

Foreword

Tuberculosis continues to be a significant cause of morbidity and mortality in Zimbabwe. In 2009, Zimbabwe was ranked 17th of the 22 TB high burdened countries that together account for approximately 80% of all new TB cases arising each year in the world. The estimated TB prevalence rate in 2008 was 714 cases per 100 000 population per year and 265 deaths per 100 000 per year were attributed to TB alone in 2007.

The TB epidemic in Zimbabwe is being fuelled by the severe parallel HIV epidemic, as in the Southern African Development Community (SADC) region. This resulted in more than a five fold increase in the number of TB cases registered, from less than 10 000 cases in 1990 to more than 59 000 in 2002. It is estimated that of all TB cases 72% are estimated to be co- infected with HIV. HIV is known to make the diagnosis of TB more difficult, and of note is that TB is the leading cause of death among people living with HIV (PLHIV).

The focus of TB control is to detect TB cases, particularly the smear positive cases, and provide them with effective treatment in a supportive manner such that no drug resistant TB cases are created. TB case detection is unacceptably low at 24 % and treatment success of these cases is at 74%. This performance is below the global benchmark target for effective TB control of at least 70% case detection and 85% treatment success rate.

Zimbabwe supports the targets for reducing the burden of TB that are set in the Millennium Development Goals (MDGs) and by the Stop TB Partnership. The targets are that the TB incidence should be falling by 2015 and the prevalence and death rates should be halved by 2015 compared with their levels in 1990. Achieving these targets is the focus of national efforts and this document serves to guide the national TB programme towards attaining these targets.

Multi-Drug resistant (MDR) and Extensively-Drug resistant (XDR) TB have been reported in the SADC countries and pose enormous diagnostic and treatment challenges. Management of drug- resistant TB places an extra strain on the national TB programme which is already severely stretched by the HIV epidemic. The true extent of the problem in Zimbabwe and the region is yet to be determined, and human, financial and material resources are needed to tackle this challenge.

This document has been revised based on new evidence and best practices in line with the current international standards. For example, case definitions, standard treatment regimens, monitoring during treatment and management of TB in children have been revised. Activities aimed at strengthening TB/HIV collaboration are further emphasized to ensure better survival of PLHIV and TB patients. Early identification and early treatment of cases remain the major focus in the fight against MDR and XDR TB. A section has been added that enlists the community with the aim of involving and increasing their participation in the fight against TB.

The Government of Zimbabwe remains committed to the control of TB. This is

demonstrated by the adoption of the DOTS Strategy in 1999 and the Stop TB Strategy in 2006 as the recommended approach for TB control. As such the Ministry of Health and Child Welfare commits to the provision of human, material and financial resources for the implementation of approaches as outlined in this document till TB is no longer a public health problem.



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Acknowledgements

The Government of Zimbabwe, Ministry of Health and Child Welfare, would like to extend its profound gratitude to all who contributed to the production of this manual.

The Ministry is grateful to the World Health Organization and USAID and The Union through TB Control Assistance Programme (TB CAP) programme for the technical and financial support for the development and printing of the manual.

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Glossary and Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
ACSM	Advocacy, Communication and Social Mobilisation
ADE	Adverse drug effects
AFB	Acid fast bacilli
ART	Anti-Retroviral Therapy
BCG	Bacille Calmette-Guérin
CBOs	Community Based Organizations
CI	Contact investigation
CSOs	Civil Society Organizations
CPT	Cotrimoxazole Prophylactic Therapy
CVs	Community Volunteers
DHS	Director of Health Services
DHE	District Health Executive
DHMT	District Health Management Team
DMO	District Medical Officer
DOT	Directly observed therapy
DOTS	Directly Observed Treatment Short course
DR-TB	Drug resistant TB
DST	Drug susceptibility test
DTC	District TB Coordinator
EPTB	Extrapulmonary Tuberculosis
EQA	External quality assurance
FBOs	Faith-Based Organizations
HBC	High burden TB countries
HbsAg	Hepatitis A surface antigen
HIV	Human Immunodeficiency Virus
IEC	Information, Education and Communication
IPT	Isoniazid Preventive Therapy
ISTC	International Standards for Tuberculosis Care
LTBI	Latent TB Infection
LED	Light-emitting diode
M&E	Monitoring and Evaluation
MDGs	Millennium Development Goals
MDR-TB	Multi-drug Resistant TB

MOHCW	Ministry of Health and Child Welfare
NAC	National AIDS Council
NGOs	Non-Governmental Organizations
NNRTI	Non-nucleotide reverse transcriptase inhibitor
NTP	National TB Control Programme
PEDCO	Provincial Epidemiology and Disease Control Officer
PHC	Primary Health Care
PHE	Provincial Health Executive
PI	Protease Inhibitor
PITC	Provider initiated testing and counselling
PLWHIV	People living with HIV/AIDS
PMD	Provincial Medical Director
PPM	Public-Public and Public-Private Mix
PPM-DOTS	Private-Public Mix DOTS
PTB	Pulmonary Tuberculosis
PTBC	Provincial TB coordinator
RTR	Retreatment
SOPs	Standard Operating Procedures
SSM+	Sputum Smear Positive
STI	Sexually Transmitted Infection
TB	Tuberculosis
TOT	Training of Trainers
TST	Tuberculin skin test
WHA	The World Health Assembly
WHO	World Health Organization
XDR-TB	Extensively drug resistant TB

CHAPTER 1

Introduction

1.1 Rationale for a New Guidelines

The third edition of the national TB guidelines was published and printed in 2007. The management of TB keeps evolving which calls for the regular review of the national guidelines. Control strategies and control policies have been refined as per the STOP TB Strategy and in response to HIV/TB co-infection, multi-drug resistance TB and the role of communities and the private sector in TB control. The increase of HIV/TB co-infection globally and in Sub-Saharan Africa requires changes in strategies to effectively deal with the dual infection. Priority is also being given to research to support evidence-based programming in TB control as well as the strengthening of health systems.

These guidelines are a summary of the many guidance and information produced from best practice and emerging evidence and is an overview of the full range of activities that need to be done to meet the TB-related Millennium Development Goals (MDGs) as well as the Stop TB Partnership targets set for 2015. It also follows the organisation and structure of the components of the Stop TB Strategy.

In the care and prevention of TB, the approach must be patient-centred and must be a partnership between the patient, the community and the health system. It must be integrated in all aspects of health care, including HIV care and prevention. These guidelines focus on the care and management of patients and the reduction of risks for others. Tuberculosis is one of the few diseases in which clinical care and public health are integrated to achieve cure and prevention. These guidelines therefore emphasise both aspects of the health of the population and attempts to interweave them seamlessly.

1.2 The Stop TB Strategy.

The Stop TB strategy underpins the Global Plan to Stop TB 2006-2015. It is designed to meet the TB-related MDGs as well as the Stop TB partnership targets. This is summarised in Table 1.

Table 1: The Stop TB Strategy

THE STOP TB STRATEGY AT A GLANCE

VISION	A WORLD FREE OF TB
GOAL	To reduce dramatically the global burden of TB by 2015 in line with the Millennium Development Goals (MDGs) and the Stop TB Partnership targets
OBJECTIVES	To achieve universal access to high-quality diagnosis and patient-centred treatment

TARGETS	<p>To reduce the suffering and socioeconomic burden associated with TB</p> <p>To protect poor and vulnerable populations from TB, TB/HIV and MDR-TB</p> <p>To support development of new tools and enable their timely and effective use</p> <p>MDG 6: Target 8 - to have halted and begun to reverse the incidence of TB by 2015</p> <p>Targets linked to the MDGs and endorsed by the Stop TB Partnership:</p> <ul style="list-style-type: none"> - By 2005, detect at least 70% of new sputum smear-positive TB cases and cure at least 85% of these cases - By 2015, reduce TB prevalence and death rates by 50% relative to 1990 levels - By 2050, eliminate TB as a public health problem (<1 case per million population)
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COMPONENTS OF THE STRATEGY AND IMPLEMENTATION APPROACHES

1. **Pursue high-quality DOTS expansion and enhancement**
 - a. Political commitment with increased and sustained financing
 - b. Case detection through quality-assured bacteriology
 - c. Standardized treatment, with supervision and patient support
 - d. An effective drug supply and management system
 - e. Monitoring and evaluation system, and impact measurement

2. **Address TB/HIV, MDR-TB and other challenges**
 - a. Implement collaborative TB/HIV activities
 - b. Prevent and control MDR-TB
 - c. Address prisoners, refugees and other high-risk groups and situations

3. **Contribute to health system strengthening**
 - a. Actively participate in efforts to improve system-wide policy, human resources, financing, management, service delivery, and information systems
 - b. Share innovations that strengthen systems, including the Practical Approach to Lung Health (PAL)
 - c. Adapt innovations from other fields

4. **Engage all care providers**
 - a. Public-Public and Public-Private mix (PPM) approaches
 - b. International Standards for Tuberculosis Care (ISTC)

5. **Empower people with TB, and communities**
 - a. Advocacy, communication and social mobilization
 - b. Community participation in TB care
 - c. Patients' Charter for Tuberculosis Care

6. Enable and promote research

- a. Programme-based operational research
- b. Research to develop new diagnostics, drugs and vaccines

SOURCE: The Stop TB Strategy: building on and enhancing DOTS to meet the TB-related Millennium Development Goals. Geneva, World Health Organization, 2006 (WHO/HTM/TB/2006.368).

1.3 Global and African Tuberculosis Burden

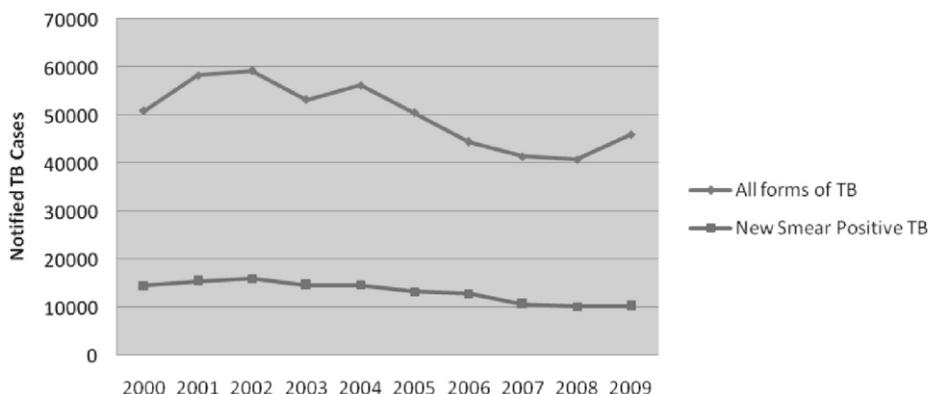
Tuberculosis (TB) is the number one single infectious disease killer, taking nearly 3 million lives per year. So great is concern about TB that in 1993, the World Health Assembly (WHA) declared TB a "global emergency." About one-third of the world's population is infected with *Mycobacterium tuberculosis* and an estimated 9.27 million new cases of TB were reported in the world in 2007, an increase from 9.24 million in 2006. An estimated 1.37 million TB cases (15% of total) were HIV positive; 79% of these cases were in the African region. Globally TB incident rates peaked at 142 cases per 100,000 population in 2004 and declined to 139 incident cases per 100,000 population in 2007. However, the rate of decline is less than 1% per year and is therefore slow.

In Africa, at least 2.8 million new cases are notified every year¹. The WHO African Region contains only 12% of the world's population but contributed 31% of the global total of notified TB cases in 2007. More than 23 countries of the region have TB prevalence rates equal to or greater than 300 cases per 100,000 populations. Among the 15 countries in the world with the highest estimated TB incidence rates per capita, 13 are in Africa and the highest notification rate of 1198 cases per 100,000 population was in the Region (Swaziland).

In response to the global TB problem, the World Health Assembly in 1991 and 2000 set TB control targets of detecting 70% of new infectious cases and successfully treating 85% of those detected by 2005. These targets have been adopted and extended by the Millennium Development Goals (MDGs) and the Stop TB Strategy (see Section 2 above). The latest data however suggest (i) that the incidence rate has been falling since 2004 (ii) that the prevalence and death rates will be halved in at least three of the six WHO regions by 2015 compared to the baseline of 1990, but that these targets will not be achieved for the world as a whole.

1.4 Tuberculosis burden in Zimbabwe

Zimbabwe was ranked 17th among the 22 high burden TB countries (HBC) in the world in 2009. It has an estimated incidence of about 40,000 new smear positive TB cases (incident rate of 298/100,000) and incidence of 104,000 of all forms of TB (incident rate of 782/100,000). The estimated burden of all forms of TB disease increased by over six fold from 121 cases/100,000 population in 1991 to 782 cases/100,000 population in 2007. However, the notification of all forms and new smear positive TB cases increased steadily from 2000, peaked in 2004 (see Figure 1) and declined afterwards. For instance, the notified cases of all forms declined from 56,162 in 2004 to 40,689 cases in 2008. Similarly, the notified new smear TB cases in the same period declined by 27.4% (i.e. 14,581 to 10,041).

Fig1: Trend of TB case notifications in Zimbabwe 2000 - 2009

This observed decline is attributable mainly to operational and systemic issues such as the weakness in the health care delivery system, high attrition of skilled and experienced health care workers and the poor performance of the recording and reporting system. The notified cases (45 970) in 2009 compared to the estimates for the period shows that only 40% and 26.5% of all forms of TB and new smear positive, respectively, were notified, compared to the 70% global target for new smear positive cases. It is also of great concern that up to 30% of pulmonary TB cases are put on treatment without any sputum smear microscopy being performed.

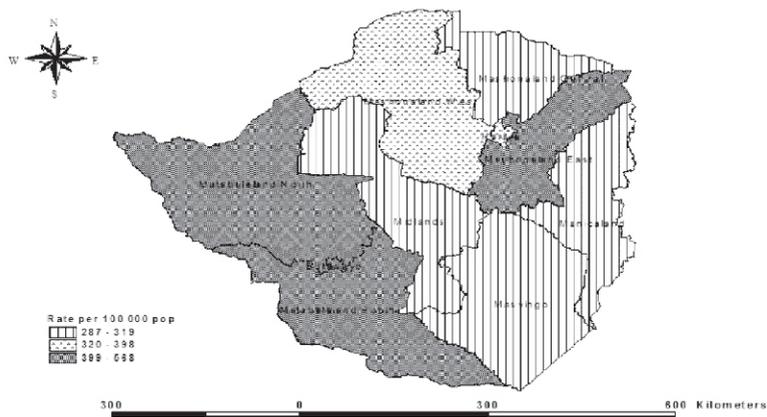
Table 2 shows the influence of HIV on TB indicators in 2007. TB remains the commonest cause of death among people living with HIV/AIDS (PLWHIV). Health facility based data and WHO estimates put the TB/HIV co-infection rate at 72% in Zimbabwe, however the proportion of TB patients with a recorded HIV result in the TB register is still low i.e. not more than 15% (2009). There is therefore need to reinforce provider initiated testing and counselling (PITC) and improve on the recording and reporting using the recently revised M&E tool

Table 2: Impact of HIV infection on TB in Zimbabwe in 2007

INCIDENCE	ALL	IN HIV+ PEOPLE
All forms of TB (thousands of new cases per year)	104	72
All forms of TB (new cases per 100 000 pop/year)	782	539
New ss+ cases (thousands of new cases per year)	40	25
New ss+ cases (per 100 000 pop/year)	298	189
HIV+ incident TB cases (% of all TB cases)	69	
Mortality for all TB cases (per 100,000 pop/year)	265	213

The distribution of TB in the country is not uniform being higher in the south and in Harare than the north of the country (see Figure 2).

Figure 2: Distribution of TB notification rates in Zimbabwe 2009



The last drug resistance survey performed in Zimbabwe in 1995, showed a prevalence of less than 3% multi-drug-resistant strains of TB among new cases and less than 9% among patients on re-treatment. It has been estimated that in 2007, 1.9% and 8.3% of all new and re-treatment TB cases, respectively, were MDR-TB. The NTP needs to establish drug resistance surveillance for TB.

Treatment outcome analyses of smear-positive cases registered between 1996 and 2001 showed that treatment success increased steadily from 62% in 1996 to 71% in 2001, while the proportion of defaulters decreased from 12% to 6% during the same period, with 10% to 12% of patients dying. However, these and other treatment outcomes have been gradually reversed since then as shown in Table 3.

Table 3: TB Treatment Outcomes in Zimbabwe 2000-2007

	2000 ¹	2001 ²	2002 ³	2003 ⁴	2004 ⁵	2005 ⁵	2006 ⁷	2007 ⁹
Treatment success (new ss+ patients, %)	69	71	67	66	54	68	60	78
Re-treatment success (ss+ patients, %)	-	61	63	62	53	60	57	50
Defaulted (%)	-	8	7	12	8	7	5	6
Not evaluated (%)	-	0	0	0	15	0	19	-
Died (%)	-	12	11	12	12	12	8	8
Tuberculosis death rate per year per 100,000 population ⁹	184.8	196.6	216.5	253.5	252.9	263.4	268.0	264.8

- ² WHO. Global tuberculosis control: surveillance, planning, financing: WHO Report 2004. WHO/HTM/TB/2004.331
- ³ WHO. Global tuberculosis control: surveillance, planning, financing: WHO Report 2005. WHO/HTM/TB/2005.349
- ⁴ WHO. Global tuberculosis control: surveillance, planning, financing: WHO Report 2006. WHO/HTM/TB/2006.362
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- ⁷ WHO. Global tuberculosis control: surveillance, planning, financing: WHO Report 2009. WHO/HTM/TB/2009.411
- ⁸ WHO. Global tuberculosis control: a short update to the 2009 report. WHO/HTM/TB/2009.426. Accessed at http://www.who.int/tb/publications/global_report/2009/update/en/index.html on June 3, 2010.
- ⁹ UNSTAT. The Millennium Development Goals Indicators. Accessed at <http://mdgs.un.org/unsd/mdg/Data.aspx?cr=716> on May 24, 2010.

CHAPTER 2

National Tuberculosis Control Programme

2.1 Health Policy

The National Health Policy in Zimbabwe advocates equity and quality in health, consistent with the economic policy embedded in "Growth with Equity: A People's Right". The policy focuses on redressing inequitable access to health and health services.

2.2 National Tuberculosis Policy

The four key points of the TB policy are:

- Sputum microscopy for diagnosis and follow up provided free of charge.
- Short-course chemotherapy provided free of charge in the public health sector.
- TB services available at all levels of the health delivery system, being integrated into the primary health care system to ensure efficient case finding, particularly for sputum smear positive patients.
- Collaborative TB/HIV activities at all levels.

Table 4: National TB Control Strategy

ZIMBABWE NATIONAL TB CONTROL STRATEGY AT A GLANCE

Vision	A TB-free Zimbabwe
Goal	To dramatically reduce the mortality, morbidity, and of tuberculosis in Zimbabwe, in line with the Millennium Development Goals and the Stop TB Partnership targets
transmission	To detect at least 70% of new infectious TB cases
Objectives	To successfully treat at least 85% of new infectious TB cases
	To reduce the prevalence of and death due to TB and so reduce the social and economic burden placed by TB upon families and communities
Expected Impact	To eliminate TB as a public health problem in Zimbabwe
	By achieving and maintaining the above targets, the NTP will achieve the following impact:
	- Rapid reduction of TB mortality, prevalence and transmission of TB
	- Gradual reduction of TB incidence as control efforts are maintained
	- Prevention of the development of resistance to anti-TB drugs
Strategy	The national TB control strategy is based on the STOP TB Strategy with the following strategic and implementation approaches:
	- DOTS expansion and enhancement
	- Addressing TB/HIV, MDR-TB and other challenges
	- Contributing to health system strengthening

- Greater involvement of all health care providers
- Engagement of people with TB and affected communities, through advocacy, communication and social mobilisation
- Enabling and promoting operational research

2.3 Collaborative TB/HIV Activities

The range of collaborative TB/HIV interventions at different levels within the district health system is wide, as shown in Table 5 below. Each district and province should consider which intervention should be introduced and in what order of priority.

Table 5: Range of TB/HIV Collaborative Interventions

LEVEL OF HEALTH CARE	TB/HIV INTERVENTIONS
Home and community Community based organisations, non governmental organisations, faith based organisations, government community health programmes	TB, HIV, and STI, IEC activities Condom promotion Nutritional advice and support Psychological support Community DOT for TB Community based palliative and terminal care
Primary care Government health centres or clinics, mission health centres, private health centres	Provider Initiated Testing and Counselling (PITC) TB case finding and treatment Intensified case finding Isoniazid/ Cotrimoxazole provision Condom promotion STI syndromic management Management of HIV related opportunistic infection and palliative care Prevention of mother to child transmission
Secondary and tertiary care Government hospitals, mission hospitals, private hospitals	Diagnosis and treatment of HIV related diseases In patient palliative care Anti retroviral therapy

The NTP and the HIV/AIDS programmes are already implementing these collaborative activities but they need to be strengthened. Non-governmental organizations (NGOs), community-based organizations and the private sector, are being encouraged to implement such activities under the coordination of the Ministry of Health and Child Welfare.

2.4 Structure and roles of the NTP at various levels

2.4.1 The Central Level

The Central Unit plans, coordinates, supervises, implements, monitors and evaluates the activities of the NTP, including work plans, budgets and reports. It is involved in strengthening collaboration between TB and HIV & AIDS programmes to ensure better management of co-infected patients. The Unit also coordinates laboratory services and the procurement and distribution of anti-TB drugs and laboratory reagents and materials at all levels. Other responsibilities include recruitment of higher cadres, training, health data compilation and analysis. The Central unit liaises closely with other departments in the Ministry of Health and Child Welfare, the National AIDS Council (NAC), NGOs, private sector, bilateral, and multi-lateral organisations in the coordination of TB related activities. Coordination of research and raising public awareness about TB and TB/HIV and resource mobilisation is also the responsibility of the Central level.

2.4.2 Central Hospital Level

These hospitals manage TB patients i.e. diagnosis, treatment, referral of patients to appropriate local authorities, and have the responsibility for the management of complicated or severe forms of TB such as TB meningitis or pericardial TB. Consultant physicians lead clinical management of TB. Coordination of programme management, recording and reporting is done by the infection control sister/TB focal nurse. Central Hospitals refer all diagnosed TB cases to the local authorities for case notification, treatment continuation and contact tracing.

2.4.3 The Provincial Level and Local Authority

At provincial level, the Provincial Medical Director (PMD) is overall in charge of the TB programme, through the Provincial Epidemiology and Disease Control Officer (PEDCO), a medical officer with public health training. The PEDCO in managing the TB programme in the province is assisted by a Provincial TB & Leprosy coordinator (PTLC). At local authority level the Director of Health Services is overall in charge and is assisted by a TB Focal person, who in turn is supported by TB coordinators.

The key functions at provincial or local authority levels are:

- Collaboration with the district management teams in planning TB activities so that the provincial work plan is a sum of all the district work plans
- Recruitment of human resources and capacity building of the new recruits
- Ensuring that districts have adequate supplies of TB forms, laboratory materials and consumables and anti TB drugs
- Ensure that staff at district level are knowledgeable about stock management principles
- Supervising the recording, reporting and submission of TB returns
- Liaising with health workers working in the HIV and AIDS programmes to ensure improved management of patients with co-infection
- Conducting comprehensive supportive supervisory visits that include laboratory and pharmacy services as it pertains to TB control activities
- Partnering with NGOs, the private sector and other organizations offering TB services

2.4.4 The District Level

The District Health Management Teams (DHMTs) supervise the delivery of all health care services in hospitals and primary level centres. The District Medical Officer (DMO) has overall responsibility for the organization and management of TB control activities at district level, with the assistance of a District TB Coordinator. The district hospital is the basic management unit in tuberculosis control.

