

**Federal Ministry of Health
Ethiopia**

**Tuberculosis, Leprosy and
TB/HIV Prevention and Control
Programme**

Manual

Fourth Edition

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FOREWORD

Tuberculosis and leprosy are chronic infectious diseases affecting thousands of people in Ethiopia every year. The prevention and control as well as eventual elimination of these two ancient scourges of mankind require concerted effort by all.

Tuberculosis is a major cause of morbidity and mortality in Ethiopia. Ethiopia belongs to the list of countries most affected. Compounded with HIV/AIDS, TB has become a formidable threat to the country. The burden of TB in Ethiopia is estimated at 168 new smear-positive cases per 100,000 population according to the World Health Organization global TB report 2008. Efforts made to identify and treat those cases are far below satisfactory. This will further worsen our situation until the trend is reversed.

Successful fight against TB calls for implementation of Tb/HIV collaboration which is basically enabling all people living with HIV/AIDS benefit from packages of TB diagnosis and care and enabling all TB suspects benefit from packages of Provider Initiated HIV Counseling, Testing and subsequent services.

Leprosy is a major cause of disability for people affected by it. If left untreated leprosy will continue to be a significant problem for decades to come even the elimination target (a prevalence rate of patients on treatment below 1 per 10,000 population) has been reached at country level a couple of years ago. It is wise to note that new leprosy cases will continue to occur, and will need to be detected at an early stage of the disease and enrolled to regular and complete treatment with multi drug therapy (MDT). Significant proportion of patients coming to health facilities show disability at diagnosis and many will be at risk of developing (further) disability after diagnosis. This indicates the need for aggressive Advocacy, Communication and Social Mobilization (ACSM) to ensure that patients come at an earlier stage and complete treatment without accompanying disability.

The prevention and control effort against TB and Leprosy has been since 1994. This fourth edition of TBL and TB/HIV manual is a revised version and an outcome of efforts to accommodate all the latest developments in TB, Leprosy and TB/HIV worlds in line with the Stop TB Strategy for TB and TB/HIV collaborative activities, as well as the global strategy for further reducing the leprosy burden and sustaining leprosy control activities for leprosy. This manual will serve the purpose of a tour guide in the fight against TB, Leprosy and TB/HIV to all stakeholders in general and frontline health workers in particular. It is with great pleasure that I recommend this fourth edition to be your companion day-in day-out.

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LIST OF ABBREVIATIONS

AAU	Addis Ababa University
ACSM	Advocacy, Communication and Social Mobilization
AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal Care
ARI	Annual Risk of Infection
ART	Anti-Retroviral Treatment
CBOs	Community Based Organizations
CDC-E	Centers for Disease Control and prevention, Ethiopia
CO	Central Office
CPT	Cotrimoxazole Preventive Treatment
CRL	Central Reference Laboratory
CU-ICAP-E	Columbia University-International Center for AIDS Care and Treatment Programs-Ethiopia
DACA	Drug Administration and Control Authority
DOTS	Directly Observed Treatment, Short-Course
DPCD	Diseases Prevention and Control Department
DST	Drug Sensitivity Test
EC	Ethiopian Calendar
EHNRI	Ethiopian Health and Nutrition Research Institute
EPTB	Extra-pulmonary Tuberculosis
EQA	External Quality Assurance
FBOs	Faith Based Organizations
FHI-E	Family Health International, Ethiopia
FMOH	Federal Ministry of Health
FY	Financial or Fiscal Year
GC	Gregorian Calendar
GF	Global Fund
GFATM	Global Fund to Fight AIDS, TB and Malaria
GLRA	German Leprosy and TB Relief Association
HAART	Highly Active Anti Retroviral Treatment
HAPCO	HIV/AIDS Prevention and Control Office

HBCs	High Burden Countries
HC	Health Center
HCT	HIV Counseling and Testing
HESP	Health Extension Service Package
HEWs	Health Extension Workers
HF	Health Facility
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
HPPD	Health Programmes Provisional Department
HQ	Head Quarter
HS	Health Station
HSDP	Health Sector Development Programme
HSEP	Health Service Extension Programme
HW	Health Worker
IEC	Information, Education and Communication
IEC/BCC	Information, Education and Communication/Behavior Change Communication
IP	Infection Prevention
IPT	Isoniazid Preventive Therapy
IR	Infection risk
IRIS	Immune Reconstitution Inflammatory Syndrome
ISTC	International Standards for Tuberculosis Care
I-TECH-E	International Training and Education Center for HIV, Ethiopia
JHU-E	John Hopkins University, Ethiopia
LMIS	Logistic Management Information System
M&E	Monitoring and Evaluation
MB	Multi-Bacillary
MDGs	Millennium Development Goals
MDR-TB	Multi-Drug Resistant TB
MDT	Multi-Drug Therapy
MOH	Ministry of Health
MSH-E	Management Sciences for Health, Ethiopia

NGOs	Non-Governmental Organizations
NTCP	National Tuberculosis Control Programme
NTLCP	National Tuberculosis & Leprosy Control Programme
OI	Opportunistic Infection
PB	Pauci-Bacillary
PHCU	Primary Health Care Unit
PIHCT	Provider Initiated HIV Counseling and Testing
PLHIV	People Living With HIV/AIDS
PMTCT	Prevention of Mother-to-child transmission of HIV
PPD	Planning and Programming Department
PPM	Public-Private Mix
PTB	Pulmonary Tuberculosis
QC	Quality Control
RHB	Regional Health Bureau
RNE	Royal Netherland Embassy
RRL	Referral Regional Laboratory
RTLCC	Regional TB and Leprosy Control Coordinator
SCC	Short Course Chemotherapy
SNNPR	Southern Nations Nationalities and Peoples Region
SOPs	Standard Operation Procedures
SSA	Sub Saharan Africa
TB	Tuberculosis
TB/HIV	TB and HIV Co-infection
TBL	Tuberculosis & Leprosy
TLCP	TB and Leprosy Prevention and Control Programme
TLCT	TB and Leprosy Prevention and Control Team
UCSD-E	University of California San Diego, Ethiopia
UNAIDS	The joint United Nations Programme on HIV/AIDS
USAID	United States Agency for International Development
VCT	Voluntary Counseling and Testing

WCDC	Woreda Communicable Diseases Control Coordinator
WHO	World Health Organization
XDR-TB	Extensively Drug Resistant Tuberculosis
ZCDC	Zonal Communicable Diseases Control Coordinator

1. INTRODUCTION

Tuberculosis and Leprosy have been recognized as major public health problems in Ethiopia more than half a century ago. The effort to control tuberculosis began in the early 1960s with the establishment of TB centres and sanatoriums in three major urban areas in the country. In 1976, in order to address effectively the TB challenge, the Central Office (CO) of the National Tuberculosis Control Programme (NTCP) was established.

An organized leprosy control programme was established within the Ministry of Health (MOH) in 1956 and a detailed policy was issued in 1969. Leprosy control was strongly supported by the German Leprosy Relief Association (GLRA). The programme was rather vertical and well funded and has scored notable achievements in reducing the prevalence of the disease, especially after the introduction of Multiple Drug Therapy (MDT) in 1983. However, the annual new case detection did not show comparable decline.

Global efforts to control TB were strengthened in 1991, when a World Health Assembly resolution recognized TB as a major global public health problem. Two targets for TB control were established as part of this resolution – 70% of case detection rate and 85% of cure rate by the year 2000, which means that at least the 70% of new smear positive cases should be detected and at least the 85% of these cases should be treated. These two targets were embedded within the DOTS strategy launched by WHO in 1994, and subsequently endorsed by the WHO STOP TB Strategy in 2006. Ethiopia, implementing the DOTS and STOP TB Strategy, adopted the global targets for TB control.

In 1992 a standardized TB prevention and control programme, incorporating **Directly Observed Treatment, Short Course (DOTS)**, was started as a pilot in Arsi and Bale zone, Oromia Region. The DOTS strategy has been subsequently scaled up in the country and implemented at national level. Currently the DOTS geographic coverage reaches 90%, whereas the Health Facility coverage is 75%.

In view of the achievements made by combined tuberculosis and leprosy control programmes in other countries, including those in

sub-Saharan Africa, it was decided in 1994 to combine the two programmes in Ethiopia into the National Tuberculosis & Leprosy Control programme (NTLCP) under the co-ordination and technical leadership of the CO.

In June 2000 the previous Epidemiology/AIDS Department of the MOH was re-structured and named Disease Prevention and Control Department (DPCD). The TB and Leprosy Control Programme was subsequently accommodated within this Department, together with Malaria and other Vector-Borne Diseases Prevention and Control Team, Integrated Diseases Surveillance and Response Team, other Communicable and Non-Communicable Diseases Prevention and Control Team. The former CO was then named Tuberculosis and Leprosy Control Team (TLCT).

The leprosy component of the combined TB and Leprosy control program has been fully integrated into the general health services by the end of 2001. Integration means that TB and leprosy prevention and control activities became the responsibility of the general health service.

This Manual contains the technical and managerial aspects of TB, TB/HIV and Leprosy control activities in Ethiopia. This revised version of the Manual was developed in the framework of the new Stop TB Strategy, with significant updating of diagnostic and clinical management criteria of TB and is including all aspects of TB Control, including TB/HIV, Multi-Drug Resistant-TB and Public-Private Mix (PPM)-DOTS. Regarding Leprosy, the manual has been significantly updated; in line with the global strategy for further reducing the leprosy burden and sustaining leprosy control activities (2006 – 2010) as well as the operational guideline for the implementation of the global strategy.

This manual is primarily intended for general health workers who are responsible for the diagnosis and treatment of both diseases, for program coordinators at different levels of the health system and development partners in the health sector. Furthermore, it is an important reference material for academic and research institutions.

2. THE GLOBAL and NATIONAL BURDEN OF

TUBERCULOSIS AND LEPROSY

2.1 Global burden of tuberculosis

TB is a major public health problem throughout the world. According to the WHO Global Report 2007, one-third of the world's population is estimated to be infected with tubercle bacilli and hence at risk of developing active disease. Globally, in 2005, the annual incidence of TB, expressed as the number of new TB cases, was about 8.8 million people (7.4 million of these in Asia and sub-Saharan Africa), and the annual number of deaths due to TB was 1.6 million, including 195,000 patients infected with HIV. In developing countries, TB comprises 25% of all avoidable adult deaths. It is estimated that nearly one million (11%) of the total TB cases are children less than 15 years of age.

The 22 High Burden Countries (HBCs) account for approximately 80% of the estimated number of new TB cases (all forms) arising worldwide each year. These countries are the focus of intensified efforts in DOTS expansion. The HBCs are not necessarily those with the highest incidence rates per capita; many of the latter are medium-sized African countries with high rates of TB/HIV co-infection.

Recent evidences tend to demonstrate that TB prevalence and TB death rates are globally decreasing after having reached a peak. Since 2005, the TB incidence rate is in decline in all six WHO regions. However, the TB case-load continues to grow in Africa, and Eastern Europe.

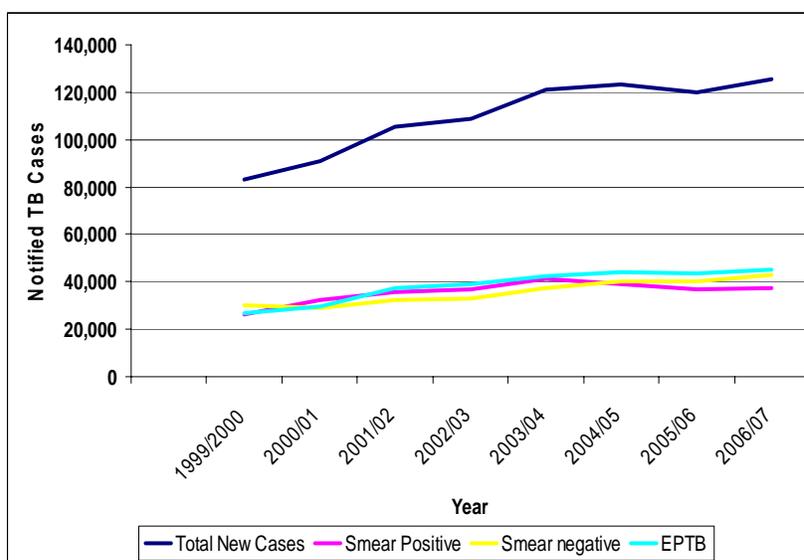
2.2 National burden of tuberculosis:

According to the 2007 WHO estimates, the incidence of TB of all forms and smear positive TB stand at 341 and 152 per 100,000 population, respectively. The prevalence and mortality of Tuberculosis of all forms is estimated to be 546 and 73 per 100,000 population respectively. In the year 2006/7 Ethiopia registered 129,743 cases of TB. According to latest estimates, Ethiopia stands 7th in the list of High Burden Countries for TB.

Table 1: Eight-year overview of TB case notification in Ethiopia, 1999-2007 (1992-1999 E.C); TB Data, TLCT, FMOH

Year (G.C.)	Total New Cases	Smear Positive	%	Smear Negative	%	EPTB	%	Case notification rate per 100,000 population		Treatment success rate
								Smear Positive	All forms	
1999/2000	83,334	26,459	32	30,333	36	26,542	31	42	131	
2000/01	90,729	32,423	36	28,994	32	29,312	32	50	139	
2001/02	105,250	35,915	34	32,197	31	37,138	35	53	157	
2002/03	108,488	37,014	34	32,656	30	38,818	36	54	157	
2003/04	121,026	41,430	34	37,119	31	42,477	35	59	173	
2004/05	123,090	38,800	31	40,269	33	44,021	36	53	169	81%
2005/06	120,163	36,674	31	40,234	33	43,255	36	49	160	78%
2006/07	126,809	38,040	30	43,500	34	45,269	36	49	164	85%

Figure 1: Notified cases of TB in the last eight years, 1992-1999 E.C. (TBL Data, TLCT, FMOH)



According to the MOH hospital statistics data, tuberculosis is the leading cause of morbidity, the third cause of hospital admission (after deliveries and malaria), and the second cause of death in Ethiopia, after malaria.

Tuberculosis is an obstacle to socio-economic development; 75% of people affected by TB are within the economically productive

age group of 15-54 years.

The HIV epidemic worsened the TB situation by:

- Accelerating the progression from primary infection to disease;
- Increasing the reactivation rate of TB;
- Increasing the re-infection rate.

It is estimated that 50 to 60% of HIV infected people will develop TB disease in their lifetime in contrast with HIV negative persons, whose lifetime risk is only 10%.

Seroprevalence of HIV among adult TB patients is 11% according to WHO report 2007, and 31% according to more recent national data from 1999 EC (2006/07).

Another challenge to TB control in Ethiopia is the emergence of multi-drug resistant TB (MDR-TB). The data from DST survey conducted in the country between 2003 and 2006 shows that levels of MDR-TB are: 1,6% and 11,8% in new cases and re-treatment cases of TB patients, respectively. However, these figures translate into large absolute number of MDR-TB cases, who can transmit drug resistant strains to others, especially in overcrowding condition, high prevalence of HIV and malnutrition. For these reasons, this emerging problem calls for serious consideration and urgent action.

The incidence of TB in children is less compared to adults, but they are likely to suffer from more serious forms of TB and may die if not treated properly.

2.3 Global burden of leprosy

The WHO elimination strategy (elimination of leprosy is defined as reducing the registered prevalence of leprosy to less than 1 per 10,000 inhabitants), based on the widespread implementation of multi-drug therapy (MDT), has led to a dramatic reduction of the prevalence of registered leprosy. The impact of MDT on the prevalence of leprosy is due to the greatly reduced duration of treatment. The global registered prevalence of leprosy at the beginning of 2007 stood at 224,717 cases, while the number of

new cases detected during 2006 was 259,017. During 2006, the number of new cases detected fell globally by more than 40,019 cases (13.4%) when compared with 2005. Since 1985, prevalence of leprosy has been reduced globally by more than 90% and over 14.5 million patients have been cured through multidrug therapy (MDT).

2.4 National burden of leprosy

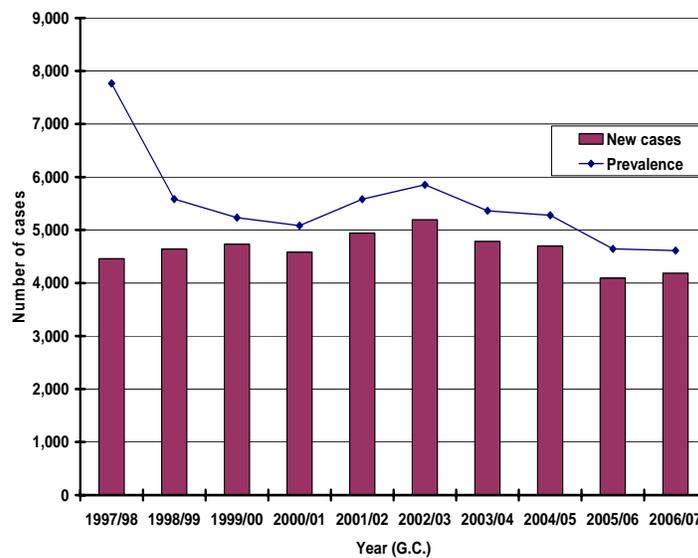
The national registered prevalence of leprosy at the end of June 2007 is 4,611, while the number of new cases detected during 2006/07 (1999 EC) is 4,187. The prevalence rate of registered cases of leprosy, therefore, stood at 0.6 per 10,000 inhabitants at the end of June 2007. However, the registered prevalence varies considerably from region to region. The proportion of children and disability grade 2 among newly detected cases during 2006/07 (1999 EC) is 7% and 10% respectively.

Table 2 below illustrates trend in leprosy new case detection in Ethiopia over the past five years.

Table 2: Ten-year overview of Leprosy case notification, 1997/98 – 2006/07 (1990 – 1999 EC) (Source: Annual leprosy data TLCT, FMOH)

Year (G.C.)	Prevalence	New cases			
		New cases	Child rate (%)	Grade II disability (%)	MB proportion (%)
1997/98	7,764	4,457	6	16	74
1998/99	5,585	4,643	7	12	79
1999/00	5,233	4,732	6	13	81
2000/01	5,081	4,584	7	13	84
2001/02	5,580	4,940	6	15	86
2002/03	5,852	5,193	6	15	88
2003/04	5,364	4,787	7	14	88
2004/05	5,277	4,698	7	13	88
2005/06	4,646	4,092	8	11	75
2006/07	4,611	4,187	7	10	93

Figure-2: Leprosy case notification, 1997/98 - 2006/07 (1990 - 1999 EC)



3. PRINCIPLES OF TB AND LEPROSY CONTROL

3.1 Global Strategy to prevent and control TB

In 1994, WHO launched the Directly Observed Treatment, Short-course (DOTS) Strategy, which is the brand name of the internationally recommended strategy for TB control. The DOTS strategy ensures that infectious TB patients are identified and cured using standardized drug combination. The five key components of DOTS strategy are:

1. Government commitment to ensure sustained and comprehensive TB control activities, increase human and financial resources and make TB control a nationwide priority;
2. Case detection by sputum smear microscopy among symptomatic patients self reporting to health facilities;
3. Standardized short-course chemotherapy using regimens of six to eight months, for all diagnosed cases of tuberculosis under proper case-management conditions, including direct observation of treatment;
4. Regular, uninterrupted supply of all essential anti-tuberculosis drugs and laboratory supplies;
5. Standardized recording and reporting system that allows assessment of case finding and treatment result for each patient and of the tuberculosis control programme performance overall.

One of the most important components of DOTS is the direct observation of treatment, which means that a health worker must watch the patient taking each dose. Direct observation of treatment is important to:

- Ensure that patients take the correct treatment regularly;
- Notice rapidly when a patient misses a dose, find out why, and solve the problem;
- Monitor any problem that the patient may experience with the disease, the treatment or other condition.

The DOTS framework has subsequently been expanded and implemented in 182 countries. It has helped countries to improve national TB control programmes (NTPs) and make major

progress in TB control. By 2005, more than 26 million patients had been notified in DOTS programmes worldwide, and 10.8 million new smear-positive cases were registered for treatment by DOTS programmes between 1994 and 2004. In 2005, nearly 5 million TB patients were notified under DOTS.

DOTS programmes detected an estimated 53% of all new cases and 60% of new smear-positive cases in 2005. The detection rate achieved by DOTS programmes, of both smear-positive and all new TB cases, has accelerated sharply since 2000. However, the increase in the smear-positive case detection rate under DOTS is slowing: the increment between 2004 (54%) and 2005 (60%) was 6%, which is less than in the two preceding yearly intervals. In 2005 the point estimate of 60% smear-positive case detection rate by DOTS programmes is below the 70% target.

At present, cure rate among cases registered under DOTS is globally 77%, and a further 7% completed treatment (no laboratory confirmation of cure), giving a reported, overall treatment success rate of 84%, i.e. 1% below the 85% target set for the 2004 cohort. However, out of all patients treated under DOTS, 10% had no reported outcome. A total of 496 719 patients were reported to have been re-treated under DOTS in 2004. While some patients remained on treatment, the re-treatment success rate by the end of 2005 was 73%.

3.2 The STOP TB Strategy:

The STOP TB Strategy was launched by WHO in 2006. It comprises of the following elements:

1. Pursue quality DOTS expansion and enhancement, improving case-finding and cure through an effective patient-centred approach to reach all patients, especially the poor.
2. Address TB/HIV, MDR-TB and other challenges, by scaling up TB/HIV joint activities, DOTS-Plus, and other relevant approaches.
3. Contribute to health system strengthening by collaborating with other health programmes and general

services, for example in mobilizing the necessary human and financial resources for implementation and impact evaluation, and in sharing and applying achievements of TB control.

4. Involve all care providers, public, nongovernmental and private, by scaling up approaches based on a public-private mix, to ensure adherence to the International Standards for TB Care.
5. Engage people with TB and affected communities to demand, and contribute to, effective care. This will involve scaling up community TB care; creating demand through context specific advocacy, communication and social mobilization; and supporting development of a patients' charter for the TB community.
6. Enable and promote research for the development of new drugs, diagnostics and vaccines. Research will also be needed to improve programme performance.

The new Stop TB Strategy acknowledges the need to provide care to all TB patients, whether drug susceptible or drug-resistant bacilli cause their disease.

3.3 Global Plan to Stop TB 2006-2015

The Global Plan for 2006-2015 fully adopts the WHO-recommended Stop TB Strategy; its implementation over a 10-year duration should bring the following achievements:

- Expansion of equitable access for all to quality TB diagnosis and treatment.
- About 50 million people will be treated for TB under the Stop TB Strategy, including about 800 000 patients with MDR-TB, and about 3 million patients who have both TB and HIV will be enrolled on antiretroviral therapy (ART).
- Some 14 million lives will be saved from 2006 to 2015.
- The first new TB drug for 40 years will be introduced in 2010, with a new short TB regimen (1-2 months) soon after 2015.
- By 2010, diagnostic tests at the point of care will allow rapid, sensitive and inexpensive detection of active TB.

By 2012, a diagnostic toolbox will accurately identify people with latent TB infection and those at high risk of progression to disease.

- By 2015, a new, safe, effective and affordable vaccine will be available with potential for a significant impact on TB control in later years.

3.4 Global Strategy for Further Reducing the Leprosy Burden and Sustaining Leprosy Control Activities

The main principles of leprosy control, based on timely detection of new cases and their treatment with effective chemotherapy in the form of multi drug therapy, will not change over the coming years. The emphasis will remain on providing patient care that is equitably distributed, affordable and easily accessible.

The main elements of the strategy are as follows:

- Sustain leprosy control activities in all endemic areas of the country
- Use case detection as the main indicator to monitor progress
- Ensure high-quality diagnosis, case management, recording and reporting
- Strengthen routine and referral services
- Discontinue the approach by campaign
- Develop tools and procedures that are home/community-based, integrated and locally appropriate for the prevention of disabilities/impairments and for the provision of rehabilitation services.
- Promote operational researches in order to improve implementation of a sustainable strategy.
- Encourage supportive working arrangements with partners at all levels.

This strategy will require endorsement and commitment from everyone working towards the common goal of controlling leprosy, to ensure that the physical and social burden of the disease continues to decline throughout the world.

4. TB AND LEPROSY CONTROL PROGRAMME IN ETHIOPIA

4.1 General objectives of TLCP (Tuberculosis and Leprosy Control Program)

The general objectives of TB and Leprosy control are to:

1. Interrupt transmission of the infections;
2. Reduce morbidity, mortality and disability;
3. Prevent emergence and spread of drug resistance;
4. Reduce burden of TB among people living with HIV;
5. Reduce HIV burden among TB patients.

4.2 Specific objectives of TLCP

1. Expand and strengthen the access to high quality DOTS in order to meet the Stop TB Partnership targets for TB Control: to identify at least 70% of people with infectious TB (under the DOTS strategy), and to cure at least 85% of these patients.
2. Expand and strengthen high quality leprosy prevention, control and care that is equitably distributed, affordable and easily accessible, in order to meet the targets for leprosy control: to reduce the proportion of disability grade 2 among new leprosy cases to less than 5% by identifying new cases as early as possible as well as achieving and maintaining MDT completion rate to at least 90%.
3. To address adequately TB/HIV, by strengthening the collaboration between TB and HIV Prevention and Control Programmes at all levels, in order to reduce burden of TB among People Living with HIV (PLWH) and to reduce the burden of HIV and AIDS among TB patients
4. Reduce the burden of TB, Leprosy and TB/HIV among more vulnerable communities

5. Ensure community participation in the promotive and preventive activities for TB, leprosy and TB/HIV, in order to empower people with TB and Leprosy and communities.
6. Enable and promote program-based operational researches

4.3 Basic strategies in reaching the objectives

In order to reach the national objectives and targets, the TB and Leprosy Control Program of Ethiopia is aligned with the globally recommended Stop TB Strategy and Global Strategy for Leprosy Prevention and Control. The basic strategies are:

1. Early case detection
2. Adequate chemotherapy
3. Provision of comprehensive & standard patient care
4. Enhanced case management
5. Accurate Monitoring and Evaluation (M & E) of program performance
6. Community participation

The most efficient method for preventing transmission is identification (through early case detection and diagnosis) and the cure of the most potent sources of infection: pulmonary tuberculosis patients excreting tubercle bacilli.

The targets of an effective TBL Control Programme are:

- To achieve and maintain detection of at least 70% of new sputum smear-positive TB cases;
- To achieve and maintain a cure rate of at least 85% among these patients (through DOTS);
- To reduce the proportion of grade 2 disability among new leprosy cases to less than 5%.
- To achieve and maintain a treatment completion rate of leprosy to at least 90%.

These strategies are cost effective for the individual patients, their families and the community at large. Therefore, establishment of

early case finding and adequate chemotherapy with a standardized combination of drugs (SCC for TB and MDT for leprosy), remains top priority to cure the patient, interrupt transmission of infection and prevent death and complications caused by both diseases.

4.4 Organizational structure and functions

Disease prevention and control measures that serve the needs of people must be carried out throughout the whole country and the services including laboratory should be placed as close as possible to the community. In Ethiopian context, the only way to apply this is to incorporate the programmes into the existing general health services.

Within this integrated health system, the TLCP relies on supervisory staff at National, Regional, Zonal, Sub-cities, City Administration and Woreda levels, staff equipped with expertise and skills on TB, TB/HIV and Leprosy.

The functions of TB and leprosy control can be classified as community, patient-and programme-management activities:

a. ***Community management activities*** (mainly carried out by Health Extension Workers and community volunteers/promoters):

<i>Activity</i>	<i>TB</i>	<i>Leprosy</i>	<i>TB/HIV collaboration</i>
Education of the community	Yes	Yes	Yes
Identification of suspects	Yes	Yes	Yes
Referral of suspects to health facilities	Yes	Yes	Yes
Support for adherence to treatment	Yes	Yes	Yes
Retrieval of absentees	Yes	Yes	Yes
Contact tracing	Yes	Yes	Yes

b. Patient management activities (mainly carried out by General Health Workers at the health facility level) are:

Activity	TB	Leprosy	TB/HIV collaboration
Case detection	Yes	Yes	Yes
Contact examination	Yes	Yes	Yes
Case holding	Yes	Yes	Yes
Patient education	Yes	Yes	Yes
Infection control	Yes	Yes	Yes
Prevention of disability	+	+++++	+
Rehabilitation	+	+++++	+
HIV Counselling and Testing	+	-	+
Cotrimoxazole Preventive Therapy	Yes for HIV pos	Yes if HIV pos	Yes if HIV pos
Linkage for HIV chronic care & treatment	Yes if HIV pos	Yes if HIV pos	Yes if HIV pos
Isoniazide Preventive Therapy	Yes for high risk contacts (children below 5 years)	-	Yes for HIV- pos clients, after ruling out active TB
Recording and reporting	Yes	Yes	Yes

c. Programme management activities (carried out by specialized units of TLCP) are:

Activity	TB	Leprosy	TB/HIV collaboration
Planning	Yes	Yes	Yes
Guideline development & developing strategic policy directives	Yes	Yes	Yes
Training	Yes	Yes	Yes
Co-ordination	Yes	Yes	Yes
Advocacy, Communication & Social Mobilization (ACSM)	Yes	Yes	Yes

Monitoring and evaluation (supportive supervision, review meetings, epidemiological surveillance)	Yes	Yes	Yes
Data collection and analysis	Yes	Yes	Yes
Drugs and supplies management	Yes	Yes	Yes
Establishment of quality assured laboratory services	Yes	-	Yes
Resource mobilization	Yes	Yes	Yes
Operational research	Yes	Yes	Yes

The success of TB and Leprosy Prevention and Control Programme entirely depends on integrity of the structure, which is made of the different levels in the health system. Details of duties and responsibilities of the different levels (National, Regional, City Administration, Zonal, Sub-cities, Woreda, Health facility level and laboratories) are described under annex I.

5. TUBERCULOSIS

5.1 Definition

Tuberculosis (TB) is an infectious diseases caused by *Mycobacterium tuberculosis*, a rod-shaped bacillus called “acid-fast” due to its staining characteristics in laboratory. Occasionally the disease can also be caused by *Mycobacterium bovis* and *Mycobacterium africanum*.

The bacilli usually enter the body by inhalation (breathing). They may spread from the initial location in the lungs to other parts of the body via the blood stream, the lymphatic system, via the airways or by direct extension to other organs. Tuberculosis is broadly classified into:

Pulmonary TB (PTB): accounts for 85 % of all TB cases, and it is further classified in:

- a. Smear-positive PTB: comprises 75 – 80% of PTB cases, worldwide
- b. Smear-negative PTB: comprises 20 – 25% of PTB cases, worldwide

Extra-pulmonary TB (EPTB): it is the result of the spread of tuberculosis to other organs, most commonly pleura, lymph nodes, spine, joints, genitor-urinary tract, nervous system or abdomen and it represents 14% of all TB cases in the world and 12% of all TB in HBC.

5.2 Transmission and pathogenesis

Tuberculosis is most commonly transmitted by inhalation of infected droplet nuclei (very small and light drops), which are discharged in the air when somebody with untreated sputum-positive pulmonary TB coughs or sneezes. Persons living in the same household, or who otherwise are in frequent and close contact with an infectious patient have the greatest risk of being exposed to the bacilli. In addition, consumption of raw milk containing *M.bovis* is a possible way of getting infected by TB,

though it is much less frequent.

TB affects individuals of all ages and both sexes. There are, however, groups, which are more vulnerable to develop the disease:

Poverty, malnutrition and over-crowded living conditions have been known for decades to increase the risk of developing the disease. HIV infection has been identified as a major risk factor for developing tuberculosis.

The age group mainly affected is between 15 and 54 years, and this leads to grave socio-economic consequences in a country with a very high prevalence of the disease.

5.3 Natural history

In the great majority (90-95%) of persons infected with *M. Tuberculosis* the immunological defence either kills the inhaled or ingested bacilli or perhaps more often, keeps them suppressed (silent focus) causing **latent *M. Tuberculosis* infection**.

Only about 5-10% of such infected persons (primary infection) develop active disease.

Active TB disease arises from progression of the primary lesion as a continuous process within a year or so after infection, or from endogenous reactivation of latent foci, which remained dormant since the initial infection or exogenous re-infection. Post primary TB usually affects the lungs (more than 85%) but can involve any part of the body.

