

International Council
of Nurses

TB GUIDELINES

**for Nurses in the Care
and Control of Tuberculosis
and Multi-drug Resistant
Tuberculosis**

2nd Edition



Biography

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Abbreviations

AFB	Acid-fast bacilli
BCG	Bacille Calmette Guerin
DOT	Directly observed treatment
DOTS	The internationally recommended strategy for TB control
DRS	Drug resistance surveillance
DST	Drug susceptibility testing
FQ	Fluoroquinolone
G	gram
GLC	Green Light Committee
HIV	Human immunodeficiency virus
ICN	International Council of Nurses
ILO	International Labour Organization
The Union	The International Union Against Tuberculosis and Lung Diseases
MDR-TB	Multi-Drug Resistant Tuberculosis
Mg	milligram
NGO	Non-governmental organisation
TB	Tuberculosis
WHO	World Health Organization
XDR-TB	Extensively Drug-Resistant TB

Anti-tuberculosis drug abbreviations

Am	Amikacin	Lfx	Levofloxacin
Amx/Clv	Amoxicillin/Clavulanate	Lzd	Linezolid
Cfx	Ciprofloxacin	Mfx	Moxifloxacin
Cfz	Clofazimine	Ofx	Ofloxacin
Clr	Clarithromycin	PAS	Para-aminosalicylic acid
Cm	Capreomycin	Pto	Protionamide
Cs	Cycloserine	R	Rifampicin
E	Ethambutol	S	Streptomycin
Eto	Ethionamide	T	Thioaceazone
FQ	Fluoroquinolone	Trd	Terizidone
Gfx	Gatifloxacin	Z	Pyrazinamide
H	Isoniazid		
Km	Kanamycin		

Preface

Tuberculosis (TB) has reached epidemic proportions in many parts of the world. As many as two million people die every year from a disease that is curable and preventable in most cases, even in very resource poor settings. Everywhere in the world, nurses encounter patients with TB, suspected TB and those who have symptoms of the disease.

The information in these guidelines by the International Council of Nurses (ICN) is intended to help nurses in their important role of detecting TB cases, providing care and managing TB treatment. It sets out a nursing approach to planning and delivering patient care, aimed at improving access and quality of care throughout the treatment period.

These guidelines offer a review of TB and Multi-drug resistant TB (MDR-TB), the new Stop TB Strategy, and the component addressing MDR-TB, as well as guidance on how to adapt TB control information for local programme implementation. Also included is an overview of organisational issues that can have an important impact on TB control programmes.

This publication is the first in a series of ICN products on TB and is intended to be a comprehensive pocket guide for the busy nurse. Other ICN publications on TB will address practice development with regard to TB care, TB-related stigma and occupational issues. ICN trusts that the series will provide a complete understanding of TB and MDR-TB and strengthen nursing competence in tackling this growing epidemic.

Gini Williams MSc Bnurs RGN HV, ICN TB/MDR-TB Project Director was the main contributor to these guidelines. ICN also gratefully acknowledges the review and comments from Donna Barry (Partners In Health), Kai Blöndal (Royal Netherlands Chemical Society Tuberculosis Foundation), Lasha Gogvadze (International Federation of Red Cross and Red Crescent Societies), Ernesto Jaramillo (WHO), Oksana Ponamorenko (Partners In Health), Michael Rich (Partners In Health/WHO) and Ted Torfoss (Norwegian Association of Heart and Lung Patients). Elaine Papp (Occupational Safety and Health Administration) developed the first draft and her input is appreciated as is the contribution made by Uta Grosse to this latest edition. This publication is supported in part by an unrestricted educational grant from The Eli Lilly Foundation.

Introduction

The International Council of Nurses (ICN) prepared these guidelines to strengthen nursing capacity related to TB and to enhance the effectiveness of TB control measures worldwide. Because nurses play a crucial role in TB control programmes, it is essential for them to have a solid understanding of TB: its aetiology, pathogenesis, epidemiology and treatment, as well as the best practices for TB control. This strengthened understanding is essential in the light of the current resurgence of TB in many countries.

Undetected and improperly treated cases of tuberculosis resulting from ineffective TB management are major reasons for the spread of the disease and the development of MDR-TB. More recently the emergence of Extensively Drug-Resistant TB (XDR-TB) has added to the complexity of TB care and treatment. Ineffective TB management of this type often results from a scarcity of adequately trained personnel, poor capacity at a management level, and/or inadequate resources to sustain treatment.

If they are properly informed and mobilised, nurses can positively influence TB disease prevention and management, particularly because of their close involvement with patients. Some nurses specialise and work solely with TB programmes, but the vast majority work within general health services, encountering patients for a wide variety of reasons – pregnancy, injury, illness, or to receive immunisations. Thus, nurses are in an ideal position to detect previously unsuspected cases of TB, since the patients they see for other reasons may also have symptoms of TB.

This publication approaches TB control from a best practices perspective and provides practical TB information for nurses in their day-to-day work. A section on organisational issues gives the reader a useful perspective for managing TB control. Sections devoted to standards of care for TB case finding and patient holding provide additional examples of best practices for implementation and adaptation to local practice. These standards have been further developed to form The Union guide: “Best practice for the care of patients with TB” which is available on-line at www.icutld.org. Another important set of International Standards for Tuberculosis Care (ISTC) has been developed by the Tuberculosis Coalition for Technical Assistance (TBCTA) and the World Care Council and is available online on URL www.who.int/tb/publications/2006/istc/en/index.html

ICN believes that information is only valuable when it is utilised at the local level. Blending the measures of the expanded TB control strategy with local customs enhances nursing practice and provides the best of two worlds – standardised care that is individualised to meet the constraints and the needs of local nursing practice. ICN sincerely hopes that the best practice approach offered in these guidelines enhances TB control programmes in your local community and strengthens your own individual nursing practice.

CHAPTER 1

Tuberculosis: The Clinical Context

History of tuberculosis

Tuberculosis (TB) is as old as the human species. Fragments from the spinal column of Egyptian mummies dating from 2400 BC show definite pathological signs of tubercular decay. The name “tuberculosis” has been used from the middle of the last century.

Tuberculosis, also called phthisis or consumption, and nicknamed “white plague”, first appeared in Greek literature. At around 460 BC Hippocrates described it as the most widespread disease of its time.

Exact aetiological and pathological descriptions of TB began to appear in the 17th Century when the earliest references to the infectious nature of the disease appeared in Italian medical literature. Although this allowed for some progress to be made towards prevention, a cure was still not within sight.

The introduction of the sanatorium provided the first hope for a TB cure. These special centres were located in areas with a healthier climate, where patients were continuously exposed to fresh air. Improving social and sanitary conditions, and ensuring adequate nutrition were all that could be done to strengthen the body's defence against TB. It is still unknown whether sanatoria really helped people with TB. There were also many people with TB who could not afford to go to a sanatorium, and who died at home.

In 1865, a French military doctor, Jean-Antoine Villemin, demonstrated that TB could be passed from humans to cattle and from cattle to rabbits. On the basis of this evidence he postulated that TB was contagious and a micro organism was the cause of the disease.

In 1882, a German scientist, Robert Koch, discovered the *Mycobacterium tuberculosis* and the fight against TB really began.

A further milestone came in 1895, when Wilhelm Konrad von Roentgen discovered radiation. Now the progress and severity of a patient's disease could be followed and reviewed.

The French bacteriologist, Albert Calmette, worked together with Camille Guérin to develop a vaccine against TB. By 1921, they had developed a bacillus harmless to man, yet with the ability to stimulate the production of antibodies. From 1924, to a large extent, the vaccination of newborns was practiced. The Bacille Calmette Guérin (BCG) vaccine is still used today.

In 1943, in the middle of the Second World War, an American scientist, Selman A. Waksman, discovered streptomycin, an antibiotic that could kill TB bacteria. In the following years, a rapid succession of anti-TB drugs appeared. This was essential because with streptomycin monotherapy, resistant mutants began to appear, endangering the success of antibiotic therapy. Following streptomycin, isoniazid (1952), pyrazinamide (1954), ethambutol (1962) and rifampicin (1963) were introduced as anti-TB agents. These anti-TB drugs are still used today and their application will be described later in greater detail. The effects of TB on the population during the last centuries and its current global situation and epidemiological trends will be described in the next section - Epidemiology of tuberculosis.

Epidemiology of tuberculosis

TB caused great public concern in the 19th and early 20th centuries as the endemic disease of the poor. After the development of the antibiotic streptomycin in 1943, medical treatment rather than prevention became a possibility. Prior to this medical treatment, only surgical intervention was possible along with the purported benefits of sanatoria.

Following the development of effective treatment for TB in the 1950s the general view, especially in industrialised countries, was the disease no longer posed a public health threat (Raviglione 2003). In industrialised countries the steady drop of TB incidence began in the mid-1980s and then stagnated or even began to increase.

Increases in TB figures, seen in both the USA and Europe, were alarming in the late 1980s, highlighting the need to refocus efforts on TB control. The reasons for the increases in the USA were largely attributed to the rising rates of HIV, worsening poverty in urban areas, and poor TB control practices. Hopes that TB could be completely eliminated have been dashed since the rise of multi-drug resistant strains in the 1980s. In Europe the increases were mainly associated with urban poverty. In recognition of the fact that in both the USA and Europe, increases in TB prevalence were associated with immigration from countries with high rates of TB, the disease had to be addressed as a global issue (Raviglione 2003). In order to intensify efforts to limit its spread, in 1993, TB was declared a “global emergency”.

TB is the most common infectious disease in the world today. To date, TB ranks seventh as a global cause of death, and, unless more focused attention is given to the control of the disease, it is likely to remain a major killer through 2020 (Murray and Lopez 1996). The following figures from 2005 highlight the TB epidemic:

- 2 billion people, i.e. one-third of the total human population, estimated to be infected with *M. tuberculosis*.
- 8.9 million new cases of TB (140/100,000)
 - In 2003, the TB incidence rate was falling or stable in all regions except Africa, but growing at 1% globally. The overall picture is one of slow global growth in annual case notifications with 9 -10 million new cases being expected in 2010 (Dye 2003). The rise in global incidence is slowing but it is unclear when the global incidence rate will begin to decline.

- The number of new cases roughly correlates with economic conditions. Of the 8.9 million of new TB cases in 2004, 80% lived in African, South-East Asia and Western Pacific regions with the lowest gross national products

- 1.7 million people (27/100,000) died from TB including those co-infected with HIV (248,000).

Pathology

TB is a bacterial infection caused by *Mycobacterium tuberculosis* (*M. tuberculosis*) also referred to as tubercle bacilli. The *M. tuberculosis* is a Gram-positive aerobic bacterium. It is a small rod-like bacillus with a complex cell wall, which can withstand weak disinfectants and survive in a dry state for weeks, but can only grow in a host organism.

It most commonly affects the lungs, producing pulmonary TB. However, transported by the blood or lymphatic system, the TB bacilli can infect almost any part of the body, including lymph glands, joints, kidneys, and bone – extra-pulmonary TB. It is critical to understand the disease, its aetiology and its epidemiology to develop a strong TB control programme.

Early symptoms of pulmonary TB are often vague and easily attributable to other conditions, with the result that many cases of active, infectious TB can remain undetected for some time. Thus, the disease spreads from one person to another.

TB is spread when an infectious person coughs, sneezes, talks or sings, releasing droplets containing the bacilli into the air. However, TB can also be spread when TB bacilli are aerosolised by treatments, such as irrigating a wound that is infected with TB. In either case, a susceptible person inhales the airborne droplets, which then traverse the upper respiratory tract and bronchi to reach the alveoli of the lungs. Once in the alveoli, alveolar macrophages take up the TB bacilli, holding some in the lungs, and transporting others throughout the body. Usually within 2-10 weeks, the immune response limits further multiplication and spread of the bacilli.

Some patients may go on to active disease from this stage while others may be able to contain the infection. In the patients who contain the infection some may eliminate all the bacteria; however, in many of the patients the bacilli remain dormant and viable for many years, resulting in a condition referred to as “latent TB infection”. Persons with latent TB infection usually have positive TB skin tests but have no symptoms of the disease and are not contagious¹. In fact, most people who are infected with TB never go on to develop active disease and therefore present no risk to the people around them.

Pulmonary TB

Pulmonary TB is the most common and potentially most contagious type of active TB. Small areas in the lung infected with the bacilli gradually merge to form a bigger lesion filled with infected material. This material can become liquid, which is then coughed out, leaving a cavity in the lung². The process continues causing extensive damage to the lung tissue and its blood vessels, generating more infectious material and inflammation – the damage to blood vessels can result in some patients coughing up blood (haemoptysis). Some healing may occur in parts of the lung resulting in scar tissue.

In the early stages of this process someone with pulmonary TB may well not be infectious and have few easily definable symptoms. As the disease progresses and causes more damage, they will become infectious and experience worsening symptoms. The challenge is to identify people in the early stages to prevent transmission.

Extra-pulmonary TB

TB can affect any organ in the body including:

- cervical lymph glands (most common).
- bone (particularly the spine).
- pleural cavity (causing pleural effusion).
- kidney and genitourinary tract.
- intestines and peritoneum.
- pericardium.
- Skin.

Although extra-pulmonary TB is treatable in most forms, the lasting damage may be permanently crippling (in the case of spinal TB) or even fatal (in TB meningitis). Bacillary load, extent of disease and anatomical site determine the severity of extra-pulmonary TB. One of the most lethal forms of TB is tuberculosis meningitis.

Some forms of extra-pulmonary TB are more common in particular geographical areas, ethnic groups or age groups. By knowing the most common types of extra-pulmonary TB in the local community, the nurse is more alert to the symptoms and may detect a case of extra-pulmonary TB that would otherwise have gone unnoticed. Extra-pulmonary TB is common in patients infected with HIV.

Signs and symptoms of pulmonary and extra-pulmonary TB

The symptoms of pulmonary and extra-pulmonary TB may differ but some are common to both. Most people have only a few of these symptoms. However, the presence of three or more symptoms for three or more weeks increases the suspicion of TB.

