

BEST PRACTICE FOR THE CARE OF PATIENTS WITH TUBERCULOSIS

A Guide for
Low-Income Countries

2007

International Union Against Tuberculosis
and Lung Disease

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Abbreviations

- AFB – acid-fast bacilli
- AIDS – acquired immune-deficiency syndrome
- ART – anti-retroviral treatment
- BMU – Basic Management Unit
- CDC – Centers for Disease Control and Prevention (USA)
- DOT – directly observed treatment
- DOTS – TB control strategy recommended by the WHO
- HIV – human immunodeficiency virus
- IMAI – Integrated Management of Adolescent and Adult Illness
- KNCV – Royal Netherlands Tuberculosis Foundation
- NAP – National AIDS Programme
- NTP – National Tuberculosis Programme
- TB – tuberculosis
- The Union – The International Union Against Tuberculosis and Lung Disease
- WHO – World Health Organization

I. INTRODUCTION

This guide has been developed for workers in low-income countries who are involved in detecting and caring for patients with TB in primary, community and acute (hospital) health-care settings. It aims to improve the quality of patient care and in turn improve the outcomes of TB control programmes. Detailed guidance is provided regarding good practice for the management of people presenting to health services with suggestive symptoms and the ongoing care of patients with active disease.

The guidance is based on existing good practice and has been developed in collaboration with nurses working in a wide variety of settings. 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 that are adaptable to local services in low-income countries and which encourage evaluation through the use of measurable outcomes. Each standard corresponds to a significant point in a TB patient's diagnosis or treatment based on the TB management strategy recommended by The Union¹ and treatment regimens recommended by the WHO.^{2,3} Throughout this guide, readers will be directed to the relevant information published in The Union's 'Orange Guide' entitled *Management of Tuberculosis: A Guide for Low-Income Countries*,¹ and other key reference material.

The TB management strategy, which was developed by The Union and officially adopted by the WHO as the DOTS strategy (Table I.1), provides an effective way of implementing and evaluating a series of clinical and organisational interventions aimed at controlling TB. Resources during planning, implementation and review tend to focus on these interventions without explicitly addressing key components of patient care. This may be due to the fact that patient care as a concept is difficult to describe in specific or practical terms. As a result, the care being offered to patients varies in quality both within and among countries, as it depends on the attitudes, skills and competence of individual health-care workers. This is an issue that is likely to receive increased attention now that the WHO is recommending expansion of the strategy to take into account the difficulties many, especially poor, patients face in accessing quality TB care.⁴

Table I.1 The DOTS strategy

The DOTS strategy is based around five key elements:

- 1. Sustained political commitment** to increase human and financial resources and make TB control a nationwide priority integral to the national health system
- 2. Access to quality-assured sputum smear microscopy** for case detection among persons presenting with, or found through screening to have, symptoms of TB (most importantly, prolonged cough)
- 3. Standardised short-course chemotherapy** for all cases of TB under proper case management conditions, including **direct observation of treatment**
- 4. An uninterrupted supply of quality-assured drugs**
- 5. A recording and reporting system enabling outcome assessment** of all patients and assessment of overall programme performance

This guide aims to use a recognised system of quality assurance, i.e., standard setting based on the available evidence and existing good practice in order to offer more definitive guidance with regard to 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 the type of health-care providers who will be using the guide in practice.** Those working in better resourced areas may wish to develop additional standards to cover 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 II, where guidance is also offered as to how to implement best practice on the ground. The next step is to test the standards in practice using the built-in evaluation measures. Essentially, this guide is intended to be used to develop evidence-based practice for the care of those affected by TB.

An important note regarding terminology:

Due to the variety of terms used to describe various health care facilities in different parts of the world this guide will use the internationally agreed terms published by the WHO,⁵ set out in Table I.2.

Table I.2 Definitions for TB diagnosis, treatment and management units⁵

The following terms are used throughout this document to refer to points of TB diagnosis, treatment and/or management. TB treatment facilities and TB microscopy units exist within general integrated health service facilities and health management structures in the case of Basic Management Units (BMUs). These are not stand-alone or vertical TB facilities or units but have been given a specific name to help describe their nature and function in terms of TB control programmes.

Basic Management Unit*

A BMU is defined in terms of management, supervision and monitoring responsibility. A unit for TB control may have several treatment facilities, one or more laboratories, and one or more hospitals. The defining aspect is the presence of a manager or coordinator (in this document this person is referred to as the Unit Coordinator) who oversees TB control activities for the unit and who maintains a master register of all TB patients being treated, which is used to monitor the programme and report on indicators to higher levels. Typically, the units correspond to the government's second subnational administrative division, which might be called, for example, a "district", "county", or "rayon". The TB control programme may choose to lump or split these divisions to form operational units that are manageable (in terms of the population served, the geographic area covered and the laboratory services available). It is internationally recommended that a BMU cover a population between 50,000 and 150,000, or up to 300,000 for large cities.

A BMU is implementing the DOTS strategy when all components of the internationally recommended approach to TB control are in place. These include political commitment; uninterrupted drug supply; use of smear microscopy in diagnosing TB cases; standardised short-course treatment regimens; direct observation of treatment, at least during the initial phase of treatment and during any phase that includes rifampicin in the treatment regimen; and monitoring of treatment outcomes for 100% of patients with TB.

*Referred to as the "unit of management" in the Orange Guide¹

Table I.2 (cont'd)

TB treatment facility

A TB treatment facility is defined as a facility that provides standardised short-course treatment regimens for TB patients. A DOTS treatment facility includes all components of the internationally recommended approach to TB control, including standardised short-course treatment regimens; direct observation of treatment, at least during the initial phase of treatment and during any phase that includes rifampicin in the treatment regimen; and monitoring of treatment outcomes for 100% of patients with TB.

TB microscopy unit

A TB microscopy unit (TMU) is defined as a unit where sputum smear microscopy is performed. This unit should have adequate supplies and trained staff to perform the proper functions for diagnosis. It is internationally recommended that a TMU cover a population between 50,000 and 150,000. In most settings, this results in workloads within the recommended range of 2 to 20 smears per day.

II. 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 patients with TB. The aim is to improve the quality of care through a system of standard setting and clinical audit.

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 the resources available. It also offers an objective way of finding out whether or not one has achieved what one set out to do by defining measurable outcomes.

It is essential that ‘levels of excellence’ are defined locally, and it is intended that these standards should be both used as a guide and adapted to the local setting. This is essential to foster a sense of ownership and promote professional credibility.⁶ 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 setting⁶ which is used in this guide provides a framework that consists of the standard statement, rationale, resources, professional practice and outcomes (Table II.1). This in turn allows standards to be based on available evidence while being appropriate to the local environment.

1.1 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 control measures on the ground. The aim is to provide realistic guidance for those involved in providing care to patients suffering from TB in low-income countries and other poorly resourced settings.

Table II.1 The framework for standard setting⁶

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	<p>What is required to meet the defined level of care:</p> <ul style="list-style-type: none"> • People <ul style="list-style-type: none"> – knowledge and skills required by health care professionals – availability of relevant training and education – required members of the multi disciplinary team – role and function of the management in relation to meeting the requirements. • Equipment <ul style="list-style-type: none"> – availability of specialist and non specialist items required – availability of written materials for patients – policies and procedures available to staff. • Environment <ul style="list-style-type: none"> – patient environment (e.g., privacy, possibility for isolation, etc.) – staff environment (e.g., space for both clinical and administrative work; storage, etc.)
Professional practice	<p>Critical elements of assessment, planning, implementation and evaluation</p> <p>Highlighting of specific aspects of professional practice relevant to the patient’s problem/need</p> <p>Suggestions with regard to the identification of</p>

Table II.1 (cont'd)

Component	Definition
	and referral to the appropriate care providers Documentation required in terms of patient records and for evaluation purposes.
Outcome	Expected results of the planned intervention which can be assessed through <ul style="list-style-type: none"> • patient satisfaction • staff satisfaction • documentary evidence.