If untreated, TB leads to deaths within 2-3 years in at least half the patients. Without treatment, about 20 to 25% would have natural healing and 25 to 30% would remain chronically ill, thus continuing to spread the disease in the community.

Table 3: Overview of active and latent TB

The table below provides an overview of active and latent TB.

ACTIVE TB = TB DISEASE/ = A CASE OF TB	LATENT TB = TB INFECTION/ = NOT A CASE OF TB People with latent (inactive) TB = TB carriers
Definition <ul style="list-style-type: none"> ● TB bacteria is active in the body; the immune system is unable to stop the bacteria from growing. 	<ul style="list-style-type: none"> ● Bacteria are inside the body, but not active. ● Body is able to fight off the bacteria and stop growth. May eliminate all TB bacteria. ● For the most part, the bacteria remain dormant and viable for years.
Transmission Contagious <ul style="list-style-type: none"> ● TB bacteria can be spread through the air; people with active TB can pass the bacteria on to anyone with whom they come into close contact. ● Droplet infection: breathing, coughing, sneezing, spitting, talking or even when TB bacilli are aerosolised by treatments (e.g. irrigating a wound that is infected with extra-pulmonary TB): people nearby may breathe in the TB bacillus. The tiny particles, containing M. tuberculosis are called droplet nuclei and can remain in the air for several hours. ● The bacteria then traverse the upper respiratory tract and bronchi to reach the alveoli of the lungs. Once in the alveoli, alveolar macrophages take up the TB bacilli, holding some in the lungs, and transporting others throughout the body. 	Not Contagious <ul style="list-style-type: none"> ● People with latent TB cannot spread the disease.
Symptoms <ul style="list-style-type: none"> ● Cough, fever, weight loss. 	<ul style="list-style-type: none"> ● No symptoms.
X-ray <ul style="list-style-type: none"> ● Chest x-ray is usually abnormal. 	<ul style="list-style-type: none"> ● Chest x-ray is usually normal.
Sputum sample <ul style="list-style-type: none"> ● Sputum smears and cultures positive. 	<ul style="list-style-type: none"> ● Sputum smears and cultures negative.
TB skin test <ul style="list-style-type: none"> ● TB skin test reaction is usually positive (because of TB bacilli in the body) <p style="text-align: center;">↓</p> <ul style="list-style-type: none"> ● Left untreated each person with active TB will infect, on average, 10-15 people every year. 	<ul style="list-style-type: none"> ● TB skin test reaction is usually positive (because of TB bacilli in the body) <p style="text-align: center;">↓</p> <ul style="list-style-type: none"> ● Most people infected with TB never develop active disease.

5.4 Case Detection, Case Finding

Detection of the most infectious cases of tuberculosis – sputum smear-positive pulmonary cases – is an essential component of the control of tuberculosis; it's case finding.

5.4.1 Objectives

Basically the objectives of case finding are:

1. To cut the chain of transmission;
2. To start the treatment early, with better outcome.

The first objective of case finding is to identify the source of infection in the community, that is, individuals who are discharging large number of tubercle bacilli. *Treatment of those infectious patients rapidly renders them non infectious, thereby cutting the chain of TB transmission.*

The identification of TB suspects (cough for more than 2 weeks) and screening them by examination of sputum smears allows discovering those who are transmitting tuberculosis.

The second objective of case detection is to minimize the delay in initiating treatment, thereby increasing the possibility of cure. Successful treatment of these patients has a rapid effect on tuberculosis prevalence, mortality and transmission.

Community education should be provided so that people are made aware that persistent cough is abnormal, informed where health services are available, and convinced to consult a health provider promptly for sputum smear examination.

Systematic identification of adults with persistent cough among outpatients in general health facilities can detect a large proportion of sources of tuberculosis infection and identify infectious patients who are at risk to the community and to other patients and staff.

Contacts of smear-positive tuberculosis patients are at high risk of getting infection and developing tuberculosis, thus justifying active case detection in these individuals. Examination of contacts, particularly of contacts of sputum smear-positive patients, is therefore recommended to identify and treat additional tuberculosis cases and to provide preventive treatment to those at highest risk, such as children and people infected with HIV. Among residents of institutions with a high risk of tuberculosis transmission (prisons, shelters for homeless, hospitals), evaluation for cough on admission and periodic assessment are useful to detect and treat sources of infection.

The regular screening for TB among HIV-positive clients, at every stage of the disease, is one key TB/HIV collaborative activity, with the aim to reduce the burden of TB in PLWH.

5.4.2 Case finding strategies:

1. Identification of suspects among patients who present on their own initiative at health facilities or in the community;
2. Proper diagnosis through examination of sputum of patients with symptoms suggestive of TB;
3. Promotion of awareness in the community, amongst the medical staff and the Community workers regarding respiratory symptoms, notably persistent cough for 2 weeks or more, and the need to obtain and examine 3 sputum specimens for the diagnosis of TB;
4. Contact screening: examination of household contacts of smear-positive TB patients; irrespective of the duration of cough;
5. Intensified TB screening in high-risk groups.

5.5 Identification of suspects

Health extension workers and community volunteers can perform the identification of suspects at the health facility, or at community level. Once a suspect is identified, he/she should be

immediately referred to health facility providing DOTS service for examination and treatment.

All patients have to be interviewed and examined for signs and symptoms described below.

The TB suspects can be roughly divided in:

- Pulmonary TB (PTB) suspects;
- Extra-pulmonary TB (EPTB) suspects.

Pulmonary TB:

A person is a suspect of Pulmonary Tuberculosis when presenting with
persistent cough for two weeks or more

Cough is usually with **expectoration**, with or without **blood stained sputum** and can be accompanied by one or more of the following symptoms:

- Weight loss;
- Chest pain;
- Shortness of breath;
- Intermittent fever;
- Night sweats;
- Loss of appetite;
- Fatigue and malaise.

Every adult patient with respiratory symptoms attending the health facility must be asked about symptoms suggestive of tuberculosis, with particular attention to cough persisting for 2 weeks or more.

A patient is most likely to be suffering from PTB if, in addition to one or more of the above symptoms, he/she is a/has a/lives in close contact with contact of a PTB+ patient or/and if she/he is HIV+.

Moreover, any person who for any other medical reasons has got a chest x-ray examination and whose chest x-ray findings are suggestive of PTB must be dealt with as a TB-suspect.

Extra-pulmonary TB

The signs and symptoms of *Extrapulmonary Tuberculosis (EPTB)* depend mainly on the organ(s) involved.

The most common forms and their respective presentations are:

Tuberculous lymphadenitis

- Slowly developing and painless enlargement of lymph nodes, followed by matting and eventual drainage of pus. See appendix VI.

Tuberculous pleurisy

- Pain while breathing in, dull lower chest pain, intermittent cough, breathlessness on exertion.

TB of bones and/or joints

- Localized pain and/or swelling, discharge of pus, muscle weakness, paralysis, stiffness of joints.

Intestinal TB

- Loss of appetite and weight, abdominal pain, diarrhoea or constipation, mass in the abdomen, fluid in the abdominal cavity (ascites).

Tuberculous meningitis

- Headache, fever, vomiting, neck stiffness and mental confusion of insidious onset

Whenever a person presents with signs and symptoms suggestive of EPTB, he/she should be referred to a health center or a hospital where there is a clinician and better diagnostic facility.

Table 4: symptoms of PTB and EPTB

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

5.6 Diagnostic methods

All suspects of any form of TB must be examined according to the standardized diagnostic procedures of which the microscopic examination of sputum is the most important and reliable. By rank of importance the diagnostic methods to confirm/exclude TB are:

- Microscopic examination of sputum smears
- Radiological investigation
- AFB culture
- Histo-pathology

5.6.1 Microscopic examination of sputum smears

Sputum microscopy is the most efficient way of identifying sources of tuberculosis infection, and the primary tool for diagnosing TB; it is easy to perform at the peripheral laboratories, not expensive and specific. It can be used for diagnosis, monitoring and defining cure. Therefore, this is the key diagnostic tool used for case detection.

Three sputum specimens must be collected and examined in two consecutive days (**spot-early morning-spot**). Detailed information on the method of sputum collection is given in annex IV.

Every individual suspected of having tuberculosis must have an examination of 3 sputum smears, to determine whether or not they have infectious tuberculosis.

According to the latest recommendation by WHO and the national AFB microscopy laboratory manual, the result of the sputum

smear should be indicated as follows:

Examination finding	Result as recorded	Laboratory result	No. of fields examined
No AFB in 100 oil immersion fields	Negative	NEG	100
1 to 9 AFB in 100 oil immersion fields	Positive	1-9 (Scanty)	100
10-99 AFB in 100 oil immersion fields	Positive	(+)	100
1-10 AFB per oil immersion field	Positive	(++)	50
> 10 AFB per oil immersion field	Positive	(+++)	20

PTB+ is confirmed when at least 2 out of three smear results are positive for AFB.

PTB + is also confirmed when one sputum specimen is positive for AFB **in addition to** radiographic abnormalities consistent with active PTB (see flowchart: annex III).

Only one positive smear result in HIV-negative patients does not justify starting TB treatment since errors, made during the handling of the specimen, can never be excluded.

In HIV-positive patients (or in presence of a strong clinical suspicion of HIV-infection), only one positive smear result is necessary to make diagnosis of smear-positive pulmonary TB.

The laboratory should keep all positive and negative slides (in separate boxes for positive and negative slides) to facilitate the Quality Assurance procedures according to the “AFB smear microscopy and external quality assurance Manual”.

The sputum specimen collection procedures, the guidelines for sputum smear examination and quality assurance are provided in the National TB and Leprosy Laboratory Manual, edition 2007.

5.6.2 Radiological examination

For the diagnosis of pulmonary TB, X-ray is sensitive but **less specific**, because abnormalities identified on a chest X-ray suggestive of TB may also be caused by a variety of other conditions.

Suggestive X-ray findings are:

- Upper lobe infiltrates (bi-lateral or uni-lateral right).
- Cavitation (with a thick wall >2mm).
- Patchy, nodular shadows around the cavity.

No shadow is typical for TB, and 40% patients diagnosed as having TB by X-Ray alone may not have active TB disease. Some individuals, in fact, who had TB in the past that has been cured (and therefore do not require treatment) may still have a chest X-ray suggestive of active TB.

Chest radiography is useful for differential diagnosis of pulmonary disease among patients with negative sputum smears, miliary and childhood TB, when interpreted in conjunction with presenting signs and symptoms.

Readings of chest X-rays should, whenever possible, be made by a radiologist or an experienced physician.

Only bacteriology provides proof of TB

**Remember: Chest X-ray is supportive to microscopy!
It is a major error to omit sputum examination and
diagnose TB
based on X-ray findings alone!**

5.6.3 Culture

The probability of finding acid-fast bacilli (AFB) in sputum specimens by smear microscopy is directly related to the concentration of bacilli in the sputum. In comparison, mycobacterial culture can detect far lower numbers of TB bacilli. Moreover, the culture makes it possible to identify the mycobacterial species on the basis of biochemical and other properties.

Culture of *Mycobacterium tuberculosis* bacilli is very sensitive and specific but is expensive, as it is a complex and sophisticated tool, which requires a specialized laboratory set-up; culture results are available only after several weeks. Culture with Drug Sensitivity Testing (DST) is even longer. If available, culture can be used for diagnosis or confirmation of the diagnosis of TB in patients with PTB- and EPTB but it is not recommended routinely as a primary diagnostic method.

Beside surveillance purpose, culture with sensitivity testing (DST) is valuable for diagnosis and management of drug-resistant TB: treatment failure, poor response to correct treatment, re-treatment, and chronic cases.

The National Reference Laboratory for TB in Ethiopia is the EHNRI Institute, Addis Ababa, and culture facilities should be scaled up to main Regional Reference laboratories in the coming years, according to the national plan for the laboratory strengthening.

5.6.4 Histo-pathological examination

Pathology can play a complementary role in confirming the diagnosis of EPTB, such as tubercular lymphadenitis. Multiplication of tubercle bacilli in any site of the human body causes a specific type of inflammation, with formation of characteristic granuloma that can be found on histological examination. Samples can be taken from the following:

- Fine needle aspiration of the lymph nodes: affected peripheral lymph nodes, particularly cervical nodes, can be aspirated.
- Effusions of the serous membranes can be aspirated. However, the liquid aspirated is much less useful for

diagnosis than histology and culture of a pleural (membrane) biopsy specimen.

- ❑ Tissue biopsy (serous membranes, skin, endometrium, bronchial, pleural, gastric or liver tissue), can be taken, with or without surgery; surgical intervention can be performed to confirm diagnosis of TB by sampling of a deep or superficial lymph node, a bone fragment or part of an organ.
- ❑ Post mortem; after death from an unknown cause, tissue samples taken at autopsy can be analyzed.

Due to the scarcity of facilities for histo-pathological services, this procedure is not routinely practiced in Ethiopia.

5.7 General definitions

Tuberculosis suspect:

A person who presents with symptoms and/or signs suggestive of tuberculosis, in particular cough for two weeks or more.

Case finding:

The act of identifying active tuberculosis cases through sputum examination, among TB suspect attending a health facility.

Case of tuberculosis:

A patient in whom tuberculosis has been bacteriologically confirmed, or has been diagnosed by an experienced medical officer

A proven case of tuberculosis:

A patient with two sputum smears or culture positive for *Mycobacterium tuberculosis* (one sputum positive is enough for HIV positive patients).

5.8 Classification of tuberculosis cases

Cases are classified according to the site of the lesions as either **pulmonary** or **extra-pulmonary**.

Pulmonary (PTB) cases are further classified as either:

- Sputum smear-positive;

- Sputum smear-negative (which include smear result unknown).

a. Smear-positive pulmonary TB (PTB+)

A patient with at least two initial sputum smear examinations positive for AFB by direct microscopy,

Or

A patient with one initial smear examination positive for AFB by direct microscopy and culture positive,

Or

A patient with one initial smear examination positive for AFB by direct microscope and radiographic abnormalities consistent with active TB as determined by a clinician.

b. Smear-negative pulmonary TB (PTB-)

A patient having symptoms suggestive of TB with at least 3 initial smear examinations negative for AFB by direct microscopy, and

1. No response to a course of broad-spectrum antibiotics, and
2. Again three negative smear examinations by direct microscopy, and
3. Radiological abnormalities consistent with pulmonary tuberculosis, and
4. Decision by a clinician to treat with a full course of anti-tuberculosis

Or

A patient whose diagnosis is based on culture positive for M. tuberculosis but three initial smear examinations negative by direct microscopy

c. Extra-pulmonary TB (EPTB)

TB in organs other than the lungs, proven by one culture-positive specimen from an extra-pulmonary site or histo-pathological evidence from a biopsy,

Or

TB based on strong clinical evidence consistent with active EPTB and the decision by a physician to treat with a full course of anti-TB therapy.

- Other

Any patient with both sputum smear positive pulmonary TB (PTB+) and Extra-pulmonary TB (EPTB), should be classified as PTB+.

Cases of TB pleurisy and TB mediastinal lymphadenopathy, without lesions in the lung, should be classified as EPTB, provided the sputum smears are negative.

5.9 Definition of type of cases

A case of TB is a patient in whom tuberculosis has been confirmed bacteriologically or diagnosed by a clinician.

New case (N):

A patient who never had treatment for TB, or has been on previous anti-TB treatment for less than four weeks.

Relapse (R):

A patient declared cured or treatment completed of any form of TB in the past, but who reports back to the health service and is now found to be AFB smear-positive or culture positive.

Treatment Failure (F):

A patient who, while on treatment, is smear-positive at the end of the fifth month or later, after commencing. Treatment failure also includes a patient who was initially sputum smear-negative but who becomes smear-positive during treatment.

Return after default (D):

A patient previously recorded as defaulted from treatment and returns to the health facility with smear-positive sputum.

Transfer out (T):

A patient who started treatment in one treatment unit and is transferred to another treatment unit to continue treatment.

Chronic (C):

A TB patient who remains smear-positive after completing a re-treatment regimen.

Other (O):

A patient who does not fit in any of the above mentioned categories (e.g., a PTB smear negative who returns after treatment interruption).

5.10 Seriousness of illness:

The severity of the illness depends on the bacillary load, the extent and the anatomical site of the disease and the background condition of the patient. The involvement of an anatomical site helps in classifying if the disease is severe, depending on whether it is life threatening or has high risk of developing subsequent severe handicap or both. The following forms of extrapulmonary TB and smear negative pulmonary TB are classified as “seriously ill”.

Extra-pulmonary TB classified as “seriously ill”	Smear-negative pulmonary TB classified as “seriously ill”
<ul style="list-style-type: none">• Meningitis• Pericarditis• Peritonitis• Bilateral or extensive pleural effusion• Spinal TB with neurological involvement• Intestinal• Genito-urinary• Co-infection with HIV• All forms of paediatric EPTB other than lymph node TB and unilateral pleural effusion• Concomitant diabetes mellitus, chronic steroid use, other severe diseases	<ul style="list-style-type: none">• Miliary TB• Extensive parenchymal infiltration (bilateral involvement or > 50%)• Co-infection with HIV• cavitary disease• All forms of paediatric sputum smear-negative• Concomitant diabetes mellitus, chronic steroid use, other severe diseases

Patients with the following symptoms should be referred urgently to hospital for proper management:

- Coughing up blood.
- Increasing breathlessness.
- Suddenly increasing chest pain.
- Progressively deteriorating general condition.

5.11 Treatment of TB

The main objectives of anti-TB treatment are to:

1. Cure the patient of TB (by rapidly eliminating most of the bacilli);
2. Prevent death from active TB or its late effects;
3. Prevent relapse of TB (by eliminating the dormant bacilli);
4. Prevent the development of drug resistance (by using a combination of drugs);
5. Decrease TB transmission to others.

Chemotherapy is considered to be adequate when it:

- Rapidly and substantially reduces the number of actively multiplying bacteria.
- Cures patients.
- Prevents relapse of the disease
- Prevents the development of resistance to the drugs.

The requirements for adequate chemotherapy are:

- An appropriate combination of drugs.
- Prescribed in the correct dosage.
- Taken regularly by the patient.
- For a sufficient period of time.

5.11.1 Drugs used for the chemotherapy of TB

The drugs used for TB treatment are safe and effective if properly used.

The following drugs are used as **first line treatment** of TB in Ethiopia:

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

The drugs available in fixed dose combination (FDC) are:

- Rifampicin, Isoniazid, Pyrazinamide and Ethambutol (RHZE 150/75/400/275 mg);
- Rifampicin and Isoniazid (RH 150/75 mg);
- Ethambutol and Isoniazid (EH 400/150 mg).

The drugs available as single drugs are:

- Ethambutol 400 mg;
- Isoniazid 150 mg and 300 mg;
- Streptomycin sulphate vials, 1 g;

Streptomycin is administered by injection while the other drugs are to be taken orally.

All the drugs should be taken together as a single, daily dose, preferably on an empty stomach.

5.11.2 Phases of chemotherapy

The treatment of TB has two phases:

Intensive (initial) phase

This phase consists of three or more drugs for the first 8 weeks for new cases, and 12 weeks for re-treatment cases. It renders the patient non-infectious by rapidly reducing the load of bacilli in the sputum, usually within 2-3 weeks (except in case of drug resistance).

During the intensive phase, the drugs must be collected daily by the patient and must be swallowed under the direct observation of a health worker. Sundays only can be skipped.

Continuation phase

This phase immediately follows the intensive phase and is important to ensure cure or completion of treatment. It is necessary in order to avoid relapse after completion of treatment. This phase requires at least two drugs, to be taken for 4 - 6 months.

During the continuation phase, the drugs must be collected every month and self-administered by the patient, except for re-treatment cases and for regimens containing Rifampicin.

5.11.3 Patient categories and treatment regimens

In order to establish treatment priorities, WHO recommends that tuberculosis patients should be classified into four categories:

Category I: consists mainly of new, smear-positive tuberculosis cases, but includes new smear-negative cases with extensive parenchymal lesions, and new cases with severe extrapulmonary tuberculosis (disseminated, meningeal, pericardial, peritoneal, bilateral pleural, spinal, intestinal and genito-urinary). A new case is defined as a patient who has never previously been treated for tuberculosis or who has received treatment for less than one month.

Category II: smear-positive cases who have already received treatment for at least one month in the past and who need to receive re-treatment. Among these patients three groups can be distinguished in:

“Relapses” – patients who have been treated and declared cured, but whose smear examinations are once again positive.

“Failures” – patients whose smear examinations have remained positive or have once again become positive five or more months after starting treatment.

“Return after interruption” – patients who return to the health centre smear-positive after interrupting treatment for more than two consecutive months.

Category III: new cases of smear-negative pulmonary or extrapulmonary tuberculosis (excluding those with severe forms,

included in Category I) who have never previously been treated for as much as one month in the past.

Category IV: chronic cases defined as smear-positive cases of pulmonary tuberculosis who have previously received a supervised re-treatment regimen.

Table 5: Treatment Category by Type of Patient

Category of treatment	Type of patient
I	New sputum smear-positive Seriously ill ¹ new sputum smear-negative Seriously ill ¹ new EPTB Others
II	Sputum smear-positive Relapse Sputum smear-positive Failure Sputum smear-positive Return after default PTB- patients who become smear positive after 2 months of treatment (case definition = other). Return after default from re-treatment (only once retreatment again). Relapses after retreatment (only once retreatment again).
III	New sputum smear-negative, not seriously ill New EPTB, not seriously ill
IV	Chronic and MDR-TB cases (still sputum positive after supervised retreatment)

¹ 'Seriously ill' includes:

- Life threatening disease = acute disseminated miliary TB, TB meningitis or TB peritonitis.
- Risk of severe disability = spinal TB, TB pericarditis, bilateral TB pleural effusion, renal TB.
- Extensive X-ray lesions without cavitation in immunocompromised patients, e.g., diabetics, HIV-positives, or patients with other concomitant disease.

5.11.4 Treatment regimen for Category I and III:

Patients belonging to category I and III will be treated with the same regimen, which is 2ERHZ/ 6EH.

This regimen consists of 8 weeks treatment with Ethambutol, Rifampicin, Isoniazid and Pyrazinamide during the intensive phase, followed by six ‘months’ (1 ‘month’ = 4 weeks) with Ethambutol and Isoniazid: 2ERHZ/6EH.

Table 6. Dosage of category I and III regimens: 2ERHZ/6EH

Regimen	Initial phase (2 months)	Continuation phase (6 months)
	2 (HRZE) daily	6 (EH) daily
Patients weight	H 75 mg + R 150 mg + Z 400 mg + E 275 mg	H 150 mg + E 400 mg
	Number of tablets	
20-29	1 ½	1
30-39 Kg	2	1 ½
40-54 Kg	3	2
55-70 Kg	4	3
Over 70 Kg	5	3

Special consideration for Extra-pulmonary TB:

➤ **Pericardial tuberculosis**

For patients with pericardial tuberculosis, a 8-month regimen is recommended. Corticosteroids (prednisolone) are recommended as adjunctive therapy for tuberculous pericarditis, daily during the first 11 weeks of antituberculosis therapy.

For adults the prednisone dose is 60 mg/day (or the equivalent dose of prednisolone) given for 4 weeks, followed by 30 mg/day for 4 weeks, 15 mg/day for 2 weeks, and finally 5 mg/day for week 11 (the final week). Children should be treated with doses proportionate to their weight, beginning with about 1 mg/kg body

weight and decreasing the dose as described for adults.

➤ **Pleural tuberculosis**

A 8-month regimen is also recommended for treating pleural tuberculosis. A number of studies have examined the role of corticosteroid therapy for tuberculous pleural effusions, but prednisone (or prednisolone) administration did not reduce the development of residual pleural thickening.

Tuberculous empyema, a chronic, active infection of the pleural space containing a large number of tubercle bacilli, usually occurs when a cavity ruptures into the pleural space. Treatment consists of drainage (often requiring a surgical procedure) and antiTB drugs. Surgery, when needed, should be undertaken by experienced thoracic surgeons. The optimum duration of treatment for this unusual form of tuberculosis has not been established.

➤ **Tuberculous meningitis**

Before the advent of effective antituberculosis chemotherapy, tuberculous meningitis was uniformly fatal. Tuberculous meningitis remains a potentially devastating disease that is associated with a high mortality and sequelae, despite prompt initiation of adequate chemotherapy. HIV-infected patients appear to be at increased risk of developing tuberculous meningitis but the clinical features and outcomes of the disease are similar to those in patients without HIV infection. Patients presenting with more severe brain impairment such as drowsiness, neurological signs, or coma have a greater risk of neurological sequelae and a higher mortality.

Chemotherapy should be initiated with RHZE in an initial 2-month phase. After 2 months of four-drug therapy for meningitis caused by susceptible strains, Z and E may be discontinued, and RH continued for an additional 7 to 10 months. Repeated lumbar punctures should be considered to monitor changes in CSF cell count, glucose, and protein, especially in the early course of therapy.

Adjunctive corticosteroid therapy with dexamethasone is recommended for all patients, particularly those with a decreased

level of consciousness, with tuberculous meningitis. The recommended regimen is dexamethasone in an initial dose of 8 mg/day for children weighing less than 25 kg and 12 mg/day for children weighing 25 kg or more and for adults. The initial dose is given for 3 weeks and then decreased gradually during the following 3 weeks.

5.11.5 Treatment regimen for Category II [Retreatment regimen]

This regimen is to be prescribed for patients previously treated for more than one month with TB drugs and who are still smear positive. The treatment regimen for this category is:
2 S(ERHZ) / 1(ERHZ) / 5 E3 (RH)3.

Table 7 Dosage for Category II regimen: 2 S(ERHZ) / 1(ERHZ) / 5E3(RH)3

Regimen	Initial phase (3 months)		Continuation phase (5 months)
		2 (HRZE)S/1(HRZE) daily	
Patients weight	H 75 mg + R 150 mg + Z 400 mg + E 275 mg	S (vials, IM) 1 g	(H 75 mg + R 150 mg) + E 400 mg
20-29	1 ½	½	1 ½ + 1
30-39 Kg	2	½	2 + 1 ½
40-54 Kg	3	¾	3 + 2
55-70 Kg	4	1 g	4 + 3
Over 70 Kg	5	1 g	5 + 3

- Streptomycin should not be included in the re-treatment for pregnant women.
- For patients over 60 years of age, the dose of streptomycin is 0.75 gm.
- Throughout the duration of re-treatment, including the continuation phase, the drugs must be taken under the direct observation of a health worker.

5.11.6 Side effects

Serious side effects are rare. The possible side effects of the drugs and the management of these side effects are listed Table 8.

Table 8. Symptom-based approach to management of drug side effects.

	Side-effects	Drugs	Management
a. Minor [Continue anti TB drugs]	Anorexia, nausea, abdominal pain	Rifampicin Pyrazinamide	Give tablets with small meals or as last thing at night
	Joint pains	Pyrazinamide	Aspirin
	Burning sensation in feet	Isoniazid	Pyridoxine 100mg daily
	Orange/red urine	Rifampicin	Reassurance
b. Major [Stop responsible drug(s)]	Itching, skin reaction	Streptomycin; Rifampicin or isoniazid	Stop and replace with ethambutol; Stop, then reintroduce with desensitization ¹
	Deafness	Streptomycin	Stop streptomycin and replace with Ethambutol
	Dizziness (vertigo, imbalance and nystagmus)	Streptomycin	Stop streptomycin and replace with Ethambutol
	Jaundice; hepatitis	Most anti-TB drugs	Stop all anti-TB drugs and refer
	Vomiting and confusion	Most anti-TB drugs	Stop all anti-TB drugs and refer
	Visual impairment	Ethambutol	Stop Ethambutol and refer
	Shock, purpura and acute renal failure	Rifampicin	Stop Rifampicin and refer

Management of cutaneous reaction

¹Desentization: If a skin reaction develops, all anti-tuberculosis drugs must be stopped. Once the reaction has resolved, anti-TB drugs are reintroduced. The idea of desensitization is to start with a small dose of drugs: if a reaction occurs, it will be less severe than the reaction to a full dose. The dose is gradually increased

over three days. There is no evidence that this process gives rise to drug resistance. It may be necessary to extend the treatment regimen. This prolongs the total time of TB treatment, but decreases the risk of relapse.

Management of drug-induced hepatitis

Most anti-TB drugs can damage the liver. Isoniazid, pyrazinamide and rifampicin are most commonly responsible, ethambutol rarely. When a patient develops hepatitis during TB treatment, the cause may be the TB treatment or something else. It is important to rule out other possible causes before deciding that the hepatitis is drug induced.

If the diagnosis is drug-induced hepatitis, the anti-TB drugs should be stopped. The drugs must be withheld until liver function test have reverted to normal. Sometimes it is not possible to perform liver function test; in these situations, it is advisable to wait an extra 2 weeks after the jaundice has disappeared before recommencing TB treatment. Asymptomatic jaundice without evidence of hepatitis is probably due to rifampicin.

Once drug-induced hepatitis has resolved, the same drugs are reintroduced. However, if the hepatitis produced clinical jaundice, it is advisable to avoid pyrazinamide. The suggested regimen in such patients is a 2-month initial phase of daily streptomycin, isoniazid and ethambutol, followed by a 10-month continuation phase of isoniazid and ethambutol (2 SHE/10EH).

A severely ill TB patient with drug-induced hepatitis may die without antituberculosis drugs. In this case, the patient should be treated with two of the least hepatotoxic drugs, streptomycin and ethambutol. After the hepatitis has resolved, usual TB treatment should be restarted.

5.11.7 Anti-TB drug treatment in special situations

- *Pregnancy*

Most anti-TB drugs are safe for use in pregnancy with the exception of streptomycin. Therefore ask women patients whether they are or may be pregnant: **Do not give streptomycin to a pregnant woman** as it can cause permanent deafness in the baby. Pregnant women who have TB must be treated, but their drug regimen does not include streptomycin and ethambutol is use instead of streptomycin.

- ***Oral contraception***

Rifampicin interacts with oral contraceptive medications with a risk of decreased protection against pregnancy. While receiving treatment with rifampicin, a woman who takes the oral contraceptive pill may choose between the following two options: (1) after consulting with a clinician, she could take an oral contraceptive pill containing a higher dose of estrogen (50 µg). (2) Alternatively, she could use another form of contraception.

- ***Breastfeeding***

A breastfeeding woman who has TB can be treated with the regimen appropriate for her disease classification and previous treatment. The mother and baby should stay together and the baby should continue to breastfeed in the normal way. Give the infant a course of preventive therapy (isoniazid) for a minimum of six months, after ruling out active TB. When preventive therapy is completed, give the infant BCG if not yet immunized.

- ***HIV patients on antiretrovirals***

TB patients with HIV infection or HIV/AIDS may experience a temporary worsening of symptoms and signs after beginning TB treatment. In TB patients infected with HIV, treatment with antiretrovirals (ARV) may interact with treatment of TB, reducing the efficacy of antiretrovirals and of anti-TB drugs and increasing the risk of drug toxicity. **In patients with HIV-related TB, the priority is to treat TB.** Options are to defer antiretroviral treatment until TB treatment is completed; defer until completing the initial phase and use H +E in the continuation phase; or use antiretrovirals that are less likely to interact with anti-TB drugs. Detailed management of co-infected

patients is provided in the Manual “TB/HIV implementation guidelines, Edition 2008” and in the TB Care with TB-HIV co-infection; IMAI module, 2008.

Patients infected with HIV respond equally well to TB treatment as those without HIV infection. However, they are more likely to die during the course of treatment, usually from causes other than TB.

Because of the association between TB and HIV infection, great care must be taken to prevent the spread of both infections. When injections have to be given, every health worker should strictly adhere to the universal precaution for safe injection, using a new disposable syringe and needle for each injection to each patient. Used needles and syringes should be disposed safely.

One syringe and one needle for one injection for one patient!!

- ***Treatment of patients with TB and leprosy***

Patients suffering from both TB and leprosy require appropriate anti-TB chemotherapy in addition to the standard MDT. Rifampicin will be common to both regimens and it must be given in the doses required for TB. Once the anti-TB course is completed, the patient should continue his anti-leprosy treatment (or the other way round).

- ***Treatment of patients with renal failure***

Avoid Streptomycin and Ethambutol; therefore the recommended regimen is 2RHZ/4RH.

