintained at all times:
  - Staff can identify and triage people who are coughing and fast track the patients
  - Waiting areas and consulting rooms are well-ventilated
  - Posters are displayed with illustrations to encourage good cough hygiene and HCWs encourage people to follow the instructions
  - Instructions and equipment are provided to encourage people to dispose of sputum safely and HCWs reinforce these instructions
  - Surgical masks are available for coughing patients and those being evaluated for TB
  - N95 (or FFP2) respirators are available for staff who are in contact with people with infectious or potentially infectious TB.
- There is sufficient privacy to maintain patient confidentiality during assessment and follow-up consultations
- The patient who needs sputum examination can be given accurate and clear instructions as to how to produce good samples as well as being made to feel comfortable and confident in the services offered
- The patient can be given accurate and clear instructions on how and where to collect the results of his or her examinations
- Information is provided in a way that the patient and family members can understand and is provided in the appropriate language for the patient and his or her family
- TB diagnosis and treatment are available free of charge and this fact is emphasised to the patient
- Health facilities should have a steady and reliable supply of assured quality drugs, forms, registers, personal protective equipment (PPE), sputum cups, diagnostic reagents, etc.

### 3.1.4 Professional Practice

The healthcare provider will:

- Begin to build a relationship with the patient by listening to his or her concerns and remaining non-judgmental
- Reassure the patient that all personal information given will remain confidential and ensure that patient information is secured appropriately and patient confidentiality is maintained
- Take the patient's personal details including name, home and work address, contact telephone numbers, as well as contact details (mobile number) for family members and friends
- Take a full medical history, including duration of symptoms and presence of other comorbid medical conditions (e.g., HIV, diabetes, etc) and behaviours like smoking (using tobacco) or substance use
- Assess how likely it is that the patient may have TB
- Explain to the patient what tests will be done, how the tests will be done, and the reasons for doing them
- Inform the patient as to when to expect the results to be available and how these results will be conveyed (e.g., during a subsequent appointment at the health facility, a telephone call from the HCW, etc.)
- Check to see if each patient came back to collect his or her results
- Check the laboratory register and the TB patient register on a weekly basis to ensure that all those with a positive sputum smear or positive Xpert MTB/RIF result have started treatment[2]
- Offer relevant health education about TB and how to prevent transmission. Health education messages should be given according to what a patient can digest at any given time to avoid overwhelming the patient
  - One-to-one: be sensitive to the patient's response to being tested for TB, answer questions as clearly as possible and reinforce the fact that effective treatment is available and free-of-charge
  - Family: assess the family's reactions and be ready to answer questions, correct misconceptions and emphasise the need to support the patient, instruct on TB symptoms to watch for and to bring in for evaluation any family or community member who may be displaying symptoms.
  - Group: give health education sessions to waiting patients including a question and answer session
  - Media: videos, posters, handouts, brochures, web-based and social media as available.

### 3.1.5 Outcome

Patients will be diagnosed without delay and will already have some understanding about the disease and its treatment. Patients will feel confident in the service, which will be demonstrated by their return for results and follow-up appointments. This can be measured by the correspondence between the laboratory register and the TB patient register.

## 3.2 Standard: Sputum collection for diagnosis

### 3.2.1 Standard statement

The patient produces good quality sputum specimens, delivers them to the appropriate place at the appropriate time and returns for the results.

### 3.2.2 Rationale

*Good quality specimens*

Good specimens, i.e., are sufficient (minimum half a teaspoon: 3-5ml) and containing solid or purulent material,[28] are required to give the laboratory technician the best chance of detecting TB bacilli via smear microscopy, Xpert MTB/RIF, LPA or culture for the service to identify the most infectious patients.

If the sample is inadequate (e.g., saliva only) or contains food particles, it may not be possible to detect AFB signifying TB even if the patient is infectious.

*Accurate labelling and completion of sputum request forms*

Accurate documentation is essential to save time and prevent errors. It is vital that the correct information is written on the sputum request form[2] and that the side of the sputum container is clearly labelled to ensure that there is no confusion either when the specimen goes to the laboratory or when the result comes back. If a mistake is made during this process, the patient may end up receiving the wrong results and/or being given the wrong treatment. The request and reporting form for ordering culture and DST is necessarily more complex than a straightforward AFB microscopy request form but the same principles apply. All fields should be accurately and clearly filled to avoid mistakes in the interpretation of results.

*Minimising delays*

Every effort should be made to ensure that specimens are delivered to the laboratory and then examined without delay; preferably within three days.[29] This is essential in preventing the continued spread of TB. Close cooperation with the laboratory produces quick results, resulting in the sputum-positive patient being started on the correct treatment as soon as possible. For instance, delays can occur and patients can be lost, if they are expected to collect results from the laboratory themselves. It is also important that the HCW involved in caring for the patient gives and explains the results rather than a laboratory technician. This will enable the patient to ask questions and get accurate information about the treatment and care provided. The use of telephones, text messages or other m-health applications can be useful to communicate results and/or send requests for patients to return to the clinic to receive their results.

*Precautions before and during specimen transit (transportation)*

As well as ensuring that specimens are transferred to the laboratory without delay, specimens collected for culture and DST may need to be protected and handled in a special way (e.g., transported in a cold box) to reach the laboratory in good condition for examination. Instructions should be provided by the laboratory and they must be closely followed to ensure the specimen does not deteriorate in transit. Specimens should be sent to the lab as soon as possible, but less than three days.

*Building a good relationship with the patient*

The patient may be very nervous at this stage and feel overwhelmed with information. It is important to check that the patient understands the process and can raise any problems he or she might foresee. There is a real risk that the patient may not return future specimens or return for results if he or she feels unwelcome or confused. Beginning to develop a good relationship with the patient at this stage will help to ensure his or her cooperation in the future.

*Patient and staff safety*

All precautions possible need to be taken to prevent transmission and protect patients, visitors and staff (see Standard 3.1). Implementing appropriate infection control measures will prevent further human suffering from TB and save valuable resources. Particular care needs to be taken when healthcare providers are supervising the collection of sputum samples. Although there are risks associated with sputum collection, quality samples can be collected safely with minimal risk to the HCW. Healthcare workers assisting patients with sputum collection should wear an N95 (or FFP2) particulate respirator and collect the specimen in a well-ventilated area and away from others.

### 3.2.3 Resources

- A functional, well-stocked and staffed laboratory is able to carry out sputum smear microscopy and/or Xpert MTB/RIF on a daily basis[2] with a system in place for quality assurance
- The healthcare provider responsible for ordering tests has the necessary knowledge and skills to instruct the patient as to how to produce a good specimen and when and where to deliver it
- Sufficient and appropriate sputum containers are available for:
  - sputum smear microscopy or Xpert MTB/RIF (wide-necked, **clear plastic**, disposable containers with screw-top lids)
  - culture and DST (50ml sterile plastic conical tubes with a screw cap (Falcon type)[3]
  - rapid molecular tests (e.g., specific cartridges used for Xpert MTB/RIF).
- Sputum request forms and laboratory registers are available and completed as soon as possible by competent staff members
- There is a place to store specimens appropriately and safely if they are kept in a clinical setting before being sent to the laboratory (e.g., at the right temperature, out of direct sunlight)
- If the laboratory is not on-site, transport should be available to deliver the samples safely and as quickly as possible. If transport is not available, the patient can be given clear instructions as to precisely where specimens should be delivered
- Quality assured laboratory services must be in place to ensure prompt examination of sputum specimens and feedback of results, preferably with someone from the management unit routinely collecting the results or the results transmitted electronically (SMS, computer, etc.) or by telephone
- A named staff member is responsible for coordinating the process with a deputy to cover in case of absence
- Good communication is maintained between the laboratory and the management unit/clinic.

### 3.2.4 Professional practice

Healthcare providers involved with the collection of sputum specimens should adhere to the following principles:

- A specimen collected with explanation, demonstration and support and supervision of a competent person is likely to be of better quality than a specimen collected without supervision
- Sputum collection should take place in the open air (that is, outdoors in settings where the climate permits). If not possible, like in cold climates, it should be collected in a well-ventilated room used only for this purpose. Alternatively, the patient can be instructed to collect an early morning specimen at home and to deliver it to the appropriate place the same day it is collected
- The patient is likely to prefer to be out of sight of other people when he or she is producing a sputum specimen
- A minimum of two specimens (one spot collected under supervision at the health facility and one early morning specimen collected at home and delivered by the patient)[2] should be sent with fully completed sputum request forms.
- In some settings, national guidelines still require three specimens if using smear microscopy. However, WHO recommends two sputum specimens.[4] In settings where Xpert MTB/RIF is used, only one on the spot sputum specimen may be required per the national guidelines. (See Table 3.1)
- The same principles followed when collecting specimens in the hospital or healthcare facility should be applied when giving someone instructions about how to produce a good specimen at home, in addition to information about delivering the specimens to the right place at the right time
- Sputum specimens produced in the early morning offer the best chance of achieving an accurate diagnosis (if the patient is hospitalised, two early morning specimens should be taken)

- If the patient is very sick, he or she should be referred to an appropriate healthcare provider for further investigation
- A mechanism should be in place for the feedback of results managed by a designated person who maintains good communication with the laboratory to minimise delays. Delays can be reduced significantly if the laboratory reports directly to somebody within the management unit/clinic who can disseminate this information
- If one or more of the sputum samples is positive, the person is registered as a TB patient and treatment is started (see standard 4.1)
- If the results from all of the initial samples are negative but symptoms persist, the patient should be referred to a competent medical officer for further investigation. If diagnosed with TB, the patient will be registered as a sputum smear-negative case and started on treatment.

**Table 3.1: Best practice for sputum collection**[29]

| |
|---|
| **Labelling** |
| • The body of the container is clearly labelled, before it is used |
| • Details should include the name/code of health facility and the name of the patient, the date the sample was received and whether it is sample 1 or 2 (this information may vary but should be consistent). |
| **Sputum collection** |
| • The reason for collecting the specimen is explained to the patient |
| • Each step is explained clearly and slowly in language the patient can understand |
| • The patient is encouraged to ask questions and clarify anything he or she does not understand |
| • The patient is encouraged to rinse his or her mouth with water, especially if they have been eating food, before coughing up sputum and spitting it into the container |
| • The clean (whether new or sterilized) labelled container is given to the patient |
| • The patient is asked to be careful to direct the sputum into the container to avoid contaminating the outside for hygienic and safe handling |
| • The healthcare worker demonstrates a deep cough from the bottom of the chest, beginning with deep breathing |
| • The healthcare provider supervises the collection standing behind the patient |
| • The lid on the container is closed (screwed on) carefully and tightly |
| • The specimen is checked by the HCW with the patient present – if it is insufficient (e.g., saliva only) the patient is asked to cough again and add to it |
| • The HCW thanks the patient when a good quality specimen has been received and explains once more to the patient how he or she will receive the result. |
| **Prevention of transmission** |
| • The healthcare worker supervises the collection wearing a N95 (or FFP2) particulate respirator standing behind the person attempting to produce the sputum |
| • The patient and the HCW wash their hands with soap and water after collecting the specimen |
| • Ideally there should be a separate well-ventilated area for sputum collection, preferably outside the building avoiding the use of the toilets |
| • Care should be taken during the processing and disposal of the sputum specimen. |

**Table 3.1: Best practice for sputum collection**[29]

| |
|---|
| **Sputum storage** |
| • The specimen is sent to the laboratory as soon as possible after collection |
| • For samples sent for culture and or LPA for DST, it is essential that the samples are stored between 2-8 degrees Celsius and transported in a cold pack |
| • The date the specimen was collected and sent to the laboratory are recorded |
| • If necessary, the patient is advised how to store a sputum specimen safely at home to prevent contamination, i.e., the lid is tightly closed and the container is kept out of the reach of children and out of direct sunlight. |
| **Documentation** |
| • The specimen is categorised as pre-treatment (diagnostic) or follow up |
| • The sputum examination request form is completed accurately and the reason for the request is clearly marked, i.e., for diagnosis or follow up (indicating the month) of treatment[2] |
| • The laboratory register is completed clearly and accurately[2] |
| • Dates of taking the specimens are entered into the laboratory register, the TB register and the patient's treatment card as appropriate |
| • Dates of results and the results themselves are recorded promptly and accurately into the laboratory register, the TB register and the patient's treatment card as appropriate |
| • Any positive result is recorded in red ink. |

### 3.2.5 Outcome

The relevant number of good quality sputum samples will be received by the laboratory for investigation. A system will be in place (including an agreed turnaround time from receiving specimens to reporting results) to ensure that results are reported back accurately and without delay. From the laboratory and other TB registers it will be possible to see how many specimens were examined per patient and the percentage of positive results among patients coming for diagnosis or for follow up.

# 4

## Starting treatment: caring for patients, their families and close contacts

Treatment should start as soon as possible after bacteriologically confirmed or clinical diagnosis is made. Before treatment is started, it is essential to assess each patient for the risk of drug resistance and carry out or refer for further tests if required according to local policy. The care described in the following standards is based on the patient receiving treatment according to a regimen recommended by the WHO.[4, 5, 30]

Research has shown that taking medication according to instructions for long periods is NOT a normal human behaviour, and the patient requires support to successfully complete the necessary course of treatment.[31] The standards presented in this section focus on providing physical, social and psychological care for the patient at the point he or she receives the diagnosis and starts treatment. The aim is to maximise the patient's ability to adhere to treatment.

