TUBERCULOSIS CASE DETECTION AMONG HIV POSITIVE PERSONS IN A HOSPITAL IN ETHIOPIA

by

Tedla Mezemir Damte

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ABSTRACT

Collaborative TB/HIV management is essential to prevent and treat TB among HIV-positive TB patients, and to ensure that HIV-positive TB patients are detected and treated appropriately.

This quantitative, descriptive, contextual study identified problems encountered during the implementation of TB case detection among HIV-positive individuals in one Ethiopian hospital. During December 2012, 300 checklists were completed about HIV-positive patients' TB/HIV collaborative management, as reflected in their files.

Only 60.2% of HIV-positive patients, who should have received Isoniazid preventive treatment (IPT), were placed on this treatment. X-rays and laboratory examinations of sputum samples were not done according to the Ethiopian guidelines. Most TB patients’ initial screening was done by nurses, not doctors, and included only symptom screening without CD4 count considerations.

Managers and healthcare personnel should improve IPT, especially for those with early HIV infection and timely effective treatment for those suffering from TB, before complications arise.

Keywords: Isoniazid preventive treatment (IPT), TB case detection, TB/HIV collaborative management, TB and HIV in Ethiopia
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DEDICATION

I dedicate this research to my forever missed late parents (Mezemir Damte and Tsehay Atera) as well as to Zelalem Mezemir. I wish you were alive to see this. Let God keep your souls in peace.
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CHAPTER 1
INTRODUCTION AND BACKGROUND INFORMATION

1.1 INTRODUCTION

Tuberculosis (TB) is a chronic infectious disease caused by Mycobacterium Tuberculosis (MTB), an acid-fast bacillus (AFB), which is rod-shaped (WHO 2011:3). Transmission of this infection occurs through the airborne spread of droplets containing bacilli expelled by infected persons' coughing and sneezing, which are then inhaled by other persons. In general, a relatively small proportion of people infected with MTB will develop the TB disease. However, the probability of developing TB is much higher among people infected with the human immunodeficiency virus (HIV) (WHO 2011:3). In 2010, there were 8.8 million incident cases of TB globally, 1.1 million deaths from TB among HIV-negative people, and an additional 0.35 million deaths from HIV-associated TB. During the same year, there were 5.7 million notifications of new and recurrent cases of TB, equivalent to 65% of the estimated number of incident cases in 2010. India and China accounted for 40% of the world’s notified cases of TB in 2010, Africa for a further 24%, and there were 22 high-TB burden countries (HBCs), accounting for 82% of TB cases, according to estimates from the World Health Organization (WHO 2011:10).

According to the WHO (2011:3), despite the decades-long availability of highly effective anti-TB treatment, TB remains a major global health problem. In 1993, the WHO declared TB a global public health emergency, at a time when an estimated 7–8 million TB cases and 1.3–1.6 million TB deaths were occurring each year. In 2010, there were an estimated 8.5–9.2 million cases and 1.2–1.5 million deaths (including deaths from TB among HIV-positive people), according to the WHO (2011:3). TB is the world’s second deadliest infectious disease, after HIV, which for its part caused an estimated 1.8 million deaths in 2008. However,
if TB is detected early and treated effectively, people with TB can become non-
infectious within 72 hours and can be effectively cured after six months’
treatment. Today, multidrug-resistant TB (MDR-TB) and extensively drug-
resistant TB (XDR-TB), HIV-associated TB, and weak healthcare systems pose
major challenges for the effective implementation of TB control programmes

According to the WHO (2011:10), about 13% of TB cases occur among people
living with HIV. TB is strongly associated with HIV, because HIV leads to
progressive immune deficiency and increased susceptibility to infections,
including TB. The WHO (2007a:36) has stated that HIV increases susceptibility
to infection with MTB, and that HIV also increases the risk of MTB’s rapid
progression. This risk increases with progressive immune suppression. HIV not
only increases the risk but also the rate of progression of recent or latent MTB
infections into the TB disease. The annual risk of developing TB, amongst people
living with HIV (PLWHIV) for those co-infected with MTB, has reached 50.0%, as
compared to a 5-10.0% life-time risk for HIV-negative individuals. HIV also
increases the likelihood of TB re-infections and relapses (WHO 2007a:38).

According to the WHO (2011:29) a definite case of TB is defined as a patient with
MTB identified from a clinical sputum specimen, either by culture, or by a newer
method such as molecular line probe assay. In countries that lack the laboratory
capacity needed to routinely identify MTB, a pulmonary case with one or more
initial AFB positive sputum specimens is also considered to be a “definite” case,
provided that there is functional external quality assurance, including the blind re-
checking of laboratory results.

According to WHO (2007b:38) , the prevalence and mortality of all forms of TB
(pulmonary and extra-pulmonary TB combined) is estimated to be 546 and 73
per 100 000 of the population respectively.
1.2 BACKGROUND INFORMATION

The African region has the world’s highest TB incidence rate per capita of 363 per 100 000 persons (WHO 2008a:1). According to the Ethiopian Federal Ministry of Health (FMoH: 2008b:3), Ethiopia stands at seventh place in a global ranking by estimated number of pulmonary TB (PTB) cases, and during the years 2006 and 2007, Ethiopia registered a total of 129 743 cases of TB. The estimated incidence of TB in Ethiopia is 152 and 341 per 100 000 persons for new smear positive pulmonary and all forms of TB respectively. TB has been recognised as a major public health problem since the 1950s and remains a major public health problem in many countries, including Ethiopia. After the introduction of a National TB Control Programme (NTP) by the WHO, Ethiopia adopted, and subsequently instituted, the National TB Control Programme in 1976 (FMoH 2005:1). Since then, the rate of TB case detection has increased, treatment and immunisations have been scaled up, and the disease pattern has started to decline in this country. As part of a global movement to eradicate TB, the possibility of eradicating TB also appeared to be on the horizon in Ethiopia.