The functions of the district level include:

- Diagnosis, treatment and follow-up of patients and tracing of contacts,
- Generation of TB data
- Supervision of TB control activities at primary health care facilities.
- Ordering of drugs, reagents and stationery for all health facilities in the district.
- Coordinates establishment of the community DOTS programme
- Consolidation, analysis and submission of TB reports

2.4.5 Primary Care Level

TB services are integrated into the Primary Health Care (PHC) system. PHC facilities are responsible for:

- The initial investigation of TB suspects
- Initiation of treatment on all sputum positive cases
- Provision of TB drugs and conducting DOT.
- Maintain facility TB records and registers.
- Referral of sputum negative TB suspects
- Supervise treatment supporters or community based health workers

2.4.6 Community, Community Based Organizations, & Non-Governmental Organizations

These organisations complement the NTP in providing TB control services at the community. The range of interventions they provide includes DOT, patient, family and community education; supporting case-finding activities; nutritional support; patient charter and lobbying for greater political commitment to TB control.

2.4.7 Private Practitioners and Institutions

Most private medical care is available at a fee for service basis, often with the support of medical insurance companies. The private health sector supports the NTP mainly in the diagnosis of TB and referral of diagnosed cases to government or designated health facilities for notification and treatment. Some large corporations have developed company-based TB control programmes using the DOTS strategy in accordance with the national guidelines and are benefiting from the medicines and diagnostics provided by the national programme. These examples of Private-Public Mix DOTS (PPM-DOTS) will be expanded in the near future in order to engage all TB care providers (private and public) to harness synergy to improve case detection, access to treatment and case holding with the aim of improved treatment outcomes.

2.4.8 Laboratory Services

The TB laboratory system in Zimbabwe is tiered. It comprises of a network of the National Tuberculosis Reference Laboratory (NTBRL) at Mpilo Central Hospital in Bulawayo and the second TB Culture Laboratory based at National Microbiology Reference Laboratory (NMRL) in Harare, 10 intermediate (province/city) and 96 peripheral level laboratories. Ideally for the population in the country, about 520 sputum smear microscopy centres and 3 TB culture facilities are required. All intermediate and peripheral laboratories perform sputum smear microscopy and refer re-treatment and failure cases for culture and drug susceptibility testing to the NTBRL. The NTBRL provides overall technical assistance and external quality assurance (EQA) to all laboratories in the network; in addition, provincial levels supervise and support district laboratories, which in turn support the microscopy centres. There are more than 30 private laboratories that perform smear microscopy for private and public providers but that are not yet involved in the NTBRL EQA. These will be linked into the EQA network when the PPM-DOTS strategy is fully operational.

2.4.9 Anti-Tuberculosis Drugs and Other Supplies

Drug management is the responsibility of the Department of Pharmaceutical Services via the National Pharmaceutical Company (NatPharm) with the active participation of the NTP Programme Manager. See Chapter 12 for more details

TB FOCAL PERSON:

Every health institution should have a TB focal person, and every local authority, district and province should appoint co-ordinators of the National Tuberculosis Programme.

At every level within the Ministry of Health and Child Welfare and local authority level, there must be a capable officer to co-ordinate TB control efforts.

CHAPTER 3

Diagnosis of TB in Adults and Case Definitions

3.1 Introduction

The objective of this chapter is to present the clinical and laboratory diagnosis of TB and to explain the purpose, importance, determinants and uses of case definitions.

The first step in the control of TB is the detection of cases in the community. The ability to detect a case of TB is determined by:

- The patients' and the community's knowledge of the symptoms and signs of TB,
- The health seeking behaviour of patients and the community, that is, the activities that patients' and community take to seek solution to their health problems.
- Geographic and financial access to health facilities and care, whether the health facility is close to or far away from the patients and communities and whether they have the finances to take transport to go to a health facility and while there to pay for TB care.
- Clinical evaluation by all health-care workers, including doctors, nurses, medical assistants, clinical officers, record officers etc, and the making of the diagnosis.
- Access to a reliable and functioning laboratory network which confirms the clinical diagnosis.

These factors need to be taken into cognisance, as failure to do so may result in delayed case detection and treatment.

TB is transmitted from a person who has sputum positive pulmonary TB, and who is not on TB treatment to another person. Coughing, sneezing, spitting and even talking produce very small droplets containing droplet nuclei. The droplet nuclei float in the air and another may inhale the droplet nuclei and become infected. Whether a person becomes infected or not is determined by the dose of contaminated droplet nuclei, the duration of exposure and the person's immune system.

Tuberculosis disease usually develops over time, and patients are often not aware until the disease has progressed. It is therefore vital for health staff to develop a high index of suspicion in patients who present with signs and symptoms suggestive of TB at all health facilities.

In Zimbabwe an estimated 72% of all TB cases are co-infected with HIV. The co-infection of TB with HIV alters the clinical presentation of TB and its complications. HIV also increases the incidence of TB, the proportion of smear-negative pulmonary TB and extra-pulmonary TB. Patients who are dual infected with TB and HIV have poorer treatment outcomes particularly during the early phase of treatment. There is therefore a need to speedily diagnose smear negative and extra-pulmonary TB in our setting.

3.2 Clinical Diagnosis

3.2.1 Pulmonary TB

The presence of pulmonary tuberculosis should be suspected in individuals presenting with Cough for 2 weeks or longer, and one or more of the following complaints:

- Production of sputum, which may be bloodstained
- Night sweats
- Fever
- Loss of weight
- Shortness of breath
- Chest pain
- Loss of appetite
- A general feeling of being unwell

Anyone with one or more of the above symptoms particularly a cough of 2 or more weeks, should be considered as a "TB Suspect". All TB suspects should have a sputum examination and a thorough general examination and an examination of the respiratory system. It is important to remember that no symptoms or clinical findings on examination are specific for TB, but the more signs and symptoms a person has, the greater the likelihood of having TB, especially if there is a history of previous contact with a TB patient.

All patients presenting at all health facilities should be asked about history of signs and symptoms of TB using the TB screening questionnaire (see Annex 6) and should be recorded in a "TB Suspect Register" (Annex 1). The use of the TB Suspect Register increases the chances of detecting TB among clients presenting to health facilities, often for reasons other than cough. The TB Suspect Register is also useful for health facilities without microscopy services for monitoring sputum specimens sent to other laboratories, and for evaluating the proportion of TB suspects at first level health facilities.

3.2.2 Extra-pulmonary TB

Patients usually present with constitutional symptoms such as fever, night sweats, weight loss, and local features related to the site of disease. For instance, chest pain may arise due to tuberculosis pleural effusion; swellings in the neck may develop due to TB lymphadenitis, there may be a sharp angular deformity on the back due to tuberculosis of the spine.

3.2.3 Diagnosis of TB in People Living with HIV

The effect of HIV on TB is dependent on the level of immunodeficiency produced by HIV. In the early stages of HIV infection, TB presentation in HIV positive persons is similar to that in HIV negative patients described above. With more advanced immunodeficiency the initial clinical features of TB tend to become non-specific, with a predominance of systemic symptoms and a higher incidence of smear negative and extra-pulmonary TB. Other atypical presentations of TB, such as diarrhoea, enlarged liver and spleen, are also seen more frequently in late stages of HIV infection.

3.3 Investigative Aids to Diagnosis

3.3.1 Sputum smear examination

The most important screening test for PTB suspects is direct smear microscopy (DSM) of stained smears, which allows the detection of acid-fast bacilli (AFB). The collection of sputum specimens and their handling before examination is critical in getting the best results from microscopy. The patient should be educated about the importance of sputum examination and the procedure of sputum production and collection.

3.3.1.1 Number of Sputum Specimens to be collected

Two sputum specimens should be collected within 24 hours and sent for direct microscopy. At the patient's first visit, a specimen is collected on the spot (spot specimen) and examined by the laboratory immediately. The patient is then given one sputum container for collection of an early morning specimen the next day at home with instructions to take the specimen to the laboratory or the health facility. Where in the case a patient lives far from a health facility, or there is a possibility of not returning, 2 sputum specimens can be collected 2 hours apart on the same day. For sputum collection procedure see Annex 2: How to collect a satisfactory sputum specimen.

3.3.2 Sputum Culture

Culture of mycobacterium is the most reliable way of diagnosing disease and assessing drug susceptibility. Specific laboratory request forms should be used.

3.3.2.1 Indications for sputum culture:

When Drug Resistant -TB is suspected, e.g.,

- All relapses.
- Patients on category 1 treatment who are sputum positive at 3 or 5 months.
- Patients on category 2 treatment who are sputum positive at 4 months (at end of prolonged intensive phase).
- Patients on category 2 treatment who are sputum positive at the end of treatment.
- Patients who are sputum smear positive and have been in contact with confirmed X/MDR TB cases.
- Patients who were sputum smear negative at diagnosis but are sputum smear positive at the end of two months of treatment.
- Other special cases as decided by a medical officer.

One sputum specimen should be submitted for culture and drug susceptibility testing.

3.3.3 Chest x-ray

3.3.3.1 Indications for chest x-ray:

- HIV positive patient who is sputum negative.
- No clinical response to broad-spectrum antibiotics taken for the correct duration in sputum negative and HIV negative patient.
- When suspecting complications, e.g., pneumothorax or pleural effusion
- When frequent and severe haemoptysis occurs
- Pericardial effusion.
- When other lung diseases are suspected by the medical officer

Chest x-rays should NOT be routinely used for diagnosing pulmonary TB. In sputum positive patients a chest x-ray is not necessary.

NOTE: In the presence of clinical improvement, it is not necessary to monitor the response of pulmonary TB to treatment by chest x-rays.

3.3.3.2 Possible causes of chest x-ray abnormalities

Many other diseases/conditions besides TB can present with chest x-ray findings similar to those associated with pulmonary tuberculosis, e.g., upper lobe infiltrates, bilateral infiltrates, cavitation, and pulmonary fibrosis. Such diseases include bacterial pneumonia, lung abscess, fungal infection, bronchial carcinoma, connective tissue disease, occupational lung disease, sarcoidosis, lymphoma, among many other diseases. Specific tests might be needed to rule out these conditions.

3.3.3.3 Contra-indications to chest x-rays

Chest x-rays are contra-indicated in pregnancy especially during the first trimester.

3.3.4 Other tools for diagnosing TB

- Tuberculin skin test (TST)/ Mantoux test
 - Light-emitting diode (LED) fluorescence microscopy has been recently introduced and will be widely available in due course
- The investigations below will be available in major centres in the country:
- Molecular line-probe assays.
 - Automated liquid culture and DST.

3.3.5 Diagnostic tests for Extrapulmonary TB

Depending on the part of the body affected, the following diagnostic tests may be used to reach a diagnosis of EPTB: needle aspirate, biopsy, culture of sample of biopsy or needle aspirate, x-ray, ultrasound, bacteriology and histology. Extra-pulmonary TB is usually a diagnosis of exclusion and should only be made by a medical officer.

3.4 HIV counselling and Testing

All TB suspects should be offered HIV counselling and testing (PITC). It is recommended that the HIV test is done as much as possible at the same facility where the sputum is collected.

3.5 Summary of TB Diagnosis:

A reliable diagnosis of TB can be straightforward when sputum smear microscopy demonstrates the presence of acid-fast bacilli (AFB). It can, however, be more difficult when smears are negative, when further investigations, such as x-rays are needed. The diagnosis of TB in any patient with negative smear (or culture) results and of extra-pulmonary TB should only be made by an experienced clinician after careful consideration and exclusion of other diseases. A clinician may be a doctor, clinical officer or nurse.

Use the algorithms shown in Figures 3, 4 and 5 to diagnose PTB. Note that all TB suspects should be counselled for and offered HIV testing.

A CAUTIONARY NOTE:

TB should not be diagnosed lightly in the absence of sputum smears, as treatment with 6-8 months of TB medication is a heavy burden for the patient and family in terms of costs, potential side effects and stigma.

Figure 3: Algorithm 1 for Diagnosis of TB

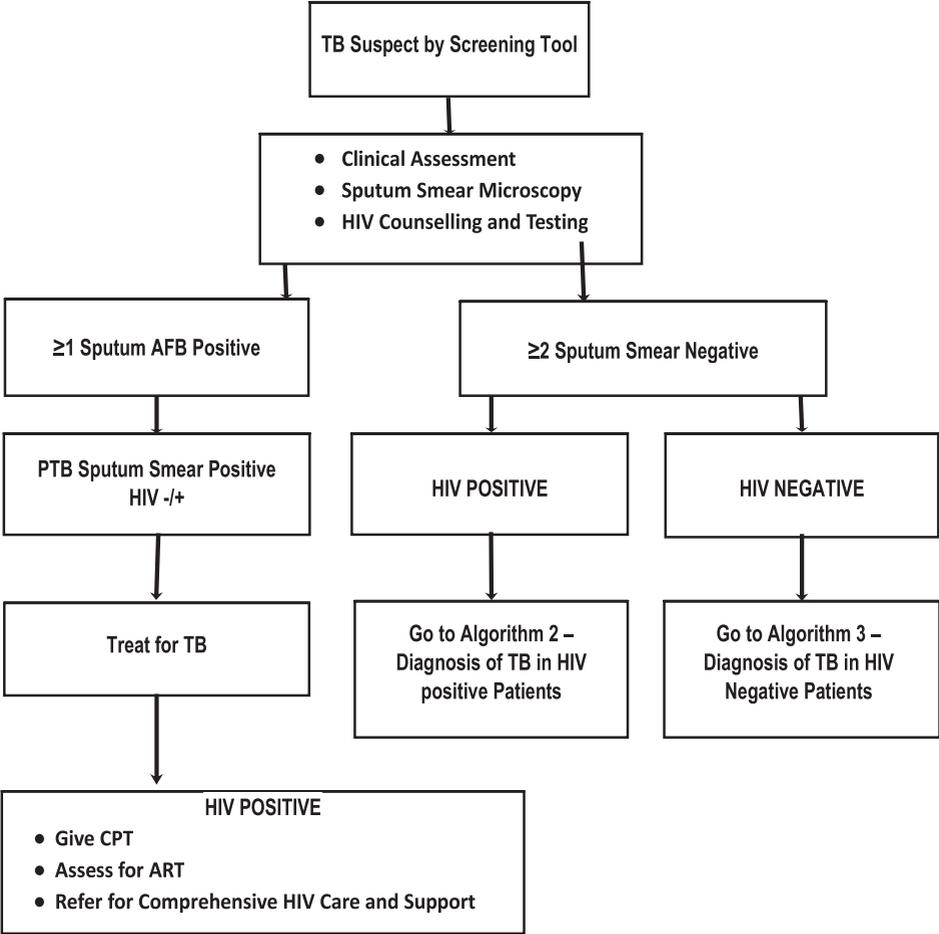


Figure 4: Algorithm 2 for the Diagnosis of TB in HIV positive Sputum Smear negative Patient

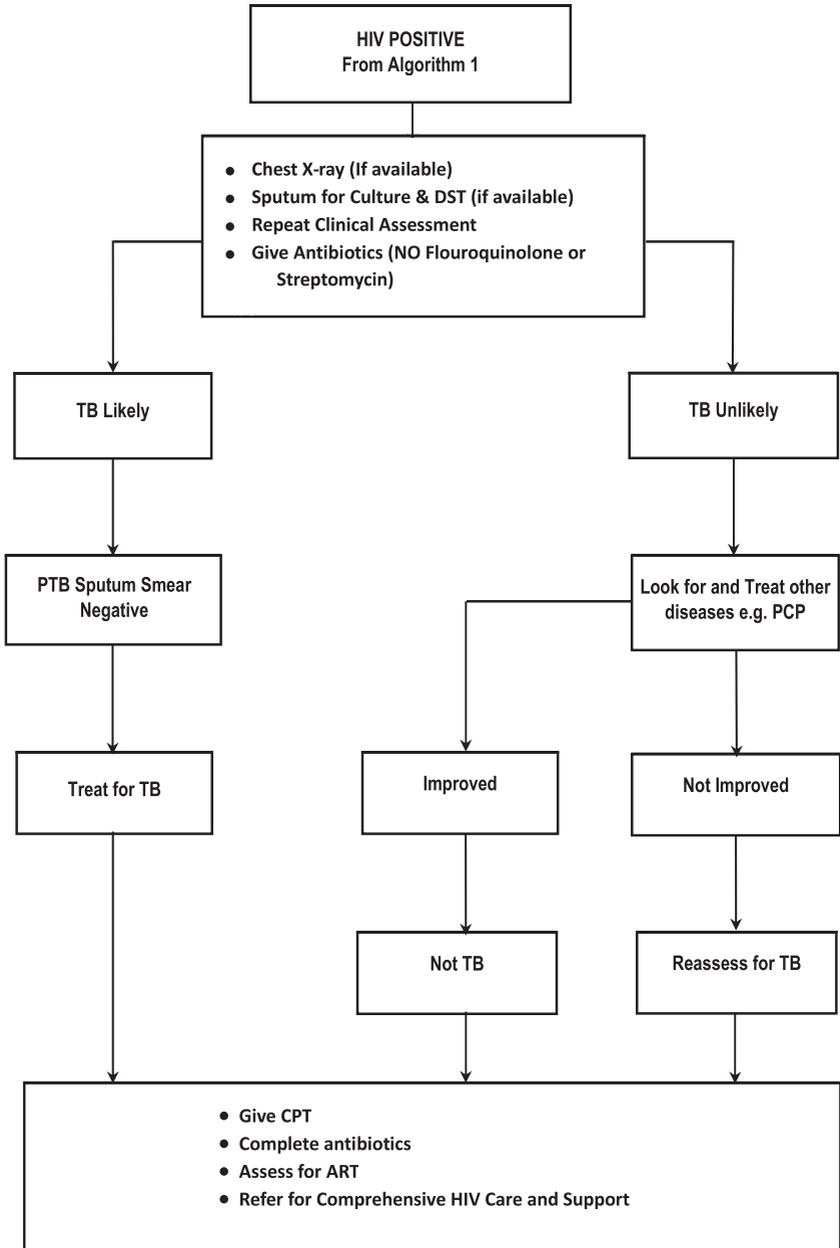
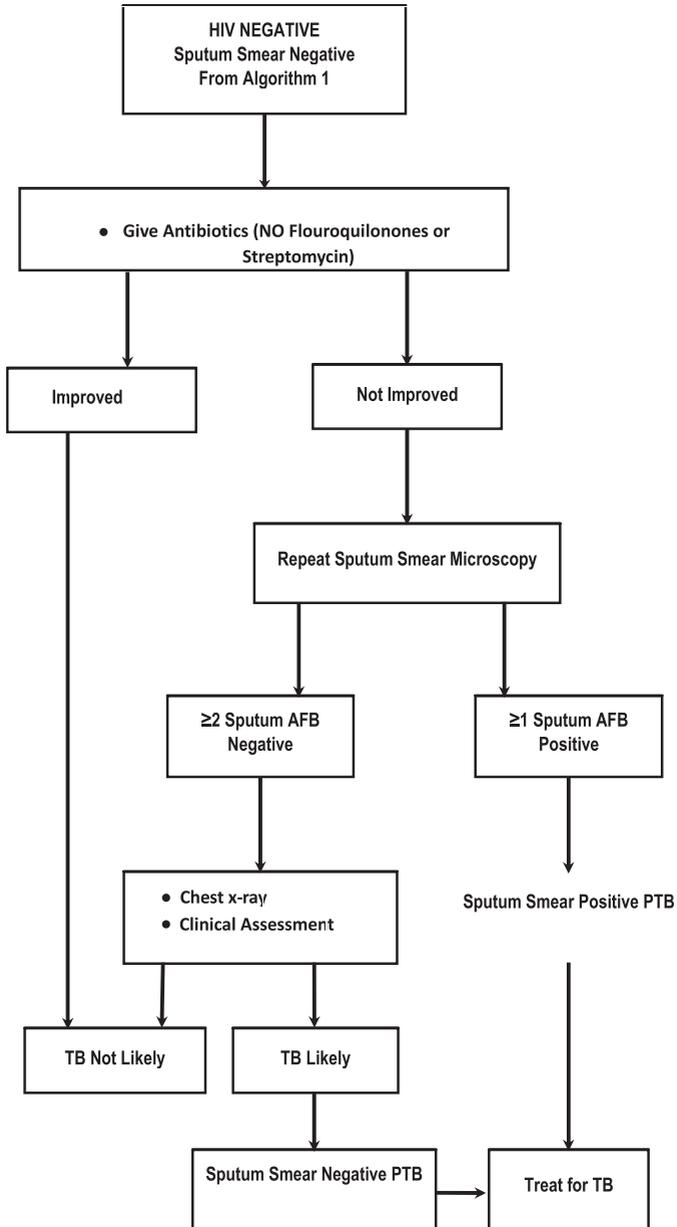


Figure 5: Algorithm 3 for the Diagnosis of TB in HIV negative initially Sputum Smear negative Patients



3.6 Case Definition of Tuberculosis

Following the diagnosis of TB in a patient the next step is to make a case definition and classify the TB case. This is necessary for determining the treatment and all other activities in the NTP.

3.6.1 Importance of Case Definitions

Case definitions are made in order to:

- Correctly register patients and notify cases;
- Allocate cases to the appropriate standardized treatment regimens;
- Facilitate the evaluation of case detection activities and treatment outcomes i.e cohort analysis of treatment outcomes.
- Accurately evaluate TB control activity and resulting TB case trends and make comparisons nationally and internationally.

3.6.2 Case Definitions

Tuberculosis suspect. Any person who presents with symptoms and/or signs suggestive of TB, in particular unexplained productive cough of 2 weeks or more.

Case of tuberculosis. A definite case of TB (defined below) or one in which a clinician has diagnosed TB and has decided to treat the patient with a full course of TB treatment.

Definite case of TB. A case of TB in which the *Mycobacterium bacillus* has been identified by culture, by newer diagnostic tools or one or more sputum smear was/were positive for acid fast bacilli (AFB).

NOTE: Any person who is commenced anti-TB treatment should be recorded as a case

3.6.3 Classification of Case definitions

TB cases are classified based on the following:

1. Site of TB disease (pulmonary or extrapulmonary)
2. Bacteriology (result of sputum smear microscopy, culture or histology)
3. History of previous treatment for TB

3.6.3.1 Site of TB disease (pulmonary and extrapulmonary)

In general, treatment regimens do not depend on the site of disease, being similar for both pulmonary and extra-pulmonary TB. The defining of TB by site is primarily for the purposes of identifying the more infectious patients (pulmonary TB) and for recording and reporting purposes.

- Pulmonary tuberculosis (PTB) refers to disease involving the lung tissue.
- A patient with both pulmonary and extra-pulmonary TB should be classified as a case of pulmonary TB.
- Extra-pulmonary tuberculosis (EPTB) refers to tuberculosis of organs other than the lungs, e.g. pleura, meninges, lymph nodes, abdomen, genitourinary tract, skin, joints and bones.

Diagnosis of EPTB should be based on histological or strong clinical evidence consistent with active EPTB, or a culture-positive specimen, followed by a decision by a clinician to treat with a full course of anti-TB treatment. The case definition of an extra-pulmonary TB case with several sites affected depends on the site representing the most severe form of the disease.

3.6.3.2 *Bacteriology in pulmonary TB*

Defining the result of sputum smear microscopy in pulmonary TB is important to:

- Identify smear-positive cases, who are the most infectious cases, and who usually have higher death rates if left untreated;
- Identify smear-negative cases particularly who are HIV positive as they have a higher incidence of death;
- Record, report and evaluate programme performance
- The following are bacteriological definitions of pulmonary TB:
- Pulmonary tuberculosis, sputum smear-positive (PTB+)
 - One or more sputum smear examinations positive for AFB (irrespective of quantity of AFBs seen on microscopy).
 - Pulmonary tuberculosis, sputum smear-negative (PTB-)
 - Two or more negative smears, and
 - Radiographic abnormalities consistent with active PTB as determined by a clinician, and
 - Decision by a medical officer to treat with a full course of anti-TB medicines and
 - Following failure to respond to an adequate course of broad-spectrum antibiotics (not including fluoroquinolones, streptomycin and other anti-TB medicines). All HIV positive patients should receive a course of broad spectrum antibiotics. The response to treatment should no longer be used to diagnose PTB in PLHIV as they may have two or more chest infections including PTB. Such patients are likely to improve on broad spectrum antibiotics and PTB will be missed
 - This group includes patients whose sputum smears are negative but whose culture is positive.

NOTE: Under programme conditions, when microscopy laboratory services are available and diagnostic criteria are properly applied, PTB smear-positive cases represent at least 65% of PTB cases in adults, and 50% or more of all TB cases. These proportions may be lower in high HIV-incidence populations.