It is essential that all patients diagnosed with TB are registered at an appropriate management unit so that their progress can be routinely monitored and programme performance can be assessed. Several TB treatment facilities may be linked to any given management unit and/or patients may attend the management unit itself for ongoing care and treatment. However services are organised, all patients should be registered at the management unit which covers the area where their treatment facility is located. There should be a TB Coordinator in each management unit who has a supervisory role and is responsible for ensuring that all TB activities are carried out correctly throughout the unit from case finding to treatment monitoring and documentation. The coordinator has a very important part to play in recording and reporting and checking that all the registers are up-to-date and patients are receiving the correct care according to their results. For instance, those diagnosed have been started on treatment and those who have completed the intensive phase have been tested before moving on to the continuation phase. They are also responsible for enabling adherence by encouraging good communication with patients, assisting with accommodation for patients who are far from home and coordinating the prompt follow up of any patient who does not attend his or her appointment.

### 4.1 Standard: Registration and care of newly diagnosed TB patients

#### 4.1.1 Standard Statement

Each patient is registered appropriately, started on an appropriate approved and quality assured treatment regimen and given practical advice, support and information according to their individual needs and concerns.

#### 4.1.2 Rationale

*Identification of the appropriate management unit*

For patients who are diagnosed with TB in institutions where there is not a TB management unit, it is necessary to identify the management unit where the patient will be referred after discharge. Similarly, TB centres can be overburdened by large numbers of patients.

This presents difficulties to both the unit that struggles to care for the large numbers of patients as well as to the patients who often have to travel long distances to access care. Costs in terms of time and money can become prohibitive to the patients, who find it difficult to attend for treatment, and for the unit which does not have the capacity to trace the patients if they do not attend. That may lead to interruption of TB treatment and should be prevented in all possible ways. Once diagnosis is made, patients should therefore be given the option to choose to be referred to the management unit most convenient for them. This process should occur as soon as possible.

For TB patients referred to a management unit (either because treatment is not available where the diagnosis was made or because it is more convenient for the patient), it is essential to keep a record in the centre where the diagnosis of TB was made to provide a means for checking that patients have been registered and started treatment at the appropriate management unit. This record should ideally be kept in the laboratory register.

*Clear, accurate and timely documentation*

All documentation including the TB register, DR-TB register, the treatment card and any patient-held card must be completed clearly and accurately. The sooner the information is recorded, the more likely it is to be accurate and the less likely it is that results and other important details will be omitted.

It is important to get details of the patient's address as well as details such as mobile phone numbers of a relative or close friend through whom the patient can be contacted. The earlier this information is documented the better, in case for some reason the patient does not attend and needs to be traced (see Standard 5.2). Some patients may be reluctant to give accurate contact details (address and mobile phone numbers) at first and may only do so once they have gained trust in the service, so it is useful to check regularly if any of the details have changed or are due to change.

*Identifying and recording the appropriate treatment category and dosage of drugs*

If TB is treated inadequately, drug resistance may develop. If someone has TB which is already resistant to one or more first-line drugs, the risk of resistance to other drugs is even greater. It is essential to find out whether or not the patient has ever received treatment for TB before as this will determine how they need to be treated. Patients are categorised according to the treatment regimen they need, and their TB history needs to be recorded clearly in both their treatment card and the TB register. This not only ensures that the patient is given the correct treatment but it is also necessary for quarterly reports on patient progress and programme performance.[2, 3]

*Offering an HIV test*

Due to the close association between TB and HIV, it is recommended that all patients diagnosed with (or presumed to have) TB should be offered HIV counselling and testing to receive care for both diseases according to their needs. This is covered in more detail in Chapter 7.

In addition, due to the increased risk of TB among patients with diabetes, these patients should be screened for TB. Patients newly diagnosed with TB should also be screened for diabetes.[17]

*Assessing the patient's social and psychological needs*

**Newly diagnosed TB patients may be very anxious about their diagnosis. TB can often be a stigmatising disease and patients may feel isolated and rejected. It is essential that they begin to understand their condition and their treatment from the very beginning to avoid the risks highlighted in Table 4.1.**

A thorough assessment of the patient's psychosocial needs will enable the healthcare team to identify areas that are amenable to intervention and support. A diagnosis of DR-TB may be even more stressful to a patient

who may have heard information about the morbidity and mortality associated with DR-TB, so it is essential to talk to patients about their concerns and fears.

*Assessing the patient's knowledge and understanding of TB*

Each patient will have a different level of knowledge and understanding about TB depending on what they have already heard and whether they know someone who has had the disease. It is important to find out what they know so that they can be given the information they need, correcting misconceptions and concentrating on the areas they are most concerned about. Clearly sharing and explaining information about issues that are important to the patient supports the patient's adherence to treatment. The use of appropriate visual materials can be helpful but should never replace one-to-one discussion. Finally, the amount of information covered at any one time will depend on the individual patient's needs and concerns.

*Continuing to build a good relationship*

Being diagnosed with TB can be a very traumatic event in a person's life and presents many challenges for the patient and their family. A good relationship can be built by listening carefully to the patient. It is important at the beginning of treatment to create a time to counsel patients regarding their disease, the prescribed treatment, potential side effects and how the diagnosis and treatment may affect their lifestyle. This will encourage them to attend for treatment and follow-up visits. ***Spending time with patients early on can save time in the long run by preventing irregular attendance, loss to follow-up, treatment failure and prolonged treatment.*** Confidentiality is essential and the patient should again be reassured that confidentiality will be maintained throughout treatment so the patient can have confidence in the services offered.

*Addressing concerns about transmission of TB*

It is important to clarify what the patient understands about how TB is transmitted and correct any misinformation, as well as give clear and accurate information about how the disease is spread and how that risk can be reduced by good cough hygiene and ventilation. Concerns about people who might have already been affected need to be addressed and the patient encouraged to advise anyone he or she knows who is displaying TB symptoms to attend the nearest clinic to be assessed. Contact investigation is covered in more detail in Standard 4.3.

**Table 4.1: Potential emotional reactions and helpful responses associated with receiving a diagnosis of TB**

| *Potential emotional reactions* | *Helpful responses* |
|---|---|
| Patients feel intimidated | Create a welcoming environment and show interest in the patient's concerns. |
| Fear of:<br>• taking medications<br>• dying<br>• adverse drug effects<br>• experience of TB including DR-TB<br>• infecting others<br>• rejection and discrimination (stigma)<br>• loss of employment<br>• loss of accommodation<br>• being HIV-infected | Education involving:<br>• patient<br>• family<br>• workplace<br>• communities<br>• contact tracing<br>• counselling<br>• on-going support |

| *Potential emotional reactions* | *Helpful responses* |
|---|---|
| Denial/refusal | Information/Support (identify significant others, e.g., family members who can also offer support). |
| Other priorities which overshadow the disease | Offer tangible support – address problems identified by patient. |
| Emotional turmoil<br>• guilt<br>• anger | Address feelings<br>Check understanding and response to messages (patient and family). |
| Co-morbidities<br>• HIV infection and AIDS<br>• Diabetes<br>• Smoking<br>• Substance abuse | Work with other services if available.<br>Inform patient of local services which may offer assistance.<br>Offer HIV testing, counselling and ongoing treatment, support and care. |
| Lack of social support<br>• e.g., patients living alone | Identify potential support from friends or family, community groups, etc. |

### 4.1.3 Resources

In places where many patients tend to go to one large, well-known TB centre, a system should be in place for those diagnosed with the disease to be offered a choice of management unit to attend for ongoing care. They should then be referred to this management unit to be registered and commenced on treatment. The referral system should be monitored by the Regional Coordinator to make sure that the people referred arrive, are registered and receive treatment and care at the appropriate management unit.

- Treatment cards and TB registers must be available and the healthcare provider should know how to complete them clearly, promptly and accurately.[2]
- Good communication skills (Table 4.2) are needed to:
  - Assess the patient's existing knowledge about TB and its treatment
  - Give accurate information according to the patient's needs and understanding
  - Show that the service cares about him or her
  - Encourage the patient to return to the clinic as arranged
- Healthcare providers responsible for diagnosing TB are competent to choose and record the correct treatment regimen and commence the appropriate treatment or refer, if necessary, for DR-TB treatment according to local policy
- The healthcare provider has sufficient knowledge about the disease and its treatment to assess the level of information required by the patient and respond to their questions accurately
- Healthcare providers have access to appropriate reference literature on TB and its management
- Supporting information is available in leaflet form in the appropriate languages, which can be given to the patient to reinforce the main messages
- There is someone available if the patient has a problem and needs advice, and the patient has clear details as to how to get help if they need it.

**Table 4.2: Pointers for good communication**

- Listen carefully
- Use open-ended questions, e.g., those starting with 'what', 'how', 'why' and so on to encourage fuller responses
- Think about it from the patient's point of view
- Listen to and respect patient's beliefs, values, customs and habits
- Work together with the patient as an equal partner
- Smile and look at the patient when they are speaking and when you are talking to them
- Check with the patient that you understand by repeating back a summary of what he or she has told you
- Take a long-term view
- Use touch (e.g., squeezing or shaking the hand) if appropriate to reassure and show support
- Be aware of body language (e.g., be friendly and open but respectful)
- Use patient's preferred language wherever possible

### 4.1.4 Professional Practice

- Patients diagnosed in management units a long way from where they live will be referred to a unit which is more convenient and accessible to the patient for receiving treatment and follow-up care.
  - Patients should only be able to choose a management unit from an official list, and once a choice has been made, he or she should be given clear and accurate information about the need to register at that unit and start treatment as soon as possible
  - It is essential for the healthcare provider involved in this initial discussion to answer any questions the patient might have and ensure that the patient understands what he or she needs to do next and why
  - The healthcare provider must also document which management unit the patient has been referred to in the laboratory register or referral record. The system used may vary, but the nurse should follow the national guidelines
- The healthcare provider at the management unit where the patient is registered should carry out an initial assessment of the patient's past experience with TB, comorbidities, family and support network, and feelings and fears about treatment and its possible outcomes. Table 4.3 sets out the topics and questions which should be included in the early interviews with a patient recently diagnosed with TB. It is unlikely that it will be possible to cover everything at once, and it may be helpful to focus on areas which appear to be of particular concern. It is worth focusing on thoroughly assessing the patients as early as possible so problems can be addressed to keep patients motivated
  - Information and support are provided according to the patient's individual needs, ensuring he or she understands: TB can be cured; how TB is spread; precautions which need to be taken to prevent further transmission; how it is treated; the fact treatment is free-of-charge; the importance of regular, observed and full treatment; when and where he or she can get help; and the difference between harmful and harmless adverse drug effects and what to do about them
  - The healthcare provider should discuss expectations of the treatment duration, identify potential barriers to completing treatment, give emotional support, and identify if the patient needs to take their medicines in another "TB treatment facility" than the management unit itself
  - A plan of care is agreed between the healthcare provider and the patient based on the patient's individual needs and concerns
  - The patient is categorised appropriately and registered correctly[2]

- The TB register and the patient's treatment card are completed with all the necessary information including dates, contact details, unit details, site of disease, results, treatment category, treatment regimen, HIV status and other comorbidities like diabetes, and TB treatment facility for DOT[2]
- The patient is assessed regularly (e.g., at agreed intervals while on DOT or every time they return to collect medication during the continuation phase) regarding the impact of TB and the treatment on the patient and their family.

**Table 4.3: Topics to be covered in early patient interviews**

| *Topic* | *Questions* |
|---|---|
| Attitude to diagnosis | • How do you feel about being diagnosed with TB?<br>• Do you have any questions or concerns?<br>• What will your family and closest friends think? |
| Knowledge about TB | • What do you know about TB?<br>• What have you been told about this disease?<br>• How do you think people get TB?<br>• What questions or concerns do have at this time? |
| History of TB treatment, previous treatment problems, potential for repeated loss to follow-up | • Have you ever been treated for TB before?<br>• If so, when, where and for how long?<br>Do you have your old TB patient card? May I see it please?<br>• Which drugs did you take to treat your TB?<br>• What was it like?<br>• What problems, if any, did you experience? |
| Knowledge about TB treatment<br>**Please note:** Female patients need to be aware of interaction between rifampicin and oral contraceptives to avoid unwanted pregnancy | • What do you know about TB treatment?<br>• What do you think will happen if you are not treated?<br>• How will you manage to take the tablets regularly?<br>• Do you understand that the treatment is free of charge? |
| Knowledge about possible adverse drug effects<br>**Please note:** Patients need to be informed that their urine will turn red due to the rifampicin, and reassured that this is normal AND harmless | • Have you ever experienced any side effects when taking medication?<br>• What do you know about the side effects of TB treatment?<br>• Are you currently taking in other medications (e.g., antiretrovirals)? |
| Possible barriers to care: lifestyle factors, cost, distance between health facility and home, service hours | • Do you have any other health problems at the moment, if so what? (Probe: HIV, diabetes, etc.)<br>• Who else do you ask/see/visit about your health?<br>• Where are you living at the moment? |

**Table 4.3: Topics to be covered in early patient interviews, contd.**

| *Topic* | *Questions* |
|---|---|
| Possible barriers to care: lifestyle factors, cost, distance between health facility and home, service hours | • How long will you be able to stay there?<br>• How do you get to the clinic?<br>• How long does this take to get to the clinic?<br>• How much does it cost?<br>• Do you have any dependents (young children, elderly or sick relatives)?<br>• Are you working? What do you do? Unemployed?<br>• How will you manage attending all the necessary appointments?<br>• How often do you drink alcohol, smoke cigarettes, use tobacco or take drugs? If so, would you like any help or not? (To examine in more depth later in assessment) |
| Other health concerns or problems | • Are you affected by any other health conditions, for instance diabetes or HIV?<br>• Are you taking any other medications, and if so, how you do feel about adding TB treatment?<br>• What other health concerns do you have at the moment?<br>• Do you smoke/use tobacco? How many cigarettes do you smoke per day?<br>• How much alcohol do you drink per week?<br>• How often do you use recreational drugs? |
| Social support available: family, friends, community | • Who can you turn to if you have any problems (staff/family/ friends)?<br>• How can we help you? |
| Conclusion | • Do you have any further questions or concerns?<br>• What are you going to do next?<br>• Remind patient to communicate with the nursing staff regarding:<br>- side effects to the treatment<br>- travel plans<br>- additional medication for other conditions<br>- any circumstances which may interfere with their treatment |

**NB:** Contact investigation is covered in Standard 4.3

### 4.1.5 Outcome

Patients will be accurately registered at an appropriate management unit and all information including results will be correctly entered in the treatment card and TB register. Patients will understand his or her condition, its treatment and where he or she can go if they need help. The initial assessment will provide the basis for a patient-centred plan of care, which will minimise barriers to treatment, including the selection of the best "TB treatment facility" where DOT will be performed. The success of this standard can be measured by comparing the information in the TB register with: the information on the treatment card and laboratory register, loss to follow-up rates in the intensive phase, and direct feedback from patients.