Table 1: Signs and symptoms of TB

General symptoms	Pulmonary symptoms	Extra-pulmonary symptoms
Fever	Dry or productive cough	Localised pain/swelling (depending on site of disease)
Night sweats	Chest pain	
Weight loss	Shortness of breath	
Fatigue	Later blood traces are coughed up in the sputum (haemoptysis)	
Loss of appetite		

A patient with both pulmonary and extra-pulmonary TB should be classified as a pulmonary case.

Risk factors for TB

Risk factors combined with TB symptoms are strong indicators for further diagnostic workup and early detection of the disease.

Some of the main risk factors for TB include:

- History of TB, personally, or amongst friends or family
- Compromised immunity due to illness, e.g., HIV infection.
- Migration from a country with a high incidence of TB.
- History of travel to an area with a high incidence of TB.
- Alcohol and/or drug abuse.
- Malnutrition.
- Homelessness.

Managing and preventing risks

Those who are responsible for managing TB programmes must consider the five levels that can be ascribed to the risks of TB transmission and progression. The risks must be considered in relation to the population of the region and local community, but also how they apply to the nurses and other TB programme staff. The risk levels are the following³:

- 1) the risk of exposure,
- 2) the risk of infection,
- 3) the risk of developing active disease,
- 4) the risk of developing MDR-TB, and
- 5) the risk of death.

The number and severity of risk factors present in any given community affects the epidemiology of TB disease in that community. Successful TB control programmes recognise, assess and manage these risk factors effectively.

Risk of exposure

The risk of exposure is associated with the frequency and duration of contact with an infectious case of TB. Exposure is very much linked to:

- Time spent with potentially infected individuals in confined and poorly ventilated spaces.
- Overcrowded accommodation due to poverty or social norms of living together in extended family groups; working conditions; and other social habits and behaviours, e.g., communal drug-taking.
- A higher risk of exposure to TB is also associated with urban areas where people are living, travelling and working in cramped conditions.
- TB is more prevalent in residential institutions such as prisons and hostels, where accommodation may be overcrowded. The higher the prevalence of the disease in a community, the greater the likelihood of contact with an infected person, and the higher the risk of exposure to TB bacilli.

Risk of infection

The risk of infection depends on:

- Numbers of Mycobacteria inhaled.
- Duration of the exposure.
- Virility of the bacilli.
- Strength of the person's immune system⁴.

For example, some people exposed to just a few TB bacilli may be naturally more susceptible and will develop active TB disease. Others when exposed to a large number of bacilli will only develop a latent TB infection. Others may be exposed, but develop neither a latent TB infection nor active TB disease.

The longer a person with active TB who is smear positive remains undetected and untreated, the higher the likelihood that others will be exposed and infected. The more people there are living in overcrowded conditions with a person with undetected TB, the higher the risk of someone contracting the infection.

Risk of developing active disease

WHO estimates that one-third of the world's population is infected with *M. tuberculosis*⁵. In general, people who become infected with *M. tuberculosis* have approximately a 10% risk of developing active disease in their lifetime. This risk is greatest during the first two years after infection. The risk of developing active disease relates to the individual's health status, and most particularly to the status of the immune system. HIV increases the risk of developing active TB once infected.

WHO estimates that one third of the approximately 40 million people living with HIV at the end of 2003 will develop active TB. Other factors contributing to the risk of developing active disease, once the TB infection takes hold, are smoking⁶, exposure to smoke from biomass stoves⁷, Vitamin D deficiency⁸, and the malnutrition often associated with poverty, alcohol and substance abuse, and other debilitating conditions⁹. Internally displaced people, asylum seekers, migrant workers and refugees, all face difficulties compounding their vulnerability to TB, including crowded and poorly ventilated housing, poor access to health and social care, and reduced personal security.

Risk of developing MDR-TB

The WHO and International Union Against Tuberculosis and Lung Disease (The Union) Global Project on Drug Resistance Surveillance has found an overall multi-drugresistance prevalence rate of 4% of new cases of TB in Eastern Europe, Latin America, Africa, and Asia. Given the increasing trend toward globalisation, trans-national migration and tourism, all countries are potential targets for outbreaks of MDR-TB¹⁰.

As described earlier, drug resistance can emerge from the improper use of anti-tuberculosis agents in the therapy of drug-susceptible TB patients and is found

in all countries. Some programmes do not yet have adequate laboratory capacity and resources for treating MDR-TB cases. Nonetheless, all TB programmes in poor resource areas should develop, in conjunction with a good DOTS programme, adequate laboratory facilities to diagnose MDR-TB and an effective strategy of MDR-TB treatment. Treatment for MDR-TB is effective, feasible and cost-effective.

Risk of death

Among infectious diseases, TB is the second highest cause of adult mortality, resulting in approximately two million deaths a year worldwide¹¹. In addition, TB kills more people with HIV than any other associated disease or opportunistic infection. Two main factors are the principal determinants of TB case fatality: 1) the site and type of disease; 2) the appropriateness and timeliness of the intervention and care provided. Inadequate treatment is likely to result in early death: 30-40% of untreated sputum smear positive TB cases will die within a year, and 50-60% will be dead within five years¹². HIV infection, malnutrition and severe pulmonary disease are all associated with a greater risk of death from TB. Inadequate treatment for those suffering from MDR-TB also increases the risk of death.

TB and HIV

HIV is one of the main risk factors for developing active TB from both recently acquired and latent TB infection and poses one of the greatest challenges to TB control. 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. With adequate treatment, a TB patient who is coinfecting 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 in order to give him/her the best chance of recovery.

Immuno-compromised patients with TB may present different clinical pictures, according to their level of immuno deficiency¹³. It is estimated that one-third of the 40 million people living with HIV/AIDS worldwide are co-infected with TB. People with HIV are up to 50 times more likely to develop TB in a given year than HIV-negative people.

Those in the early stages of HIV infection are more likely to develop sputum smear positive pulmonary disease and present in a similar way to their immuno-competent counterparts. In the later stages of HIV infection, due to suppression of the immune response, patients are more likely to be smear negative, or suffer from extra-pulmonary TB and present with less definable symptoms. In addition, TB skin tests may be negative and x-rays may not show the typical TB picture. In fact, in rare cases, x-rays may appear as normal¹⁴. As TB and HIV are becoming increasingly common co-infections, nurses must follow national treatment guidelines and recommendations for treatment with ARV therapy.

Drug-resistant tuberculosis

There will always be a few bacteria, among those multiplying and causing disease in someone with TB, that will be resistant to any one of the anti TB drugs. If only one drug is used a population of bacteria resistant to this drug will develop. If more than one drug is used, then any bacteria resistant to one drug will be dealt with by another. This is why it is recommended that TB is treated with multiple drugs.

A person may become infected with a TB strain that is already drug-resistant. This is termed primary drug resistance. This is the principal reason why patients fail the standard category I regimen when properly administered. If multi-drug resistance develops while the person is receiving drug therapy, the resistance is called acquired drug resistance. It often develops because a patient is treated incorrectly or the patient is not able to adhere to the treatment regimen. In both cases, the patient has not been receiving a strong enough dosage of the drugs over a long enough period of time to kill the bacilli, so the organisms are given time to develop resistance to one or more of the drugs.

Drug-resistant TB can only be defined through laboratory confirmation of in vitro resistance to one or more anti-TB drugs. In well-resourced settings all specimens are sent for culture and sensitivity testing, in areas where there are fewer resources, specimens of high risk cases may be sent for further investigation but in some areas it is not possible to offer any culture and sensitivity testing. Results are defined as follows:

- **Mono-resistant TB:** TB in patients whose infecting isolates of *M. tuberculosis* are confirmed to be resistant in vitro to one first-line anti-TB drug.
- **Poly-resistant TB:** TB in patients whose infecting isolates are resistant in vitro to more than one first-line drug, other than isoniazid and rifampicin.

- **Multi-drug resistant TB:** is active TB involving *M. tuberculosis* organisms that are resistant to at least both isoniazid and rifampicin, the two most powerful anti-TB agents. An MDR-TB strain can be resistant to more than these two antibiotics and in most cases it is resistant to other first-line drugs.
- **Extensive-drug resistant TB:** is defined as resistance to at least rifampicin and isoniazid, in addition to any fluoroquinolone, and to at least one of the three following injectable drugs used in anti-TB treatment: capreomycin, kanamycin and amikacin.

Multi-drug resistant tuberculosis (MDR-TB)

Although MDR-TB varies widely across regions, it occurs in all geographical settings able to produce data and is therefore a world-wide problem. WHO estimates a global prevalence of one million MDR-TB cases, and some 300,000 -600,000 new cases emerging every year. China, India and the Russian Federation account for 68% of the annual incidence of MDR-TB cases¹⁵.

Of the estimated 300,000-600,000 new cases of MDR-TB, about half of them are new TB patients (primary drug resistance) and the other half have been previously treated (acquired drug resistance). It is estimated that the average MDR-TB patient infects up to 20 other people in her/his lifetime.

Table 2: Causes of inadequate anti-tuberculosis treatment¹⁶

Health care providers: Inadequate regimens	Drugs: Inadequate supply/quality	Patients: Inadequate drug intake
Inappropriate guidelines	Poor quality	
Noncompliance with guidelines	Unavailability of certain drugs (stock-outs or delivery disruptions)	Poor adherence (or poor DOT)
Absence of guidelines	Poor storage conditions	Lack of information
Poor training	Wrong dose or combination	Lack of money (no treatment available free of charge)
No monitoring of treatment		Lack of transportation
Poorly organized or funded TB control programmes		Adverse effects Social barriers Malabsorption Substance dependency disorders

A multi-drug resistant organism requires treatment with second-line drugs and falls under WHO diagnostic category IV treatment. While treatment of MDR-TB is more complicated and longer than treatment with first-line drugs, it has been proven cost-effective and very efficacious. Patients who are identified early with MDR-TB can have greater than an 85% chance of cure. The treatment is also feasible in low resource areas. It is extremely important to treat MDR-TB patients both to prevent their deaths and to prevent those who remain infectious from spreading drug-resistant TB in the community.

Good history taking is essential when people present with TB symptoms to determine previous TB treatment, its length and the drugs used. In addition, during history taking the patient may reveal contact with someone who suffered from drug-resistant disease. This patient's sputum should be cultured for drug sensitivity when risk factors for MDR-TB are detected. In some areas there are no resources for culture and sensitivity testing, but in those settings, a history of inadequate treatment, or past treatment with only one drug, or a past default on treatment, followed by a return of symptoms, may be considered as reasonable suspicion that one is dealing with MDR-TB.

When MDR-TB is confirmed by culture and sensitivity testing, or is suspected based on the patient's history, the first phase of treatment should include at least four drugs susceptible to the infecting strain. Often, since susceptibility cannot be guaranteed, five or six drugs are recommended initially (category IV treatment). The first phase, which uses an injectable agent, should be a minimum of 6 months and many programmes extend treatment if the patient has not converted both smear and culture. The entire treatment period is 18-24 months past smear and culture conversion.

Patients with MDR-TB take more tablets for a longer period of time, may experience more adverse effects and require increased support to continue treatment and/or to monitor adverse effects. Detecting and controlling adverse effects in a timely manner prevents adherence problems and defaults. Nurses play a critical role in their rapid detection and management. See the table on page 43 for common adverse effects of essential and reserve medications used in treating drug-sensitive and drug-resistant TB.

Extensively drug-resistant tuberculosis (XDR-TB)

Extensively Drug-Resistant TB (XDR-TB) is a rare type of MDR-TB. XDR-TB is defined as resistance to rifampicin and isoniazid (which is the definition of MDR-TB), in addition to any fluoroquinolone, and at least one of the three following injectable drugs used in anti-TB treatment: capreomycin, kanamycin and amikacin.

Because XDR-TB is resistant to first- and second-line drugs, patients are left with treatment options that are less effective. However, it can be identified early, can be treated and cured in some cases under proper TB control conditions. Successful treatment outcomes depend on the extent of the drug resistance, the severity of the disease and the immune response of the patient.

XDR-TB strains have been found in all regions of the world. XDR-TB is rare, but in some places 19% of MDR-TB cases were XDR-TB cases¹⁷. Drug-resistant TB occurs as a result of poorly managed TB control programmes and underlines the need for the development of new TB diagnostics, treatments and vaccines, since the current tools are outdated and insufficient.

XDR-TB poses a grave global public health threat, especially in populations with high rates of HIV. The international response to the XDR-TB emergency began with the establishment of a WHO Global Task Force on XDR-TB. The recommendations of this Task Force include¹⁸:

- Immediate strengthening of TB control in countries along with scaling up universal access to HIV treatment and care.
- Improved management of XDR-TB suspects in settings of high and low HIV prevalence.
- Implementation of programmatic management of XDR-TB and treatment design in HIV-negative and positive individuals.
- Dissemination of revised laboratory XDR-TB definition and laboratory strengthening.
- Implementation of appropriate infection control measures and protection of health-care workers, with emphasis on settings with high HIV prevalence.
- Embedding surveillance of XDR-TB in existing drug resistance surveillance systems to increase access to second-line DST.
- Establishment of an XDR-TB task force on advocacy, communication and social mobilization within existing structures.

- Resource mobilization: development of a fully budgeted plan for raising the resources and funding required addressing XDR-TB.
- Research and development related to XDR-TB.

For further information please visit:

www.who.int/hq/2007/WHO_HTM_TB_2007.375_eng.pdf

CHAPTER 2

Measures to diagnose, treat and control tuberculosis

The Global Plan to Stop TB 2006-2015

Whilst wealthy industrialised countries with good public health care systems can be expected to keep TB under control, in much of the developing world the disease remains an urgent public health problem.

A concerted effort is being made by the World Health Organization (WHO) together with the national TB programmes to expand the coverage of effective TB control measures based on the DOTS Strategy. The United Nations Millennium Development Goals include a target for the incidence of TB to have been halted and on its way to being reversed by 2015. In addition the StopTB Partnership has agreed a target to half prevalence and the number of deaths from TB by 2015 in comparison to 1990. The Stop TB Partnership has developed an ambitious Global Plan to Stop TB that covers the period 2006-2015 (WHO, 2006) which requires a threefold increase in investment in order to achieve these targets. The plan involves:

- continuing DOTS expansion through the implementation of the StopTB Strategy ensuring that more people are treated and deaths are prevented
- increasing the number of people treated for MDR-TB
- increasing the access to antiretroviral therapy for people with TB and HIV
- increasing local availability of rapid diagnostic tests by 2010
- introducing a new TB drug shortly after 2015 to reduce the duration of treatment
- developing a new vaccine by 2015.