3.6.3.3 *History of previous treatment for TB*

In order to prescribe appropriate treatment and to identify patients at increased risk of having drug-resistant TB, it is important to determine whether a patient has previously received TB treatment. This distinction is also useful for epidemiological monitoring of the TB epidemic at national and regional levels.

TB is classified according to history of previous treatment as follows:

- New Case.
 - A patient who has never had treatment for TB or who has taken anti-TB drugs for less than 1 month.

- Previously treated Case
 - A patient who has received 1 month or more of anti-TB drugs in the past. Patient may have positive or negative bacteriology and may have disease at any anatomical site.

Patients previously treated for TB are further classified by the outcome of their most recent course of treatment as follows:

Relapse	A patient previously treated for TB who was declared cured or treatment completed, and is diagnosed with smear or culture positive TB
Treatment after failure	A patient who is started on a re-treatment regimen after having failed previous treatment and is sputum positive after 5 months of treatment.
Treatment after default	A patient who returns to treatment following interruption of treatment for 2 months or more, with smear or culture positive TB
Transfer in	A patient who has been transferred from another tuberculosis register to continue treatment in the receiving district or city.
Other	Patients for whom it is not known whether they have been previously treated or patients who were previously treated but with unknown outcome of that previous treatment or a patient who has returned to treatment with smear negative PTB or bacteriologically negative EPTB

A previously treated patient whose sputum is smear-positive at the end of (or returning from) a subsequent course of treatment is therefore no longer defined as "chronic" but as either relapsed, defaulted or failed.

NOTE. Smear-negative pulmonary and extra-pulmonary cases may also be relapses, failures, return after default. This should, however, be rare and should be supported by pathological or bacteriological evidence (histology or culture).

3.6.4 *HIV Status*

Determining and recording the patient's HIV status is critical for treatment decision as well as for monitoring trends and assessing programme performance. Patients diagnosed with TB should be offered HIV counselling and testing which should be extended to the patient's family and household. HIV Counselling and Testing must be done at the same health facility where TB is cared for.

CHAPTER 4

Tuberculosis In Children

4.1 Introduction

Tuberculosis in children represents between 10 to 20% of all TB cases in the community. The source of transmission of TB to a child is usually an adult or adolescent (often a family member) with sputum-smear positive PTB. Cases with sputum smear-negative pulmonary TB are generally less infectious, but may still infect children, particularly mothers and/or primary caregivers. TB infection may also occur without known exposure and the absence of a potential source case does not exclude TB:

The incidence of childhood TB depends on the number of infectious cases in the community, the closeness and duration of contact with an infectious case, and the age of the child when exposed to TB. Smear-positive TB is unusual in children and therefore children with TB are usually not infectious. TB in children is therefore mainly as a result of failure of TB control in adults.

A good TB control programme is the best way to prevent TB in children

4.2 Risk Factors for TB infection

Risk of infection depends on extent of exposure to infectious droplet nuclei.

- Household contact with a newly diagnosed smear- positive case
- Age less than 5 years
- HIV infection

4.3 Risk of progression of infection to disease

- Most children with infection will not develop active TB disease.
- Many children will become ill within one year of infection and most within 2 years. For infants the interval may be quite short, and PTB can present as an acute pneumonia rather than a chronic pneumonia.
- Infants and young children have an immature immune system and are therefore at greater risk of developing disease (up to 20%), which may be disseminated.
- Illnesses or stresses, which weaken the immune system, may trigger progression from infection to disease. This occurs in HIV infection, malnutrition and after other infections especially measles and whooping cough.

4.4 Spectrum of Disease

- The commonest age of presentation is between 1 and 4 years. TB is less common between 5 and 12 years and then increases in adolescence.
- The commonest type of TB in children is smear-negative PTB. Smear- positive PTB is usually diagnosed in children older than 6 years.
- Other common types of TB include TB lymphadenitis, miliary and meningeal TB, pleural, pericardial and peritoneal and spinal TB
- Young children are susceptible to severe forms of disseminated disease following primary infection

4.5 Diagnosis of TB in children

The diagnosis of TB in children can be difficult for the following reasons:

- Clinical signs and symptoms are non-specific. e.g. children with TB may have cough, weight loss, fever, diarrhoea, enlarged glands and seizures.
- Most children are too young to provide a sputum specimen for smear microscopy. Therefore alternative method of obtaining specimens, such as gastric washings (which need to be cultured) may be required.
- The diagnosis of TB in children is therefore nearly always presumptive

4.5.1 Clinical Assessment

Suspect TB in a child with any of the following:

1. History of Contact with an adult or older child with TB. Most often, it is the child's mother or another carer. It is important to remember that the contact may have occurred anytime up to 2 years previously.
2. Chronic cough or wheeze lasting more than 2 weeks in a child who has received a course of broad-spectrum antibiotics or other appropriate treatment. Other causes of chronic cough, which include asthma, HIV infection, aspirated foreign body, cardiac failure and bronchiectasis, should be excluded as much as possible.
3. Failure to thrive or loss of weight; Documented loss of weight or failure to thrive during the past 3 months especially if not responding to nutritional rehabilitation is a good indicator of chronic disease and TB may be the cause. It may also be due to poor nutrition, recurrent diarrhoea or HIV infection.
4. Fatigue or reduced playfulness
5. Persistent fever ($>38^{\circ}\text{C}$) >2 weeks
6. A painless enlarged mass of matted lymph nodes ($>2 \times 2$ cm) in the neck (without a visible local cause on the scalp or response to a course of antibiotics)
Children known or suspected of having HIV infection should be screened for TB at each visit; recent TB exposure and/or symptoms suggestive of TB should be documented routinely. Children, in particular HIV-infected children, can develop TB more than once.

4.5.2 *Danger signs requiring urgent hospital referral:*

- Severe respiratory distress (TB pneumonia with/without bacterial super-infection)
- Severe wheezing not responding to bronchodilators (signs of severe airway compression)
- Headache (especially if accompanied by vomiting), irritability, drowsiness, neck stiffness and convulsions (signs of TBM)
- Hepatosplenomegaly (signs of disseminated TB)
- Breathlessness and peripheral oedema (signs of pericardial effusion or severe pulmonary disease and malnutrition)
- Distended abdomen with/without ascites (signs of abdominal TB)
- Angulation of the spine (gibbus - a sign of TB spine)

NOTE: The suspicion of TB in infants should always lead to the investigation of the mother/caregiver for PTB

4.5.3 Recommended approach to diagnose TB in children

1. Careful history (including history of TB contact and symptoms consistent with TB)
2. Clinical examination (including growth assessment)
3. Tuberculin skin testing
4. Bacteriological confirmation whenever possible
5. Investigations relevant for suspected pulmonary TB and suspected extrapulmonary TB
6. HIV testing

4.5.4 Bacteriological confirmation whenever possible

It is always advisable to confirm diagnosis of TB in a child using whatever specimens and laboratory facilities are available. Appropriate specimens from the suspected sites of involvement should be obtained for microscopy and, where facilities and resources are available, for culture (and also histo-pathological examination). Appropriate clinical samples include sputum, gastric aspirates and certain other material (e.g. lymph node biopsy or any other material that is biopsied). Fine-needle aspiration of enlarged lymph glands - for both staining of acid-fast bacilli and histology - has been shown to be a useful investigation, with a high bacteriological yield.

4.5.5 Investigations

4.5.5.1 CXR

A child suspected of TB should have a CXR taken at presentation. Repeat the CXR after one month if the child does not improve on appropriate broad-spectrum antibiotic.

Suspect TB on CXR if there is:

- Unilateral hilar or paratracheal lymph node enlargement,
- Airway compression with segmental or lobar hyperinflation as a result of a ball valve effect from enlarged lymph nodes
- or lobar collapse/consolidation
- Pleural effusion which is not purulent (i.e. always requires chest aspiration)
- Miliary picture or extensive changes not matched by clinical findings.

NB Lymphocytic Interstitial Pneumonitis (PIP) can look remarkably like miliary TB.

4.5.5.2 The Tuberculin Skin Test (TST)

The TST measures the delayed type hypersensitivity response to a purified protein derivative (PPD) from tubercle bacilli also known as tuberculin. A positive TST indicates infection with *Mycobacterium tuberculosis* and not necessarily TB disease. Tuberculin skin test, if available, should be done using the Mantoux technique where 0.1ml of PPD is injected intradermally on the volar aspect of the left forearm. It may provide supportive evidence of TB disease. [See annex 7 on Mantoux Testing]. Interpretation of TST result.

1. A negative tuberculin skin test

A tuberculin test is not significant or "negative" when the diameter of skin induration is less than 10 mm (or less than 5 mm in an HIV-infected or severely

malnourished child). This is regardless of whether the child had BCG.

A negative tuberculin skin test does not exclude TB.

Conditions that may suppress the tuberculin skin test are:

- HIV infection
- Disseminated TB and/or TB meningitis
- Severe malnutrition, severe bacterial infections, including TB, viral infections (e.g., measles or chicken pox), cancers,
- Immunosuppressive drugs, e.g. high dose steroid therapy
- Recent exposure to TB (2-3 month delay in conversion)
- Incorrect injection and storage of tuberculin

2. A positive tuberculin skin test

Following BCG vaccination a reaction to tuberculin usually persists for at least a few years. This reaction is usually weaker (diameter of skin induration is often less than 10 mm) than the reaction to natural infection with *M. tuberculosis*.

A tuberculin test is considered significant or "positive" when the diameter of the skin induration is at least 10 mm (Table 6). However, if the child is HIV infected or malnourished the tuberculin test is considered positive if the induration is 5 mm or more.

Table 6: Interpretation of Tuberculin Skin test

	PERSON WITH NORMAL IMMUNITY	PERSON WITH DEFECTIVE IMMUNITY
Positive test (skin induration)	10 mm	5 mm

A positive tuberculin test is only one piece of evidence in favour of the diagnosis of TB. The younger the child and the greater the diameter of induration, the stronger is this one piece of evidence.

4.6 Standard case definitions of TB in Children

Case definition of TB in children is the same as that for adult. However, in the situation where no sputum-smear is obtained, which in majority of those less than 6 years of age, the patient is classified as sputum-smear negative PTB.

4.7 The decision to start TB treatment in Children

Notify and start TB treatment in the following situations:

1. Children with CONFIRMED TB:
 - a. AFB are seen on microscopy
 - b. Culture of *M. tuberculosis* has been obtained from any body tissues, fluids or secretion

2. Children with PROBABLE TB:
 - a. Positive (Mantoux test) tuberculin skin test
 - b. CXR showing unilateral hilar or paratracheal adenopathy, or a miliary picture
 - c. Histology suggestive of TB
3. Children with SUSPECTED TB
 - a. Very young and acutely ill children in the absence of robust evidence of disease. If the child is older and not acutely ill, there is no urgency for starting the treatment. Wait and assess. Any child with a persistently negative Mantoux reaction and whose condition remains good or improves over months does not have TB.

Once TB treatment is started, it should be completed. The patient should be notified and registered in the district TB register

4.8 Treatment of TB in children

TB in children is treated similar to that of adults with a few exceptions. The dose per weight in children is higher than in adults. The recently revised and accepted WHO daily dosage (range) recommendations are:

- Rifampicin: 15 mg/kg/d (10 to 20 mg/kg/day)
- Isoniazid: 10 mg/kg/d (10 to 15 mg/kg/day)
- Pyrazinamide: 35 mg/kg/d (30 to 40 mg/kg/day).
- Ethambutol: 20 mg/kg/d (15 mg to 25 mg/kg/d).

Recent evidence has shown that it is safe to use ethambutol in children as it has less ocular toxicity in children of all ages than thought of before. The purpose of the ethambutol, given as a 4th drug, is to prevent the emergence of drug resistance in the face of a larger bacillary load and prevent further broadening of the resistance spectrum if there is pre-existent isoniazid resistance. Ethambutol is therefore indicated for all new cases of childhood tuberculosis.

1. All children with diagnosed TB disease should be notified and receive a full course of directly observed TB treatment (DOT).
2. Once TB treatment is started, it should be completed unless an alternative diagnosis has been confirmed.
3. Fixed dose combinations enhance patient adherence and should be used. Dose adjustments based on weight changes should take place during the course of treatment.
4. Commencement of TB therapy should be documented on the Child Health Card (Road to Health Card) for children under 5 years of age.
5. Monthly weight should be documented on the TB treatment card and Child Health Card where applicable. Failure to gain weight may indicate poor response to therapy.
6. The treatment doses should be adjusted as soon as they change weight bands. Children weighing more than 30 kg should be treated using the adult treatment guidelines.

7. Children with severe malnutrition should be given drugs at the lower end of the dose range and closely watched for hepatotoxicity

4.8.1 Categories of TB Treatment in Children

Table 7: Categorisation of TB Cases for Treatment in Children

CATEGORY	DESCRIPTION OF TB CASE	REGIMEN
New Cases	-All forms of intra-thoracic disease without cavitation or extensive alveolar consolidation -Uncomplicated extra-pulmonary disease e.g. -TB lymphadenitis and Tuberculous pleural effusion. -Sputum smear-positive disease -Extensive parenchymal involvement on CXR -Cavitating pulmonary TB -TB pericarditis -Abdominal TB -All children with HIV co-infection	2HRZE/4RH
	-TB meningitis, miliary TB and osteo-articular TB	2HRZE/10RH
Retreatment	-Previously treated smear-positive pulmonary TB: -Relapse -Treatment after interruption -Treatment failure	2HRZES/ 1HRZE/5HRE

4.8.2 Treatment dosages by weight and category in children

A. Category I regimen

1. For children in the weight band of 3kgs - 10.9kgs (using pediatric formulations)

Intensive Phase: (RHZ)HE for 2 months, daily

WEIGHT BANDS (IN KGS)	RIFAMPICIN: ISONIAZID: PYRAZINAMIDE (DISPERSIBLE TABS) 60mg:30mg: 150mg	ADDITIONAL INH 100MG TAB	ETHAMBUTOL TABS 100MG
3 - 5.9	1½ tabs	¼ tab	1 tab
6 - 10.9	2 tabs	½ tab	2 tabs

Continuation Phase: (RH) for 4 months, daily (except in severe cases like TB meningitis and TB spine where this phase should be of 10 months)

Weight bands (in kgs)	Rifampicin:Isoniazid 60mg:60mg	Additional INH 100mg
3 - 5.9	1 tab	¼ tab
6 - 10.9	2 tabs	½ tab

2. For children in the weight bands of 11-30.9kgs and more, use adult kits with additional INH

Intensive Phase: (RHZE)H for 2 months

Weight bands (in kgs)	Rifampicin: Isoniazid: Pyrazinamide: Ethambutol tabs 150mg: 75mg: 400mg: 275mg	Additional INH 100mg tab
11 - 15.9	1 tab	1 tab
16 - 20.9	2 tabs	1 tab
21-30.9	2 tabs	2 tabs

Continuation Phase: (RH) for 4 months, daily (except in severe cases like TB meningitis and TB spine where this phase should be of 10 months)

	Rif: INH 150:75	Additional INH 100mg tab
11 - 15.9	1 tab	1 tab
16 - 20.9	2 tabs	1 tab
21 - 30.9	2 tabs	2 tabs

3. For children weighing more than 30.9kg, use adult kits, without additional INH:

Cat I = 2(RHZE)/4(RH), i.e. Intensive phase 2 months of (R150/H75/Z400/E275), then Continuation phase 4 months of (R150/H75)

B. Category II regimen (for all re-treatment cases, except for non-seriously ill defaulters)

1. For children in the weight band of 3kgs - 10.9kgs (using pediatric formulations)

Intensive Phase: (RHZES) for 2 months, and (RHZE) for the following 1 month, daily

Weight bands (in kgs)	Rifampicin: Isoniazid: Pyrazinamide (Dispersible tabs) 60mg:30mg: 150mg	Additional INH 100mg Tab	Ethambutol tabs 100mg	Streptomycin injections (for first 2 months only)
3-5.9	1½ tabs	¼ tab	1 tab	100mg
6-10.9	2 tabs	½ tab	2 tabs	200mg

Continuation Phase: (RH)E for 5 months, daily

Weight bands (in kgs)	Rifampicin:Isoniazid 60mg:60mg	Ethambutol 400mg
3-5.9	1 tab	¼ tab (16.9-33.3)
6-10.9	2 tabs	½ tabs (13.8-25)

2. For children in the weight bands of 11-30.9kgs and more, , use adult kits with additional INH

Intensive Phase: (RHZE)HS for 2 months, and (RHZE)H for following 1 month, daily

Weight bands (in kgs)	Rifampicin: Isoniazid: Pyrazinamide: Ethambutol tabs 150mg: 75mg: 400mg: 275mg	Additional INH 100mg tab	Streptomycin injections (for first 2 months only)
11-15.9	1 tab	1 tab	250mg
16-20.9	2 tabs	1 tab	400mg
21-30.9	2 tabs	2 tabs	500mg

Continuation Phase: (RHZ)H for 5 months, daily

Weight bands (in kgs)	Rif: INH:Eth 150:75:275	Additional INH 100mg tab
11-15.9	1 tab	1 tab
16-20.9	2 tabs	1 tab
21-30.9	2 tabs	2 tabs

4.8.3 TB meningitis, Osteo-articular TB and miliary TB in Children

These 3 conditions represent the most severe forms of TB in children and require the use of drugs that cross the blood brain barrier. Up to one third of cases of miliary TB will have meningeal involvement. The preferred doses of drugs are also higher:

- Isoniazid 15-20 mg/kg/day (maximum daily dose 400mg)
- Rifampicin 15-20 mg/kg/day (maximum daily dose 600mg)
- Pyrazinamide 30-40 mg/kg (maximum daily dose 2g)
- Ethambutol 15-25 mg/kg (maximum daily dose 500mg)

4.8.4 Re-treatment Cases

Attempts should be made to establish the microbiological diagnosis when a child presents with a second episode of TB.

4.9 Adjuvant therapy

Steroids (usually oral prednisolone) should be used for the following forms of complicated TB:

- TB Meningitis where mortality is reduced
- TB pericarditis where the risk of developing constrictive pericarditis is reduced
- Severe airway obstruction from lymph node compression where steroid use may reduce the obstruction and subsequent need for surgical intervention.
- Oral prednisolone 2mg/kg/daily (maximum 60mg daily) is given for 4 weeks and tapered over 2 weeks (duration of steroid treatment 6 weeks).

4.10 Pyridoxine supplementation

INH may cause symptomatic pyridoxine deficiency, which manifests as peripheral neuropathy. It is recommended that the following categories of children receive 5-10mg/kg of supplemental pyridoxine:

- malnourished
- TB-infected
- breastfeeding infants
- adolescents
- children on high-dose INH therapy (>10mg/kg/day)
- children with diabetes mellitus
- children with renal failure

4.11 Monitoring therapy

Remember to assess nutritional status of every child and manage according to national guidelines

Children should be reviewed 2 weeks after starting therapy and monthly thereafter. The following should be done: symptom assessment and clinical examination, weight check, adherence and adverse events. Response to therapy is assessed by clinical response, weight gain and improvement in general well-being. Radiological features such as mediastinal lymph node enlargement may persist for more than year after successful treatment therefore CXR should not be routinely used to monitor.

4.11.1 Paradoxical Reactions

Temporary exacerbation of signs and symptoms and radiological features can occur following initiation of anti-tuberculous therapy in both HIV-infected and uninfected children. This is a result of immune reconstitution and inflammatory responses due to nutritional recovery, the TB treatment or antiretroviral therapy in TB-infected children. Clinical improvement in terms of weight gain is observed in these children despite a worsening of the clinical features. TB therapy and antiretroviral therapy should be continued unless there are life-threatening symptoms.

4.12 TB and HIV in children

- HIV makes the diagnosis and management of TB more difficult because:
- HIV -associated chronic pulmonary disease and TB present in a similar way.
- The tuberculin skin test is less reliable in the presence of HIV infection
- The HIV pandemic has led to increased prevalence of TB in adults and consequently increased risk of TB infection in the children. Early mortality due to TB (and HIV co-infection) in adults has resulted in large number of orphans without adequate care.
- Just as in adults, all children who are suspected of having TB should be offered HIV counselling and testing.
- HIV -infected children are at higher risk for TB infection and TB disease than HIV -uninfected children.
- HIV infected children are more likely to have more severe disease and therefore require a 4th drug (ethambutol) during the intensive phase.
- HIV -infected children receiving TB therapy should also receive supplemental pyridoxine.
- Cotrimoxazole prophylaxis should be given.

The co-management of TB/ HIV with anti-TB drugs and ART is complicated by the following: high pill burden and therefore potential for non-adherence, overlapping toxicities and drug-drug interactions leading to altered pharmacokinetics. There is also the possibility of worsening of the signs and symptoms upon ART initiation (IRIS).

4.12.1 Guidelines for use of ART in TB/HIV co-infection in Children

The optimal time for initiating ART is not known, but evidence from adults favours an early rather than delayed start. The following are recommendations of when to start ART when there is TB/HIV co-infection:

1. Extra-pulmonary TB (except lymph node TB): start ART between 2-8 weeks after start of TB therapy
2. Pulmonary TB and lymph node TB: If CD4 count or % are below the threshold for starting ART, start ART between 2-8 weeks after start of TB therapy
3. If there is no facility for CD4 measurement, and there is an excellent response to TB therapy, ART can be delayed till the end of TB treatment. If there is a poor clinical response to TB therapy, start ART between 2-8 weeks after start of TB therapy.

4.12.2 ART regimens in children and infants already started on anti-TB therapy

Rifampicin interacts with the NNRTI and PI classes of ART drugs because of similar metabolic pathways. Rifampicin decreases EFV levels by 20% but serum levels remain adequate to suppress the virus in vitro. EFV is therefore the preferred NNRTI to nevirapine. However, EFV cannot be used in children <3years and/or <10kg body weight.

The following are ART regimen choices in a child who is already started anti-TB therapy:

Table 8: ART Regimen in Child already on Anti-TB treatment.

Preferred 1st line ART regimen:		
Triple NRTI:		d4T+3TC+ABC AZT+3TC+ABC
Alternative 1st line ART regimen:		
1.	Children >3yr of age or >10kg 2 NRTI+ EFV	d4T+3TC+EFV AZT+3TC+EFV
2.	Children <3yr of age or <10kg and Infants with prior NNRTI (NVP) exposure 2 NRTI + boosted LPV/r or NVP at maximum dose	d4T+3TC+LPV/r (or NVP) AZT+3TC+LPV/r (or NVP)

NB: LPV/r needs additional boosting with ritonavir to reach mg equivalence (0.75ml ritonavir per ml of LPV/r)

- NVP should be started at maximum dose (bd) in children receiving rifampicin to avoid sub-therapeutic NVP levels.
- Where there is no boosted LPV/r, NVP should be used at its maximum dose based on 200mg/m² body surface area rather than per body weight, mg/kg. Body surface area (BSA) is calculated using the formula: $BSA (m^2) = \left(\frac{[Height(cm) \times Weight(kg)]}{3600} \right)$ or in inches and pounds: $BSA (m^2) = \left(\frac{[Height(in) \times Weight(lbs)]}{3131} \right)$.

4.13 Prevention of TB in children

See Chapter 9.

4.14 Directly observed treatment (DOT) in Children

A treatment supervisor should be identified, and this will usually be the caregiver. Many children with TB are orphans. Adherence to INH preventive therapy can be monitored at Family and Child Health clinics. Good records and proper notification are paramount for successful treatment.

CHAPTER 5

Drug-resistant Tuberculosis

5.1 Introduction

Drug resistant TB (DR-TB) is the presence of bacilli resistant to one or more anti-tuberculosis drugs and includes multidrug-resistant tuberculosis (MDR-TB) and extensively drug-resistant TB (XDR-TB).

MDR-TB, which is TB caused by bacilli that are resistant to at least isoniazid and rifampicin, the two most powerful first-line anti-TB drugs, continues to be a great threat to the control of TB disease. Recently, the emergence of XDR-TB defined as MDR-TB that is resistant as well to any one of the fluoroquinolones and to at least one of three injectable second-line drugs (amikacin, capreomycin or kanamycin), has heightened this threat. It would seem that no country is exempt, as XDR-TB has been identified in all regions of the world since 2006. In the African Region, by the end of December 2009, 33 countries had reported at least a case of MDR-TB, and eight of them including neighbouring countries of Botswana, Lesotho, Mozambique, the Republic of South Africa and Swaziland has also reported at least a case of XDR-TB. Treatment outcomes are significantly worse in XDR-TB patients than in MDR-TB patients.