## 4.2 Standard: Starting treatment – arranging directly observed treatment (DOT) in the intensive phase

### 4.2.1 Standard statement

DOT will be arranged in the most convenient and reliable way possible taking into account the patient's needs and wishes as well as local resources.

### 4.2.2 Rationale

*Directly observed treatment*

DOT is a process designed to 1) assist the patient in completing a full course of TB treatment to prevent development of drug-resistance and 2) document by direct observation that the patient took the medication. It is recommended that DOT should be given during the intensive phase of treatment for all patients and should continue during the continuation phase and the entire treatment for patients on retreatment regimens or DR-TB regimens,[3] as this has been shown to reduce the development of further drug resistance[2] and improve treatment completion.[32]

*Minimising the cost to the patient by identifying the most convenient treatment facility where DOT will be carried out*

It is important to keep costs as low as possible for the patient. Although treatment is mostly provided free of charge, transport can become expensive and the time needed to attend for DOT can interfere with work and/or family commitments. Reducing these costs will help the patient adhere to his or her treatment. This can be achieved by identifying which designated TB treatment facility would be most convenient for the patient to attend. It is important that the patient chooses the facility, which may be near home or work or indeed convenient in some other way. **NB:** Some patients prefer to attend a facility some distance from their home to maintain anonymity.

*Ensuring those responsible for administering DOT have the necessary skills, knowledge and support to do so*

DOT needs to be administered in a caring and understanding manner. If the person responsible for administering DOT does not, for instance, understand his or her role, is unfriendly or does not listen to the patient's concerns, the patient may become demotivated and stop attending for treatment. Equally, if the person responsible does not receive adequate support or supervision, he or she may become demotivated or give the patient misleading information or the incorrect treatment.

*Maintaining a good relationship with the patient*

It is essential to inform the patient about the different options that the management unit can offer for DOT. The selected option needs to be realistic for both HCWs and patients; otherwise it will not succeed. Healthcare providers should emphasise the support rather than the surveillance aspect to encourage the patient's cooperation.

*Documentation of medication intake*

Every dose of medication taken by the patient and every test result should be recorded immediately on the treatment card in order that the patient's progress can be assessed and nonattendance can be identified daily.

### 4.2.3 Resources

- However DOT is organised, it should be realistic, manageable and sustainable for both the patient and the management unit where the patient is registered
- Arrangements for DOT using TB treatment facilities outside of the management unit should be clearly defined in local and/or national guidelines and policies
- The patient should be involved as much as possible in the choices made about their treatment arrangements, and as such, needs to be properly prepared
- The treatment card should be held by the person observing treatment and this person should be able to complete it clearly, accurately and promptly
- Alternatives to using the management unit for administering treatment for TB will vary depending on the local setting and the resources available.

*Possible alternatives for DOT outside of the management unit*

A patient may receive DOT outside of the management unit while maintaining the principle that they should be observed swallowing their tablets by a trained and supervised person.[33] The patient can attend a designated TB treatment facility daily to receive their treatment from a healthcare provider or in the community by a trained treatment supporter.[32] There may be several designated TB treatment facilities offering DOT, and the patient should be referred to one that is most convenient for them, i.e., that they choose. Other arrangements may be made depending on the local context but only if regular monitoring can be provided by the management unit. However, the principle that patients should be observed swallowing their tablets by a trained and supervised person must be maintained.[32, 33]

*Personnel responsible for direct observation of treatment*

Those who carry out direct observation of treatment are frequently not the same individuals as those designated as Unit Coordinators. Those designated to carry out the task must be named, trained and supported through regular visits to help them to undertake their tasks at a high level of quality. In most instances, this implies monthly visits from the Unit Coordinator.

*Identifying an appropriate person*

The individual responsible for DOT needs to:

- Be acceptable to the patient
- Express willingness for the task
- Be responsible and caring
- Be able to respect confidentiality
- Show dedication to a task
- Be prepared to broaden their knowledge by attending training and refresher courses
- Understand the nature of the work.

*Training*

The training of the individual responsible for direct observation must be clearly defined, standardized and with ongoing oversight and mentoring.

The designated individual will have knowledge about:

- TB transmission and the disease process
- Other comorbidities such as HIV, diabetes, etc.
- Infection and transmission prevention
- First- and second-line TB treatment and associated possible adverse effects
- TB treatment and its interactions with other drugs such as ART, anti-psychotic medication and oral contraception
- The potential impact of alcohol and substance misuse during TB treatment
- When to refer the patient back to an appropriate management unit.

The designated individual will be able to:

- Observe and record the intake of medication according to what is prescribed
- Maintain a safe environment when visiting patients and advise the patient and household about infection prevention and control through good ventilation and cough hygiene
- Be aware of when the patient needs to attend clinic appointments and remind patients as necessary (diaries, schedules or calendars may help)
- Follow up with patients when they miss treatment – after one day by telephone, text messages, home visit, etc.
- Support and encourage patients
- Assess and observe patients for signs of adverse drug effects and respond appropriately
- Refer patients back to the management unit if a problem arises
- Refer presumed TB cases to the appropriate local health facility
- Create awareness about TB in the community/workplace
- Attend training updates.

*Supervision*

However DOT is organised, good links to the management unit should be maintained. The patient will continue to attend for follow-up appointments and **the Unit Coordinator must make regular supportive visits (at least once per month) to the person overseeing DOT**. A process needs to be in place so that any problems can be identified, reported and addressed as soon as possible. Transport needs to be available to Coordinators so they can make these monthly supervisory visits. If it is not possible to arrange adequate supervision, alternative arrangements for DOT outside of the management unit should not be considered.

In ALL circumstances, the responsibility for care of patients, including DOT, rests with the local management unit and its staff.[2]

### 4.2.4 Professional practice

- The patient's needs and circumstances are assessed at the start of treatment
- DOT is organised taking these as well as service resources into account
- There needs to be careful negotiation with all those involved and a clear plan as to who is responsible for what
- The Unit Coordinator provides monthly supervision and support to the person responsible for observing the patient's treatment
- The Unit Coordinator is ultimately responsible for the success of the treatment

- Good communication should be maintained between all those involved in the care of the TB patient from the management unit to the hospital clinic to the person designated to undertake DOT.

#### 4.2.5 Outcome

DOT is implemented successfully. This can be demonstrated by the treatment cards, which have every dose recorded and any gaps accounted for.

### 4.3 Standard: Contact tracing and investigation

#### 4.3.1 Standard statement

Contact tracing and investigation is carried out according to locally agreed protocols.

#### 4.3.2 Rationale

*Identification of vulnerable contacts*

Contact investigation is recommended for those closest in physical proximity to the patient, as they are at the highest risk of being infected with TB bacilli and developing TB disease. The process varies according to available resources, but as a minimum, all contacts should be screened for symptoms of TB and anyone with symptoms and living in the same household as a patient with bacteriologically confirmed TB (with AFB smear microscopy or an Xpert MTB/RIF result – according to the national guidelines) should be investigated for TB. Children under five or anyone with HIV infection or diabetes are at the highest risk and should therefore be prioritized for screening and investigations if symptomatic.[2, 13]

*Identification of active cases*

Contact investigation is the most effective means of active case detection due to the fact that the people closest to a recently diagnosed case of infectious TB are the most likely to be infected or themselves have active disease.[34]

The investigation may identify the person from whom the disease was contracted, who may be unaware of their condition and therefore remain untreated and infectious. Although always a possibility, sources of adult TB are not often detected, as the patient could have been infected at any previous time in their life. If, however, the patient is a child, it is likely that they have recently been infected by an adult or adolescent with active disease, such as a member of their household, close relative or family friend.

*Education*

The investigation of at least the household contacts provides a valuable opportunity to educate people who may potentially have TB so they can recognise signs and symptoms and seek the necessary help and treatment if they develop the disease in the future. This is also important where resources are not available to investigate any further than the patient's household. Patients themselves need to be equipped and encouraged to discuss their condition with others who have been in contact with them and are showing signs and symptoms of disease.

*Preventive therapy*

Treatment of latent TB infection (LTBI) to prevent the development of active disease is most effective for children and other vulnerable people, especially those living with HIV.[35, 36] The most common treatment regimen is comprised of daily isoniazid at a dose of 7-15mg/kg (usually 300 mg/day) for a minimum of six months and is called IPT.[36, 37] Any possibility of active disease must be ruled out before preventive treatment is started to avoid the possibility of partial treatment, which could lead to the development of drug resistance. There is currently no recommended preventive therapy for contacts of patients with DR-TB. In cases where there has been contact with a DR-TB patient, advice should be sought from DR-TB centres of excellence regarding the local policy.

Where available, tuberculin skin testing (TST) can identify latent TB and preventive treatment can be offered to those at highest risk of developing disease. Where tuberculin is not available The Union and WHO recommend that in the absence of active disease, preventive therapy should be offered to all children under five-years old living in the same household as someone with bacteriologically confirmed active pulmonary TB disease. Evidence has shown that this is the most efficient and effective way of preventing TB in young children.[34]

*Sensitivity and discretion*

Contact tracing can often be a traumatic experience for the patient who may well feel very exposed and vulnerable due to the stigmatising nature of TB. Therefore, it is vital that the whole process is handled with as much sensitivity and discretion as possible and that sufficient explanation and consent is provided to the patient. Every effort must be made to maintain the patient's confidentiality. In some cases, patients will not even want their spouse or close family to know their diagnosis. In other situations, patients may feel guilty about the fact they may have infected the people closest to them. For some, it will be a relief to know that the people closest to them will be tested and given any treatment they may need. As previously discussed, reactions to the diagnosis of TB can vary greatly, and it is important to assess each patient on an individual basis to give them the appropriate level of support and reassurance.

**PLEASE NOTE:** Anyone who does not know his or her status and is showing signs of HIV (Appendix 3), or has relevant risk factors, should be encouraged to be tested as he or she could benefit from IPT.[35] See Standard 7.1.

### 4.3.3 Resources

It is essential to ask the patient whether there are any children under five-years old within the household and in addition, whether any of the people closest to him or her are showing any signs or symptoms of TB. It is also important to check if any of the household members may be immunocompromised, specifically if they might be HIV infected. If, on assessment, there is a risk that someone in the household may be HIV infected and his or her status is unknown, a test should be offered. These contacts can then be examined and treated accordingly.

- TB patients themselves are a vital resource in detecting TB as they can become very alert to people who may be suffering with TB symptoms similar to theirs. If they themselves have received good treatment, support and information, they will encourage others to seek help
- Healthcare providers involved in caring for TB patients need to be given sufficient information to understand the disease and how it is transmitted to assess levels of risk accurately and prioritize those who need investigation
- Time and space is required for a confidential discussion with each patient about the importance of identifying anyone else he or she is in close contact with who may be infected with TB, especially children under five and anyone they know to be (or think might be) infected with HIV
- Transport should be available for healthcare providers to travel to the patient's home to assess the home environment
- Equipment and training should be provided in order to implement testing for LTBI according to local protocols (e.g., TST).