Since Ethiopia detected two cases of Acquired Immune Deficiency Syndrome (AIDS) in 1984, the HIV and TB epidemics in the country have grown rapidly. The HIV epidemic started to fuel TB, and TB continues to be one of the top causes of mortality in Ethiopia (FMoH 2008a:12). According to the FMoH (2012:43), approximately 41% of newly identified HIV-positive TB cases received treatment for both TB and HIV in 2009 and 2010. Routinely collected health facility data from 2010 indicate that 43% of notified TB patients were tested for HIV, and 15% had HIV co-infection. Among the identified HIV positive TB patients, 69% were given co-trimoxazole prophylactic (CPT) therapy, while 39% were given highly active anti-retroviral therapy (HAART). In addition, 44% of HIV-positive patients were screened for TB, and 6.6% of HIV-positive patients were provided with isoniazid prophylactic therapy (IPT).
The main objectives of TB case detection are to cut the chain of transmission and to start earlier and more effective treatment (FMoH 2008b:25). All suspected cases of any form of TB must be examined according to standardised diagnostic procedures, of which the microscopic examination of sputum is the most important and reliable. By rank of importance the diagnostic methods used to confirm or exclude TB are microscopic examination of sputum smears, radiological investigation, acid-fast bacillus (AFB) culture, and histo-pathology, all of which are available in Ethiopia (FMoH 2008b:25).

No part of the world has been spared from the HIV/AIDS epidemic. In Ethiopia the adult prevalence of HIV was estimated to be 2.2% in 2008; the prevalence rates among the urban and rural populations were estimated at 7.7% and 0.9% respectively (FMoH & FHAPCO 2007b:6). The total number of PLWHIV in the same period was estimated to be 1 037 267 adults and 68 136 children. The estimated number of PLWHIV in Ethiopia in need of ART in 2008 was 289 734 adults and 17 274 children under the age of 14 (FMoH & FHAPCO 2007c:6).

Based on lessons learned from the promotion of the HIV testing (ProTEST) model, a WHO project piloted and used voluntary counselling and testing (VCT) as an entry point in three countries of sub Saharan Africa (SSA) with a high HIV prevalence and TB burden. The WHO subsequently appealed to four SSA countries, including Ethiopia, with a high HIV prevalence and TB burden to introduce and implement TB/HIV co-management programmes by the end of 2001 (FMoH & FHAPCO 2007c:13). The FMoH expressed its commitment to the WHO’s call, and co-ordinated the establishment of a TB/HIV advisory committee in 2002. The TB/HIV implementation programme in Ethiopia was then piloted at nine sites which served as testing grounds for the development of training materials, recording and reporting formats, referral systems, and TB/HIV implementation guidelines. During August 2007, TB/HIV collaborative activities were implemented in 138 hospitals and 280 health centres and private clinics providing ART services throughout Ethiopia (FMoH & FHAPCO 2007c:12).
According to the FMoH and FHAPCO (2007b:1), one hospital in the Oromiya region was one of the pilot sites for the implementation of the TB/HIV collaborative activities in Ethiopia (FMoH 2006:12). According to this hospital’s data, this HIV clinic attends to an average of five new PLWHIV and 150 follow up PLWHIV each day, totalling 155 patients per day. In this study, the researcher will assess TB case detections among PLWHIV at this hospital by reviewing the records of HIV patients who had been diagnosed at least six months prior to the date of data collection.

The main objective of the WHO and the FMoH TB/HIV Guidelines are to establish a co-ordinating mechanism for TB and HIV programmes and to increase the detection of TB among PLWHIV and the vice versa (WHO 2008a:1; FMoH & FHAPCO 2007c:9).

According to the WHO (2008a:1) and the FMoH and FHAPCO (2007c:10), the guidelines for collaborative TB/HIV management include the following twelve activities:

- Setting up a coordinating body for TB/HIV activities effective at all levels
- Carrying out joint TB/HIV planning
- Conducting monitoring and evaluating processes
- Establishing intensified TB case-finding
- Ensuring TB infection control in healthcare and congregate settings
- Conducting surveillance of HIV prevalence among TB patients
- Introducing Isoniazid Preventive Therapy (IPT) for all PLWHIV
- Providing HIV testing and counselling to all TB patients
- Introducing HIV prevention methods
- Introducing co-trimoxazole preventive therapy (CPT) for all PLWHIV
- Ensuring HIV/AIDS care and support
- Introducing ART when the patient is eligible for treatment
According to the Ethiopian TB/HIV Guidelines (FMoH & FHAPCO 2007b:23), an HIV-positive patient is eligible to start IPT after excluding active TB (requiring effective TB treatment). Regular screening for TB among HIV-positive patients, at every stage of the disease, is one of the key TB/HIV collaborative activities (FMoH 2008a:25), with the aim of reducing the burden of TB in PLWHIV. Screening for TB is conducted at HIV clinics. Based on the result of this screening, patients will start TB prophylaxis with Isoniazid (INH) if the screening result is negative, or will be referred to a TB clinic for effective treatment of TB if the HIV patient is diagnosed as suffering from TB.