- ***Treatment of patients with (previously known) liver disease***

Most anti-TB drugs can cause liver damage. Do not give Pyrazinamide because this is the most hepatotoxic anti-TB drug. Isoniazid and Rifampicin plus one or two non-hepatotoxic drugs such as Streptomycin and Ethambutol, can be used for a total treatment duration of eight months. Hence for TB patients with

liver disease, recommended regimens are 2SERH/6RH, 9 RE or 2SEH/10EH.

5.11.8 Indications for hospitalization

In the majority of cases it is **not** necessary to hospitalize tuberculosis patients, either to achieve cure, or to avoid infecting the patient's family. Only a few days after beginning adequate treatment tuberculosis patients are no longer infectious, provided that their bacilli are susceptible to the major medications used in their treatment; if members of their families are infected they may have been infected before the patient began treatment.

This is why tuberculosis patients need to be hospitalized only in the following situations:

- Severe deterioration of the patient's general state, making outpatient treatment difficult or impossible;
- Tuberculosis-related complications: massive haemoptysis, pneumothorax;
- Complications associated with treatment: major side-effects such as jaundice, purpura or severe allergic skin reaction;
- Severe concomitant disease necessitating hospital care and specific surveillance, such as unstable or complicated diabetes, kidney failure, or stomach ulcer.

The period of hospitalization varies depending on the cause; it often lasts less than 2 weeks, and the patient can be discharged as soon as the reasons for hospitalization have resolved.

5.12 Follow-up during treatment

The organization of TB clinics must facilitate (1) the implementation of directly observed treatment (DOT) at least during the initial phase and (2) the adherence of patients to their treatment until cure.

Tuberculosis can be cured only if the anti-TB drugs are taken regularly. The choice of the place of treatment depends on two factors: the **state of the patient**, and the ability of the health staff to **provide treatment to patients**.

5.12.1 Follow-up during the initial phase of treatment

During the initial phase of treatment, which always contains rifampicin, the patient must take the drugs in front of the health worker who is responsible for verifying that the patient **swallows all of the prescribed drugs every day**.

- If the patient lives, or can be housed, near a TB clinic, he or she must attend every morning to take the drugs.
- If the patient lives near a health post with staff that are trained and acknowledged to be capable by the TB clinic coordinator, treatment can be delivered by this health post staff; the follow-up of the patient must continue to be done by the TB clinic, and health post staff must be closely supervised. More information on this issue can be found in the Community DOTS chapter of this Manual.
- If directly observed treatment cannot be provided on an out-patient basis, or if the condition of the patient requires it, the patient should be hospitalized during the whole of the initial phase of treatment, but this is quite costly.

5.12.2 Follow up during the continuation phase of treatment

The continuation phase of the treatment of TB can be “self-administered”: in that case a supply of drugs in fixed-dose combination is given to the patient at fixed regular intervals, and the patient is given the responsibility to take the drugs correctly every day. The recommended interval between visits for drug supply is not more than one month, and must be set jointly by the health worker and the patient, depending on the ease of access to the health center and the adherence requirements.

Whatever facility is providing drugs during the continuation phase, all TB patients must be clearly advised to go the TB clinic where they are registered, for clinical check and bacteriological tests, at defined stages and at the end of their treatment. During these follow up visits, efficiency and outcome of treatment is monitored, drug tolerance is assessed and sputum is taken for microscopic examination for PTB+ patients. Follow up laboratory tests is

necessary in order for cure to be confirmed and the patient's final status to be correctly recorded.

For tuberculosis patients who are in a precarious situation (homeless) and those who are drug addicts, alcoholics or who have mental problems, the organization of follow-up must aim at reducing the lack of compliance common in these population groups: for example, a fully supervised intermittent treatment can be selected if it is thought that the patient will comply with it more easily, and health staff should try to make themselves more available to these patients.

In order to avoid the emergence of strains that are multi drug resistant (MDR: resistant to both to isoniazid and rifampicin), all rifampicin-containing treatment should be taken under the direct observation of a health worker.

5.12.3 How to improve treatment compliance

The organization of anti-TB treatment is the key to a programme's success. The uninterrupted availability of drugs and rigorous organization of treatment delivery will ensure patients' compliance with treatment. In order to improve the compliance of the patient, it is necessary to:

□ Enhance patients' access to the health services

For every patient, the treatment center is the TB clinic where the patient is registered and that is in charge of laboratory and treatment follow up and recording. It must be the more convenient place for the patient: usually it is the facility closest to the patient's home. It may differ from the place where diagnostic of TB was made.

Whatever regimen is given and wherever it is given, treatment must be monitored during follow-up visits. For all follow up visits, arrangement should be made so that patients do not wait long and get discouraged.

□ Communicate with the patient

During all phases of treatment, the patient and family members (in the case of children) have to be educated on the importance of regularly taking the prescribed medications during the prescribed duration –even if they may feel better- the risks linked to default from treatment, and the major side-effects of the drugs and the need to report whenever side-effects occur.

Health education is an ongoing process that allows health staff and other patients to inform patients about their illness and its treatment, to motivate patients, and to respond to any questions that might be asked by patients and their families. It should aid in creating an immediate relationship with the patient. For more information refer to the ACSM chapter in this Manual.

□ Organize treatment follow-up and schedule regular appointments

These dates are scheduled from the beginning of treatment.

New smear-positive cases (2nd, 5th and 7th months)

Laboratory follow up

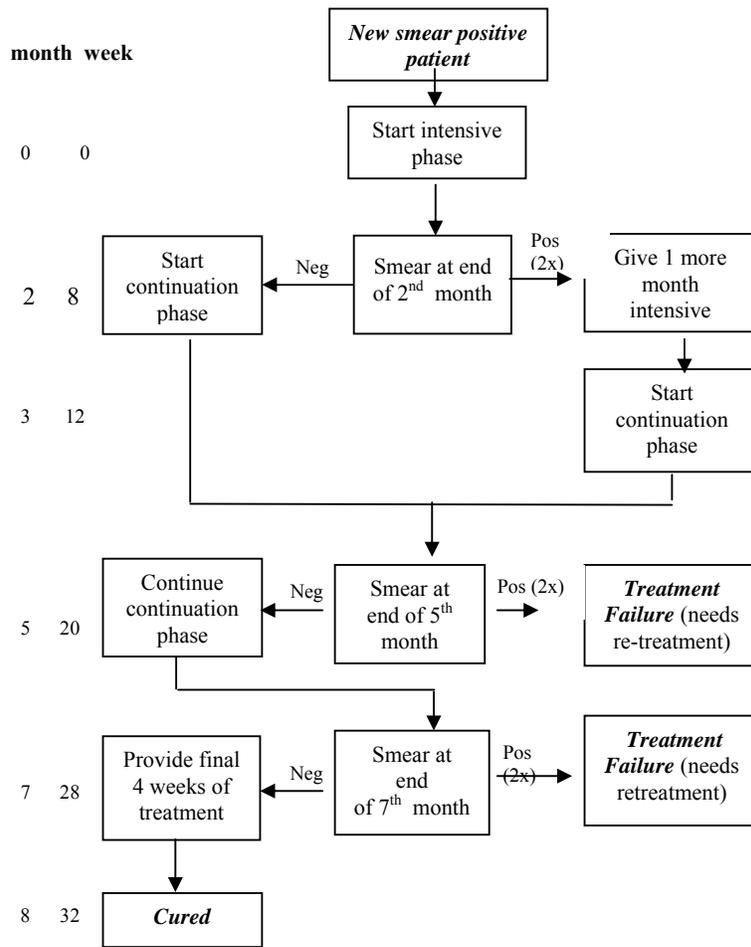
As a routine, all sputum-positive patient on TB treatment must have one sputum specimen examined at the end of the 2nd, 5th and 7th month. Dates and results of direct sputum examinations should be entered in the Unit TB Register.

- If the direct smear is negative at the end of 2nd month, the continuation phase can be started.
- If the smear is positive at the end of the 2nd month of intensive phase, the intensive daily treatment should be continued for additional 4 weeks with ERHZ. After these additional 4 weeks of intensive treatment the continuation phase should be started without an additional sputum examination.
- In the continuation phase of treatment, if the smear result at the end of 5th month of treatment is negative, the patient should continue with the same treatment. If the smear result is positive at the end of 5th month or more after the start of chemotherapy, sputum smear examination should be repeated.

If the second sputum smear result is positive, the patient is declared as *treatment failure*. The patient should be registered as treatment failure and started with re-treatment regimen (Cat II).

- The sputum is examined again at the end of 7th month or during the last month. If the result is negative the patient will be provided with the last 4-week dose and is declared *cured* (if at least one previous sputum examination, either at the 2nd or 5th month was negative). If the result is positive in 2 smears at 5 or 7 months, the patient is a *treatment failure* and must start the re-treatment regimen.
- If for whatever reason after 7 months of treatment, the final sputum examination cannot be done and the sputum result at 5th month was negative or not done, the patient should be declared *treatment completed*.

Figure 3. Flow chart for follow-up of new smear-positive pulmonary TB patients



Compliance follow-up

- The total duration of treatment for short course regimen is 8 months (32 weeks) or 6 months (24 weeks) for children who receive RH in the continuation phase. If a patient misses some treatment during the continuation phase, the number of doses missed should be added on at the end, so

that the complete course of treatment is given.

- A patient who does not collect drugs for a period of 8 consecutive weeks or more (after vigorous attempts to trace him/her have failed) will be declared *default*. For management of smear-positive cases, who present after interrupting treatment for less than 8 consecutive weeks, see table 8.

Table 9: Management of patients initially smear positive, who interrupted TB treatment for less than 8 consecutive weeks

Duration of treatment before interruption	Duration of interruption	Smear result at return	Treatment
< 4 weeks	< 2 consecutive weeks	No smear	Continue the same treatment.
	2 - 8 consecutive weeks	No smear	Re-start the same treatment.
4 - 8 weeks	< 2 consecutive weeks	Negative	Continue the same treatment.
		Positive	Start re-treatment regimen.
> 8 weeks	2 - 8 consecutive weeks	Negative	One-month extra intensive phase.
		Positive	Start re-treatment regimen.
> 8 weeks	< 8 consecutive weeks	Negative	Continue the same treatment.
		Positive	Start re-treatment regimen.

- Patients who interrupted treatment for more than 8 consecutive weeks are recorded as *default*. A patient who returns after default and who is PTB+ should be registered in a new cohort as “return after default” and should be treated with the re-treatment regimen.

Smear-negative pulmonary and extra-pulmonary cases

The treatment of *PTB-* is followed up by monitoring the clinical progresses and the regularity of drug collection.

- Any *PTB-* patient, whose condition has not improved or gets worse by the end of the intensive phase should be assessed by a

physician and two specimens of sputum should be examined. If one smear is positive, two other specimens should be examined.

- If out of these, one more is positive, the patient has PTB+ and has to start a full course of the re-treatment regimen. This group of patients are registered under the category = ‘*failure*’.
- If the condition of the patient deteriorates while the sputum remains negative, X-ray is advisable to aid the diagnosis. If findings on X-ray are consistent with active TB (exclusion of lung cancer, pneumonia, etc.), the initial anti-TB treatment may be repeated this group of patients are registered under the category = ‘*others*’.

Any PTB- patient, who interrupted the treatment for more than 8 consecutive weeks (defaulting) and returns for continuation of treatment should be assessed by an experienced medical officer and two specimens of sputum should be examined. Out of these smears, if one or more is positive, the patient has PTB+ and must start a full course of the re-treatment regimen (case definition = *return after default*). If the smears remain negative, the patient should be treated with the original regimen (case definition = ‘*other*’).

A patient who returns after default and who is PTB- (as proven by deterioration of the X-ray not due to other diseases) should be registered in a new cohort as “*other*” and be treated with a full course of the original regimen.

Any EPTB patient, who interrupted the treatment for more than 8 consecutive weeks (defaulting) and who returns for continuation of treatment should be assessed by an experienced medical officer. If the condition remains the same or gets worse the patient should be treated with the full course original regimen.

Re-treatment cases

The sputum is examined at the end of the intensive phase of 12 weeks.

- If the result of the sputum is negative, the continuation phase is started.

- If the sputum is positive at the end of 12 weeks, the intensive phase of 4 drugs (ERHZ) daily will be continued for other 4 weeks. Thereafter, the continuation phase is started, without an additional sputum examination. For these patients, possible MDR TB must be considered and sputum culture with Drug Sensitivity Testing (DST) should be carried out in a reference laboratory. The possible outcomes of treatment are the same as for the new smear-positive cases.
- If the patient is found still smear-positive at the end of 5th month of treatment in 2 different specimens, the patient is declared as *treatment failure* and should be assessed for MDR-TB (with culture and DST whenever available). The decision about the next treatment will be taken according to the specific MDR-TB national guidelines.

□ **Trace any patients who defaults (retrieval of absentees)**

If, during the intensive phase, a patient has not attended on the appointed clinic day and fails to report for 2 days thereafter, or if the patient fails to report for 1 week during the continuation phase of treatment, he/she has to be considered as an absentee and should be retrieved.

In case of absenteeism the following measures are suggested:

- a. Inquire from fellow patients as to why the patient has failed to collect his/her drugs and ask them to contact and advise the absentee if and when this is possible.
- b. Notify the contact person, recorded in the register, through available means and request his/her assistance to encouraging the patient to return for treatment.
- c. Communicate with health extension worker or community volunteer to retrieve the patient.
- d. Send out messages through health workers who may travel to the patient's village for outreach health programmes like EPI.
- e. Visit the home of the patient.

All available means need to be put into action when a patient misses a scheduled visit but the methods of tracing patients differ from one centre to the next: it can be done by telephone, home visits, or even visits by a neighbour being treated at the same

centre. The longer the absence, the less likelihood there is of finding the patient.

When the patient is found, further care and treatment is based on the duration of treatment already received and the patient's bacteriological status.

5.13 Definitions of treatment outcome

Cured:

A initially smear-positive patient who is sputum smear-negative at, or one 'month' prior to, the completion of treatment and on at least one previous occasion (usually at the end of the 2nd or 5th month).

Treatment completed:

A patient who completed treatment but for whom smear results are not available at 7th month or one month prior to the completion of treatment.

Treatment failure:

A patient who remains or becomes again smear-positive at the end of 5 "month" or later during treatment. Or a patient who was PTB-negative at the beginning and turned out smear-positive at the end of the intensive phase.

Died:

A patient who dies for any reason during the course of treatment.

Defaulter:

A patient who has been on treatment for at least 4 weeks and whose treatment was interrupted for 8 or more consecutive weeks.

Transfer out:

A patient who started treatment and has been transferred to another reporting unit and for whom the treatment outcome is not known at the time of evaluation of treatment results.

Treatment success:

The sum of patients who are declared "cured" and those who have "completed" treatment.

6 TUBERCULOSIS IN CHILDREN

Most children exposed to an infectious adult in their close environment (the household), may acquire tuberculosis **infection**. This exposure leads to the development of a primary lesion in the lungs with spread to the regional lymph node(s). In the majority of cases, the resultant immunity will contain the disease process at this stage. Progression to **TB disease** occurs more commonly in children under 5 years of age and in immuno-compromised HIV-infected children/post measles/malnourished, etc.

Children at greater risk of developing TB are:

- **Children who are contacts of a newly diagnosed smear-positive case**
- **Children less than 5 years of age**
- **HIV-infected children**
- **Severely malnourished children.**

Tuberculosis disease presents in children in various clinical forms:

- primary pulmonary tuberculosis;
- acute disseminated tuberculosis: meningitis and miliary tuberculosis;
- post-primary pulmonary tuberculosis;
- extra-pulmonary tuberculosis.

6.1 Primary pulmonary tuberculosis

Primary pulmonary tuberculosis occurs most often in children less than 5 years of age.

- **Primary infection is asymptomatic** in the majority of cases, and goes unnoticed. This is termed infection and must be distinguished from disease.
- **In 10% of cases primary infection has clinical manifestations** and presents with certain symptoms and radiographic abnormalities.

- **Generalized symptoms** are often minor: slight fever, loss of weight, apathy and listlessness can attract the attention of the parents. Sometimes the symptoms are more obvious

(e.g. a high fever of 39–40 °C and profound lethargy), and alert the parents to the fact that something is wrong.

- **Mucocutaneous manifestations**, although infrequent, are highly characteristic:

Erythema nodosum appears in the form of painful nodules (lumps) under the skin in two to three bursts: on the shins (legs), sometimes on the back of the arms and rarely on the front,. They are painful, red, raised lesions that may turn purple and take on the appearance of a bruise.

Phlyctenular conjunctivitis begins with generalized pain and irritation in one eye accompanied by watering and photophobia. On examination, grey or yellow lesions can be observed where the cornea joins the white of the eye; a number of blood vessels enter the lesions, giving an appearance of vascular engorgement of the conjunctiva. Each lesion persists for about a week, then disappears, to be replaced by others. In severe cases the cornea may ulcerate.

The course of primary tuberculosis is usually benign, with or without treatment, and most children recover completely without sequelae. They may, however, subsequently develop active tuberculosis (reactivate) after a period of quiescence.

Local complications of primary tuberculosis, while unusual, are well recognized:

Fistulation of the lymph node into the bronchi: the lymph node swells and erodes into the bronchus. This can be a serious event for small infants, where the caseous material can create acute bronchial obstruction; in older children it usually causes cough;

The formation of a primary tuberculous cavity at the site of infiltration is a more unusual complication.

In both cases the child is usually incapable of producing sputum, but if a sample of bronchial or gastric aspiration is obtained, acid-fast bacilli can be recovered from smear microscopy.

Delayed local complications can occur. Without treatment, lymphadenopathy can compress a lobar or segmental bronchus,

creating breathing difficulties. **Bronchiectasis** may develop in the poorly ventilated area of the lung, creating bronchial superinfections and repeated episodes of haemoptysis. The most characteristic feature of this type of sequelae is “**hilar disease**” or “right middle lobe syndrome” seen on X ray.

6.2 Acute disseminated tuberculosis

These are early complications of primary infection (within 2–10 months). Caused by the dissemination of bacilli from the primary infection through the bloodstream, they can occur at all ages, but do so most often in very young children (<2 years of age), particularly if they have not been vaccinated with BCG. They are very serious, and are often fatal if diagnosed late.

➤ Tuberculous (TB) meningitis

Clinical signs of tuberculous meningitis are often initially unclear in children, particularly under 5 years. It may start simply with a lack of interest in playing, irritation, headache or vomiting. Later on, changes in state of consciousness, strabismus, and possibly neck rigidity indicate signs of meningeal tuberculosis. The diagnosis is obvious at a later stage, with the infant in foetal position, photophobia and extreme neck rigidity; in the final stage the child is in a coma, prostrate and stiff-legged. When the disease progresses to such an advanced stage, there is almost no chance of cure; even if the child survives, major neurological sequelae are expected, such as paralysis, deafness or blindness.

➤ Acute miliary tuberculosis

This is a disseminated form of TB ; it can occurs within the first weeks after primary infection and is also common in late HIV/AIDS disease. It's often accompanied with TB meningitis. It is a severe condition with high fever at 39–40°C, confusion, vomiting. There are respiratory abnormalities: dyspnoea, cyanosis and occasional respiratory distress and characteristic spotted shadows on X Ray. Unlike typhoid fever, there is no splenomegaly, and the pulse is elevated. In HIV-infected child it may be difficult to differentiate from lymphocytic interstitial pneumonia (LIP). The diagnosis rests on strong clinical suspicion

and treatment must be started urgently, once other causes of childhood acute febrile miliary disease have been ruled out (such as viral illness or staphylococcal infection). If treatment is delayed, the prognosis may be badly affected.

6.3 Post-primary pulmonary tuberculosis

This type of tuberculosis, a delayed result of primary infection, usually occurs in adults but may appear in children (especially older children and adolescents), particularly in the presence of malnutrition.

Symptoms of childhood TB

Children with TB develop chronic symptoms in most cases, although TB may be a more acute disease in the presence of HIV infection. The commonest symptoms are:

- **Chronic cough:** chronic cough is a persistent cough, present for more than three weeks (21 days) and that is not improving.
- **Fever:** fever of greater than 38⁰C for 14 days after common causes like malaria, pneumonia have been excluded.
- **Weight loss:** documented weight loss or failure to gain weight, even after being treated in a nutritional rehabilitation program.

Signs of childhood TB

- The clinical picture of Pulmonary TB is similar to that of pulmonary tuberculosis in the adult

Additional signs are *suggestive of EPTB*:

- Physical signs highly suggestive of tuberculosis:
 - Gibbus (angulation of the spine), especially of recent onset
 - Non-painful enlarged cervical lymphadenopathy with fistula formation
- Physical signs requiring investigation for TB:
 - Meningitis not responding to treatment with antibiotics, with sub-acute onset
 - Pleural effusion or pericardial effusion

- Distended abdomen with ascites
- Non-painful enlarged joints

Unlike the acute forms, where treatment must be given promptly, this type of tuberculosis does not represent an emergency, and the physician can take the time to exclude the other definitive diagnoses, particularly acute respiratory infections, before proceeding to treatment.

6.4 Extra-pulmonary tuberculosis in children

In children, the most common EPTB are:

- **Tuberculous lymphadenitis** from far the most common form.
- **Tuberculosis of the spine or joints** is the second most common form of childhood EPTB, and may occur within the first few years following primary infection.
- **Tuberculosis of the serous membranes:** TB pleurisy and peritonitis are rare in small children, although frequent in adolescents. Peritonitis with ascites is relatively more common, particularly in girls aged 10–14 years and localized forms can cause sterility due to obstruction of the fallopian tubes.

6.5 Diagnosis of Paediatric TB

Criteria for the diagnosis of childhood tuberculosis

Categories	Supportive evidence	Diagnostic confirmation
Primary pulmonary tuberculosis	Mediastinal lymphadenopathy with or without infiltration TS-positive	Positive sputum culture (rare, only if there is fistulization of the lymphadenitis into the bronchi)
Post-primary pulmonary tuberculosis	Pulmonary infiltration affecting upper zones with cavities	AFB on smear and culture of sputa/gastric aspiration
Tuberculous meningitis	Meningeal syndrome, strabismus, sometimes miliary pattern and choroid tubercles Clear CSF: high protein levels and lymphocytosis	Positive CSF culture
Miliary tuberculosis	General deterioration Typical miliary image on X Ray Signs of dissemination (tubercles, meningitis)	Culture (pleural fluid, CSF, etc.) or biopsy of another lesion (liver, pleura, etc.)
Other tuberculosis	X-ray and clinical signs TST positive Cytochemical examination of effusions (high protein level and lymphocytosis)	Positive culture (of sero-fibrinous effusion or pus) Tissue biopsy (culture and histology)

Tuberculosis in children is difficult to diagnose, even pulmonary

TB; children rarely produce sputum, whereas laboratory is the cornerstone of diagnosis in adults.

For older children capable of expectorating, sputum samples should be collected as for adults. For all other children, gastric aspiration may be performed to get adequate material for smear examination.

The diagnosis of childhood TB therefore makes use of a systematic approach where a number of clinical signs are interpreted and it depends on careful evaluation of all the available evidences. A clinical diagnosis of childhood TB is possible in the majority of cases. There are two key factors in diagnosing tuberculosis in children (1) identification of an infectious adult close to the child, especially in the family, and (2) loss of weight or failure to thrive.

In most children, TB presents with symptoms of chronic disease after they have been in contact with an infectious source TB case.

To make the diagnosis of childhood TB with a fair degree of accuracy the following tests are useful: tuberculin skin test (TST), chest radiograph, sputum smear microscopy and HIV testing. These tests, coupled with the history of contact with a smear-positive case and the presence of symptoms suggestive of TB, are used to make the diagnosis.

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 test (if available)
4. Bacteriological confirmation whenever possible
5. Investigations relevant for suspected pulmonary TB (Chest X-Ray) and extra-pulmonary TB (lumbar puncture, etc.)
6. HIV testing

6.5.1 Contact with a TB case

A close contact is defined as living in the same household or being in frequent contact with a person (e.g. caregiver) who is smear-positive TB. Patients who are sputum smear-negative but culture positive are also infectious, but to a lesser degree.

6.5.2 Sputum microscopy

Sputum is difficult to obtain from young children and most children are sputum smear-negative. However, in children who are able to produce sputum, it is worth doing smear microscopy (and culture where available). In older children and adolescents and in children with severe disease, sputum smears are more often positive for AFB. Gastric aspiration or sputum induction are more elaborate methods to detect TB bacilli.

6.5.3 Chest radiography

Chest radiography is useful for the diagnosis of TB in children. In the majority of cases the chest X-ray shows abnormalities suggestive of TB. The commonest picture of active TB is that of persistent pulmonary abnormalities together with enlarged mediastinal lymph nodes. Patients with persistent pulmonary abnormalities who do not improve after a course of antibiotics should be investigated for TB. Chest radiographs should preferably be read by a radiologist or an experienced physician.

The radiological signs of primary pulmonary tuberculosis are characteristic:

- **Typical primary complex**, the most frequent manifestation, consists of a small area of *infiltration* at any location in the lung parenchyma, accompanied by unilateral *mediastinal lymphadenopathy*. The infiltration nodular shadow is usually small (3 to 10 mm in diameter) and is sometimes surrounded by a lighter shadow with irregular edges. On lateral X-ray, mediastinal lymphadenopathy appears as a rounded or oval latero-tracheal or hilar shadow. In some cases, isolated mediastinal lymphadenopathy may occur without any visible changes in the pulmonary parenchyma.

- Occasionally, primary infection lesions may present as segmental (or lobar) consolidation associated with mediastinal lymphadenopathy. This is shadowing of a discrete area (usually right middle lobe, or lingula on the left), with clear margins and no bronchial markings, caused by compression.

Adolescent patients with TB have chest radiographic changes which are similar to adult patients with large pleural effusions and apical infiltrates with cavity formation being the most common forms of presentation. A miliary pattern of shadowing in non HIV-infected children is highly suggestive of TB.

When a child presents with acute febrile illness with miliary X-ray images, treatment for tuberculosis should be given unless there is evidence of a viral or staphylococcal infection. This is particularly the case if the child has not been BCG-vaccinated and/or if there has been contact with a case of pulmonary tuberculosis.

6.5.4 Tuberculin Skin Test (TST or Mantoux Test)

Tuberculin test, when available, may be useful as an additional tool for diagnosing paediatric TB, in whom a positive test is more likely to reflect recent infection with TB and indicates a higher risk of developing TB disease.

6.5.5 Lumbar puncture for TB meningitis:

Lumbar puncture is the key investigation in TB meningitis where CSF is clear or opalescent, pressure is elevated, with plenty of lymphocytes, and the glucose level is low. Protein is elevated (0.6–2 g/l): the higher the level, the worse the prognosis.

Bacteriological examination of CSF (microscopy and especially culture), preferably of three different samples collected after lumbar puncture, will aid in identifying tubercle bacilli in the majority of cases. Treatment must be instituted immediately if the

disease is strongly suspected, without waiting for the final results of the CSF culture.

Differential diagnosis to consider for meningitis with clear CSF in children are: (i) inadequately treated bacterial meningitis, (ii) meningococcal meningitis (iii) viral meningitis and (iv) meningeal reactions during the course of other infections in children.

If the evidence of tuberculosis is not sufficiently convincing, it is still wise to begin treatment for tuberculosis unless there is other evidence to confirm another cause of meningitis.

High protein levels with an elevated lymphocyte count in a clear cerebrospinal fluid is sufficient evidence to begin treatment for tuberculosis, especially in a child less than 5 years of age who has not been BCG-vaccinated and/or who is in contact with a case of pulmonary tuberculosis.

6.5.6 Diagnosis of Tuberculosis in HIV-positive children

As in adults, PTB is the most common manifestation of TB in HIV-positive children. The diagnosis of PTB in children under 4 years old has always been difficult, and HIV infection further compounds this diagnostic challenge.

The approach to diagnosing TB in HIV-infected children is essentially the same as for HIV-uninfected children, i.e. the presence of three or more of the following should strongly suggest the diagnosis of TB:

- chronic symptoms suggestive of TB
- physical signs highly suggestive of TB
- a positive TST (diameter of induration >5 mm, as the child is HIV-infected)
- CXR suggestive of TB.

Many children who present with chronic symptoms suggestive of TB may not have been tested for HIV infection. In high HIV prevalence settings (and in all settings where HIV infection in a

child is suspected), children and their families should be offered HIV counseling and testing as part of routine TB management.

Because it is often difficult to distinguish HIV-related pulmonary disease from pulmonary TB, childhood pulmonary TB is probably over-diagnosed in many areas. Classification of childhood TB is similar to that of adult TB.

Drug-resistant TB

TB in children may be drug-resistant as drug-sensitive. Drug-resistant TB is a laboratory diagnosis. However, drug-resistant TB should be suspected if any of the features below are present.

1. Features in the source case suggestive of drug-resistant TB:
 - Contact with a known case of drug-resistant TB
 - Remains sputum smear-positive after 3 months of treatment
 - History of previously treated TB
 - History of treatment interruption
2. Features of a child suspected of having drug-resistant TB:
 - Contact with a known case of drug-resistant TB
 - Not responding to the anti-TB regimen
 - Recurrence of TB after adherence to treatment

6.6 Treatment of tuberculosis in children

The lesions of primary tuberculosis have a smaller number of M. tuberculosis organisms than those of adult-type pulmonary tuberculosis. Thus, treatment failure, relapse, and development of secondary resistance are less common among children. Children with pulmonary TB usually have low bacterial load, as cavitating disease is relatively rare. On the other hand, children more often develop extra-pulmonary TB (EPTB). Very severe and disseminated TB (e.g. miliary TB and TB meningitis) is found in the young (<3 years old) child.

Because tuberculosis in infants and children younger than 4 years of age is more likely to disseminate, treatment should be started as soon as the diagnosis is made.

Children and adolescents with adult-type pulmonary tuberculosis should be treated with the four-drug initial phase regimen. Three times weekly therapy is not recommended for children. Pyridoxine is recommended for infants, children, and adolescents who are being treated with INH and who have nutritional deficiencies, symptomatic HIV infection, or who are breastfeeding.

DOT should be used for all children with tuberculosis. Even when drugs are given under DOT, tolerance of the medications must be monitored closely. Parents should not be relied on to supervise DOT.

In general, extra-pulmonary tuberculosis in children can be treated with the same regimens as pulmonary disease. Exceptions are the disseminated TB disease, and meningitis, for which the recommended duration is 9 to 12 months.

TB diagnostic category	TB cases	Regimen ^a	
		Intensive phase	Continuation phase
I	New smear-positive pulmonary TB New smear-negative pulmonary TB with extensive parenchymal involvement Severe forms of extrapulmonary TB (other than TB meningitis) Severe concomitant HIV disease	2HRZE	4RH
I	TB meningitis	2HRZS ^b	4HR
II	Previously treated smear-positive pulmonary TB: Relapse Treatment after interruption Treatment failure	2HRZES/ 1HRZE	5HRE
III	New smear-negative pulmonary TB (other than in category I) Less severe forms of extrapulmonary TB	2HRZ ^c	4RH
IV	Chronic and MDR-TB	Specially designed standardized or individualized regimens	

^aDirect observation of drug administration is recommended during the initial phase of treatment and whenever the continuation phase contains rifampicin

^bIn comparison with the treatment regimen for patients in

diagnostic category I, streptomycin replaces ethambutol in the treatment of TB meningitis.

°In comparison with the treatment regimen for patients in diagnostic category I, ethambutol may be omitted during the initial phase of treatment for patients with non-cavitary, smear-negative pulmonary TB who are known to be HIV-negative, patients known to be infected with fully drug-susceptible bacilli and young children with primary TB.

Table 10: Recommended doses of paediatric treatment:

Drug	Recommended dose			
	Daily		Three times weekly	
	Dose and range (mg/Kg body weight)	Maximum (mg)	Dose and range (mg/Kg body weight)	Maximum (mg)
Isoniazid	5 (4-6)	300	10 (8-12)	-
Rifampicin	10 (8-12)	600	10 (8-12)	600
Pyrazinamide	25 (20-30)	-	35 (30-40)	-
Ethambutol	20 (15-25)	-	30 (25-35)	-
Streptomycin	15 (12-18)	-	15 (12-18)	-

The recommended dose of Ethambutol is higher in children (20 mg/Kg) than in adults (15 mg/Kg), because the pharmacokinetics is different. Although ethambutol was frequently omitted from treatment regimens for children in the past, due in part to concerns about the difficulty of monitoring for toxicity (particularly for optic neuritis) in young children, a literature review indicates that it is safe in children at a dose of 20 mg/Kg [range 15-25 mg/Kg/daily].