### 4.3.4 Professional Practice

It is recommended that any symptomatic child under the age of five years who lives in the same household as a person with recently diagnosed active TB should receive full treatment for presumptive active TB, and this treatment should reflect the resistance pattern of the person he or she has been in contact with.[3] All other children younger than five years of age from the household should receive preventive therapy.[37]

The healthcare provider caring for the newly diagnosed patient will:

- Assess the patient carefully with regard to the home environment to establish the number of contacts, potential active cases (is anyone coughing?) and those at highest risk of infection (young children, people living with HIV/AIDS (PLWHA), diabetics, pregnant women, elderly, etc.).
- Use good communication skills to discuss the process of contact tracing and investigation and respond appropriately to the patient's concerns.
- Maintain an open dialogue about possible contacts throughout the patient's treatment and develop the patient's expertise in recognising possible cases among their family and friends, and encouraging them to seek help.
- Educate the patient and their family (with the patient's consent) about TB.
- Document clearly and accurately on the patient record/treatment card and/or any associated NTP contact tracing forms the high-risk contacts identified, those tested and any action taken (a piece of paper may be attached to the patient record with a hand-written table such as that suggested in Figure 4.1).
- Reassure the patient's family and close friends and provide clear and accurate information about TB and what will happen to them as a result of being in contact with a person with TB:
  - some will undergo investigations and have full treatment if found to have TB
  - others who are found to have LTBI may be offered preventive treatment
  - others will simply receive advice and reassurance and be encouraged to seek advice if they develop symptoms.
- Explain the value of preventive therapy in preventing active disease, especially in young children and people living with HIV.

Conduct a home visit, if possible, to assess the home environment with regard to household members, size and occupancy of rooms and ventilation.

**Figure 4.1: Possible format for recording information on household contacts**

| *Name* | *Age* | *Weight* | *Symptoms* | *Date tested** | *Result** | *Action taken* |
|---|---|---|---|---|---|---|
| | | | | | | |

* If testing is available

The WHO has created a checklist for conducting contact investigations that can be found at the following link: http://apps.who.int/iris/bitstream/10665/77741/1/9789241504492_eng.pdf.[38]

**NB:** A HCW or treatment supporter who visits the home of a patient on treatment for TB should be particularly observant of the other members of the household and use the visit to reinforce the importance of recognising symptoms and coming forward for investigation.

### 4.3.5 Outcome

Contacts at the greatest risk will be identified, evaluated and managed appropriately. Records will be available to demonstrate how many contacts have been identified, how many have been evaluated, and a breakdown of evaluation results and what action was taken.

# 5

## Care during the intensive phase: promotion of adherence

Many people are extremely shocked when they are told they have TB. Some refuse to accept it and others are relieved to find out what is wrong and that treatment to cure them is available. As already discussed, the reaction depends on many factors, including cultural beliefs and values, previous experience, and knowledge of the disease. Even though TB is more common among vulnerable groups, it can affect anyone, and it is important for patients to be able to discuss their concerns in relation to his or her own context. Nurses and other HCWs have an important role in providing a caring environment for all TB patients. The cure for TB relies on the patient receiving a full, uninterrupted course of treatment, which can only be achieved if the patient and the health service work together. The standards in this chapter focus on processes to maximise the patient's ability to adhere to the treatment prescribed, for however long that might be, and with whatever combination of medications. The underlying principles for treating TB and DR-TB are the same, although it is acknowledged that people taking more complex regimens for DR-TB using second-line drug regimens will require prolonged support and care. In some extreme cases, it may even be necessary to consider palliative care.

### 5.1 Standard: Patient care and monitoring

#### 5.1.1 Standard statement

Patient progress and DOT arrangements are monitored according to a schedule agreed between the Unit Coordinator, all HCWs and other individuals designated to be involved in the care of TB patients.

#### 5.1.2 Rationale

*Addressing patient priorities*

Patients with TB often have many other concerns, which they may feel are more important and so may affect their ability to adhere to treatment. Simply providing food can have a major impact on a patient's ability and motivation to attend treatment, especially as it also helps people tolerate the treatment more easily. Access to a variety of local support services that address the patient's broader needs can make the difference between a patient being able to continue treatment or not. Patients should be treated with respect and feel they can discuss problems as they arise. The service should be able to respond to problems promptly to minimise the potential for treatment to be interrupted. If the patient trusts the service, he or she is more likely to give their correct contact details. The patient will also be more likely to inform the service if something has happened which will prevent them from attending clinic, for example, if he or she needs to attend to other commitments or will be traveling to a different location. It is very important that an open dialogue is maintained between the patient and the healthcare worker so that issues such as these can be discussed as they arise and arrangements can be made to prevent treatment being interrupted.

*Management of adverse drug effects*

The patient needs to be encouraged to recognize and report adverse drug effects so that he or she can be properly managed. A patient experiencing severe adverse effects such as jaundice or severe abdominal

discomfort should be instructed to stop treatment immediately and be referred to a medical officer. Minor adverse effects, such as nausea or itchy skin, although not serious enough to warrant a change in medication, can be very concerning or uncomfortable for the patient and so need to be taken seriously by the healthcare provider. Support, treatment and understanding can ease a patient's discomfort and encourage him or her to continue with the medication.

In all cases, it is important to establish whether or not the reported condition is being caused by a reaction to the TB treatment as opposed to something unrelated that might require additional intervention. If not, a patient's TB treatment may be changed unnecessarily and/or a separate condition may go untreated. A detailed list of adverse drug effects and the medications most likely to cause them can be found in the WHO's Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis http://apps.who.int/iris/bitstream/10665/130918/1/9789241548809_eng.pdf?ua=1&ua=1.5

*Management of patients who miss appointments*

A patient who fails to attend when expected should be contacted as soon as possible to minimise treatment interruption (see Standard 5.2). The prompt, persistent and sympathetic follow up of patients who miss appointments, although time consuming, can demonstrate to the patient that people care, which can in turn motivate him or her to continue treatment. Every possible effort should be made to ensure the patient can continue treatment and not be lost to follow-up.

*Follow-up sputum examination*

A follow-up sputum AFB smear examination is required to confirm that the disease has converted from smear positive to smear negative. This is not only important in terms of the progress of the individual patient but also to direct the proper treatment of the patient (for example, changing from the initial intensive phase to the continuation phase of treatment). It should be remembered that Xpert MTB/RIF does not play a role in follow-up sputum examinations except in situations where DR-TB is questioned (for example, in patients with good treatment adherence without sputum conversion at the end of the intensive phase of treatment). It is important to identify resistance as soon as possible and initiate the patient on appropriate treatment.

As for diagnosis and follow-up examination, the correct completion of sputum request forms and labelling of sputum containers for follow-up examination is essential to the accurate and timely feedback of results. It is important to remember that up to 25% of patients with drug-sensitive TB can still be smear positive after having being treated correctly for two months. Most of them will be cured with further treatment.

*Accurate documentation*

Throughout the intensive phase, the treatment card, the TB register and the laboratory register must be kept up-to-date to monitor the progress of individual patients as well as provide accessible, accurate information for monitoring the regularity of treatment during the intensive phase.

*Support for the person responsible for directly observed treatment*

The person designated as responsible for observing treatment needs to feel valued and encouraged in order to stay motivated and to be able to continue to motivate the patient. If not, he or she may feel taken for granted and withdraw support, especially if the relationship with the patient breaks down.

*Support for the hospitalised patient*

If a patient is very sick or is treated for DR-TB, he or she may be hospitalised for prolonged periods of time. This can be very stressful, especially if the patient is a long way from home and separated from family members including their own children. Whether patients with DR-TB are treated in hospital, at home, or in the community, infection prevention and control measures need to be in place to protect the patient and others that may be exposed to TB. It is essential to provide care as compassionately as possible.

If not, the patient may become depressed or try to leave the hospital against advice with no arrangements for their on-going treatment or support. The correct protective equipment must be available (N95 or FFP2 particulate respirators for staff and visitors and surgical masks for patients) to encourage social interaction between staff and patients, otherwise staff are likely to try and protect themselves by spending minimal time with patients. Opportunities to talk and socialise in well-ventilated areas, ideally outside, are helpful, as are entertainment such as television and radio, exercise equipment, recreational games (e.g., pool tables), and hobbies such as arts and crafts. It may not be possible for the hospital to provide these things but local community organisations and/or NGOs may be able to help.

*Care for people receiving daily injections*

A patient who requires daily intramuscular (IM) injections, especially if he or she is underweight, may suffer a great deal of pain and discomfort at the injection site. This may discourage him or her to attend clinic if care is being provided on an outpatient basis. Listening to the patient, taking good care of the injection sites and assisting with nutrition may help to alleviate the situation. For patients with DR-TB requiring daily IM injections for an extended period of time (i.e., 6-8 months), special care must be taken to ensure there is sufficient muscle mass to accommodate the volume of medication to be injected, the injection site should be rotated daily, and injection sites should be regularly assessed for signs of injection-associated complications (e.g., abscess, infection, etc.). This is particularly important for young children and infants who may be at greater risk for injection-related injuries.

### 5.1.3 Resources

- Up-to-date information to equip healthcare workers with knowledge and understanding of TB/DR-TB and its treatment
- Training to equip healthcare providers who can recognise and refer patients with severe adverse drug effects and manage patients with minor adverse drug effects
- A system which allows HCWs to assess and respond to factors that affect adherence (See Table 5.1), have a caring attitude and take responsibility for treatment outcomes
- Availability of the necessary forms and registers, and HCWs who can complete them clearly, promptly and accurately
- Management units and associated TB treatment facilities with a system in place to follow up with patients who miss appointments or do not attend for DOT (see Standard 5.2)
- Collaboration with support services and other organisations that could assist the patient in particular access to food or nutritional support
- Possibility of admitting very sick patients, although this may result in other costs to patients which need to be taken into account
- Supervision to maintain good practice
- Regular support and supervision of the provider observing treatment
- All equipment and supplies available to a competent, trained healthcare provider to provide daily injections if required
- Adequate isolation facilities, well-ventilated social spaces and PPE available in inpatient and outpatient facilities
- Efficient, well-staffed, well-stocked and quality-assured laboratory services are needed to ensure prompt examination and reporting of follow-up sputum smears (and cultures or LPA results for patients with DR-TB)
- Access to laboratory testing to monitor for drug toxicities and pharmacovigilance for patients on second-line anti-TB regimens
- Access to adjuvant medications to address common adverse drug effects from second-line anti-TB regimens (e.g., anti-emetics, pyridoxine, potassium chloride, thyroid replacement).

**Table 5.1: Factors that could present barriers to adherence**

| *Patient variables* | *Potential response* |
|---|---|
| ***Socio-economic factors and personal circumstances*** | |
| Lack of personal resources | • Provide access to any available benefits/incentives |
| Overwhelming competing priorities such as work, tending animals and/or crops, basic family nutrition and welfare. | • Assess and assist where and if possible<br>• Adjust treatment routine to cater for patient circumstances |
| Age-related issues, e.g., child, adolescent, elderly | • Adjust advice and involve appropriate others according to age |
| Loss of employment – due to stigma and/or discrimination | • Advise regarding potential sources of support, e.g., local NGOs |
| Social/family duties and constraints (e.g., attending to other commitments, work, visiting or assisting relatives) | • Anticipate by discussing with the patient what would happen regarding the treatment if he or she has to leave for an unexpected event |
| Homelessness – already homeless or made homeless due to stigma and/or discrimination | • Assist where possible e.g., voluntary organisations<br>• Discuss and agree how treatment can best be arranged |
| ***Psychological and emotional factors*** | |
| Personal and cultural beliefs and misconceptions about TB | • Assess and inform with respect and sensitivity |
| Apathy, pessimism, depression, denial | • Assess and support |
| Lack of social support system | • Identify avenues for support – health centre, community volunteer, other patient, patient or community groups, etc. |
| Dissatisfaction with healthcare worker, negative experiences with healthcare providers in the past | • Assess problems and expectations. Feedback if appropriate and lead by example |
| Embarrassment - feeling stigmatized about the disease | • Inform and reassure<br>• Apply discretion<br>• Work with patient, family and community groups as appropriate |
| Lack of control over life | • Let the patient choose, if possible, where he or she receives treatment |
| ***Health-related factors*** | ***Potential response*** |
| Previous history of nonadherence | • Assess previous circumstances – what prevented adherence before |
| Impatience with level of progress / response to treatment | • Readdress expectations and reassure |
| Sensory disabilities | • Identify best way to communicate and work closely with carers |
| Inability to follow treatment plan | • Assess to identify problem and change accordingly |

**Table 5.1: Factors that could present barriers to adherence contd.**

| *Patient variables* | *Potential response* |
|---|---|
| ***Health-related factors*** | ***Potential response*** |
| Alcohol and substance misuse | • Assess with understanding and sensitivity.<br>• Refer to appropriate services if possible. Otherwise accept and support according to what is possible for the patient |
| Concern about also being HIV positive | • Offer ongoing support and counselling.<br>• Refer for treatment and additional help, if appropriate and available |
| ***Treatment Variables*** | ***Potential response*** |
| Complexity and/or duration of treatment | • Offer clear instructions, information and support |
| Characteristics of medication (number of pills, adverse drug effects , etc.) | • Offer support; give clear information about adverse drug effects and encourage patients to present with problems. Offer help to alleviate effects where possible. Severe adverse drug effects must be reported and acted on without delay |
| Interaction of medication with food: e.g., patients may feel nauseous | • Assess and advise regarding diet and timing of medication |
| ***Disease Variables*** | ***Potential response*** |
| Coexisting conditions: | |
| - HIV | • Establish status; offer counselling and testing; work with HIV services, especially if ART is being given; and monitor drug interactions |
| - Diabetes | • Advise regarding diet and review treatment for diabetes |
| - Malnutrition | • Assess access to food, increase access to food where possible and advise regarding diet |
| - Mental health problems | • Check to ensure no conflicting medication e.g., anti-psychotics<br>• Work closely with carers. If none, identify alternative additional support |
| ***Health system variables*** | ***Potential response*** |
| Inaccessibility of clinic / treatment supporter | • Organise treatment as far as possible at the convenience of the patient |
| Long waiting times at clinic | • Rearrange the service so that patients do not have to wait for along time, for example, by allowing TB patients their own entry without queueing |
| Fragmented, uncoordinated services overworked) | • Ensure coordination and establish good relationships with other services, communicate regularly and share protocols, etc. |