5.2 Definitions

- Drug-resistant tuberculosis (DR-TB):
- The presence of bacilli resistant to one or more anti-tuberculosis drugs (this can be in patients with or without prior treatment for TB)
- Multi-drug resistant tuberculosis (MDR-TB):
- The presence of bacilli resistant to at least isoniazid and rifampicin.
- Extensive-drug Resistant Tuberculosis (XDR-TB)
- the presence of TB bacilli resistant to both isoniazid and rifampicin plus resistance to at least a flouoroquinolone and an injectable anti-TB drug

5.3 Causes of drug-resistant tuberculosis (DR-TB)

DR-TB is a man-made problem and can be due to one or more of the following:

- Health worker related factors:
1. Lack of knowledge of and Inappropriate use of guidelines for the management of TB cases
 2. Non- compliance with the national treatment guidelines
 3. Inadequate monitoring of patients on anti-TB treatment
- Health system related factors:
1. Poor quality anti-TB medicines
 2. Poor storage conditions for anti-TB medicines resulting in low bioavailability

3. Stock outs of certain anti-TB medicines due to poor stock management
4. Absence of clear guidelines or out dated guidelines
5. Poor or inadequate training of health workers to provide TB services
6. Poor supervision and monitoring of TB activities

Patient related factors:

1. Poor adherence
2. Lack of information about TB and its management HCWs factors
3. Patient has difficulties accessing the health facility e.g no money for transport, charging of consultation fees etc System factors failure to provide enabling environment.
4. Experiencing adverse drug effects
5. If patient has an alcohol or drug abuse problems and fails to adhere to treatment

5.4 Prevention of MDR-TB

MDR-TB is difficult and expensive to treat. Treating a case of MDR-TB may be as high as 25 times the cost of treating an uncomplicated drug-susceptible case. Therefore due diligence should be taken when managing TB cases and the principles of the DOTS strategy should be adhered to. In our setting of high HIV burden, an untreated case of MDR-TB can infect large numbers of HIV positive individuals, rapidly leading to significant outbreaks of MDR-TB with high case fatalities.

Adequate anti-TB treatment is the key to prevention of MDR-TB. In new patients, the best prevention is to ensure that each patient completes an adequate course of category I treatment, with appropriate weight-adjusted doses of anti-TB drug doses. All treatment regimens containing rifampicin should be directly observed preferably by a health care worker at least during the intensive phase of TB treatment.

In previously treated patients who remain sputum smear-positive after the first course of anti-TB treatment, category II treatment given under direct observation can cure the majority of patients. In situations where DR-TB is being produced, the programme needs to identify and correct the causes shown in Section 5.3 above. Early identification of DR-TB and adequate treatment regimens (Category IV regimens) administered early in the course of the disease are essential to stop primary transmission.

MDR-TB treatment is less successful than category I treatment of TB patients with susceptible strains. Even with early and extensive treatment, the cure rate among HIV-negative MDR-TB patients is at its best 50-60%. The long-term treatment success rates are lower due to relapses. In HIV-positive patients outcomes are less favourable than in HIV negative patients.

The National TB Control Programme must ensure that regular and sufficient stocks of quality controlled anti-TB drugs are available in the country at all times. PMDs, central hospitals and local authority health departments should register all TB patients to facilitate correct estimation of annual anti-TB drug requirements.

NOTE: The priority is prevention of MDR-TB plus early identification and appropriate management of MDR-TB

In the event that a Medical Officer suspects MDR TB, a sputum sample must be sent to the NTBRL or NMRL depending on the region of the health institution. If the results do confirm MDR TB, the Medical Officer must contact the regional MDR TB team (Bulawayo and Harare City lead the two teams) before transferring the patients. Meanwhile screening of household contacts should be conducted and provision of health education on infection control and possible duration of treatment should commence so that the patient and relatives know the nature of the condition.

Patients with resistance to multiple drugs always have a long and unfortunate history of therapeutic errors, which are sometimes difficult to detect. Always take a detailed and directed history of previous drugs.

CHAPTER 6

Treatment of tuberculosis

6.1 Introduction

This chapter provides a review of the use of anti-TB drugs in the treatment of TB. It looks at the aims of treatment, directly observed treatment (DOT), the means of ensuring that patients receives the right drugs, and it outlines standardized treatment regimens for the different categories of adult patients. It briefly mentions the other treatment supports that enable TB patients to complete treatment and describes treatment of TB in other specialised situations.

The aims of treatment are to:

- Cure the patient and ensure full quality of life
- Prevent death from TB or its complications
- Prevent relapse of TB
- Decrease transmission of TB
- Prevent the development and transmission of drug resistant TB

6.2 Directly observed treatment (DOT)

Directly observed treatment is one of the core elements in the DOTS strategy. This requires a supervisor to watch a patient swallowing the tablets. This ensures that the patient takes right drugs, in the right doses and completes the treatment. The best supervisors are health workers and community health workers and least being family members/guardians.

Once a diagnosis of TB is made it is the responsibility of the health care worker to ensure that the patient is notified and registered, and completes the full course of TB treatment. All TB patients should be treated on ambulatory basis, with the exception of severely ill patients. Patients with confirmed DRTB should be managed according to National DRTB guidelines.

6.3 Essential anti-TB drugs

The five first line drugs (FLDs) that are the main stay of TB treatment are:

- Isoniazid (H)
- Rifampicin (R)
- Pyrazinamide (Z)
- Ethambutol (E)
- Streptomycin (S)

It is important to use multiple drug therapy to attack the bacilli in their different states within the body . The three drugs (H,R,Z) are combined to provide modern short course chemotherapy (SCC) of TB. Ethambutol is added in case there may be pre-existing resistance to one of these drugs. The drugs are also given in combination to prevent the development of drug resistance; it is very unusual for one bacillus that has never been exposed to anti-TB drugs to be resistant to more than one drug. The other drugs therefore kill all possible resistant bacilli.

6.4 Phases and duration of TB Treatment

All TB treatment is delivered in two phases:

1. **Intensive Phase:** the initial, intensive phase is designed for rapid killing of actively growing bacilli and killing of semi- dormant bacilli. The duration of this phase is 2 - 3 months.
2. **Continuation phase:** this phase eliminates bacilli that are still multiplying and reduces the rate of failure and relapses. The duration is between 4 -6 months depending on the severity of the disease and previous treatment history.

6.5 Standardized Regimens

All patients in a particular group are given the same treatment regimen. Standardized regimens have the following advantages over individualized prescription of drugs:

- Facilitate estimates of drugs needs, purchasing, distribution and monitoring
- Reduce errors in prescription thereby reducing the risk of development of drug resistance
- Facilitate staff training
- Reduce costs
- Facilitate regular drugs supply when patients move from one area to another

6.6 Initiation of Treatment

Due to human resource constraints and for the convenience of patients, patients who are confirmed smear positive by bacteriology (microscopy or culture) can be immediately started on the appropriate regimen by clinicians (doctors and nurses) at the point of diagnosis. It is imperative that the patient is notified and registered into the District TB register (see chapter 8). It is just as crucial that these patients are monitored and followed up as recommended (see chapter 7).

6.7 Treatment of New Cases of TB in Adults (CATEGORY I)

New cases of TB, those who have never taken or have taken anti-TB treatment for less than one month, are given 6 months of treatment consisting of:

Intensive phase: HRZE given daily for 2 months

Continuation phase: HR given daily for 4 months

New TB Patient: 2HRZE/4HR

The use of the combination of isoniazid and ethambutol (HE) in the continuation phase has been phased out in Zimbabwe.

In sputum smear-positive cases, if the sputum is still positive at the end of two months, the extension of the intensive phase is not longer necessary. The continuation phase of 4 months is started. The total duration of treatment is 6 months.

6.8 Treatment of Extra-pulmonary TB

Patients with EPTB are given the standardised treatment regimen for 6 months as above except for those with TB of the meninges, bone, joint, pericardium, disseminated or spinal disease with neurological complications who should have a prolonged continuation phase of six months, i.e. 2HRZE/6HR. Streptomycin should be used instead of ethambutol in case of TB meningitis.

6.9 All previously treated cases of any form of TB (CATEGORY II)

All previously treated cases of any form of TB are given "standard re-treatment regimen with first line drugs" for 8 months:

Intensive phase: SHRZE given daily for 2 months followed by HRZE given daily for 1 month

Continuation phase: HRE given daily for 5 months

Previously treated TB Patient: 2SHRZE/1HRZE/5HRE

The re-treatment regimen is the last opportunity for the sputum positive patient to be cured.

Intensive phase: 2SHRZE/1HRZE

Five drugs: isoniazid, rifampicin, ethambutol, pyrazinamide supplemented with streptomycin are given for the first two months, followed by the same drugs without streptomycin for another four weeks (under direct observation). Streptomycin is not given for more than 2 months because of the risk of damage to hearing.

If at the end of the initial three months the sputum is smear negative or positive the continuation phase is started. If the sputum smear is positive at three months (12 weeks), another sputum sample should be collected at the end of four months. If the patient is still smear positive at the end of four months, all drugs should be stopped for three days and a sputum specimen sent to the National Reference Laboratories for culture and susceptibility testing.

Continuation phase: 5HRE

Five months of daily isoniazid, rifampicin and ethambutol (under direct observation).

Patients who remain smear positive after the end of a fully supervised continuation phase will derive no benefit from another re-treatment regimen, should be classified as previously treated failure cases and referred to specialised centres. Refer to DR-TB guidelines.

6.10 Fixed Dose Combination of anti-TB Drugs

The essential anti-TB drugs now come in fixed dose combinations (FDCs) such that each tablet has 2 (2-FDC), 3 (3-FDC), or 4 (4-FDC) drugs. The FDCs available in Zimbabwe are:

- Rifampicin, Isoniazid, pyrazinamide and ethambutol: (RHZE)
- Rifampicin, Isoniazid and ethambutol: (RHE)
- Rifampicin and isoniazid: (RH)

The benefits of FDCs are:

- Less pill burden (maximum of 5 instead of 15-16 tablets per day) therefore better compliance.
- Simplifies both treatment and management of drug supply.
- Reduced chance of development of drug resistance, as all drugs are guaranteed to be taken together with no chance of monotherapy.

The number of FDC tablets is determined by a weight range of each patient at the start of treatment and this is shown in the Tables 9 and 10 below.

Table 9: New adult (> 12 years) - Number of FDC tablets per day for each Weight band

Patient's Weight	Initial phase (2 months) 2(RHZE) daily (Isoniazid 75mg+ Rifampicin 150mg + Pyrazinamide 400mg + Ethambutol 275mg)	Continuation Phase (4 months) 4(HR) daily (Isoniazid 150mg + Rifampicin 150mg)
30-39kg	2	1.5
40-54kg	3	2
55-70 kg	4	3
70kg +	5	3

Table 10: Retreatment in Previously treated adult (> 12 years)

Patient's Weight	Initial Phase (3 months) 2(RHZE)S / 1(RHZE) daily (Isoniazid 75mg+ Rifampicin 150mg + Pyrazinamide 400mg + Ethambutol 275mg)	Streptomycin (IM) 2 months	Continuation (5 months) 5(HRE) daily (Isoniazid 75 mg + Rifampicin 150 mg + Ethambutol 275mg)
30-39 kg	2	0.50g	2
40-54 kg	3	0.75g	3
55-69 kg	4	1 g*	4
70 kg +	5	1 g*	5
*0.75 g if 60 years or over.			

6.11 Recording patient information (filling out the TB treatment card)

Tuberculosis is a chronic disease which requires long duration of treatment. Under the National TB control programme, this takes 6-8 months. Thus, in order to keep track of every patient and to report on him/her appropriately, we need to document every step

of the management process. Detailed information on every patient is very important. Careful recording of information also improves patient care and management and enables assessment of programme activities and performance.

The TB treatment card is a record of all the details of a TB patient, including his or her personal details, information about the diagnosis, classification and category of TB and the HIV status. The details of the treatment regimen and actual doses prescribed are recorded. A record is also made of when doses are taken and whether these are supervised or not. A treatment Card is shown in Annex 9.

Important points to remember about completing the front of the TB treatment card are:

- The full name of the patient and other popular names,
- Full details of how to find the patient or complete physical address -not the postal address.
- The District TB number is the number given to the patient from the TB register. This number is added to the TB treatment card at the time the patient is registered.
- The health facility where the patient is registered and receiving treatment (either the diagnostic or treatment centre) is also recorded on the treatment card.
- The details of whether the patient has sputum positive or negative, pulmonary or extra-pulmonary, and new or re-treatment TB are all recorded on the TB treatment card.
- The treatment category and doses of drugs are also recorded in the boxes.
- The pre-treatment weight is recorded at diagnosis and used to calculate the correct doses of drugs. At review appointments weigh patient at each visit and adjust treatment accordingly.

6.12 Treatment of Drug Resistant TB

Where patients remain or become smear positive after completing a fully supervised retreatment regimen, there is a very high likelihood of multidrug-resistant tuberculosis, and such cases should be managed according to the DR guidelines.

Note: Although smear negative PTB and extra-pulmonary cases may also be treatment failures, relapses or chronic cases, this is a rare event and should be supported by pathological and/or bacteriological evidence.

6.13 Management of TB and HIV co-infection

The association between TB and HIV is now well documented with an estimated 72% of TB patients in Zimbabwe co-infected with HIV. Management of TB and HIV requires close collaboration between the NTP and AIDS programmes. This will help reduce the burden of TB in HIV and the burden of HIV in TB patients.

The activities to be undertaken in the management of TB/HIV co-infected persons are summarised below.

Summary of Management of TB/HIV co-infection

1. HIV testing and counselling should be routinely offered to all persons suspected or known to have TB
2. HIV-related prevention, care and support services should be routinely offered to all persons suspected or known to have TB
3. Case definitions and anti-TB treatment regimens are the same for HIV-positive and HIV-negative TB patients, and drug dosages in mg/kg are also the same.
4. In TB HIV co-infection the first priority is to initiate anti -TB treatment followed by CPT, and then ART
5. All TB patients co-infected with HIV should be given co-trimoxazole preventive therapy (CPT) for the whole duration of TB treatment.
6. All people living with HIV with active TB disease, irrespective of CD4 cell count and the site of TB disease, should be initiated on ART as soon as practicable . See National ART guidelines.
7. All PLHIV should be screened for TB at every contact with health services
8. PLHIV who develop TB should be started anti-TB treatment immediately.
9. TB/HIV patients benefit from the use of steroids for the same indications as found in HIV-negative TB patients

In TB Meningitis streptomycin replaces ethambutol because ethambutol is not able to cross the blood brain barrier.

6.14 Treatment regimens in special cases

6.14.1 *Pregnant women*

Every woman of childbearing age should be asked whether she is pregnant before commencing anti-TB treatment. Most anti-TB drugs are safe in pregnancy, except for streptomycin, which is ototoxic to the foetus and should be omitted. The successful outcome of pregnancy depends on the successful completion of TB treatment.

6.14.2 *Breastfeeding women*

Full TB treatment is safe, and is the best way to prevent transmission of TB to the baby. If the mother has smear-positive TB then the baby should receive INH preventive treatment (10 mg/kg for 6 months), followed by BCG vaccination, as described in Chapter 4: Tuberculosis in Children under Five Years of Age. As far as possible, mother and child should stay together for the entire duration of treatment.

6.14.3 *Women taking the oral contraceptive pill*

Rifampicin reduces the efficacy of the contraceptive pill. Dual protection through both hormonal and barrier methods is recommended.

6.14.4 *Patients with liver disorders and established chronic liver disease*

Provided there is no clinical evidence of chronic liver disease, patients with the following conditions can receive the usual short-course chemotherapy: hepatitis virus carriage, a past history of acute hepatitis, and excessive alcohol consumption.

Patients with chronic liver disease should not receive pyrazinamide. Safe drugs in such patients are INH, rifampicin plus one or two non-hepatotoxic drugs such as ethambutol or streptomycin which can be used for a total of four months.

6.14.5 Acute hepatitis (e.g. acute viral hepatitis)

It may be prudent to defer treatment in some cases, while in others it may be necessary to continue with anti-TB treatment. It is wise to consult with or refer to a specialist.

6.14.6 Patients with renal failure

INH, rifampicin and pyrazinamide are excreted almost entirely by the hepatobiliary system or metabolised into non-toxic compounds. In severe renal failure, give pyridoxine to prevent INH-induced peripheral neuropathy. Streptomycin and ethambutol are excreted by the kidneys, and should be avoided unless there is specialised care. The safest regimen to give in renal failure is 2HRZE/4HR.

6.15 Role of adjuvant steroid therapy

Steroids are often beneficial as adjuvant therapy in some form of TB disease.

6.15.1 Indications for steroids

- TB meningitis (decreased consciousness, neurological deficits, and spinal block)
- TB pericarditis (with effusion or constriction)
- TB pleural effusion (large with severe symptoms). Drainage through a wide-bore intravenous canula often relieves the acute distress and improves the prognosis by reducing the risk of pleural scarring and encasement.
- Massive lymphadenopathy with pressure effects
- Severe hypersensitivity reactions to anti-TB drugs
- More rarely: hypo-adrenalism, renal tract TB (to prevent ureteric scarring) TB laryngitis with life-threatening airway obstruction

6.15.2 Dose for Steroid Therapy

Table 11: Recommended doses of adjuvant steroid therapy

Indication	Prednisolone treatment
TB meningitis	60 mg/d for 4 weeks then taper off
TB pericarditis	60 mg/d for 4 weeks, then 30 mg/d for 4 weeks then taper off over several weeks
TB pleural effusion	40 mg/d for 1-2 weeks then taper off over several weeks

NOTE:

Any care provider treating a patient for TB assumes a public health function that includes not only prescribing an appropriate regimen, but also ensuring adherence to the regimen until treatment is completed. ISTC Standard 7.

CHAPTER 7

Monitoring TB Treatment

7.1 Introduction.

This chapter describes how to monitor the patient during treatment including monitoring drug adherence, the response to treatment and actions to take from the results obtained and preventing and managing TB drug side effects.

7.2 Monitoring of patient during treatment

Once a patient with TB is started on treatment, he/she must be followed up regularly. The frequency of monitoring depends on the level of care. At the health facility level, this is usually every month by the clinician and daily by the DOT nurse; at the Community level, the treatment supporter should monitor the patient daily during the intensive phase and at least weekly during the continuation phase. All patients on treatment should be monitored to know whether he/she is:

- Adhering to the treatment, i.e. taking the treatment as per regimen, and
- Responding to treatment and/or
- Having problems with the treatment.
- Monitoring also enables patients to complete their treatment.

7.3 Drug Adherence

As stated before, each patient must take the right regimen at the right dose for the right duration until end of treatment. It is not only the duty of the patient to take his/her drugs but it is also the duty of the health care system, particularly the facility health care workers who are treating the patient, to ensure this. This is drug adherence and is an on-going activity.

Every health care worker must use every contact with a TB patient to ensure that drug adherence is as near to 100% as possible

Therefore

1. Ask the patient:
 - a. If he/she is taking the drugs,
 - b. How many are left (ask to see the tablets he/she has brought in and count them and compare with what was dispensed and what is expected),
 - c. What time he/she takes each drug and
 - d. Whether he/she takes the drugs before meals or after meals.
2. Check and see if the patient is regularly obtaining treatment - review his/her Tuberculosis Treatment Card and see if drugs were collected and taken at the scheduled times.

7.4 Response to Treatment

The primary aim of treatment is to cure the patient. Treatment should result in improvement of the patient and decrease in symptoms within a reasonable time. At each visit, you must therefore monitor the patient to see if he/she is improving.

Monitoring the response to treatment involves:

- Clinical monitoring
- Bacteriological monitoring

7.4.1 Clinical Monitoring

Clinical monitoring must be done for all patients. For cases of TB where bacteriological monitoring cannot be done (EPTB) this is the only way of monitoring response to treatment. Clinical monitoring consists of re-taking history and performing physical examination as appropriate. Check the weight of each patient, ask about his/her well being and ask if the previous symptoms were still present or not at each visit to the clinic. A patient who is doing well will progressively have increased energy, feel better, increased appetite, increase in weight and have a decrease, if not disappearance, of symptoms and signs.

7.4.2 Bacteriological Monitoring

This is using sputum smear microscopy to monitor the response to treatment. In special situations such as cases of suspected treatment failure after a course of retreatment regimen, mycobacterium culture may also be used in bacteriological monitoring. Examination of sputum smears for conversion from positive to negative is the best indicator that the treatment is being taken regularly and that it is effective.

For most people on treatment, the sputum becomes sterile, i.e. any bacilli in it are dead, after two weeks of treatment. After 2 months of chemotherapy, more than 80% of new pulmonary smear-positive cases should be smear-negative and after 3 months, the rate should increase to at least 90%.

NOTE: Routine use of Chest-Xray in monitoring patient response to treatment is unnecessary, wasteful of resources and is not recommended

Sputum specimens of smear-positive patients will convert to smear-negative and will remain smear-negative when the patients take their prescribed medication on a regular basis for the required period.

A positive sputum at the end of the intensive phase should trigger a review of the quality of supervision and support provided by the programme and the adherence to treatment by the patient and appropriate remedy provided.

The schedule of sputum smear examination, what the results mean and what to do depending on the results are shown in Table 13.

Table 12: Bacteriological monitoring using Sputum Smear microscopy applied to treatment categories and actions to take based on the results obtained.

Category	Sputum examination, interpretation and actions to take.
New sputum smear positive PTB	<p>Examine sputum at end of months 2, 5, 6.</p> <p>If positive at:</p> <p>End of month 2 then:</p> <ul style="list-style-type: none"> - Start continuation phase - Repeat sputum smear exam at the end of month 3 <p>End of month 3 then:</p> <ul style="list-style-type: none"> - Send sputum for culture and DST. - If necessary, modify treatment regimen when DST results are available - see DR-TB Treatment Guidelines. <p>End of month 5 or 6:</p> <ul style="list-style-type: none"> - Assess outcome as treatment failure, - Close patient's treatment card, - Re-register the patient as treatment failure - Take sputum for culture and DST and - Put him/her on Retreatment regimen. - Consult the Regional MDR TB Team when DST results are available - see National DR-TB Treatment Guidelines
New sputum smear negative TB	<p>Examine sputum at month 2 only, thereafter by clinical monitoring.</p> <p>If positive at month 2 then:</p> <p>Check laboratory to make sure there were no errors either with the initial or present report.</p> <ul style="list-style-type: none"> • If no error then there is disease progression despite treatment so: <ul style="list-style-type: none"> - Take sputum for culture and DST, - Start continuation phase - Repeat sputum exam at the end of month 3. • If negative at end of month 3 then: <ul style="list-style-type: none"> - Consult the Regional MDR TB Team when DST results are available - see National DR-TB Treatment Guidelines. • If positive at end of month 3 then: <ul style="list-style-type: none"> - Assess treatment outcome as treatment failure, - Close the patient's register and treatment card, - Re-register patient - Take sputum for culture and DST and - Put him/her on Retreatment regimen. Consult the Regional MDR TB Team when DST results are available - see National DR-TB Treatment Guidelines

Category	Sputum examination, interpretation and actions to take.
Previously treated sputum smear positive PTB.	<p>Examine sputum at the end of Months 3, 5, 8.</p> <ul style="list-style-type: none"> • If sputum positive at: End of month 3 then: <ul style="list-style-type: none"> - Take sputum for culture and DST. - Start the continuation phase. Consult the Regional MDR TB Team when DST results are available - see National DR-TB Treatment Guidelines. <p>Examine sputum at Month 4 only if positive at month 3.</p> <ul style="list-style-type: none"> • If at the end of 4 months the sputum is still positive then: <ul style="list-style-type: none"> - Repeat sputum culture and susceptibility. - Continue the continuation phase. Consult the Regional MDR TB Team when DST results are available-see National DR-TB Treatment Guidelines.
Children	Examine sputum at the end of months 2, 5, 6 in children who produce sputum. Manage as for adults above.