The Stop TB Strategy

While new tools such as drugs and vaccines are essential to combating TB in the longer term, the targets set for 2015 will only be achieved if more people have access to existing good quality diagnosis and treatment. For this reason The Global Plan to Stop TB 2006 - 2015 adopts the new WHO-recommended Stop TB Strategy which consists of the following six key elements:

- 1) Pursue quality DOTS expansion and enhancement (based on the 5 elements of the DOTS Strategy), improving case-finding and cure through an effective patient-centred approach to reach all patients, especially the poor.
- 2) Address TB/HIV, MDR-TB and other challenges, by scaling up TB/HIV joint activities, DOTS-Plus, and other relevant approaches.

- 3) Contribute to health system strengthening by collaborating with other health programmes and general services, for example in mobilizing the necessary human and financial resources for implementation and impact evaluation, and in sharing and applying achievements of TB control.
- 4) Involve all care providers, public, nongovernmental and private, by scaling up approaches based on a public-private mix, to ensure adherence to the International Standards for TB Care.
- 5) Engage people with TB and affected communities to demand, and contribute to, effective care. This will involve scaling up community TB care; creating demand through context specific advocacy, communication and social mobilization; and supporting development of a patients' charter for the TB community.
- 6) Enable and promote research for the development of new drugs, diagnostics and vaccines. Research will also be needed to improve programme performance.

The new Stop TB Strategy recognizes the need to provide care to all TB patients, whether the disease is caused by drug susceptible or drug-resistant bacilli. Nurses are absolutely crucial to ensuring the successful implementation of this strategy.

Elements of the DOTS Strategy

The DOTS Strategy remains at the heart of the Stop TB Strategy. It combines five elements or essential principles that must be fully implemented to achieve effective TB control:

1. Political commitment to effective TB control.
2. Case detection by sputum smear microscopy among symptomatic people.
3. Standardised treatment regimen of 6-8 months with first-line anti-TB drugs, administered under proper case management conditions, including direct observation for the first two months.
4. Uninterrupted supply of all essential anti-TB drugs.
5. Standardised recording and reporting system, allowing monitoring and evaluation of treatment results.

1. Political commitment

Only political commitment to the TB control programme can ensure its successful implementation. Political support at community, regional, national and global level will provide technical guidance, and required financial and human resources. Sustainable partnerships will guide the achievement of short, middle and long-term goals in fighting TB. Concerted efforts of communities, non-governmental organisations, faith-based organisations and patient groups can improve political commitment and increase access to care.

- **Globally**, commitment is needed from the richer countries to pursue poverty eradication in the developing world as well as to contribute financially to the efforts being made in poorer countries to establish effective TB control programmes.
- External aid can only be effective if **national governments** allocate sufficient available resources to maintain a **National TB Control Programme**. This includes:
 - development of a National TB control strategy;
 - identification of a team with sufficient administrative capacity to manage the programme nationally;
 - purchase and distribution of adequate drugs and supplies;
 - human resource development and planning to implement the strategy on the ground.
- A **regional or district body** needs to make decisions about resource allocation. It is recommended that there should be, on average, one basic **local TB management unit** to offer diagnostic and treatment facilities for a population of 100,000. This unit should be fully integrated into existing health services.

2. Case detection and monitoring by sputum smear microscopy

In order to control TB effectively it is necessary firstly to reduce the infectious pool in the community by finding and treating the most infectious cases. Sputum smear microscopy is the most reliable and cost effective method of identifying infectious cases of TB and should be the first test done when investigating someone with pulmonary symptoms.

The tubercle bacillus has a number of unique properties. It has an unusually thick cell wall, which is impermeable by acids, alkalis and detergents and it is very slow growing. This means that specific tests are required to investigate TB. The Ziehl-Nielsen stain is the most commonly used for direct microscopy. Auramine staining followed by fluorescence microscopy is faster although not universally available and needs to be confirmed using the Ziehl-Nielsen method (Brewis et al, 1995).

For accuracy of diagnosis, three sputum specimens should be taken from someone suspected of having TB. In some areas, due to pressures of the workload, only two are taken. Ideally, the initial specimen is collected at the first patient interview under the nurse's supervision. Depending on the availability of laboratory services, if AFB are seen on direct microscopy, the specimen should be cultured to confirm the identity of the bacilli and check their sensitivity to the various anti-TB drugs. If AFB are not seen and laboratory services allow, the sputum specimen should be cultured for at least 8 weeks before being considered negative¹⁹.

Apart from being an essential diagnostic tool, sputum smear microscopy is also used to monitor the progress of each patient with TB. If the sputum has not converted from smear positive to smear negative, or, if the sputum becomes smear positive having been smear negative, the patient may not be receiving adequate treatment, or the patient may have MDR-TB.

During the course of TB treatment, sputum smears must be taken at least three times for monitoring purposes:

1st time	At the end of the 2nd month of treatment when 75-85% of initially sputum-smear positive patients should be sputum -smear negative (sputum conversion). ²⁰
2nd time	At the end of the 5th month of treatment in order to confirm TB cure.
3rd time	At the end of the 6th month of treatment in order to confirm TB cure.

3. Standardised treatment regimen

The objective of chemotherapy is to cure as high a percentage of smear positive patients as possible. Well-run programmes can cure greater than 90% of all detected smear positive cases.

The main requirements for adequate chemotherapy in DOTS are the:

- right combination of anti-TB drugs
- right dosage
- right schedule, taken regularly without interruption
- right length of treatment
- patient entry is not in a critical or severe condition
- bacilli are not resistant to isoniazid and rifampicin.

Establishing a treatment regimen that is adequate and adapted to the situation of the individual patient can be facilitated by placing each patient in an appropriate TB Treatment Category (see table 4). The diagnostic categories are used for each new or current TB patient, and they can be modified to account for culture and drug sensitivity testing (DST) results obtained.

4. Regular, uninterrupted drug supply

Since it is imperative for a TB patient to complete a full, uninterrupted course of treatment to prevent drug resistance, and since in most countries TB drugs are procured centrally with a nation-wide system for ordering and distribution, the government must commit to organise and manage resources to insure a consistent supply of drugs. Enough medication to effectively treat all patients is based on the number of cases detected and on the roster, including a reserve amount. This is imperative to prevent treatment interruptions. Thus, accurate reporting and recording systems are vital. Also, security is essential for storage and transport of supplies. Drugs must be protected from adverse conditions, such as extreme temperatures, water damage, accidents, animal interference, etc. Governments must ensure that they are procuring quality medications from trustworthy manufacturers. The Global TB Drug Facility (GDF) is available to help governments and non-governmental organisations procure a continuous supply of quality TB drugs.

5. Standardised recording and reporting systems

Standardised recording and reporting systematically evaluate patient progress and treatment outcome and give a picture of how the programme is performing overall. There are four essential components: the laboratory register, the patient treatment card, the TB register and quarterly reports. These components should be able to be cross-checked to evaluate completeness, accuracy and promptness of record keeping, and programme accountability.

- The **laboratory register** logs all patients who have submitted a sputum sample for analysis by microscopic examination of a smear and by culture and sensitivity testing. Completed by the laboratory technician, it includes basic patient details, dates of the tests and results.
- **Patient treatment cards** contain basic patient details and clinical information, including the medication, dosage and dates prescribed for each patient. The card has a calendar grid for recording each dose of medication, allowing the nurse and the patient to see the treatment status, get timely sputum tests and ensure adequate medication supplies. The treatment card is an

important indicator of treatment completion and is particularly important if the patient is unable to produce a sputum specimen at the end of the treatment or if the TB was extra-pulmonary. If medications are self-administered or supervised at home, the patient or a family member maintains the card and needs training to use it.

- The **TB patient register** lists all persons who have been diagnosed with TB, including MDR-TB and who are under treatment at a particular facility. It is maintained locally and allows the facility to monitor its own performance. This register feeds into a district registry that enables monitoring of the TB situation at district level, as well as consolidating information about the overall epidemic.
- **Quarterly cohort analysis** includes data on all TB patients registered during a three-month period. This type of report enables health facilities to monitor their performance, identify and address local problems, and order appropriate quantities of drugs and supplies. At a district and national level, cohort analysis compares TB programme progress to TB control targets.

The DOTS Strategy and drug-resistant tuberculosis

The DOTS framework with its five elements is applied for the management of drug-resistant TB. DOTS programmes ensure that second-line drugs are used safely and appropriately within a comprehensive management system. Without this strategic approach, drug supplies may become erratic, recording is likely to be inadequate, and the use of second-line drugs risks being inconsistent, which can lead to second-line drug resistance. Second-line drugs should only be used by a project that follows the published WHO protocols for standardised or individualised DOTS treatment regimens for MDR-TB²¹. Effective TB control based on the DOTS Strategy is the first step in the fight against drug resistance.

Green Light Committee

Second-line drugs used in the treatment of MDR-TB are significantly more costly than first-line drugs. The Green Light Committee (GLC) was launched in 2000 and is based at WHO Headquarters in Geneva. It is made up of experts from a number of different organisations, and provides a mechanism for low and middle-income countries to obtain high quality second-line TB drugs at a lower cost than in the open market. Funds are made available through the Global Fund to Fight AIDS, tuberculosis and malaria and the international drug purchase facility called

UNITAID. The GLC also promotes technical assistance to DOTS programmes and promotes the rational use of second line anti-TB drugs worldwide. Countries with a strong DOTS programme and a solid plan to manage MDR-TB approved by the GLC are eligible to benefit from the pooled procurement mechanism of second-line anti-TB drugs. Approval depends on the project's adherence to the described guidelines²². As the guidelines are revised regularly, nurses must consult the recent publication. For information on GLC see the WHO web site: www.who.int/tb/dots/dotsplus/management/en

By December 2006, 53 GLC-approved projects had been approved for implementation in 42 countries, providing treatment to more than 26,000 MDR-TB cases in resource-limited settings.

TB diagnosis

Diagnosis of pulmonary TB

Several measures are used to diagnose pulmonary TB the most important of which is sputum smear microscopy. This is due to the fact that it will diagnose the most infectious cases, i.e. those that are sputum smear positive and, if facilities are available to culture the sputum specimen, it will be possible to confirm the presence of *M. tuberculosis*. If facilities are also available for drug sensitivity testing it will be possible to identify drug resistance.

- **Sputum smear microscopy:** To confirm active disease, the patient's sputum must be examined. *M. tuberculosis* is identified microscopically by its staining characteristics: it retains certain stains after being treated with acid solution. Therefore, it is classified as an "acid-fast bacillus" (AFB). The most common staining technique is the Ziehl-Neelsen stain. AFB are stained bright red, which stands out clearly against a blue background. In addition, AFB can be visualised by fluorescent microscopy, and by an auramine-rhodamine stain.
 - In addition, all specimen should be isolated and identified by means of a sputum culture. Culturing the specimen means growing the mycobacteria on media, substances that contain nutrients, in the laboratory. When the mycobacteria have formed colonies they can be identified.
- **Chest x-ray:** helpful in suspects found to be smear negative to look for cavitations, areas of consolidation and infiltration, enlargements of the hilar lymph nodes and pleural effusion.

- **Computer Tomography (CT) and Magnetic Resonance Imaging (MRI):** useful for guiding the diagnosis process in some difficult cases, but frequently not available.

- **Tuberculin skin test:** In this test, a substance called tuberculin is injected into the skin of the arm. Tuberculin is protein derived from tubercle bacilli that have been killed by heating. In most infected people, the immune system will recognise the tuberculin because it is similar to the tubercle bacilli that caused infection. This will cause reaction to the tuberculin. Tuberculin is used for diagnosing; it is not a vaccine.

Tuberculin testing is useful for:

- **examining a person who is not sick but who may have TB infection,** such as a person who has been exposed to someone who has TB. In fact, the tuberculin test is the only way to diagnose TB infection before the infection has progressed to TB disease;
- **screening groups of people for TB infection;**
- **examining a person who has symptoms of TB disease.**

Different types of tuberculin tests are available. The Mantoux tuberculin skin test is the preferred type of skin test because it is the most accurate:

Patients with pulmonary TB are referred to as either smear positive or smear negative

This is an important distinction as smear positive patients tend to have more advanced disease with more damage to their lungs so they cough up more infectious material and are therefore more contagious. Without treatment, the outcome of their disease is poorer than that of smear negative patients.

Pulmonary TB; sputum smear positive (PTB+):

- Is the most infectious form of TB.
- Refers to patients who have enough TB bacilli (AFB) in their sputum that they can be identified under a microscope when a Ziehl Neelsen or auramine stain (AFB Smear) is used:
 - at least two initial sputum smear examinations need to be positive for AFB; or
 - one sputum specimen AFB+ and radiographic abnormalities consistent with active pulmonary TB; or
 - one sputum specimen AFB+ culture positive for TB bacilli.

Pulmonary TB; sputum smear negative (PTB-):

If a patient has symptoms suggestive of TB, at least three sputum examinations negative for AFB, and radiographic abnormalities consistent with active pulmonary TB, the patient should receive a full course of anti-TB therapy.

Knowing whether the patient is smear negative or smear positive is important for two reasons:

1. Sputum conversion from smear positive to smear negative or vice versa is one of the indicators of a patient’s progress.
2. The status of the sputum smear can determine how to allocate scarce resources. In such situations smear positive patients take priority in treatment over less infectious smear negative cases.

Diagnostic tests for TB include:

Pulmonary

- sputum smear microscopy
- chest x-ray
- bronchoscopy

- imaging, e.g., by computer tomograph or magnetic resonance imaging
- tuberculin skin test
- gastric washing

Extra-pulmonary

- biopsy at site
- fine needle aspiration at site
- lumbar puncture (if TB meningitis is suspected)

- imaging, e.g., by computer tomograph or magnetic resonance imaging
- tuberculin skin test

Children are often treated empirically since it is harder to get a sputum specimen. Gastric lavage and/or bronchoscopy are not often used since it is not always fruitful and is difficult to do in many resource poor settings²³.