Streptomycin should be avoided when possible in children because the injections are painful and irreversible auditory nerve damage may occur. The use of Streptomycin in children is mainly reserved for the first 2 months of treatment of TB meningitis.

Management of TB meningitis and miliary TB

TB meningitis and miliary TB are more common in young children and are associated with high rates of death and disability, particularly if the diagnosis is delayed. It is therefore important to consider these diagnoses in young children as early as possible, especially in children who have a history of contact with an adult with infectious TB.

Children with TB meningitis or miliary TB should be hospitalized, preferably for at least the first 2 months. Due to different degrees of drug penetration into the central nervous system, some experts recommend modifying the standard anti-TB treatment regimen for children with meningitis, as follows.

Selected regimens for treatment of TB meningitis in children

- 2HRZS/4HR
- 2HRZ(S or Eth)/7–10HR

Corticosteroids (usually prednisone) are recommended for all children with TB meningitis in a dosage of 2 mg/kg daily for 4 weeks. The dose should then be gradually reduced (tapered) over 1–2 weeks before stopping. The dosage of prednisone can be increased to 4 mg/kg daily (maximum 60 mg/day) in the case of seriously ill children because rifampicin will decrease corticosteroid concentrations, but higher doses carry a risk of greater immune suppression.

Children with TB meningitis are at high risk of long-term disability and therefore benefit from specialist care, where this is available.

Management of TB in HIV-infected children

Most current international guidelines recommend that TB in HIV-infected children should be treated with a 6-month regimen as in HIV-uninfected children. Where possible, HIV-infected children should be treated with rifampicin for the entire treatment duration, as higher relapse rates among HIV-infected adults have been found when ethambutol is used in the continuation phase. Most children with TB, including those who are HIV-infected, have a

good response to the 6-month regimen. Possible causes for failure, such as non-compliance with therapy, poor drug absorption, drug resistance and alternative diagnoses should be investigated in children who are not improving on anti-TB treatment. As in children not infected with HIV, a trial of anti-TB treatment is not recommended in HIV-infected children. A decision to treat any child for TB should be carefully considered, and once this is done, the child should receive a full course of treatment.

Cotrimoxazole prophylaxis

Daily cotrimoxazole prophylaxis (20 mg trimethoprim (TMP) + 100 mg sulfamethoxazole (SMX) if under 6 months of age; 40 mg TMP + 200 mg SMX if aged under 5 years; 80 mg TMP + 400mg SMX if 5 years or older) prolongs survival in HIV-infected children and reduces the incidence of respiratory infections and hospitalization. All HIV-infected children with advanced immunosuppression should be started on cotrimoxazole.

Antiretroviral therapy

HIV-infected children benefit from treatment of HIV with ART. In HIV-infected children with confirmed or presumptive TB, however, the initiation of anti-TB treatment is the priority. Treatment of TB in HIV-infected children on ART or who are planned to start on ART needs careful consideration, especially rifampicin, and some of the non-nucleoside reverse transcriptase inhibitors and protease inhibitors cause clinically significant drug interactions. Furthermore, the adverse events of the anti-TB drugs and the antiretroviral drugs are similar and can cause confusion as to which drugs need to be stopped.

The clinical and immunological condition of the HIV-infected child should guide the decision whether to:

- start ART treatment soon (2–8 weeks) after the start of anti-TB treatment;
- delay ART until after completion of the initial phase of anti-TB treatment;
- delay start of ART until anti-TB treatment is completed.

Where possible, the initiation of ART should be deferred for at least 2–8 weeks in children starting anti-TB treatment who have not yet started ART.

6.7 Administering treatment and ensuring adherence

Many children with TB can be managed on ambulatory basis. Conditions that necessitate hospitalization include:

- a) TB meningitis or miliary TB, preferably for the first 2 months of anti-TB treatment;
- b) Any child with respiratory distress;
- c) Spinal TB;
- d) Severe adverse events, such as hepatotoxicity;

6.8 Follow Up

Each child should be assessed (i) 2 weeks after treatment initiation, (ii) at the end of the intensive phase and (iii) every 2 months until treatment completion. At a minimum assessment should include symptom assessment, an assessment of adherence, inquiry about any adverse events, and weight measurement. Medication dosages should be adjusted for weight gain. A follow-up sputum smear microscopy at 2 months should be obtained for any child who was smear-positive at diagnosis.

Because of the difficulties in isolating *M. tuberculosis* from children, bacteriological examinations are less useful in evaluating the response to treatment and clinical and radiographic examinations are of relatively greater importance. However, hilar adenopathy may require 2 to 3 years to resolve. Thus, a persisting abnormality on chest radiographs is not necessarily a criterion for continuing therapy.

A child who is not responding to TB treatment should be referred for further assessment and management. Recognition of treatment failure or relapse in a child is subject to the same difficulties as making a diagnosis. Thus, clinical and radiographic worsening may not be accompanied by positive AFB smears or mycobacterial cultures. A decision to modify the drug regimen

should not be made without due consideration, but must be based on sound clinical grounds.

6.9 Adverse reactions to TB drugs in children

Adverse events are less common in children than in adults. The most common adverse reaction is the development of hepatotoxicity, which can be caused by Isoniazid, Rifampicin or Pyrazinamide. Serum liver enzyme levels should not be monitored routinely, as an induction of liver enzymes (<5 times normal values) is not an indication to stop treatment. However, the occurrence of liver tenderness, hepatomegaly, or jaundice should lead to investigation of serum liver enzyme levels and the immediate interruption of all potentially hepatotoxic drugs.

Patients should be screened for other causes of hepatitis, and no attempt should be made to reintroduce these drugs until liver functions have normalized. An expert should be involved in the further management of such cases.

Isoniazid may cause symptomatic pyridoxine deficiency, particularly in severely malnourished children. Supplemental pyridoxine (5-10 mg/day) is recommended in malnourished children and in HIV-infected children.

7 TB/HIV COLLABORATIVE ACTIVITIES

7.1 Impact of HIV on Tuberculosis

The Human Immunodeficiency Virus (HIV) pandemic presents a massive challenge to the control of tuberculosis (TB). The synergy between TB and HIV/AIDS is strong: in high HIV prevalence populations, TB is a leading cause of morbidity and mortality, and HIV is fuelling the tuberculosis epidemic in Ethiopia. This unprecedented scale of the epidemic of HIV-related tuberculosis demands concerted and urgent action.

HIV increases susceptibility to infection with *M. tuberculosis*, the risk of progression to TB disease, and the incidence and prevalence of TB. It also increases the likelihood of re-infections and relapses of TB.

Mechanisms in the development of HIV-associated TB:

- Re-activation of latent TB infection (acquired prior to HIV infection).
- Rapid progression to disease, following recent TB infection.
- Re-infection with another strain of *M. tuberculosis*

HIV has a number of impacts on prevention and control of TB, including:

- Increased number of patients developing side-effects from anti-TB drugs
- Worsened stigma and discrimination
- Increased workload of health care providers that can compromise quality of service
- Depletion of resources.

It has also been found that latent TB-infection in HIV-positive persons reactivates at a rate of 10% per year (as opposed to 5%-10% over a lifetime for HIV-negative persons). HIV-positive persons are prone to re-infection with new strains of TB from the

community and drug resistance may occur more frequently.

Health care workers should strongly recommend and routinely offer HIV TESTING for all TB patient and TB suspects, after providing them with adequate information on the benefits of HIV testing.

7.2 Impact of Tuberculosis on HIV

- TB is the leading cause of illness and death among PLHIV;
- TB increases the occurrence of other opportunistic infections;
- TB hastens the rate of HIV progression;
- TB influences ART in various ways: drug-drug interactions, side effects and Immuno Reconstitution Inflammatory Syndrome;
- Late TB diagnosis contributes to increased death rates in PLHIV.

Ethiopia is one of the highly affected countries by the TB/HIV co-epidemic. The WHO Global Report 2008 estimates that in Ethiopia 40% of TB patients tested for HIV are HIV positive, while routine data from 1999 EFY (2006/7) estimates that 31% of TB patients are HIV positive.

The dual epidemics have a number of impacts on the health sector. They increase TB and HIV burden, demand for care and worsen the situation of the already overstretched health care delivery system in the country. Hence, they deplete resources, worsen stress and aggravate attrition of health workers at service delivery points. Therefore Tuberculosis and HIV Prevention and Control Programmes share mutual concerns: prevention of HIV is a priority for tuberculosis control and prevention and care of TB are priority concern for HIV/AIDS prevention and control programme.

The expanded scope of the new strategy for tuberculosis control in high HIV prevalence population comprises

- a) Interventions against TB (intensified case-finding, treatment and Isoniazide Preventive Therapy - IPT)

and

- b) Interventions against HIV (and therefore indirectly against tuberculosis), e.g. safe sexual practice, STI treatment, Co-trimoxazole Preventive Therapy (CPT) and Anti-Retroviral Treatment (ART).

WHO recommends twelve main collaborative activities between TB and HIV/AIDS control programmes.

A. Establish the mechanisms for collaboration
A.1 Set up a coordinating body for TB/HIV activities at all levels A.2 Conduct surveillance of HIV prevalence among tuberculosis patients A.3 Carry out joint TB/HIV planning A.4 Conduct monitoring and evaluation
B. Decrease the burden of tuberculosis in people living with HIV
B.1 Establish intensified tuberculosis case-finding B.2 Introduce Isoniazid preventive therapy B.3 Ensure tuberculosis infection control in health care and congregate settings
C. Decrease the burden of HIV in tuberculosis patients
C.1 Provide HIV testing and counseling C.2 Introduce HIV prevention methods C.3 Introduce co-trimoxazole preventive therapy C.4 Ensure HIV/AIDS care and support C.5 Introduce antiretroviral therapy

NB: For details on the collaborative activities refer to TB/HIV implementation guideline, MOH, 2008

7.3 Diagnosis of TB in HIV-positive patients

In the early stages of HIV infection, when immunity is only partially compromised, the features are more typical of tuberculosis, commonly with upper lobe cavitation, and the disease resembles that seen in HIV- negative TB patients. As immune deficiency advances, HIV-infected patients present with atypical pulmonary disease, resembling primary tuberculosis or extrapulmonary (like pleurisy) and disseminated (miliary)

disease, commonly with hilar adenopathy and lower lobe infection. In the advanced stages there is a tendency to develop smear-negative TB.

Pulmonary tuberculosis is the most common manifestation of tuberculosis in adults infected with HIV. Tuberculosis occurs at various stages of HIV infection, with the clinical pattern correlating with the patient's immune status and could broadly be classified as early and late presentation.

From the clinical point of view, the clinical features in pulmonary TB are generally similar in HIV-infected and HIV-negative patients. However, cough and haemoptysis are reported less frequently by HIV-infected patients.

Most of HIV-infected pulmonary TB patients are sputum smear-positive, however the proportion of smear-negative patients is much greater in HIV-infected than in HIV-negative TB patients.

HIV-infected, smear-positive patients also tend to excrete significantly fewer bacilli in sputum than HIV-negative patients. This can lead to AFB being missed if not enough fields are examined by microscopy.

**Sputum smear remains the cornerstone to confirm the diagnosis of pulmonary TB, including in HIV-positive patients.
It also helps identifying infectious patients so that transmission can be stopped.**

TB and the chest X-ray in HIV-positive patients

If the sputum-smear remains negative, a chest X-ray can be of additional value in the diagnosis. However, the appearance of the X-ray may not be typical for TB.

HIV-infected patients with relatively well-preserved immune function will often show typical radiological features.

As immunosuppression worsens, however, chest radiographs more often show atypical features such as pulmonary infiltrates affecting the lower lobe rather than the upper lobes and

intrathoracic lymphadenopathy, In addition, TB tends to be disseminated with absence of cavitation.

There are many other lung conditions in HIV-positive patients that are indistinguishable from TB on the chest X-ray! Therefore the flow chart for the diagnosis of TB should be followed strictly in case of negative sputum smears (annex III).

Diagnosis of TB in the HIV-infected therefore requires a high index of suspicion. The following table summarizes differences in presentation between early and late stages of HIV-infection:

Table 11. Differentiation between early and late stages of HIV-infection

TB & HIV	Stage of HIV-infection	
	Early stage	Late stage / clinical AIDS
Clinical picture	Cough > 2 weeks Productive sputum	<ul style="list-style-type: none"> • Dry cough, not productive
X-ray appearance	<ul style="list-style-type: none"> • Upper lobe infiltrates • Cavitation • Nodular or patchy shadows 	<ul style="list-style-type: none"> • Lower lobe infiltrates, no cavitation • Often mediastinal lymphadenopathy and/or pleural effusion • Sometimes miliary or interstitial pneumonia
Sputum smear	<ul style="list-style-type: none"> • Often positive (>80%) 	<ul style="list-style-type: none"> • Often negative (< 50%)

The main manifestations of EPTB in HIV-infected patients are lymphadenopathy, pleural effusion, pericardial effusion, and miliary TUB.. Presentation of EPTB in HIV-infected patients is generally not different from that in HIV-negative patients. However, HIV-related TB lymphadenopathy can occasionally be acute and resemble an acute pyogenic bacterial infection. The definitive diagnosis of EPTB is often difficult because of the scarcity of diagnostic facilities. Diagnosis can be made with fine needle aspiration, (pathology), and examination of direct smears

from the cut surface.

In TB meningitis, the CSF can be completely normal in HIV-infected patients. Disseminated TB can be extremely difficult to diagnose. Pericardial TB is not rare and may be diagnosed presumptively from the characteristic balloon-shaped appearance of the cardiac shadow on chest radiography.

***TB CLASSIFICATION in HIV-POSITIVE PATIENTS
(according the revised case definition from WHO 2006)***

Smear-positive pulmonary tuberculosis

- One sputum smear examination positive for Acid Fast Bacilli (AFB) by direct microscopy, **and**
- Laboratory confirmation of HIV infection **or**
- Strong clinical evidence of HIV infection

Smear-negative pulmonary tuberculosis

- At least two sputum specimens negative for AFB and
- Radiographical abnormalities consistent with active tuberculosis and
- Laboratory confirmation of HIV infection **or**
- Strong clinical evidence of HIV infection and
- Decision by a clinician to treat with a full course of anti-tuberculosis chemotherapy

OR

- A patients with AFB smear-negative sputum which is culture-positive for *Mycobacterium tuberculosis*

Extra-pulmonary tuberculosis

- One specimen from an extra-pulmonary site culture-positive for *Mycobacterium tuberculosis* or smear-positive for AFB

OR

- Histological or strong clinical evidence consistent with active extra-pulmonary tuberculosis **and**
- Laboratory confirmation of HIV infection **or**
- Strong clinical evidence of HIV infection **and**
- Decision by a clinician to treat with a full course of anti-tuberculosis chemotherapy

7.4 Prevention and Management of TB among PLHI

7.4.1 Isoniazid Preventive Therapy (IPT)

TB disease is one of the major opportunistic infections that cause death among PLHIV. All newly-identified HIV-infected adults and children should be screened for TB symptoms (prolonged cough ≥ 2 weeks), followed by sputum smear microscopy and in some cases chest radiography. After ruling out active TB, IPT should be considered for PLHIV in order to protect them from developing TB disease (for details see TB/HIV Implementation Guideline).

Where HIV prevalence is high among cases with smear positive PTB, children of index cases may be at risk of both TB and HIV. It is important to know HIV status of children (if not, consider HIV testing). If the child contact is HIV- positive and otherwise well, then consider IPT for all ages including those 5 years and older. IPT must not be given to any child, who has active or possible TB (for details see TB/HIV Implementation Guideline).

7.4.2 Co-trimoxazole Preventive Therapy (CPT)

It is well-documented that administration of CPT decreased morbidity and mortality among HIV-infected TB patients. Co-trimoxazole is standard of care for this category of patients and is given to HIV-positive TB patients (for details see the TB/HIV Implementation Guideline).

7.4.3 Treatment of TB in PLHIV

The treatment of TB in PLHIV is essentially the same as in HIV-negative patients. It is well tolerated and in general the outcome of treatment is good, particularly in patients in the early course of HIV infection. TB treatment must therefore be commenced without delay in PLWH. However, due in part to HIV-related complications, predominantly in the first months of TB treatment, death occurs more commonly in HIV-positive than in HIV-negative TB patients, with a higher risk of death in the late stage of HIV infection. These complications can be decreased to a large extent by prescribing Cotrimoxazole (2 tablets or one double strength tablet daily) to all HIV-positive TB patients irrespective of the stage of HIV infection. When available, ART

substantially decreases the risk of death in HIV-infected TB patients. For more detail refer to TB Care with TB-HIV co-infection; IMAI module.

7.4.4 Anti-TB Treatment and Anti-Retroviral Therapy (ART)

Anti-TB treatment and ART together give rise to a number of potential problems, such as drug interactions, increased risk of adverse effects and increased frequency of “Immune Reconstitution Inflammatory Syndrome” (IRIS).

Management of co-infected patients is detailed in the “TB Care with TB-HIV co-infection; IMAI module”. Possible options for ART in patients with TB include:

- Delayed start of ART after completion of TB treatment.
- Delayed start of ART after completion of the initial phase of TB treatment and, then, use Ethambutol and Isoniazid in the continuation phase.
- Treatment of TB with a Rifampicin-containing regimen as indicated in national ART guideline.

8 DRUG-RESISTANT TB AND MULTI-DRUG RESISTANT TB

Like for all infectious diseases, the bacilli responsible for TB may be, or become, resistant to antibiotics. TB bacilli are naturally, spontaneously, resistant to penicillins or cotrimoxazole for instance. They may also become resistant to anti-TB drugs, possibly any anti-TB drug.

When a patient has TB with TB strain/bacilli that are not sensitive anymore to a given antibiotic (for instance INH), these bacilli will not be affected by this drug, and therefore using this antibiotic for this patient will not help him. It will furthermore tend to select resistant strains, because they can grow in the presence of INH, whether sensitive strains will not. This is actually the reason why TB patients must always be treated with a combination of drugs.

Therefore resistance to TB drug(s) usually occurs as a consequence of an inadequate treatment, be it irregular, too short or too weak. It develops because a patient is treated incorrectly or is not able to adhere to the treatment regimen. In both cases, the patient has not been receiving a strong enough dosage of the drug over a long enough period of time to kill the bacilli, so the organism are given time to develop resistance to anti-TB drugs. A good TB control program—especially with regard to patient follow up and adherence- will not generate much resistance. Resistance is man made, most of the time. Mostly people who have already received TB treatment—specially sub optimal care- have resistant TB bacilli.

Once it is created, resistant TB can be transmitted like any other TB. It is estimated that the average MDR-TB patient infects up to 20 other people in her/his lifetime. Some people who have never been previously treated for TB may get resistant bacilli. Resistance to anti-TB drug can only be confirmed by a reference laboratory by Drug Sensitivity Testing (DST):

- Mono-resistant TB: TB in patients whose infecting isolates of *M.tuberculosis* are confirmed to be resistant in

- vitro to one first-line anti-TB drug.
- Poly-resistant TB: TB in patients whose infecting isolates are resistant in vitro to more than one first-line drug, other than Isoniazid and Rifampicin
 - **Multi-drug resistant TB (MDR)**: is active TB involving *M. Tuberculosis* organism that are resistant to at least both Isoniazid and Rifampicin, the two most powerful anti-TB agents. A MDR-TB strain can be resistant to more than these two antibiotics and in most cases it is resistant to other first-line drugs.
 - **Extensive-drug resistant TB (XDR)**: is defined as resistance to at least Rifampicin and Isoniazid, in addition to any Fluoroquinolone, and to at least one of the three following injectable drugs used in anti-TB treatment: Capreomycin, kanamycin and Amikacin.

Table 12: Causes of Inadequate anti-tuberculosis treatment

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

8.1 MDR-TB or Multi Drug Resistant Tuberculosis

In Ethiopia, according to a national survey (2003-2006), it is estimated that MDR-TB represents about 1,6 % of new TB cases (never treated previously) and 11,8% of re-treatment cases.

Treatment of MDR-TB is more complicated and longer than treatment of TB with no resistance. It is important to treat MDR-TB patients both to prevent their death and to limit the dissemination of drug-resistant TB in the community.

Good history taking is essential when people present with TB symptoms to determine previous TB treatment, its length and the drugs used. In addition, during history taking the patient may reveal contact with someone who suffered from drug-resistant disease.

The diagnosis of MDR TB is made only by reference laboratories performing culture of TB strains, with additional testing of anti TB drug sensitivity (DST: drug sensitivity testing). It requires a specimen of fresh sputum and the final result takes 2 to 3 months to be on hand with common techniques. The test will gradually be available in Regional and National Reference laboratories in Ethiopia.

The main indications for TB culture and DST in search for MDR-TB are:

- Retreated cases who fail to respond to category II regimen.
- Chronic cases.
- New cases that are contact cases of known or suspected MDR cases.
- Unclear treatment failure with good compliance .

Specific guidelines for MDR case detection and indication for DST in Ethiopia will soon be developed and circulated.

8.2 Extensively Drug-Resistant Tuberculosis (XDR-TB)

Extensively Drug-Resistant Tuberculosis (XDR-TB) is a rare type of MDR-TB. XDR-TB is defined as resistance to Rifampicin and Isoniazid (which is the definition of MDR-TB), in addition to any Fluoroquinolone, and at least one of the three following injectable drugs used in anti-TB treatment: Capreomycin, Kanamycin and Amikacin.

Because XDR-TB is resistant to first – and second line drugs, patients are left with very few efficient treatment options. However, it can be identified early, can be treated and cured in some cases under proper TB control conditions. Successful treatment outcomes depend on the extent of the drug resistance, the severity of the disease and the immune response of the patient. In many XDR cases there is no efficient treatment available.

8.3 Treatment of MDR-TB

The best measure regarding TB MDR is to prevent its occurrence

The prevention of MDR can only be achieved through proper TB case detection, rational diagnosis, standard treatment and, most of all, successful follow up and high adherence of patients.. Clearly an efficient DOTS program is the best weapon against MDR. There are not enough second line options to cope with widespread surge of MDR and XDR TB

For established and proven MDR, anti-TB drugs efficient for MDR (Second line TB drugs) will gradually be accessible in Ethiopia. It is however of crucial importance that this “last chance” second line drugs are used in a very rational way to maintain their effectiveness. If they are not properly used, resistance will extend to these second line drugs. Every health worker has to be aware that, beyond these second line TB drugs, there is no other option left, and the presence of untreatable communicable TB in the community would be a serious threat for all, especially health workers.

When MDR-TB is confirmed by culture and sensitivity testing, or is suspected based on the patient’s history, a specific treatment regimen has to be given: Patients with MDR TB mustn’t be treated only with usual TB drugs and standard regimens (I, II or III): this would simply generate more resistance to TB drugs (because at least 2 major ant-Tb drugs are already useless in those cases).

The treatment is complex, very long and expensive; severe side effects are quite common and success rate is lower than with common TB (non MDR).

MDR-TB patients should be treated with a combination of second line drugs and, if advisable, first line TB drugs that still have proven efficacy. *Regimens should consist of drugs with either certain, or almost certain, effectiveness.*

The treatment should be standardized or individually adjusted on the basis of result of Drug Sensitivity Testing. Since susceptibility

to all TB drugs cannot be assessed routinely, and as comprehensive result may not be available before several weeks, five or six drugs are recommended initially. The first phase, which injectable drug, should be a minimum of 6 months and initial treatment may be extended if the patient does not convert both smear and culture. The entire treatment period is 18-24 months after smear and culture conversion.

Classification of Anti-TB drugs

Grouping	Drugs (abbreviations)
Group 1 – First-line oral antituberculosis agents	Isoniazid (H), rifampicin (R), ethambutol (E), pyrazinamide (Z)
Group 2 – Injectable antituberculosis agents	Streptomycin (S); Kanamycin (Km); Amikacin (Am); Capreomycin (Cm); Viomycin (Vi)
Group 3 – Fluoroquinolones	Ciprofloxacin (Cfx); Ofloxacin (Ofx); Levofloxacin (Lfx); Moxifloxacin (Mfx); Gatifloxacin (Gfx)
Group 4 – Oral bacteriostatic second-line agents	Ethionamide (Eto); Protionamide (Pto); Cycloserine (Cs); Terizidone (Trd); <i>P</i> -aminosalicylic acid (PAS); Thioacetazone (Th)
Group 5 – Antituberculosis agents with unclear efficacy (not recommended by WHO for routine use in MDR-TB patients)	Clofazimine; amoxicillin/clavulanate; clarythromycin; linezolid

8.4 Follow-up of MDR TB patients

Ideally second line treatment for MDR-TB patients should be directly observed for the full course of treatment, and patients closely monitored at least until they become non-infectious. MDR treatment centers facilities should be adequately equipped for infection control.

Patients with MDR-TB take more tablets and receive more injections for a longer period of time, may experience more adverse effects and require increased support to continue treatment and/or to monitor adverse effects. Detecting and controlling adverse effects in a timely manner promotes adherence and prevents default to treatment.

The Ministry of Health, backed by the international community, has decided to start providing treatment for MDR TB patients at a TB Specialized Center in Addis Ababa, with particularly trained staff and reinforced infection control measures. For the coming years only this selected specialized Centre will be equipped for MDR cases management. The Ministry of Health will issue case finding and treatment guidelines that must be strictly followed by every health worker and clinician.

9 PREVENTION OF TB

The best measure for primary prevention of tuberculosis is the treatment of **infectious** cases. The disease being transmitted only by –coughing- TB patients to other contact(s).

Primary prevention can also be promoted through good public health practice to reduce the transmission of infection in institutions by adequate ventilation and isolation of infectious patients.

Prevention of TB also includes two measures: BCG vaccination and prescription of Isoniazid chemoprophylaxis for groups at risk.

9.1 Main groups at risk

“Groups at risk” are population groups whose risk of contracting tuberculosis is 5–10 times higher than that of the general population, either because they have a greater risk of being infected, or because they have a greater likelihood of progressing to disease once infected. They include:

1. Groups most exposed to sources of infection

- **The family circle of index cases**

Subjects living in contact with smear-positive cases have a risk that is directly proportional to their contact with the patient. The greatest risk is observed in individuals who live in the same household as a smear-positive pulmonary tuberculosis case.

- **Health institutions**

Individuals present in health facilities at the same time as untreated or drug-resistant tuberculosis patients, and health personnel working in tuberculosis services or in bacteriology laboratories handling sputum, are more exposed to sources of infection than the general population.

2. Groups with lowered immunity

This group mainly consists of individuals who are HIV-positive

or who have AIDS. Other diseases (such as silicosis, lymphoma and diabetes) and immunosuppressive treatment provoke a lowering of immunity that is much less significant. Drug dependence and alcoholism favour reduction in immunitary defences.

3. Underprivileged and marginalized groups

Individuals in precarious situations, those who are homeless, and those who live in poor areas of big cities and prisoners often experience overcrowded living conditions that increase the intensity of exposure to tubercle bacilli excreted when someone in the environment has tuberculosis. HIV infection may also be higher in underprivileged population groups.

4. Individuals with extensive sequelae from untreated tuberculosis

These individuals have a higher risk of recurrence of tuberculosis through reactivation of bacilli that have remained latent after their disease has become quiescent. This is principally the case if they have had inadequate or no treatment for their previous episode of tuberculosis.

9.2 Measures of prevention

□ *Treatment of smear-positive pulmonary tuberculosis*

Detection and treatment of sources of infection are still the best methods of tuberculosis prevention. To improve this means of prevention, it is essential to improve access to health care for the population in general and for groups at risk in particular. It is also important for health practitioners to maintain a high level of awareness regarding tuberculosis.

Every effort must be made to improve the accessibility of care for these population groups, by:

- Providing free timely tuberculosis care and treatment;

- Decentralizing health services to make them more accessible for marginalized groups, in the poorest urban and rural areas, in prisons, etc.

□ *Treatment of latent tuberculosis infection (preventive chemotherapy)*

Treatment of latent tuberculosis infection (preventive chemotherapy) prevents disease from appearing in infected individuals. It is targeted mainly at contacts aged less than 5 years living in the same household as a newly identified case of pulmonary tuberculosis. Depending on the situation, preventive chemotherapy may be extended to other groups at risk. The regimen consists of isoniazid given at doses of 5 mg/kg for 6 months.

Contacts of pulmonary TB case

- **Children in contact with a pulmonary tuberculosis case**

All children in contact with a pulmonary TB case should undergo clinical examination, and those identified as tuberculosis suspects should undergo further testing. Children diagnosed with tuberculosis should receive a full course of preventive treatment; all other children aged under 5 years who have been exposed to a smear-positive case should receive treatment for latent TB infection whether or not they have been BCG-vaccinated.

- **Adult contacts**

All adults who have been in contact with a pulmonary tuberculosis case should be examined, and tuberculosis suspects should be asked for three sputum samples for bacteriological examination.

Systematic case-finding among contacts beyond individuals living in the same household is not feasible. This is why it is preferable to educate the entire population about tuberculosis symptoms and to improve access to health care.

HIV-infected individuals

Controlled clinical trials have confirmed the efficacy of

preventive chemotherapy in HIV-infected individuals in lowering the risk of active TB. More details are provided in the chapter regarding TB/HIV.

□ ***Infection Prevention: Measures that reduce the risk of transmission of TB infection in health facilities***

Smear-positive cases are virtually no longer infectious 2 weeks after starting treatment, provided they are not MDR TB. Where patients are multidrug-resistant, they have a high risk of infecting those around them and, where this is likely to occur, very careful precautions must be taken to isolate such patients from those at risk of becoming infected by contact with them.

Simple measures that should be taken in order to avoid the spread of TB infection include:

- treat the majority of TB patients on an outpatient basis as soon as they are diagnosed;
- increase the ventilation of rooms where tuberculosis patients are hospitalized and let as much sun into them as possible; UV light are also useful in that regard.
- avoid, as much as possible, all contact between tuberculosis patients and those patients who are known or suspected to be HIV-positive or have AIDS; they should never be hospitalized in the same wards.
- Ensure there is adequate ventilation in laboratories collecting and handling sputum, or undertaking culture of *Mycobacterium tuberculosis*, and in areas where patients cough, such as bronchoscopy suites. When sputum specimens are collected, it is best to ask all patients to produce the specimen in the open air.

□ ***BCG vaccination***

BCG vaccine consists of bacilli whose virulence has been attenuated. When these bacilli are injected into the body, the development of protective immunity is stimulated, and the person's means of defence is increased without causing disease.

BCG should be administered:

At birth, on the same day as the BCG vaccination is given, the newborn should be given a dose of oral polio vaccine;

After 2 months, the first vaccination against diphtheria, pertussis, tetanus and poliomyelitis can be given at the same time as BCG;

After 9 months, BCG vaccination can be given at the same time as the measles vaccine.

It is unusual for complications to occur if the vaccination is given correctly. In about one in 1000 children lymphadenopathy may develop in the axilla or inside the elbow, which may become fluctuant and fistulize. Treatment consists of an incision to drain the node, and application of dry dressings until scarring. It will heal within several days or weeks.

If the infant has –symptomatic- AIDS, BCG is contraindicated; however, infants who are HIV-positive should be BCG-vaccinated, as the risk of tuberculosis in such infants is greater than the risk of complications from the vaccine. Infants born to HIV-positive mothers should also be vaccinated, unless they present symptoms of AIDS.

BCG vaccination does not protect children from *Mycobacterium tuberculosis* infection, but from its immediate consequences. It is now agreed that **BCG gives protection against the acute severe forms of tuberculosis in childhood**: disseminated disease and TB meningitis.

The protective effect of BCG lasts for 10 to 15 years, but revaccination has no proven benefit. To reduce the number of infectious cases, it is much more important to give adequate treatment to all patients who constitute sources of infection, i.e. cases of smear-positive tuberculosis.

PREVENTION OF TB

Among the various methods of preventing tuberculosis, the most effective is the identification and effective treatment of patients with infectious pulmonary tuberculosis.

It is important to pay careful attention to adequate ventilation in institutions where TB patients may be encountered, in order to prevent infection of those in contact with them. Isolation of infectious TB patients (especially where there is an increased possibility that the patient may have multidrug-resistant TB) is important to prevent infection.