7.5 Outcome assessment and recording

The performance of the TB control programme is assessed at various stages and levels but of paramount importance is the outcome available for every patient registered and managed. Treatment outcome assessment shall be done for all patients at the end of the treatment. This information, so far, is available on the patient treatment card, DOT register and District TB register. Accurate and complete recording of the treatment card thus enable us to monitor our patients and the progress of our health units with regards to achieving local and national targets.

Various treatment outcomes are indicated on the reverse of the treatment card. For most patients the treatment outcome is decided at the end of the treatment period. However, for a few patients it can be decided earlier (for example transfers out or deaths).

At the end of the treatment course for each patient the District TB Coordinator should record the treatment outcome in the District TB Register, as per definitions shown in Table 14 below.

Definitions of Standardised Treatment Outcomes

Cure	A patient whose sputum smear or culture was positive at the beginning of treatment and who was sputum smear- or culture-negative in the last month of treatment and on at least one previous occasion.
Treatment completed	A patient who has completed treatment but who does not have a negative sputum smear or culture result in the last month of treatment and on at least one previous occasion. The sputum-smear or culture may not have been done or the results are not available.

Treatment success	The sum of patients who were initially sputum smear or culture positive and were cured and those who completed treatment.
Treatment Failure	<p>Patient who is sputum smear- or culture-positive at 5 months or later during treatment.</p> <p>Patient who was initially smear-negative before starting treatment and became smear-positive after completing the intensive phase of treatment.</p> <p>Any patient who is found to have MDR-TB at any point of time during the treatment, whether they are smear-negative or -positive.</p>
Died	Patient who dies for any reason during the course of treatment
Default	Patient whose treatment was interrupted for two consecutive months or more
Transfer out	Patient who has been transferred to another recording and reporting unit and for whom the treatment outcome is not known.

7.6 Approach to Management of Adverse Drug Effects

All health staff should know, and be able to recognise and manage the common side effects. All TB patients should always be informed on starting treatment about the possibility of side effects and what to do if any develops.

Most TB patients complete their treatment without any significant adverse drug effects. However, a few patients do experience adverse drug effects. In general, a patient who develops minor adverse effects should continue with the TB treatment and be given symptomatic treatment. If a patient develops a major adverse effect, the treatment or the offending drug should be stopped. Further management depends on the nature of the adverse reaction and is shown in Table 13. Patients with major adverse reactions should be managed in hospital. TB treatment is withheld until the affected organ or system returns to normal, usually in 2-3 weeks. Afterwards you can try reintroduction of the treatment with possible desensitisation (see below).

7.6.1 The Adverse Drug Effects of Anti-tuberculosis drugs.

Adverse drug effects (ADEs) of anti-TB drugs are classified into major and minor ones and are shown in Table 13. This shows a symptom-based approach to their management.

Table 13: Symptom-based approach to adverse effects of TB drugs

Side Effects	Drug Probably Responsible	Management
Minor		Continue anti-TB drugs, check drug doses
Anorexia, nausea, abdominal pain	Pyrazinamide Rifampicin	Give drug last thing at night. May give ranitidine, omeprazole, or antacid
Joint pains	Pyrazinamide	Aspirin, Ibuprofen or paracetamol
Burning sensation in feet	Isoniazid	Give Pyridoxine 100 mg daily
Skin rash with mild itchiness, no mucous membrane involvement or blisters	Most anti-TB drugs	Chlorpheniramine 4 mg tds or Promethazine 25-50 mg at night. Aqueous cream, Calamine skin lotion.
Peripheral neuropathy	Isoniazid	Pyridoxine 50 mg 1-3 times daily
Orange/red urine	Rifampicin	Reassure patient. Let patient know this before treatment.
Major		Stop responsible drugs. Refer patient to a medical officer and/or admission.
Itching of skin with rash, mucous membrane involvement, blistering	Thiacetazone Streptomycin Rifampicin Isoniazid, Pyrazinamide	Stop anti-TB drugs and refer to hospital
Deafness (no wax on auroscopy)	Streptomycin	Stop Streptomycin Use ethambutol
Dizziness (vertigo and/or nystagmus)	Streptomycin	Stop anti-TB drugs
Jaundice (other causes excluded)	Most anti-TB drugs (especially HZR)	Stop anti-TB drugs. Do liver function tests.
Vomiting & confusion: suspect drug-induced acute liver failure	Most anti-TB drugs	Refer to hospital for admission. Stop anti-TB drugs, do urgent liver function tests, HBsAg and prothrombin time
Visual impairment (other causes excluded)	Ethambutol	Stop Ethambutol
Shock, purpura (bleeding under the skin), acute renal failure	Rifampicin	Stop Rifampicin

7.6.2 Prevention and Management of Peripheral neuropathy

Certain adverse effects can be prevented by drug administration; for example, isoniazid induced peripheral neuritis. This usually presents as numbness, tingling or burning in the feet. It often occurs in: pregnant women, alcoholics, chronic liver disease, HIV, malnutrition and diabetes. Give such patients 10 mg pyridoxine daily for the whole duration of treatment to prevent the side effects. For treatment in those who develop peripheral neuropathy the dose of pyridoxine is 50 mg up to three times daily.

7.6.3 Management of skin reactions

If a patient develops itching without a rash and there is no obvious cause (e.g. scabies), the recommended approach is to try symptomatic treatment with anti-histamines, continue anti-TB treatment and observe the patient closely. However, if a skin rash develops, then all anti-TB drugs must be stopped. Once the reaction has resolved, anti-TB drugs can be cautiously re-introduced.

If a patient develops itching with a rash especially with a fever it is essential to stop all anti-TB drugs at once. Do not wait to see the widespread rash with peeling skin, blisters or raised red spots of severe allergic reaction called Steven Johnson's syndrome. The eyes and/or mucous membranes may also be affected. This patient is very ill with fever, hypotension and is a medical emergency. Such a patient may need intravenous fluids and high dose steroids (60 mg prednisolone a day). Such a patient must never receive the offending drug again. In view of this severe reaction, all health workers should take the smallest itching skin rash seriously and stop all drugs as above. You may have to apply Chloramphenicol eye ointment to the patient's eyes if they are involved, give a course of antibiotics (e.g. amoxicillin plus clavulanic acid) if the blisters look infected. Anti-TB treatment is only restarted once the skin reaction has completely resolved, usually up to 4 weeks and more depending on the severity.

7.6.4 Management of drug-induced hepatitis

Most anti-TB drugs can damage the liver. Isoniazid, pyrazinamide and rifampicin are most commonly responsible. Ethambutol and streptomycin are rarely responsible. When a patient develops hepatitis during anti-TB treatment, it may be due to the anti-TB treatment or other cause. It is important to rule out other possible causes before deciding that the hepatitis is drug-induced. If the diagnosis is drug-induced hepatitis then stop the anti-TB drugs and check the liver function tests regularly. After jaundice has resolved, the same regimen can often be re-introduced (see below).

If drug-induced hepatitis has been severe, then it is advisable to avoid pyrazinamide and also rifampicin. Refer patient to a medical officer. A suggested regimen in such patients is a two-month initial phase of daily streptomycin, isoniazid and ethambutol followed by a ten-month continuation phase of isoniazid and ethambutol (2SHE/10 HE). Note that pyrazinamide is not used because it is selectively metabolised by the liver only.

7.6.5 Re-introduction of anti-TB drugs and Desensitization following drug reaction.

The reintroduction of treatment and desensitisation should not be attempted in patients who have developed severe toxic reactions. In such cases that are life threatening, a new regimen not including the implicated drug in the reaction should be used.

The principles and steps are:

1. Reintroduce the treatment, drug by drug (one drug at a time), in progressively increasing dose.
2. Start with the drug least likely to have caused the ADE. Add the other drugs from least to most likely to have caused the ADE.
3. Start with low dose of the drug, often a sixth of the total dose and gradually increase the dose, for example, double the dose each day until full dose. This would take up to 4-6 days for full reintroduction of each drug, a time too short for the selection of resistant strains to the particular drug.
4. When the full dose of a particular drug is introduced without any ADE, then an additional drug should be reintroduced in the same way as the previous drug.

All reintroduction and desensitization must be done in hospital under the care of an experienced medical officer. Before attempting to reintroduce treatment and desensitization, a plan should be established on how to proceed in the event of the adverse effect reoccurring. Some recommend treating three days before with prednisolone 40-60 mg and continuing with this for 2 weeks after reintroduction of anti-TB drugs.

The table below shows the standard approach to re-introducing anti-TB drugs after a drug reaction. The drug least likely to produce the side effect is started first and when its regular dose is achieved without any side effects the next less likely drug is introduced as shown in Table 14.

The last drug to be re-introduced before the recurrence of a reaction is the cause and that drug should be replaced (see Section 7.6.7 below). This may require a decision by a medical officer with extensive experience in management of TB; you may therefore have to refer the patient for further care.

Table 14: The Standard approach to re-introduction of anti-TB Drugs after a drug reaction.

Drug	Day
	Day 1
	Day 2
	Day 3
	Day 4
	Day 5
	Day 6
	Day 7
	Day 8
	Day 9
	Day 10
	Day 11
	Day 12
	Day 13
	Day 14
	Day 15

7.6.6 FDC and side effects

Drug side effects are not any more common when FDCs are used compared to single drugs. However, when side effects to one of the components in a FDC are suspected, there will be a need for single-drug formulations. Limited stocks of single-drug tablets will be available in district/provincial/ referral hospitals where patients with severe drug side effects will be managed under supervision.

7.6.7 Alternate Regimens when first-line drugs cannot be used

It becomes extremely complicated when any of the first-line treatment drugs cannot be used. For this reason, it is advised that an experienced physician - the Provincial TB clinician or the nearest TB specialist - care for patients in whom one or more of the first line drugs cannot be used. The principle is to use as many first-line drugs as possible in any treatment regimen.

In the event that one first-line drug cannot be used, due for example to severe drug adverse effects or demonstrated resistance to one drug, then use the regimens below:

Drug that cannot be used	Alternate Regimen
Pyrazinamide	2HRE/7HR
Isoniazid	2REZ/10RE
Rifampicin	2HEZ(S)/10HE
Ethambutol	2HRZS/4HR

7.6.8 Drug interactions with anti-tuberculosis drugs

Isoniazid interacts with anticonvulsants, and may cause their concentration in the body to increase to toxic levels. It is advisable to monitor serum concentration levels of anticonvulsant drugs, if possible. If this cannot be done, it may be necessary to reduce the dosage of anticonvulsant drugs during isoniazid-containing treatment. The absorption of isoniazid is decreased by aluminium hydroxide.

Rifampicin induces several liver enzymes that metabolise drugs to reduce their blood levels (the cytochrome P-450 system). This results in faster elimination and lower blood concentrations of many drugs ranging from anti-coagulants and cardiac medications to hormones, anti-fungals and antiretroviral drugs. Treating patients with rifampicin and these other drugs at the same time would result in lower blood levels and therefore less effect of those drugs.

7.6.9 Rifampicin, ART and contraceptive methods

Rifampicin may decrease the efficacy of all hormonal contraceptive methods because of the above reason. Therefore, TB patients on hormonal contraceptives should be advised to abstain from sex or to use barrier methods correctly and consistently. Dual protection is always necessary unless the patient and spouse are both HIV-negative and live in a mutually monogamous relationship. The effects of rifampicin on contraceptives and antiretroviral drugs are summarized in Table 15 below.

Table 15: Rifampicin interactions with hormonal contraceptive methods

Contraceptive method	Interaction with Rifampicin	Recommendation
Oral contraceptives containing < 50 mcg of ethinylestradiol	Efficacy reduced by rifampicin and pregnancy may occur	Change to high-dose OC, Depo-Provera or IUCD and use condoms correctly and consistently (unless two spouses are known HIV-negative and live in a mutually monogamous relationship)
Progestin-only-pill	Efficacy reduced by rifampicin and pregnancy may occur	Change to high-dose OC, Depo-Provera or IUCD and use condoms correctly and consistently
Depo-medroxyprogesterone (Depo-Provera®)	No known interaction	DUAL PROTECTION necessary
Hormonal implant	Efficacy reduced by rifampicin and pregnancy may occur	Use IUCD concomitantly or use condoms correctly and consistently
Intrauterine contraceptive device (hormone releasing or not)	No known interaction	May increase transmission of HIV DUAL PROTECTION necessary

The recommended first line ART regimen for TB patients are those that contain Efavirenz, since interactions with anti-Tb drugs are minimal. (refer to national ART and TB/HIV management guidelines)

7.6.10 Patient information about anti-tuberculosis drug side effects and interactions

To ensure good compliance during treatment, it is essential for patients, treatment supporters and family members to know basic facts about anti-TB drugs, their side effects and what to do in case of drug side effects.

Because TB patients are seen daily for directly observed treatment, at least during the initial (intensive) phase of treatment, health staff are encouraged to use more than one consultation to explain the symptoms of side effects and check that patients have understood. It is also important to ask and look for any possible signs of side effects.

'Ready made' messages adapted for local situations should be used as much as possible. Table 18 presents several examples of actual messages.

Example of health education messages

Anti-TB drugs are powerful medicines and they can also cause side effects.

Common side effects are nausea, vomiting, abdominal pain and discomfort, joint pains, itching, skin rash, numbness, tingling or loss of sensation or burning sensation in feet and hands, yellow discolouration of eyes, diminished hearing or sight. Contact your clinic without delay and tell your doctor or nurse if you develop any of these symptoms.

Rifampicin colours all body fluids red or orange. This is not dangerous.

If your patient is female and is on modern contraception, find out what method she is using and discuss what additional method she is going to use during anti-TB treatment. Remember the importance of dual protection.

Talk with all female TB patients during continuation phase about their reproductive plans and advise them about the benefits of starting to use of contraception if she is not planning a pregnancy. This is particularly important if your patient is also HIV-positive.

If your patient is taking anti-epileptic drugs: check what medication s/he uses and explain that the effect of anti-epileptic medication may be decreased. Suggest that the patient keeps a seizure diary if it is not possible to measure drug levels, and s/he reports to you immediately if an increase in seizures is observed. Discuss management with a doctor.

If your patient is HIV-positive and is also on antiretroviral treatment: check what medication s/he uses and explain that added toxicities could occur and that it is important for the patient to contact you if nausea, vomiting, abdominal pain, skin rash or jaundice is appears. Discuss management with a doctor.

KEY POINTS TO NOTE:

At every contact with a TB patient, ask about symptoms, such as nausea, vomiting, abdominal pains and discomfort, itching, joint pains and numbness, tingling or burning sensation or loss of sensation in hands and feet

At every contact with a TB patient, look for skin rash, jaundice, jaundice with continued nausea and vomiting. Then diagnose and decide appropriate management of the side effect

CHAPTER 8

Prevention and management of treatment interruption

8.1 Introduction

This chapter describes the role of the key players: the patient, the TB programme, other providers, and the community, in ensuring the cure of TB, treatment supervision and directly observed therapy; patient-centred care; measures to prevent interruption of treatment and management of those who return to treatment after interruption.

Patient's adherence to TB treatment is very important in achieving cure of TB, in preventing the development of drug resistance and also in protecting the community from the spread of TB. The emergence and spread of MDR- and XDR-TB reinforces the absolute necessity of all concerned to help and support TB patients not to miss any drug doses. Supervision and patient support therefore are cornerstones of DOTS. There must therefore be a partnership between patients, health-care workers and the community; these are the key players in TB control.

8.2 Roles of Key Players

8.2.1 *Patient centred care.*

Patients are active partners and not just passive recipients of services according to the Patient's Charter for TB care. They have a right to care, dignity, information, privacy, food supplements and/or other types of support and incentives, if needed. They also have the right to participate in TB programme development, implementation and evaluation. With their rights patients also have responsibilities which include: sharing information with the health provider, following treatment, contributing to community health, and showing solidarity by passing expertise gained during treatment to others in the community. They are also important in stigma reduction and supporting treatment completion of new patients particularly after they have been cured of TB.

8.2.2 *Role of NTP and health Staff*

The NTP and health-care staff have the responsibility to ensure uninterrupted intake of all the drugs by the patient. Patient adherence is promoted by a patient-centred approach based on the following elements:

- Facilitating access to treatment and care (free drugs and tests, rapid attention, reduction in cost of transport for care)
- Choosing with the patient the most convenient time and place for drug intake under direct observation and who to supervise the treatment.
- Providing comprehensive social and medical services to the patient as needed through community-based care.

8.3 Indications for Hospital Admission

Hospital admission is not necessary for the treatment of most patients with TB. Indeed, studies have shown that treating people at home, in a supervised and well-controlled programme, is as effective but less expensive, compared to hospitalisation. Patients should be admitted to hospital not because they have TB but because they have an illness, the type and severity of which makes it best for in-patient treatment and care.

Therefore admit only patients with the following:

1. Disease severity: The patient is severely ill, is semi-conscious, has respiratory failure, very high fever, dehydrated etc. TB of the central nervous system (encephalo-meningitis), pericardium, vertebrae are regarded as severe TB and should be admitted.
2. TB complications or sequelae (likely consequences): Patient with haemoptysis (irrespective of how insignificant it may seem at the time of presentation), empyema, pneumothorax, etc. should be admitted.
3. Adverse drug effects: Serious adverse drug effects should be managed in hospital as they may be life threatening (see Chapter 7).
4. Treatment of MDR-TB with second line drugs: Admit all patients for at least the first few weeks of treatment with second line anti-TB drugs, so as to manage the likely drug intolerance from the adverse drug effects.
5. Patients who have problems with drug adherence: Admit patients who have been treated more than once for treatment default, especially who are still sputum positive and on retreatment regimen if the programme cannot ensure full adherence in the community.
6. Psycho-social factors: Patients who have no fixed abode (homeless etc.), alcoholics, drug addicts, psychiatric patients, the extremely poor and who the programme cannot provide community treatment support or who live far away from a health facility, may be admitted for TB treatment. The principle here is that admission is a form of support for these people. It also allows the health and social services time to arrange the necessary support.

8.4 Referral

A referral occurs when a patient is sent to another unit for services but his/her TB treatment and registration are still in the same district TB register. A patient may be referred for non-TB services such as diabetic care or for TB service such as referral from a District hospital to a subdistrict health centre for DOT in the same district.

A referral form should be filled in accurately and with all necessary details.

All the information pertaining to the patient's diagnosis and treatment should be recorded on the patient's "tuberculosis treatment card". The patient should be given the outpatient treatment card on the initiation of treatment and he/she must carry it every time he/she comes to the health facility. The TB focal person must properly fill the card to ensure that the patient is aware of his/her next review date.

8.5 Transfer of Patients

A transfer occurs when a patient moves from one TB register to another, that is, from one district to another. A transfer form should be filled in triplicate. One copy goes with the patient, another is sent to the receiving TB diagnostic facility, and the third remains at the transferring facility. Upon arrival at the receiving facility, the TB coordinator registers the patient as a "transfer in", and fills in the tear-off form and sends it back to the transferring facility to inform about the arrival of the patient. Patients should be given one week's supply of medications irrespective of whether they are in the intensive phase or continuation phase upon transfer as the programme now uses rifampicin throughout the treatment period.

The transferring unit should ensure that it obtains and records the final treatment outcome from the receiving unit. "Transfer out" should only be recorded in the initial register if the outcome is not known. It is the responsibility of the transferring unit to find out the treatment outcome of all patients that it transfers out. This should be done in collaboration with the receiving facility. Patients should be sent to a TB diagnostic facility upon transfer, from which they can then be referred to a peripheral clinic.

Note: for reporting purposes this applies only when patients move from one reporting unit (district) to another. For treatment outcome reports, these transfers should be resolved in all cases. Patients moving within the district are not transfers but referrals and their treatment outcomes must be resolved by the DTC before reports are made.

Diagnostic units should therefore make every effort to find out from the newly diagnosed patient where he/she wants to take treatment, fill the treatment card, but refer him/her with the card to this other unit for registration and start of treatment as much as possible.

8.6 Community-based TB Care

Community participation in health care delivery is central to the primary health care concept of providing accessible and cost-effective care tailored to local needs. The integration of TB services into public health systems helped to increase access to TB services but the continued limited coverage and the unprecedented increase of TB cases in Zimbabwe has increased the pressure on public TB services. Community contributions to TB care should be seen as complementing and extending NTP activities, not replacing the NTP activities.

8.6.1 Benefits of Community-Based TB Care

The benefits of community-based TB control include:

- Widespread implementation of program activities
- Improved treatment outcomes
- More efficient use of available resources

8.6.2 Objectives of Community-Based TB Care

The objectives of community involvement in TB care are to:

- Facilitate access to health services and bring services to where people live.
- Promote a partnership between health services and communities for patient and community empowerment.
- Bring about behavioural change, avoid health risks in future and become more self-reliant.
- Promote institutional support, based on principles of equity and social justice, for Initiatives in which community members express their responsibility and solidarity towards those who are suffering.

8.6.3 Treatment Supporter

A patient's adherence to treatment instructions is an important factor in treatment success. Directly observing treatment (DOT), that is, watching the patient swallowing every scheduled dose, is the most effective method to promote adherence. This would either be community based- or health facility based-DOT depending on the situation.

A TB patient who travels far each day to obtain treatment is unlikely to complete treatment. One of the aims of the NTP is to organize TB services as a part of general health services expanded to the community, so that TB treatment is available as close to a patient's home or workplace as possible. Before the patient is sent to his/her community, the health care worker must educate the patient about the importance of adhering to treatment.

For TB patients that live or work close to a health facility, a health worker will/should directly observe their treatment - health facility based DOT. However, for patients that live far from the health facility, a treatment supporter in the community is needed to directly observe treatment at a place and time more convenient for the TB patient - community based DOT.

8.6.3.1 Identifying a community TB treatment supporter

The Institutional TB Coordinator and patient must identify a treatment supporter (health care worker, a family member, a co-worker, a neighbour, a member of a local NGO, Community Based Organisation, Faith Based Organisation, etc.) who is acceptable to the patient. The patient and treatment supporter should enjoy a supportive relationship that motivates the patient to complete their treatment. A negative attitude can cause a patient to default from treatment. The community treatment supporter should listen empathetically to the patient's concerns and encourage the patient to complete treatment. The treatment supporter must be acceptable to the patient, conveniently placed and must be able to manage drugs. The supporter must also have easy access to the health facility for monitoring and obtaining resupply of drugs.

The treatment supporter may be selected from among the following, in order of preference;

- A health facility member of staff living in the same community
- A trained community/village health worker
- A volunteer in the community, workplace
- Or a family member, as the last resort

8.6.3.2 Arrange a meeting for the Community TB Treatment Supporter and TB patient (and family)

Inform the patient and family about the TB treatment and the role of the community TB treatment supporter. Discuss with the patient and family and assist them in identifying a suitable community TB treatment supporter. Set an appointment for the TB patient and family to meet with the community TB treatment supporter. The community TB treatment supporter and the TB patients should then agree on the appropriate place and time where the patient will take the drugs.

If a family member can directly observe the TB patient while taking treatment, the community TB treatment supporter then plays an oversight role by supporting the family and patient.

8.6.3.3 Roles of the Community TB Treatment Supporter

The Community TB Treatment Supporter performs many functions all with the aim of enabling the patient complete treatment. These include:

1. Observing patient swallow tablets.
2. Updating the patient's TB treatment card.
3. Collecting resupply of drugs on behalf of the TB patient.
4. Reporting any problems related to the patient to the health facility.
5. Following up on patients that miss an appointment or dose.
6. Supporting and encouraging the TB patient to take drugs for the duration of treatment.
7. Monitoring the TB patient's progress and observing any side effects.
8. Referring patient to the health facility for further information, management or review.
9. Informing and educating the patient, family and community about TB and related conditions.
10. Conducting contact tracing and referring suspects to the health facility for further investigation.

8.6.3.4 Supervision of the community TB treatment supporter

The health worker at the health facility assists the TB patient in identifying a suitable treatment supporter and trains the treatment supporter on basic facts of TB. Training needs of the treatment supporters will vary depending on the individuals' literacy level. The treatment supporter must be trained to give directly observed treatment, mark the TB treatment card, observe and record the patient's progress and side effects.