Diagnosis of extra-pulmonary TB

The diagnosis of extra-pulmonary TB can be difficult as it is less common than pulmonary disease and there may be numerous differential diagnoses. It is therefore essential to recognise the general symptoms of TB that are common to both pulmonary and extra-pulmonary TB. Specific symptoms for extra-pulmonary TB vary according to the site of disease but severe pain is common – this can be excruciating when it causes destruction in bones and joints.

In some cases, particularly with regard to lymph node TB, it may be possible to collect pus by aspirating the infected site. Biopsies may also be useful, but it is important to remember to send specimens for both histo-pathological as well as microbiological examination. If at all possible diagnosis should be based on culture positive specimen, or historical or strong clinical evidence consistent with active TB, followed by a decision by a clinician to treat with a full course of anti-TB chemotherapy. A list of diagnostic tests is included in the table above. There is likely to be varied availability of these tests especially, imaging, according to local resources.

Contact tracing

In some countries contact tracing is initiated at the initial assessment. The patient provides a list of those people closest to him/her. These people are then invited for screening: a symptoms check, a tuberculin skin test and/or a chest x-ray. If resources are scarce, the patient is encouraged to identify anyone he knows who is showing signs or symptoms of the disease and to encourage them to come to the health clinic for investigation. As a minimum, all children under the age of five living in the patient’s household are examined. Whatever the circumstances, this is a distressing process, since the patient may not want others to know that he has TB. Contact tracing offers a good opportunity to educate others about TB and address stigma, thus increasing the patient’s support system. Contract tracing must always be conducted sympathetically, with the greatest possible effort to maintain confidentiality.

TB treatment

TB classification

Once diagnosed, patients should be classified by whether they have had previous treatment for TB, and its outcome. This helps to identify patients at increased risk of drug resistance and to prescribe appropriate treatment. WHO uses the following definitions²⁴.

Table 3: Classification of TB

Type of case	Definition
New	No previous treatment or treatment for less than one month.
Relapse	Previously treated and declared cured, or treatment completed in the past, and now diagnosed with smear- or culture-positive TB.
Treatment after failure	Started on re-treatment regimen, having failed previous treatment, e.g., remained smear positive after five months of treatment.
Treatment after default	Returning to treatment with positive smear or culture, following default at least a two month interruption of treatment.
Transfer in	Transferred from another TB register to continue treatment.
Other	All other cases, e.g., chronic cases who remain smear positive at the end of a re-treatment regimen.

Essential drugs against TB

More than 10 million bacteria exist in the actively multiplying bacterial population in any given patient, and there are always a few *Mycobacteria* resistant to one or another of the anti-TB drugs. If only one drug is used, bacteria resistant to that drug will continue to develop and multiply. However, if more than one drug is used, the bacteria that may be resistant to the first drug are killed by the second drug – this is the rationale behind the use of multiple drug therapy.

Anti-TB drugs have three main actions: bactericidal activity, sterilising activity and the ability to prevent resistance. Isoniazid and rifampicin are the most powerful bactericidal drugs. Rifampicin is the most potent sterilising drug and pyrazinamide and streptomycin are also bactericidal. Ethambutol and thioacetazone are used in association with more powerful drugs to prevent the development of resistant TB bacilli²⁵. The table below shows²⁶ the main anti-TB drugs and recommended dose. The range is shown in parenthesis. Essential medications used in fixed-dose combinations are shown in table 5.

Table 4: Essential (first-line) drugs¹⁶

Drug (abbreviation)	Recommended dose mg/per kg, daily	Recommended dose mg/per kg, 3 times weekly
Isoniazid (H)	5 (4-6)	10 (8-12)
Rifampicin (R)	10 (8-12)	10 (8-12)
Pyrazinamide (Z)	25 (20-30)	35 (30-40)
Streptomycin (S)	15 (12-18)	15 (12-18)
Ethambutol (E)	15 (15-20)	30 (20-35)
Thioacetazone (T)*	2.5	(Not applicable)

*WHO discourages the use of thioacetazone because of the risk of severe toxicity, in particular in HIV-infected individuals. It should be replaced by ethambutol, especially in areas where HIV infection is common." (WHO 2004)

WHO recommends the use of fixed-dose combination tablets for the TB treatment provided in the table below.

Table 5: Fixed-dose combination of drugs¹⁶

Drug	Dose form	Strength for daily use	Strength for use 2-3 times weekly
Isoniazid + rifampicin	Tablet	75 mg + 150 mg 150 mg + 300 mg	150 mg + 150 mg
	Tablet or pack of granules*	30 mg + 60 mg	60 mg + 60 mg
Isoniazid + ethambutol	Tablet	150 mg + 400 mg	–
Isoniazid + Thioacetazone	Tablet	100 mg + 50 mg 300 mg + 150 mg	–
Isoniazid + rifampicin + pyrazinamide	Tablet	75 mg + 150 mg + 400 mg	150 mg + 150 mg + 500 mg
	Tablet or pack of granules*	30 mg + 60 mg + 150 mg	–
Isoniazid + rifampicin + pyrazinamide + ethambutol	Tablet	75 mg + 150 mg + 400 mg + 275 mg	–

*For paediatric use.

Standard code for TB treatment regimens²⁷

TB treatment regimen should have a standard code. Each anti-TB drug has an abbreviation:

Isoniazid	H
Rifampicin	R
Pyrazinamide	Z
Streptomycin	S
Ethambutol	E
Thioacetazone	T

For category I and III patients, treatment with the drugs recommended by WHO is divided into two phases:

1) **Initial intensive phase** – four drugs given daily (isoniazid, rifampicin, pyrazinamide, and ethambutol) in fixed dose combination, and directly observed for at least 2 months. This rapidly improves clinical symptoms and reduces the bacterial population without allowing drug resistance.

2) **Continuation phase** – a combination of two drugs (isoniazid and rifampicin) in fixed dose combination, three times per week, for 4 more months to eliminate remaining bacilli and prevent relapse.

For category II, the initial phase is 2 months of daily drug treatment with isoniazid, rifampicin, pyrazinamide, ethambutol and streptomycin. The continuation phase is 5 months with isoniazid, rifampicin and ethambutol.

In the standard code the number before a phase is the duration of the phase in months. Letters in parenthesis indicate fixed-dose combinations of those drugs. A number in subscript (e.g. 3) after a letter or letters in parentheses indicates the number of doses of that drug per week. If there is no subscript number, treatment is daily (or 6 times weekly, excluding for instance Sundays). One example is shown below:

2 (HRZE) / 4 (HR)₃

The initial phase is 2 (HRZE). The duration of this phase is 2 months. Drug treatment is daily, with isoniazid (H), rifampicin (R), pyrazinamide (Z) and ethambutol (E) in fixed combination. The continuing phase is 4 (HR)₃. The duration is 4 months, with isoniazid and rifampicin, in fixed-dose combination, 3 times per week.

Table 6: Recommended treatment regimens for each diagnostic category²⁵

TB diagnostic category	TB patients	TB treatment regimes ⁱ	
		Initial phase	Continuation phase
I	<ul style="list-style-type: none"> New smear positive patients; new smear negative patients with extensive parenchymal involvement; concomitant HIV disease or severe forms of extra-pulmonary TBⁱⁱ. 	Preferred 2 HRZE ⁱⁱⁱ	Preferred 4 HR 4 (HR) ₃
		Optional 2 (HRZE) ₃ or 2 HRZE ^{iv}	Optional 4 (HR) ₃ or 6 HE ^v
II	Previously treated sputum smear positive pulmonary TB:	Preferred 2 HRZES / 1 HRZE ^{vi}	Preferred 5 HRE ^{vi}
	<ul style="list-style-type: none"> relapse; treatment after default 	Optional 2 (HRZES) ₃ / 1 HRZE ₃	Optional 5 (HRE) ₃
	Treatment failure of Category I ^{vi} in settings with:	Specially designed standardized or individualized regimens are often needed for these patients.	
	<ul style="list-style-type: none"> adequate program performance; representative DRS data showing high rates of MDR-TB and/or capacity for DST of cases, and availability of Category IV regimens 		
	In settings where:	Preferred 2 HRZES / 1 HRZE	Preferred 5 HRE ^{vi}
	<ul style="list-style-type: none"> representative DRS data show low rates of MDR-TB or individualized DST shows drug-susceptible disease or in settings of: <ul style="list-style-type: none"> poor program performance, absence of representative DRS data, insufficient resources to implement Category IV treatment 	Optional 2 (HRZES) ₃ / 1 HRZE ₃	Optional 5 (HRE) ₃
III	New smear negative pulmonary TB (other than category I) and less severe forms of extra-pulmonary TB	Preferred 2 HRZE ^{viii}	Preferred 4 HR 4 (HR) ₃
		Optional 2 (HRZE) ₃ or 2 HRZE	Optional 4 (HR) ₃ or 6HE
IV	Chronic (still sputum positive after supervised re-treatment); proven or suspected MDR-TB cases ^{ix}	Specially designed or individualized regimens	

- i Numbers preceding regimens indicate length of treatment (months). Subscripts following regimens indicate frequency of administration (days per week). When no subscripts are given, the regimen is daily. Direct observation of drug intake is always required during the initial phase treatment and strongly recommended when rifampicin is used in the continuation phase and required when treatment is given intermittently. Fixed -dose combinations are highly recommended for use in both the initial and continuation phase of treatment.
- ii Severe forms of extra-pulmonary TB are listed in the paragraph about extrapulmonary TB.
- iii Streptomycin may be used instead of ethambutol. In tuberculous meningitis ethambutol should be replaced by streptomycin.
- iv Intermittent initial phase therapy is not recommended when the continuation phase of isoniazid and ethambutol is used.
- v This regimen may be considered in situations where the preferred regimen cannot be applied as recommended. It is associated with a higher rate of treatment failure and relapse compared with the 4HR continuation phase regimen. Intermittent initial phase treatment is not recommended when followed by the 6HE continuation phase regimen.
- vi Daily treatment is preferred. Thrice weekly treatment during the continuation phase or during both phases is an acceptable option.
- vii Treatment failures may be at increased risk of MDR-TB, particularly if rifampicin was used in the continuation phase. DST is recommended for these cases if available. Treatment failures with known or suspected MDRTB should be treated with a Category IV regimen.
- viii Ethambutol in the initial phase may be omitted for patients with limited, non-cavitary, smear-negative pulmonary TB who are known to be HIV-negative, patients with less severe forms of extrapulmonary TB, and young children with primary TB.
- ix Drug susceptibility testing is recommended for patients who are contacts of MDR-TB patients.

Nurses must be familiar with the adverse reactions of anti-TB drugs and refer to WHO and National Tuberculosis Programme guidelines on essential drugs.

Medication adverse effects

Minimising medication adverse effects helps ensure patient adherence to treatment. The nurse should teach every patient about the possible adverse effects and encourage them to report any symptoms as soon as possible. Adverse effects fall into two groups depending on their severity, minor and major.

Minor adverse effects include:

- Discolouration of urine.
- Nausea, occasional vomiting, abdominal discomfort, loose stools.
- Lack of energy.
- Mild rash, itching.

The patient experiencing minor adverse effects needs support to complete his treatment. The nurse may need to think of ways to help alleviate his suffering such as changing the medication time, diet, and/or offering mild anti-emetics, antacids or anti-histamines.

Treatment is usually stopped if the patient suffers any of the following major adverse effects:

- Persistent vomiting.
- Hepatic toxicity/jaundice.
- Peripheral neuropathy.
- Severe rash.

For more detailed guidance, please see [Adverse Effect Management Table on page 79](#).

After a short break in treatment to permit some recovery from the adverse effects, each drug is reintroduced, one at a time, to identify the problem drug. Once identified, the problem drug is replaced with an alternative. This does mean that the treatment period is extended.

Adherence

To encourage adherence to treatment protocols, TB services must be flexible enough to give the patient a choice about where they receive treatment, e.g., at home, in the clinic or in the workplace. If the patient chooses to take the drugs in his home or workplace, treatment observers, other than those associated with the clinic, are encouraged. These observers can be anyone who is willing, trained, responsible, acceptable to the patient and accountable²⁷. Close family members, such as spouses, can be manipulated by the patient and caution is needed to ensure adherence.

Failure to adhere to standardised treatment due to adverse effects or other reasons can lead to treatment failure and the emergence of MDR-TB. Therefore, the patient's commitment to the prescribed therapy plays a key role in successful treatment outcomes. Nurses must listen to patients' concerns and provide information and education that is tailored to each patient's needs. The importance of treatment adherence and obtaining patient commitment are vital for treatment success.

CHAPTER 3

Guidelines for patient care: nursing principles and processes²⁸

Role of nurses in TB control

Nurses make up by far the largest group of health care workers in any part of the world and as in most areas of health care they often undertake the bulk of the work in TB control. According to the ICN Code of Ethics “Nurses have four fundamental responsibilities: to promote health, to prevent illness, to restore health and to alleviate suffering. The need for nursing is universal.”²⁹ In relation to TB, nurses promote health in order to prevent people becoming vulnerable to the disease in the first place; they prevent illness by reducing transmission of TB in the community by finding and treating active cases; they restore health by ensuring patients receive the treatment they need; and alleviate suffering by organising support for patients according to their individual needs.

Many people are extremely shocked when they are told they have TB, some refuse to accept it and others simply take it in their stride. The reaction depends on many factors including cultural beliefs and values, previous experience, and knowledge of the disease. TB now has a higher profile in the media; the reports are often alarmist and a stigma still remains attached to 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. Nurses are well-placed within communities, working closely with patients and their families, to play a crucial role in providing a caring environment for all patients suffering from TB. This is essential to the success of TB control programmes which need to offer good access to effective diagnostic and treatment facilities.

The nurse's role in relation to the five key elements of the DOTS Strategy

The roles that nurses play in TB management and control vary according to their work setting. While some will be involved in all of the activities described below, others will take on various elements. Nurses with additional qualifications may change their job titles thereby becoming less visible as nurses, but continuing, nonetheless, to carry out nursing activities. Nurses working in primary health care settings are often first to see people who present with symptoms and so are crucial to the early identification and management of suspect TB and MDR-TB cases. To ensure a high level of case detection, a cornerstone of TB control, nurses working with individuals, families, communities and other services need to understand their role in controlling this preventable disease.