Treatment of latent TB infection with Isoniazid (IPT) has limited, individual indications, and applies above all to children aged under 5 years living in close contact with smear positive TB patient and to people living with HIV in whom active TB is ruled out.

BCG vaccination is of proven efficacy in protecting small children against severe, acute forms of tuberculosis.

10 LEPROSY

10.1 EPIDEMIOLOGY

Definition

Leprosy is a chronic infectious disease caused by *Mycobacterium Leprae*. It usually affects the skin and peripheral nerves.

Source of infection

Untreated Multi-bacillary leprosy patients discharging bacilli are the main source of infection.

Route of transmission

Route of transmission is uncertain. However, transmission of infection through air-borne spread of droplets containing the bacilli expelled by untreated infectious persons and inhaled by healthy persons is believed to be the most important route of transmission. Persons living in the same household or who otherwise are in frequent contact with an infectious person have the greatest risk of being exposed to the bacilli.

Population affected

Leprosy affects persons in all age groups and both sexes. The age group mainly affected is between 15 and 45 years. Factors related to poverty increase the risk of developing the disease.

Natural evolution

Under normal circumstances, only a very small proportion (less than 5%) of all individuals who are **infected** by the leprosy bacilli will develop the **disease** during their lifetime. In the majority of people, the immunological defence kills all the bacilli. The disease has a long incubation period, ranging from 3 to 5 years, but it may vary from 6 months to more than 20 years. If not treated, leprosy can cause severe disability, mainly as a result of peripheral nerve damage.

Association of Leprosy with HIV

Research conducted in various countries showed that there is no strong association between these two diseases.

10.2 CASE-FINDING

Case-finding means the detection of active cases of leprosy by examination of suspects attending health facilities.

A case of leprosy is a person with clinical signs of leprosy, who requires chemotherapy. A leprosy patient who has completed a full course of chemotherapy should no longer be regarded as a case of leprosy, even if sequelae of leprosy such as skin lesions, disability and/or disfiguration remain.

Leprosy is diagnosed by finding at least one of the cardinal signs of leprosy.

The **cardinal signs** of leprosy are:

1. Definite loss of sensation in a pale (hypopigmented) or reddish skin lesion.
2. Thickened or enlarged peripheral nerve, with loss of sensation and/or weaknesses of the muscles supplied by that nerve.
3. The presence of acid-fast bacilli in a slit skin smear.

The main aim of case-finding is to:

- To identify the sources of infection in the community, that is, individuals who are discharging large number of leprosy bacilli. Treatment of those infectious patients rapidly renders them non infectious, thereby interrupting the chain of transmission.
- Diagnose and cure leprosy cases before irreversible nerve damage has occurred
- Minimizes the delay in initiating treatment, thereby increasing the possibility of cure before irreversible nerve damage ensues

There are two methods of case detection:

- a) Passive case-finding
 - Self reporting.

- Examination of contacts brought to health facilities by the patients.
- b) Active case-finding
- Contact tracing.
 - Institutional survey (school, prison, military camps).
 - Population (mass) survey e.g. Leprosy Elimination Campaign (LEC), Special Action Project for Elimination of Leprosy (SAPEL).

However, active case detection is not recommended, except in remote areas where health infrastructures are inadequate.

The following activities are implemented for case-finding:

- Physical examination: “cotton wool test“ of hypopigmented skin lesion for all self-presenting persons with symptoms suggestive of leprosy.
- Examination of all household contacts of newly detected patients (annex XII).
- Examination of a skin smear by direct microscopy for the presence of AFB: mostly for doubtful cases or cases difficult to diagnose.

Leprosy should be suspected in people with any of the following symptoms or signs:

- Pale or reddish patches on the skin (**the most common sign of leprosy**).
- Loss, or decrease, of sensation in the skin patch.
- Numbness or tingling of the hands and/or feet.
- Weakness of the hands, feet or eyelids.
- Painful and/or tender nerves.
- Burning sensation in the skin.
- Swellings or lumps in the face and earlobes.
- Painless wounds or burns on the hands or feet.

A person is likely to be suffering from leprosy if, in addition to one or more of the above signs and symptoms, he/she is contact of a patient with MB leprosy.

10.3 Diagnostic methods

Over 95% of leprosy cases can be diagnosed on clinical grounds. Laboratory is indicated for confirmation of doubtful cases and patient's classification.

Clinical

A. *History taking*

The following information must be obtained from the patient and recorded on the Patient Record Card:

- General information on the patient: name, sex, age, complete address, distance from home to the clinic (in km and travel time) and occupation.
- Main complaints and duration of signs
- History of previous leprosy treatment
- Contact information: other leprosy patients in the household and/or family

B. *Physical examination*

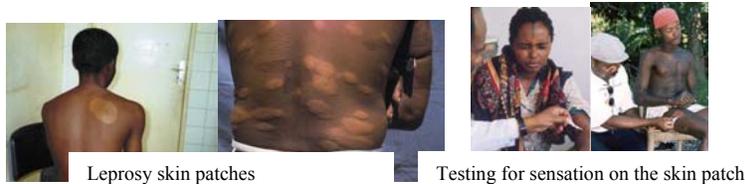
Physical examination includes:

1. Examination of the skin:

- The patient is asked to remove all garments.
- Examination must always be carried out with adequate light (preferably natural light) and sufficient privacy for the patient to feel at ease.
- Examination must be carried out systematically to ensure that no important signs are missed. First the head, then neck, shoulders, arms, trunk, buttocks and legs.
- First the front side of the body and then the backside.

The skin should be examined for:

- Presence of skin lesions (patches or nodules).
- Presence of loss of sensation in the skin lesions (patches)
- Number of skin lesions



Sensation of the skin lesions is tested with a wisp of cotton-wool as follows:

- Roll the end of a wisp of cotton wool into a fine point.
- Explain to the patient the purpose of the test and what is expected from him.
- Touch the skin with the fine point of the cotton wool until it bends.
- After the explanation a trial test is done by touching the patient on normal skin with the patient's eyes open so that he/she can exactly see what is done. Continue until the patient has shown that he/she understands the purpose of the test.
- Then do the testing with the patient's eyes closed. First test on normal skin. When he/she points correctly, test in the skin patches, while touching normal skin now and then. Watch at every touch that the patient keeps his/her eyes closed.

A patient points accurately to areas of normal skin, but sometimes points away from where the skin in a patch is tested. This is called misreference, and shows diminished sensation in the patch. If this is consistent during repeated testing of a patch, it is a cardinal sign and thus a diagnosis of leprosy is made.

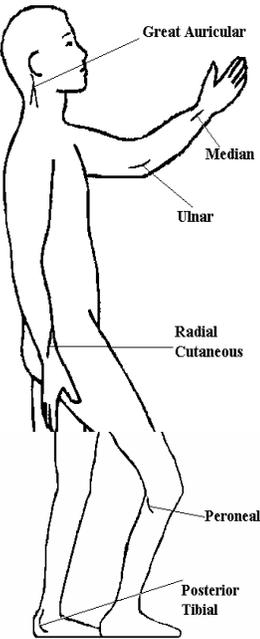
2. Examination of the nerves:

2.1 Nerve palpation

- Palpate the nerves starting from the head and going to the feet.
- The following nerves are to be examined in leprosy. However, the two most commonly affected are the ulnar and peroneal nerves. Hence, these two nerves are

commonly enlarged and can be felt quite easily.

Figure 4: Sites where nerves can be felt



Palpating the nerves

- Peripheral nerves are examined for:
 - ✓ Enlargement or thickening
 - ✓ Tenderness
- When palpating a nerve always use 2 or 3 fingers.
- The nerve should be rolled over the surface of the underlying bone.

Error



Palpating the Ulnar



Palpating the Ulnar nerve



Palpating the Peroneal nerve

2.2 Nerve function testing

The functions of the following peripheral nerve fibres are examined:

- Motor nerve fibres by Voluntary Muscle Testing (VMT)
- Sensory nerve fibres by Sensory Testing (ST)
- Autonomic nerve fibres by checking for dryness of palms and soles

2.2.1. Voluntary Muscle Testing (VMT)

Muscle strength is measured with VMT. The strength should be graded as Strong (**S**), Weak (**W**) or Paralyzed (**P**). Test the muscle strength of eyes, hands and feet as follows:

Voluntary muscle testing (VMT) of the eyes

Eye closure:

Ask the patient to close his eyes lightly as in sleep. Observe whether or not the closure is complete. Inability to fully close the eye is called lagophthalmos (paralysis “labeled as P” of the eyelid muscles). If there is lagophthalmos, measure the lid gap. If the patient is able to fully close his/her eyes, then ask the patient to close his eyes firmly while you gently check for strength and grade the strength as weak (W) or strong (S).



Lid gap measuring procedures

1. Explain the procedure to the patient
2. Ask the patient to close his/her eyes lightly, as in sleep.
3. Measure and record any gap in mm as illustrated on the right side.
4. If closure is normal, record: “0 mm.”

Voluntary Muscle testing (VMT) of hands and feet:

VMT of hands and feet should be done as shown below.

1. **A check of range of movement** to see whether normal, reduced or absent due to muscle paralysis (in the table below, black arrows show movement required).
2. If movement is normal, **test for resistance**. Press gently whilst asking the patient to maintain the position, resisting the pressure as strongly as possible.
3. Then press gradually more firmly and judge whether resistance is strong or weak. (White arrows show where resistance is applied)
4. Always compare the right hand or foot with the left

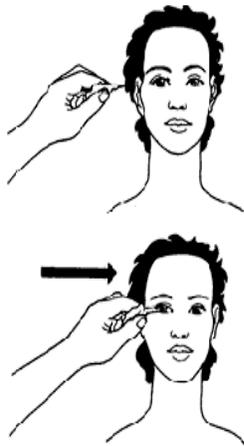
a. Is movement full?	b. Is resistance full?
<p>Little finger in...a test of ulnar</p>  <p>Hold these 3 fingers straight</p>	<p>Nerve function</p> <p><i>Patient tries to hold a card between ring- and little fingers. Assessor pulls card gently.</i></p> 
<p>Straight Thumb up...a test of</p>  <p>Patient moves thumb base fully out and across</p>	<p>Median nerve function</p> <p>Assessor resists at side of thumb (not at front or back)</p> 
<p>Wrist up.....a test of radial</p> 	<p>Nerve function</p> 
<p>Foot upa test of peroneal</p> 	<p>Nerve function</p> 

2.2.2. Sensation testing (ST)

Test the sensation of eyes, hands and feet as follows:

Sensation of the eyes (cornea):

Observe the patient's blink when talking to him/her. If the blink is normal, corneal sensation will be normal and there is no need for testing sensation. If there is no blink, the eye is at risk. Look at the illustration below to see how corneal sensation test is done.



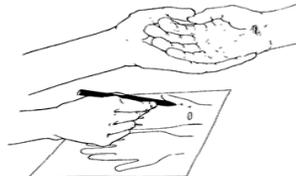
1. The health worker should wash hands before testing, then make a point out of a wisp of cotton wool and explain the test to the patient.
2. The patient should look to the opposite side and upwards.
3. The assessor should:
 - Stand behind the patient.
 - Approach from the side.
 - Touch the edge of the cornea.
 - Observe the reaction.
4. Record on the Patient Record Card:
 - If sensation is normal, write **Yes**
 - If sensation is absent, write **No**

Sensation of palms and soles:

ST on palms and soles should be done with a ball-point pen. The tests are done on ten standard points.

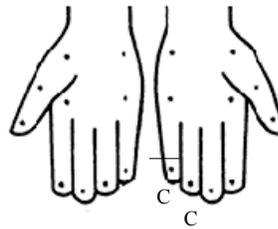
Hand and foot mapping, including sensation test (ST)

1. Explain the test to the patient. Rehearse it with the patient. Then test. A book should be held before the eyes, so the patient cannot see.
2. Compare sensation of the little finger with that of the thumb and sensation of one hand with the other, to see if there is difference. Compare findings with those shown on any earlier records.
3. Support the patient's hand or foot so that fingers/toes are well supported to prevent joint movement during the test.
4. Record:
If the patient feels, √
If not, X



5. Mark any wounds (◐), open crack (◑), clawing of digits (c) and bone loss or absorption (—) on the Patient Record Card or VMT/ST Form.

6. Dent the patient's skin by 1 - 2 mm at dot sites using a ball-point pen - asking the patient to point to the exact site whenever he/she feels. The stimuli should be irregular in timing and placing.



7. Look for any CHANGE. Make sure that the change is real and not due to inaccuracies in testing.

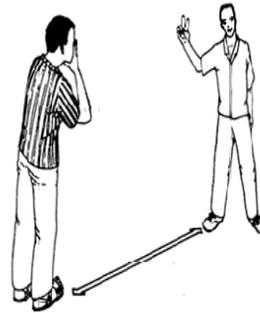
3. Examination of eyes, hands and feet for disabilities

Examination of the eye

➤ *Visual Acuity:*

Vision of both eyes of the patient should be tested according to the demonstration below and should be recorded on the Patient Record Card.

- Test vision with good light falling on the assessor.
- Ask the patient to cover one eye, then count the number of fingers that the assessor holds up.
- Test at 6 meters. If the patient cannot see at 6 meters, re-test at 3 meters.
- Record the findings



➤ *Other eye problems/complications:*

Look for: Injury of cornea and loss of vision due to incomplete blink and/or eye closure.

Examination of hands and feet

Patients should also be examined for the following complications, which result from nerve damage:

- Skin cracks on palms and soles with sensation loss.
- Wounds on palms and soles with sensation loss.
- Clawed fingers and toes.
- Foot drop.
- Wrist drop.
- Shortening and scarring in fingers and toes with sensation loss.

4. Disability grading.

Every new case of leprosy must be assessed for disability and

assigned a Disability Grade, which shows the condition of the patient at diagnosis. The grade is 0, 1 or 2. Each eye, each hand and each foot is given its own grade, so the person actually has six grades, but the highest grade given is used as the disability status for that patient.

Disabilities should be graded as follows:

Eyes

- Grade 0:** No disability found. This means there is no eye problem due to leprosy, no loss of vision.
- Grade 1:** The eyes are not given a grade of 1.
- Grade 2:** Visible damage or disability is noted. This includes the inability to close the eye fully (lagophthalmos) or obvious redness of the eye (typically caused by a corneal ulcer or uveitis). Visual impairment or blindness (vision less than 6/60 or inability to count fingers at 6 meters) also gives a disability grade of 2.

Hands and feet

- Grade 0:** No disability found. This means there is no loss of sensation or visible deformity or damage.
- Grade 1:** Loss of sensation has been noted in the palm of the hand or sole of the foot, but no visible deformity or damage.
- Grade 2:** Visible deformity or damage present. This includes wounds and ulcers as well as deformity such as a foot drop or a claw hand.

C. Laboratory

1. *Microscopic examination of skin smears*

Bacteriological examination of a skin smear is done for doubtful cases to confirm the diagnosis and/ or classification of leprosy. Only one slide, with smears taken from 2 sites must be collected

and examined. The slit skin smear examination procedure is provided by the National TB and Leprosy Laboratory Manual, Edition 2007. One positive smear result is enough for diagnostic and justifies starting MB treatment.

2. *Histo-pathological examination*

Biopsies may sometimes play a role in the confirmation of the diagnosis or classification of leprosy, however, this is not yet practiced in Ethiopia.

D. Differential diagnoses of leprosy

Without careful examination, leprosy can easily be mistaken for a number of skin diseases. Likewise, some skin diseases can be mistaken for leprosy. If patients are examined carefully, mistakes in diagnosis should not occur as none of the cardinal signs of leprosy are found in the common skin diseases. The differential diagnoses of leprosy are listed below.

- **Tinea versicolor.** The lesions are hypopigmented, but without loss of sensation. They often itch. When an anti-fungal ointment is applied they usually clear up within 6 weeks.
- **Ringworm.** The lesions are well-defined areas of hypopigmentation with white scales and without loss of sensation. They usually clear up within 6 weeks when an anti-fungal ointment is applied.
- **Vitiligo.** There are usually completely white areas of skin. The skin texture is normal and there is no loss of sensation.
- **Birthmarks.** Lightly or deeply pigmented areas of different sizes, which are present since birth or shortly after birth and do not change.
- **Psoriasis.** Raised areas with white fatty scales, which itch and bleed easily on scratching (pin point bleeding). There is no loss of sensation.
- **Molluscum contagiosum.** Nodular lesions with a depression in the centre. Firm squeezing results in the appearance of a creamy substance.
- **Onchocerciasis** (in endemic areas). Hypopigmented macules are often one of the manifestations. There is itching and no

loss of sensation. In a later stage there are mottled lesions, in particular on the loins and shins. Previous complaints of itching exclude leprosy.

- **Cutaneous leishmaniasis** (Nodular lesions in endemic areas). To differentiate with MB leprosy, skin smears should be examined as Leishman bodies are found, no AFB are seen.
- **Post kala-azar cutaneous leishmaniasis** (in endemic areas). Nodular, papular lesions and diffuse infiltrates, usually located on the face. These may occur one or more years after treatment of visceral leishmaniasis. Skin smears are negative for AFB.
- **Neurofibromatosis**. Multiple soft nodules, rarely on the earlobes. Skin smears are negative for AFB.
- **Syphilis**. Secondary syphilis presents with a considerable variety of lesions, e.g. papular and nodular lesions. Skin smears are negative for AFB. Positive serology for treponematosiis.
- **Kaposi's sarcoma**. In HIV positive patients Kaposi's sarcoma often presents with nodules on the face and ear lobes. There are often lesions within the mouth and the throat, which may bleed. Skin smears are negative for AFB.

In children two common dermatological conditions that should be differentiated from leprosy are:

- **Pityriasis alba**. The lesions are often restricted to the face making differentiation from leprosy difficult since loss of sensation in the face is not easy to demonstrate. The lesions subside spontaneously, leaving hypopigmented macules and at the same time new lesions may appear at other sites.
- **Nutritional deficiencies**. Usually over the cheek, single or multiple, ill-defined, hypopigmented patches with other features of vitamin deficiencies such as glossitis, stomatitis. The patches will clear after the administration of vitamins.

E. Disease classification

For the choice of the MDT regimen, patients should be classified into either the PB or MB group. If there is doubt about the classification, the patient should be classified as MB and treated accordingly.

Patients should be classified according to:

- The number of leprosy skin lesions.
- The result of the skin smear examination

1. Multibacillary (MB) leprosy:

- Six or more skin lesions.
- Less than six skin lesions, which have a positive slit skin smear result.

2. Paucibacillary (PB) leprosy

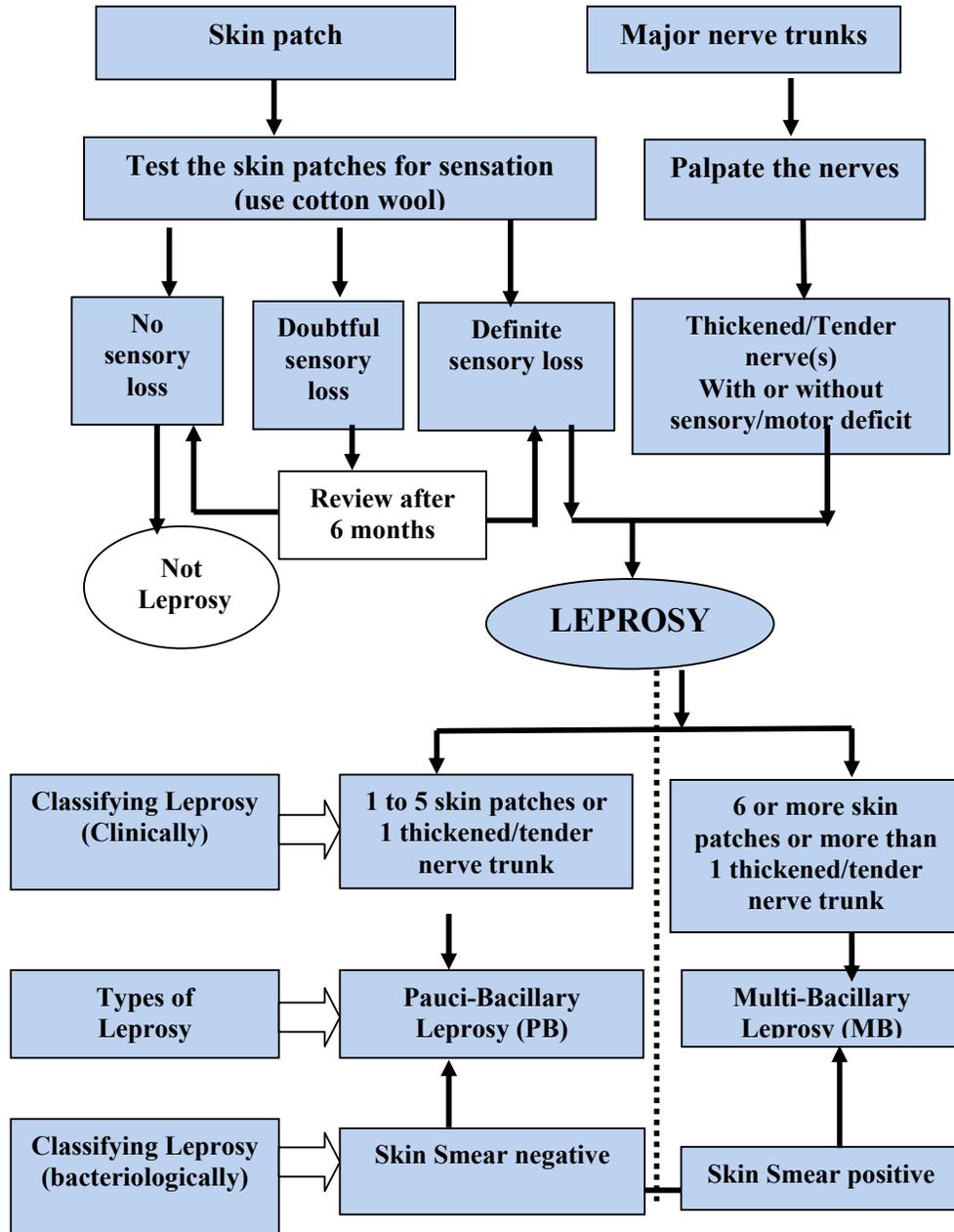
- One to five leprosy skin lesions.

3. Pure neural leprosy

These are patients, who do not have any skin lesion, but who have clearly thickened nerves with or without signs of nerve damage.

- Patients with pure neural leprosy should be reported and treated as a PB case if only one nerve is affected and the nerve biopsy smear result is negative.
- If two or more nerves are affected, or the nerve biopsy smear is positive, the patient should be reported and treated as an MB case.

Figure 5: Flowchart for Diagnosis and Classification of Leprosy



10.4 Case definitions

New case (N):

A patient with MB or PB leprosy who has never received treatment for leprosy before.

Relapse after MDT (R):

A patient declared "treatment completed" after a full course of MDT, but who reports back to the health service and is found to have active leprosy (see section 3.2.6) of the same classification as the original classification.

N.B. A patient who has MB disease after being treated as a PB case is a mis-classification and is defined as 'other'.

Return after default (D):

An MB patient who returns for treatment, after having missed more than 3 four-weekly doses of MDT.

Transfer in (T):

A patient started treatment in one health institution and moved to another health institution to continue treatment. The result of treatment of all such cases should be reported back to the original health institution where the patient was notified.

Other (O):

Any leprosy patient requiring chemotherapy who does not fit in any of the above mentioned categories, including patients who relapse after treatment with dapsone monotherapy in the past.

10.5 Signs of active leprosy:

- Previous lesions becoming more erythematous or reddish.
- Previous lesions becoming more raised.
- Appearance of new skin lesions.
- Raised Bacteriological Index (BI) or Morphological Index (MI)

10.6 CHEMOTHERAPY

Leprosy is treated with Multi Drug Therapy (MDT). MDT is the use of a combination of two or three anti-leprosy drugs to treat leprosy:

Transmission of leprosy is interrupted after the very first dose of MDT. In other words, patients are no longer infectious to others after being administered the first dose of the treatment regimen. There are virtually no relapses, i.e. no recurrences of the disease after treatment is completed.

No resistance of the bacillus to MDT has been detected

PB patients treated with MDT are cured within six months.

MB patients treated with MDT are cured within 12 months.

The objective of the treatment is to:

- Cure leprosy by rapidly eliminating the bacilli
- Prevent the emergence of drug resistance
- Prevent relapse
- Prevent disability

MDT is very safe, effective and available free of charge in all treatment centers. easy to apply in the field.

DRUG REGIMENS

MDT drugs

- | | | |
|-------------------|--------|-------|
| ▪ Rifampicin (R) | 150mg, | 300mg |
| ▪ Clofazimine (C) | 50mg, | 100mg |
| ▪ Dapsone (DDS) | 50mg, | 100mg |

Rifampicin is given once a month. No toxic effects have been reported in the case of monthly administration. The urine may be coloured slightly reddish for a few hours after its intake; this should be explained to the patient while starting MDT.

Clofazimine is most active when administered daily. The drug is well tolerated and virtually non-toxic in the dosage used for MDT. The drug causes brownish black discoloration and dryness of skin. However, this disappears within few months after

stopping treatment. This should be explained to patients starting MDT regimen for MB leprosy.

Dapsone. This drug is very safe in the dosage used in MDT and side effects are rare. The main side effect is allergic reaction, causing itchy skin rashes and exfoliative dermatitis. Patients known to be allergic to any of the sulpha drugs should not be given dapsone.

Except for children below 10 years, the drugs are provided in blister calendar packs, **each pack containing four weeks (one month) supply**.

The appropriate dose for children under 10 years of age can be decided on the basis of body weight. [Rifampicin: 10 mg per kilogram body weight, clofazimine: 1 mg per kilogram per body weight daily and 6 mg per kilogram monthly, dapsone: 2 mg per kilogram body weight daily. The standard child blister pack may be broken up so that the appropriate dose is given to children under ten years of age. Clofazimine can be spaced out as required.]

There are two types of MDT regimens. The Paucibacillary (PB)-MDT and Multibacillary (MB)-MDT:

10.6.1 PB-MDT regimen

This regimen consists of Rifampicin and Dapsone for a total duration of 6 months. It is to be prescribed to all cases classified as **Paucibacillary (PB)** leprosy.

Drugs	Child < 10 years	10 – 14 years	≥ 15 years
Rifampicin	300 mg monthly	450 mg monthly	600 mg monthly
Dapsone	25 mg daily	50 mg daily	100 mg daily

For adults the standard regimen is: Rifampicin: 600 mg once a month; Dapsone: 100 mg daily Duration= six months

10.6.2 MB-MDT regimen

This regimen consists of Rifampicin, Dapsone and Clofazimine, for 12-month duration. It is to be prescribed to all cases classified as **Multibacillary (MB)** leprosy.

Drugs	Child < 10 years	10 – 14 years	≥ 15 years
Rifampicin	300 mg monthly	450 mg monthly	600 mg monthly
Clofazimine	100 mg monthly	150 mg monthly	300 mg monthly
Clofazimine	50 mg twice a week	50 mg every other day	50 mg daily
Dapsone	25 mg daily	50 mg daily	100 mg daily

For adults the standard regimen is: Rifampicin: 600 mg once a month, Dapsone: 100 mg daily Clofazimine: 300 mg once a month and 50 mg daily Duration= 12 months.

10.6.3 Phases of chemotherapy

MDT regimens consist of two phases:

- 1. Supervised:** drugs are administered under the direct observation by the health worker on fixed clinic days at four weekly intervals.
- 2. Unsupervised:** drugs are self administered by the patient.

The drugs are to be taken orally and should be taken in a single dose on an empty stomach if not two hours after meal

MDT blister packs for adults



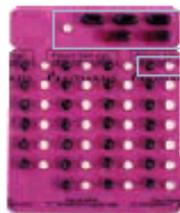
PB adult blister pack

PB adult treatment:

- Once a month:** Day 1
– 2 capsules of rifampicin (300 mg X 2)
– 1 tablet of dapsone (100 mg)

- Once a day:** Days 2–28
– 1 tablet of dapsone (100 mg)

Full course: 6 blister packs



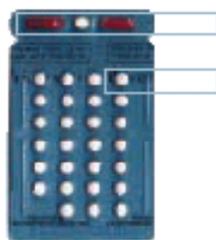
MB adult blister pack

MB adult treatment:

- Once a month:** Day 1
– 2 capsules of rifampicin (300 mg X 2)
– 3 capsules of clofazimine (100mg X 3)
– 1 tablet of dapsone (100 mg)

- Once a day:** Days 2–28
– 1 capsule of clofazimine (50 mg)
– 1 tablet of dapsone (100 mg)

Full course: 12 blister packs



PB child blister pack

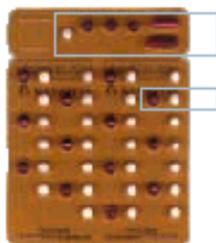
PB child treatment (10–14 years):

Once a month: Day 1
– 2 capsules of rifampicin (300 mg+150 mg)
– 1 tablet of dapsone (50 mg)

Once a day: Days 2–28
– 1 tablet of dapsone (50 mg)

Full course: 6 blister packs

For children younger than 10, the dose must be adjusted according to body weight.



MB child blister pack

MB child treatment (10–14 years):

Once a month: Day 1
– 2 capsules of rifampicin (300 mg+150 mg)
– 3 capsules of clofazimine (50 mg X 3)
– 1 tablet of dapsone (50 mg)

Once a day: Days 2–28
– 1 capsule of clofazimine every other day (50 mg)
– 1 tablet of dapsone (50 mg)

Full course: 12 blister packs

For children younger than 10, the dose must be adjusted according to body weight.

10.7 Treatment of special cases

Treatment during pregnancy and breast-feeding

The standard MDT regimens are safe, both for the mother and the child and therefore should be continued during pregnancy and breast-feeding.

Treatment for patients also infected with HIV

Patients infected with HIV usually respond equally well to leprosy treatment as those without HIV infection.

Treatment for patients with Leprosy and TB

Patients suffering from both TB and leprosy require standard TB treatment in addition to the standard MDT. Hence, skip the monthly dose of rifampicin in the leprosy MDT regimen. Once the TB treatment is completed, the patient should continue his/her MDT, or the other way round.

10.8 Adverse effects of MDT

MDT is remarkably safe and serious adverse effects are very rare.

Table 13: Adverse effects of MDT Drugs

	Side-effects	Drug (s)	Action
Minor	Itching and skin rash	Rifampicin	Reassurance
	Loss of appetite, nausea and abdominal pain	Rifampicin	Give drugs with food
	Orange/red urine, faeces, saliva and sputum	Rifampicin	Reassurance
	Brown discoloration of skin lesions and pigmentation of the conjunctiva	Clofazimine	Reassurance
	Dryness and ichthiosis of skin	Clofazimine	Apply Vaseline ointment

	Insomnia	Dapsone	Give the drug in the morning
	Anaemia	Dapsone	Give iron and folic acid
Major	Jaundice	Rifampicine Dapsone	Stop treatment and refer
	Itching of the skin and skin rash	Dapsone	Stop treatment and refer
	Shock, purpura and renal failure	Rifampicin	Stop treatment and refer
	Allergy, urticaria	Dapsone & Rifampicin	Stop treatment and refer

10.9 Follow-up during treatment

MDT must be delivered as close to the patient's home as possible. The treatment should be given on fixed clinic days. Adequate time should be allocated to the patients and long queue should be avoided. Patients who cannot attend on the fixed clinic day should be allowed to collect drugs on any of the subsequent days or the drugs should be given through family member or treatment should be brought to the patient's home if necessary.

During all phases of treatment, the patient has to be educated on the importance of regularly taking the prescribed medications, the major side-effects of the drugs and signs and symptoms of reactions/neuritis and on the need to report immediately to the nearby treatment center whenever these occur.

During MDT, monitoring nerve function (with VMT and ST of the eyes, hands and feet) is extremely important as a tool to detect nerve function impairment early and to prevent the occurrence of disability.

MB cases

MB patients should complete 12 four-weekly doses of MDT within a maximum period of 15 months.

- After completion of the 12 doses of MDT, the patient should be released from treatment (RFT) and recorded as ***treatment completed***.