Nurses are often the designated focal point or Unit Coordinator for TB control programmes and, as such, are involved in other activities such as management of supplies, preparation of quarterly reports and health promotion. Although there is guidance available elsewhere on these themes, patient-centred care within the framework of the DOTS strategy has not yet been clearly defined. 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.

2. Clinical audit

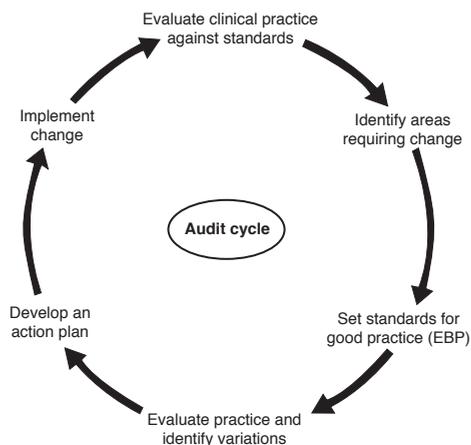
The first step to improving the overall quality of patient care is to look at the strengths and weaknesses of the existing service. Clinical audit provides a systematic approach to evaluating current practice against agreed standards and making changes with a built-in process for evaluation. Health-care workers using this guide will discover that much of their practice reflects what is described in the standards. 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?

2.1 Key components of the clinical audit process

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; and evaluation of changes made against set standards (Figure II.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 II.1 Audit cycle⁷



It is important to assess a service's strengths and build on these to motivate staff and support small changes that are likely to show improvements within a short period of time. This is the best way to achieve successful change in the first instance and give staff confidence and enthusiasm to look at other areas that 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. The standards described in this guide offer a basis for the setting of local standards for the care of patients with TB. 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). An implementation tool based on the clinical audit cycle has been put into a table format, which can be found in Appendix 1: Implementation tool.

2.2 Training and practice development

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 that simply focuses on the dissemination of information.⁷ Health-care workers 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 health-care workers to change their practice without taking into account the conditions under which they have to work.

2.3 Evidence-based practice

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. This in turn will begin to inform evidence-based practice (EBP) and encourage others to use similar processes.

3. 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 in order 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 in order to become effective in a different setting.⁸

In TB control nurses routinely collect data relating to case finding and treatment outcomes, which 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 with regard to rates of sputum conversion, defaulting, etc. The Unit Coordinator responsible for undertaking the analysis can work through the outcome data with the relevant health-care 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.
- Treatment outcome data can highlight monitor rates of default, failure or death.
- Patient record 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, staff reaction, etc., depending on who is involved in the change.

III. IDENTIFYING AN ACTIVE CASE OF TB*

The diagnostic phase is critical to effective case finding. By the time an individual 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.

1. Standard: Assessment of a patient who might have TB

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.

1.2 Rationale

1.2.1 *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 because the sooner someone is diagnosed and started on treatment the shorter the time they remain infectious. It also benefits the patient physically, because organ damage will increase the longer the disease remains untreated.

1.2.2 *Identifying a suspect case for further investigation*[†]

It is recommended that all patients who have been coughing for 2-3 weeks or more should have their sputum sent for AFB smear examination, as chronic cough is the most common symptom of TB.⁹ Other symptoms include breathlessness, chest pain, loss of appetite, weight loss, malaise, fatigue, night sweats and fever. These symptoms are even more indicative of TB if the patient has had contact with someone known to have the disease. Ensuring that health-care workers have an adequate level of awareness about TB symptoms

*Orange Guide Chapter II and VI, Appendix¹

[†]Orange Guide Chapter II.B1 & 2

will prevent cases being missed. Special care should be taken when assessing children, as symptoms vary and they seldom produce sputum, which means they are more difficult to diagnose.‡

NB: The development of clinically significant drug resistance is usually a result of mismanagement of TB by health-care workers and has severe consequences for both the patient and his or her community. Its prevention 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 treatment of the patient when first presenting to the health service. Patients at highest risk are those who have previously been treated for TB. It is absolutely vital that these patients be correctly identified prior to being given treatment and that they are prescribed a retreatment regimen.

1.2.3 Ordering the appropriate tests

It is important to order the appropriate tests in order to save time and money. The most effective test for finding infectious TB is sputum smear microscopy for AFB. Chest radiographs may be useful in diagnosing the disease in the smear-negative patient but their interpretation can be unreliable in identifying active TB.§

1.2.4 Assessing the patient's thoughts and feelings about TB

TB can be a stigmatising disease, and it is essential to assess the patient's attitudes and feelings towards the fact that he or she may have the disease in order to respond appropriately. The patient's response to the possibility that he or she may have TB will vary according to:

- his or her knowledge and understanding of the disease, and
- any experience he or she has either personally or through family or friends who may have suffered from it.

1.2.5 Building trust

A good relationship needs to be developed at the earliest contact with the patient so that 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

‡ Orange Guide Chapter II.B3.4 p9-10

§ Orange Guide Chapter II.B3

areas where the patient has to pay for investigations, it is essential that he or she understand the need for the tests – especially the need for more than one sputum test.

1.3 Resources

- Staff in health-care facilities where people are most likely to present with symptoms are alert to TB and levels of the disease in the local community.
- The health-care worker assessing the symptomatic patient:
 - has been given the responsibility and appropriate training to do so
 - is familiar with the signs and symptoms with regard to TB
 - is familiar with the treatment available for TB
 - can assess each patient's response to the fact that he or she may have TB and react accordingly
 - is able to order the correct tests or refer the patient to the appropriate facility.
- The patient is who very sick can be referred to an appropriate medical officer.
- 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 as to how and where to collect the results of his or her examinations.
- TB treatment is available free of charge, and this fact is emphasised to the patient.

1.4 Professional practice

The health-care worker will:

- Begin to build a relationship with the patient by listening to his or her concerns and remaining non-judgemental.
- Reassure the patient that all personal information given will remain confidential.
- Take personal details, including name, home and work address, contact telephone numbers, etc.

- Take a full medical history, including duration of symptoms and presence of other medical conditions.
- Assess how likely it is that the patient is suffering from TB.
- Explain to the patient what tests will be done and the reasons for doing them.
- Inform the patient when to expect the results to be available and the how these results will be conveyed – during a subsequent appointment at the health facility, a telephone call from the health-care worker, etc.
- Check to see if each patient came back to collect their results.
- Check the laboratory register and the TB patient register on a weekly basis to ensure that all those with a positive sputum smear result have started treatment.[¶]
- Offer relevant health education:
 - 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
 - Group: give health education sessions to waiting patients, including a question and answer session.

1.5 Outcome

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

“Every individual suspected of having tuberculosis must have an examination of sputum to determine whether or not they have infectious tuberculosis.”[#]

[¶] Orange Guide Chapter IV A1 p 25

[#] Orange Guide Chapter II.B3

2. Standard: Sputum collection for diagnosis

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.

2.2 Rationale

2.2.1 Good quality specimens

Good specimens – i.e., specimens that are sufficient (3-5 ml) and contain solid or purulent material** – are required to give the laboratory technician the best chance of seeing AFB under the microscope and therefore for the service to identify the most infectious patients. If the sample is inadequate (e.g., saliva only), it may not be possible to see AFB even if the patient is infectious.

2.2.2 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†† 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.

2.2.3 Minimising delays

Every effort should be made to ensure that specimens are delivered to the laboratory and then examined without delay. This is essential to prevent 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 health-care worker involved in caring for the patient gives him or her the results rather than a laboratory technician. This will enable the patient to obtain accurate information about the treatment and care provided.

** Orange Guide p 64

†† Orange Guide Appendix 2, Form 1

2.2.4 Building a good relationship with the patient

The patient may be very nervous at this stage and feel bombarded with information. It is important to check that the patient understands the process and can bring up any problems he or she might foresee. There is a real risk that the patient may not return future specimens 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.