1.3 RESEARCH PROBLEM

According to the WHO (2011:28), between 1995 and 2010, 55 million TB patients were treated in TB national programmes that had adopted the DOTS/Stop TB Strategy; 46 million (83.6%) of these people were successfully treated. These treatments saved an estimated 6.8 million lives compared with the pre-DOTS standard of care. In 2010, 34% of notified TB patients knew their own HIV status. The highest rates of HIV co-infection in TB patients are in the African Region, where 44% of TB patients, who had used VCT services, were HIV-positive in 2010. The global coverage of ART for TB patients living with HIV remains low (only 46%), despite the large increase in HIV testing among TB patients, and the WHO recommendation that ART should be provided to all TB patients living with HIV regardless, of their CD4 cell count (WHO 2011:59).

Ethiopia is one of the worst affected countries by the TB/HIV co-epidemic. The WHO Global Report 2008 estimated that in Ethiopia 40% of TB patients tested for HIV were HIV-positive, while routine data from health facilities indicated that 31% of TB patients were HIV-positive (FMoH 2008a:73). No obvious explanation could be found from available reports to explain this apparent discrepancy in estimates of HIV prevalence among TB patients.
According to the FMoH (2008:3), Ethiopia has reached a 36% rate of TB case detection and an 85% rate of treatment outcome targets. The WHO’s standards require 70% case detection and 85% treatment outcome rates. Ethiopia has adequate treatment outcomes for TB patients, but the rate of case detection remains below the WHO standard (FMoH 2008b:1, 4; WHO 2011:13, 28).

This study’s research problem could thus be summarised as: Ethiopia’s TB/HIV collaboration guidelines specify that HIV-positive patients should be screened for TB. It is unknown to what extent this activity is implemented and, if implemented, the outcomes of such screening activities are unknown. Consequently, this study will investigate HIV patients’ referrals for TB screening and subsequent TB diagnoses and treatment at one hospital in Ethiopia.

1.4 RESEARCH QUESTIONS

The researcher posed the following research questions:

- What problems are encountered during the implementation of the TB/HIV guidelines at one hospital in Ethiopia?
- Are TB case detections among HIV-positive persons conducted according to the TB/HIV co-management guidelines?
- What diagnostic procedures are used to detect TB among HIV-positive persons?
- How long after being diagnosed as HIV-positive was a patient referred for TB investigations?

1.5 PURPOSE OF THE STUDY

The purpose of this study was to identify the procedures followed to implement TB case detection among HIV-positive persons at one hospital in Ethiopia. The time and type of TB diagnostic procedures were examined, as well as the prescribed anti-TB treatment. Based on the findings of this study,
recommendations might be provided for the improvement of existing TB/HIV management guidelines. In addition, the findings might be of value for improving TB diagnosis amongst HIV-positive persons, and for increasing the number of HIV-positive patients referred for effective TB treatment at the participating hospital.

1.6 RESEARCH OBJECTIVES

Specific objectives of this study were to:

- Identify problems encountered during the implementation of the TB/HIV guidelines at one hospital in Ethiopia
- Assess whether TB case detections among HIV-positive persons are conducted according to the TB/HIV management guidelines
- Identify what diagnostic procedures have been used to detect TB among HIV-positive persons
- Identify how long after being diagnosed as HIV-positive a patient was referred for TB investigations.

1.7 ASSUMPTIONS UNDERLYING THE STUDY

According to Shields and Tajalli (2006), conceptual frameworks include working hypotheses, descriptive categories, practical ideal types, models of operations research, and formal hypotheses. The objectives of this study and the TB/HIV guidelines provided by the WHO and FMoH formed the basis for the conceptual framework and assumptions underlying this study.

This framework guided the research process. For adequate TB case detection, it is reasonably assumed that all PLWHIV registered at a specific HIV clinic must receive TB screening, proper recording, and follow-up treatment and
consultations. These assumptions framework were adopted for the logical organisation of data collection during this study’s review of the patients’ records.

1.8 SIGNIFICANCE OF THE STUDY

This study was deemed to be valuable for the following reasons:

- This study might contribute to the existing body of knowledge related to TB diagnosis of HIV-positive persons at one hospital in Ethiopia, as well as about the referral of HIV patients for TB screening, diagnosis and treatment.
- It could also provide information about the outcomes of INH prophylaxis and TB treatment for specific HIV-positive persons
- Recommendations could be made, based on the research findings, that might contribute to the enhancement of TB case detection among HIV-positive persons, as well as the improvement of TB/HIV collaborative services provided at one hospital in Ethiopia.
- Ultimately, TB treatment and INH outcomes amongst HIV-positive persons could be improved with benefits for the patients concerned and considerable savings for Ethiopia’s healthcare services.

1.9 RESEARCH METHODOLOGY

This study adopted a quantitative, descriptive, and contextual research design in so far as the researcher was interested in analysing quantifiable data available from the HIV positive patients’ files.