**Table 5.1: Factors that could present barriers to adherence contd.**

| *Health-related factors* | *Potential response* |
|---|---|
| Staff issues (lack of motivation, shortage, overworked) | • Ensure staff supervision.<br>• Ensure staff feel valued and appreciated; listen to their ideas; introduce staff incentive schemes, e.g., rewards for good practice/training opportunities |
| Stigma and discrimination by staff | • Health facility campaigns and education<br>• Challenge stigmatising behaviour at all levels<br>• Ensure organisational policies are not stigmatising or discriminatory |

### 5.1.4 Professional practice

- The healthcare provider responsible for providing patient care should be able to assess each patient according to the variables set out in Table 5.1, which may affect the patient's ability to adhere to the treatment prescribed
- Infection prevention and control measures must be adhered to according to local polices. The healthcare provider should advise patients, visitors, and other staff about cough hygiene and correct use of available personal protection. N95 (or FFP2) respirators must be fit-tested for each individual using them, stored appropriately in a clean and dry environment and discarded safely. Any patient given a surgical mask (N95/FFP2 respirators should NOT be given to patients) should be advised as to how to use and discard it safely
- In the case of drug-susceptible (DS-TB), at the end of the intensive phase the patient needs to be clinically examined to ensure adequate progress has been made. It is recommended that one specimen should be obtained and examined by microscopy in the week before the end of the intensive phase. Regardless of the result, the patient should be started on the continuation phase[2]
- All DS-TB patients who remain smear positive after two months of treatment need to be assessed with regards to:
  - Is the regimen that the patient has been prescribed during the intensive phase appropriate
  - Any problems they may have had taking treatment as prescribed
  - Any misunderstandings about the treatment regimen, e.g., are they taking the correct dose at the correct intervals
  - Any problems regarding the person supervising their treatment.

  **NB: at this point it is recommended that sputum is collected and sent for Xpert MTB/RIF testing or for DST (TB culture or LPA),** depending on the national guidelines.
- Patients on longer regimens for DR-TB will need to be followed up according to locally agreed protocols which the healthcare worker needs to be aware of
- Good communication is required between the healthcare worker providing on-going daily care to the patient with DR-TB and the specialist medical team, so that any problem arising can be reported and dealt with promptly and appropriately
- Care should be planned and regularly assessed as much as possible according to individual patient needs
- As at any time during treatment, severe adverse drug effects should be identified, recorded and referred to an appropriate healthcare provider without delay

- Minor adverse drug effects should be identified, recorded and managed at the management unit[2]
- Documentation including the TB register, treatment cards and the laboratory register should be kept up-to-date. An identified person should check the treatment cards against the TB register every week to ensure the information is complete. Particular attention should be paid to the transcription of the two-month smear examination result in the TB register for each patient with drug-susceptible TB and the six-month smear and culture examination for each DR-TB patient who is on a second-line anti-TB regimen
- Uninterrupted supplies of drugs, injection equipment, PPE and other materials should be maintained at all times
- If a patient does not attend for DOT, it is necessary to mark this clearly on the treatment card. The patient should be visited at home to find out why and to ensure that treatment is resumed appropriately and without delay
- Coordination with other agencies in the local area may be needed to give patients access to additional support according to their needs.

### 5.1.5 Outcome

The intensive phase of treatment is completed successfully. This can be measured using the patient treatment card and the TB register.

## 5.2 Standard: Tracing patients who do not attend appointments (late patients)

A system needs to be in place to trace patients who miss their appointments for treatment (late patients) to prevent treatment interruptions and loss to follow-up. The best success will be achieved through the use of flexible innovative and individualised approaches, such as using telephones, instant messaging or other m-health applications. The treatment and care the patient has received will inevitably have an impact on his or her willingness to attend in the future.

In many cases, there may be a simple obstacle that needs to be overcome to enable the patient to continue treatment successfully, so it is essential to find out what the problem might be. There will be patients who cannot be traced and not all those found will return for treatment. However, it is important to make every attempt to return as many patients as possible to treatment.

**NB:** A well-defined system to trace late patients is mandatory in all situations. However, when the rates of patients lost to follow-up are high (above 10%), any tracing system will be useless without also examining the service as a whole. Such an examination is necessary to identify and address the wider problems making it difficult for patients to attend or reasons the patient chooses to not attend.

### 5.2.1 Standard Statement

Patients who do not attend TB services when expected will be followed up, assessed and enabled to resume treatment as soon as possible.

### 5.2.2 Rationale

*Prioritisation of the most infectious patients*

Patients with a positive sputum smear or Xpert MTB/RIF results who do not come to the facility for treatment or miss an appointment must be given priority, as they are most likely to be infectious and could continue to spread the disease and are also most at risk of dying if not successfully treated. Every effort should be made to ensure that these patients receive a full uninterrupted course of treatment. By doing so, the number of infectious people in the community will be reduced, increased drug resistance will be prevented, more patients will be cured and fewer people will die.

*Prompt action*

Late patients must be identified as soon as possible to avoid long gaps in treatment. The quicker they can be traced and encouraged to return to their treatment centre, the lower the risk of their condition deteriorating.

*Clear, accurate and timely documentation*

Accurate contact details should be documented as soon as the patient starts treatment and regularly checked for any changes (see Standard 4.1).

Clear and prompt marking of the treatment card is essential to alert staff to patients who have not attended. Treatment cards are very useful in demonstrating how much of the course has been completed and how regularly drugs have been taken. In addition, they can help the patient see what progress he or she is making and how important every dose of medication is.

*Ongoing analysis of the reasons given for nonattendance*

It is useful to collect information as to why the patient did not attend to identify and address the barriers he or she may be facing. It may be possible to make an adjustment to treatment arrangements if there is a problem for an individual, but equally, if a problem is common to a number of patients, something more drastic may have to be done in terms of the way the whole service is offered.

*The use of flexible and innovative approaches*

To address issues as to why a patient has not attended the clinic to collect treatment or has not adhered to treatment, healthcare providers need to be flexible and adjust the services to best fit the patient's needs. A satellite clinic may need to be set up to cater for a number of patients in a certain locality; clinic times may need to be modified or extended to accommodate patients' work schedules or other commitments. Patients may also require ongoing education to address any knowledge gaps about the disease and treatment.

### 5.2.3 Resources

- In each management unit and TB treatment facility there needs to be an agreed process (including agreed timeframes) for following up late patients. Named people with defined responsibilities should coordinate this process, and it should be monitored by the Unit Coordinator
- Skilled personnel are required who understand the importance of continuous treatment, both within identified TB services and other organisations that might be providing services to the patient, such as social workers, pharmacists and so on. The importance of receiving a full course of treatment must be reinforced by all those involved with the care of the patient
- Good communication with patients, families and communities can assist in locating a patient who has not come for treatment as expected
- Good communication is essential both between and within organisations involved in patient care
- Patients need to understand from the very beginning that every effort will be made to enable them to receive a full course of treatment and the steps that will be taken if they do not attend. They should be encouraged to contact the clinic if they are unable to attend for appointments so alternative arrangements can be made. Clear details need to be given as to whom they should contact and how. They should also be confident that they will be dealt with in a kind and caring manner
- Accurate, clear and prompt record keeping with a reliable supply of treatment cards is essential to monitor adherence and attendance.

### 5.2.4 Professional Practice

The healthcare provider involved will:

- Establish a system whereby the treatment cards of all patients expected for treatment on any particular day are placed in a slot and, when the patient is seen and registered, moved to a second slot, thereby immediately identifying any patient who was expected but who did not show up for the scheduled appointment during the day
- Ensure documentation is filled out promptly and correctly. If a patient does not attend for treatment, the box on the treatment card representing the day of the appointment must be left blank (or marked as missed) thereby clearly identifying the patient's failure to attend. The same thing is true if the patient leaves the hospital unexpectedly. Treatment cards are an essential tool to be used in monitoring the progress and adherence of patients on treatment
- Ensure that all those whose treatment cards remain in the first slot must be contacted / visited as soon as possible, preferably at the end of the day, to encourage them to return to the appropriate facility to continue treatment
- Use good communication skills to negotiate with late patients in a caring and cooperative manner. If a patient feels he or she will be reprimanded on returning to the management unit or other treatment facility, he or she may be reluctant to do so.
- Liaise with other agencies which are involved with (and trusted by) patients, e.g., social workers, teachers, pharmacists, etc., so that the importance of compliance can be reinforced and better monitoring can take place
- Establish the reason for the patient's non-attendance. There are numerous reasons for people failing to keep appointments, and it is important to address the situation in a friendly and non-judgemental manner. Multiple attempts may be needed to track down a patient. If he or she is not located within two months, they need to be recorded as a 'lost to follow-up'. If the patient subsequently arrives at the treatment facility, he or she will need to have initial investigations repeated, e.g., sputum examination for TB using Xpert MTB/RIF or culture to assess for possible drug-resistance
- Negotiate effectively with the patient who cannot (or will not) return to the treatment facility to develop an alternative plan of care which is acceptable to both the patient and the nurse or healthcare provider. Incentives or enablers need also to be considered (see Table 5.2)
- Respond appropriately if the patient cannot be found by leaving information with appropriate friends or relatives encouraging the patient to come to the clinic whenever he or she is able to do so.

**NB:** If late patient rates are generally high, healthcare workers need to look at the service as a whole and try to establish what the problem is, seeking advice from local supervisor and if necessary, senior members of the TB control programme. Clinic or health centre staff may also consider conducting exit interviews with patients to assess quality of care and patient satisfaction.

*Alternative plans of care*

If a patient is having difficulty adhering to treatment due to transport difficulties, reluctance to comply or simply forgetfulness, it may be necessary to make alternative arrangements. The plan should be agreed between the patient and the healthcare provider depending on the local/national policies. Any alternative arrangements must be recorded in the patient's notes and evaluated on a regular basis by the Unit Coordinator.

*Incentives/Enablers*

The use of incentives to motivate the patient with TB to adhere to treatment is defined in local/national policies. Several examples of incentives and enablers used in a variety of settings can be found in Table 5.2. It is important to remember that simple things like complimenting patients for keeping appointments and being pleased to see them can work as effective incentives.

While more elaborate incentives and enablers can enhance the interaction between the healthcare provider and the patient, they can also complicate this interaction and need to be organised very carefully with a number of clear 'rules' from both the patient and the healthcare worker's perspective. For instance, if the healthcare worker promises the incentive and does not deliver it, the relationship between the patient and the healthcare provider will quickly deteriorate. It is essential that the healthcare provider be as compliant as they want the patient to be. Word travels fast around a community when a health department staff member does not follow through with what was promised.

When giving incentives it is essential to differentiate between the patients' needs and the needs perceived by them. Many HCWs feel that patients should assume total responsibility for their health and subsequently for their treatment and want to protect those around them. This type of attitude can create a barrier, as patients who have suffered from poverty and social injustice may have become indifferent to the problems of others.

These factors also result in the loss of self-esteem, and some people will consider themselves not to be good enough to be worthy of care. Often, with the giving of incentives, changes take place between the patient and the healthcare provider. The expression of caring and concern reflected by the healthcare provider in using the combination of DOT and the incentives programme can be the most "attention" some people have received for years. Getting to know the patient is essential to the effective use of incentives and the subsequent successful therapy. It is also important to prepare the patient for the end of treatment as an abrupt withdrawal of care can be distressing.

**Table 5.2: Examples of incentives/enablers**

| |
|---|
| • Food, especially for patients with no income and/or taking MDR-TB treatment or patients co-infected with HIV taking ART |
| • Support groups (helpful if these can be run by or with the involvement of people who have themselves recovered from TB) |
| • Award ceremonies, e.g., certificate on successful completion of treatment |
| • Reimbursement for transportation |
| • Visits/phone calls to patients in hospital by staff from the health facility to encourage them |
| • "Tea of thanks" (a tea party) for the family of patients on TB treatment to acknowledge the support that they give |
| • Remembering a patient's birthday or anniversary to make them feel special |
| • Reward for completion of the intensive/continuation phase of treatment. |

### 5.2.5 Outcome

Gaps in treatment will be kept to a minimum. It will be possible to see the patient's attendance pattern and any missed doses from the treatment card. Information will be available for each patient who did not attend with regard to reasons given for nonattendance and action taken, and it will be possible to calculate the number of late patients, how many were subsequently found and how many resumed treatment.

# 6

## Care during the continuation phase

As the patient's treatment progresses, symptoms start to disappear, patients feel better and they become more familiar with the treatment. The standards in this section focus on the types of things that need to be considered as the patient begins to have less contact with the TB service and resumes his or her 'normal' activities. Treatment for TB takes a minimum of six months, and during this time, changes to the treatment regimen and personal changes associated with making a recovery can create barriers to continuation of treatment. Lifestyle and other changes, which may occur during six months of anybody's life, can complicate or be complicated by TB treatment. Efforts must therefore be made to maintain contact with the patient and adjust care according to any changes in his or her personal circumstances.