2.2.5 Patient and staff safety

Consideration for the safety for both patients and staff in is essential to reduce the risk of transmission.**

2.3 Resources

- A functional, well-stocked laboratory is able to carry out sputum smear microscopy on a daily basis^{§§} with a system in place for quality assurance.
- The health-care worker responsible for ordering tests has the necessary knowledge and skills to instruct the patient how to produce a good specimen and when and where to deliver it.
- The appropriate sputum containers are available – wide-necked, disposable containers with screw-top lids.
- Sputum request forms and laboratory registers are available and completed promptly by competent staff members.
- There is a place to store specimens safely if they are kept in a clinical setting before being sent to the laboratory.
- 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.^{¶¶}
- A system is in place for the prompt feedback of results, preferably with someone from the management unit routinely collecting the results.
- A named staff member is responsible for coordinating the process with a deputy to cover absence.
- Good communication is maintained between the laboratory and the management unit.

** Orange Guide Chapter VI Appendix 1

§§ Orange Guide Chapter IV.C

¶¶ Orange Guide Chapter VI

2.4 Professional practice

Health-care workers involved with the collection of sputum specimens should adhere to the following principles:

- A specimen collected under the 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. If not it should be collected in a well-ventilated room used only for this purpose, or an early morning specimen should be collected at home and delivered to the appropriate place by the patient.
- The patient is likely to prefer to be out of sight of other people when he or she is producing a sputum specimen.
- Three specimens (one spot specimen, one early morning specimen collected at home and delivered by the patient, and another spot specimen; if the patient is hospitalised three early morning specimens should be taken) should be sent with fully completed sputum request forms. In some settings, national guidelines require only two specimens.
- It is recommended that the first specimen, a ‘spot’ specimen, is collected under supervision before the patient leaves the health facility.^{##} A step-by-step guide with regard to the practical aspects of this process is presented in Table III.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 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 very sick, he or she should be referred to a medical officer for further investigation.
- The mechanism in place for the feedback of results should be 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 who can disseminate this information.

^{##} Orange Guide Chapter II.B 3.1

- If one or more of the sputum samples test positive, the person is registered as a TB patient and treatment is started (Chapter IV).
- If all of the samples are AFB smear-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.

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 fed back accurately and without delay. From the laboratory register it will be possible to see how many specimens were examined per patient and the percentage of positive results among patients attending for diagnosis or for follow-up. There will be a correlation between the laboratory register, the TB register and the patient treatment cards.

Table III.1 Best practice for sputum collection⁶

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, 2 or 3 (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 fully and slowly, in language that the patient can understand.
- The patient is encouraged to rinse their mouth with water, especially if they have been eating food, before expectorating into the container.
- The 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 health-care worker demonstrates a deep cough from the bottom of the chest, beginning with deep breathing.
- The health-care worker supervises the collection, but without standing in front of the person attempting to produce the sputum.

Table III.1 (cont'd)

- The lid on the container is closed carefully and tightly.
- The specimen is checked by the health-care worker with the patient present – if it is insufficient (e.g., saliva only) the patient is asked to cough again and add to it.

Prevention of transmission

- The health-care worker supervises the collection, but without standing in front of the person attempting to produce the sputum.
- The patient and the health-care worker wash their hands with soap and water after collecting the specimen.
- The specimen must be handled carefully and the lid closed tightly.
- Ideally, there should be a separate well-ventilated area for sputum collection, preferably outside the building, avoiding use of the toilets.
- Care should be taken during the processing and disposal of the sputum specimen.^{***}

Sputum storage

- The specimen is sent to the laboratory as soon as possible after collection.
- The dates on which the specimen was collected and on which it was 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.

Documentation

- The specimen is categorised as pre-treatment 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 (usually month 2 or month 5) of treatment.^{†††}
- The laboratory register is completed clearly and accurately.^{‡‡‡}
- Dates of the taking of 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.

^{***} Orange Guide Chapter VI, Appendix 1

^{†††} Orange Guide Appendix 2, Form 1

^{‡‡‡} Orange Guide Appendix 2, Form 2

IV. STARTING TREATMENT: CARING FOR PATIENTS, THEIR FAMILIES AND CLOSE CONTACTS*

Treatment should start as soon as possible after a diagnosis of TB is made i.e., when one or more laboratory reports indicate smear positive results OR the suspicion of TB is very high, the patient is very sick and has been assessed by a medical officer.† The care described in the following standards is based on the patient receiving treatment according to a regimen recommended by the WHO.^{2,3}

Research has shown that taking medication according to instructions for long periods is NOT normal human behaviour and the patient requires support to successfully complete the necessary 6-8 month course of treatment.¹¹ 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 for all patients who are diagnosed with TB to be registered at an appropriate management unit (see Table I.2) so that their progress can be routinely monitored and programme performance can be assessed. A number of TB treatment facilities may be linked to any given management unit 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 that covers the area where their treatment facility is located. The Unit Coordinator is responsible for:

- Identification of the appropriate management unit where the patient will be registered (usually the one where the diagnosis was made, but not always, especially in big TB centres of large cities or in teaching hospitals where there are no management units for TB).
- Registration of the patient in the management unit's TB register.
- Keeping the TB register in order.

* Orange Guide Chapter III

† Orange Guide Chapter III. A1 p12

- Ensuring the patient record card (if used) and the TB treatment card[‡] are filled out correctly.
- Ensuring that the correct regimens and dosages are applied.
- Identification of the treatment facility where DOT will be carried out correctly.
- Ensuring that all smear-positive patients are started on treatment.
- Monitoring default and systems for tracing late patients, including a tracing system for those who are smear-positive but don't show up (early defaulters).
- Reporting on results from all patients covered by the management unit.[§]

1. Standard: Registration and care of newly diagnosed TB patients

1.1 Standard statement

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

1.2 Rationale

1.2.1 Identification of the appropriate management unit

In some big institutions there is no management unit for TB because they cannot offer good treatment follow-up. For patients who are diagnosed with TB in such institutions, it is necessary to identify right away to which management unit the patient will be referred after being discharged. Similarly, in large cities some big TB centres can be overburdened by large numbers of patients. This presents difficulties for both the unit that is struggling to care for the large numbers of patients as well as the patients who often have to travel large 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 the unit, which does not have the capacity to trace them if they do not attend. Once a diagnosis is made, patients should therefore be given the option to choose to be referred to another management unit that is more convenient for them and alleviate the pressure from the big TB centre. This process should occur without delay.

[‡] Orange Guide Chapter VII Appendix 2 - form 3

[§] Orange Guide p 29

For TB patients referred to a management unit (either because treatment was 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 in order 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.

1.2.2 Clear, accurate and timely documentation

All documentation, including the TB register, the treatment card and any patient-held card, must be completed clearly and accurately. The sooner 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 of a close friend or relative 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 V.2). As some patients may be reluctant to give accurate contact details at first, and may only do so once they have gained trust in the service, it is useful to check regularly if any of the details have changed or are due to change.

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

If TB is treated inadequately, drug resistance may develop. 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,^{2,3} and their category 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.[†]

1.2.4 Offering an HIV test

Due to the close association between TB and HIV, it is recommended that all patients diagnosed with TB should be offered an HIV test in order to receive care for both diseases according to their needs. This is covered in more detail in Chapter VII.

[†]Orange Guide Chapter V C. 1

1.2.5 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 leading to patients feeling rejected and isolated. It is essential that they begin to understand their condition and their treatment from the very beginning in order to avoid the risks highlighted in Table IV.1. Thorough assessment of each individual patient is essential in order to demonstrate interest in them as a person as well as the fact that they have TB and, as a result, to be able to plan appropriate care for them.

1.2.6 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 have known 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. A motivated health-care worker who clearly shares and explains information about issues that are important to the patient can increase adherence to treatment. The use of appropriate visual materials can be helpful, but should never replace one-to-one discussion, and the amount of information covered at any one time will depend on the individual patient's needs and concerns.