1.9.1 Study design

This study was descriptive in nature because the researcher observed a situation (the referral of HIV-positive persons for TB screening) and then described what
had been observed (Donald et al 2010:27). The description of the phenomenon covered TB diagnosis among HIV-positive patients in one hospital in Ethiopia. This study was a formal, objective, systematic quantification used to describe a situation (Burns & Grove 2005:44), comprising reviews of records of registered HIV-positive patients to identify whether their TB screening had been conducted in accordance with Ethiopia’s TB/HIV collaborative guidelines. Statistics were used to summarise and describe the data.

1.9.2 Research setting

The researcher conducted the study at one of the nine Ethiopian public health facilities where TB/HIV collaborative management has been piloted since 2005. The patients who received TB/HIV co-management services at this hospital came from diverse backgrounds in terms of race, religion, gender, education, geography, and income.

1.9.3 Research population

A research population is the full data set on which the researcher focuses. The site population for this study would comprise all hospitals and all clinics providing services to HIV-positive patients in Ethiopia.

1.9.4 Sample and sampling technique

Sampling is the process of selecting a portion of the population to represent the entire population and a sampling design refers to decisions concerning whether probability (random) or non-probability (non-random) sampling will be done (Polit & Beck 2004:291).

According to Polit and Beck (2004:292), probability sampling is more respected because of the greater veracity placed on the representativeness of probability
samples. Probability sampling constitutes a random selection of elements from a population. Random sampling involves a selection process in which each element in the population has an equal, independent chance of being selected (Polit & Beck 2004:295). In this study, simple random sampling was used to select the records of HIV positive persons visiting the participating clinic during the month of data collection.

Simple random sampling was implemented on a daily basis. The numbers of all files, belonging to patients who visited the clinic on a specific date, were written on slips of paper and placed into a container. An independent individual was asked to draw 15 numbers blindly from this container. These 15 files were acquired and checked. If any patient was younger than 18, or had been diagnosed as being HIV-positive less than six months prior to the date of data collection, these files were excluded from the sample and additional numbers were drawn blindly from the container until 15 files had been selected for every day.

Only one HIV clinic at one hospital in Adama, Ethiopia, participated in this study. This clinic has been offering TB/HIV collaborative services since 2002 and was intentionally selected as it offers services to about 3,000 follow-up and 100 new PLWHIV per month, and it has been implementing TB/HIV collaborative services for ten years.

A sample size of 300 patients’ files was used, equivalent to 10% of the estimated 3,000 follow-up HIV patients who visit this clinic on a monthly basis.

1.9.5 Data collection instrument

A pre-tested checklist was used as a research instrument to collect information. The checklist had three sections. The first section was biographic. The second section collected information about TB screening and diagnosis. The third section
investigated whether HIV patients had been properly screened, diagnosed, and treated for TB at the HIV clinic.

The validity and reliability of this study’s checklist will be discussed in chapter 3 of this dissertation.

1.9.6 Data collection

Record reviews were the primary data sources for this study. The researcher numerically assigned a number to each checklist (ranging from 001 to 300) before commencing data collection. The researcher kept a list indicating the checklist number and the corresponding patient’s HIV file number in an Excel sheet. Only the researcher had access to this list, the hard copy was kept locked-up, and the MS Excel version was protected by a secure password on a computer to which only the researcher and the statistician had access. After their numerical assignment, the following information was transcribed from the HIV registers onto the checklists:

- Demographic profiles: age, gender, educational status, address of the patient, and marital status.
- Was the HIV-positive patient screened for TB?
- Was the HIV-positive patient referred from the HIV clinic to the TB clinic for treatment?
- When was the first TB screening conducted?
- What tests were used for TB screening?
- Which category of healthcare professional performed the TB screening?
- Which category of healthcare professional made a TB or non-TB diagnosis?
- Was the patient eligible for TB treatment?
- Was he/she treated for TB?
- What was the outcome of the TB treatment?
• Did the patient receive INH prophylaxis?
• If INH prophylaxis was administered, what was the outcome?

1.9.7 Data analysis

The data collected in this study were analysed using the Statistical Package for the Social Sciences (SPSS) version 17. The analysis comprises descriptive statistics such as frequency tables and graphs, chi-squares, p-values, and correlations (Pearson rho) to summarise and describe the data. The researcher entered the data into SPSS version 17 and a statistician checked the data entries from the completed checklists and assisted the researcher in calculating and interpreting the relevant statistics.

1.10 ETHICAL CONSIDERATIONS

According to David (2010:12), ethics provide guidelines for fair treatment of people participating in research. This quantitative study used self-designed checklists, completed by the researcher, to record from the patients' files. A list of each patient’s file, and his/her correlated respondent number, have been kept under lock and key by the researcher in case the healthcare service or participating hospital authorities might wish to recheck the study’s findings. No patient’s name and no healthcare worker’s name has been mentioned. In addition, neither the participating HIV clinic’s name, nor the hospital’s name, were mentioned in any report to avoid ethical issues.

After completion of the research, the researcher will provide recommendations based on his research findings to the hospital studied. Subsequent to the acceptance of the research report, all information recorded on hard copies and electronically will be destroyed by the researcher.
1.10.1 Anonymity and confidentiality

No names were provided on the completed checklists, but each checklist had a specific respondent number (001-300). The researcher kept a separate list indicating the patient’s file number opposite the respondent number, in case any audit of the recorded data might be required by the healthcare authorities or by the examiners of this dissertation.