Element	Strategy and rationale	Nurses' role
Political commitment	Investment essential at national and local levels to implement and sustain a successful TB control programme	Advocacy and lobbying Experience of work closely with patients and communities can inform policy and strategic decision making and assist implementation
Case detection by smear microscopy	Most cost-effective option Identifies infectious cases	Identification of suspect cases Support for worried patients Advice to produce good sample Access for delivery of sample Documentation (dates & results)
Standardised treatment with DOT	To ensure effective treatment prescribed and good adherence to medication Treatment observers should be willing, trained, responsible, and acceptable to the patient	Ensuring equitable access Individualised care planning Education of patient and family Monitoring and documentation of medication and progress Support for pt, family and treatment observer
Standardized reporting and recording	Systematic evaluation of a) patient progress and treatment outcome b) overall programme performance	Clear, accurate and prompt record keeping using – Laboratory register – Treatment cards – TB register Communication re individual and collective progress
Regular uninterrupted drug supply	Minimising the possibility of treatment interruption	Ensuring there is a sufficient supply for patients seen according to level of responsibility (manager of a TB Unit to DOTS supervisor)
Additional logistical aspect: Training and supervision	Vital to ensure quality and proper management of actual and possible TB cases	Personal professional development Provision of education for patients their families, communities and volunteers etc.
Additional operational aspect: Flexibility	The range of geographical, environmental and cultural contexts requires flexibility in the implementation of DOTS components	Nurses play a key role in providing flexible TB services by providing individualised patient-centred care

The nursing process, DOTS and MDR-TB management strategies

The nursing process is a systematic approach to providing individualised, patient-centred care through a cycle of assessment, planning, implementation and evaluation. It offers a scientific basis for decision-making and improves the quality of planning. Actions made explicit during the planning phase allow for evaluation of the effectiveness of the interventions undertaken.

Like the nursing process, DOTS and MDR-TB management strategies have quality and effectiveness at its core. The DOTS Strategy in particular offers a standardised approach for the control and management of TB. The management of MDR-TB is much more complex although there are some opportunities for standardising certain aspects such as elements of diagnosis and treatment monitoring. Although the technical aspects of TB control are standardised, to be effective, TB services must be flexible and based on the needs of the patient, their family and the local community.

Adherence to TB treatment

Adherence to TB treatment, a major factor in the successful outcome of TB treatment, reduces the potential for developing acquired MDR-TB and is the main reason the DOTS Strategy was developed in the first place. Adherence is the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes – follows the agreed health care recommendations³⁰.

Adherence is complex, with a number of factors that can adversely impact treatment completion including: socio-economic factors and issues related to the organisation of TB treatment in the community; patient variables; treatment variables; treatment of adverse effects; disease variables; and organisational variables. The nurse must understand the barriers for adherence to treatment regimens and reduce or eliminate these barriers. A patient-centred approach which includes facilitating access to treatment, deciding with the patient the most convenient time and place for direct observation of treatment (DOT), and when possible providing other social and medical services is more effective than default tracing.³¹ DOT is a key element of the policy package for TB control and requires that an observer watch the patient swallow the medicines. The observer can be a health worker or a trained and supervised member of the community.

Best adherence indicators include:

- Smear conversion from positive to negative.
- Improvement in symptoms.
- Clinical improvement.

The use of incentives to motivate the TB patient to adhere to treatment can be effective and enhance the patient/nurse relationship. Some ideas for incentives are: support groups; award ceremonies on successful completion of treatment; reimbursement for travel, food, visits, and phone calls; "Thank you teas" for patients and their families; and birthday or anniversary greetings. In many countries, malnutrition is a serious problem and food is considered an enabler – necessary for treatment success – rather than an incentive.

Giving incentives carries responsibility for both the patient and the nurse. Both must keep their promises. If the nurse promises the incentive and does not deliver it, the relationship with the patient and credibility in the community may be adversely affected. To effectively use incentives, the nurse must also get to know the patient and recognise the difference between the nurse's perception of the patient's needs and his/her reality.

Patient-centred approach to TB control and care

The patient-centred model links nursing process with the DOTS and MDR-TB management strategies, identifying case finding and patient holding as intertwined cycles of intervention. Cases are constantly being found, prompting further investigation, which leads to more cases being discovered. Since the individual patient's needs may change during the time they are on treatment, the nurse's constant evaluation and reassessment ensures appropriate care at each stage and enhances the patient's adherence to TB treatment protocols.

Case finding

Patients enter the patient roster through passive case finding or active case finding. Active case finding is TB screening of populations, recommended only in areas where treatment success is at least 85% and where treatment and follow-up services are available. Screening can be expensive, so it is more cost effective to target the highest risk groups based on epidemiological trends within a local population. Often screening is targeted at hard-to-reach groups, which means identified cases are a challenge to treat.

Passive case finding occurs when people present themselves with symptoms. It relies on good public information and accessible services for people to recognise TB symptoms and know where to get help. If TB is suspected, the person is tested.

If diagnosed with active TB, the nurse registers the patient and starts him/her on treatment. Diagnosis usually leads to an investigation of the patient's contacts to see if any of them have active TB (active case finding). Those with TB are registered and treated, and so on.

Patient holding

Once diagnosed, the patient enters the patient holding cycle and remains there until TB cure. In this cycle, the nurse ensures that the patient can adhere to the drug treatment as easily as possible. She assesses his status, implements the treatment plan, and continuously evaluates progress and problems.

To ensure appropriate assessment, planning and implementation, the nurse needs a range of skills: clinical skills; detecting and managing adverse effects; counselling; communication and teaching; as well as organisational skills for co-ordinating the patient's care, especially if a number of different care givers are involved, e.g., advocates, community workers, volunteers.

Assessment

Assessment includes evaluating the patient's physical, psychological and social status in relationship to the management of his TB care by collecting data from medical notes, and communicating with and observing the patient. The nurse must listen to the patient and assess what is important to him/her, what he/she is trying to achieve, and how the TB diagnosis has affected him/her.

The TB patient often cares for him/herself and may not appear to have problems. Yet, there may be something happening that prevents adherence to treatment – depression, financial difficulty, pregnancy, alcohol or drug dependency, working illegally, bereavement, homelessness, etc.

Planning

Defining treatment goals and expected outcomes at the beginning of treatment reduces confusion and misunderstandings. Planning as a team, the nurse and the patient agree on short term, intermediate and/or long term goals with specified and measurable outcomes. Including his/her personal goals in the treatment plan gives the patient a vision beyond the absence of disease.

Planning must be realistic and achievable, and services promised must be accessible. To do this, each person must understand his role and the role of the others, know the available services, and have an accurate understanding of the treatment goals.

A clear understanding of the patient's situation is key. For instance, if the patient has to work from early in the morning until late at night or has to leave home for several weeks during his treatment, directly observed treatment at the clinic will not be successful. The nurse and patient must establish a different treatment plan. Once the patient's concerns are known, the nurse can work with him/her to develop an individualised plan including support systems. Doing so minimises disruption in his/her life, motivates adherence and enhances completion of drug treatment.

Implementation

Having assessed and planned care with the patient it is essential to do what was agreed. A range of skills is required to provide care for patients only few of which are manual such as tuberculin testing, injections, wound care and so on. Core skills include counselling, communication, and teaching. As discussed below, good organisational skills are also required to ensure, for instance, that the correct medication is available and provided as prescribed.

The nurse should record the patient's progress promptly, clearly and accurately and any changes or problems should be referred as appropriate. Obviously, the availability of support services will vary from place to place and best use needs to be made of local resources.

Evaluation

During long-term TB treatment (especially in patients with MDR-TB), many factors could change so the nurse must evaluate the patient's progress at regular intervals as agreed with the patient. This may involve a weekly review to begin with followed in later stages by fortnightly or even monthly follow up. Any changes in the patient's clinical condition, personal circumstances, mood, attitude, appearance should be noted.

In addition the patient should be assessed and their progress documented at specific intervals in accordance with the local TB control programme:

- Usually after 2 months of treatment to ensure progression to non-infective condition, sputum conversion from smear positive to smear negative.
- With MDR-TB patients:
 - usually at 3-4 months to ensure the patient's sputum has converted to negative; and
 - 6 months after this point (when the injectable medication, which is used in the first phase of treatment for a minimum of 6 months, is stopped) as this is the point when many patients move from in-patient to out-patient treatment settings.
- At the end of treatment, to evaluate and record the treatment outcome.

CHAPTER 4

Organisational and workforce issues

Organisational issues

Organisational issues related to a successful TB Control Programme include:

- Human resource issues, such as staffing and worker protection.
- Practice development issues including training and quality assurance.
- Programme evaluation and TB research.
- Social advocacy and community mobilisation.

Some of the most common and important organisational issues were identified by WHO in the 2002 survey of National TB Programme Managers in 22 high-burden countries. These issues are:

- Lack of qualified staff.
- Weak political commitment.
- Inadequate health infrastructure.
- Non-compliance of the private sector with DOTS.

By understanding the problems and potential resolutions, nurses can advocate for strong TB control programmes at a local, regional or national level.

Workforce issues

A number of factors adversely affect nurses and their ability to function effectively:

- Staff shortages.
- Lack of protective devices such as face masks.
- Work-related stress.
- Lack of support (in terms of payment, value and development opportunities).

Some of the main issues are discussed here as they relate to TB.

Maintaining a healthy workforce

A health care facility is a workplace as well as a place for giving and receiving care. Nurses need protection from workplace hazards. Yet, protection and safety of nurses and other health professionals is often a neglected area. In order to protect themselves from TB infections and to maintain a continued high level of patient care, it is important for nurses to understand the risks of contracting TB and to know the recommended methods of protection.

Given the global prevalence of TB, protection of the nurse's health is pertinent to every TB discussion. The prevalence of disease in the wider community has always been a significant factor in determining occupational exposure for nurses. Historically,

TB has long been a recognised hazard for nurses. In fact, it has been reported that entire nursing classes had been infected with TB by the time they graduated³².

Although it is important for countries to establish regulations and legislation to protect nurses, with or without that legislation, employers still have a responsibility to protect their workers. In most countries, according to the International Labour Organization (ILO), the employer is responsible for occupational safety and health programmes. Moreover, ILO contends that disease and injury are not inevitable consequences of work, and poverty does not excuse an employer's disregard for his employee's safety and health. This is true for nurses as well as other workers.

While some measures recommended to protect nurses are costly, others can be implemented at a low cost including:

- Pre-employment screening for TB symptoms.
- Checking BCG status.
- TB skin testing.
- Giving BCG vaccination.
- Taking a chest x-ray, if indicated.
- Educating nurses about the signs and symptoms of TB and encouraging them to seek medical attention promptly if signs appear.
- Educating patients about 'safe' coughing i.e. turning the head away and cover the mouth and nose with a cloth or tissue while coughing
- Maximising natural ventilation in waiting areas, clinical examination rooms and on hospital wards (e.g. by opening windows)
- Prioritising the investigation of potentially infectious cases to minimise their time in a clinical area
- Collecting sputum specimens in the open air
- Strict hand-washing following the handling of sputum specimens

Since immuno-compromised people (especially HIV-positive individuals who have reached the stage of declining immune defences) have a greater risk of developing active disease when exposed to TB, immuno-compromised nurses should be encouraged to avoid work in areas of enhanced TB exposure.

More costly protection recommendations include providing nurses with high filtration masks, isolating patients with active TB in negative pressure isolation rooms, and providing mechanical ventilation such as window fans and exhaust ventilation systems where necessary.

The most effective way to protect staff and patients from TB exposure is to be alert to potential cases and isolate patients with suspicious symptoms until a diagnosis of active TB can be ruled out. The health care facility should institute a policy allowing the nurse to place a patient in isolation or in a separate waiting area if it is suspected that he/she has active TB. This helps minimise exposure that can occur while waiting for a physician to make the diagnosis.

Since patients with active TB are the most infectious, they should remain in isolation for the first 2 weeks of treatment or at least separated from patients who do not have TB. Patients being treated for MDR-TB generally convert by month 3 or 4. This is particularly important in facilities where HIV infection is likely to be prevalent. After two weeks of treatment, most patients with TB are no longer infectious³³. However, if there is a suspicion that the patient has MDR-TB, he/she should be isolated until there are good signs of clinical improvement and, if possible, until sputum becomes smear negative. One of the major difficulties with TB management is identifying the organism and its sensitivities, which can take up to eight weeks and only then if there is a laboratory equipped to carry out drug sensitivity testing. Consistently maintaining isolation precautions is essential to minimise the spread of TB disease. Therefore patients, staff and visitors should know, understand and adhere to the isolation precautions. Visitors to patients in isolation should be restricted to those who have already had close contact, including their children³⁴. In many places, isolation is not possible and alternative arrangements must be made to reduce the risk of transmission. Maximising natural ventilation in patient waiting areas as well as on the wards if the patient requires admission will help to reduce exposure.

Practice development

Practice development encompasses a broad range of interventions designed to improve practice and patient care services³⁵. Training and quality assurance are essential elements of practice development.

Staff Training

Training and supervision of health personnel are essential to the success of any TB control programme. They are equally important at all levels of nursing – those working specifically in TB control programmes as well as primary health care workers, who are often the first to identify suspect cases. Participatory education with regular follow-up is usually more effective than didactic approaches that simply disseminate information³⁶. The best training provides ongoing support and helps integrate the learning into practice.