1.2.7 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 that they must cope with. 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, and how the diagnosis and treatment may affect their lifestyle. This will encourage them to attend for their treatment and follow-up visits. If patients feel that staff are rude or too busy to care, they are unlikely to want to come back. Spending time with patients early on can save time in the long run by preventing irregular attendance, default, treatment failure and prolonged treatment.

Table IV.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 Show interest in the patient's concerns
Fear of <ul style="list-style-type: none"> • taking medications • dying • adverse drug effects • experience of TB • infecting others • rejection and discrimination • loss of employment • loss of accommodation • being HIV-infected 	Education <ul style="list-style-type: none"> • patient • family • workplace • communities • contact tracing
Denial/refusal	Information/support (identify significant others, e.g., family members who can also offer support)
Other priorities that overshadow the disease	Offer tangible support – address the problems identified by patient
Emotional turmoil <ul style="list-style-type: none"> • guilt • anger 	Address feelings Check understanding and response to messages (patient and family)
Co-morbidities <ul style="list-style-type: none"> • HIV infection and AIDS 	Work with other services if available Inform patient of local services that may offer assistance Offer HIV testing, counselling and ongoing support and care
Lack of social support <ul style="list-style-type: none"> • e.g., patients living alone 	Identify potential support from friends or family, community groups, etc

1.3 Resources

- In places where the bulk of 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 ensure that the people referred arrive and are registered at the appropriate management unit.
- Treatment cards and TB registers must be available and the health-care worker should have the knowledge to complete them clearly, promptly and accurately.#
- Good communication skills (Table IV.2) are needed to:
 - assess patients' existing knowledge about TB and its treatment
 - give accurate information according to their needs and understanding
 - show that the service cares about them
 - encourage them to return to the clinic as arranged.
- Health-care workers responsible for diagnosing TB are competent to choose and record the correct treatment category and commence the appropriate treatment regimen.
- The health-care worker 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.
- Health-care workers have access to appropriate reference literature regarding 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 he or she needs it.

Orange Guide Appendix 2 Forms 3 and 4

Table IV.2 Pointers for good communication

- Listen carefully.
- Use open questions, e.g., those starting with “what”, “how”, “why”, etc., to encourage fuller responses.
- Think about it from the patient’s point of view.
- Hear and respect patients’ 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.

1.4 Professional practice

- Patients diagnosed in management units that are within large central institutions need to be given the option of attending a unit where they can be registered for their treatment that is more convenient for them and therefore help them to complete their treatment. Patients should only be able to choose a management unit from an official list, and once a choice has been made they 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 health-care worker involved in this initial discussion to answer any questions the patient might have and ensure that the patient understands what they need to do next and why. This health-care worker must also document which management unit the patient has been referred to, ideally in the laboratory register as well as in an additional referral record, depending on the system in place.
- The health-care worker at the management unit where the patient is registered should carry out an initial assessment of the patient’s past experience of TB, family and support network, feelings about treatment and its possible outcomes. Table IV.3 sets out the topics and questions that should be included in the initial interview with a patient recently diagnosed with TB.

- Information and support is provided according to the patient’s individual needs, ensuring they understand: how TB is spread; how it is treated; the fact treatment is free-of-charge; the importance of regular, observed and full treatment; when and where they can get help; and the difference between harmful and harmless adverse drug effects.
- The health-care worker should discuss expectations of the treatment period, identify potential barriers to completing treatment, give a sense of emotional support, and identify if the patient needs to take his or her medicine in a “TB treatment facility” other than the management unit itself.
- A plan of care is agreed between the health-care worker and the patient based on the patient’s individual needs and concerns
- The patient is categorised appropriately and registered correctly.**
- 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, and TB treatment facility for DOT.††
- The patient is assessed regularly at agreed intervals with regard to the impact of TB and the treatment on the patient and his or her family.

1.5 Outcomes

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 their condition, its treatment and where they can go to if they need help. The initial assessment will provide the basis for a patient-centred plan of care, which will be 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, default rates in the intensive phase, and direct feedback from patients.

** Orange Guide Chapter IV D1.2

†† Orange Guide Appendix 2 Forms 3 and 4

Table IV.3 Topics to be covered in early patient interviews

Topic	Questions
Knowledge about TB	What have you been told about your diagnosis? How do you think people get TB? What do you know about TB?
History of TB treatment, previous treatment problems, potential for repeated default	Have you ever been treated for TB before? If so, when, where and for how long? Which drugs did you take to treat your TB? What was it like? Did you have any problems?
Knowledge about TB treatment NB: Female patients need to be aware of drug-drug interaction between rifampicin and oral contraceptives	What do you know about the treatment for TB? What do you think will happen if you are not treated? How will you manage to take the tablets regularly? Do you understand that the treatment is free of charge?
Knowledge about possible adverse drug effects NB: Patients need to be warned that their urine will turn red due to the rifampicin, and reassured that this is normal as well as harmless	Have you ever suffered any side effects when taking medication? What do you know about the side effects of TB treatment?
Attitude to diagnosis	How do you feel about being diagnosed with TB? What will family and closest friends think?
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? Who else do you ask about your health? Where are you living at the moment? How long will you be able to stay there? How do you get to the clinic?

Table IV.3 (cont'd)

Topic	Questions
	<p>How long does this take? How much does it cost? Do you have any dependents (young children, elderly or sick relatives)? Are you working or unemployed? Do you foresee any problems attending appointments? Do you regularly drink alcohol, smoke cigarettes or take drugs? (To examine in more depth later in assessment) If so would you like any help or not?</p>
<p>Social support available: family; friends; community</p>	<p>Whom can you turn to if you have any problems (staff/family/friends)? How can we help you?</p>
<p>Conclusion</p>	<p>Do you have any questions/concerns? What are you going to do next? Remind patient to communicate with the nursing staff regarding: – side effects of treatment – travel plans – additional medication for other conditions – any circumstances that may interfere with their treatment</p>

NB: Contact investigation is covered in standard IV.3

2. Standard: Starting treatment – arranging directly observed treatment in the intensive phase

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.

2.2 Rationale

2.2.1 Directly observed treatment

DOT is a process designed to 1) assist the patient in completing a full course of TB treatment and 2) document the patient's intake of medication. It is recommended that DOT should be given during the intensive phase of treatment for all sputum smear-positive TB patients, the continuation phase of rifampicin-containing regimens and the whole retreatment regimen, as this has been shown to reduce the development of drug resistance.⁹

2.2.2 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 to 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 treatment facility, which may be near home or work or convenient in some other way.

NB: Some patients prefer to attend a facility some distance from their home to maintain anonymity.

2.2.3 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 example, understand his or her role, is unfriendly or does not listen if the patient has 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.

2.2.4 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 health-care workers and patients, otherwise it will not succeed. Health-care workers should emphasise the support rather than the surveillance aspect in order to encourage the patient's cooperation.

2.2.5 Documentation of medication intake

Every dose of medication taken by the patient and every AFB sputum smear result should be recorded immediately on the treatment card so that the patient's progress can be assessed and non-attendance can be identified daily.

2.3 Resources

- However DOT is organised, it should be realistic, manageable and sustainable for both the patient and the management unit at which 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 patients themselves should be involved as much as possible in the choices made about their treatment arrangements and as such need 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. However, the principle that patients should be observed swallowing their tablets by a trained and supervised person must be maintained.⁹

2.3.1 Possible alternatives for DOT outside 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.⁹ The patient can attend a designated TB treatment

** Orange Guide Appendix 2 Form 3

facility daily to receive their treatment from a health-care worker. There may be a number of designated TB treatment facilities offering DOT and they 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.

2.3.2 Personnel responsible for direct observation of treatment

Those designated to carry out DOT 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.

2.3.3 Identifying an appropriate person

The individual responsible for direct observation of treatment 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.

2.3.4 Training

The training of the individual responsible for direct observation must be clearly defined, standardised and regular.

The designated individual will have knowledge about:

- TB transmission and the disease process.
- TB treatment and its possible adverse effects.
- When to refer the patient back to the appropriate management unit.