Only the researcher had access to this list which was kept under lock and key and would be destroyed after the acceptance of this research report. The MS Excel list was protected by a secure password on a computer to which the researcher had sole access. This list would be deleted (and again deleted from the ‘deleted items’ section of the computer) as soon as the hard copy had been printed and locked up. The participating hospital’s name was not mentioned in any report.

1.10.2 Ethical approval

The research proposal was submitted to the Higher Degrees Committee of the Department of Health Studies, University of South Africa (Unisa), and obtained ethical approval. Thereafter, permission was received from the management of the participating hospital and Provincial Ministry of Health administration where the study was conducted (please see Annexure C).

1.11 SCOPE AND LIMITATIONS OF THE STUDY

The participating hospital is situated in an urban area, in Adama, about 100 km from Addis Ababa, the capital city of Ethiopia. As a result, problems with out-of-stock supplies, such as medicines, might be minimal compared to other hospitals and clinics in Ethiopia.
Only hospital records were used to produce information about the TB diagnosis of HIV-positive persons. However, these records might not reflect all of the actual screening, diagnostic, treatment, and referral procedures. For the purpose of this study, treatment not recorded was considered as treatment not administered. Only the recorded aspects could be examined and this depended on the completeness of the hospital’s records. Incomplete records might have impacted on the reliability of the findings.

Interviewing healthcare service providers and HIV-positive patients might have revealed different results, but interviews could not be conducted within the limited time and financial constraints applicable to this dissertation. (During the study the researcher was transferred to another country and could thus not conduct interviews).

1.12 DEFINITIONS OF KEY CONCEPTS

The following terms have been used throughout this dissertation and their meanings are defined in order that the researcher and readers could share the same understanding of these concepts.

A Pulmonary TB case refers to a patient with TB disease involving the lung parenchyma (WHO 2011:29).

A TB case implies a definite case of TB is one in which a healthcare worker has diagnosed TB according to the NTG and treated the patient with a full course of TB treatment (WHO 2011:29).

New TB case is a patient who has never had treatment for TB or who has taken anti-TB drugs for less than one month (WHO 2011:29).
A smear-negative pulmonary TB case implies that a patient with PTB does not meet the criteria for smear-positive TB. Diagnostic criteria should include at least two sputum smear examinations negative for AFB, radiographic abnormalities consistent with active pulmonary TB, no response to a course of broad-spectrum antibiotics (except in a patient for whom there is laboratory confirmation or strong clinical evidence of HIV infection), and a decision by a clinician to treat a patient with a full course of anti-TB chemotherapy. A patient with a positive culture, but a negative AFB sputum examination, is also a smear-negative case of PTB (WHO 2011:29).

A smear-positive pulmonary TB case refers to a patient who has one or more initial sputum smear examinations (direct smear microscopy) AFB-positive; or one sputum examination AFB-positive and radiographic abnormalities consistent with active pulmonary TB as determined by a clinician. Smear-positive cases are the most infectious, and thus of the highest priority, from a public health perspective (WHO 2011:29).

1.13 LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>AFB</td>
<td>Acid-Fast Bacillus</td>
</tr>
<tr>
<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
</tr>
<tr>
<td>ART</td>
<td>Anti-retroviral therapy</td>
</tr>
<tr>
<td>CD4</td>
<td>Cluster of Differentiation 4</td>
</tr>
<tr>
<td>CPT</td>
<td>Co trimoxazole Prophylaxis Therapy</td>
</tr>
<tr>
<td>DOTs</td>
<td>Directly Observed Treatment – Short Course</td>
</tr>
<tr>
<td>EPTB</td>
<td>Extra-pulmonary Tuberculosis</td>
</tr>
<tr>
<td>FHAPCO</td>
<td>Federal HIV/AIDS Prevention and Control Programme</td>
</tr>
<tr>
<td>FMoH</td>
<td>Federal Ministry of Health</td>
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<tr>
<td>HAART</td>
<td>Highly Active Anti-retroviral Therapy</td>
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<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<tr>
<td>INH</td>
<td>Isoniazid</td>
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1.14 ORGANISATION OF THE REPORT

This dissertation has been organised according to the following five chapters.

Chapter 1 introduced the study and provided background information about TB and HIV/AIDS in the world, SSA, Eastern Africa, and Ethiopia in particular. It also highlighted the provision of TB/HIV co-management and HAART in Ethiopia.

Chapter 2 discusses the literature reviewed on TB case detection among HIV-positive patients and TB/HIV management.
Chapter 3 describes the research methodology used in collecting data for this study.

Chapter 4 presents an analysis of the data collected and a broader discussion of the study’s findings.

Chapter 5 discusses the conclusions and limitations of this study and provides recommendations for enhancing TB case detection among HIV-positive patients, suggestions for improving TB/HIV co-management, and for conducting similar studies in future.

1.15 SUMMARY

This chapter provided background information on TB and HIV/AIDS internationally, continentally, regionally, and at country level (in Ethiopia). The following topic areas were discussed in detail: the research problem, research questions, purpose of the study, research objectives, assumptions underlying the study, significance of the study, research methodology, scope and limitations of the study, definitions of key concepts, organisation of the report, and its conclusion.