Table 7: Key nursing capabilities in TB control and prevention

CAPABILITY REQUIRED	KNOWLEDGE
<ul style="list-style-type: none"> ● Recognise a suspect case ● Describe the local TB situation ● Explain how TB is spread ● Discuss the main principles of TB management 	<ul style="list-style-type: none"> ● Signs and symptoms of TB ● Local and national statistics ● How TB is transmitted ● Local and national policy for treatment and management of TB
Primary/Community Care facilities	
In addition to the above:	In addition to the above:
<ul style="list-style-type: none"> ● Order appropriate tests ● Give the patient / family basic information, e.g., TB is curable ● Refer to the appropriate service ● Complete appropriate documentation 	<ul style="list-style-type: none"> ● Diagnostic tests available for TB ● Support required by patient when suspected of having TB ● Local services responsible for TB ● Recording and reporting procedures associated with TB management
Acute hospital services	
In addition to the above:	In addition to the above:
<ul style="list-style-type: none"> ● Apply hospital infection control procedures appropriately ● Observe treatment given during patient's stay in hospital ● Recognise and report adverse adverse effects ● Discuss treatment with patient (and family) ● Plan discharge to local TB services/unit 	<ul style="list-style-type: none"> ● Infection control strategy for inpatient facilities ● Treatment for TB ● Adherence issues ● Range of adverse effects from TB medication
TB Units	
In addition to the above:	In addition to the above:
<ul style="list-style-type: none"> ● Support and monitor patients throughout their treatment ● Order subsequent tests at the correct time and record results accurately ● Refer or manage adverse effects as appropriate ● Liaise with other support services according to patient need ● Complete reports as appropriate 	<ul style="list-style-type: none"> ● Recommended TB control and management procedures ● Complexity of patients' needs; methods to maximise adherence ● Essential monitoring issues, e.g., patient progress; sputum conversion ● TB treatment, possible minor and severe adverse effects ● Reporting procedures

Evaluation is essential to reinforce, maintain and disseminate best practices. Developing new practices requires establishing measures for evaluating change. Since changes in community nursing practice may have a far reaching impact on a variety of stakeholders, no developments should be planned without outlining expected measurable outcomes, including looking downstream at the impact on the wider community.

The type of data collected during an evaluation should also reflect the purpose of the evaluation. If the purpose is to influence physicians and TB coordinators, quantitative data may be most appealing. However, for nurses and patients, qualitative data may be more meaningful.

Data collection is absolutely intrinsic to the DOTS programmes

– gathering the right data is essential for correctly identifying a problem, developing a practice to resolve the problem, and evaluating the impact of the change:

- Quarterly cohort analysis gives regular feedback about overall programme performance and highlights rates of sputum conversion, defaulting, etc.
- Comparing laboratory records with the TB patient registry shows how many sputum smear positive cases started treatment, and within what time period.
- Treatment outcome data demonstrates rates of success, default, failure or death.
- Patient record cards illustrate treatment adherence patterns.

In addition to evaluating nursing practices and patient outcomes, worker health protection must be regularly evaluated to determine if it is successfully protecting health care workers from contracting TB. In most settings, TB skin tests are done when new staff is first employed, every 6 months or annually thereafter (based on the level of TB found in the community and in the health facility), and whenever an employee has signs and symptoms of active TB³⁷. In addition, mechanical ventilation and negative pressure isolation rooms are routinely checked to ensure that the controls are functioning properly. Nurses wearing respiratory protection must also perform fit checks regularly to ensure that the masks fit their faces appropriately. If a mask does not fit correctly, its protection is compromised.

Social mobilisation and advocacy

Social mobilisation, the active recruitment of patients and community members to support TB control strategies, is necessary to sustain support for TB control. TB affects whole communities and has social and economic as well as physical consequences. Social mobilisation means that community representatives become partners in the TB control programme and work closely with the health services involved. It requires a strong relationship between the community and the TB control programme.

The four main activities of social mobilisation are:

- Advocacy.
- Health Education.
- DOT Support.
- Programme Support.

Not all activities have to be implemented to achieve successful social mobilisation. In fact, the local community and the setting determine which activities are appropriate.

Advocacy

A suitable environment can be created for sustainable TB control when a community has strong and effective leadership and mobilises to demand appropriate services and political commitment. For example, in Peru in the early 1990s, TB patients held a street demonstration demanding access to effective drug treatment for TB. The president of Peru responded, increased funding for TB services, and strengthened the national TB programme with positive results³⁸.

Events, such as World TB Day on March 24th each year, raise TB awareness and help establish the need for commitment to effective TB control, adequate government funding and appropriate organisation of services.

Health education

Education of the public about TB is important. It should be part of an effective control programme that has a good cure rate as well as raising awareness about access to care and treatment. Increasing the knowledge of TB usually increases the demand for services and can result in advocacy for people's right to treatment and improved quality of care.

The health education plan must be relevant to available services and community needs. Before initiating a campaign, planners must carefully consider who should be involved and clarify the aim of the education. For example, one area for educational campaign could be to combat the stigma associated with TB patients. Stigma can be attached to any number of falsely held beliefs and myths. People may believe, for instance, that TB is incurable, runs in the family, is caused by having a dirty household, or is the result of a curse. The stigmas must be exposed and addressed before public TB education will be successful.

DOT treatment support

As mentioned earlier, members of the community can often provide invaluable support to patients on treatment. With appropriate training and support from the nurse, they can supervise a patient's treatment using the patient's treatment card and drugs provided by the TB service. Receiving treatment from a community member is often a very convenient alternative to the health clinic. This can enhance the patient's adherence to the treatment regimen and facilitate successful completion and cure. For example, in South Africa, local pharmacists and shopkeepers are trained to offer DOT and, in Malawi, volunteers act as guardians for TB patients³⁹. In Peru, for the two-year treatment of MDR-TB in 2002-2004, community volunteers were trained to observe two or three patients. In return the volunteers received a basket of staples each month valued at US\$ 30. Nurses trained and supervised the volunteers.

Programme support

Community-based approaches rely on good organisation and support from the health services responsible for treating TB patients and require strong support from the district and national level.

The types of support needed for a successful community programme are:

- Ongoing training and supervision of involved community members.
- A mechanism for providing essential supplies, such as TB drugs and sputum containers.
- Good communication between the community and the local health service to address questions and concerns.

Conclusion

Nurses play a significant role in the control of drug-sensitive and drug-resistant TB all around the world. To be effective, the nurse must understand the disease, recognise the signs and symptoms of TB, and support patients' adherence to TB treatment. By adapting the best practice standards described in the next section of this guide to local settings and advocating for strong TB control programmes, nurses can maximise their role and have a real impact on TB control practices. However, nurses must also be protected while they care for others, and worker protection programmes must be instituted to enhance the nurse's ability to provide high quality care. On-going programme evaluation ensures programme effectiveness and enables continuous process improvement.

TB control involves all levels of the health system – international and national policy makers, regional and district TB coordinators and TB specialty nurses, as well as primary care nurses working in a variety of settings. The general practice nurse is the first line of defence in TB control worldwide, and this important role must be recognised and strengthened. ICN encourages you to learn more about TB in your community and to actively participate in establishing effective TB control programmes.

Standards for TB Care and Treatment

Applying the nursing process to the care and control of tuberculosis through standard setting

The most appropriate and effective management of TB is achieved by developing standards of care. Standards are achievable, observable, desirable and measurable, and should be evidence-based or driven by expert consensus. The most effective standards are developed by the staff to meet the specific circumstances of the local community. Locally defined standards of excellence foster a sense of ownership and promote professional credibility, particularly in resource poor settings. By the consistent application of standards of care, the goals of both the nursing process and DOTS and DOTS-Plus programmes can be met. This will allow care to be individualised, while remaining compatible with a standard treatment protocol adapted to match local community resources.

The best practice standards below are based on the Marsden approach to standard setting⁴⁰ – a framework consisting of the standard statement, rationale, resources, professional practice and outcomes. The standards in this guideline include an outcome measurement component and reflect best practice in high prevalence TB areas.

Standards for case finding

Standard I: Assessing the patient who may have TB/MDR-TB

A. Standard statement

Symptoms, signs and risk factors consistent with a diagnosis of TB are identified, and appropriate investigations for accurate diagnosis are conducted, while developing a good rapport with the patient.

B. Rationale

- Early diagnosis and treatment of active TB is essential in controlling TB and preventing transmission.
- Recognising the signs, symptoms, and risk factors associated with TB and ordering the correct tests ensure that as many potential cases are identified as early as possible in the course of the disease.
- The patient's initial contact with the nurse sets the tone for the relationship with the clinic and may strongly influence his/her treatment adherence. When a patient feels welcome, cared about and at ease, he/she is more likely to return for future treatment visits.

- To enhance the patient's potential for returning to the clinic, he/she must know and understand the number of tests required for a proper diagnosis, the reason for testing, the disease process and the treatment that will follow.
- TB diagnosis often carries a stigma and patients need support.
- Contact tracing helps identify other people who may have TB disease.

C. Required resources

- Staff alert to TB.
- Nurses with good communication skills and knowledge of community resources
- Facility to refer a very sick patient to an appropriate medical officer.
- Sufficient privacy to maintain patient confidentiality
- TB treatment available free-of-charge

D. Professional practice

The nurse assessing the symptomatic patient:

- Has a good knowledge of the signs, symptoms and risk factors with regard to TB, and has the skills to assess each patient's response to potential TB diagnosis, reacting accordingly.
- Treats the patient with respect and establishes a rapport.
- Takes personal details including name, home and work address, contact telephone numbers, as well as contact details of an alternative person to make it easier to find him/her if a problem arises.
- Takes a full medical history including duration of symptoms, other medical conditions, previous health-seeking behaviour and outcome thereof, previous treatment for or exposure to TB or MDR-TB.
- Explains the tests to be done and the reason for doing them, e.g., sputum testing, and x-ray, if available. Three sputum samples will be tested.
- Informs the patient about when to expect test results and how the results will be conveyed – at next clinic visit or by other means.
- Is sensitive to the patient's response to being tested for TB, answers questions as clearly as possible, and reinforces the fact that effective treatment is available and free-of-charge.
- Registers the person as a TB patient, and starts treatment if more than one of the sputum samples tests positive or refers the patient to the TB control programme for treatment.
- Refers the person to a clinician linked to the TB control programme for further investigation if only one of three samples is positive, or if all are smear negative but symptoms persist.

E. Outcome

The patient is diagnosed without delay and has an understanding of TB disease and treatment. He/she feels welcome, has confidence in the TB service and returns for follow-up appointments.

F. Outcome measurement

- The outcome is measured by comparing the laboratory register to the TB patient register. The former indicates those who were tested and the results of the tests. The patients found positive in the laboratory register should all be found in the TB patient register.
- Review of patient treatment cards and the TB patient register shows whether a patient is returning for treatment.
- The patient's level of confidence in the service is measured qualitatively through discussions with him/her.

Standard II: Sputum collection for diagnosis

A. Standard statement

The patient is given clear instructions about when, where and how to produce good sputum specimens and all related documentation is completed promptly, clearly and accurately.

B. Rationale

- Accurate diagnosis requires good sputum specimens.
- Correct labelling of the specimen container and the request form eliminates confusion and minimises treatment errors.
- The patient may not return for treatment if he/she is confused.
- To reduce the risk of transmission, patient and staff health and safety issues must all be considered in the handling of specimens.

C. Required resources

- Knowledgeable skilled staff to instruct the patient on how to produce a good specimen and when and where to deliver it.
- Appropriate sputum containers – preferably wide-necked, disposable containers with screw-top lids.
- Necessary forms and registers.

- Transport available to deliver the samples safely and quickly to the laboratory as soon as possible, certainly within 5 days.
- A secure place for storing specimens while they wait to be sent to the laboratory.
- A system for the prompt feedback of results.
- One staff member responsible for co-ordinating the process.

D. Professional practice**The nurse advising patients about producing sputum specimens****● General rules**

- i Collects specimen under the supervision of a competent person to enhance specimen quality.
- ii Collects specimen in the open air, or in a well-ventilated room used only for this purpose.
- iii Maintains patient's privacy during specimen collection (although in some circumstances such as prisons where the patient may gain from being diagnosed with TB, strict observation of sputum behind glass should be done).
- iv Collects and sends three specimens to the laboratory with fully completed forms, including information about previous TB treatment. This is essential for laboratory staff to facilitate identification of potential primary or acquired drug resistance. The Union recommends the examination of three specimens⁴¹.
 - a. an initial 'spot' specimen taken when the patient first presents with symptoms,
 - b. an early morning specimen, the next day if possible, and
 - c. another 'spot' specimen when the patient returns with the second (i.e., the early morning) specimen.

● For specimen collection, the nurse:

- i Clearly labels the container first (i.e., before it is used) with the name of the clinic / hospital; the name of the patient; and the patient's clinic or hospital number.
- ii Indicates whether specimen is a pre-treatment, follow-up, or end-of-treatment specimen.
- iii Writes clear instructions regarding which investigations are required (e.g. microscopy, culture, or culture and sensitivity).
- iv Refers the patient to a physician for further investigation if he/she is very sick or has other symptoms associated with TB.

● Method

- i Explains the reason for collecting the specimen.
- ii Explains the steps fully in language that the patient understands.
- iii Allows the patient to rinse his/her mouth with water, especially after eating.
- iv Gives the labelled container to the patient.
- v Asks the patient to carefully direct the sputum into the container, and not to contaminate the outside of it, which puts others at risk.
- vi Demonstrates a deep cough from the bottom of the chest, beginning with deep breathing.
- vii Supervises the collection, but without standing in front of the person attempting to produce the sputum.
- viii Closes the lid on the container carefully and tightly.
- ix Checks the specimen with the patient present to ensure that it is sputum and not just saliva. If it is insufficient (e.g., saliva only), asks the patient for another specimen.
- x Washes hands with soap and water.

● Sputum storage

- i Places the sputum specimen container in a plastic bag, if possible, to prevent contamination.
- ii Stores the specimen in a specimen refrigerator or in a cool spot, if transport is not available immediately. Does not store it in the freezer.
- iii Sends the specimen to the laboratory as soon as possible after collection. The sooner the specimen is tested, the sooner the patient can be put onto treatment if smear positive.
- iv Records the date the specimen is sent to the laboratory.

● Transport of sputum specimens

- i Uses a cooler bag that is reserved for transporting TB specimens to the laboratory. High temperatures during transit will kill the bacilli.
- ii Ensures that specimens are protected from exposure to direct sunlight during transport.
- iii Explains to the driver/messenger the reasons for transporting the specimens, ensuring that specimens go directly to the laboratory.

● Nursing management

- i Ensures that a responsible person checks the sputum register to see which results are outstanding each day.
- ii Contacts the laboratory to get results of any outstanding specimens. (Close co-operation with the laboratory ensures that smear-positive patients are started on appropriate treatment quickly).

● Documentation

- i Accurately and promptly records all information on the laboratory register, the patient treatment card and the TB patient register.
- ii Includes dates showing when specimens were sent to the laboratory and when results were received.
- iii Documents the test results.