The designated individual will be able to:

- Observe and record the intake of medication according to what is prescribed.
- Follow up patients when they miss treatment – after 1 day.
- Remind patients of clinic appointments.
- Support and encourage patients.
- Refer patients back to the management unit if a problem arises.

- Refer suspect TB cases to the appropriate local health facility.
- Create awareness about TB in the community/workplace.
- Attend training updates.

2.3.5 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 undertaking direct observation of treatment. 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 for Coordinators so they can make these monthly supervisory visits. If it is not possible to arrange adequate supervision, alternative arrangements for DOT outside the management unit should not be considered.

In ALL circumstances, the responsibility for care of patients, including direct observation of treatment, rests with the local management unit and its staff.^{§§}

2.4 Professional practice

- The patient's needs and circumstances are assessed when they start 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 for 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 direct observation of treatment.

2.5 Outcomes

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

^{§§} Orange Guide Chapter III.A.3

3. Standard: Contact tracing and investigation

3.1 Standard statement

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

3.2 Rationale

3.2.1 Identification of vulnerable contacts

Contact investigation is recommended for those closest to the patient, as they are at the highest risk of being infected with TB. The process varies according to available resources, but as a minimum anyone in the same household as a patient with AFB smear-positive TB who has symptoms should themselves be investigated for TB. Children aged under 5 years and anyone with HIV infection are at the highest risk when exposed to sputum smear-positive TB and should therefore be prioritised for investigation.¹¹

3.2.2 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 sputum smear-positive TB are the most likely to be infected or themselves have active disease.¹²

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 lives. If, however, the patient is a child, it is likely that they have recently been infected by an adult with active disease, such as a member of their household, close relative or family friend.

3.2.3 Education

The investigation of at least the household contacts provides a valuable opportunity to educate people who have potentially been infected with TB so they can recognise signs and symptoms and seek the necessary help and

¹¹Orange Guide Chapter III.C

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.

3.2.4 Preventive therapy

Treatment of latent TB infection to prevent the development of active disease is most effective for children and other vulnerable people who have been infected by the patient. The treatment consists of daily isoniazid at a dose of 5 mg/kg for a minimum of 6 months.^{##} Any possibility of active disease must be ruled out before preventive treatment is started in order to avoid the possibility of partial treatment, which could lead to the development of drug resistance.

Where available, tuberculin skin testing 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 recommends that in the absence of active disease, preventive therapy should be offered to all children aged under 5 living in the same household as a smear-positive case of TB. Evidence has shown that this is the most efficient and effective way of preventing TB in young children.¹²

3.2.5 Sensitivity and discretion

Contact tracing can often be a traumatic experience for the patient, who may feel very exposed and vulnerable due to the stigmatising nature of TB, so it is vital that the whole process is handled with as much sensitivity and discretion as possible. 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 cases, patients may feel guilty about the fact they may have infected people they are close to. 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 in order to give them the appropriate level of support and reassurance.

^{##} Orange Guide p 23

3.3 Resources

It is essential to ask the patient whether there are any children aged under 5 within their household, and in addition, whether any of the people closest to them are showing and signs or symptoms of TB.^{***} These can then be examined and treated accordingly.

- TB patients can become very alert to people who may be suffering with symptoms of TB, and if they themselves have received good treatment, support and information they will encourage others to seek help. They can therefore become a vital resource in detecting TB.
- Time and space is required for a confidential discussion with the patient about the importance of identifying anyone else they are in close contact with who may be infected with TB, especially children aged under 5 and anyone they know to be infected with HIV.
- Health-care workers involved in caring for TB patients need to understand the disease and how it is transmitted in order to assess levels of risk accurately and prioritise those who need investigation.
- The patient, his or her family and close friends will need reassurance as well as clear and accurate information about TB and what will happen to them as a result of being in contact with the disease. Some will undergo investigation and potentially full or preventive treatment. Others will simply receive advice and reassurance and be encouraged to seek advice if they develop symptoms.

3.4 Professional practice

It is recommended that any symptomatic child under the age of 5 who lives in the same household as a person with recently diagnosed smear-positive TB should receive full treatment. All other under-fives from the household should receive preventive therapy.^{†††}

The health-care worker 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 and those at highest risk of infection.

^{***} Orange Guide Chapter III.C

^{†††} Orange Guide Chapter III.C

- 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 card 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 IV.1).

NB: A health-care worker 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.

3.5 Outcome

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

Figure IV.1 Possible format for information regarding household contacts

Name	Age	Weight	Symptoms	Date tested*	Result*	Action taken

* If testing is available

V. 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 is available. 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 their own individual context. Nurses and other health-care workers have an important role to play in providing a caring environment for all patients suffering from TB.¹³ 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.

1. Standard: Patient care and monitoring

1.1 Standard statement

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

1.2 Rationale

1.2.1 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. 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 that will prevent them from attending clinic, for example, if he or she needs to attend a funeral in another locality. It is very important that an open dialogue is maintained between the patient and the health-care worker so that issues such as these

can be discussed as they arise and alternative arrangements can be made to prevent treatment being interrupted.

1.2.2 Management of adverse drug effects

The patient needs to be encouraged to recognise and report adverse drug effects so that they 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 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 demoralising for the patient and so need to be taken seriously by the health-care worker. 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.

1.2.3 Management of late patients

A patient who fails to attend when expected should be contacted as soon as possible in order to minimise treatment interruption (see standard V.2). Prompt, persistent and sympathetic follow-up of late patients, although time-consuming, can demonstrate to the patient that people care, which can in turn motivate him or her to continue treatment.

1.2.4 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 important not only 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 to the continuation phase of treatment). As for diagnosis, the correct completion of sputum request forms and labelling of sputum containers for follow-up examination is essential for the accurate and timely feedback of results.

1.2.5 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.

1.2.6 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.

1.3 Resources

- Health-care workers with knowledge and understanding of TB and its treatment.
- Health-care workers who can recognise and refer patients with severe adverse drug effects and manage patients with minor adverse effects.*
- Health-care workers who understand factors that affect adherence (Table V.1) have an attitude of caring and are prepared to take responsibility for treatment outcomes.
- Availability of the necessary forms and registers and health-care workers who can complete them clearly promptly and accurately.
- Each management unit and associated TB treatment facility needs to have a system in place to follow up irregular patients (see standard V.2).
- Collaboration with support services and other organisations that could assist the patient.
- Possibility of admitting very sick patients, although this may result in other costs to patients.
- Supervision to maintain good practice.
- Regular support and supervision of the service provider observing treatment.

1.4 Professional practice

- Each patient should be assessed according to the variables set out in Table V.1, which may affect his or her ability to adhere to the treatment prescribed.
- At the end of the intensive phase the patient needs to be assessed physically to ensure adequate progress has been made and his or her

* Orange Guide Chapter III. A 4.4

sputum has converted from smear-positive to smear-negative.[†] Sputum specimens should be obtained and examined in the week before the results are needed so that they are available to evaluate whether the patient can progress to the continuation phase. If not, i.e., the sputum smear remains positive, intensive phase treatment should be pursued for one more month. If the patient was initially diagnosed with extrapulmonary TB, other signs of physical improvement should be sought. General improvement in symptoms as well as weight gain are useful signs of progress.

- Up to 25% of patients can still be smear-positive after having being treated correctly for 2 months. Most of these will be cured with further treatment. However, all those who remain smear-positive after 2 months of treatment need to be assessed with regard to:
 - The regimen they have been prescribed during the intensive phase: e.g., is it 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 with regard to the person supervising their treatment.
- 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 medical officer without delay.
- Minor adverse drug effects should be identified, recorded and managed at the management unit.[‡]
- 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 2-month smear examination result in the TB register
- Supplies of drugs and materials should be maintained.[§]
- 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 effectively.

[†] Orange Guide Chapter IV A3

[‡] Orange Guide Chapter III.A.4.4

[§] Orange Guide Chapter IV E

- Liaison with other agencies in the local area may be needed to give patients access to additional support according to their needs.