The treatment supporter should visit the health facility once every month, to report and discuss progress and bring the TB patient's treatment card for resupply.

If the treatment supporter fails to come to the health facility, make a visit immediately to the home of the treatment supporter to ascertain the problem.

Discuss with the patient to determine the quality of care being provided by the treatment supporter. Find out if the treatment supporter has been timely, supportive, and whether the patient wants to continue with the treatment supporter.

While community care and DOT is more cost-effective than hospital based care, resources are still needed for training and supervising community treatment observers. Community volunteers need regular support, motivation, instruction and supervision by relevant staff to ensure that quality outcomes are maintained. Selection of community volunteers should be a cooperative activity including health care workers involved in TB, patients, community representatives and community group leaders.

Training requirements may vary depending on the setting, ranging from "on the job instruction" by NTP staff to more formal short courses of instruction supported by regular updates. Effective community contributions to TB care, especially community based DOT, require a strong reporting system, access to laboratory facilities and a secured drug supply, through district support.

Existing community groups and organisations should be approached to determine how they might contribute to community TB care, rather than setting up new systems. This is an example of Private-Public Mix DOTS (PPM-DOTS).

Note: The ultimate responsibility for community-based TB care remains with the health services

8.7 Prevention of treatment interruption

The emphasis in the NTP is to promote patient adherence to treatment by patient-centred TB care to prevent treatment interruption rather than devoting resources to tracing patients.

The following factors increase the risk of treatment interruption:

- Poor access to treatment (financing - cost of transport, distance)
- Stigma
- Poor understanding of TB disease
- Fear of loss of income while seeking treatment
- Mental illness

To prevent treatment interruption, the health facility staff should undertake:

1. Address verification. This is done before treatment is started. It may require a physical visit to the patient at the stated address. The aim is to ensure that the patient is traceable to a fixed address.

2. Home visits.

- a. Patients who miss a daily DOT attendance are followed up at their home addresses within 2 days
- b. Education of family members at home

8.8 Tracing patients who interrupt treatment

Note: A patient is defined a defaulter if treatment has been interrupted for a consecutive period of at least 2 months and all efforts to retrieve the patient have failed. Thus, any patient interrupting treatment should be traced before he/she is classified as a defaulter. We should trace all patients who interrupt treatment and only declare them as defaulters if we fail to bring them back on treatment within 2 months of their treatment interruption.

As soon as a patient misses a date for review or drug collection, the TB coordinator should immediately start the process of patient tracing. If a patient on community-based TB care moves away or his/her whereabouts becomes unknown between two visits, the treatment supporter should immediately notify the TB coordinator or TB focal nurse at the health facility where the patient was getting his/her medications.

8.9 Management of those who interrupt treatment

Despite strict prevention activities, there are patients who interrupt treatment. In the management of treatment interruption the presence of the factors below should raise caution, as there is an increased risk of MDR-TB:

- The patient returns with smear- or culture-positive TB.
- Interruption occurred in the intensive, rather than the continuation, phase.

- Interruption occurred early (rather than later) in the continuation phase.
- The interruption was of long duration.
- The patient is immunocompromised (living with HIV or another condition).
- The patient had poor response to treatment before the interruption.
- Drug-resistant disease is known or suspected.

After a patient who has interrupted treatment is retrieved, the causes for treatment interruption are established. Each case has to be managed on its merit. Management of patients after treatment interruption is based on review of information about treatment before interruption and current smear results of the patient. It is based on:

- Patient's previous TB treatment category.
- Length of treatment before interruption.
- Length of interruption.
- Smear results after interruption (is not always necessary to do so).

A simple decision tree is provided in Table 16 below.

The following steps are taken:

1. Find and solve cause of interruption
2. Do 2 sputum smears.
3. Culture and DST should be performed upon return of patients who interrupt treatment for at least 2 consecutive months.
4. The possible treatment options are to continue the initial treatment, restart treatment or use another regimen.

In general, the following principles apply:

- Where the interruptions of less than 2 weeks duration, there is no need to repeat patient's sputum. Continue with patient's treatment as before but extend the duration by the number of days missed.
- Longer interruptions (8 weeks or more) always necessitate making an outcome assessment either as default or treatment failure.
 - If the patient could not be retrieved, he is assessed as default. This means that the patient's "Treatment form" should be "closed" after entering the treatment outcome and not used again.
 - If the patient returns, he/she should be re-registered as either new smear positive, treatment after default or other (treatment failure).
- The definition for treatment failure applies to those also who have interrupted treatment. That is:
 - if the sputum after return is still positive for patient who had completed the intensive phase of treatment or after a prolonged interruption (>2 months), then the patient should be assessed as treatment failure.
 - Any one who interrupts treatment after the intensive phase and returns after more than 2 weeks interruption with positive sputum should be assessed as treatment failure.
- If the return after interruption sputum is negative or if the patient has EPTB you should continue the patient's treatment for the total number of doses left. Those who have interrupted treatment for more than 8 weeks should have an outcome assessed as default.

Table 16: Actions to take to manage a Patient who has returned after Treatment Interruption.

Duration of Interruption Treated	Months Previously Result	Repeat Sputum	Treatment Assessment	Outcome	Re-Registration
<2weeks		-	Continue	None	No
2-8 weeks	< 1 month	Positive	Re-start	None	No
		Negative	Continue	None	No
	1-2 months	Positive	Extra month induction	None	No
		Negative	Continue	None	No
> 8 weeks	> 2 months	Positive	Start RTR	Treatment Failure	Other (treatment failure)
		Negative	Continue	None	No
	< 1 month	Positive	Re-start	Default	New SSM+
		Negative	Continue	Default	Treatment after default
	1-2 months	Positive	Start RTR	Treatment failure	Other (Treatment Failure)
		Negative	Continue	Default	Treatment after default
	> 2 months	Positive	Start RTR	Treatment failure	Treatment after default
		Negative	Continue	Default	Treatment after default

9 CHAPTER 9

Interventions For Tuberculosis Control

9.1 Introduction

This chapter discusses the interventions in tuberculosis control or elimination strategies taken to reduce or eliminate the adverse impact of epidemiological risk factors that promote the acquisition of infection and its progression to disease.

The prevention of TB can be done through the following interventions:

1. Treatment of Tuberculosis (See chapter 6)
2. Vaccination with Bacille Calmette-Guérin (BCG)
3. Contact Investigation
4. Prophylactic treatment
5. Preventive chemotherapy
6. Addressing risk factors
7. Infection control (See chapter 10)
8. Treating HIV co-infection (see chapters 4 and 6)

9.2 BCG Vaccination

Vaccination with BCG before acquisition of infection with *M. tuberculosis* aims to prime the immune system, reducing the risk of progression from latent infection to disease in infancy. It is important to note that vaccination with BCG does not protect against infection with *M. tuberculosis*, but reduces the development of disseminated and meningeal TB in infants (86% on average).

9.2.1 *When should BCG be administered?*

In Zimbabwe children will often be exposed to TB early in life, therefore BCG is given soon after birth or at the earliest possible time in the first year of life

BCG vaccine is given routinely to ALL neonates at birth except symptomatic HIV patients.

Children on TB prophylaxis or preventive therapy should be given BCG at the end of such treatment.

9.2.2 *Complications of BCG*

A small number of children (1-2%) develop complications following BCG vaccination. These most commonly include local abscesses, secondary bacterial infections, suppurative adenitis and local keloid formation.

9.2.3 *Treatment of BCG complications*

Most reactions will resolve over a few months. However, children who develop disseminated BCG disease should be investigated for immunodeficiencies and treated for TB as shown in below. Management of adverse reactions in HIV-infected children or children with other immunodeficiencies is more complicated and requires referral to a specialist.

Treatment of Complications of BCG Vaccination

Subcutaneous abscess:	Require pain relief with simple analgesics If secondary infection occurs, antibiotics may be required with local treatment of ulcers Aspiration of abscesses is recommended rather than incision and drainage.
Local ulcers:	Simple cleaning of ulcers. Treat with a two months course of Isoniazid (10mg/kg).
Swelling of lymph nodes site:	Requires no specific treatment and anti-TB adjacent to vaccination treatment is not indicated. The swelling of the nodes can persist for several weeks or months
Systemic complications due to generalized BCG infection:	These are very rare. May be controlled with a full course of anti-TB treatment. Note that PZA is ineffective because it does not kill <i>M. bovis</i> , the attenuated pathogen in BCG.

9.3 Contact Investigation

Contacts of TB patients should be investigated for the presence of disease. This process is contact investigation (CI).

The benefits of contact investigation are:

- Finding and treating additional TB disease cases (potentially interrupting further transmission)
- Finding and treating persons with LTBI to avert future cases.

Contact investigations are activities that involve different expertises in the health system and require teamwork.

9.3.1 Definitions for Contact investigation(CI) of TB

Case: A particular instance of a disease (e.g. TB). A case is detected, documented, and reported.

Index Case: The first case or patient who comes to attention as indicator of a potential public health problem.

- All smear-positive PTB cases should be regarded as index cases and their contacts investigated for TB.
- All children with TB should be considered index cases. Since children are most often recipients of TB infection the purpose of CI in children is to identify the source of TB transmission to them.

Contact: Someone who has been exposed to *M. tuberculosis* by sharing air space with a person with infectious TB. The type of contact depends on the closeness and duration of exposure to the index case.

- Household contacts, particularly, children less than 5 years of age should be assessed for TB.
- High priority should also be given to those who are HIV positive and those with other underlying risk factors for TB such as alcoholism, diabetes, etc.
- Contacts may also be found in aggregate settings such as workplace, schools (dormitories and classrooms), hostels, health facilities, prisons if prolong contact with an index case has taken place.

Source case or patient: The case or person who was the original source of infection for secondary cases or contacts; can be, but is not necessarily, the index case.

9.3.2 *Process of Contact Investigation*

The first step is to decide which contact investigations should be assigned a higher priority and which contacts to evaluate first. The priority is to investigate patients who have characteristics that increase the risk of TB transmission. These are:

- Positive sputum smear
- Pulmonary, laryngeal, or pleural TB
- Cavitation on chest radiograph
- Household contacts of children with TB

The index case should be interviewed to identify contacts and the place(s) of contacts. Every effort should be made to investigate children, PLHIV and those with other conditions and situations associated with increased risk of TB. All identified prioritised contacts should be invited to the health facility and investigated for TB using symptom questionnaire and physical examination. Sputum smear microscopy should be carried out on those with a cough of 2 or more weeks. The options after contact investigation are:

1. Those who are diagnosed as having active TB should be registered and given full TB treatment.
2. Children <5 years with no evidence of TB should receive TB chemoprophylaxis (see Section 9.4 below).
3. Children >5 years who are healthy should be followed up on a clinical basis and do not need treatment. They should be educated to report any persistent cough (2 weeks or more) to the nearest health facility.
4. PLHIV who are close contacts with TB but who do not have evidence of TB should receive isoniazid prophylaxis therapy (see Section 9.5).

9.3.3 **Infants of mothers with PTB**

An infant born to a mother with sputum positive TB should not be given BCG at birth. The neonate should receive a thorough clinical examination, including an abdominal examination, as trans-placental infection with *M. tuberculosis* occurs through the umbilical vein with the primary focus situated in the liver. If the baby is symptomatic (respiratory rate >60/min or difficulty breathing, feeding problems or poor weight gain, abdominal distension, enlarged liver or spleen or jaundice) then he/she needs to be referred to hospital for evaluation.

The child should be given isoniazid 10mg/kg/day prophylaxis for 2 months after which a TST/Mantoux test should be performed. If the TST/Mantoux test is positive, the infant is infected and should receive full TB treatment. If the TST/Mantoux test is negative, the infant should continue with INH prophylaxis for four more months to make a total period of 6 months, followed by BCG vaccination if not HIV-infected. The mother should be encouraged to breast-feed. Mother and neonate should not be separated, as establishment of breast-feeding can be critical for child survival.

9.4 Prophylaxis against Tuberculosis

Prophylactic treatment is given to prevent progression of latent infection to disease. It is indicated in a newborn child with a potentially infectious parent, especially the mother, or in a child under the age of five years who is a household contact of a person with sputum smear-positive TB. Such children are at high risk of rapid progression from infection to disease. Some of these children will not yet have acquired TB infection and will thus receive true prophylactic treatment, as shown in Table 17 below.

Table 17: Management of children exposed to an adult with infectious (smear-positive) TB

IF:	AND:	THEN:
The child does not have symptoms of tuberculosis	A medical or clinical officer determines that the child does not have TB	Give the child prophylactic treatment for latent TB infection: Isoniazid 10 mg/kg for 6 months
The child has symptoms of tuberculosis	A medical or clinical officer determines that the child has TB	Give a full course of anti-TB treatment

The management of children exposed to TB is summarised in Figures 6 and 7.

9.5 Isoniazid Preventive Therapy (IPT)

Current challenges to the National TB Programme and National OI/ART Programme make programmatic institution of IPT NOT recommended at this time in Zimbabwe as public health policy.

Preventive chemotherapy is treatment of latent infection with *M. tuberculosis*, given to reduce the risk of progression from latent infection to active TB disease. A positive Mantoux or other new diagnostic tools can be used to diagnose latent TB infection.

IPT may be provided for:

- Children under 5 years of age who are household contacts of smear-positive TB patients.
- Infants and young children with latent *M. tuberculosis* infection (Mantoux positive) who are at high risk of rapidly developing disease.
- Infants 2 years of age or younger who are at particularly high risk of developing life-threatening tuberculous meningitis or miliary tuberculosis.
- Persons co-infected with HIV and *M. tuberculosis*.

Isoniazid Preventive Therapy (IPT) (6 to 9 months of isoniazid 10 mg/kg, maximum 300 mg only) can safely be given to people living with HIV without TB disease, reducing the risk of developing TB by between 33 to 67% for up to 4 years. It is currently recommended for all PLHIV in areas with a prevalence of latent TB infection >30%, and for all PLHIV with documented latent TB infection or exposure to an infectious TB case, regardless of where they live. More recent evidence has shown that the combined use of IPT and antiretroviral therapy among people living with HIV significantly reduces the incidence of TB; and the use of IPT in patients who have successfully completed a course of TB therapy has been shown to markedly reduce the risk of subsequent active TB.

However, IPT should never be initiated unless active TB is confidently excluded. Due to the high incidence of TB in patients who have begun ART within 4 months of treatment, it is especially critical to thoroughly exclude active TB before initiating IPT in this group of patients.

The following criteria also exclude a patient from consideration for IPT:

- Signs and symptoms of TB, i.e., patients who are currently ill with new or worsening cough or sputum production, haemoptysis, night sweats, fever, or measured weight loss of more than 5%
- Abnormal chest X-ray (even if TB has not been confirmed)
- Poor prognosis (terminal AIDS)
- Presence of jaundice or active hepatitis (acute or chronic)
- Has had TB treatment in the past 2 years
- History of alcoholism (or daily alcohol use)

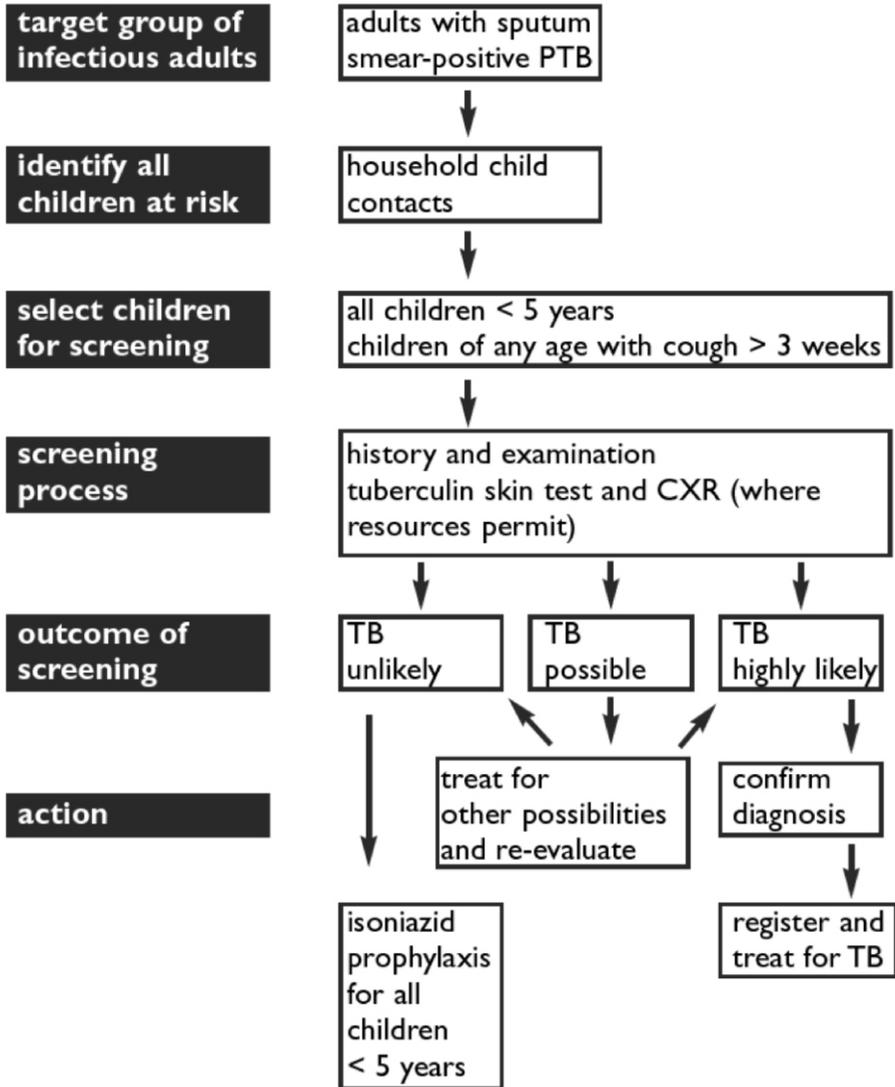
IPT is used most safely in asymptomatic PLHIV who are infected with *M. tuberculosis* e.g., those identified early in the course of their HIV infection through VCT centres or antenatal clinics.

9.6 TB Prevention through Addressing Risk Factors

While the NTP does not have much ability to reduce the prevalence of the following risk factors for TB infection and disease, it can advocate the need to address such risk factors and support the implementation of other public health programmes as part of integrated service delivery in primary health care. These risk factors are: smoking, malnutrition, diabetes, crowding, indoor pollution, alcoholism and occupational lung diseases.

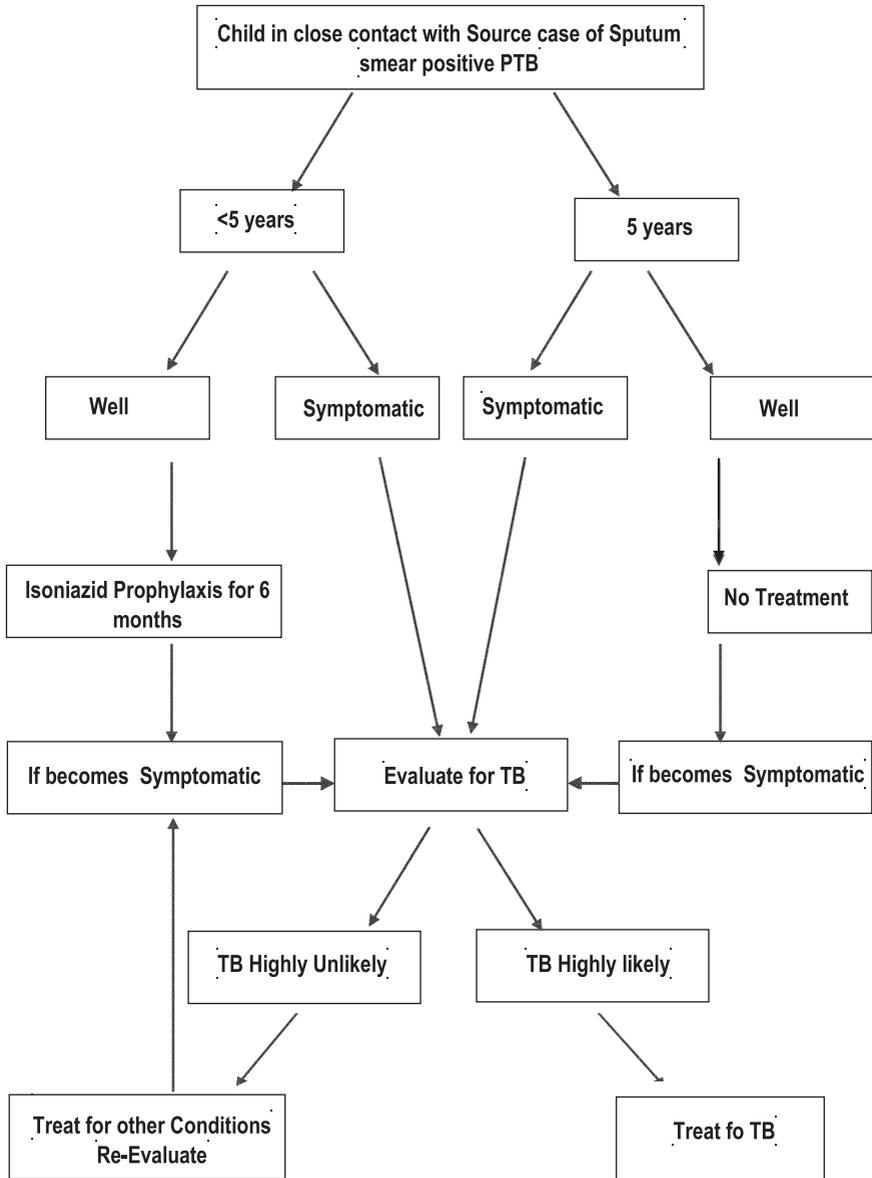
Passive and active smoking increase susceptibility to TB infection, progression to active TB disease and the risk of adverse anti-TB treatment outcomes. It is therefore reasonable for the NTP to support activities to control use of tobacco at national and local levels. Smoking cessation is part of the services under Practical Approach to Lung Health (PAL).

Malnutrition increases risk of TB disease through decreased immunity caused by protein, calorie and micronutrient deficiencies. Clinicians should ensure that malnourished children are provided good nutritional support according to national guidelines in addition to the anti-TB drugs.

Figure 6: How to identify and manage Child Contacts of Infectious adults

Reproduced from WHO. TB/HIV: A clinical manual. 2nd Edition. WHO/HTM/TB/2004.329. WHO. Geneva.

Figure 7: Approach to Contact Management when Chest X-ray and Tuberculin Skin Test are not readily available



Modified from WHO: Guidance for national tuberculosis programmes on the management of tuberculosis in children. WHO/HTM/TB/20 06.371

CHAPTER 10

TB Infection Control

10.1 Introduction

This chapter discusses the TB infection control measures to reduce TB transmission in health-care facilities, congregate settings and households.

With the increasing importance of DRTB, the need for stringent TB infection control is paramount. Many persons infected with TB attend health facilities and so do immunocompromised persons. In the absence of appropriate infection control policy and practice, there is a high risk of transmission and spread of TB among hospital patients, hospital workers and the community. Studies have shown that the incidence of latent TB infection (LTBI) and TB disease among health workers in health-care facilities and individuals in congregate settings, such as prisons, and among contacts in household settings, is greater than that among the general population or among health workers not exposed to health-care facilities.

TB infection control is a set of activities aimed at reducing the risk of TB transmission within populations. The greatest risk of transmission occurs when TB patients remain undiagnosed and untreated. The basic principles of infection control therefore are early diagnosis and proper management of TB patients.

10.2 TB Infection Control in Health-care Settings

The TB infection control programme is based on a three-level hierarchy of control measures:

1. Administrative (managerial) level: to reduce health care worker (HCW) and patient exposure.
2. Environmental (engineering) level: to reduce the concentration of infectious droplet nuclei in health facilities.
3. Personal level (respiratory protection): to protect health care workers in areas where the concentration of droplet nuclei cannot be adequately reduced by administrative and environmental controls.