### 6.1 Standard: Patient assessment during transition from intensive to continuation phase

#### 6.1.1 Standard Statement

Patients are assessed at the end of their intensive phase of treatment and a plan is developed with the patient for the continuation phase, during which they are likely to have less contact with the management unit.

#### 6.1.2 Rationale

*Managing the change in treatment*

As the patient begins to feel better, other priorities may start distracting him or her from the treatment. If the patient has had DOT in the intensive phase and this is stopped in the continuation phase, it may be a signal to the patient that the treatment is not so important. The same may occur when a patient who has been receiving daily injections progresses to oral medication only. It is essential to reiterate the need for ongoing treatment and support.

*Reassessment of the patient's needs*

Reassessment of the patient's physical, social and psychological needs will assist in the planning of appropriate patient-centred care in the continuation phase as the patient takes more control of and responsibility for his or her own treatment. Additional support may still be needed if, for instance, the patient is co-infected with HIV or has another condition such as diabetes. Other sources of support should be explored with the patient, if necessary, to ensure a continuation of care following the completion of TB treatment.

*Managing unforeseen events*

All sorts of life events can have an unexpected impact on treatment and the patient's ability to continue. He or she may encounter other commitments, change jobs or need to move away at short notice. This is a particularly challenging for migrant workers or cross-border patients. It is important to be prepared for such events and help the patient to readjust to his or her new circumstances while continuing to adhere to the treatment regimen. It is particularly important to discuss this with the patient when the treatment changes, as he or she will have less contact with the service in the continuation phase.

### 6.1.3 Resources

- Good communication and assessment skills are needed more than ever as the patient's treatment changes. Adequate time is needed to reiterate important messages about the need to continue treatment without interruption and to encourage the patient to inform the healthcare facility if there are likely to be changes in personal circumstances that may affect his or her ability to continue treatment and/or attend for follow-up appointments
- Healthcare providers need to know when to send follow-up sputum specimens for microscopy examination to the laboratory according to the patient category and resistance pattern. (A step-by-step guide regarding the practical aspects of collecting sputum samples is presented in Table 3.1. The same principles should be applied when giving the patient instructions to produce subsequent specimens at home in addition to information about delivering the specimen to the right place at the right time.)
- Documentation is essential at this time regarding the ordering and results of laboratory tests (sputum smear or culture) as required
- Efficient, well-staffed, well-stocked, and quality-assured laboratory services are needed so that there is no delay in the examination of follow-up sputum smears and cultures and the treatment can be changed at the appropriate time.

### 6.1.4 Professional practice

*Documentation*

It is essential that all documentation is completed accurately at the time samples are collected. Laboratory request forms for sputum examination and culture should clearly show that the examination is required for follow up and during which month of treatment the specimen was taken. Results and any changes in treatment should be entered clearly on both the treatment card and the TB register. This is particularly important regarding the sputum smear examination for AFB performed at the end of the intensive phase of standard first-line treatment (also smear and culture performed at month six of treatment for patients on second-line anti-TB regimens for RR-TB); no entry or an entry indicating 'smear not done' in the TB register can be a sign of loss to follow-up or inadequate follow up and should be investigated.

*Practical advice for patients beginning to take treatment at home*

It is helpful to discuss with the patient a system for remembering to take the pills (before a routine activity such as a meal is useful). Safe storage of the drugs is necessary in a dark, dry place away from the reach of children.

This is a critical time to ensure that a good relationship is maintained with the patient so he or she will report any problems should they arise. Any potential barriers to adherence should be assessed, such as a change in routine, potential for misplacing drugs or having them stolen, substance abuse and so on (Table 5.1).

*Ongoing support and follow up*

The patient needs to know about follow-up appointments, specimens and tests that are needed. Patients also need to be reminded that adverse drug effects are rare but they should be taught how to recognise any potential serious adverse effects and report them, e.g., skin rashes, jaundice, visual disturbances, gastrointestinal problems, tingling in the fingers and toes, and even hearing loss from second-line (MDR-TB) treatment to name a few.

The patient needs to be assessed on an ongoing basis to monitor his or her progress and keep up-to-date with any changes which may affect treatment and care. A variety of factors should be assessed including:

- Ability and motivation to continue adhering to the treatment regimen
- Clinical progress at key milestones:
  - First-line standard treatment – two-month sputum, five-month sputum, and completion of treatment
  - Second-line treatment – according to local protocols, but generally includes a culture at six months as an interim outcome
- Correct medication prescribed
- Availability of drugs
- Ability to attend appointments
- Any confusion and/or questions
- Anything which could disrupt treatment: adverse drug effects, pregnancy, work or other commitments, conflicting information, migration, cross-border issues, etc.

A routine for regular follow up should be agreed between the patient, the Unit Coordinator and the healthcare provider who supervised the initial phase of treatment. This may involve home or clinic visits or a mixture of both according to patient preference and available resources. However it is organized, patients need to be seen at least monthly during the continuation phase. It is essential that patients know whom to turn to if they have a problem and the service needs to respond promptly and appropriately.

### 6.1.5 Outcome

Patients progress from the intensive to the continuation phase following re-examination of sputum. Information is available on each individual patient treatment card and the TB register. Patients continue treatment while developing greater self-reliance, gaining confidence and maintaining contact with TB service.

## 6.2 Standard: Case management during the continuation phase

### 6.2.1 Standard statement

Ongoing support is available according to patient need and the necessary follow-up investigations are carried out.

### 6.2.2 Rationale

*Reassessment of patient needs*

The patient is gaining more control and responsibility having become accustomed to the treatment and moved on from feeling unwell and vulnerable as he or she did in the intensive phase. It is important at this stage to reassess the patient's needs and update plans of care to reflect this new situation, especially if he or she is transferring from DOT to self-administered medication. If not, the patient may feel that it does not matter too much whether they continue medication or not. As also mentioned before, if the patient has been receiving daily injections and now transfers to oral medication only, this may send the same message. Some patients who are receiving second-line treatment for DR-TB may have been in hospital for some, if not all, of their treatment, and DOT will need to be arranged (see Standard 4.2).

*Flexibility in response to problems faced by the patient*

Responses should be prompt and appropriate with a continued commitment to care. Trust can be built and patients can be motivated if they feel that their priorities are taken seriously. The problem may not be directly related to the patient's treatment but, if ignored, may present a barrier to treatment in the future.

*Minimising the cost to the patient*

Costs to the patient should be kept to a minimum to maintain his or her ability to continue treatment. For example, unnecessary clinic appointments, which may incur transportation costs and interrupt the patient's work, should be avoided.

*Follow-up sputum smear examination*

For DS-TB, a follow-up AFB sputum smear examination is required after five months of treatment for all patients who were originally sputum smear-positive in order to either confirm progress or identify treatment failures.[2]

For DR-TB, the frequency of sputum monitoring may vary; however, both sputum smear and culture should be assessed during the continuation phase to ensure the patient is not failing treatment. Documentation of 'cure' for patients with rifampicin-resistant TB requires three or more consecutive negative sputum cultures taken at least 30 days apart.[5]

*Assessing treatment outcomes*

Assessing and recording the treatment outcome for each patient is essential to understanding the performance of the TB program. Sputum is re-examined at the end of the patient's treatment to confirm that 'cure' has occurred, which is a much stronger indicator of treatment success than 'treatment completion'.[2]

*Documentation*

As for diagnosis and the first follow-up specimen, the correct completion of sputum request forms and labelling of sputum containers is essential for the accurate and timely feedback of results. Results should be entered in the laboratory register, the treatment card, and the TB register as soon as they become available so that any healthcare provider can assess the patient's progress and ensure the correct treatment is being given. The accuracy of quarterly reports on treatment outcomes relies on the accuracy of the information in the TB register. Quarterly reports in turn demonstrate how well the programme is performing.[2]

### 6.2.3 Resources

- Adequate human resources to enable appropriate case load management
- Effective, well-staffed, well-stocked, and quality-assured laboratory services are needed to ensure prompt examination and reporting of follow-up sputum specimens for smear or culture
- If, on assessment, a potential problem has been identified, it is important to make an appropriate plan of care and evaluate progress regularly as agreed with the patient
- The patient needs to be able to contact the appropriate healthcare provider if a problem arises
- The service needs to respond promptly to address the problem and ensure any possible action is taken to prevent any potential interruption in treatment
- It may be necessary to refer the patient for additional support so it is necessary for the healthcare provider to have links to other services, including both governmental and non-governmental or community-based organizations
- There needs to be a system in place where incentives and enablers can be provided as and when necessary to reduce the risk of treatment interruption
- The healthcare provider is competent to order five-month sputum examination and respond appropriately to results for patients on first-line regimens, and to order sputum for smear and culture as per national protocol and respond appropriately to results for patients on second-line regimens.

### 6.2.4 Professional practice

- It is the responsibility of the healthcare provider managing the case to maintain contact with the patient and regularly evaluate his or her progress, even if there is someone in the community supporting the patient with DOT. If the patient is receiving DOT for DR-TB, it is essential that regular contact is maintained with treatment supporters. If the patient continues to have a designated person supporting them, the relationship may change with less frequent follow up in the continuation phase
- Each patient needs to be re-assessed at least monthly according to the level of support he or she may need Consideration should still be given to the factors affecting adherence outlined in Table 5.1, as the patients' circumstances may change during the continuation phase. This is especially critical for the patient who is on prolonged treatment for DR-TB, as he or she will need on-going encouragement and support to continue treatment
- The healthcare provider is competent to assess and record treatment outcomes
- Sputum is re-examined at the end of treatment to confirm that 'cure' has occurred. Prompt and accurate documentation of tests ordered, dates and results is essential. If it is impossible for patients to produce sputum, it may be necessary to collect and process saliva in order to have comprehensive treatment information
- If a patient fails to collect a supply of medication as arranged, it is necessary to mark this clearly on the treatment card. A patient who does not attend when expected should be traced using a non-judgmental approach and the reasons for their non-attendance assessed and addressed (see Standard 5.3)
- A number of patients will find it difficult to adjust to separation from the TB service at the end of their treatment. Some may be concerned that they will become ill again, whereas others may have developed a dependence on the social connections the service has given them. It is important to prepare the patient for the end of his or her treatment well in advance by beginning to talk about it at least two months before completion is due and transfer back to other services. This is particularly important where patients still need to continue lifelong treatments for other conditions such as HIV or DM
- At the end of treatment all records should be complete and accurate
- Missing information in the TB register should be regularly cross-checked with the patient card and the laboratory register to ensure that any missing information corresponds to an absence of data and not to poor record keeping, e.g., the absence of a sputum examination result at five months in the TB register means the sputum examination was not performed, only if we are sure it is not due to a lack of reporting or documentation.

### 6.2.5 Outcome

Patients will be sufficiently supported to improve chance of achieving 'cure' and to minimize interruptions in treatment. All outcomes will be recorded promptly and accurately allowing for quarterly cohort analysis of treatment outcomes.

## 6.3 Standard: Management of transfer

### 6.3.1 Standard statement

Treatment is continuous throughout the course and appropriate arrangements are made if the patient needs to transfer his or her care to another management unit.

### 6.3.2 Rationale

*Accommodating patient mobility*

During a minimum of six-months treatment, patient care may be transferred between healthcare providers. This may be from hospital to community care as the patient becomes stronger; from one location to another, if the patient moves home or travels for any length of time; or from an urban to a community clinic, e.g., if

the patient went to a central location for diagnosis but returned home for ongoing treatment. If the patient has a good relationship with the healthcare worker and understands the need to continue treatment, he or she is more likely to inform the service if personal circumstances change and he or she can no longer attend the same clinic for treatment. Particular care needs to be taken when providing care for migrant workers so that the transfer of care and treatment can be managed safely.

*Minimising gaps in treatment*

Special attention needs to be paid to the continuation of treatment while the patient's care is being transferred from one management unit to another. Treatment should not be interrupted, as gaps in treatment increase the risk of relapse and the development of drug resistance.

*Documentation regarding patient transfer*

Patients who move from one management unit to another need to be recorded as a 'transfer out' from the unit they leave and a 'transfer in' at the new unit. Treatment outcomes for those who 'transfer in' should be sent to the management unit where they were first registered and included in that unit's quarterly reports. This prevents duplication or omission in the reporting of treatment outcomes.[2]

### 6.3.3 Resources

- A referral system is in place which is common to and understood by all management units
- The healthcare provider is competent to organise the transfer and complete all necessary documentation clearly, promptly and accurately
- Transfer forms are available and used correctly
- Good communication with other management units is helpful to keep track of patients as they move.