E. Outcome

The number of good quality sputum samples received by the laboratory for investigation equals the number of specimens taken.

F. Outcome measurements

- The number of good quality specimens is measured by comparing the laboratory register to the number of patients tested.
- Poor specimens are identified.

Standards for patient holding

Standard I: Communicating with the TB/MDR-TB patient

A. Standard statement

Each patient receives practical advice, support and information according to his/her individual needs and concerns.

B. Rationale

- A patient who is newly diagnosed with TB may be very anxious. Being diagnosed with TB is a traumatic event in a person's life and presents many challenges.
- To enhance adherence to treatment, the patient must clearly understand his/her disease, the treatment and the importance of completing the entire treatment regimen.
- Creating a time specifically for the patient, when he/she is first diagnosed, enables a one-to-one discussion important for establishing rapport and learning about his/her needs.
- Conducting a thorough assessment of each individual patient is essential to plan appropriate care. Each patient has a different level of knowledge and understanding about TB depending on what he/she has heard and whether he/she knows someone with TB. It is important to determine the

patient's knowledge level, offer the necessary information, correct misconceptions and concentrate on issues important to him/her.

- When a patient feels welcome, he/she is more likely to return for follow-up.

C. Required resources

- Staff knowledgeable about TB, its treatment and able to advise patients and family.
- Good communication skills which are essential to assess a patient's existing knowledge about TB and its treatment, give accurate information according to his/her needs and communicate caring.
- The nurse is knowledgeable about TB and its treatment and able to respond to questions accurately.
- Supporting information in leaflet form in the appropriate languages.
- The nurse is available to help address the patient's problems.

D. Professional practice

The nurse:

- Conducts an interview with the recently diagnosed patient and assesses the patient's knowledge, support systems, past experience of TB, feelings about treatment and its possible outcomes, including the following questions. (Note: Open questions, i.e., those starting with 'what', 'how', and 'why', encourage fuller responses).
 - i **Information about the disease:**
 - What have you been told about your diagnosis?
 - What do you understand about what you were told?
 - What do you know about TB?
 - Why do you think you have it?
 - What do you think will happen if you are not treated?
 - ii **Information about the treatment:**
 - What do you know about the treatment for TB?
 - How will you manage to take the tablets regularly?
 - How will you cope with taking treatment at the appropriate time?
 - Who can you turn to if you have any problems (staff, family or friends)?
 - How can we help you?
 - iii **Personal treatment plan:**
 - How will you manage to meet each day with your chosen DOT supporter for the treatment?
 - Explore possible barriers to the patient's adherence to treatment.

iv Conclusion:

- Do you have any questions/concerns?
- What are you going to do next?
- Reminds the patient to communicate with the nursing staff about any adverse effects to the treatment that may appear, and any other problems or worries the patient may have.
- Assesses the family's knowledge and understanding of TB and provides information and support accordingly.
- Conducts regular patient follow-up interviews (periodically, when they return for medication) and assesses the impact of TB and its treatment on the patient and other family members.

E. Outcomes

- The patient understands his/her condition, the treatment and where to go for help.
- Potential problems are predicted and plans made to avert them at an early stage.

F. Outcome measurements

There is evidence from clinic attendance that the patient has been able to follow advice and instructions given. A record has been kept of problems identified, plans to address them and action taken.

Standard II: Organising Directly Observed Treatment (DOT) – the intensive phase

A. Standard statement

DOT is arranged in the most convenient way possible for the patient.

B. Rationale

- DOT is designed to help the patient complete a full course of TB treatment and to document the patient's intake of medication.
- All sputum smear positive TB patients receive DOT during the initial, intensive phase of their treatment to improve treatment success and reduce the risk of disease transmission, treatment failure, relapse and drug resistance. Where possible, DOT should be continued throughout the entire course of therapy, especially in the case of MDR-TB.
- It is essential to give the patient as many options as possible for this observed approach to treatment, emphasising support rather than the surveillance aspect of treatment.

- If the patient can get treatment after hours or at a convenient time and place, thereby continuing his/her normal daily routine, he/she is more likely to be able to adhere to the treatment regimen.

C. Required resources

● Possible locations for providing DOT:

i In the community:

A treatment supporter is available to monitor and support the patient through his/her treatment period.

ii At the workplace:

The patient at his/her workplace can identify the treatment supporter.
A Non Governmental Organisation (NGO) may be identified to train the treatment supporter.

iii At school or crèche:

A treatment supporter can be identified to supervise the TB patient.

iv At the local clinic:

The patient attends the local clinic daily to receive his/her treatment.

v At another service used by the patient:

A treatment supporter can be identified within a drug, housing, nutritional/food or welfare service.

● The treatment supporter has the following:

i Attributes:

- Acceptable to the patient.
- Willing to do the task.
- Responsible and caring.
- Able to respect confidentiality.
- Dedicated to the task. Prepared to broaden his/her knowledge by attending training and refresher courses.
- Understands the nature of voluntary work or receives stipends or remuneration for their work.

ii Knowledge:

- TB transmission and the disease process.
- TB treatment and its adverse effects.
- When to refer the patient to the health facility.

iii Role:

- Observes and records the intake of medication according to what is prescribed.
- Follows up patients when they miss treatment – after 1 day.
- Reminds patients of clinic appointments.

- Supports and encourages patients.
- Refers patients to relevant services.
- Recognizes early signs of adverse effects and initiates measures to manage them.
- Refers suspect TB cases to the local clinic.
- Creates awareness about TB in the community/workplace.
- Attends training updates.
- Is accountable to the service ultimately responsible for treating the patient.

D. Professional practice

The nurse:

- Ensures that the patient understands:
 - The value of taking the many drugs, even when he/she is feeling better.
 - That all doses of each drug must be taken.
 - That the drugs must be taken for the time prescribed.
 - The basics of TB and how it is spread.
 - Drug resistance and how it occurs.
 - The importance of close supervision.
 - The possible adverse effects of the drugs.
- Fully assesses the patient's circumstances and organises the DOT according to the patient's circumstances and service resources.
- Supervises and monitors the patient – this is one of the most critical keys to success, to patient cure, to averting drug resistance, and to preventing further spread of TB. Supervision of this type is especially important if a community volunteer or other person is observing treatment.
- Supervises and supports the treatment supporter.
- Maintains ultimate responsibility for the patient's treatment.

E. Outcomes

The intensive phase is completed successfully with evidence of sputum conversion. Treatment is successfully completed.

F. Outcome measurement

Sputum converts to negative as indicated by comparing the patient treatment card to the TB patient register. The treatment card is completed fully and accurately and is evidence of good adherence to treatment.

Standard III: Transition phase assessment: from intensive treatment to continuation of care

A. Standard statement

Programmes are encouraged to do universal DOT for all patients in the continuation phase. However, some programmes do not have resources to do this and patients are assessed and plans developed for less frequently supervised treatment.

B. Rationale

- As a patient begins to feel better, other priorities may distract him/her from the treatment. All sorts of life events can have an unexpected impact on treatment and on the patient's ability to continue – bereavement, job change or relocation.
- If the patient has been on DOT in the intensive phase, and it is stopped in the continuation phase, it may signal that the treatment is not important.
- The need for ongoing treatment and the patient's responsibility must be stressed as he/she takes more control.
- The patient may need assistance readjusting to his/her new circumstances while maintaining his/her treatment regimen.
- Drug therapy must be working before moving to the continuation phase, to ensure the patient's recovery from TB, to safeguard the community from the spread of the disease, and to ensure that MDR-TB does not develop. Thus, the patient must be tested for sputum conversion to negative.
- If the patient remains smear positive or fails to make clinical progress, the reason must be identified and addressed before moving on. One of the reasons for non-conversion could be that this is a case of MDR-TB.
- Documentation regarding the ordering and results of sputum smear tests at this time of transition is vital for the National TB programme to monitor the performance of the service.

C. Required resources

- Nurses with good communication and assessment skills.
- Adequate time to re-iterate important messages about the need to continue treatment without interruption.
- The patient informs the health care facility of any changes in his/her circumstances that affect his/her ability to continue treatment and/or keep follow up appointments.

D. Professional practice

The nurse:

- For sputum conversion
 - i Assesses the patient physically to ensure adequate progress has been made, before changing the patient's treatment.
 - ii Obtains and tests two sputum specimens to establish whether or not the sputum has converted from smear positive to smear negative.
 - Takes the specimens the week before the results are needed to ensure they are available to evaluate whether the patient is ready to progress to the continuation phase.
 - after 7 weeks of treatment for categories I and III
 - after 12 weeks for category II
 - monthly smear and culture are used in the management of MDR-TB.
 - iii In regular TB patients, if after 2 months of treatment, the sputum smear remains positive, and in MDR-TB patients after 3-4 months of treatment the sputum remains positive or if the patient fails to make clinical progress:
 - Reassesses the patient regarding:
 - the medication regimen prescribed during the intensive phase – was it appropriate?
 - problems he/she has had taking treatment as prescribed.
 - misunderstandings about the treatment regimen: e.g., was he/she taking the correct dose at the correct intervals?
 - Addresses any identifiable reasons for the patient's lack of sputum conversion to negative:
 - inappropriate treatment regimen;
 - problems getting access to ongoing treatment;
 - clarification of information, etc.
 - After the assessment and identification of problems, maintains the patient on his/her intensive phase drug regimen, and follows strict treatment observation.
 - If resources are available, sends a specimen for culture and sensitivities
 - reviews and records the results.
 - adjusts the treatment regimen as necessary based on the results.
 - Re-tests the sputum in one month.
 - If the specimen remains smear positive and MDR-TB is not detected, starts treatment with a category II regimen. The patient should be assessed to enter category IV treatment.

- iv If the patient was sputum-smear negative originally and becomes sputum-smear positive,
 - takes another specimen to check the laboratory result.
 - If the patient is still sputum-smear positive, restarts treatment with category II re-treatment regimen. The patients should be assessed to enter category IV treatment.
- v If the patient was initially diagnosed with extra-pulmonary TB:
 - seeks other signs of physical improvement, such as general improvement in symptoms, weight gain etc.
- **For documentation**
 - i Completes all documentation promptly and accurately.
 - ii Includes on the laboratory request forms for sputum examination:
 - that the examination is required for follow-up.
 - the patient's clinic/hospital number (i.e. his/her number in the TB patient register).
 - the results of the test.
 - any changes in treatment, on both the treatment card and the TB patient register⁴².
- **For patient consultation**
 - i Provides practical advice to the patient who is taking treatment at home:
 - ideally take the pills first thing in the morning before breakfast to maximise absorption.
 - most importantly, take pills at a regular time.
 - develop a system for remembering to take the pills (before a routine activity such as a meal).
 - keep drugs safely stored in a dark, dry place away from the reach of children.
 - ii Discusses and assesses potential barriers to adherence, such as
 - changes in routine.
 - potential for mislaying drugs or having them stolen.
 - alcohol addiction, etc.
 - iii Ensures that the patient knows
 - about follow-up appointments,
 - specimens and tests that are needed,
 - adverse effects to the drugs
 - that adverse effects are rare, and
 - how to report and recognise them: skin rashes, jaundice, visual disturbances, vertigo, hearing impairment, gastrointestinal problems, tingling in the fingers/toes, etc.

E. Outcome

The patient progresses from the intensive to the continuation phase appropriately. Information is available on each individual patient. The patient continues treatment while developing greater self-reliance, gaining confidence and maintaining contact with TB service.

F. Outcome measurement

Each patient has an accurate record and shows sputum conversion. The TB programme's effectiveness is measured by the number of patients who have sputum conversion to negative compared to those that do not convert – the ratio or the rate of conversion.

Standard IV: Case management during the continuation phase

A. Standard statement

Ongoing support is available according to patient need: some need continued DOT, while others can reliably self-medicate (although most studies have shown that health care workers are unable to predict who will adhere to treatment).

B. Rationale

- The patient is becoming the 'expert' regarding his/her condition. He/she has more control and responsibility as life goes back to normal.
- The patient is encouraged to continue drug therapy by keeping his/her costs to a minimum, e.g., avoiding unnecessary clinic appointments, which may incur travel costs and interrupt his/her work.
- A plan of care must be developed to address any problems or barriers for treatment.
- The patient's progress must be evaluated regularly, on an agreed schedule, to ensure his/her progress.
- Any new problem reported by the patient may not be directly related to TB treatment but, if ignored, may present a barrier to the continuation of treatment.
- Patients may 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.

C. Required resources

- The patient is able to access to the service if a problem arises.
- The service can respond promptly and appropriately.
- with the service has a continued commitment to care and accessibility.
The patient will be more motivated if he/she believes his/her priorities are taken seriously. Since the patient may need referral to other resources, the nurse must have links to other services in the community, both governmental and voluntary.

D. Professional practice

The nurse:

- **Maintains monthly contact with the patient and regularly evaluates his/her progress.**
 - i Assesses each patient according to the level of support he/she needs.
 - Knowing the relationship between the patient and his/her treatment supporter may change as follow-up becomes less frequent.
- **Ensures that sputum is re-examined.**
 - i Patients, who were originally registered as 'new pulmonary' cases (category I and smear negative category III) need to have their sputum examined at 5 months to ensure that it is still negative.
 - If the sputum smear is negative, conducts another test at 6 months to confirm the 'cure' (a much stronger indicator of treatment success than 'treatment completion').
 - If the sputum smear is positive, records it as a treatment failure.
 - If the patient cannot produce sputum records that they have completed their treatment based on information provided by the patient and available records.
 - ii For Category IV/MDR-TB patients, monthly smear and cultures need to be done as this is the basis for documenting cure (treatment continues for 18 months after smear conversion) and treatment completion.
- **Records all contacts with patients**
 - i Promptly and accurately documents the dates that tests are ordered and the results.
 - If the patient has not remained smear negative, records the case as a treatment failure.
 - ii If a patient does not attend directly observed treatment or fails to collect his supply of medication as arranged, marks this clearly on the treatment card.

- Visits the patient at home to find out why and to ensure that treatment is resumed effectively and promptly.
- Addresses the situation in a friendly and non-judgemental manner.
- Ensures that numerous attempts are made to find the patient. If the patient is not located within two months record him/her as a 'default'.
- If the patient subsequently arrives at the health care facility, conducts an initial investigation, e.g., sputum examination for TB.
- Prepares the patient for separation from the clinic by beginning discussion 2 months before the treatment is due to be completed.