10.2.1 Administrative (managerial) controls

The first and most important level of infection control is the use of administrative measures to prevent droplet nuclei from being generated, thus reducing the exposure of HCWs and patients to *M. tuberculosis*. Administrative controls are the cheapest and most effective interventions and they ensure early diagnosis and treatment of potentially infectious TB patients. These measures include:

- Assessment of the risk of transmission in the facility
- The development of an infection control plan
- Assigning responsibility and authority for the implementation of the infection control plan to one individual
- Adequate training of HCWs and other staff to implement the plan

- Administrative support for procedures contained in the plan, including quality assurance
- Early diagnosis of potentially infectious TB patients and their prompt separation
- Prompt initiation of appropriate anti-TB treatment.
- Education of patients and increasing community awareness.
- Proper design of health institutions e.g. wards, out-patient departments.
- Ensuring that TB-positive HCWs do not work in areas of high TB transmission or with MDR-TB patients.

All health care facilities should develop and implement a TB infection control plan designed to ensure prompt detection and treatment of persons who have suspected or confirmed TB disease or prompt referral of such persons. A baseline TB infection control assessment should be conducted in order to guide the development of a facility-specific plan.

An infection control committee should be established to plan, implement, monitor and evaluate the infection control plan. The tasks of this committee include: develop a written TB infection control plan tailored to the specific health facility setting, assign a designated TB infection control officer in charge at the health facility level who is responsible for monitoring the implementation of the plan at the health facility, assign designated health workers responsible for monthly monitoring of the plan implementation in each unit, evaluate the plan implementation on a quarterly basis and revise it on an annual basis.

The infection control plan should include but not limited to the steps shown in Table 18.

Table 18: Five steps for Patient management to prevent transmission of TB in Health Care Settings

Step	Action	Description
1	Screen	Early recognition of patients with suspected or confirmed TB disease can be done through questioning patients about cough on arrival.
2	Educate	Instruct these patients on cough etiquette/respiratory hygiene.
3	Separate	Patients identified as TB suspects or cases must be separated from other patients and requested to wait in a separate well-ventilated waiting area.
4	Provide prompt health services	Triaging symptomatic patients to the front of the line for the services they are seeking (e.g. outpatient consultation, voluntary TB/HIV counselling and testing, medication refills).
5	Investigate for TB or refer	TB diagnostic tests should be done onsite or, if not available onsite, the facility should have an established link with a TB diagnostic centre to which collected sputum can be sent.

The following should also be part of the plan:

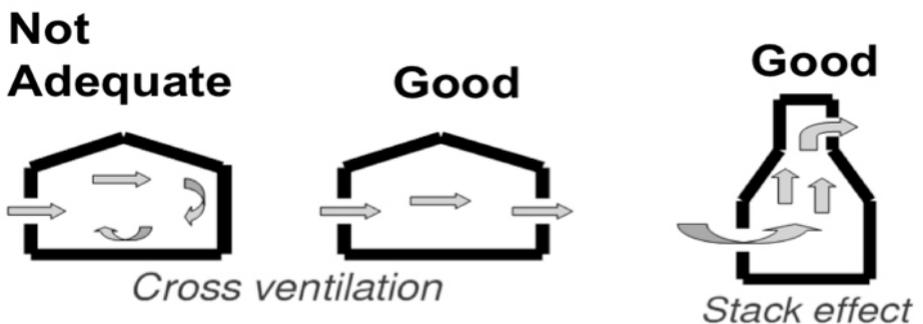
1. Using and maintaining environmental control measures.
2. Routine screening for TB using the TB screening tool (see Annex 1) and/or X-ray among health care workers on annual basis.
3. Training and educating staff on TB, TB control and the TB infection control plan.
4. Providing voluntary, confidential HIV counselling and testing for staff with adequate access to treatment.
5. Job relocation of staff who are TB positive from high to low TB exposure areas.

10.2.2 Environmental control measures

It is often not possible to completely eliminate the exposure to infectious droplet nuclei, but various environmental control methods can be used in high-risk areas to reduce the concentration of droplet nuclei in the air. Such measures include:

- Natural ventilation should be maximized by keeping clinic windows and doors open during working hours, even during winter and promoting cross ventilation (opening of windows or doors on opposite walls) and "stack effect", which increases airflow using indoor/outdoor temperature difference (see Figure 8). Open-air shelters with a roof to protect patients from sun and rain are recommended. Patients should not wait for services in narrow, poorly ventilated corridors.
- Controlling the direction of airflow e.g. with strategically placed fans, which also cause air mixing increases the effectiveness of other environmental controls.
- Sunlight is a natural source of ultraviolet light, which can kill TB bacilli. Waiting areas and wards should have an open plan to let in the sunlight.
- A reduced crowding in patient waiting area is very important; waiting areas in open-air shelters should be favoured over enclosed corridors.

Figure 8: Promoting Natural Ventilation



Health staff should be mindful of the direction of airflow to ensure the patient is closest to the exhaust fans and the staff are closest to the clean air source.

10.2.3 Personal respiratory protection

Personal respiratory protection protects HCWs, where concentration of droplet nuclei cannot be adequately reduced by administrative and environmental control measures, through the use of devices designed to fit over the mouth and nose and filter out infectious TB particles (see Figure 9). The paper or cloth surgical masks commonly used by HCWs do NOT filter out infectious droplet nuclei. They may be of some use if placed on patients to prevent the generation of such nuclei. Personal respiratory protective devices capable of adequately filtering out infectious particles are called respirators and are more expensive than surgical masks and are the least effective of the three infectious control measures. They should not replace more effective, less expensive, infection control measures and are discouraged in normal settings. N95 masks are only indicated in specialized settings, e.g., referral facilities nursing MDR-TB patients, and only when all other infection control measures have been fully implemented.

Figure 9: Face masks and Respirators .



Surgical Face Mask



N95 Particulate Respirator

10.2.4 Protection of Health-care Workers

Staff should be encouraged to seek medical attention if they have cough of more than 2 weeks. All investigations, including a chest x-ray, for TB in staff should be done free of charge.

Encouraging and enabling health care workers and all staff to know their HIV status should be a priority of all health care services, and TB care programs, in particular. Providing accessible, acceptable, confidential HCT, including periodic retesting, to staff, can facilitate this. Policies that prioritize ART for health care workers who need it can motivate them to know their HIV status. Health-care workers who are HIV positive should not work in areas of high TB exposure, particularly where there is exposure to MDR-TB.

Infection control is effective only if each person working in a facility understands the importance of TB infection control policies and his/her role in implementing them. All

health facility staff, including medical and administrative staff, technicians and laboratory staff, laundry, cleaners and any other workers, should be targeted for training.

10.2.5 Construction of health facilities according to TB Infection Control measures

A multidisciplinary team to coordinate demolition, construction, and renovation projects and consider proactive preventive measures at inception should be established at the MOHCW. It should include members from the National TB infection control committee, and Ministry of Public Works. Mandatory adherence agreements for TB infection control should be incorporated into construction contracts, with penalties for non-compliance and mechanisms to ensure timely correction of problems.

10.3 Control of TB transmission in prisons, holding cells and other congregated settings

All the TB infection control measures described in this guideline applies also to medical services in refugee camps, prisons and other congregated settings. They have to be implemented according to the level of the health service (e.g. hospital, clinics, rural health centre).

Tuberculosis occurs up to 100 times more commonly in prisons than in civilian populations. This is because the spread of tuberculosis is worsened poor prison living conditions such as overcrowding and by late diagnosis and treatment of infectious cases.

Therefore the following measures are highly recommended:

- Early diagnosis of TB cases and their prompt and effective treatment, using DOT.
- Screening of all new inmates by history (TB Screening Tool) and sputum smear microscopy if the inmates are symptomatic for TB.
- Encourage all staff in congregated settings to undergo TB diagnostic investigation if they have signs and symptoms suggestive of TB.
- Separate TB suspects from other inmates and isolate sputum positive inmates in adequately ventilated area until sputum-smear conversion.
- Penal reforms and improvement in prison living conditions should be used as strategies for early case detection, rapid effective treatment to reduce morbidity and mortality in prisons and to interrupt the chain of transmission.
- Offer TB information and HIV testing and counselling to all staff and persons residing in the area. If found to be HIV-positive they should be offered the package of prevention and care that includes regular screening for active TB.
- There should be "Equivalence" of care in the prisons, i.e., all prisoners have the right to the same standard of health care as the state provides for the general community.
- There should be particular attention on integrating prison and civilian TB services so that there is continuation of care after discharge.

10.4 Reducing TB transmission in Households

The period of household transmission is greatest before diagnosis of TB and whether the patient remains at home or is admitted to hospital does not impact on household transmission, provided the patient is treated effectively. Again, early case detection and prompt treatment is the key to reduction TB in households. TB contact investigation should be undertaken as described in Chapter 9 Section 9.3. Information, education and communication messages including basic infection control behaviour-change should be provided. Coughing etiquette and respiratory hygiene in the household before and after diagnosis of TB should be emphasised. Stigma reduction should not be forgotten.

Environmental control measures to reduce exposure should be emphasized. Natural ventilation should be improved in households particularly in rooms where people with TB spend much time. Smear-positive TB patients in the first 2-4 weeks of treatment should spend as much time as possible outdoors, sleep alone in a well ventilated room, if possible, and spend as little time as possible in congregate settings or in public transport. Children less than 5 years old should spend as little time as possible in the same living spaces as sputum-smear positive TB patients. Children contact of MDR-TB should be followed up regularly with TB screening and if possible culture and DST.

10.5 Summary of Infection Control

The best method of infection control is the early diagnosis of infectious cases and the prompt initiation of effective treatment. It is standard infection control practice in hospitals to separate patients with infectious TB from other patients until treatment has rendered them non-infectious. This usually takes about two weeks from the start of effective treatment. Similarly, prisoners with smear-positive TB should not share cells with other prisoners until their sputum has become negative for AFBs. Under no circumstances should a prisoner share a cell with another prisoner with smear-positive or drug-resistant TB.

CHAPTER 11

Tuberculosis Medicines And Commodities Management

11.1 Introduction

The aim of this chapter is to discuss the importance, role and management of TB medicines and related commodities in the national TB Control Programme.

The management of TB medicines and commodities is an important part of the DOTS strategy for the following reasons:

- TB drugs are life saving (99% effective in curing TB) and have no effective substitutes.
- Interruption of treatment or use of poor quality drugs, have serious consequences

Health care facilities with well-managed stock control systems achieve good availability of medicines and medical supplies, with fewer and shorter stock-out periods. A facility that runs out of anti-TB medicines contributes negatively to TB control and to the general health services. Successful treatment of patients depends on a regular supply of anti-TB medicines. Interrupted anti-TB treatment leads to poorer treatment outcomes and the development of drug resistance. The public loses confidence in the health care system, which can lead to the community not coming for other services such as immunisations, family planning services etc.

11.2 Selection of anti -TB drugs

The National Drugs and Therapeutic Advisory Committee (N.D.T.P.A.C) selects anti-TB medicines in consultation with the NTP after taking into account latest developments in the field. Selection is usually guided by the latest W.H.O guidelines.

11.2.1 Fixed Drug Combinations (FDC) available in Zimbabwe

The FDCs available in the country are shown in Table 19.

Table 19: Available Fixed Dose Combination Drugs in the Country (May 2010)

Drug	Dose form	Strength for daily use
Rifampicin + isoniazid (RH)	Tablet Dispersible tablet*	150 mg + 75 mg 60 mg + 30 mg
Rifampicin + Isoniazid+ Pyrazinamide (RHZ)	Tablet Dispersible tablet*	60 mg + 30 mg + 150 mg
Rifampicin+Isoniazid+ Ethambutol (RHE)	Tablet	150mg +75mg +275mg
Rifampicin + Isoniazid+ Pyrazinamide + Ethambutol (RHZE)	Tablet	150 mg + 75 mg + 400 mg + 275 mg

*For paediatric use

11.2.2 Products for each level

Table 20: Availability and management of TB medicines by health care level

Drug	Health Facility
TB Fixed Dose Combination (FDCs) and Streptomycin	All health facilities i.e. diagnosing and continuation sites
TB Single formulation medicines	District, local authority provincial and central hospitals only. All other facilities should order these medicines from any of the facilities mentioned above if they have a patient that reacts to FDCs.

11.3 Stock Management

Each health care facility should adhere to the national stock management system, as in the Zimbabwe Essential Medicines Action Programme (ZEDAP) guidelines, in order to avoid under-stocking or over-stocking, or items expiring on the shelf. All health facilities should have enough stocks of anti-TB medicines for all patients on treatment. Each facility should;

- Maintain a separate stock card for every TB medicine that they are managing
- Carry out a physical count for every product once every month
- Monitor stock levels at least once every month
- Monitor expiry dates once a month.
- Update minimum, maximum and emergency point levels once every month.

11.3.1 Short dated stock

Any stock with a shelf life of three (3) months or less should be handled as follows:

- Determine whether stocks will be consumed before expiry
- Inform the district pharmacy manager (continuation sites) or provincial pharmacy manager (district hospitals). The managers concerned will advise on how the short dated stock should be handled.

11.3.2 Expired Stocks

All expired stocks should be handled according to the national guidelines on the reporting and destruction of expired stocks. Delivery teams will withdraw all expired stocks from continuation sites to the district hospital.

11.4 Inventory Levels

Health facilities should maintain stocks of all TB medicines within the following stock levels in order to ensure that enough stocks are available to cater for current patients as well as new cases. NatPharm branches countrywide will maintain buffer stocks.

Table 21: Level of Health Facility and the Stock levels of TB Medicines.

Health Facility level	Minimum Stock	Maximum Stock	Emergency Order Point (EOP)
Continuation Site	3 months	6 months	1 month
Diagnosing site	3 months	6 months	1 month
NatPharm Branch	9 months	15 months	

11.5 Supply of TB medicines to health facilities.

TB medicines will be delivered to each and every facility once every quarter by a NatPharm team led by the District Pharmacy Manager. Health facilities are not expected to submit an order to NatPharm except in emergency situations (see below on how to place an emergency order). Supplies delivered are based on the latest reported consumption, losses/adjustments as well as stock on hand.

11.5.1 Placing an emergency order

Stocks of TB medicines should not be allowed to fall below one month consumption at all times. Follow the following procedure if your stocks are equal to or less than 1-month consumption. Contact the District Pharmacy Manager with the fastest means of communication (phone, visit) if you are at a continuation site or the nearest NatPharm branch using the fastest means of communication (phone, e-mail or visit) if you are at a diagnosing site.

11.6 Logistics Management Information System

At the end of each delivery run, data will be captured into software at national level and the following reports produced:

- National stocks available (site and central level)
- Average monthly consumption (AMC)
- National months of stock
- Months of stock by province
- Months of stock by district
- Months of stock by facility
- Losses and adjustments.

These reports will be distributed to the appropriate levels after each quarterly delivery run. The NTP manager and Director of Pharmacy Services should ensure that the buffer stock reported in the quarterly report on programme management actually exists at NatPharm. Every supervisory visit to the districts should include a physical check of the actual stock level of each drug.

11.7 Estimating Laboratory Materials Requirements

Health units require an adequate supply of sputum containers for diagnosis and follow-up of patients. All health facilities that see TB suspects should have sputum containers. Laboratories need a regular supply of slides, reagents and other materials to perform the tests required. It is important to ensure that reagents and other materials meet minimum standards.

The estimation of specimen jars and laboratory supplies required for microscopy examinations depends on the expected prevalence of TB among TB suspects presenting at the health facility. Generally, the proportion of smear-positive cases ranges from 5-15% among TB suspects.

A shortage of specimen jars is a serious problem. As with drugs, the estimation of quarterly specimen jars requirements needs is based on the number of cases treated the previous quarter. To calculate the number of specimen jars needed for diagnosis multiple the number of specimen jars used in the previous quarter by 2. For other related laboratory commodities such as microscope slides, reagents, microscopes, refer to TB smear microscopy Standard Operating Procedures.

CHAPTER 12

Advocacy, Communication And Social Mobilization

12.1 Introduction

The aim of Advocacy, communication and social mobilisation (ACSM) is to cause behavioural change. It involves activities targeted at different audiences.

- Advocacy is geared towards changing the behaviour of leaders, politicians, and decision-makers at all levels.
- Communication is geared towards individuals and small groups.
- Social mobilisation is targeted at communities.

Advocacy, communication and social mobilisation are very important in TB control as they help address four key objectives of the NTP:

1. Improving case detection and treatment adherence
2. Combating stigma and discrimination
3. Empowering people affected by TB
4. Mobilising political commitment and resources for TB.

ACSM addresses the following challenges of the NTP:

- Delay in case detection and treatment
- Lack of access to TB services
- Difficulty in completion of treatment - poor case holding
- Lack of knowledge and information about TB leading to stigma and discrimination and delayed diagnosis and treatment
- Poor political support for TB programmes particularly at district and community levels
- Insufficient funding for the NTP

There is an urgent need to intensify our efforts to involve civil society in the control and elimination of TB. The framework for this action is shown below.

Framework For Action On Advocacy, Communication And Social Mobilization In Zimbabwe

1. Building national, provincial and district ACSM capacity
2. Fostering inclusion of patients and affected communities
3. Ensuring political commitment and accountability
4. Forging country-level ACSM partnerships within the context of the NTP
5. Learning, adopting and building on good ACSM practices and knowledge exchange

12.2 Advocacy

Advocacy for TB is a broad set of coordinated interventions, designed to place TB high on the political and development agenda, foster political will, increase and sustain financial and other resources. This is the first item of the DOTS strategy. The NTP through its structures will continue to advocate for support and the strong commitment of the Government of Zimbabwe to sustain the implementation of NTP policies.

Activities for advocacy

The NTP will continue to focus on administrative and corporate mobilisation through among others:

- Interactions with politicians, community and religious leaders,
- Press conferences,
- Radio and TV talk shows,
- Publishing articles in the newspapers,
- Summits, conferences and symposia, partnership meetings,
- Use of celebrity spokespersons,
- Meetings with various government ministries and departments, civil organisations,
- Patient groups and health-care providers.

The NTP will continue to highlight the growing TB problem and the socio-economic impact of TB to these decision makers and community leaders.

12.3 Communication

The NTP through its structures will use communication primarily to inform, create and improve awareness among the general public about TB (e.g. its symptoms and curability), the TB control services available (e.g. free diagnosis and treatment) and improve interpersonal communication (IPC) between patients and health-care workers contributing to behavioural change such as cough etiquette. It will continue to communicate specific designed messages about the disease and what the public and the individual can do about TB. Behaviour-change communication (BCC) messages such as "seek treatment if you have cough more than 2 weeks" and "TB is curable" will continue to be sent to the public. Effective behaviour-change communication and messages need to convey more than just the medical facts, as on their own, these facts do not necessarily motivate people to visit a TB clinic or complete their treatment. The messages should take into account the reasons why people do or do not take action on the information they receive, and then focus on changing the actual behaviour by addressing the causes identified - social norms or personal attitudes for example.

Activities for communication

- Mass media campaign - use of radio, TV, print media as a distance-learning tool
- Interpersonal communication (IPC) - peer education, traditional folk media, non-conventional media in communities, schools and among health care workers
- IEC materials for mass distribution
- Target audience includes: General public, School going youth, Teachers, Health care workers, Journalists etc.

12.4 Social Mobilisation

This is the process of bringing together "allies" to raise awareness of and demand for TB control, to assist in the mobilization and delivery of resources and services and to empower communities to participate and be self-reliant in TB control. Partnership forming is the key to social mobilization. It involves forming partnership with organised institutions/groups, such as decision-makers, policy-makers, NGOs, CBOs,

professional and religious groups, corporate bodies, development partners, and the media, communities and individuals. The primary aim of social mobilization is the empowerment of communities for action to fight stigma and eliminate TB as a public health threat.

One important activity in social mobilization is the empowerment and involvement of TB patients in the planning and implementation of TB control activities at all levels. The NTP will develop tools for empowerment of TB patients/ex-patients in TB related activities, advocate and support pre-service training for health workers on the concept of empowerment of communities and those affected in disease control and the documentation of experiences.

The NTP will continue to lead as an equal partner the all-inclusive TB partnership at national, provincial and district levels. This partnership will continue to plan and implement ACSM activities in the country. Although distinct from one another, advocacy, communication and social mobilization (ACSM) are most effective when used together. ACSM activities should therefore be developed in parallel and not separately.

12.5 Basic Health Education messages

- Tuberculosis is an infectious disease caused by bacteria called Mycobacterium tuberculosis and it commonly affects the lungs. Other parts of the body such as the heart, bones, brain, spine and the abdomen may also be affected.
- TB is spread through small droplets in the air when people with infectious TB cough, sneeze, talk or sing.
- A person with TB commonly presents with a cough of 2 weeks or more, with or without fever, sweating at night and loss of weight.
- Everybody is at risk of getting TB but the more vulnerable are
 - Children under the age of 5 years
 - People living with HIV
 - Those who are malnourished
 - People above 60 years of age
 - People with diabetes mellitus
 - People who drink alcohol excessively
- It is important to be tested for HIV when one has TB and to be screened for TB when one is HIV positive.
- All people with signs and symptoms of TB should be investigated for TB by sputum microscopy at the nearest health centre.
- Sputum microscopy is FREE in Zimbabwe.
- TB is curable and is available at every health facility in Zimbabwe.
- TB is curable even in HIV positive people.
- TB treatment is FREE for everyone in Zimbabwe
- Anti-TB drugs are now much easier to take with the introduction of fixed dose combinations (FDCs) meaning one now takes much less tablets at a time.
- It is very important to continue taking drugs and complete the treatment even when you start feeling better for you to be cured and to avoid the creation of drug resistance.
- Patients who develop side effects of TB medication should visit the nearest health facility immediately for management and advice.
- Prevent children from getting severe forms of TB by sending them for BCG vaccination.
- All TB patients should cover their mouths and noses when coughing and sneezing.
- Households with TB patients are encouraged to open their windows
- Practise good personal hygiene

CHAPTER 13

Monitoring & Evaluation of Programme Performance

13.1 Introduction

Monitoring and evaluating (M&E) the performance of the NTP involves assessing activities, monitoring costs and expenditure, determining the extent of programme coverage, evaluating treatment outcomes and determining the impact of the programme on the epidemiology of the disease in Zimbabwe. An M&E plan has been written for 2010-2014 and this chapter summarises that plan.

13.2 Purpose of Monitoring and Evaluation of NTP

M&E activities periodically measure and evaluate progress of the programme vis-à-vis the set objectives and targets of the NTP strategic plan. The purpose of M&E is to:

- Ensure that training, supervision, logistics and communication activities are being carried out effectively at each level from the national level to the primary health-care level;
- Ensure that data needed to assess case notification rates and treatment outcomes are collected, analysed and sent to the central unit by all health facilities;
- Help identify technical and operational problems, determine the reasons for the problems which will enable the management to take the necessary corrective actions;
- Provide evidence which will enable staff to improve standards of practice in patient care and support.

13.3 Recording and Reporting

The data used for M&E of the NTP comes from the routine recording and reporting from all levels of the health service. Recording and Reporting (R&R) of TB cases is an essential part of the Stop TB strategy. TB is a notifiable disease according to the Public Health Act [Chapter 15:09]. The purpose of recording and reporting is to:

- Provide relevant information for the planning, management and policy formulation and assessment of overall program performance of the NTP in Zimbabwe
- Maintain accurate records for each patient, update registers and produce regular reports of data to the central unit. This is essential for the proper management of the TB program at all levels.
- Satisfy legal requirements.

The tools used to record and report data in the NTP are in the annexes.

Using TB Registers at the health facility, the District Tuberculosis Coordinator prepares:

1. Quarterly summary of all notifications and narrative programme report
2. Quarterly outcomes of cohorts
3. Annual reports on cases and cohorts

The District TB Coordinator sends quarterly and annual reports to the Provincial Tuberculosis Coordinator, who compiles and analyses the provincial returns and reports, and then sends them to the central unit of the NTP. Collecting information quarterly allows for cohort analysis of data for a given district or province. It is important that at each level the data is analysed and utilised at the point of collection to allow for quick action in order to improve programme activities as shown in Table 22.