1.5 Outcomes

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

Table V.1 Factors that could present barriers to adherence

Socio-economic factors relating to the patient	Potential response
Lack of personal resources	Provide access to any available benefits/incentives
Overwhelming competing priorities	Assess and assist where and if possible Adjust treatment routine to cater for patient circumstances
Age-related issues, e.g., child, adolescent, elderly	Adjust advice and involve others as appropriate, according to age
Loss of employment – due to stigma and/or discrimination	Advise re potential sources of support, e.g., local NGOs
Homelessness – already homeless or made homeless due to stigma and/or discrimination	Assist where possible, e.g., voluntary organisations Discuss and agree how treatment can best be arranged
Patient variables	Potential response
Personal and cultural beliefs and misconceptions about TB	Assess and inform
Social/family duties and constraints (e.g., attending distant funerals, 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
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

Table V.1 (cont'd)

Dissatisfaction with health-care worker, negative experiences with health-care providers in the past	Assess problem and expectations. Feedback if appropriate. Lead by example.
Previous history of non-adherence	Assess previous circumstances – what prevented adherence before?
Impatience with level of progress/ response to treatment	Readdress expectations. Reassure
Sensory disabilities	Identify best way to communicate – work closely with carers
Inability to follow treatment plan accordingly	Assess to identify problem and amend accordingly
Embarrassment – feeling stigmatised about the disease	Inform and reassure Apply discretion Work with patient, family and community groups as appropriate
Lack of control over life	Let the patient choose if possible, e.g., where he or she receives treatment
Alcohol and substance abuse	Refer if possible. Otherwise accept and support
Concern about also being HIV-positive	Offer ongoing support and counselling Refer for 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)	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 effects must be reported and acted on without delay

[†]Orange Guide Chapter III. A 4.4

Table V.1 (cont'd)

Interaction of medication with food: e.g., patients may feel nauseous	Assess and advise about diet and timing of medication
Disease variables	Potential response
Coexisting conditions: – Diabetes – Malnutrition – HIV/AIDS – Mental health problems	Advise about diet and review treatment for diabetes Assess access to food and advise about diet Establish status, offer counselling and testing, work with HIV services, especially if antiretroviral therapy is being given Check to ensure no conflicting medication, e.g., anti-psychotics Work closely with carers. If none, identify alternative additional support
Organisational 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	Keep clinic visits to a minimum and rearrange the service so that patients do not have to wait for a long time
Fragmented, uncoordinated services	Establish good relationships with other services and share protocols, etc
Staff issues (lack of motivation, shortage, overwork)	Ensure staff feel valued; 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

2. Standard: Tracing patients who do not attend for appointments (late patients)

A system needs to be in place to trace patients who miss their appointments for treatment (late patients). The best success will be achieved through the use of flexible, innovative and individualised approaches. 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 have made every attempt to return as many patients as possible to treatment.

NB: A well-defined system of late patient tracing is mandatory in all situations. However, when the rates 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.

2.1 Standard statement

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

2.2 Rationale

2.2.1 Prioritisation of the most infectious patients

Sputum smear-positive patients who do not attend for treatment must be given priority, as they are most likely to be infectious and are 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, drug resistance will be prevented, more patients will be cured and fewer people will die.

2.2.2 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.

2.2.3 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 IV.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 to demonstrate 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.

2.2.4 Ongoing analysis of the reasons given for non-attendance

It is useful to collect information as to why the patient did not attend in order to identify and address the barriers he or she may be facing. It may be possible to make adjustments 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.

2.2.5 The use of flexible and innovative approaches

Flexibility is required to adjust services in order to address issues identified in the analysis of reasons given for poor attendance. A satellite clinic may need to be set up to cater for a number of patients in a certain locality; clinic times may need altering, possibly with an overlap so that some staff start early and others stay late; messages may need changing, for instance, in the initial and/or ongoing education given to patients, etc.

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, within both identified TB services and other organisations that might be providing services to the patient, such as social workers, pharmacists, etc. The importance of receiving a full

course of treatment must be reinforced by all those involved in the care of the patient.

- Good communication with patients, families and communities can assist in locating a patient who has not attended the clinic as planned.
- 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 that 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 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.

2.4 Professional practice

The health-care worker 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 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, thereby clearly identifying the patient's failure to attend. The same is true if the patient leaves 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 chastised on returning to the management unit or other treatment facility, he or she may be reluctant to do so.

- Liaise with other agencies that are involved with (and trusted by) patients, e.g., social workers, teachers, pharmacists, etc., so that the importance of adherence 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. Numerous attempts may be needed to track down a patient. If he or she is not located within 2 months they need to be recorded as a 'default'. If the patient subsequently arrives at the treatment facility he or she will need to repeat the initial investigations, e.g., sputum examination for TB.
- Negotiate effectively with the patient who cannot (or will not) return to the treatment facility to develop an alternative plan of care that is acceptable to both the patient and the nurse. Incentives or enablers need also to be considered (see below).
- 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, health-care workers need to look at the service as a whole and try to establish what the problem is, seeking advice from the local supervisor and, if necessary, senior members of the TB control programme.

2.4.1 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 upon between the patient and the health-care worker depending on local/national policies. Any alternative arrangements must be recorded in the patient's notes and evaluated on a regular basis by the Unit Coordinator.

2.4.2 Incentives/enablers

The use of incentives to motivate the patient with TB to adhere to treatment is defined in local/national policies. A number of examples of incentives and enablers used in a variety of settings can be found in Table V.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 health-care worker and the patient, they can also complicate this interaction. They need to be organised very carefully with a number of clear “rules” from both the patient’s and the health-care worker’s perspective. For instance, if the health-care worker promises the incentive and doesn’t deliver it, the relationship between the patient and the health-care worker will quickly deteriorate. It is essential that the health-care worker 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 for them. Many health-care workers 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 health-care worker. The expression of caring and concern reflected by the health-care worker 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 success of treatment. It is also important to prepare the patient for the end of treatment, as an abrupt withdrawal of care can be distressing.

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 non-attendance 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.

Table V.2 Examples of incentives/enablers

- Support groups.
- Award ceremonies, e.g., certificate on successful completion of treatment.
- Reimbursement for travel.
- Food.
- Visits / phone calls to patients in hospital by staff from the health facility to encourage them.
- “Tea of thanks” 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.

VI. CARE DURING THE CONTINUATION PHASE

As the patient's treatment progresses, symptoms start to disappear and he or she becomes 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 6 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 that may occur during 6 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.

1. Standard: Patient assessment during transition from intensive to continuation phase

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.

1.2 Rationale

1.2.1 Managing the change in treatment

As the patient begins to feel better, other priorities may start distracting him or her from 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. It is essential to reiterate the need for ongoing treatment.

1.2.2 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. Other sources of support should be explored with the patient, if necessary, to ensure continuation of care following the completion of TB treatment.

1.2.3 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 bereavement, change jobs or need to move away at short notice. 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.

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 health-care 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.
- Health-care workers need to know when to send follow-up sputum smears to the laboratory according to the patient category. (A step-by step guide on the practical aspects of collecting sputum samples is presented in Table III.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 sputum smear tests, as described in standard III.2.
- Efficient laboratory services are needed so that there is no delay in the examination of follow-up sputum smears and so that treatment can be changed at the appropriate time.

1.4 Professional practice

1.4.1 Documentation

It is essential that all documentation is completed promptly and accurately,

as described in III.2. Laboratory request forms for sputum examination 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 with regard to the sputum smear examination for AFB performed at the end of the intensive phase – no entry or an entry indicating “smear not done” in the TB register can be a sign of default or inadequate follow-up and should be investigated.

1.4.2 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 that 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 mislaying drugs or having them stolen, alcohol addiction, etc., (Table V.1).

1.4.3 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 at the same time they should be taught how to recognise any potential adverse effects and report them, e.g., skin rashes, jaundice, visual disturbances, gastrointestinal problems and tingling in the fingers and toes.