Chapter 2 presents a wider discussion of the relevant literature reviewed related to this study’s research questions and pertaining to TB/HIV co-management globally, in SSA, and in Ethiopia.
CHAPTER 2
LITERATURE REVIEW

2.1 INTRODUCTION

The literature review covers published and unpublished reports related to TB/HIV, HIV/AIDS, TB, ART, TB case detection among PLWHIV, and factors associated with TB/HIV collaborative management. Reviewed documents were obtained from WHO publications, articles, series publications and journals, documents from the FMoH (published and unpublished), TB/HIV-related websites, and journals such as the official *Journal of the International AIDS Society*, *Brazilian Journal of Infectious Diseases*, *American Journal of Respiratory and Critical Care Medicine*, and the *International Journal of Tuberculosis and Lung Disease*. The literature review covered the period from 2002 to 2012.

2.2 TB/HIV CO-MANAGMENT

Key concepts of the literature review included: TB case detection among PLWHIV, TB/HIV collaborative management, HAART and TB- DOTS (directly observed treatment – short course), cotrimoxazole prophylaxis therapy (CPT), isoniazid prophylaxis treatment (IPT), HIV voluntary counselling and testing (VCT), measurement and indicators of TB/HIV collaboration, and factors affecting TB/HIV co-management.
2.2.1 Definitions

The terms ‘TB/HIV initiative,’ ‘TB/HIV collaborative activities,’ and ‘TB/HIV co-management’ are used interchangeably by different authors, and this practice will be followed in this dissertation.

The terms ‘TB case detection among PLWHIV,’ ‘TB screening among PLWHIV,’ and ‘TB tracing among PLWHIV’ are also used interchangeably by different authors, and this practice will also be followed in this dissertation.

According to the WHO and Constella Futures (2007e:6), the phrases ‘TB/HIV’ and ‘HIV/TB’ are commonly used to indicate the intersecting epidemic of TB and HIV. A third of the world’s population is infected with MTB, the bacterium that causes TB. In 2011, there were an estimated 8.7 million new cases of TB, and among these 13% were co-infected with HIV (WHO 2012:2). The term TB/HIV refers to this intersection.

Collaborative TB/HIV activities are activities recommended by the interim policy of the WHO on TB/HIV to address the dual epidemic of TB and HIV. These activities aim to create mechanisms of collaboration between TB and HIV/AIDS programmes, reduce the burden of TB among PLWHIV, which includes TB screening among PLWHIV, and to reduce the burden of HIV among TB patients (WHO 2004a:2). The WHO and Constella Futures (2007e:10) categorise countries according to their TB/HIV collaborative activities. These include:

- Category I: Countries in which the national adult HIV prevalence rate is greater than or equal to 1% (generalised epidemic level) or in which the national HIV prevalence among a certain population group (such as TB patients or injected drug users) is greater than or equal to 5% (concentrated epidemic level). These countries should implement all 12
collaborative TB/HIV activities, as mentioned in chapter 1 of this dissertation. Ethiopia has been categorised into this group.

- Category II: Countries in which the national adult HIV prevalence rate is below 1%, but in which there are administrative areas with an adult HIV prevalence rate of greater than or equal to 1%. These countries should implement all collaborative TB/HIV activities in those administrative areas with an adult HIV prevalence rate of 1% or greater, and should implement activities as category III countries in other parts of the country.

- Category III: Countries in which the national adult HIV prevalence rate is below 1% and in which there are no administrative areas with an adult HIV prevalence rate of greater than or equal to 1%. These countries should implement the activities aimed at decreasing the burden of TB in PLWHIV (intensified TB case finding, IPT, and TB infection control in healthcare and congregate settings).

The WHO interim policy on collaborative TB/HIV activities does not call for the creation of new specialists or disease control programmes that would address TB/HIV co-management. Instead, the argument is made that simple collaboration between TB and HIV/AIDS disease programmes, in place of creating a new separate disease control programme or integrating the two programmes, should be the main method used to deliver collaborative TB/HIV activities (WHO and Constella Futures 2007e:11; WHO 2004a:4).

The term ‘public private mix’ (PPM) refers to the practice of engaging private health care providers of TB/HIV activities in areas with high HIV prevalence in order to take advantage of their potential to scale-up collaborative TB/HIV activities (WHO 2008e:12). According to the FMoH (2006:1), the term ‘PPM TB/HIV’ is defined as public private and public-public partnerships established to enhance TB/HIV implementation. This approach reduces the time between
diagnosis and treatment as well as the costs of treatment provided to patients by eliminating or reducing the common practice of “shopping” for care. PPM can also cut costs to patients by reducing transport expenses and ensuring free drugs and other services (WHO 2008e:8) closer to their homes and/or jobs than would have been the case without such collaborations.

2.2.2 The concept of TB/HIV co-management and TB case detection among PLWHIV

Tuberculosis (TB) is a leading cause of death among PLWHIV. At least one in four deaths among PLWHIV can be attributed to TB, and many of these deaths occur in areas with limited resource access (WHO 2010:3). Collaborative TB/HIV activities are essential to prevent, diagnose, and treat TB among people with HIV and HIV among TB patients, and to ensure that HIV-positive TB patients are identified and treated appropriately. In recent years, the implementation of collaborative TB/HIV activities has been rising globally (WHO 2010:3; FMoH & FHAPCO 2007a:15).

According to the WHO (2011:65), until 2010 data on intensified screening for TB among people living with HIV and the provision of IPT to those without active TB, were requested from national TB programmes (NTPs) on global TB data collection forms. It has been noted that the monitoring of access to these two interventions at the country level was weaker than for other interventions, such as ART.