### 6.3.4 Professional practice

- The WHO recommends the use of the 'Tuberculosis Referral/Transfer Form', which should be completed in triplicate with one copy given to the patient to take with them to the new management unit, another kept by the referring management unit and the third given to the District Tuberculosis Coordinator[39]
- When the patient arrives at the new management unit, they should be registered as a transfer in and the bottom part of the transfer form will be sent back to the referring unit to confirm the transfer has taken place. If this does not occur, the referring management unit needs to contact the new unit to check whether or not the patient has arrived. If not, the District Tuberculosis Coordinator needs to be informed
- If patients have been well supported throughout their treatment and understand the importance of finishing the course, then they are more likely to inform the facility they attend for their treatment if they are planning to go away
- Before leaving, patients need to be very clear about the importance of continuing their treatment. The healthcare worker should check their understanding of what they are being asked to do: i.e., when and where they need to present themselves
- Patients who are going to another country or are not sure of their destination should be given advice about seeking help on arrival. They should be encouraged to present to a health facility as soon as possible with a record of their diagnosis, the duration and type of treatment they have received and the address of the management unit where they are registered. In these instances, it helps to have some knowledge of health systems in other areas, although this may well be difficult
- The patient should be given a reasonable supply of medication to cover their period of travel before they are likely to be able to register elsewhere for ongoing treatment

- The healthcare provider most involved with the patient's treatment should see it as their responsibility to ensure that the patient's treatment is continued elsewhere, rather than feeling that it is no longer their concern
- It is the management unit which starts the patient's treatment that should record the treatment outcome no matter where the patient has gone.

### 6.3.5 Outcome

Patients will remain on the appropriate treatment in spite of moving away from their original management unit. This can be monitored via the TB register and quarterly cohort analysis.

# 7

## HIV testing and care of the patient with both TB and HIV

HIV infection poses one of the greatest challenges to TB care and prevention, as TB kills more people with HIV infection than any other opportunistic infection.

The association between the two diseases is so significant that one cannot be managed without consideration of the other. With better care and treatment opportunities becoming available to those infected with HIV, there is now a greater incentive for individuals to establish their status. At the same time, HCWs need to be adequately prepared to provide the best care and treatment available.[2]

The standards in this chapter cover provider-initiated HIV counselling and testing (PICT) and the care of PLWHA who also have TB. It is acknowledged that people caring for patients with TB should ensure that PLWHA are transferred for the appropriate ongoing care once their TB treatment has been completed. In some cases, referral for specialised HIV-related treatment and care may be necessary during treatment for TB.

It is essential that all activities follow the national policies and guidelines.

### 7.1 Standard: HIV testing

All patients with both presumed and diagnosed TB who have not previously been tested for HIV or know their status should be offered an HIV test.[4] Failing to do so is to deny people access to care and treatment they might need, especially in the context of the wider availability of treatments which prevent infections associated with HIV, such as co-trimoxazole preventive therapy (CPT) and antiretroviral mediations (ARVs). A clearly defined plan for care for those found to have both TB and HIV must be in place with procedures to ensure that the patient has access to this care prior to offering routine testing for HIV in persons with TB. It is recommended that testing is offered on an opt-out basis, i.e., that it will be carried out routinely unless the patient declines to be tested.

#### 7.1.1 Standard statement

HIV testing and counselling will be offered routinely to all patients with TB who do not know their HIV status in a caring, consensual and confidential manner and with their informed consent.

#### 7.1.2 Rationale

*Association between HIV and TB*

HIV is the strongest known risk factor for developing TB disease in individuals with TB infection. On the other hand, TB is the most frequent opportunistic infection among HIV-infected individuals.[2] Mortality during and after TB treatment is also higher in HIV-infected than in HIV-uninfected TB patients.

*Benefits of early diagnosis of HIV infection*

As TB is one of the main opportunistic infections associated with HIV, all patients with TB (drug-resistant or not) should be tested for HIV. The earlier it is found that someone is infected with HIV, the sooner he or she can be offered advice and treatment (ART, CPT, etc.) that can reduce incidence of opportunistic infections, prolong life and decrease the possibility of further transmission. It will also present an opportunity to offer diagnostic and care services to the patient's partner who may be at significant risk from contact with both HIV and TB.

*Managing patient anxiety*

The level of anxiety about HIV and TB, both heavily stigmatised and potentially fatal conditions, can lead the patient to feel very vulnerable and confused. This is especially acute when, having just been diagnosed with TB, the patient is confronted with the possibility that he or she may also be HIV-positive. It is essential to assess the patient's thoughts, feelings and understanding about HIV in order to respond appropriately. Just as in the case of TB, the patient's response to the possibility that he or she is infected with HIV will vary according to:

- knowledge and understanding of the infection
- any experience he or she has had either personally or through family or friends who may be infected
- access to care and treatment for HIV, including ART.

The conversation about HIV can continue throughout the course of TB treatment if necessary, as it may be difficult for the patient to consider everything at the same time.

*Maintaining trust and patient confidentiality*

The development of a good relationship with the patient is essential to maintain the patient's trust and confidence in the service being provided. This is underpinned by an open commitment to maintain patient confidentiality and address discrimination.

*Documentation*

Clear, prompt and accurate record keeping following agreed policies and procedures is necessary to ensure that those who test positive for HIV receive appropriate care. The TB program must monitor the number of TB patients tested for HIV, the number who test positive for HIV, the number initiated on ART and CPT, and TB treatment outcomes.

### 7.1.3 Resources

- Arrangements for offering HIV tests to patients with TB need to be agreed and clearly defined by the National TB and HIV Programmes and local service providers in national and local guidelines in relation to who offers the test, who collects the samples, who performs the test, who gives the results to the patient, how ongoing care and counselling will be offered and by whom
- Discrimination and stigma still stop many people agreeing to an HIV test, especially if the HCW offering the test has not been well-informed and/or is uncomfortable about the process. Any staff involved in these discussions should be aware of their own thoughts and feelings about HIV and have addressed any personal prejudices
- When staff are trained to offer HIV testing, they should be encouraged to express their views and concerns and even be tested themselves, to better understand the process and empathise with the patients they are working with
- The offering of HIV testing is unlikely to be effective without access to integrated prevention, treatment and care services. The offer of testing needs to be reinforced by the reassurance that additional support and treatment will be available should the patient test positive

- A system for the training and supervision of care givers needs to be in place to ensure competence in carrying out a pre-test discussion and post-test counselling. HCWs offering HIV tests need to have an adequate level of knowledge about both TB and HIV, the way the diseases interact and the treatment available to inform the patient accurately and answer questions appropriately. Leaflets may be helpful to reinforce messages, but they may be neither available nor appropriate in certain settings and should not take the place of a face-to-face discussion
- A suitable space is needed for the healthcare worker to talk openly and confidentially with the patient while maintaining privacy
- Clinical supplies and competent laboratory personnel need to be available to carry out the test and a good mechanism needs to be in place to feedback results while maintaining patient confidentiality. If rapid tests are being used by non-laboratory staff, a quality assurance system is required
- A system needs to be in place which follows national policy for documenting (e.g., on the treatment card) the fact that the patient has been offered an HIV test and if and when the test was done. As with all information, this should remain confidential and the patient's records should be kept safe
- The best possible infection prevention and control needs to be maintained in health facilities to reduce the risk of transmission of TB to patients and staff who may be infected with HIV.[40]

### 7.1.4 Professional Practice

*Before HIV testing*[41]

- First, the healthcare provider needs to establish whether or not the patient already knows his or her HIV status. If the patient's most recent test was negative, the healthcare provider needs to discuss the need to repeat it, depending on when it was performed and the patient's risk behaviour and potential exposure to HIV infection since that time. It is also helpful to find out whether or not anyone else in the household or close to the patient has been tested for HIV. If the HIV status is not known or another test is required, the patient needs to:
  - understand the purposes, risks and benefits of being tested or not and
  - feel fully informed and able to choose whether or not to go ahead with the test.

WHO recommends a human-rights-based approach to the offering of HIV testing based on the '5 Cs': informed consent, confidential services, with counselling, correct test results and connections to care.[41, 42]

*Confidentiality*

As with any other condition, the patient's confidentiality should be maintained throughout. It is essential that the patient is reassured that this will be the case to ensure he or she can trust the health care providers and have confidence in the services offered.

*Counselling*

The pre-test discussion and counselling should include:[41]

- An assessment of the patient's knowledge and understanding of HIV and its relationship to TB
- Identification of any behaviour or circumstance which may suggest the patient has a higher risk of being infected with HIV, such as the incorrect or inconsistent use of condoms during sexual intercourse; the chance of the patient having received a blood transfusion or blood products not screened for HIV; the possibility that the patient may have been injected with an unsterilized needle or a needle shared during intravenous drug use; multiple sexual partners
- An assessment of any clinical features suggestive of HIV infection (Appendix 2)
- A description of what the test involves

- Information about how and when the result will be given to the patient
- A discussion about the possible impact of a positive or negative result
- Information about the care and treatment available should the result be positive
- Information about HIV transmission and risk reduction, as appropriate.

*Consent*

According to the Joint United Nations Programme on HIV/AIDS (UNAIDS)[43] and WHO,[41, 42] there is a minimum amount of information needed by patients to be able to provide informed consent (Note: informed consent does not need to be written):

- The clinical benefit and the prevention benefits of testing
- Health benefits of available treatments
- Knowing HIV status may allay anxiety
- A positive test may motivate the patient to reduce risk activities
- Opportunity to reduce risk of transmission to others.
- The fact that he or she maintains the right to refuse – testing initiated by a healthcare provider must ensure that the patient can 'opt out' of the test when it is offered systematically
- What follow-up services will be offered
- In the event of a positive test result, the importance of anticipating the need to inform anyone at ongoing risk who would otherwise not suspect he or she was being exposed to HIV infection.
- If the patient chooses not to have the test, during the patient's subsequent visits to receive care and treatment for TB, the healthcare provider should:
  - find out why the patient would prefer not to be tested
  - re-iterate the value of testing and the care available during subsequent clinic visits
  - encourage the patient to avoid exposure to HIV and/or prevent HIV transmission to his or her sexual partner(s).
- If the patient gives consent, the appropriate samples should be taken or the patient should be sent to the appropriate place, according to the local procedures for testing. The patient should also be informed about when and where he or she will receive the results. With the availability of rapid testing, this could be within half an hour of the test being performed.

**NB:** See Appendix 4 for a sample script for pre-test counselling

*After HIV testing*

- Results should be given confidentially, in a sensitive and caring manner, whatever the result
- If the result is negative, advice should be given about how the patient can protect him or herself from infection and remain HIV-negative for life. This advice needs to be reiterated throughout the patient's treatment for TB
- If the result is positive, post-test counselling needs to include:
  - advice on how the patient can protect him or herself and others; i.e. how to practice safe sex including, if necessary, how to use condoms and where to get them
  - treatment available locally for HIV and related conditions
  - emotional, social and economic issues
  - local support services available according to patient need and preference
  - disclosure of status and encouraging testing of sexual partner(s) while managing associated risks, e.g., blame, violence, abandonment.[41]

**NB:** It may not be possible or appropriate to cover all the necessary issues in the first visit. Post-test counselling should continue for the duration of the patient's TB treatment and beyond when it will be provided by the service taking over the care of the patient (see Standard 7.2). See also Appendix 4 for sample scripts for post-test counselling.

- Referral to appropriate support services as discussed with the patient, and
- Clear, accurate and prompt documentation of results using agreed upon protocols.

### 7.1.5 Outcome

HIV testing will be offered according to agreed protocols, the uptake of which will be monitored. Those testing positive will receive the appropriate care and treatment, which is locally available, and those testing negative will receive appropriate care and support to remain negative.

## 7.2 Standard: Care of the patient co-infected with TB and HIV

With adequate treatment, a TB patient who is co-infected with HIV is as likely to make full recovery from TB as a non-HIV-infected patient.[2] The top priority must be to treat the patient's TB efficiently to give him or her the best chance of recovery. With appropriate support, advice and treatment, a patient living with HIV can maintain a good state of health. If a person is being treated for DR-TB, things do get more complicated, as the treatment has more serious adverse effects, and the pill burden for someone also on ART can be extremely difficult to bear.

### 7.2.1 Standard Statement

The patient receives prophylactic treatment against common opportunistic infections, support and information with regard to staying healthy with HIV, and commencement of treatment with ARVs as soon as TB treatment is started and tolerated by the patient.[44]

### 7.2.2 Rationale

*Treatment for TB*

Treatment of TB (drug-susceptible or drug-resistant) with an appropriate regimen should be seen as the priority, as left untreated, TB can rapidly become fatal for people with HIV infection.

*Prevention of other infections*

People infected with HIV are vulnerable to a variety of respiratory, gastrointestinal, skin and mouth, neurological and sexually transmitted infections. The risk of a number of common bacterial infections as well as those more usually associated with HIV infection can be reduced by certain preventive treatments. It is recommended that CPT be considered for all HIV-infected TB patients. It is recommended that preventive treatment be started at the same time as TB treatment.[44]

These infections can also be prevented though practical measures, such as good general hygiene, especially hand washing, the boiling of drinking water and safer sexual practices.

*Antiretroviral Therapy (ART)*

Treatment with ARV medications should begin as soon as the patient is tolerating TB treatment and within two to eight weeks of starting TB treatment. Considerations do need to be given to the number of pills the patient needs to take and how well they are likely to cope with both, but it is recommended that ART starts around two weeks of the beginning of TB treatment regardless of a person's CD4 count.[32, 44]

*Potential complications*

Taking ARVs at the same time as TB treatment can lead to drug-drug interactions, which the patient may not be able to tolerate; impose a high pill burden, which may be a barrier to compliance; and provoke an exacerbation of the TB as the immune system is reconstituted.[35] There may also be a problem with the efficacy of some of the ARV drugs and rifampicin due to drug-drug interactions. A healthcare provider with expertise in treating both HIV and TB should be involved so that any complications can be identified and managed appropriately.