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

- Adherence
- Clinical progress at key milestones: 2-month sputum; 5-month sputum; completion of treatment.
- Accuracy of medication prescribed.
- Availability of drugs.
- Ability to attend appointments.
- Any confusion and/or questions.
- Anything that could disrupt treatment: adverse drug effects, pregnancy, bereavement, conflicting information.

A routine for regular follow-up should be agreed upon between the patient, the Unit Coordinator and the health-care worker 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 organised, 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.

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 the TB service.

2. Standard: Case management during the continuation phase

2.1 Standard statement

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

2.2 Rationale

2.2.1 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 (e.g., if rifampicin is discontinued in the second phase of treatment). If not, the patient may feel that it does not matter too much whether they continue medication or not.

2.2.2 Flexibility in response to problems faced by the patient

Responses should be prompt and appropriate, with 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.

2.2.3 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, that may incur travel costs and interrupt the patient's work should be avoided.

2.2.4 Follow up sputum smear examination at 5 months

A follow-up AFB sputum smear examination is required after 5 months of treatment for all patients who were originally sputum smear-positive to either confirm progress or identify treatment failures.*

2.2.5 Assessing treatment outcomes

Assessing and recording the treatment outcome for each patient is essential to understanding the performance of the TB control programme. Sputum is reexamined 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".†

2.2.6 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 health-care worker can assess the patient's progress and ensure that correct treatment is being given. The accuracy of quarterly reports on treatment outcomes depends on the accuracy of the information in the TB register. Quarterly reports in turn demonstrate how well the programme is performing.‡

2.3 Resources

- 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 health-care worker if a problem arises.

* Orange Guide Chapter IV A3

† Orange Guide Chapter IV D 2.2

‡ Orange Guide Chapter IV D

- The service needs to respond promptly in order to address the problem and ensure all possible action is taken to prevent potential interruption in treatment.
- As it may be necessary to refer the patient for additional support, it is important for the health-care worker to have links to other services, both governmental and voluntary.
- The health-care worker is competent to order a 5 month sputum examination and respond appropriately to results.
- The health-care worker is competent to assess and record treatment outcomes.

2.4 Professional practice

- It is the responsibility of the health-care worker managing the case to maintain contact with the patient and regularly evaluate his or her progress. If the patient continues to have a designated person supporting them the relationship may change with the less frequent follow-up in the continuation phase. Each patient needs to be assessed according to the level of support he or she may need. It is recommended that there should be at least monthly contact with the TB service. Consideration should still be given to the factors affecting adherence outlined in Table V.1, as the patients' circumstances may change during the continuation phase.
- It is essential for all contact with patients to be recorded. Patients who were originally registered as “new smear-positive pulmonary” cases need to have their sputum examined at 5 months to ensure that it has remained smear negative. If the smear examination is positive at 5 months the case must be recorded as a treatment failure and started on a retreatment regimen.[§]
- Sputum is re-examined at the end of treatment to confirm that “cure” has occurred. Prompt and accurate documentation of the 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

[§] Orange Guide Chapter IV A3

does not attend when expected should be traced using a nonjudgemental approach and seeking to assess and address the reasons for their non-attendance (see standard V.2).

- A number of patients will find it difficult to adjust to separation from the 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 2 months before completion is due.
- 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 5 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.

2.5 Outcome

Patients will complete the continuation phase and be sputum AFB smear negative at the end of treatment. All outcomes will be recorded promptly and accurately, allowing for quarterly cohort analysis of treatment outcomes.

3. Standard: Management of transfer

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.

3.2 Rationale

3.2.1 Accommodating patient mobility

During a minimum of 6 months treatment, patient care may be transferred between health care 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 health-care 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.

3.2.2 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.

3.2.3 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 “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.[†]

3.3 Resources

- A referral system is in place that is common to and understood by all management units.
- The health-care worker 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.

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.¹⁴

[†]Orange Guide Chapter IV D 2.2

- When the patient arrives at the new management unit they should be registered as a transfer in. The bottom part of the transfer form will be sent back to the referring unit to confirm that 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, they are more likely to inform the facility they attend for their treatment of any plans to move or leave.
- Before leaving, patients need to be very clear about the importance of continuing their treatment. The health-care 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 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 health-care worker 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 that starts the patient's treatment that should record the treatment outcome, no matter where the patient has gone.

3.5 Outcome

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

VII. HIV TESTING AND CARE OF THE PATIENT CO-INFECTED WITH TB AND HIV

HIV infection poses one of the greatest challenges to TB control, as TB kills more people with HIV infection than any other condition.

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, health-care workers need to be adequately prepared to provide the best care and treatment available.¹⁵

The standards in this chapter cover provider-initiated HIV counselling and testing and the care of HIV-infected patients with TB. It is acknowledged that people caring for TB patients should ensure that those who are HIV-positive 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. Further technical guidance is provided by the WHO.^{16,17} It is essential that all activities follow the national policies and guidelines.

1. Standard: HIV testing

All TB patients who have not previously been diagnosed with HIV infection, should be encouraged to have an HIV test.¹⁸ Failing to do so is to deny people access to the care and treatment they might need, especially in the context of the wider availability of treatments that prevent infections associated with HIV. A clearly defined plan of care for those found to be co-infected with 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.

1.1 Standard statement

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

1.2 Rationale

1.2.1 Relationship between HIV and TB

HIV is the strongest known risk factor for developing TB disease in individuals with TB infection. Globally, an estimated 11% of new adult TB cases are infected with HIV. The proportion is highest in Africa, particularly in sub-Saharan Africa, where up to 75% of individuals with TB are co-infected with HIV.

On the other hand, TB is the most frequent opportunistic infection among HIV-infected individuals, and is often the first manifestation of HIV disease. Mortality during and after anti-tuberculosis treatment is also higher in HIV-infected than in non-HIV-infected TB patients.

1.2.2 Benefits of early diagnosis of HIV infection

As TB is one of the main opportunistic infections associated with HIV, all TB patients 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 preventive treatment that can reduce incidence of opportunistic infections, prolong life, and reduce 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.

1.2.3 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/AIDS 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/AIDS, including antiretroviral treatment (ART).

1.2.4 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 maintaining patient confidentiality and addressing discrimination.

1.2.5 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 NTP must monitor the number of patients tested and trends in results.

1.3 Resources

- Arrangements for offering HIV tests to patients with TB need to be agreed and clearly defined by the NTP, the NAP 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 will be offered and by whom.
- Discrimination and stigma still stop many people agreeing to an HIV test,¹⁹ especially if the health-care worker 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/AIDS 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, in order 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.¹⁸ The offer of testing needs to be reinforced by the reassurance that additional support and preventive 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. Health-care workers 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 in order 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 health-care 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 feed back 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 that 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.¹⁵
- The best possible infection 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.²⁰

1.4 Professional practice

1.4.1 Before HIV testing

First of all the health-care worker 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 health-care worker 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. 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
- feel fully informed and able to choose whether or not to go ahead with the test.

UNAIDS recommends a human-rights-based approach to the offering of HIV testing based on the "3 Cs": confidential, with counselling and consent.¹⁹

1.4.2 Confidentiality

As with any other condition, the patient should be reassured that his or her confidentiality will be maintained at all times.

1.4.3 Counselling

The pre-test discussion and counselling should include:

- An assessment of the patient's knowledge and understanding of HIV and its relationship to TB
- 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.

1.4.4 Consent

According to UNAIDS, a minimum amount of information needed by patients in order to be able to provide informed consent:¹⁹

- 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 health-care providers 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 health-care worker should:
 - find out why the patient would prefer not to be tested
 - reiterate 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 his or her 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 3 for a sample script for pre-test counselling

1.4.5 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
 - how to practice safer 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.²¹

NB: It may not be possible or appropriate to cover all the necessary issues in the first instance. 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 VII.2). See also Appendix 3 for sample scripts for post-test counselling.