- If a patient misses some treatment, the number of doses missed should be added on at the end, so that the complete course of treatment is given. A patient who has missed more than 3 four-weekly doses of MDT in total should be recorded as *default*.
- If an MB patient recorded as a default report at a clinic, a second course of MDT should be started, after the importance of regular treatment is discussed with the patient.
- Patients who restart treatment must be entered into a new treatment cohort, which is currently open for intake. They should be re-registered as return after default with a new registration number. The previous number should be recorded in the column 'remarks'. This implies that such patients have been included in two different cohorts, the first one being the cohort in which they did not successfully complete their treatment, the second one being the cohort whose intake period includes the point at which they started their second MDT course.
- After completion of the second course of MDT, the patient should be declared *treatment completed*.
- Patients who fail to complete the second course of MDT should not be given a third chance. These patients should be recorded as *default* immediately after they have missed the 4th four weekly doses of MDT. They should be told to report immediately as soon as signs of active disease return (section 3.2.6).

MB patients should be declared cured at the time they collect the 12th four-weekly dose of the drugs

PB cases

PB patients should complete 6 four-weekly doses of MDT within a maximum period of nine months.

- After completion of the 6 doses of MDT the patient should be released from treatment (RFT) and recorded as *treatment completed*.
- Patients who have missed more than 3 four-weekly doses of MDT in total should be recorded as *default*.

- If they return to the clinic again, they should not be given a second course of MDT unless they are found to have signs of active disease.

PB patients should be declared cured at the time they collect the 6th four-weekly doses of drugs.

Examinations during treatment

Examination of eyes, hands and feet (including VMT-ST) should be performed:

- At any time if the patient complains of loss of sensation and/or change in muscle strength or problem with vision.
- Routinely every month as long as the patient is on MDT.
- Just before release from treatment.

Nerve function assessment at the end of treatment should be compared with that at the beginning of treatment. This includes comparing disability grades and VMT-ST status at the beginning and completion of treatment. The assessment should be scored as improved (I), same (S) or deteriorated (D) and recorded in the patient record card and unit leprosy register.

Treatment for patients living in inaccessible areas

Some patients who live in geographically inaccessible areas or whose lifestyle does not permit regular visits to the health facility (e.g. pastoralists) or who cannot attend clinics at certain times (e.g. rainy season) should be given a sufficient supply of MDT blisters to cover their period of absence. It is, in exceptional cases, even acceptable to give a full course supply of MDT blisters to these patients, but the involvement of a formal or informal community leader or community health worker in the monitoring of drug intake should always be sought; patients should be strongly advised to report to the nearest health facility if they develop any complication.

10.10 Retrieval of absentees

If a patient has neither attended the fixed clinic day nor during the two weeks thereafter, he/she has to be considered as an absentee and should be retrieved. The following measures are suggested:

- a. Inquire from fellow patients as to why the patient has failed to collect his/her drugs and ask them to contact and advise the absentee.
- b. Notify the contact person, recorded in the register, through available means and request his/her assistance to encourage the patient to return for treatment.
- c. Send out messages through health workers who may travel to the patient's village for outreach health programmes like EPI.
- d. Communicate with the health extension worker or community volunteers to assist in retrieving the patient.
- e. Visit the home of the patient.

The above measures can be taken either in combination or separately and all efforts must be exerted to ensure the continuation of treatment.

10.11 Definitions of treatment outcomes

Treatment completed:

- A patient who has completed a full course of MDT within the prescribed period.

Died:

- A patient who dies of any cause during the course of MDT.

Default:

- A patient who has failed to collect more than three (consecutive or cumulative) four-weekly (monthly) doses of MDT.

Transfer out:

- A patient who has started treatment and has been

transferred to another health institution and for whom the treatment outcome is not known at the time of evaluation of the results of treatment.

Care after release from treatment (RFT)

Ex-leprosy patients should be advised to visit or report to the near-by health facility whenever they have complaints. Care to this group includes:

- Management of neuritis.
- Provision of protective foot wears.
- Provision of vaseline ointment.
- Basic medications such as analgesics, antibiotics, eye ointments etc.

These are provided to the patients free of charge *if and only if* they are made available by the control programme. When this is not the case, patients should be encouraged to buy by themselves. All these care activities should be recorded in the RFT register and some of them (like neuritis treatment and provision of protective foot wears) should be reported quarterly.

10.12 COMPLICATIONS OF LEPROSY AND THEIR MANAGEMENT

Leprosy reaction

Leprosy reaction is an immunological response to the bacillus. Most of the problems related to leprosy (deformity and disability resulting in stigma and suffering of the patient) are primarily caused by the damage that results from leprosy reactions. Early detection and adequate management of reactions are therefore important activities.

Leprosy reaction is the appearance of symptoms and signs of acute inflammation in the lesions of a leprosy patient. Clinically, there is redness, swelling and sometimes tenderness of skin lesions. There may be swelling, pain and tenderness of nerves, often accompanied by loss of function. New lesions may appear.

There are two types of reaction:

1. Reversal Reaction (or type 1 reaction)

2. Erythema Nodosum Leprosum (ENL) or type 2 reaction

Both types of leprosy reaction can occur before the start of treatment, during treatment and after release from treatment. Both can be divided into mild or severe reactions. Only when the reaction is severe, treatment with corticosteroids is necessary.

If the reaction occurs after Release From Treatment, the differentiation with a relapse can be very difficult. Relapses, however, occur very rarely.

1. Type I (reversal) reaction

a. Mild reversal reaction: signs and treatment

Mild reversal reaction is characterized by the presence of oedema and erythema **of skin lesions only**. There may be mild fever and some general discomfort. If there are any signs of neuritis such as nerve pain or tenderness or loss of nerve function, the reaction is no longer mild, and should be managed as a severe reaction.

The treatment of mild reaction is symptomatic with analgesics such as aspirin and rest with sedatives.

The patient should be examined after one week. If there are still signs of reaction, the treatment should be continued for another week, after which the patient should be examined again. Check for new nerve damage at every clinic attendance. If this has occurred, the patient is suffering from a severe reaction and should be managed accordingly. If the mild reaction continues for longer than 6 weeks the patient should also be treated as suffering from a severe reaction.

b. Severe reversal reaction: signs and treatment

A reversal reaction is considered severe and should be treated with a course of prednisolone when one or more of the following signs are present:

- Pain, or tenderness on palpation in one or more nerves, with

or without loss of nerve function.

- Change in VMT (including eye closure) of less than six months duration. The change can be from strong to weak, from weak to paralyzed, or from strong to paralysed.
- Change in ST of less than six months duration. A change is considered to be significant when any hand or foot has increased loss of sensation at two or more points.
- A raised, red swollen patch overlying or around an eye.
- Red, raised and ulcerating skin lesions.
- Oedema of hands or feet.
- A mild reaction lasting more than 6 weeks.

Patients who present with one or more of the signs given above and who do not present with any condition which requires referral to hospital should be given **ambulatory** treatment with prednisolone. Patients with nerve involvement should also be advised to rest the affected limb.

2. Type II Reaction (Erythema Nodosum Leprosum: ENL)

Severe ENL: signs and treatment

An ENL reaction is characterized by the appearance of tender, reddish skin **nodules** (erythema nodosum). It occurs in MB leprosy only. ENL is considered severe if one or more of the following signs are found:

- Appearance of ENL nodules with ulceration (ulcerating ENL).
- Tenderness on palpation or spontaneous pain in (a) nerve trunk(s).
- Loss of muscle strength and/or loss of sensation in eyes, hands or feet, for less than 6 months.
- Painful eyes, with redness around the limbus cornea, increased lacrimation, fixed narrowing (constriction) of the pupil and diminishing vision (irido-cyclitis).
- Painful testicular swelling (orchitis).
- Painful swollen fingers (dactylitis).
- General condition: fever and malaise.

Patients may experience several episodes of ENL, one after the other (recurrent ENL). MB patients may develop a reversal

reaction and an ENL reaction simultaneously. All patients with severe ENL should be referred **immediately** with their clinical records to hospital for treatment.

Ambulatory or hospital treatment

Prednisolone treatment of reversal reaction can be done in the field (ambulatory) safely, provided that certain conditions are excluded. Patients with severe ENL reaction, however, should always be admitted as this may be a life-threatening condition. For all patients with severe reversal reaction thorough history should be taken and examination should be carried out, in order to rule out the conditions which all require admission.

Criteria for admission

- **Severe ENL reaction.**
- **Deep ulcer(s).**
- **Red and/or painful eye.**
- **Pregnancy.**
- **TB or any other severe infectious disease.**
- **Younger than 12 years of age.**
- **Recent history of peptic ulcer in the stomach or duodenum.**
- **History of diabetes.**
- **General illness with fever.**
- **Patient who did not improve during a previous course.**
- **Patient who improved during previous courses, but who develops a reaction for the 3rd time.**

Prednisolone is a potent corticosteroid drug. As the drug may also affect various other conditions, always take the precautions set out in the box below before prescribing a prednisolone course.

The dosage and duration of treatment is different for PB and MB patients (table 13). Prednisolone is supplied in blister packs. Each blister contains 2 weeks treatment at different strengths, so that

only one tablet is taken daily, in the morning after a meal. Patients should be carefully educated on the requirements for successful treatment and the risks involved in steroid treatment.

Conditions to be treated before starting prednisolone treatment

Appropriate treatment should be given for the following concurrent diseases:

- Diarrhoea, with blood and/or mucus. If present, the patient may suffer from dysentery (amoebic and/or bacillary).
- Conjunctivitis and trachoma.
- Scabies.
- Worm infestations.

Treatment for the above conditions should be started immediately, but need not be finalised before the start of

Ambulatory treatment of severe reversal reaction with Prednisolone

Duration of treatment		Daily dose (do not exceed 1 mg per kg body weight)
MB	PB	
4 weeks	2 weeks	40 mg
4 weeks	2 weeks	30 mg
4 weeks	2 weeks	20 mg
4 weeks	2 weeks	15 mg
4 weeks	2 weeks	10 mg
4 weeks	2 weeks	5 mg
Total 24 weeks	Total 12 weeks	STOP

Patients should collect a two weeks dose of prednisolone blister

from the health facility. It is important that the blister pack with the correct dosage is given, according to the table above. Health staff should inquire about problems and side-effects. If problems or side-effects occur, the patient should be immediately referred to the next higher health facility. If there are no problems or side-effects patients should be examined (VMT and ST assessment) at every clinic attendance.

The standard course of prednisolone needs adjustment for the following:

- a) Any patient in whom nerve function deteriorates during the standard course or who does not show improvement after 4 weeks of prednisolone. These patients should be referred to hospital where higher dosages of prednisolone will be given.
- b) When a patient misses one blister of two weeks treatment. In these patients, the condition should be assessed. If the nerve problem still exists the dose of prednisolone due last time should be given. If the condition for which prednisolone was given is not present any more, continuation of prednisolone should be with the dose which would now be due.
- c) If a patient fails to attend for 4 weeks or more and then comes again, the condition should be assessed:
 - If the condition is still present, the course of prednisolone should be repeated, after thorough education of the patient.
 - If the condition has deteriorated, the patient should be referred to hospital, with a full explanation about the reason for referral.

When a patient has responded positively to a previous full course of prednisolone, but the reaction re-occurs or the nerve function deteriorates, then a second course of prednisolone can be prescribed, provided there are no contraindications. The examination procedures given above should be repeated.

A patient who has not responded positively to a previous course of prednisolone (did not regain nerve function, or deteriorated

during the course, or within two weeks thereafter) should be referred to hospital.

Patients who responded to prednisolone, but develop a reaction for the third time should also be referred to hospital.

Management of severe reaction in the hospital

For hospitalized patients the initial dose of prednisolone will be as high as 80mg in a daily single morning dose. The dose can be tapered by 10mg every 2-4 weeks depending on the severity and response to treatment until a level of 40mg is reached. Then normal tapering off should recommence as indicated in the table 14. If at any dosage, the clinical signs of reaction fail to improve after 5-7

days, or if nerve damage increases the prednisolone dosage should be doubled for about 2 weeks. Then reduce step wise at intervals of 2-4 weeks or so till it returns to the previous level and then normal tapering off should then recommence.

Possible complications of Prednisolone

- Exacerbation of TB, of which no symptoms were present at the time of starting treatment with prednisolone. If TB is suspected, the patient should be referred to hospital immediately.
- Signs of diabetes: thirst, excessive urination. Check the urine for glucose and, if positive, refer the patient to hospital immediately.
- Abdominal discomfort: the patient should be treated with an antacid.
- Stomach bleeding: never administer prednisolone in conjunction with aspirin or ibuprofen derivatives. These drugs strongly increase the risk of stomach bleeding when combined with prednisolone.

Prevention of (further) disability

All leprosy patients are at risk of developing disability at any time

(before, during and after treatment). Disability and deformity primarily result directly or indirectly from function loss of peripheral nerves supplying eyes, hands and/or feet.

It is, therefore, the task of all health staff working with leprosy patients to *preserve nerve function* and to prevent further deformity and disability in those cases with some irreversible disability present at the time of diagnosis.

The best ways to prevent disabilities are:

- Early diagnosis and prompt treatment.
- Recognise nerve function impairment at the time of diagnosis and start treatment with steroids if it occurred recently.
- Train patients in self-care.
- Educate patients to recognise early signs of nerve function impairment and to report this immediately.
- Recognise signs and symptoms of leprosy reactions with nerve involvement and start treatment with steroids.

Training in self-care for patients with disability of eye, hand or foot

Prevention of disability (POD) depends, to a very large extent, on the patients themselves. Priority should be given to POD by simple methods with emphasis on self-care, i.e. what the patients can do themselves to prevent development and/or worsening of disabilities. Therefore, the patient has to learn how to avoid the complications of the disease. Patients should be trained continuously by general health staff on how to prevent further disability and deformity by self-care (section 4.2.1).

Aims of self-care:

1. To promote interdependence and independence among leprosy patients living close together.
2. To promote the use of locally available self-care materials for skin care and care of small wounds.
3. To encourage ex-patients to support each other to maintain interest in life long care.

Protective footwear

Patients with sensory loss should wear protective footwear. For the patient who does not have deformed feet but has anaesthetic feet, almost any shoe that fits reasonably well is better than going barefoot out of doors. Patients should collect canvas shoes, embedded with micro cellular rubber (MCR), and other orthopaedic appliances from MDT providing health facilities and nearby orthopaedic workshops respectively. When a health facility runs short of this canvas shoes supplied by the control programme, patient should be encouraged to buy their own protective foot wear from the local market. The protective footwear should be not tight and with a soft inner layer.

Closed plastic shoes are not suitable as they enhance sweating, blister, infection of the skin and underlying tissues.

Septic and re-constructive surgery

There are surgical procedures and techniques to correct or limit the deterioration of deformities and disabilities. Sophisticated surgical procedures and techniques like tendon transfer operations, plastic surgery and others will be carried out at ALERT, the specialized referral hospital, by highly qualified surgeons.

Socio-Economic Rehabilitation (SER)

Rehabilitation may be defined as the diagnosis, treatment and prevention of de-habilitation. De-habilitation due to leprosy can cause a patient to lose his family and place in society, his work and means of livelihood, or his self-respect.

The main goals of SER:

- Restoration of dignity.
- Increased economic independence.
- Reduction of stigma and the achievement of integration of patients in the society.

Rehabilitation and reintegration of patients in society can only be achieved by the sustained efforts of patients, the health worker and the community as a whole. **It is wise to focus on patients' abilities rather than their disabilities.** This can be achieved

more effectively through a community-based approach than through the traditional institution-based approach.

The following points should be emphasised in rehabilitation:

- Rehabilitation should take place in the environment in which the patient lives, which might require some adaptation of the home.
- Health education should form an important component of rehabilitation.
- Rehabilitation of leprosy patients should be an integral part of general rehabilitation services.

10.13 PREVENTION OF LEPROSY

Chemo-prophylaxis

Unlike TB, there is no indication for chemoprophylaxis for leprosy.

BCG

BCG vaccination has a documented and substantial effect in preventing leprosy and is therefore considered as an important tool for leprosy control.

10.14 RELAPSE

A patient should be diagnosed as a "relapse" if he/she has previously completed a full course of MDT and returns 2 years later with signs of active leprosy (of the same classification as the original classification) requiring chemotherapy. Relapses after a complete course of MDT are very rare. A patient who has MB disease after being treated as a PB case is a mis-classification and has to start MB treatment (section 3.2.5).

One or more of the following signs are indications of a relapse:

- Active skin lesions: appearance of new skin lesions.
increased erythema (redness) in previously existing lesions.
- New nerve lesions: enlargement and/or tenderness of one or more nerves which were previously normal

Table 14: Differentiation between relapse and Reactions

Criteria	Relapse	Reaction
Development of signs	Slow	Sudden
Site	New patches	Over old patches
Tenderness/ pain	No	Nerves usually, skin sometimes
Damage	Slow	Sudden and rapid
General condition	Not affected	Often fever, joint pain etc.
Duration after treatment completion	> 2 years	< 2 years

Relapses after the complete course of MDT are very rare

Diagnostic procedures and management of patients suspected of having a relapse.

A patient who, after release from MDT, presents with one or more of the above mentioned signs should be fully examined. Suspected relapse cases must be referred to a health facility, which has the expertise to diagnose and treat this condition. All relevant documents must be sent along with the patient.

11 COMMUNITY PARTICIPATION IN TBL CONTROL

11.1 Objectives

The accessibility of DOTS service is a key point for TB control. The geographical DOTS coverage is 90% (it means that 90% of Woreda are covered by DOTS service); the health facilities coverage is 72.3%, hence, given the limited infrastructure in the country, only 60% of the population has access to DOTS services.

The objectives of community participation are to develop partnership between the health services and civil society aimed at contributing to Tuberculosis, Leprosy and TB-HIV care.

Responsibility for TB control remains with the NTP, but general health services become available as close as possible to the community and the awareness and demand for service increases.

Community participation can also enhance:

- Support to patients throughout treatment until cure
- Patient, family and community education and prevention
- Case detection (referral of patients with chronic cough)
- Advocacy for political commitment to TB control
- Accountability of local Health Professionals to communities

11.2 Program implementers of community-based care

The major implementers of community involvement in TBL and TB/HIV control are:

- Health Extension Workers (HEWs)
- Community members and Community organizations

- The Government of Ethiopia, based on the experience gained from Health Sector Development Programme I (HSDP I .1997 – 2000), has decided to introduce Health Service Extension Package as a sub-component of Health Sector Development Programme II (HSDP II 2002 –2005). This Health Service Extension Programme (HSEP) aims at improving equitable access to preventive essential health interventions through community based health services, with strong focus on sustained preventive health actions and increased health awareness. The health

extension service is being provided as a package focusing on preventive health measures targeting households, particularly women/mothers, at the kebele level. At present, more than 24000 HEWs have been trained and deployed, and are actually working at community level. Most have been specifically oriented and are carrying out activities concerning TB and TB/HIV prevention and control.

- “Community” refers to “a group of people who have something in common and will act together in their common interest”. Various community members can play a role in community-based care:

- Volunteer Health Promoters,
- Religious leaders,
- Traditional leaders and village leaders,
- Eddirs, Mohiber, Sembetei,
- women’s organizations,
- peer groups,
- family members ,
- influential members of the community,
- NGOs, Faith Based Organization FBOs.

The ways in which communities can potentially contribute to TB control as part of TLCP activities are therefore activities, which help to improve the community awareness on TB, the case detection rate and, ultimately, the treatment outcomes.

Once initiated, effective community contribution to TBL and TB/HIV care, especially Community based DOTS, requires a strong monitoring and reporting system, access to laboratory facilities, and uninterrupted drug supply, all components of DOTS.

11.3 IMPLEMENTATION OF COMMUNITY BASED CARE

Steps to be taken when planning to increase community contribution to TBL and TB/HIV care include:

- obtaining political commitment from local leaders and health authorities;
- conducting a situational analysis that includes all TBL and TB/HIV services and community contributions to TBL and TB/HIV care;
- identifying all relevant partners that might play a role in enabling community contribution to TBL and TB/HIV care, especially the one already providing health or social support within the community;
- specifying the roles and functions of each player in the delivery system;
- establishing partner relationships between stakeholders in the context of the existing health delivery system and CBOs;
- select appropriate providers for well defined services;
- developing and conduct a training plan for all partners and implementing it accordingly;
- designing and producing relevant tools tailored to the roles of various partners;
- setting mechanisms for monitoring and evaluation of the service;
- ensuring availability of a reliable recording and reporting system;
- check access to laboratory facilities, and regular drug supply;
- ensuring that community service is complementing but not replacing TBL and TB/HIV programmes.

The implementation of Community TBL and TB/HIV services calls for the involvement of trained and supervised community members (Health Extension Workers and/or Community Volunteers) to support TBL and TB/HIV control activities, in particular:

- disseminate information and increase community awareness on risks, transmission and prevention features of TB, Leprosy and TB/HIV through meetings and conversation within the community;
- contribute to early case detection by identifying TB and Leprosy suspects (intensified case finding) and referring them for examination;
- strengthen the operational linkage between the community and the health institutions;
- trace absentees, motivate and refer them back to the treatment health facility;
- provide counselling, support and may contribute to reducing the stigma of the diseases (TBL and TB/HIV);
- refer patients who have adverse drug reactions.

Key activities should be documented and reported to the nearest health facility, and supervised by the nearest health facilities. In particular, the Health Extension Worker (HEWs) shoulders the following responsibilities:

- developing activity plan and implementing it when it is approved.
- keeping record of all TBL patients in the kebele.
- submitting regular monthly, quarterly and annual reports to the Health Facility.
- supervising community volunteers who serve as community service providers.

Given the increasing burden of TB/HIV co-epidemics, community volunteers should be actively involved in TB/HIV collaborative activities (prevention, care and support). The community volunteers who give support to family members of the sick are instrumental in the home-based care of TB/HIV patients.

The efficient implementation of community TBL and TB/HIV care is supported by actual decentralization of the health care system, adequate community resources, community empowerment, and a functioning Health Service Extension Programme.

Constraints in implementation of community TBL and TB/HIV

care are (i) poverty and basic needs requirements, which hinder participation of community members in the care of their own sick (ii) difficulties to maintain motivation and awareness, (iii) financial constraints faced by community organizations.

Community health service is cheaper and more cost-effective than facility-based care, especially hospital-based. However initial resources are required for start up activities such as training of care providers, setting up systems, patient follow up, supervision, monitoring and evaluation. Managerial expertise is essential in creating and maintaining links between the control programmes, general health services and community care providers. Training of community care providers is essential and should focus on a limited number of activities. The community care providers should always benefit from regular, frequent and supportive supervision.

Community health care should be implemented in a phased manner and the following points are to be considered:

- introduce the service in small scope, evaluate the results and then, if successful, scale up.
- allow a sufficiently long period for any changes to be adopted and to prove themselves.
- transfer management responsibility and authority.

Successful community based TBL and TB/HIV service calls for mechanisms:

- to identify and mobilize the appropriate organizations;
- to take examples and evidences from community Dots programs doing well;
- to develop links between TBL/TB/HIV control programmes, general health services and the community organization(s);
- to train and supervise community members;
- to develop and introduce a recording and reporting system in the community;
- to provide support to patients throughout their treatment until cure

Community Based DOTS in Oromia Region

In East and West Harargae (Oromia Region), Community Based DOTS was introduced in 2006. For increasing access to DOTS services and improve the case detection, the community volunteers, health extension workers and other community health workers hereinafter named Community DOTS Supporters (CDS) were actively involved. CDS were trained to recognize TB symptoms and refer the suspect TB patients to nearby health institution for sputum examination, and to identify the adverse effects of anti-TB drugs. Through this approach the case detection rate in East and West Harargae improved from 20.8% to 32.6 % after the introduction of Community Based DOTS.

Community DOTS supporters have the role to sensitize the community about tuberculosis through delivering health education about the disease in public gatherings and through house to house visit. Community DOTS Supporters also trace individuals with symptoms of TB and motivate and convince them to go to health facilities where sputum examination service is given. After the patients are diagnosed to have TB, Community DOTS Supporters will directly observe the patients treatment.

The Community DOTS supporters are constituted by Health Extension Workers, malaria workers, family planning workers and community volunteers depending on their availability in the individual Woreda. However, the vast majority of CDS in this project are community volunteers. One CDS was trained from each Kebele; one Kebele in average had 1,000 households. The community volunteers were selected by the health workers in collaboration with Kebele authorities. The CDSs were supervised by the health worker in the health stations.

The CDSs received training in: suspect identification, diagnosis, treatment schedule, follow-up, adverse effects of the drugs, delivery of health education. The CDSs make regular house to house visits, in order to identify suspects and give health education at public gatherings. They never handle anti-TB drugs directly: the drugs are delivered to the patients and CDS make sure that the patient takes the treatment correctly.

The CDS were provided with referral cards from health facilities (on which stamp of the health station/centre is issued). As soon as the CDS identifies a suspect s/he provides the filled and signed referral card to the suspect and urge him/her to go to the nearby health facility for sputum microscopy. After the sputum test, the patient reports back to the CDS and return the referral card that states the outcome of the microscopy. The health facilities and the health workers will treat suspects bearing the referral card differently to get the sputum microscopy service immediately.

Essentially CDSs were selected voluntarily and no incentive was given for them.

12 PUBLIC-PRIVATE MIX (PPM) IN TB CARE

Improving the DOTS coverage and increasing TB case detection rate call for engaging all care providers in the country. Cognizant of the current situation in Ethiopia, one of the strategies of the national TB and Leprosy control program is to involve the private sector in TB and TB/HIV control program.

The term ‘PPM DOTS’ has evolved to represent a comprehensive approach to link all relevant health care providers for DOTS implementation. It incorporates all forms of public-private (e.g. government health office with not-for-profit private health facility), public-public (e.g. hospitals, public health centers with army, prison, etc) or private-private (e.g. traditional healers with private-for-profit health facility) collaborations for the common purpose of controlling TB in a community. This demonstrates that virtually all types of potential health care providers fit within the umbrella of PPM DOTS. However, global knowledge as well as in-country experiences is still limited to a few types of providers. At present, Ethiopia’s PPM model focused on for-profit private providers, and service provision has started in Nov 2006 with 20 private health facilities as pilot project in Addis Ababa and Oromiya region.

12.1 RATIONALE FOR PPM IN ETHIOPIA

- Quantitatively, the private sector plays a significant growing role in the delivery of health care of Ethiopia
- The private sector contains a large pool of personnel that could play an important role in increasing awareness and detecting TB and other public health problems
- The private health care provision is increasingly becoming dependable partner in Ethiopia and it is advisable to extend its contribution in the era where DOTS expansion is the strategy to successful TB control.
- Standard of care (quality) among private health care providers need to be addressed through formal engagement of these providers and assessed.

12.2 EXPERIENCE OF PPM ETHIOPIA

PPM program in Ethiopia has been implemented after holding policy dialogue with different partners and stakeholders including the private sector, preparation of PPM guidelines and rapid assessment tool in consultation with nationally established technical working group, training of private service providers, and supply of anti-TB drugs, reagents and reporting formats.

The private health facilities involved in this pilot project are reporting to their respective health office (since the 2000). Three hospitals and eight higher clinics in Addis Ababa, and one hospital and eight higher clinics in Oromia are engaged in PPM program.

They already contribute to the national efforts to increase TB Case Finding: these 20 private health facilities already reported 1,266 TB cases, out of which 262 (20.7%) are smear positives, 589 (46%) smear negatives, and 397 (31%) extra-pulmonary cases.

Generally, the willingness and commitment of private health care providers to care for TB patients is encouraging and this means new opportunity to expand the service. However, inclusion of more private health facilities in the scale up phase will put more pressure on the public health structures for program monitoring. Adequate capacity of Regional and Woreda health offices is essential in monitoring PPM program in order to bring about the desired impact of PPM at country level.

12.3 A STEP BY STEP APPROACH FOR SCALING UP PPM DOTS

Practical guidelines have been developed and tested for the implementation of PPM DOTS in Ethiopia: the approach outlined is not a one-size-fit-all approach, but it is adaptable and can be easily tailored to meet the specific needs and to address the unique challenges of particular regions and sub regions.

The guidelines emphasize clearly defined roles, and recommend close and collaborative relationship between the regional health bureaus and private sector facilities.

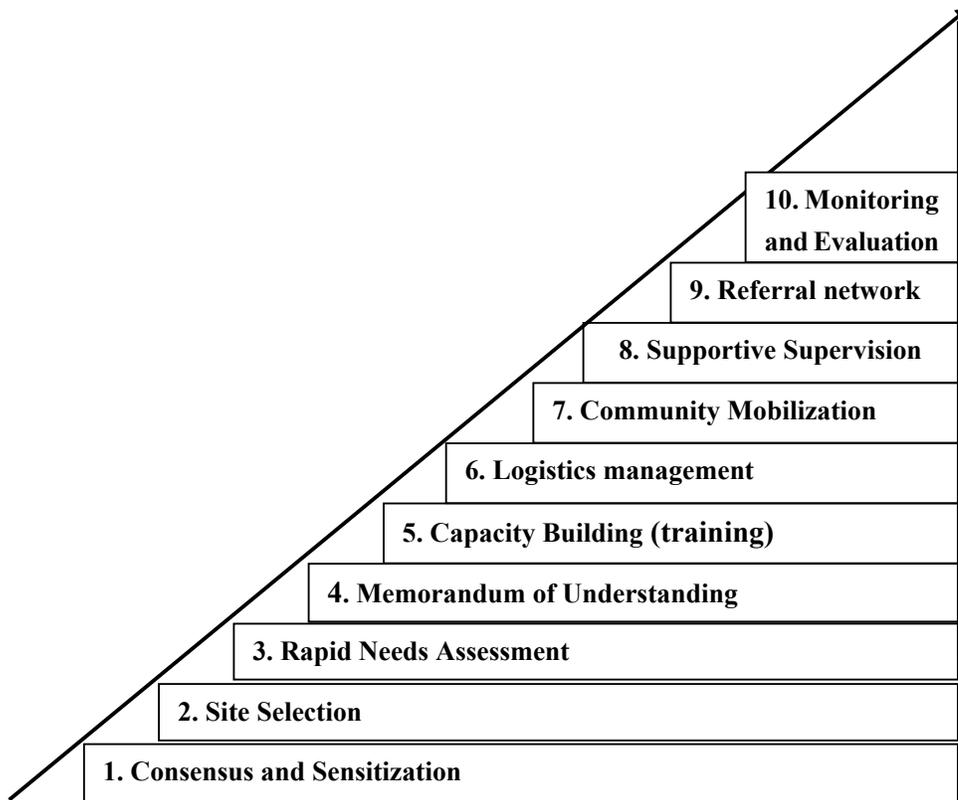
Key responsibilities of the regional / woreda health offices:

- Supply anti-TB drugs free of charge with adequate shelf life
- Establish a reliable system for re-supply
- Monitor, evaluate and serve as steward for the program

Key commitments of private providers:

- Follow the national norms and standards include in national manual for TB & TB/HIV
- Not sell or use TB drugs and supplies for other purpose
- Report on program activities following FMOH reporting format and system
- Communicate promptly to Woreda offices regarding defaulters

**TEN KEY STEPS FOR SCALING UP TB & TB/HIV CARE IN
PRIVATE HEALTH FACILITIES IN ETHIOPIA**



13 ADVOCACY COMMUNICATION AND SOCIAL MOBILIZATION (ACSM)

The purpose of ACSM is to help addressing four key challenges in controlling TBL & TB/HIV:

- combating stigma and discrimination,
- empowering people affected by the diseases, and disseminating adequate information
- mobilizing political commitment and resources.
- increase awareness and demand for services, thus improving case detection and treatment adherence,

These challenges will not be met without greater prioritisations and improvement in TBL & TB/HIV related communication activities. Health education is neither a one-way, nor a one-time undertaking, but a continuous process which should lead to a better understanding, to a change in attitude and to action aimed at coping with problems. Although DOTS/MDT solves part of the problem of non-compliance, its success depends largely on how effective health workers are in seeking and obtaining the full co-operation of the patients and the community.

Target group for ACSM

Communication for TBL control program is dealing with informing and creating awareness among the general public about the diseases, and empowering people to take action. Therefore, the main target for ACSM in TBL and TB/HIV prevention and control are patients, their families, and the community.

ACSM is a shared responsibility of the general health staff, the patients and the communities.