Table 22: The use of NTP data at each level of the Health Care System in Zimbabwe

Level	Use of Data
Health facility	The data should be used for evaluation of case detection and case management. The data is used to calculate the case detection rate and rate it against the set targets for the facility. The data should also be used also to rapidly assess the programme performance at the facility using the DOT register. Individual patients who are not doing well (e.g. those interrupting treatment, those whose sputum is not converted to negative after 2 months of intensive phase, or who have poor weight gain) should be identified and helped to make satisfactory progress.
District	The data is used for planning and distribution of resources, comparisons between health facilities, early detection of problematic areas, provision of feedback and remedying problems in the district.
Provincial	The data is used for comparisons between districts, allocation of resources to districts, early detection of problem districts and the provision of feedback and help to improve performance.
National	The data is for resource mobilisation, international reporting requirements, general TB policy formulation and advocacy for political commitment to the program.

13.4 Data flow and transmission (including reporting dates and periods)

Data is generated from the health facilities is transmitted to district, provincial, and national levels and then disseminated downwards and internationally according to agreed timelines as shown in Figure 10.

13.5 Cohort analysis of treatment outcome

A cohort is a group of patients diagnosed and registered for treatment during a specific time period (a quarter of the year).

Cohort analysis is the key management tool for evaluating the NTP performance. It allows the identification of problems, so that the NTP can institute appropriate action to overcome them and improve programme performance.

Cohort analysis takes place about a year after initiation of treatment. The District TB Coordinator should perform cohort analysis of treatment outcome every 3 months and at the end of every year. A typical cohort consists of all those new pulmonary sputum smear-positive TB patients registered during a quarter (i.e. 1 January to 31 March, 1 April to 30 June, 1 July to 30 September, and 1 October to 31 December). These are the 4 cohorts.

Each health facility TB focal point needs to analyse its own TB data and utilise it at local level.

Evaluation of treatment outcome in new sputum smear-positive patients is a major indicator of programme quality.

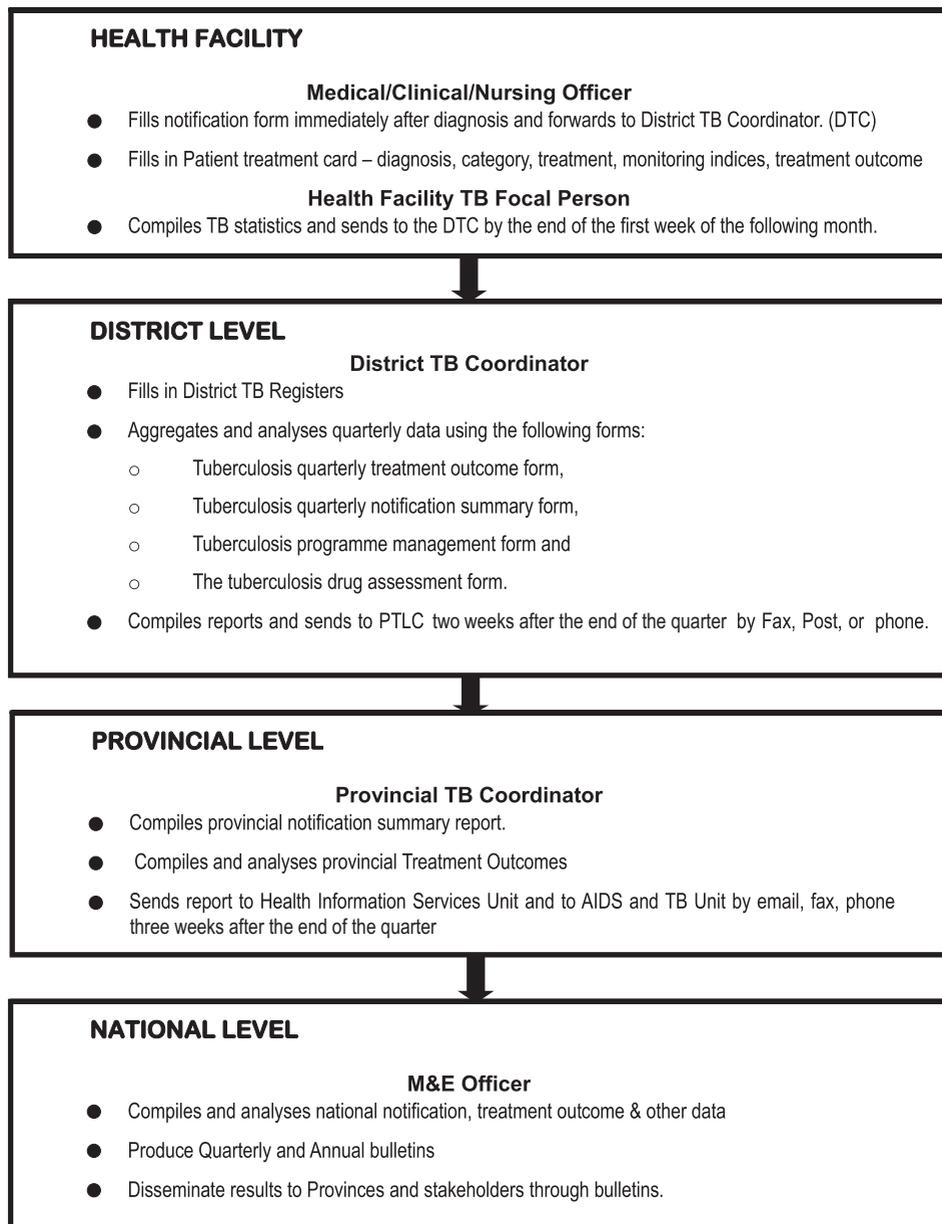
New and previously treated patients (relapses, return after default, failures) should be analysed as separate cohorts, because they have different characteristics and expected results.

Outcome in other patients (re-treatment, pulmonary smear-negative, extrapulmonary) should be analysed in separate cohorts.

Evaluation of the results of treatment and trends must be done at peripheral, district, provincial and national levels:

It is the duty of the District Medical Officer, the Provincial Epidemiology and Disease Control Officer and the Provincial TB Coordinator to verify that district reports are compiled, correct and complete and to submit the reports to the central unit of the NTP on time.

The NTP compiles cohort analysis reports on the smear-positive TB patients registered nationally, analyses and provides feedback to the programme staff. Information should be transmitted upwards and downwards, with feedback to personnel at the level of implementation.

Figure 10: Flow of Data and Timeless in Zimbabwe NTP

13.6 Indicators

Indicators help measure the programmes performance. For the NTP the broad indicator groups to be monitored are:

1. Input indicators: Human resources, Equipment, Finance and other material resources.
2. Process indicators: Training of staff, Procurement of Equipment and Production of reports.
3. Output indicators: Availability of services such as laboratory services, to perform various activities, microscopy, culture and drug sensitivity testing.
4. Outcome indicators: Case detection Rates, Treatment Outcome rates, etc.
5. Impact indicators: Prevalence and Incidence.

The main NTP indicators are:

OUTCOME AND IMPACT INDICATORS FOR GLOBAL REPORTING

- TB Case Detection Rate (CDR)
- Prevalence
- Incidence
- Treatment success
- HIV sero-prevalence among TB patients

KEY OUTCOME INDICATORS OF THE NATIONAL TB CONTROL PROGRAMME

- TB cases notified (all forms of TB per year)
- Case Notification Rate
- New smear positive cases
- Case notification rate for-new smear positive pulmonary TB cases
- New pulmonary TB cases with no smear result
- Retreatment TB cases
- New extra-pulmonary TB cases
- Sputum conversion rate at the end of the initial phase of treatment
- Treatment failure rate (first line treatment)
- Default rate
- Death Rate

Annex 1: TB Screening Tool

TB Screening Tool

Questions to Ask	Yes	No
• Do you have a cough? For how long? (YES if for 2 weeks or more).		
• Do you have night sweats? For how long? (YES if for 3 weeks or more).		
• Have you lost weight in the past 2 -3 months? (YES if the patient has lost weight, or >3 kg if able to quantify)		
• Do you have fever or "hot body"? For how long? (YES if for 3 weeks or more).		
• Does someone in the patient's household have TB now?		

If "YES" to any of the questions: the patient is a TB suspect, collect 2 sputum specimens for AFB smear if the patient is able to produce sputum, and continue evaluation for TB. Refer to higher level if necessary

If "NO" to all the questions: the patient is not a TB suspect; repeat screening with questionnaire at every visit

Annex 3: Collection of Sputum for Smear Examination

Number of Sputum Specimens to be collected

Two sputum specimens should be collected within 24 hours and sent for direct microscopy.

At the patient's first visit, a specimen is collected on the spot (spot specimen) and examined by the laboratory the same day. The patient is then given one sputum container for collection of an early morning specimen the next day at home with instructions to take the specimen to the laboratory or the health facility where patient had attended, if the laboratory is far away, that morning.

Sputum Collection Procedure (how to collect an adequate sputum specimen)

1. Use clean containers that are free from paraffin and other waxes or oils for sputum collection. The containers should have an opening that is 5 cm or more across and have at least 50 ml capacity. They should be leak proof and rigid to avoid crushing during transport to the laboratory. The container label must include the patient's name and TB suspect number, the date of specimen collection, the name of the health facility sending the specimen, and the test requested, which should all be filled in before the specimen is submitted.
2. Explain to the patient the reason and importance for proper sputum collection.
3. Sputum should be collected in open air and away from other people, with the following instructions to clients to ensure sputum of good quality:
 - Rinse the mouth before producing the specimen only for spot.
 - Take two deep breaths, holding the breath for a few seconds after each inhalation and then exhaling slowly.
 - Breathe in a third time and forcefully blow the air out.
 - Breathe in again and then cough.
4. Send the specimen to the laboratory/health centre as soon as possible

Annex 4: Request for Examination Form



**Zimbabwe National TB Programme
FORM 1
REQUEST FOR SPUTUM EXAMINATION**

Referring health facility/ code _____

Date _____

Patient's Name: _____

Age _____ Sex M [] F []

Address (Physical) _____

TB suspect number or TB number

Reason for examination (tick box):

Diagnosis: Specimen (indicate by ticking) 1st 2nd

Follow-up (tick one box): End of intensive phase End of 5months

End of continuation phase

Name and Signature of person requesting examination _____

Name and Signature of person examined the specimen: _____

RESULTS (to be completed in laboratory) _____

Laboratory Serial Number _____

Date	Specimen	Appearance*	RESULTS				
			Negative	1- 9	+	++	+++
	1						
	2						

Visual appearance (S) Salivary (M) Mucoïd
 (MS) Mucosalivary (P) Purulent (MP) Mucopurulent
 (BS) Blood stained

Annex 6: Tuberculosis Notification Form



TB NOTIFICATION FORM

Province	<input type="text"/>	District	<input type="text"/>	Centre	<input type="text"/>
TB Number	<input type="text"/>	Date of Diagnosis	<input type="text"/>		
Date of Notification	<input type="text"/>				
Surname:.....					
First Name:.....					
Physical Address 1 :.....					
(Home)					
Physical Address 2 :.....					
(Next of Kin)					
Physical Address 3:.....					
(Workplace)					
Sex	Male	<input type="checkbox"/>	Age	<input type="text"/>	
	Female	<input type="checkbox"/>			
Diagnosis (tick the appropriate box)					
Pulmonary Sputum Positive	<input type="checkbox"/>	Pulmonary Sputum Negative	<input type="checkbox"/>	Pulmonary Sputum Not Done	<input type="checkbox"/>
Extra - Pulmonary	<input type="checkbox"/>				
Type of patient (tick the appropriate box)					
New	<input type="checkbox"/>	Relapse	<input type="checkbox"/>	Retreatment after Default	<input type="checkbox"/>
				Retreatment after failure	<input type="checkbox"/>
Other	<input type="checkbox"/> Specify _____				
Treatment (tick the appropriate box)					
Category I	<input type="checkbox"/>	Category II	<input type="checkbox"/>	Category IV	<input type="checkbox"/>
New cases		Re treatments		MDR	
HIV Testing and Counseling					
Name of reporting officer _____	Offered T&C	Y	N		
	Offer Accepted	Y	N		
	HIV Result	0	1		

Annex 7: Notice of Transfer of Patient

Registration number is cumulative from 01 January to 31 December



REPUBLIC OF ZIMBABWE

(Fill in triplicate and retain the duplicate)

NATIONAL TUBERCULOSIS PROGRAMME

NOTICE OF TRANSFER OF A PATIENT

(This notice is written in triplicate and sent to referring (new) health facility by post and the other with the patient, the third is filed at notifying centre).

From:(Hosp/Clinic/HP)

To:(Hosp/Clinic/HP)

Please accept (Name)

Sex, ----- Age ----- Treatment Category -----

in your health facility for follow up and treatment.

TB No:Diagnosis.....

Name: Signature:Date ---/---/----

Tear off here

RESPONSE TO A TRANSFER OF A TB PATIENT

From:(Hosp/Clinic/HP)

To:(Hosp/Clinic/HP)

We have received the transfer form and the patient

(Patient's name, Sex/Age and TB Nr)

transferred to our hospital by -----

(name hospital)

The patient has/has not yet arrived.

Name:..... Signature: Date --/---/----

(This section to be returned within a month after receiving treatment card)

Annex 9: TB Treatment Card



ZIMBABWE NATIONAL TUBERCULOSIS PROGRAMME: TUBERCULOSIS PATIENT TREATMENT CARD

Health Facility and Code:----- Patient TB Reg no ----- Date of Registration -----/-----/-----

Name (surname, first name)	Sex	Age
	M F	
Physical Address (in full)		
Name and Address of next of kin OR Treatment supporter		

Remember!

TB can be cured!
It is very important to complete the full course, even if you feel well!
Yeukai!

TB inorapika!
Inwa mapiritsi sokurainwa kwaunenge waitwa kusvikira wapedza zvisinei kuti wava kunzwa zvirinani
Nanzelela lokhu!

Ufuba (TB) luye lapheka!
Kuqakathekile ukuba uginye wonke amaphilisi owaphiwayo aze aphele lanxa ususizwa ngcono.

Pre-treatment weightkg

INTENSIVE PHASE Regimen- FDC:				<input type="checkbox"/> SINGLE DOSES	
Adults		Children		Adults	Children
Date / Weight in kg	Daily Dose in Tablets	Date / Weight in kg	Daily Dose in Tablets	Daily Dose	Daily Dose

<input type="checkbox"/> Treatment Categories (tick)	
Category 1 (New cases) []	
Category 2 (Retreatment) []	
Category 4 (MDR) []	
P a t i e n t T y p e	New <input type="checkbox"/>
	Relapse <input type="checkbox"/>
	Retreatment after Default <input type="checkbox"/>
	Retreatment after Failure <input type="checkbox"/>
	Other, specify <input type="checkbox"/>

<input type="checkbox"/> Diagnosis (tick only one category)			
PTB sputum pos	<input type="checkbox"/>		
PTB sputum neg	<input type="checkbox"/>		
PTB sputum not done	<input type="checkbox"/>		
Extrapulmonary	<input type="checkbox"/>		
<input type="checkbox"/> SPUTUM STATUS			
	Date	Lab no.	Result
At notification			
At end of intensive phase			
At end of 5 months			
At end of continuation phase			

<input type="checkbox"/> HIV Testing and Counseling (circle)			
Offered testing	Y N	Offer Accepted	Y N
HIV Result	0	1	U
Date			

<input type="checkbox"/> HIV Care: OI number		
<input type="checkbox"/> CPT	Start Date	
	<input type="checkbox"/> Stop Date	
<input type="checkbox"/> ART	Start Date	
	<input type="checkbox"/> Type of Regimen	1 st Line <input type="checkbox"/>
		2 nd Line <input type="checkbox"/>
<input type="checkbox"/> Stop Date		
<input type="checkbox"/> ART drugs/doses		

Annex 11: Tuberculosis Quarterly Summary Notification Form



ZIMBABWE NATIONAL TUBERCULOSIS CONTROL PROGRAMME Form 6 TUBERCULOSIS QUARTERLY NOTIFICATION SUMMARY

PROVINCE: _____ DISTRICT: _____ QUARTER: _____ YEAR: _____

Age Group	PTB +ve								PTB -ve		PTB SPUTUM , NOT DONE				EPTB		Total cases
	New		Relapse		Re-treatment after Treatment Failure		Re-treatment after Default		New cases		New cases				OTHER PREVIOUSLY TREATED		
	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	
0-4																	
5-14																	
15-24																	
25-34																	
35-44																	
45-54																	
55-64																	
65+																	
Total																	

TB Suspect Screening Activities		TB/HIV activities					
No. of TB suspects examined for diagnosis by sputum smear microscopy	No. of TB suspects with positive sputum smear microscopy result	New sputum smear microscopy positive TB	All TB cases	No. TB patients tested for HIV before TB Diagnosis	No. patients found HIV positive before TB diagnosis	No. patients tested for HIV during TB treatment	No. patients found HIV positive during TB treatment

Completed by _____ Date _____

Supervisor's comments: _____

Validated by the supervisor: Date _____

Comments _____

Date submitted to province/ head office date _____.

- Printing Specifications
1. Size A4
 2. layout landscape
 3. type of paper Bond paper
 4. Style Pad with 100 sheets
 5. Quantity 500 pads

Annex 12: Tuberculosis Treatment Outcome Request Form



ZIMBABWE NATIONAL TUBERCULOSIS PROGRAMME TREATMENT OUTCOME REQUEST FORM

Name of the Patient:.....

Registered at:.....Hospital

TB Reg. Number:..... Age.....Male/Female

Diagnosis: PTB+/PTB-/EPTB Treatment Category: 1/2

Type of Patient: New / Relapse / Defaulter / Other

Date Treatment Started:..... Date Treatment Stopped:.....

Outcome (please tick appropriately)

- Cured
- Treatment Completed
- Defaulter
- Died
- Failure

Comments:.....

Name of Reporting Officer:.....Date

NB: This form serves to retrieve treatment out come results for patients transferred to other places from their original diagnostic centres. The form should be filled immediately when the patient completes treatment and the results should be forwarded to the original diagnostic centre

Annex 13: TB Quarterly Report Form on Treatment Outcome and TB/HIV Activities



Zimbabwe National Tuberculosis Control Programme:

Tuberculosis Quarterly Report Form on Treatment Outcome and TB/HIV Activities

Name of District: _____ Name of Hospital: _____ Name of TB Coordinator: _____ Signature: _____	13.6.1.1.1 Patients registered during _____ _____ quarter of year _____ Date of completion of this form: _____
--	--

TB treatment outcomes

Type of case	Total number of patients registered during quarter *	Treatment outcomes						Total number evaluated for outcomes: (sum of 1 to 6)
		Cure (1)	Treatment completed (2)	Died (3)	Treatment failure (4)	Default (5)	Transfer out (6)	
New sputum smear microscopy positive								
Previously treated sputum smear microscopy positive								
All other cases (Sputum smear negative, smear not done, EP, other previously treated ³)								

	No of TB patients offered HIV testing	No of TB patients tested	No of TB patients found positive	No of TB patients on CPT	No of TB patients on ART
All TB Cases					

Annex 14: Tuberculosis Yearly Report on Programme Management in the District



**Zimbabwe National Tuberculosis Control Programme:
Form 10:
Tuberculosis Yearly Report on Programme Management in the District**

Name of District: _____ Year: _____ Date of completion of this form: _____

Signature: _____

Block 1: Health care facilities/providers involved in TB control

Facility/provider type	Total number of facilities in the District	Facilities providing any TB control services		Facilities with laboratory facilities				Facilities providing HIV services		
		Target cumulative number to involve	Cumulative number actually involved	Target cumulative No. to involve in sputum smear microscopy	Cumulative No. involved in sputum smear microscopy	Out of (e), No. involved in Lab. Quality Assurance	Out of (e), No. providing culture services	Out of (e) No. providing DST services	Out of (c), No. providing HIV testing & counsel. to all TB patients	Out of (c) No. providing ART to TB patients
	(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
Public facility										
Private facility/provider										
Others										

Block 2: Contribution by health care facilities/ providers in TB control

Facility /provider type	No. of new sputum smear microscopy positive cases diagnosed in a year		No. of new sputum smear microscopy positive cases started on treatment in year
	Referred by	Diagnosed by	
TOTAL			
Self-referral			
Public facility			
Private facility			
Other			

Block 3: Contribution by trained and supervised community in TB control [1]

No. new sputum smear microscopy positive cases referred by the community	No new sputum smear microscopy positive cases receiving treatment support by the community

Block 4: Staff position and training

Category of staff involved in NTP	Number of positions established/ sanctioned (a)	Of them (a), number of positions filled	Of them (a), number trained in NTP in the past 12 months	Total trained in NTP
A. ALL HEALTH FACILITIES				
Medical Officers				
Nurses				
Clinical officers				
Environmental Health Staff				
Health information officers				
Pharmacy Staff				
Counsellors				
Laboratory Staff				
TB Coordinators				
HIV Coordinators				
Health Promotion Officers				
Rehabilitation staff				
Other categories (specify)				

Block 5: Advocacy Communication and Social Mobilisation

Activities	Number of Activities Planned	Number achieved
Community DOT observers trained		
Community Campaigns carried out		
Community Meetings conducted		
IEC material produced and distributed (Posters and Pamphlets)		

Block 6 Partnership

Name of Partner	Activity

Annex 15: Mantoux Testing

Indications

The Mantoux test is particularly helpful in children suspected of tuberculosis infection (contacts of sputum smear-positive) who are less than 5 years old.

Technique

There are several tuberculosis tests available, but the most accurate is the Mantoux test. Tuberculin is a protein derivative of mycobacterium which measures an individual's immune reactivity to tubercule bacilli. The standard tuberculin test is carried out with 1 IU PPD Rt 23 with Tween 80 added as stabilizing diluent. Since the concentration of IU's per ml in the vials of different manufacturers is not the same, it is of paramount importance to study the instructions on the leaflet that is enclosed in the package.

Special disposable 1 ml syringes graduated in hundredths of milliliters are used with 25 or 26 gauge, 10 mm long, disposable needles. The test is given on the dorsal aspect of the forearm. The needle-point is inserted in the superficial layer of the skin (intracutaneous, i.e. intradermal) of the forearm while the skin is slightly stretched in the direction of the needle and lengthwise of the arm. The syringe is held by the barrel only and the plunger is not touched until the needle point has been satisfactorily inserted. The 0.1 ml volume is slowly injected and the finger is removed from the end of the plunger before the needle is withdrawn.

The injection should raise a flat, pale wheal with orange skin appearance. If the injection is made into the deeper layers of the skin (as shown by a dome-shaped and less anaemic wheal) this will scarcely affect the result of the ensuing tuberculin reaction but it will make it more difficult to read! The volume injected should be exactly 0.1 ml as read on the graduation of the syringes and should not be gauged by the size of the anaemic wheal raised by the injection as this is inaccurate.

NB: The reconstituted tuberculin must be used the same day, unless stored between 4-8 degrees Celsius in a dry and dark place. This will extend the life-span by 2 days.

Measurement Of Reactions

The test is read (examined) 48 to 72 hours after it has been given. The reading is limited to the induration only. The test site is carefully palpated and if induration is present its limits are determined and its transverse diameter (transverse relative to the arm) is measured in millimetres. Use is made of a small transparent ruler (suitable length 10cm) calibrated in millimeters. The induration may be more or less easily recognizable, varying from a firm, well-circumscribed density in the skin to a soft, ill-defined swelling.

The widest transverse diameter of the induration is recorded in millimeters. If there is no palpable induration, "0" is recorded. The presence of additional features such as vesicles, bullae or lymphangitis may be noted. An induration with a visible or palpable transverse diameter of 10 mm or more constitutes a positive Mantoux test and indicates the presence of tub disease (tuberculosis infection, but not necessarily tuberculosis disease. An induration of 15 mm or more in children or young adults in contact with a source of tuberculosis infection is suggestive of tuberculosis disease.

A negative tuberculin test may be found in the presence of tuberculosis disease (i.e a so-called "false-negative" result) in the following:

1. Kwashiorkor/severe malnutrition
2. For a variable period of time during and after certain viral infections, such as measles and whooping cough.
3. Overwhelming tuberculous disease, such as military tuberculous meningitis.
4. Concurrent corticosteroid therapy.
5. During the third trimester of pregnancy.
6. AIDS and other HIV related diseases.

The categories mentioned above should only have a PPD test when focusing on positive results in non-BCG vaccinated individuals. Thus, negative results in these situations are not indicative for absence of infection.