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

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 that is available locally and those testing negative will receive appropriate care and support to remain negative.

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.* The top priority must be to treat the patient's TB efficiently to give him or her the best chance of recovery.¹⁵ With appropriate support, advice and treatment a HIV-positive patient can maintain a good state of health.

2.1 Standard statement

The patient receives prophylactic treatment against common opportunistic infections, support and information with regard to staying healthy with HIV, including treatment with antiretroviral drugs, if appropriate, while on TB treatment before being transferred for ongoing care.

2.2 Rationale

2.2.1 *Treatment for TB*

Treatment of TB with an appropriate standardised regimen should be seen as the priority, as left untreated TB can rapidly become fatal for people with HIV infection.

2.2.2 *Prevention of other infections*

People infected with HIV are vulnerable to a variety of respiratory, gastrointestinal, skin and mouth, neurological and sexually transmitted infections.¹⁷ 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, such as cotrimoxazole prophylaxis, which should be considered for all HIV-infected TB patients.¹⁵ It is recommended that preventive treatment be started 2 weeks after the beginning of TB treatment, as

* Orange Guide Chapter III.B.1

both can cause similar adverse drug effects, such as a skin rash and hepatitis. It should also be started before ART is begun, if that is being considered.

Infections can also be prevented through practical measures, such as good general hygiene, especially hand washing, the boiling of drinking water and the practice of safer sex.

2.2.3 Antiretroviral treatment

Treatment with antiretroviral (ARV) drugs is not an emergency, and other aspects of HIV care can be implemented before the patient starts ART. ART aims to maintain or restore the patient's immune function by suppressing the replication of the virus, which, in turn, prevents the patient's susceptibility to HIV-related conditions.

2.2.4 The decision to start ART

If it is available, patients with HIV infection can be prepared to start ART according to the severity of their condition. The WHO has devised a staging system using indicators, such as the level of immunosuppression based on the CD4 count (if available) or the presence of other HIV-related conditions to assist those making decisions about when to start ART.¹⁶ "Because extremely high levels of adherence are required to prevent drug resistance and treatment failure, it is critical that patients start treatment only after having been counselled in detail about possible adverse drug effects, dosing instructions, and the importance of strict adherence".¹⁵

2.2.5 The importance of adherence to ART

Every effort must be made to offer as much support as possible to enable the patient to adhere to the treatment regimen. High levels of adherence are required if ART is to be effective. One study by Paterson et al. concludes that taking more than 95% of the ARV drugs prescribed gives patients an 80% chance of stopping viral replication. This drops to only 20% if less than 80% of doses are taken.²²

2.2.6 Potential complications

Taking antiretroviral drugs (ARVs) at the same time as TB treatment can lead to drug-drug interactions that the patient may not be able to tolerate, impose a high pill burden that may be a barrier to compliance, and provoke

an exacerbation of the TB as the immune system is reconstituted.¹⁵ There may also be a problem with the efficacy of some of the ARV drugs and rifampicin due to drug-drug interactions.

Ideally, ART should not be started until the TB treatment has been completed successfully. However, if the patient is very sick, concurrent ART may be necessary. In these cases, a health-care worker with expertise in treating both HIV and TB should be involved so that any complications can be identified and managed appropriately.

2.2.7 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 with regard to practising safer 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 health care 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.¹⁷

2.2.8 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.

2.2.9 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 it should be assessed regarding TB (see standard IV.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.

2.2.10 Liaison with other services

The patient is likely to have complex needs that may benefit from a variety of services offered by local organisations outside 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.

2.2.11 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.

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 NAP and the NTP. These should include guidance about 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 cotrimoxazole prophylaxis.
- Group education covering a variety of themes associated with treatment, safer 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 procedures in place in line with WHO guidelines.^{17,23}
- A referral system for ongoing patient care following the completion of his or her TB treatment.

2.4 Professional practice

The health-care worker 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.

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.¹⁷
- If the patient is on ART, regular assessment is required with regard to:
 - 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 can also be used but are not always available

[†] Orange Guide Chapter III.A.4.4

NB: The health-care worker should be aware of immune reconstitution syndrome (IRIS), which can make TB worsen even while the immune system is improving

- Ensuring that the regimen and dosages prescribed are based on national guidelines
 - Laboratory monitoring according to local policies¹⁶
 - The patient’s adherence to the regimen prescribed.
- The principles of supporting adherence are the same for ART as they are for anti-tuberculosis treatment, namely: systems in place to ensure that medications are available and free of charge, involvement of family or community members, psychosocial support, the use of pillboxes or blister packs and DOT where possible.¹⁶
 - The health-care worker will follow local procedures for clear, accurate and prompt record keeping.
 - The health-care worker will prepare the patient for referral to an appropriate facility for the ongoing treatment and care he or she needs with regard to HIV infection.

2.5 Outcome

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

Table VII.1 Points regarding ART

The WHO recommends the use of certain first- and second- line standardised ART regimens.¹⁶

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 2 weeks and 2 months following the commencement of anti-tuberculosis treatment, i.e., when it is clear that the patient is tolerating the medication, at the start of the continuation phase or when TB treatment has been completed.

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Appendix 1: Implementation tool

Standard:

Lead person: Date:

	Who needs to be involved? Key stakeholders	What resources are needed? Materials/time/space	Who needs to do what? Action to be taken by whom?	Expected completion date?
Review and agree standard according to local conditions				
Evaluate practice and identify variations (changes that need to be made to meet the standard)				
Develop an action plan				

	Who needs to be involved? Key stakeholders	What resources are needed? Materials/time/space	Who needs to do what? Action to be taken by whom?	Expected completion date?
Implement change				
Evaluation of clinical practice against standards				
Assessment of areas requiring change				

Appendix 2: Clinical features suggestive of HIV co-infection in TB patients¹⁷

<p>Past history scar</p>	<p>Sexually transmitted infection (STI) Herpes zoster (shingles), which often leaves a</p> <p>Recent or recurrent pneumonia Severe bacterial infections (sinusitis, bacteraemia, pyomyositis) Recent treated TB</p>
<p>Symptoms</p>	<p>Weight loss (>10 kg or >20% of original weight) Diarrhoea (>1 month) Retrosternal pain on swallowing (suggests oesophageal candidiasis) Burning sensation of feet (peripheral sensory neuropathy)</p>
<p>Signs</p>	<p>Scar of herpes zoster Pruritic (itchy) papular skin rash Kaposi's sarcoma Symmetrical generalised lymphadenopathy Oral candidiasis Angular cheilitis Oral hairy leukoplakia Necrotising gingivitis Giant aphthous ulceration Persistent painful genital ulceration</p>

Appendix 3: 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 or not one is infected. Some of them are:

- Access to HIV care that can improve your health, if you are found to be infected.
- Prevention of spreading HIV to others.
- Referral to mother-to-child HIV transmission prevention services (if patient is female).
- Ability to plan for your future.

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 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. Do you know whether she has ever been tested for HIV? (Assuming he does not know:)

In that case, I recommend that you will go together to for her to be counselled and tested.

If she does not have HIV, the two of you can do enjoy your relationship as you like, always remembering the need to be mutually faithful.

If your wife is HIV-positive, you must practise safer sex and always use condoms to protect you from HIV. It is advisable not to have sex until your wife is tested and you find out if she has HIV.

We have condoms available in the clinic and you are welcome to take some.

I hope you will ask your wife to be tested before your next visit when we will discuss this again.

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?

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.

As you know, HIV can be spread through sex. It is therefore important that your husband is tested right away to determine his result. Do you think he would be interested in visiting this clinic with you when you come here next time? As you are attending TB care in this clinic, we can assist your family with testing for both conditions.

Do you have any questions?

*From examples used in practice in parts of Zimbabwe which are based on materials developed by the CDC (Centers for Disease Control and Prevention. Diagnostic HIV counseling and testing in TB clinical settings. Atlanta, GA, USA: CDC, 2005).

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