Every health worker should be involved in ACSM activities

13.1 ACSM FOR PATIENTS AND SERVICE PROVIDERS

Communication with patients about their disease and its complications - e.g. leprosy self-care for prevention of disabilities- is a continuous process. This process goes on as long as the patient requires chemotherapy or, as in leprosy 'released from treatment' (RFT), is at risk to develop further disability. The health staff must be trained and motivated to ensure effective communication with their patients.

Communication with patients should be performed in groups as well as with individual patients. The education should never be a one way approach (i.e., a lecture whereby one person gives a talk to an audience).

A two-way communication flow should always be maintained. Patients should be stimulated to give their comments, communicate their feelings, ask questions and give suggestions. Demonstrations should accompany the explanations and the patients should be requested to practice any procedures with their actions observed and encouraged accordingly.

Group education is important before starting chemotherapy in order to explain the new treatment and the importance of regular attendance. It is the key of adherence. Education in self-care to leprosy patients with similar disability problems can also be done in groups. Direct communication with the patients is the best way to obtain feedback, to understand the problems patients face and also to find possible solutions together.

13.1.1 What a patient should know at the diagnosis of TB, TB/HIV and leprosy

Tuberculosis, TB/HIV and Leprosy

- TB/Leprosy are infectious diseases caused by bacilli, not by a curse or witchcraft
- With appropriate treatment TB and Leprosy are curable, whereas HIV is manageable
- Tablets need to be taken daily, as prescribed, and at the same time each day
- Usually TB patients will become non-infectious after two weeks of the treatment
- Both HIV-positive and HIV-negative TB patients can be equally cured from TB
- Drugs should never be given to anyone else
- The patient should encourage his/her household contacts to have themselves checked
- Patients should be educated to use ABC (Abstinence, Behavioural change, Condoms) methods to prevent themselves from getting infected by HIV

TB specific messages

- For New patients in the intensive phase anti-TB drugs will be taken every day for two months under direct observation by an authorized person; drugs must be collected every month for the next six months during the continuation phase.
- For patients on Re-treatment, drugs will be taken every day for three months and every other day for five months under direct observation by an authorized person.

Leprosy specific messages

- MDT drugs must be collected from the clinic every 4 weeks on the clinic day
- Much of the damage that occurs to nerves and tissues before the patient commences MDT cannot be reversed.
- In many patients, patches will remain even after the MDT course is finished. The patches will disappear slowly in a period of 1-3 years.

What a patient should know about his/her drugs

- The colour and number of drugs that must be taken.
- The drugs must be taken in a single dose and must be kept at home out of reach of children
- The unsupervised drugs can also be taken in the evening just before going to bed in case of nausea after ingesting them.
- Awareness of the common side effects of the drugs in order to prevent interrupting the treatment, in particular normal change in the colour of the skin or the urine. What to do in case of more severe side effects must be clearly explained.
- When the patient plans to travel he/ she should inform the staff so that relevant arrangements can be made to avoid treatment interruption.
- To inform the health staff when there is intention to move to another area. The staff will then write a transfer letter and give advice on where the patient should continue treatment.
- To report to the staff if and when the condition worsens.

Leprosy specific messages

A patient on MDT should report to the staff as soon as one of the following happens:

- Patches become red and swollen again.
- Sudden weakness of muscles is noticed.
- One or both of the eyes get red and painful.
- Pain in one of the limbs is noticed.
- Appearance of red, swollen, tender nodules in the skin.

When a patient is treated with prednisolone, he/she should know:

1. The side-effects of prednisolone, the need to report these immediately
2. The danger of abrupt discontinuation of prednisolone treatment.
3. If a patient develops rashes with severe itching he should stop the treatment and report to the clinic immediately.

13.2 THE TB/HIV CO-EPIDEMIC

Communication and social mobilization should address TB/HIV co-infection, 'the two diseases in one patient'. ACSM is a shared responsibility of the general health staff, the patients, family members, all stakeholders and the communities at large, aiming at:

- Increased awareness and knowledge on the mode of transmission, prevention and control of Tuberculosis
- Providing awareness and knowledge of the individuals, families and communities on main symptoms and signs of TB and promote early health care seeking behaviour.
- Enhancing awareness and knowledge on mode of HIV/AIDS transmission and its prevention, treatment and care and support for victims of HIV/AIDS and other STIs control (ABC) and related methods and to facilitate behaviour change
- educating, motivating and helping HIV-positive clients, without active TB, to accept IPT and HIV positive TB patients to accept CPT and adhere to these
- educating, motivating and helping TB/HIV patients to adhere to anti-TB and ART treatment
- Promoting awareness and knowledge on importance of follow-up and the consequences of defaulting treatment
- Both HIV and TB are infectious diseases caused by virus and bacilli, not by a curse or witchcraft.
- Other people may have also been infected by the bacillus and may develop the TB disease. The patient should encourage his/her household contacts to have them checked (for TB if they develop cough for ≥ 2 weeks).
- Educate and counsel HIV positive client to practise safe sex and encourage to have his/her partner to have counselled and HIV tested
- Advise and counsel the HIV positive client on the indication, dosage and adherence, efficacy of IPT in preventing TB disease, side effects and importance of follow-up.
- Advise and counsel the HIV positive TB patient on the indication, dosage and adherence, efficacy of CPT in reducing mortality due to opportunistic infections, side effects and importance of follow-up.

13.3 LEPROSY PATIENT WHEN RELEASED FROM TREATMENT (RFT)

Leprosy reactions can develop after MDT and these reactions can be effectively treated. Early reporting is absolutely essential to prevent irreversible damage.

Patient should be advised:

- To report to health facility when they notice new patches or if old patches become thick and red.
- To report to health facility when they notice pain in their hands and feet or red painful eyes, or new development of loss of sensation and/or muscle strength.

The above symptoms may indicate that the disease has started again, or that a reaction is taking place.

13.3.1 Education in self-care for patients with disability of eye, hand or foot

The prevention of disability depends to a very large extent on the patients themselves. Therefore, patients must learn how to avoid the complications of the disease. Self care is intending:

1. To promote interdependence and independence among leprosy patients living close together
2. To promote the use of locally available self-care materials.
3. To encourage ex-patients to support each other to maintain interest in life long care.

13.3.2 Care of the hands

Important rules for the prevention of insensitive hands:

Think: Is this material hot? Use an area of normal sensation to test before touching with an insensitive hand.

Look: While working near hot materials, the eye is the mother who watches the hand.

Take care: Use a cloth or padded handle during managing hot materials.

13.3.3 Care of the skin and feet

When the hands or feet have lost sensation it is important to prevent them from becoming dry and cracked. For that:

- 1) Wash the feet and hands every evening after work
- 2) Soak the hands or feet in water for 20 minutes.
- 3) After soaking, scrape away any dead skin; do not use sharp materials for scraping.
- 4) Oil the skin with Vaseline.

The following are important to prevent ulcers.

- 1) Protect feet that have lost feeling by wearing the right kind of shoes, walk short distance and avoid walking on rough ground.
- 2) Inspect your feet every night after washing them. Press on pressure points of the foot. If you find any part which is red or painful on pressure or swollen: these are danger signs
- 3) If ulcer starts developing, prevent it by not walking (rest).

13.3.4 Care of the eyes

- 1) In the early stage of eyelid weakness, daily exercise can help. Exercise three times daily.
- 2) If the eyeball has no sensation, inspect your eyes every day. Use a mirror to see if there are pieces of dust in the eye and remove them with clean pieces of cotton.
- 3) At night, cover the eyes with an eye shield, a clean cloth or the beds sheet.
- 4) If sunlight hurts the eye, wear an eyeshade or a hat with a wide brim.
- 5) Wash eyes carefully every day to keep flies away.

13.4 THE PATIENT AND THE COMMUNITY

13.4.1 The patient and family members

Communication with family members should enable:

- Patient to get care and support from family members
- Counteract stigma related to TB, TB/HIV and Leprosy
- Identify other patients with early TB/Leprosy

Contacts of new PTB and leprosy patients are persons that have been living in close contact with the patient (index case) and thereby have an increased risk of having been infected with TB or leprosy.

For operational reasons contacts are defined as: *all persons that are living together with the patient in the same household.*

In the case of **TB**, all contacts aged under five years and among those who are older only those having signs and symptoms suggestive of TB should be examined.

In the case of **leprosy** encourage all newly diagnosed patients to bring their household contacts for examination at the clinic. All contacts should be examined as soon as possible after diagnosis of the patient. In some circumstances it may be more effective to undertake a visit to the household (e.g. if there are many who and they live far away).

Before visiting the household:

- the general health staff must make an appointment with the patient at a convenient time for his/ her contacts to be present.

During the visit:

- briefly describe the disease (its cause, signs, symptoms, treatment). Inform the contacts that there is a possibility that they may have the disease or may develop it in the future.
- encourage those present to give sputum for smear microscopy if they have symptoms suggestive of TB or skin lesions (for leprosy).
- contacts without TB symptoms or skin lesions should be advised to be on the lookout for TB symptoms or leprosy skin lesions and report to the clinic if these occur.
- throughout the visit to the household encourage people to ask any questions they may have.

13.4.2 The community

ACSM activities should facilitate:

- Case finding: identifying symptomatic individuals and sending them to health units;
- Treatment compliance: encouraging patients to take their drugs regularly;
- Tracing defaulters: helping in tracing and convincing defaulters to resume treatment;
- BCG vaccination: advising parents of infants to have the infants vaccinated.

The content of communication to the patient, family members and the community should basically be the same.

14 RECORDING AND REPORTING IN TB, LEPROSY AND TB/HIV

14.1 INTRODUCTION

The quarterly reporting of statistics on patients diagnosed with TB, leprosy and TB/HIV and the results of treatment is essential for the assessment of the programme. Regular assessment is done at the woreda, zonal, regional and national levels where epidemiological and operational indicators for monitoring of the TLCP are calculated and compiled. Quarterly reports are completed according to the Ethiopian fiscal year. The reporting of TB, Leprosy and TB/HIV collaborative activities will eventually be integrated into the Health Management Information System (HMIS). However, until the HMIS is fully functional, the reporting of TBL and TB-HIV activities continues to be reported through the program.

14.2 REGISTERS, RECORDS AND REPORTS

The recording and reporting forms and the instructions on how these should be filled in are given in annex XII. The following general principles apply to the TLCP in all areas of the country:

- The Health Centre (HC) and hospital usually the diagnostic centres for a defined health service area (HSA), are the focus of activities.
- All forms and registers are identical throughout the country.
- Forms and registers are designed and used for TB, Leprosy and TB/HIV collaborative activities so that a minimum number of forms must be kept as much as possible.

14.2.1 Tuberculosis and TB/HIV

Unit TB and TB/HIV Register

This is kept at each health unit providing TB or TB/HIV services. There is space for recording patient identifications, the intensive phase treatment, as well as the continuation phase. It also

provides space for recording information on TB/HIV collaborative activities. Full address of the patient and his/her contact person is required for tracing purposes.

14.2.2 Leprosy

Leprosy Patient Record Card

The front page of the leprosy patient record card is used for recording patient identification, history of the disease process, diagnosis and classification of leprosy as well as the nerve function assessment and disability grade at the time of diagnosis. The inner parts of the card provide space for follow up VMT and ST examinations to be performed on regular basis for all patients on treatment. The back-side (top half) of the card provides space for recording the results of assessments of the disability and overall condition of the patient at the time of completion of treatment. The bottom half of the back-side of the leprosy patient record card provides checklist for assessing the eligibility of the patient for ambulatory steroid treatment and for the initiation and recording of steroids. If a second course of steroids is required, a second card can be used and attached to the first one.

This card allows the detection and treatment of neuritis (new nerve damage). At each examination, one section of the card is used to record the VMT/ST findings. These findings are then compared with the last record, to detect any change, which is the most important indicator of ongoing nerve damage. If new nerve damage is detected, procedures for starting steroids should be initiated. Each leprosy patient has to be examined for VMT and ST at every visit. If a patient returns after completion of treatment for any reason, VMT/ST should be done and the results recorded in the next free section on the card.

Unit Leprosy Register

This is kept and maintained, like its TB counterpart, at every health unit treating leprosy patients and it contains the patient identifications and treatment details of every patient.

14.2.3 Forms and registers used for both TB and Leprosy

Request for sputum/skin smear examination

All suspect cases of pulmonary TB (cough \geq 2 weeks) and doubtful cases of leprosy should be sent to the laboratory with this form. When follow-up smears are done (routinely only for TB), the unit TB number and the month of follow-up should be recorded. When the form is returned, the Lab. Serial Number should be recorded in the appropriate Unit register, alongside other details of the patient.

Laboratory Register

It is used for recording TB and leprosy smear results. When follow-up smears are done (routinely only for TB) the Unit TB Number should be recorded in the Lab Register under the appropriate column.

Referral and Transfer Form

This is printed with one side for TB and TB/HIV and the other side for leprosy. It has three functions:

- Referral of patients diagnosed in one unit to initiate treatment at another unit.
- Transfer of patients on treatment to continue their treatment at another unit¹.
- Referral of patients for further investigation and management².

Quarterly Case-Finding Report Form

This quarterly report is used for both TB and Leprosy (front and back pages). The report is compiled based on the information

1 When a patient is transferred for continuation of treatment, the receiving unit is expected to complete the lower portion of the transfer form and send to the original health unit where the patient came from after the result of treatment is known.

2 The health institution that received a case for further investigation and management should use a new referral/transfer form to give complete details of the management of the patient, when the patient is referred back to the original health unit.

available in the Unit TB and Leprosy Registers. This TB and Leprosy case-finding quarterly report form will be functional until the HMIS is in full swing at which time it will be replaced by a different quarterly reporting form developed by the HMIS (the HMIS quarterly reporting form is also presented in the annexes).

Quarterly Results of Treatment Report Form

This quarterly report is used for both TB and Leprosy (front and back pages). The report is compiled based on the information available in the Unit TB and Leprosy Registers. This TB and Leprosy results of treatment quarterly report form will be functional until the HMIS is in full swing at which time it will be replaced by a different quarterly reporting form developed by the HMIS (the HMIS quarterly reporting form is also presented in the Annex 8, 12 HMIS TB, Leprosy & TB_HIV quarterly report form).

Quarterly report on TB/HIV collaborative activities

This quarterly report is used for the reporting of TB/HIV collaborative activities. The report is compiled based on the information available in the Unit TB Registers, VCT registers as well as Pre ART and ART registers. This TB/HIV collaborative activity quarterly report form will be functional until the HMIS is in full swing at which time it will be replaced by a different quarterly reporting form developed by the HMIS (the HMIS quarterly reporting form is also presented in the annexes).

Compilation and submission of quarterly reports on TB and Leprosy case-finding and results of treatment as well as TB/HIV collaborative activities

The information in the quarterly TB and Leprosy case-finding and results of treatment as well as TB/HIV collaborative activities report forms or in the HMIS quarterly report forms have to be filled in completely and correctly. The responsibilities at the different levels of the health system are explained below.

- **The Health Facilities** should compile reports, assess, analyse and act on them before forwarding to the Woreda health office or sub city health offices. The reports have to reach the Woreda or sub city health offices within 3 days of the end of

the respective quarter.

- **The Woreda Health Offices** should make sure that all health facilities in their respective Woreda have submitted quarterly TB, Leprosy and TB/HIV reports. The woreda health offices should verify the reports for completeness, correctness and consistency of information. They have to analyse the reports and act on them accordingly before forwarding them to the zonal health department/offices/desks. The Woreda health offices should also send feedback to the health facilities every quarter on regular basis. Furthermore, they have to make sure that the reports have reached the zonal level within the following 6 days.
- **The Zonal Health Departments/offices/desks or sub cities health offices** should make sure that all Woredas or HFs (in the case of AA) in their respective zones/subcities (in the case of AA) have submitted the quarterly TB, Leprosy and TB/HIV reports. The zonal health departments/offices/desks or sub city health offices should verify the reports for completeness, correctness and consistency of information. They have to analyze the reports and act on them accordingly before forwarding the zonal/sub city/special woreda aggregated reports and copies of the woreda/HF (in AA) to the regional health bureau. The zonal health departments/offices/desks or sub city health offices should also send feedback to the woredas or HFs (in AA) every quarter on regular basis. Furthermore, they have to make sure that the reports have reached the regional health bureau within the following 7 days.
- **The Regional Health Bureaus** should make sure that all zones/sub cities/special woredas in their respective region have submitted the quarterly TB, Leprosy and TB/HIV reports. The regional health bureau should verify the reports for completeness, correctness and consistency of information. They have to analyze the reports and act on them accordingly before forwarding the regional aggregated reports and copies of zonal/sub city/special woreda reports to the TLCT/FMOH and HMIS-PPD of the FMOH. The regional health bureaus should also send feedback to the zones/sub cities/special

woredas every quarter on regular basis. Furthermore, they have to make sure that the reports have reached the Federal Ministry of Health within the following 5 days.

- **The TLCT/FMOH** should make sure that all regional states and the two city administrative councils have submitted the quarterly TB, Leprosy and TB/HIV reports. The TLCT/FMOH should verify the reports for completeness, correctness and consistency of information. TLCT/FMOH has to analyze the reports and act on them accordingly before disseminating information to all concerned bodies. The TLCT/FMOH should also send feedback to the regions every quarter on regular basis. Furthermore, TLCT/FMOH has to make sure that the reports have reached at the Federal Ministry of Health within three weeks of the end of the respective quarter.

Patient Identity Card

This card, which contains personal information and the Unit TB or Leprosy Number, is carried by the patient in order to inform other medical personnel of his/her condition, in case of emergencies and to record the next date for the clinic visit. It can be written in the local language.

Quarterly TB and Leprosy Activity Report Form

Both pages of this form are to be completed at the end of every quarter and sent to the next higher level along with the case-finding and treatment outcome reports. The activities to be reported using this form are training in TBL and TB/HIV control, supervisory activities, DOTS-MDT service expansion, TBL review meeting and POD activities (See annexes)

Care after RFT register

This register is used for the registration of leprosy patients who were declared cured and presented back to the health facility with different complaints. The register provides space for recording the type of care given to the patient. The register is presented in the annexes.

15 SUPPORTIVE SUPERVISION AND REVIEW MEETINGS

Supervision aims at ensuring and improving quality, effectiveness, efficiency of services provided; it should also enhance competence and satisfaction of the staff engaged in TBL prevention and control as well as TB/HIV collaborative activities at all levels. Supervision consists of observation, discussion, support and guidance. Therefore, it is an essential tool in the management of staff and facilities and should be done on a regular basis.

The overall aim of supervision is the promotion of continuous improvement in the performance of the staff.

The immediate objectives of supervision are the following:

- To assure that TLCP and TB/HIV implementation guidelines are properly implemented.
- To ascertain that TBL and TB/HIV care is provided and recorded according to the instructions norms and standards.
- To identify factors that may inhibit or enhance proper implementation of the programme.
- To develop micro-plan with the health to improve staff performance in TBL and TB/HIV service delivery.
- To motivate, train and support all health staff and sustain high level working morale.

15.1 LEVELS OF SUPERVISION

15.1.1 Health facility level

Supportive supervision has to start from within the health facility. The head of the health facility or any other designated person should make sure that activities are carried out according to the instructions outlined in the TBL and TB/HIV manuals. The heads of the facilities or any other designated person should carry out very frequent (preferably weekly) and regular visits to the TBL clinics (units), VCT clinics and HIV chronic care units.

During his/her visit to all these units, the supervisor is expected to observe how activities are carried out, check registers and records as well as the quarterly reporting of activities and give guidance and feedback. The supervisor is also expected to motivate, encourage and support the staff actively involved in the provision of DOTS/MDT as well as TB/HIV services. Hence, the health facilities should not wait until supervisors from Woreda, zone, regional health bureau or the central level to come and tell them how they are doing.

15.1.2 Woreda (District) level

The Woreda health office is responsible to carry out TBL and TB/HIV specific supportive supervisions visits in health facilities and health posts (health extension workers) monthly on a regular basis. Supportive supervision should always be carried out using standardized checklist. During the visit of facility, he/she should observe how activities are undertaken; check registers and records as well as TBL and TB/HIV quarterly reports for completeness, correctness and consistency of information. The supervisors should encourage, motivate and support the General Health Workers engaged in the TBL and TB/HIV service delivery. During the supportive supervision, drugs and supplies should be checked thoroughly. During the visits to the health posts, the supervisors are expected to check the identification and referral of TB and leprosy suspects to the health facilities. The supervisors should encourage, motivate and support the HEWs to exert the maximum effort to mobilize the community in the fight against TB and leprosy as well as to intensify the identification and referral of TBL suspects.

The planned/scheduled visits should preferably coincide with fixed leprosy clinic days and the staff of the health facilities should usually be informed about the visits beforehand.

The supervisory findings (strengths, weaknesses and problems) and recommendations have to be discussed with the heads of the health facilities visited and those health workers engaged in the provision of TBL and TB/HIV services to try overcoming obstacles and improving performances. The supervisors must prepare comprehensive reports on their observations and findings

including recommendations and disseminate the reports to all supervised institutions and all other concerned bodies.

15.1.3 Zonal level

The Zonal health departments/offices/ or sub-cities in Addis Ababa are responsible to carry out TBL and TB/HIV specific supportive supervision to Woreda health offices, health facilities (GHWs) and health posts (health extension workers) monthly on regular basis. Before supervision, the supervisor must get previous information and reports concerning the health facility to be supervised.

During the supervisory visit, he/she should observe how activities are undertaken, check registers and records as well as TBL and TB/HIV quarterly reports for completeness, correctness and consistency of information. The supervisors should encourage, motivate and support the staff engaged in the TBL and TB/HIV program implementation. During the supportive supervision, drugs and supplies should be checked thoroughly. During the visits to the health posts, the supervisors are expected to check the identification and referral of TB and leprosy suspects for examination at the health facilities. The supervisors should encourage, motivate and support the HEWs to exert the maximum effort to mobilize the community in the fight against TB and leprosy as well as to intensify the identification and referral of TBL suspects.

The supervision has to be planned and communicated to the institutions to be supervised well ahead of time.

The supervisory findings (strengths, weaknesses and problems) and recommendations have to be discussed with the heads of the institutions visited with the aim of overcoming obstacles and improving performance. The supervisors must prepare comprehensive report on their observations and findings including recommendations and disseminate the reports to all supervised institutions and all other concerned bodies. Supportive supervision should always be carried out using standardized checklist (See annexes).

15.1.4 Regional level

The regional health bureau is responsible to carry out TBL and TB/HIV specific supportive supervision to zones, sub cities, woreda health offices, health facilities (GHWs) and health posts (health extension workers) monthly on regular basis. During the supervisory visit, the supervisor should observe how activities are undertaken, check registers, supervision reports and records as well as TBL and TB/HIV quarterly reports for completeness, correctness and consistency of information. The supervisors should also encourage, motivate and support the all engaged in the TBL and TB/HIV program implementation. During the supportive supervision, drugs and supplies should be checked thoroughly. During the visits to the health posts, the supervisors are expected to check the identification and referral of TB and leprosy suspects for examination at the health facilities. The supervisors should encourage, motivate and support the HEWs to exert the maximum effort to mobilize the community in the fight against TB and leprosy as well as to intensify the identification and referral of TBL suspects.

The supervision has to be planned and communicated to the institutions to be supervised well ahead of time.

The supervisory findings (strengths, weaknesses and problems) and recommendations have to be discussed with the heads of the institutions visited with the aim of overcoming obstacles and improving performance. The supervisors must prepare comprehensive report on their observations and findings including recommendations and disseminate the reports to all supervised institutions and all other concerned bodies.

Regional health bureaus as much as possible should adhere to monthly and regular TB, Leprosy and TB/HIV supportive supervision to zones, sub cities, woredas, health facilities and health posts under their jurisdiction for the sake of ensuring quality and standard of TBL and TB/HIV service provision. Supportive supervision should always be carried out using standardized checklist.

15.1.5 Central level

TB and Leprosy Control Team (TLCT) of the FMOH should supervise every region at least two times per year. The aim of the supervisory visit is to identify strengths, weaknesses, problems and seek solutions jointly with the respective health bureaus. The supportive supervisory is also important to provide guidance and support to the regional TB and Leprosy prevention and control program. The supportive supervision from the federal ministry should be able to reach zones, woredas and HFs as well as health posts that implement TB, Leprosy as well as TB/HIV activities. Using the standardized supervision checklist, adequate information are to be collected; registers, reports and other relevant records have to be reviewed; and drugs and supply situation is thoroughly checked. At the end of the visit, the supervisory team discusses its findings (strengths, weaknesses and problems) and workable recommendations with the heads of the bureaus, zonal and woreda health offices, in order to implement an effective control program. Following the visit, the supervisory team should send supervision report to all supervised levels.

15.2 SUPERVISION CHECKLIST AND REPORTS

In order to carry out meaningful supervision in a systematic manner, supervisors at all levels should use comprehensive and standardized supervision checklist for supervision of TLCP management levels and the health facilities.

Before each visit the supervisor should review the assessment made during the last visit, corrective action taken and features that should demands special attention during the current visit.

After each supervisory visit the supervisor (supervisory team) has to discuss strengths, weaknesses and problems identified, and recommendations with the heads of health bureaus, and TBL experts to make the control program successful. At the end of each supervision visit, supervised institutions should be provided with a supervision report and the supervisor him/herself must help resolve blockage originated at various levels of the health system.

15.3 REVIEW MEETINGS

Review meetings organized at various levels create a very good opportunity to review the status of programme implementation, achievements and challenges and came up with workable solutions for the problems and challenges encountered. They are key element for program management.

Furthermore, review meetings are forums for exchange of ideas and experiences among the health professionals and programme coordinators involved in the implementation and coordination of TB, Leprosy and TB/HIV activities. In these meetings, programme coordinators from the next lower levels will present activity reports of their respective area, including major achievements and challenges/constraints encountered during the period under review.

Review meeting is also a very good forum to convey new developments to the frontline health workers and coordinators that are actually executing programme activities on the ground. Besides, such meetings create additional opportunity to verify TB, Leprosy and TB/HIV data.

Given the size of the country, it is crucial to conduct TB review meetings at Zonal, regional and central level on regular basis: Zonal/sub city level review meetings with heads of the Woreda health offices, Woreda CDC coordinators and relevant health staff from TB diagnostic centers in attendance should be held twice a year. Activities taking place at Woreda (district) level will then be brought forward to the regional review meetings through zonal health departments/offices/desks/sub city health offices.

Regional review meetings should also be held twice a year. The regional coordinators in turn bring forward the achievements and challenges with recommendations in their respective area at a central level review meeting which is attended by officials of RHBs, TB and Leprosy control teams and other relevant staff of the RHBs, partners and all other stake holders of the program.

16 SUPPLIES AND LOGISTICS

It is very important to ensure that every health unit involved in the prevention, diagnosis and treatment of Tuberculosis, Leprosy & TB/HIV has an adequate and uninterrupted supply of drugs, laboratory reagents and equipment in order to achieve sustainable program implementation.

To ensure availability of sufficient amount of drugs there must be:

- Accurate inventory records with clear responsibilities.
- Timely requisition of drugs and laboratory supplies.
- Adherence to the current method of calculating drug requirements.
- Decentralized drug storage in adequate conditions.
- Well-defined responsibilities for the various activities and steps.
- Regular communication between the pharmacy and TBL and TB/HIV sections.

16.1 Procurement, storage, distribution and use of drugs & consumption reporting

The flow of drugs and laboratory supplies follows the existing national system for handling such supplies at all levels.

16.1.1 Procurement

TB and leprosy drugs procurement will be done in a timely effective manner if **and only if** the regional TBL team members have send on time the quarterly reports, stating caseload, drug and laboratory supplies consumption and available stocks.

The stock available at every region should be determined before new procurement procedure starts

Quantity of drugs and laboratory supplies to be procured for a given period is based on:

- The total caseload reported;
- The number of TB case increment due to HIV prevalence;

- The current stock available;
- The need for buffer stock maintenance at different levels;
- Scale up or planned expansion;
- The consideration of contingency for depletion of buffer stocks;
- Budget allocated for drugs and laboratory supplies.

16.1.2 Storage and Distribution

TLCP will prepare national distribution plan as soon as the quarterly case reports are submitted from regions or federal health institutions on the basis of the stock available at central store and at regional level.

The amount of drugs and supplies to be distributed to the regions and peripheral levels is determined by the number of patients registered during the previous quarter, the replenishment of peripheral stocks (see Table below) and must be adapted to findings of field supervisions. Then distribution order is prepared with protocol letter to PSLD/PHSDA who manages the central stock with a copy to all regions considered in the distribution. The method to calculate the drug requirements is presented in annex 7.

Table 15. Recommended stocks of drugs and supplies at different levels of the health system

Level	Order- and supply frequency	Buffer Stock
Central	yearly	1 year
Regional	6-monthly	3 months
Zonal	quarterly	1 months
Woreda	quarterly	1 months
Health Facility	quarterly	1 months

At each level of the health system the issuance should be governed by first-in first-out (FIFO) and first-expire-first-out (FEFO) principles.

16.1.2.1 Operational rules for shelf life of TB drugs

The shelf life of TB drugs is limited. In order to avoid wastage due to expiry, the following steps should be taken:

Central level:

- Drugs and medical supplies procured should be assured to have at least 5/6 of their shelf-life when they arrive at the central store.
- Periodic revision of the issuance and consumption of drugs by the Regions.

Regional, Zonal, Woreda and Health Facility Levels:

- Ordering of drugs and supplies should be based on proper quantification/consumption.
- If there is overstocked item with a shelf life of less than 6 months, it has to be immediately reported to the next higher level.
- The drug utilisation pattern of health institutions needs to be regularly monitored.

16.1.2.2 Ordering of drugs and medical supplies

Ordering of drugs and medical supplies for regional, zonal and Woreda/health unit stores is based on the quarterly case notification report and stock balance compiled by the RTLT or ZTLE in collaboration with the pharmacy unit (see annex).

16.1.3 Rational use of drugs

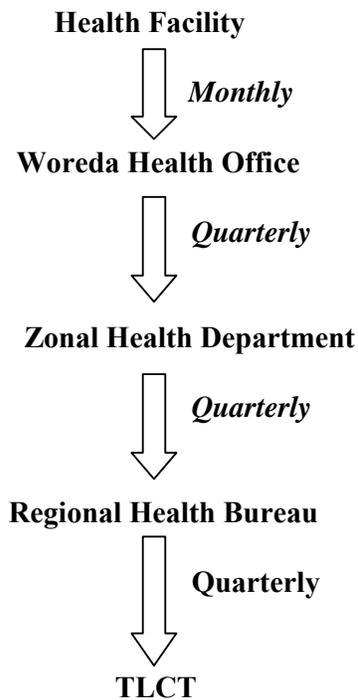
Patients must receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time free of charge.

Rational use of drugs implies promotion of rational prescribing, ensuring good dispensing practice and encouraging appropriate drug use by the patient and the community at large. This should be part and parcel of programmatic activities at each and every level.

16.1.4 Drug Consumption Reporting

This is the most important tool for TB and Leprosy drug supply. It generates information on drug consumption pattern (monthly, quarterly, yearly), current inventory and expiry status and exact time when to order or procure. It also helps to monitor the rational use of TB and Leprosy drugs.

For complete reporting of TB and Leprosy drugs consumption, health facility, woreda, zonal and regional level TLCP formats are available from TLCT and the respective RHBs. This report should be submitted attached with the drug request forms. Flow of drug consumption and available stock reporting:



16.1.5 Records and forms

The following records and forms are used for drugs and laboratory supplies:

1. All government Vouchers (models) used for ordering, receiving and issuing.
2. Stock card records and Bin cards.
3. Health facility level drug consumption reporting format.
4. Woreda level drug consumption reporting format.
5. Zonal level drug consumption reporting format.
6. Regional drug consumption reporting format.
7. Quarterly drugs and laboratory supplies order forms.

Items No 3-7 are supplied by PSLD/FMOH.

16.1.6 IEC/BCC materials

IEC/BCC materials are produced and distributed from TLCT to regions. RTLs should therefore distribute these materials on time to zones, zones to woredas and woredas to health facilities.

Funds at times are also allocated for regions so that they can produce IEC/BCC materials in local language and distribute it accordingly. The distribution of IEC/BCC materials should be made on time and the amount distributed to the next level should be well documented. It is the responsibility of all parties involved at all levels to properly use the IEC/BCC materials for the intended purpose.