E. Outcome

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

F. Outcome measurement

Review of patient records indicates whether patients have converted to a negative sputum smear and maintained negative smears until the end of treatment. Comparing the patient record to the TB patient register in the clinic indicates if treatment information has been recorded promptly.

Standard V: Managing patient transfer

A. Standard statement

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

B. Rationale

- Treatment gaps increase the risk of relapse and the development of drug resistance.
- During a course of TB treatment, the average patient may be transferred one or more times 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, returns to work, 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.

C. Required resources

- A referral system which is common to and understood by all units.
- The WHO⁴³ recommended 'Tuberculosis Referral/Transfer Form'.
- Good communication with other TB units.

D Professional practice**The nurse:**

- Ensures that the patient has been well supported throughout his/her treatment and understand the importance of finishing the drug treatment courses. Good support means that patients is more likely to inform the treatment unit/supporter if he/she planning to go away.
- Before leaving, ensures that the patient clearly understands the importance of continuing treatment.
 - i Checks his/her understanding of when and where he/she needs to present him/herself.
 - ii If the patient is going to another country or is not sure where he/she is going, advises him/her about seeking help on arrival.
 - iii Gives the patient a reasonable supply of medication to cover the time he/she is likely to be in transit before he/she can register elsewhere for ongoing treatment.

The case manager or nurse most involved with the patient's treatment:

- Ensures that the patient's treatment is continued elsewhere. Officially, the unit that starts the patient's treatment is responsible for recording the outcome, no matter where the patient has gone.
- Completes the Tuberculosis Referral/Transfer Form in triplicate.
 - gives one copy to the patient to take along to the new treatment unit,
 - sends another to the referring unit,
 - gives the third to the District TB co-ordinator.
- If there is no word from the referral unit, contacts the new unit to ensure that the patient arrived.
- Informs the District TB Co-ordinator if the patient does not go to the new referral unit.

The new treatment unit:

- Registers the patient as a transfer in when the patient arrives.
- Sends the bottom of the form to the referring unit to confirm the transfer took place.

E. Outcome

The patient remains on the appropriate treatment in spite of moving away from his/her original treatment unit.

F. Outcome measurement

The outcome is measured by monitoring the TB patient register and quarterly cohort analysis.

Table 8: TB drugs used for MDR-TB in five groups

Medication (drug abbreviation), (common presentation)	Weight class			
	< 33 kg	33-50 kg	51-70 kg	> 70 kg (maximum dose)
Group 1: First-line oral antituberculosis drugs				
Isoniazid (H) (100, 300 mg)	4-6 mg/kg/day or 8-12 mg 3 x wk.	200-300 mg daily or 450-600 mg 3 x wk	300 mg daily or 600 mg 3 x wk	300 mg daily or 600 mg 3 x wk
Rifampin (R) (150, 300 mg)	10-20 mg/kg/daily	450-600 mg	600 mg	600 mg
Ethambutol (E) (100, 400 mg)	25 mg/kg/daily	800-1200 mg	1200-1600 mg	1600-2000 mg
Pyrazinamide (Z) (500 mg)	30-40 mg/kg/daily	1000-1750 mg	1750-2000 mg	2000-2500 mg
Group 2: Injectable antituberculosis drugs				
Streptomycin (S) (1 gram vial)	15-20 mg/kg/daily	500-750 mg	1000 mg	1000 mg
Kanamycin (Km) (1 gram vial)	15-20 mg/kg/daily	500-750 mg	1000 mg	1000 mg
Amikacin (Am) (1 gram vial)	15-20 mg/kg/daily	500-750 mg	1000 mg	1000 mg
Capreomycin (Cm) (1 gram vial)	15-20 mg/kg/daily	500-750 mg	1000 mg	1000 mg
Group 3: Fluoroquinolones				
Ciprofloxacin (Cfx) (250, 500, 750 mg)	20-30 mg/kg/daily	1500 mg	1500 mg	1500 mg
Ofloxacin (Ofx) (200, 300, 400 mg)	Usual adult dose for MDR-TB is 800 mg	800 mg	800 mg	800-1000 mg
Levofloxacin (Lfx) (250, 500 mg)	Usual adult dose for MDR-TB is 750 mg	750 mg	750 mg	750-1000 mg
Moxifloxacin (Mfx) (400 mg)	Usual adult dose for MDR-TB is 400 mg	400 mg	400 mg	400 mg
Gatifloxacin (Gfx) (400 mg)	Usual adult dose for MDR-TB is 400 mg	400 mg	400 mg	400 mg
Group 4: Oral bacteriostatic second-line antituberculosis drugs				
Ethionamide (Eto) (250 mg)	15-20 mg/kg/daily	500 mg	750 mg	750-1000 mg
Protonamide (Pto) (250 mg)	15-20 mg/kg/daily	500 mg	750 mg	750-1000 mg
Cycloserine (Cs) (250 mg)	15-20 mg/kg/daily	500 mg	750 mg	750-1000 mg
Terizadone (Trd) (300 mg)	15-20 mg/kg/daily	600 mg	600 mg	900 mg
p-aminosalicylic acid (PAS) (4 gram sachets)	150 mg/kg/daily	8 grams	8 grams	8 grams
Sodium PAS		10 grams	10-13 grams	13 grams
Thiameazone (T)	Usual dose is 150 mg for adults			
Group 5: Agents with unclear efficacy (not recommended by the WHO for routine use in MDR-TB patients)				
Clofazimine (Clfz), Amoxicillin-clavulanate (Amx/Clv), Clarithromycin (Clr), Linazolid (Lzd).				
Efficacy and dosing in the treatment of drug resistant tuberculosis not fully determined.				

Table 9: Adverse effects, suspected agents and management strategies in MDR-TB treatment⁴⁴

Adverse Reaction	Suspected Agent(s)	Suggested management strategies	Comments
Seizures	Cycloserine (Cs) Isoniazid (H) Fluoroquinolone (FQ)	1) Suspend suspected agent pending resolution of seizures. 2) Initiate anticonvulsant therapy (e.g., phenytoin) 3) Consider increasing pyridoxine to 300mg daily. 4) Restart suspected agent or reinstate suspected agent at lower dose, if essential to the regimen.	1) Anticonvulsant is generally continued until MDR-TB treatment is completed or suspected agent discontinued. 2) History of prior seizure disorder is not a contraindication to the use of agents listed here if a patient's seizures are well-controlled and/or the patient is receiving anti-convulsant therapy. 3) Patients with history of prior seizures may be at increased risk for development of seizures during MDR-TB therapy.
Peripheral neuropathy	Cycloserine (Cs) Isoniazid (H) Fluoroquinolone (FQ) Streptomycin (S) Kanamycin (KM) Amikacin (AM) Capreomycin (CM) Ethambutol (E) Ethionamide (Eto)	1) Consider increasing pyridoxine to 300 mg daily. 2) Change parenteral to Capreomycin (CM) if patient has documented susceptibility to Capreomycin (CM). 3) Initiate therapy with tricyclic anti-depressants or gabapentin if available. NSAIDs or acetaminophen may help alleviate symptoms. 4) Lower dose of suspected agent, if this can be done without compromising regimen. 5) Discontinue suspected agent if this can be done without compromising regimen.	1) Patients with co-morbid disease (e.g., diabetes, HIV, alcoholism) may be more likely to develop peripheral neuropathy, but these conditions are not contraindications to the use of the agents listed here. 2) Neuropathy may be irreversible; however, some patients may experience improvement when offending agents are suspended.
Hearing loss	Streptomycin (S) Kanamycin (KM) Amikacin (AM) Capreomycin (CM) Clarithromycin (CLR)	1) Document hearing loss and compare to baseline audiometry. 2) Change parenteral to CM if patient has documented susceptibility to Capreomycin (CM) 3) Lower dose of suspected agent, if this can be done without compromising regimen (consider administration three times a week). 4) Discontinue suspected agent if this can be done without compromising regimen.	1) Patients with prior exposure to aminoglycosides may have baseline hearing loss. In such patients, it may be helpful to obtain audiometry at the initiation of MDR-TB therapy. 2) Hearing loss is generally not reversible. 3) The risk of further hearing loss must be weighed with the risks of stopping the injectable in the treatment regimen.

Adverse Reaction	Suspected Agent(s)	Suggested management strategies	Comments
Psychotic symptoms	Cycloserine (Cs) Isoniazid (H) Fluoroquinolone (FQ) Ethionamide (Eto)	1) Hold suspected agent for a short period of time (one to four weeks) while psychotic symptoms are brought under control. 2) Initiate anti-psychotic drugs. 3) Lower dose of suspected agent, if this can be done without compromising regimen. 4) Discontinue suspected agent if this can be done without compromising regimen.	1) Some patients will need to continue anti-psychotic treatment throughout MDR-TB therapy. 2) Prior history of psychiatric disease is not a contraindication to the use of agents listed here but may increase the likelihood of development of psychotic symptoms. 3) Psychotic symptoms are generally reversible upon completion of MDR-TB treatment or cessation of the offending agent.
Depression	Socio-economic circum-stances, chronic disease, Cycloserine (Cs) Fluoroquinolone (FQ) Isoniazid (H) Ethionamide (Eto)	1) Improve socio-economic conditions. 2) Group or individual counseling. 3) Initiate anti-depressant drugs. 4) Lower dose of suspected agent, if this can be done without compromising the regimen. 5) Discontinue suspected agent if this can be done without compromising regimen.	1) Importance of socioeconomic conditions and chronic illness should not be underestimated as a contributing factor to depression. 2) Depressive symptoms may fluctuate during therapy and may improve as illness is successfully treated. 3) History of prior depression is not a contraindication to the use of the agents listed here, however, these patients may be at increased risk for developing depression during MDR-TB treatment
Hypothyroidism	Para-aminosalicylic acid (PAS), Ethionamide (Eto) especially when given in combination.	1) Initiate thyroxine therapy.	1) Completely reversible upon discontinuation of Para-aminosalicylic acid (PAS) or (Ethionamide (Eto)
Nausea and vomiting	Ethionamide (Eto) Para-aminosalicylic acid (PAS) Isoniazid (H) Ethambutol (E) Clofazimine (CFZ) Pyrazinamide (Z)	1) Assess for dehydration. Initiate dehydration if indicated. 2) Initiate anti-emetic therapy. 3) Lower dose of suspected agent, if this can be done without compromising regimen. 4) Discontinue suspected agent if this can be done without compromising regimen, rarely necessary.	1) Nausea and vomiting ubiquitous in early weeks of therapy and usually abate with time on treatment and supportive therapy. 2) Electrolytes should be monitored and repleted if vomiting is severe. 3) Reversible upon discontinuation of suspected agent. 4) Severe abdominal distress and acute abdomen have been reported with the use of clofazimine. Although these reports are rare, if this effect occurs, clofazimine should be suspended.

Adverse Reaction	Suspected Agent(s)	Suggested management strategies	Comments
Gastritis	Para-aminosalicylic acid (PAS) Ethionamide (Eto) Isoniazid (H) Ethambutol (E) Clofazimine (CFZ) Pyrazinamide (Z)	1) Antacids (e.g., calcium carbonate, H2-blockers, proton-pump inhibitors). 2) Hold suspected agent(s) for short periods of time (e.g., one to seven days). 3) Lower dose of suspected agent, if this can be done without compromising regimen. 4) Discontinue suspected agent if this can be done without compromising regimen.	1) Severe gastritis, as manifested by hematemesis, melena or hematechezia, is rare. 2) Dosing of antacids should be carefully timed so as to not interfere with the absorption of anti-TB drugs (take two hours before or after anti-TB medications). 3) Reversible upon discontinuation of suspected agent(s).
Hepatitis	Pyrazinamide (Z) Rifampicin (R) Isoniazid (H) Ethionamide (Eto) Para-aminosalicylic acid (PAS) Ethambutol (E) Fluoroquinolone (FQ)	1) Stop all therapy pending resolution of hepatitis. 2) Rule out other potential causes of hepatitis. 3) Consider suspending most likely agent permanently. Re-introduce remaining drugs, one at a time with the most hepatotoxic agents first, while monitoring liver function.	1) History of prior hepatitis should be carefully analyzed to determine most likely causative agent(s); these should be avoided in future regimens. 2) Generally reversible upon discontinuation of suspected agent.
Renal failure	Streptomycin (S) Kanamycin (KM) Amikacin (AM) Capreomycin (CM)	1) Discontinue suspected agent. 2) Consider using Capreomycin (CM) if an aminoglycoside had been the prior parenteral in regimen. 3) Adjust all TB medications according to the creatinine clearance. (See Table 6)	1) History of diabetes or renal disease is not a contraindication to the use of the agents listed here, although patients with these co-morbidities may be at increased risk for developing renal failure. 2) Renal impairment may be permanent.
Electrolyte disturbances (hypokalemia and hypomagnesemia)		1) Check Potassium 2) If Potassium is low also check magnesium (and calcium if hypocalcemia is suspected) 3) Replace electrolytes as needed.	1) If severe hypokalemia is present, consider hospitalization. 2) Amiloride 5-10 mg QD or spironolactone 25 mg QD may decrease potassium and magnesium wasting and is useful in refractory cases

Adverse Reaction	Suspected Agent(s)	Suggested management strategies	Comments
Optic neuritis	Ethambutol (E)	1) Stop Ethambutol (E). 2) Refer patient to an ophthalmologist	1) Usually reverses with cessation of Ethambutol (E). 2) Rare case reports of optic neuritis have been attributed to Streptomycin.
Arthralgias	Pyrazinamide (Z) Fluoroquinolone (FQ)	1) Initiate therapy with non-steroidal anti-inflammatory drugs. 2) Initiate exercise regimen. 3) Lower dose of suspected agent, if this can be done without compromising regimen. 4) Discontinue suspected agent if this can be done without compromising regimen.	1) Symptoms of arthralgia generally diminish over time, even without intervention. 2) Uric acid levels may be elevated in patients on pyrazinamide. Allopurinol appears not to remediate uric acid levels.

(Source PIH Guide 2003)

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