Moreover, the WHO (2009f:1) has also posited that “… the unprecedented scale of the HIV-related TB epidemic demands urgent, effective, and coordinated action in order to improve diagnostic, care, and prevention services for people living with HIV and TB”. According to the WHO, however, this does not require the development of an independent programme for TB/HIV, but rather closer
collaboration between existing TB and HIV control programmes to exploit synergies, avoid overlap, and address gaps in the services provided. In locations where HIV fuels the TB epidemic, collaborative TB/HIV activities are intended to reduce the latter disease by expanding the scope of TB and HIV control programmes and by improving the quality of provided services. An increasing amount of resources is being allocated to collaborative TB/HIV activities. In many countries, innovative pilot projects are in the process of being replaced by scaled-up national TB/HIV activities (FMoH 2007b:11).

The WHO reports (2008d:1) have included the provision that as resource-limited countries rapidly expand their HIV/AIDS treatment and care programmes, TB/HIV is becoming a major public health threat for people living with HIV. Among PLWHIV, TB is the most frequent possible life threatening opportunistic disease, even for those receiving ARVs. It remains a leading cause of death.

TB control requires and complements the implementation of core HIV control interventions and the strengthening of health care systems. In addition, it has been recommended that countries should include TB infection control in their national infection prevention and control policies, and should maximise synergies between programmes that deal with infection prevention and control, especially in the case of those focusing on TB and HIV control (WHO 2009:1).

The WHO (2011:68) guidelines recommend TB screening that includes four symptoms (current cough, fever, weight loss, and night sweats), as well as the provision of IPT if these symptoms are absent. This symptom-based screening method has been found to be very effective in accelerating TB screening in settings where the prevalence of TB among people living with HIV is 5% or higher.
2.2.3 Goals of TB case detection among PLWHIV

The goal of TB case detection among PLWHIV is to detect TB as early as possible and provide treatment or prophylaxis to reduce mortality. The WHO has reported that efforts will need to be intensified in order to approach the Global Plan’s target of providing TB screening to all those enrolled in HIV care and providing IPT to all eligible patients using HIV services by 2015 (WHO 2011:65). The WHO has also argued (2009f:4) that the goal of collaborative TB/HIV activities should be understood as the reduction of TB and HIV’s scale and scope in populations affected by both diseases. This is to be done through an expansion of TB and HIV control programmes. The WHO’s objectives that underlie this goal are to establish mechanisms for collaboration between TB and HIV control programmes, to reduce the burden of TB amongst people living with HIV, and to reduce the burden of HIV amongst TB patients.

People living with HIV are more likely to be infected with EPTB or sputum smear-negative TB, especially as their immune-suppression advances. This can result in misdiagnosis and delayed diagnosis, and, in turn, higher mortality rates. Irrespective of the epidemic’s location, the WHO recommends HIV testing for all patients of all ages who arrive at a clinic with signs or symptoms that suggest TB, whether or not TB is suspected or has already been confirmed (WHO 2004b:75; WHO 2007b:46; WHO 2008a:46).

2.2.3.1 Establishing mechanisms for TB case detection among PLWHIV

TB case detection among PLWHIV could be made operational through the establishment of mechanisms for TB/HIV collaboration. According to the Republic of Tanzania’s Ministry of Health (RTMoH 2008:7), for example, all patients at HIV clinics should be screened for TB during each visit, and referred to the laboratory for diagnosis if TB is suspected. If TB is diagnosed, the patient should be referred to a TB clinic for treatment. At TB clinics, moreover, TB
patients should be tested for HIV, while making sure that they are treated first for TB and then assessed for ART by HIV officers.

The Ethiopian TB/HIV Guidelines (FMoH & FHAPCO 2007a:23) also mandate regular TB screening among HIV-positive patients at every stage of the disease (FMoH 2008a:25). This is aimed at reducing the burden of TB among PLWHIV. An HIV-positive patient is eligible to start IPT after the exclusion of active TB (which would require immediate TB treatment). TB screening is conducted at HIV clinics. Based on the results of this screening, patients will start TB prophylaxis with INH if the screening result is negative, or will be referred to a TB clinic for immediate TB treatment if the HIV patient is diagnosed as suffering from TB.

National and international bodies have additionally made the case that TB/HIV collaboration treatment can also be established through coordinating bodies, as well as through surveillance of HIV conducted among TB patients, joint planning, and monitoring and evaluation of treatment methods (WHO 2009f:5).

2.2.3.2 Decreased burden of TB among HIV-positive persons

Meta-analyses of randomised controlled trials (RCTs) have shown that, when compared to placebos, TB therapy (comprising any anti-TB drugs) reduces the risk of active TB by 32% amongst PLWHIV (relative risk [RR] 0.68, 95% confidence interval [CI]: 0.54 to 0.85), and by 62% (RR 0.38, 95% CI: 0.25 to 0.57) amongst those who are tuberculin skin test positive. IPT reduces the risk of TB by 33% (RR 0.67, 95% CI: 0.51 to 0.87) among HIV-positive patients with both positive and negative skin tests, and by up to 64% (RR 0.36, 95% CI: 0.22 to 0.61) among those with positive tuberculin skin tests (WHO 2010:5).