16.1.7 Supply of formats and registers

The Federal Ministry of Health TLCT will revise if there is a need and prepare the printing and distribution order of all formats and registers used by the control program. The share of each region is determined by TLCT/FMOH and all regions collect their share at PSLD and distribute down to zones, woredas and health facilities. The distribution of formats and registers should be governed by the rules and regulations of property administration.

16.2 Responsibilities

It is the responsibility of the TBL Team members and pharmacy unities at all levels to:

- Keep sufficient stock of supplies;
- Order new supplies in time and safe-guard timely

distribution;

- Check the shelf-life of the drugs and take necessary action;
- Keep up-to-date record and report on supplies received and distributed;
- Promote and ensure rational prescribing, dispensing and use of drugs.

According to the national Logistics master plan drug and laboratory supplies distribution will be handled by PHARMID up to Zonal level. The National TBL & TB/HIV control program will adapt the opportunity when the program become fully on board, till then Drug procurement will remain the sole responsibility of the PSLD/FMoH after getting quantification and official procurement request from the national TBL control program/FMoH.

16.3 Quality check and quality control

- It is the responsibility of the procuring department or Agency to procure quality drugs with all recommended steps in WHO prequalified companies but DACA will ensure drug registrations, onsite inspection at port arrival and sample analysis and report the result to the National TBL program/FMoH.
- Regions, Wordas and Health Facilities are encouraged to report immediately if they face quality complains from patients, health care staffs and store workers.
- Central referral and Regional/sub regional laboratories are responsible to prepare the reagents with standard procedure for periphery laboratories and regularly implement EQA.
- Drug and reagent quality assessment conducted by different parties in the country will be considered as an input for the program.

ANNEX 1: DUTIES AND RESPONSIBILITIES OF THE DIFFERENT LEVELS IN THE HEALTH SYSTEM

National level

The TLCT at the FMOH is responsible for developing guidelines, soliciting and co-ordinating external resources, providing technical assistance to the Regional Health Bureaus (RHBs), and monitoring the programme performance in accordance with the national guidelines.

Regional level

Regional TBL Team/Unit (RTL/U) is responsible for the planning, guidance and supervision of TB, TB/HIV and leprosy control activities in the Region.

Zonal level

The Zonal TBL Expert (ZTLE) is responsible for the planning, guidance and supervision of TB, TB/HIV and Leprosy prevention and control activities in the Zone.

District (Woreda) level

The Woreda TBL expert keeps the TB, TB/HIV and Leprosy registers and provides guidance and supervision to the general health staff that are responsible for implementation of the TB, TB/HIV and leprosy control activities.

Health facility level

Health Posts

Health posts provide health education, refer TB suspects for investigation and collect sputum smears (if appropriate), refer leprosy suspects, give BCG vaccinations, retrieve absentees/defaulters.

Health Centers

Health Centres and selected health stations (diagnostic centres) carry out all activities as health posts, provide microscopy services for sputum and skin smear examination, provide SCC for

TB and MDT for leprosy, diagnose and treat reactions and other complications, carry out TB/HIV collaborative activities, refer to higher level Smear negative and EPTB patients, provide support to health post and health station staff, keep patient record cards and manage drugs stock.

Hospitals

Hospitals carry out activities as health centres, provide referral services for diagnosis and treatment and provide in-patient services.

Functions of laboratories at various levels

Peripheral laboratory (primary role - service provision)

All basic services of a laboratory with special emphasis to those listed down

Technical:

- Preparation and staining of smears
- Ziehl-Neelsen microscopy and recording of results
- Internal quality control

Administrative:

- Receipt of specimens and dispatch of results
- Cleaning and maintenance of equipment (microscopy)
- Maintenance of laboratory register
- Management of reagents and laboratory supplies

Regional Referral laboratory (primary role - quality control)

All basic services of a laboratory with special emphasis to those listed down

Technical:

- fluorescence microscopy (optional)
- digestion and decontamination of specimens
- culture and identification of *M. tuberculosis*
- preparation and distribution of reagents for microscopy in peripheral laboratories

Managerial:

- training of microscopists (laboratory technicians)
- support and supervision of peripheral staff with respect to microscopy
- quality improvement and proficiency testing of microscopy at peripheral laboratories

National Referral laboratory (primary role - capacity building)

All basic services of a laboratory with special emphasis to those listed down

Technical:

- drug susceptibility testing of *M .tuberculosis* isolates
- identification of mycobacteria other than *M .tuberculosis*

Administrative:

- technical control of and repair services for laboratory equipment
- development and dissemination of guidelines on tuberculosis diagnosis , supervision and quality assurance
- collaboration with the central level of the National Tuberculosis program in defining technical specification for equipment, reagents and other materials and estimate equipment and laboratory materials for the program budget

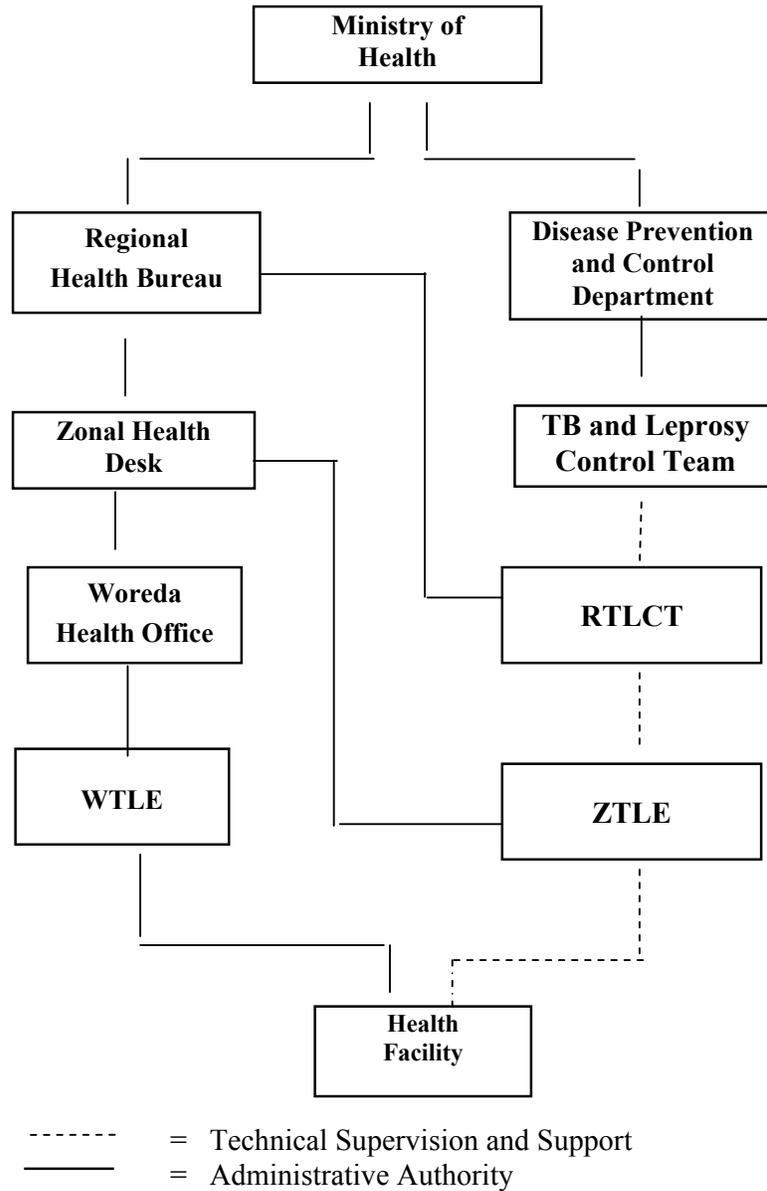
Managerial:

- training of regional referral laboratory staff in bacteriological technique and their support activities; training, supervision, quality assurance, safety measures and equipment maintenance
- Supervision of regional referral laboratories regarding bacteriological methods and their support (training & supervision) to the periphery laboratories
- Quality assurance in microscopy and culture performed at regional referral laboratories

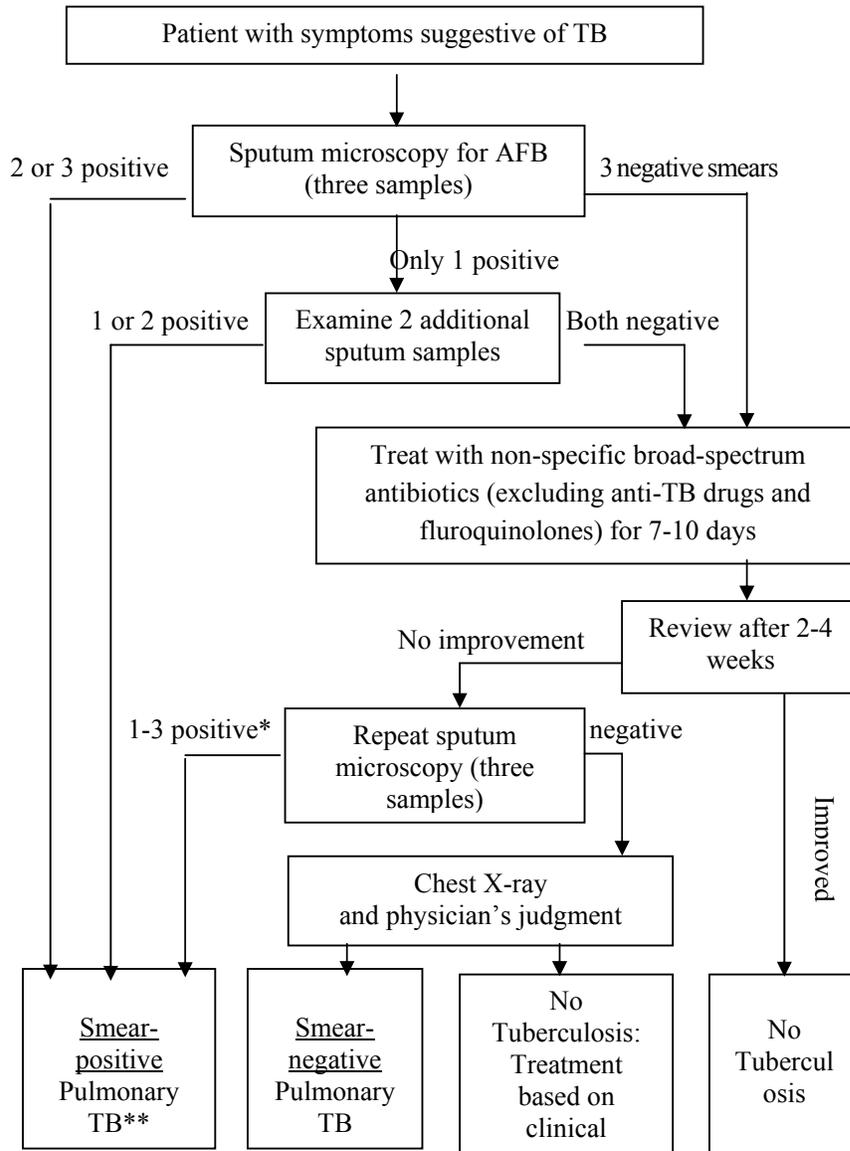
Research and surveillance:

- Organization of surveillance of primary and acquired mycobacterial drug resistance
- Operational and applied research with the requirements and needs of National Tuberculosis Control Program

ANNEX 2: ORGANOGRAM OF TLCP

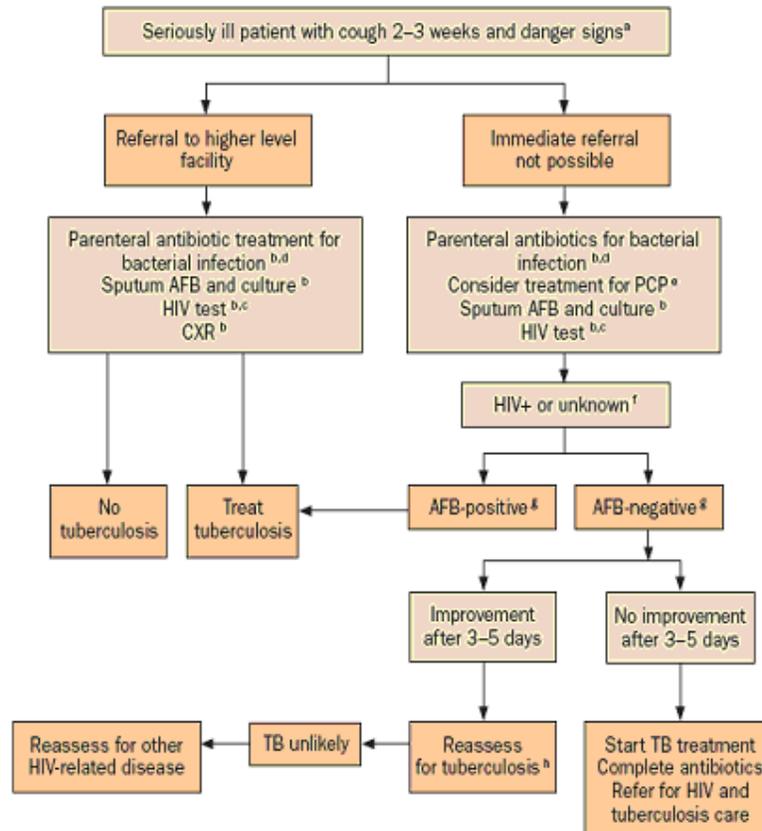


ANNEX 3: DIAGNOSTIC ALGORITHMS FOR PULMONARY TB AND EXTRA PULMONARY TB



- * If initially all three smears are negative but after antibiotics **only one** repeated smear appears positive, it is advised to carry out two additional smears. If one or both are positive, proceed with TB treatment. If both are negative, proceed with a chest X-ray and evaluation for conditions other than TB.
- ** If the patient has never been treated before, register and treat as a new PTB smear positive patient. If the patient has been treated before, register for re-treatment regimen.

Algorithm for the diagnosis of tuberculosis in seriously ill HIV-positive patient



- a. The danger signs include anyone of: respiratory rate >30/min, fever>39°C, pulse rate >120/mm and unable to walk unaided
- b. The investigations with in the box should be done at the same time wherever possible in order to decrease the number of visits and speed up the diagnoses.
- c. For countries with the adult HIV prevalence rate >1% or prevalence rate of HIV among TB patients >5%
- d. Antibiotics (except fluoroquinolones) to cover both typical and atypical bacteria should be considered
- e. PCP: *Pneumocystis carinii* pneumonia
- f. In the absence of HIV testing, classify HIV status unknown into HIV positive depends on clinical assessment or national and/or local policy
- g. AFB positive is defined as at least one positive and AFB Negative as two or more negative smears.
- h. Reassessment for TB includes AFB examination and clinical assessment

Suggested clinical characteristics to assist the diagnosis of extrapulmonary tuberculosis (ETB)

Suspect ETB in patients with

Cough for two weeks or more *or*

- Unintentional weight loss with
 - Night sweats *and*
 - Temperature >37.5 °C or feels feverish
- Breathlessness (effusion/pericarditis) *or*
- Enlarged glands in neck/armpit *or*
- Chest X-ray
 - Miliary or diffuse shadowing
 - Large heart (especially if symmetrical and rounded)
 - Pleural effusion
 - Enlarged lymph nodes inside the chest
- Chronic headache or altered mental state

Suspect disseminated tuberculosis in all people living with HIV who experience rapid or marked weight loss, fever and night sweats

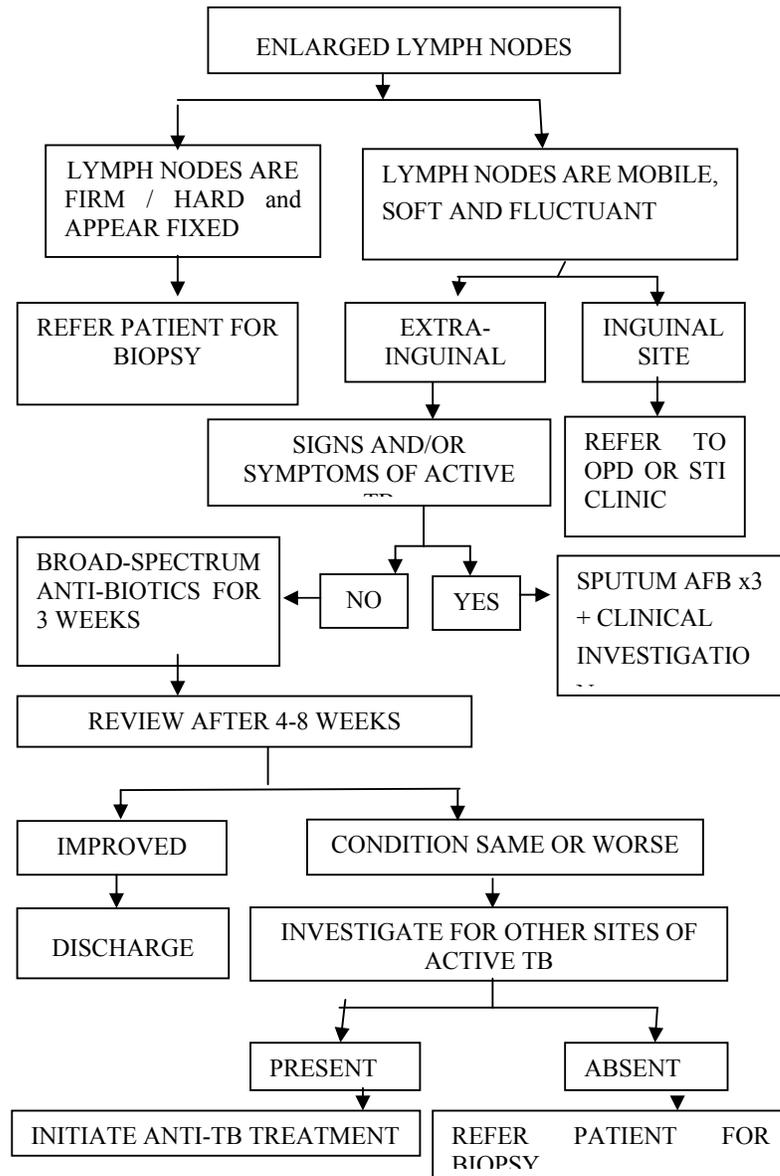
Establish HIV status if ETB is suspected

- Advise and arrange for rapid HIV testing if status is unknown or last test was negative
 - Explain that this will affect the way that this illness is investigated and treated
 - Discuss the need for antiretroviral treatment if HIV-related tuberculosis is diagnosed
 - If consent is given, try to arrange testing on the same day

Look and listen for

- Lymph nodes swelling in the neck or armpits (if present with other types of ETB it may provide the only way to confirm the diagnosis)
Possible tuberculosis lymphadenitis
- Signs of fluid in the chest
 - Absent breath sounds
 - Reduced chest wall movement
 - Dull to percussion**Possible tuberculosis pleural effusion**
- Signs of fluid around the heart
 - Heart sounds distant
 - Swollen legs and/or abdomen
 - Neck and hand veins distended with arm held above the shoulder**Possible tuberculosis pericarditis**
- Signs of meningitis
 - neck stiffness
 - confusion
 - abnormal eye movements**Possible tuberculosis meningitis**

ANNEX 4: MANAGEMENT OF ENLARGED LYMPHNODES



ANNEX 5: MANAGEMENT OF LEPROSY RELATED COMPLICATIONS

1. EYES

Lagophthalmos

- Treat with a course of steroids, if the episode is acute or recent (less than 6 months).
- Teach blinking exercise.
- Prevention of drying, especially during sleep by using eye ointment.
- If corneal sensation is impaired, the patient should be referred to a physician.

Iridocyclitis

- Give aspirin, apply 1% atropine drops and steroid ointment, cover the eye and refer.

Corneal ulcer

- Apply antibiotic ointment, cover eye and refer.

Sudden change in visual acuity

- Refer

2. HANDS

Insensitive hand

- Daily inspection.
- Use protective gloves/clothing and cooking pots with wooden handles.

Injury

- Clean wound and apply dressing.
- Advise rest or immobilize affected part with splint.
- Teach how to protect hand.

Cracks and fissures

- Teach patient to soak the hands and apply oil regularly.

Stiff joint

- Teach exercises and advise massaging with oil.

Burns

- Apply clean dressing.

3. FEET

Insensitive feet

- Daily inspection.
- Avoid long distance walking.
- Use protective footwear.

Cracks and fissures

- Teach patients to soak feet and apply oil regularly.

Blister on sole or between toes

- Dress blister with clean cloth.
- Apply cotton wool and bandage.
- Rest, if necessary use crutches for walking.
- Elevate limb.

Ulcer

- Clean and apply antiseptic dressing.
- Rest.
- If no improvement, refer.

Sudden foot drop

- Bed rest and immobilize the affected limb.
- Give full course of steroids

ANNEX 6: TLCP SUPERVISION CHECKLIST

Date of supervisory visit: _____

Name of the Organization: _____

Type of Organization:

RHB

Zonal (sub-city) health.
Dept.

Woreda Health Office

HF

HP

Region: _____

Zone/sub-city: _____

Woreda: _____

Name and responsibility of persons/officials met:- _____

Population: _____

No. of Zones:

No. of Woredas:

No. of Kebeles:

S/N	Supervisory questions	Yes	No	Comments/Remarks
1-	GENERAL (at Program Management as well as Health Facility levels):			
1.1	Is there a TB & Leprosy structure in your organization (health office or health facility)?	<input type="checkbox"/>	<input type="checkbox"/>	
1.2	If yes to 1.1 above, indicate the type of TBL structure, number of manpower approved for the structure & number currently assigned:-			
	Team (tick):	Manpower approved:	No. of experts assigned:	How many of them work fulltime for TB & Leprosy?
	Expert (tick):	Manpower approved:	No. of experts assigned:	How many of them work fulltime for TB & Leprosy?
	Other (tick), specify:	Manpower approved:	No. of experts assigned:	How many of them work fulltime for TB & Leprosy?
1.3	If a TBL structure exists, are the experts trained specifically on TB & Leprosy?	<input type="checkbox"/>	<input type="checkbox"/>	

S/N	Supervisory questions	Yes	No	Comments/Remarks												
1.4	If yes, how many of them are trained specifically on TB and Leprosy?															
1.5	If a TBL structure exists, are the experts trained specifically on TB/HIV?															
1.6	If yes, how many of them are trained on TB/HIV collaborative activities?															
2-	HEALTH SERVICES (for Program Management levels only):															
	Type of Health Facility (HF)	Number of existing HFs Vis à Vis number implementing DOTS/MDT and TB/HIV collaborative activities														
		MOH			NGO			Private			Others (specify)			TOTAL		
		Total existing	DOTS/MDT	TB/HIV	Total existing	DOTS/MDT	TB/HIV	Total existing	DOTS/MDT	TB/HIV	Total existing	DOTS/MDT	TB/HIV	Total existing	DOTS/MDT	TB/HIV
2.1	Hospital															
2.2	Health Center (HC)															
2.3	Nucleus HC or HS															
2.4	Clinic- Higher															
2.5	- Medium															
2.6	Other, specify															
2.7	Health Post (HP)															
2.8	TOTAL															

S/N	Supervisory questions	Yes	No	Comments/Remarks								
3-	TRAINING (at Program management as well as Health Facility levels):											
3.1	Was there training (or any body trained from your organization) on TB & Leprosy during the past 12 months?											
3.2	Was there training (or any body trained from your organization) on TB/HIV collaborative activities during the past 12 months?											
3.3	If the answer is yes for questions 3.1 and/or 3.2 above, fill in the following table:											
3.4	Type Training	Number of health workers (by category) trained in TB & Leprosy prevention and control as well as TB/HIV collaborative activities										
		Physicians	Health officers	S. nurse	J. nurse	Env. H.	HAs	HE Ws	Laboratory	Pharmacy	WCDC	Others
3.5	TB & Leprosy											
3.6	TB/HIV											
3.7	PPM – DOTS											
3.8	PPM – TB/HIV											
3.9	Other, specify											
3.10	TOTAL											

S/N	Supervisory questions	Yes	No	Comments/Remarks
4-	Monitoring and Evaluation (for program management and/or Health Facility levels):			
4.1	Do you carry out supportive supervision specifically for TB, Leprosy and/or TB/HIV to lower levels?			
4.2	If yes to 4.1, do you use supervision checklist?			
4.3	If yes to 4.2, check copy of the checklist:			
4.4	If yes to 4.1, how many TBL and/or TB/HIV specific supervisions have you conducted during the past 6 months?			
4.5	Do you prepare supervision report?			
4.6	If yes to 4.5, check copy of the report:			
4.7	If yes to 4.6, do you send supervision report to the supervised institutions?			
4.8	Have you been supervised specifically for TB & Leprosy?			
4.9	If yes to 4.8, by whom and when?			
4.10	If yes to 4.8 above, have you received supervision reports?			
4.11	If yes to 4.10, check copy of the reports:			
4.12	If there was no supervision, find out why:			

S/N	Supervisory questions					Yes	No	Comments/Remarks		
5-	Monitoring and Evaluation (for program management and/or Health Facility levels) cont ...									
4.13	Do you compile quarterly TBL and TB/HIV reports									
4.14	Do you receive correct and complete report from all the reporting units?									
4.15	The no. of reporting units that submitted TB & Leprosy quarterly report during previous quarter over the total no. of reporting units?									
	Zones:		Woredas:		HFs:		Remark:			
4.16	The no. of reporting units that submitted TB/HIV quarterly report during previous quarter over the total no. of reporting units?									
	Zones:		Woredas:		HFs:		Remark:			
4.17	Check the previous quarterly TB & Leprosy and TB/HIV reports for completeness & correctness of information:-									
	TB case-finding:-	Information complete:	Yes		No		Information correct:	Yes		No
	TB results of treatment:-	Information complete:	Yes		No		Information correct:	Yes		No
	Leprosy case-finding:-	Information complete:	Yes		No		Information correct:	Yes		No
	Leprosy results of treatment:-	Information complete:	Yes		No		Information correct:	Yes		No

S/N	Supervisory questions					Yes	No	Comments/Remarks		
	TB/HIV quarterly report:-	Information complete:	Yes	No		Information correct:	Yes	No		
4.18	Did you organize (or participate) review meeting specifically on TB, Leprosy and/or TB/HIV?									
4.19	If yes to 4.18 above, when was the last time?									
4.20	If yes to 4.18 above, did you prepare proceeding of the meeting?									
4.21	If yes to 4.20 above, check the proceeding of the review meeting:									
5-	Finance (for Program Management levels only):									
5.1	Do you receive money for TBL and TB/HIV activities?									
5.2	If yes to 5.1 above, from which source (indicate the source of fund, amount received and the date, amount utilized and for which activities, amount reported and the remaining balance):-									
6-	HEALTH FACILITIES (HOSPITALS, HEALTH CENTERS & GROWING HEALTH CENTERS)									
	GENERAL ABOUT THE TYPE OF SERVICES AVAILABLE IN THE HEALTH FACILITY:									
6.1	Type of TB services available in the HF:	Diagnostic & treatment services		Diagnostic services only		Treatment services only				
6.2	Type of Leprosy services available in the HF:	Diagnostic & treatment services		Diagnostic services only		Treatment services only				

S/N	Supervisory questions	Yes	No	Comments/Remarks
6.3	Does the health facility implement TB/HIV collaborative activities?			
REVIEW OF TBL & TB/HIV REGISTERS & RECORDS:				
6.4	Is the information in the TB unit register correct and complete?			
6.5	Is the information in the Leprosy patient record card correct and complete?			
6.6	Is the information in the Leprosy unit register correct and complete?			
HEALTH EDUCATION (HE):				
6.7	Do you give HE on TB to OPD attendants regularly?			
6.8	If yes to 6.7 above, how frequently?			
6.9	Do you give HE on Leprosy to OPD attendants regularly?			
6.10	If yes to 6.9 above, how frequently?			
6.11	Check the records of HE and verify:			
6.12	Do you use teaching aid tools when delivering HE messages?			
6.13	Do you give HE on TB & Leprosy to the community outside the HF?			
LABORATORY				
6.14	How many laboratory technicians are working in the laboratory?			
6.15	How many technicians are trained on AFB technique?			
6.16	Is the AFB smear microscopy and EQA manual available?			
6.17	If yes, check:			
6.18	Is the sputum specimen collection according to the guideline?			
6.19	Is the information in the AFB laboratory register correct & complete?			

S/N	Supervisory questions	Yes	No	Comments/Remarks
6.20	How many suspects have been examined during the previous quarter?			
6.21	Number of smear-positives among new suspects during the same period:			
6.22	Do you keep slides for blind re-checking?			
6.23	Do you send slides for blind re-checking?			
6.24	If yes to 6.23, who collects and transports the slides for the re-checking?			
6.25	How frequently do you send (or slides collected) for blind re-checking?			
6.26	When was the last time slides are collected (or sent) for rechecking?			
6.27	Do you receive feedback o regular basis?			
6.28	If yes to 6.27 above, check copies of feedbacks:			
6.29	Have you been supervised during the past 6 months?			
6.30	If yes to 6.29 above, by whom and when?			
6.31	Do you receive feedback reports?			
6.32	If yes to 6.31 above, check copies of reports:			
7	HEALTH POSTS (HP)			
7.1	Do you have a written guideline on TB and Leprosy?			
7.2	If yes to 7.1, check the availability of the guideline:			
7.3	If yes to 7.2, is the guideline clear & easy to understand for the HEWs?			
7.4	Have you been trained (in-service) specifically on TB and Leprosy?			
7.5	If yes to 7.4, when was the training and for how long?			
7.6	How many of you trained (in-service) specifically on TB & Leprosy?			
7.7	Did you find the training very useful for your TB & Leprosy work?			
7.8	What are the major symptoms of TB?			
7.9	What are the major symptoms of Leprosy?			

S/N	Supervisory questions	Yes	No	Comments/Remarks
7.10	Do you give HE on TB and Leprosy to the community?			
7.11	If yes to 7.10 above, check records:			
7.12	Do you conduct community conversation on TB and Leprosy?			
7.13	Do you identify and refer TB and leprosy suspects?			
7.14	If yes to 7.13, how many TB suspects have you identified and referred during the past 6 months?			
7.15	If yes to 7.13, how many Leprosy suspects have you identified and referred during the past 6 months?			
7.16	If they identify & refer suspects, check the records:			
7.17	Do you get feedback from HCs or Hosps. where suspects are referred to?			
7.18	Does the HP provide treatment for TB and Leprosy patients?			
7.19	If yes to 7.18 above, check the treatment registers:			
8-	Drugs, laboratory supplies and other Logistics			
	Check the availability of anti-TB drugs, MDT blisters and TB/HIV supplies for TB, Leprosy & TB/HIV patients during last quarter:-			
8.1	Is there shortage of anti-TB & MDT drugs and laboratory supplies?			
8.2	If yes to 8.1, which ones?			
8.3	Is there over stocks of anti-TB & MDT drugs and laboratory supplies?			

S/N	Supervisory questions	Yes	No	Comments/Remarks
8.4	If yes to 8.3 above, which ones?			
8.5	Are there expired anti-TB & MDT drugs?			
8.6	If yes to 8.5 above, write the drugs, expiry date and the quantity:			
	Check the availability of TBL and TB/HIV recording and reporting materials (RR):-			
8.7	Is there shortage of TB, Leprosy and TB/HIV RR materials?			
8.8	If yes to 8.7, which ones?			
9-	Drugs, laboratory supplies and other Logistics			
	Check the availability of TBL and TB/HIV IEC materials:-			
8.9	Do you have latest versions of IEC materials (print) on Tuberculosis?			
8.10	Do you have latest versions of IEC materials (print) on Leprosy?			
	Check the availability of POD materials:-			
8.11	Do you receive canvas shoes for leprosy patients during the past 12 months?			
8.12	If yes to 9.11 above, do you distribute them to needy patients?			
8.13	If yes to 9.12, check records for the distribution of canvas shoes to patients:			
8.14	Pairs of canvas shoes currently in store (if any):			

Follow up of the previous recommendations	Follow up of the previous recommendations
STRENGTHS	WEAKNESSES
PROBLEMS AND CHALLENGES	RECOMMENDATIONS
SUPERVISORY TEAM MEMBERS	SIGNATURE
1-	
2-	
3-	