*Prevention of transmission of HIV*

Anyone tested positive for HIV should be counselled as to how to prevent transmission to others. The patient needs to be advised regarding practising safe sex and avoiding high-risk behaviour, such as sharing needles, if he or she is an injection drug user.

The transmission of HIV between patients in healthcare facilities can be avoided if recommended sterilisation procedures are followed regarding medical, surgical and dental equipment, and if the use of injections in general is reduced. Rarely, staff may be infected through needle-stick injuries or injury involving other contaminated sharps. These risks are significantly reduced if standard infection control procedures are followed and "sharps" are disposed of safely according to local policies.

*Ongoing support and counselling*

The patient can be very distressed on finding out that he or she is infected with HIV in addition to having TB. It is essential to assess the patient's reactions and respond appropriately so that he or she develops confidence in the care offered. Disclosure of the patient's HIV status needs to be discussed, but again this may need to be addressed over time to give the patient the opportunity to come to terms with the diagnosis and develop an understanding of the condition.

*Assessing the patient's information needs*

It is essential that the patient receives the necessary information to assist him or her to stay healthy. Many issues will need to be covered, but it is important that information is offered over time, as the patient may find it difficult to absorb large amounts of information when he or she is distressed. The newly diagnosed co-infected patient should have his or her information needs regarding HIV assessed in the same way that the patient's information needs should be assessed regarding TB (see Standard 4.1). It cannot be assumed that the patient will absorb everything he or she is told, so it is important to check what the patient has understood and encourage him or her to ask questions.

*Liaison with other services*

The patient is likely to have complex needs and may benefit from a variety of services offered by local organisations outside of the management unit. The patient should be made aware of other organisations in the local community where he or she can access help. Referrals should only be made with the patient's explicit permission, as confidentiality must be maintained if he or she is to develop trust in the service.

*Documentation*

Clear, prompt and accurate record keeping is necessary to monitor the progress of each patient and his or her treatment. National policies and procedures must be followed in terms of how information regarding co-infected patients is recorded.

### 7.2.3 Resources

- Joint plans, guidelines and policies for the treatment and care of co-infected patients need to have been developed in partnership between the National AIDS Programme (NAP) and the NTP. These should include guidance regarding documentation
- Staff with understanding of both TB and HIV treatment and care
- Nursing and medical follow up with the appropriate expertise in both conditions
- Space for privacy to be maintained
- Reliable supply and storage of drugs and laboratory materials for the treatment and monitoring of TB and common HIV-related infections as well as CPT
- Group and individual education covering a variety of themes associated with treatment, safe sex and prevention of further infection
- Access to a variety of local support services, which can offer additional care to patients according to their needs
- Trained staff with access to information – WHO, IMAI, UNAIDS guidelines
- TB and HIV infection control measures in place in line with WHO guidelines[40]
- A referral system needs to be in place for ongoing patient care following the completion of TB treatment.

### 7.2.4 Professional Practice

The healthcare provider needs to assess the co-infected patient when the diagnosis of TB and HIV is made and on an ongoing basis during subsequent appointments. The following areas should be covered:

- The patient's understanding of TB and HIV, how it is transmitted and how it is treated
- The presence of HIV-related conditions that may or may not require treatment
- The patient's readiness to start ART and his or her ability to adhere to the regimen
- Psychosocial issues which may affect the patient's care or treatment
- The patient's feelings about disclosing his or her HIV and TB status to others
- Any adverse drug effects the patient is experiencing and what medication this is likely to be associated with.

**Box 7.1: Treatment regimens for ART**

The WHO recommends use of certain first and second-line standardized ART regimens.[44]

Any decision regarding ART, when to start and the treatment regimen to be used should follow national guidelines and protocols. ART can be started between two and eight weeks following the commencement of anti-TB treatment. It is recommended that patients co-infected with HIV and TB with acute immuno-suppression (a CD4 count < 50 cells/mm3) initiate ART within two weeks of starting anti-TB treatment.

Following such assessments:

- The appropriate support information can be provided at a time when the patient is most likely to need and absorb it
- Referrals can be made with the agreement of the patient according to the patient's needs and the services available locally
- Adverse drug effects can be managed appropriately whether they are related to treatment in association with TB or HIV

- If the patient is on ART, regular assessment is required regarding:
  - Any changes in the patient's condition, e.g., weight gain and the resolution of opportunistic infections, can indicate a good response to treatment; CD4 counts and viral loads can also be used but are not always available.

    **NB:** The healthcare provider should be aware of immune reconstitution inflammatory syndrome (IRIS), which can make TB worse even while the immune system is improving;
  - Ensuring that the regimen and dosages prescribed are based on national guidelines
  - Laboratory monitoring according to local policies
  - The patient's adherence to the regimen prescribed
  - The principles of supporting adherence are the same for ART as they are for anti-TB treatment, namely: systems in place to ensure that medications are available and free of charge, involvement of family or community members, psychosocial support, nutritional support, the use of pillboxes or blister packs and directly observed therapy where possible
  - The healthcare provider will follow local procedures for clear, accurate and prompt record keeping
  - The healthcare provider will prepare the patient for referral to an appropriate facility for the ongoing treatment and care he or she needs regarding HIV infection.

### 7.2.5 Outcome

Co-infected patients will successfully complete a full course of TB treatment, develop knowledge, have support and care for HIV during treatment of their TB and be referred to appropriate services for the continuation of their HIV care.

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## APPENDIX 1: Example of tools for practice assessment, planning and implementation

**This tool can be used with each standard**

| **STEP 1: Assessment and Pre-Planning** | **Assessment: where are you meeting the standard and what are the gaps?** | **Plan: what can do you do to address these?** |
|---|---|---|
| **Standard statement:** *Type in actual statement* | What is the **actual** standard of care in your setting? | Can you achieve this standard in your setting or do you need to change it to make it more relevant or realistic? If you need to change it, what would your standard statement be? |
| **Rationale** *Link to text* | What is the impact of the current standard of care on the patient/ service? | What difference will it make to the patients/service if you meet the standard you have agreed to aim for? |
| **Resources** *Type in brief with link to full text* | What resources are currently available to implement this particular standard? | What additional resources are needed and where might you get them from? Who needs to be involved? |
| **Professional practice** *Type in brief with link to full text* | What is the current practice? Who is doing what? | What needs to change in practice to meet the standard? Who needs to do what differently and how will their practice be changed? |
| **Outcome** *Type in full* | What is the current situation? What information do you have(from quarterly reports, patients or documents such as the laboratory register, the TB register, or the patient record cards) which shows there may be a problem? | How will you know you have improved the standard of care? What will you look for and how will you find the information to demonstrate change? |

**STEP 2: Planning and implementation**

**Standard statement:**

| | **Who needs to be involved?** | **What does each group / individual need to do?** | **What is the expected outcome?** | **By when?** |
|---|---|---|---|---|
| **What resources are required to meet the standard?** *(list below those identified in step 1)* | | | | |
| | | | | |
| **What elements of Professional Practice need to be improved to meet the standard?** *(list those identified in step 1)* | | | | |
| | | | | |
| | | | | |

## APPENDIX 2: TB symptom screening tool sample

**TB SYMPTOM SCREENING TOOL FOR ADULTS AND CHILDREN**

**PATIENT DETAILS**

| | |
|---|---|
| Surname: | First Name: |
| Physical Address: | Age: |
| | |
| | |
| | |
| Telephone Number: | Patient folder Number: |

**MEDICAL HISTORY**

| | | | | |
|---|---|---|---|---|
| Close contact of a person with infectious TB: | Yes | No | Unknown | (Tick √) |
| Type of index patient: | DS-TB | Rif Resistant TB | MDR-TB or XDR-TB | |
| Diabetic: | Yes | No | Unknown | |
| HIV Status: | Positive | Negative | Unknown | |
| Other: (Specify) | | | | |

**TB SYMPTOM SCREEN**

**1. ADULTS**

| **Symptoms** (Tick √) | Yes | No |
|---|---|---|
| Cough of 2 weeks or more OR of any duration if HIV positive | | |
| Persistent fever of more than two weeks | | |
| Unexplained weight loss >1.5kg in a month | | |
| Drenching night sweats | | |

**2. CHILDREN**

| **Symptoms** (Tick √) | Yes | No |
|---|---|---|
| Cough of 2 weeks or more which is not improving on treatment | | |
| Persistent fever of more than two weeks | | |
| Documented weight loss/ failure to thrive (check Road to Health Card) | | |
| Fatigue (less playful/ always tired) | | |

*If "Yes" to one or more of these questions, consider TB.*
*If the patient is coughing, collect sputum specimen and send it for Xpert testing.*
*If the patient is not coughing but has the other symptoms, clinically assess the patient or refer for further investigation.*

| | | |
|---|---|---|
| Date of last TB test: | | |
| Patient referred for assessment and investigation: | Yes | No |
| Date of referral: | Facility name: | |
| Name: | Date: | |

**Source:** *National tuberculosis management guidelines 2014.*[45]

## APPENDIX 3: Clinical features suggestive of HIV co-infection in patients with TB

| | |
|---|---|
| Past history | Sexually transmitted infection (STI) |
| | Herpes zoster (shingles), which often leaves a scar |
| | Recent or recurrent pneumonia |
| | Severe bacterial infections (sinusitis, bacteraemia, pyomyositis) |
| | Recent treated TB |
| Symptoms | Unexplained weight loss (>10kg or >10% of original weight) |
| | Unexplained chronic diarrhoea (>1 month) |
| | Retrosternal pain on swallowing (suggests esophageal candidiasis) |
| | Burning sensation of feet (peripheral sensory neuropathy) |
| Signs | Scar of herpes zoster |
| | Pruritic (itchy) papular skin rash |
| | Karposi sarcoma |
| | Symmetrical generalized lymphadenopathy |
| | Oral candidiasis |
| | Angular cheilitis |
| | Oral hairy leukoplakia |
| | Necrotizing gingivitis |
| | Giant aphthous ulceration |
| | Persistent painful genital ulceration |

For more detailed information with specific references to infants, children, adolescents and adults, please see: WHO's *Case definitions of HIV for surveillance and revised clinical staging and immunological classification of HIV-related disease in adults and children.*[46]

Follow link: http://www.who.int/hiv/pub/guidelines/HIVstaging150307.pdf?ua=1

## APPENDIX 4: Sample scripts for pre- and post-test counselling

| **A sample script for pre-test counselling** |
|---|
| *HIV infection is common among TB patients in …….. Our clinic offers HIV testing to everybody with TB because there are several benefits of knowing whether one is infected or not. Some of them are:*<br>• *Access to HIV care that can improve your health, if you are found to be infected.*<br>• *Prevention of spreading HIV to others.*<br>• *Referral to mother-to-child HIV transmission prevention services (if patient is female).*<br>• *Ability to plan for your future.*<br>*To ensure that you get the necessary services, it is important to know whether or not you have HIV. Unless you object, as part of your clinic visit today, you will receive an HIV test. What questions can I answer for you about this?* |
| **A sample script for post-test counselling (negative result)** |
| *Your HIV test result is negative. It is important that you will remain free from HIV for life. HIV infection is common in our community. You need to avoid unprotected sex with a partner who is HIV-positive or whose HIV status is not known. Sometimes couples have different HIV results. You mentioned earlier that you have a wife/husband/partner. Do you know whether she or he has ever been tested for HIV? (Assuming he/she does not know:)*<br>*In that case, I recommend that you will go together to …….. for her/him to be counselled and tested.*<br>*If she/he does not have HIV, the two of you can do enjoy your relationship as you like, always remembering the need to be mutually faithful.*<br>*If your wife/husband/partner is HIV-positive, you must practice safer sex and always use condoms to protect you from HIV. It is advisable not to have sex until your wife/husband/partner is tested and you find out if she/he has HIV.*<br>*We have condoms available in the clinic and you are welcome to take some.*<br>*I hope you will ask your wife/husband/partner to be tested by your next visit when we will discuss this.*<br>*Do you have any questions?* |
| **A sample script for post-test counselling (positive result)** |
| *I know how difficult it can be receiving this result—learning that you have HIV. It is normal to feel upset and overwhelmed at first. You need to take time to adjust to this, and I know that in time you will be able to cope. This clinic is here to help you. Also, most people find it helpful to tell someone about their problems and get support. Is there anyone that you can talk to about what has happened today?*<br>*In addition to support from family, you need medical treatment that can help you feel better even though you have TB and HIV infection. In this clinic we provide you with other tests for HIV, such as CD4 count and viral load.*<br>*As you know, HIV can be spread through sex. It is therefore important that your husband/wife/partner is tested right away to determine his/her result. Do you think you he/she would be interested to visit this clinic with you when you come here next time? Since you are attending TB care in this clinic, we can assist your family with testing for both conditions?*<br>*Do you have any questions?* |

Adapted from examples used in, Zimbabwe, which are, in turn, based on materials developed by CDC in 2005 entitled "Diagnostic HIV counselling and
testing in TB clinical Settings"[47]

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The Union

International Union Against
Tuberculosis and Lung Disease
Health solutions for the poor

International Council of Nurses
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## ABOUT THE INTERNATIONAL UNION AGAINST TUBERCULOSIS AND LUNG DISEASE (THE UNION)

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