Data from the WHO (2010:18) have demonstrated the risks of TB-associated immune reconstitution inflammatory syndrome (IRIS), which is an ART-related
complication. High incidence rates of identified TB during highly active anti-retroviral therapy (HAART) programmes in resource-poor countries have also been observed. These rates are likely to include both undiagnosed latent TB existent at the time of HAART initiation, and subclinical TB that developed during the IRIS period. IRIS is a well described condition that commonly follows the initiation of HAART in PLWHIV who are also harbouring chronic intracellular infections. It has been described together with MTB and usually manifests itself within 2-11 months with a particular set of symptoms (WHO 2004b:154; WHO 2010:18).

Mortality rates from TB are higher among HIV-positive than among HIV-negative patients (WHO 2009b:67). Case-fatality is particularly high among people living with HIV together with smear-negative PTB and EPTB, as these patients are generally more immune-suppressed than those with smear-positive TB. However, case-fatality rates have been reduced among TB patients who received concurrent ART and anti-TB treatment (WHO 2009b:68). IPT has also been determined to be effective among people living with HIV because it reduces the risk of developing active TB (WHO 2009c:12). The incidence of TB also decreased in HIV-positive patients receiving ART.

Health workers are more exposed to TB than the general population. As a result, HIV-positive health workers have been identified as a priority group for IPT. According to the WHO (2009c:12), all healthcare workers should be given appropriate information and encouraged to undergo TB diagnostic procedures if they have signs and symptoms suggestive of TB. Healthcare workers should be given appropriate information and encouraged to undergo HIV testing and counselling. If they are diagnosed with HIV, healthcare workers should be offered a package of prevention, treatment, and care that includes regular screening for active TB and access to ART. Based on a full medical evaluation, health workers should be put on either IPT or, if diagnosed with active TB, a full regimen of anti-TB treatment. HIV-positive health workers should also avoid working with
patients with known or suspected TB. In particular, they should not work with patients with MDR-TB and XDR-TB. If needed, these healthcare workers should be relocated from positions where an exposure to untreated TB is high to lower risk areas.

2.2.4 The scope of TB case detection among PLWHIV and TB/HIV co-management

The WHO (2009e:1) has reported that in 2008 almost 1.4 million TB patients around the world were tested for HIV and provided with HIV prevention, treatment and care services. This is an increase of 1.2 million from 2007. Amongst HIV-positive TB patients, 200 000 or approximately two thirds of the sample, were given co-trimoxazole treatment (CPT), while one third (100 000 patients) were given ART. In 2008, the number of PLWHIV who were screened for TB more than doubled from 600 000 in 2007 to 1.4 million. At the same time, however, this figure represented only a small fraction of the 33 million people estimated to be living with HIV worldwide. More worryingly, in 2008 only 56 000 PLWHIV, began IPT, and TB control measures remained under-implemented in many regions, particularly in SSA (WHO 2009e:2).

The FMoH and FHAPCO (2007a:17) and the WHO (2008:1; 2009f:28) defined the scope of collaborative TB/HIV activities in the following terms:

Establishing mechanisms for collaboration by

- Setting up a co-ordinating body for TB/HIV activities which would be effective at all levels
- Conducting investigations of HIV prevalence among TB patients
- Carrying out joint TB/HIV planning
- Conducting monitoring and evaluation processes
Decreasing the burden of TB in people living with HIV by:

- Establishing intensified TB case-finding
- Introducing IPT
- Ensuring TB infection control in health care and congregating settings

Decreasing the burden of HIV in TB patients by:

- Providing HIV testing and counselling
- Introducing HIV prevention methods
- Introducing CPT
- Ensuring HIV/AIDS care and support
- Introducing ART

2.2.5 Standard interventions for TB/HIV co-management

In addition to the collaborative TB/HIV activities defined by international organisations, such as the WHO and national ministries, the following 12 standard interventions, for TB/HIV co-management, have been compiled from a selection of relevant literature sources:

2.2.5.1 Establishing a coordinating body for TB/HIV co-management

Coordination is a central element of any process aimed at reaching policy consensus, developing joint strategic plans, mobilising resources, building capacity, or implementing and monitoring collaborative TB/HIV activities. This is especially true of matters such as boosting TB case detection among PLWHIV. In order to guarantee functional coordination, it becomes necessary to provide a mechanism for coordinating collaborative TB/HIV activities at all levels in a country: at the national, district and facility level. In addition, representatives from different departments and ministries involved in the activities of the TB/HIV coordinating body will need to meet regularly, if actual and effective coordination is to be provided (FMoH 2008b:1).
Evidence from operational research (FMoH & FHAPCO 2007b:12; Godfrey-Faussett et al 2002:80; WHO 2004a:3) has shown that having TB/HIV coordinating bodies operating at all levels is a feasible task. This ensures commitment and programmatic ownership. This is particularly true when stakeholders from all relevant HIV/AIDS and TB control programmes participate. This sort of coordinating body can also address governance issues in the implementation of joint TB/HIV plans (Godfrey-Faussett et al 2002:80; WHO 2004a:3).

2.2.5.2 Surveillance of HIV prevalence among TB patients

Ideally, any surveillance of HIV prevalence should include all new TB patients who have been diagnosed according to international standards. There are three main methods for the surveillance of HIV among TB patients (Talbot et al 2001:710; WHO 2004a:3):

- Routine HIV testing data can form the basis for a reliable surveillance system during all stages of the HIV epidemic (low-level, concentrated, and generalised), assuming that high surveillance coverage levels have been achieved and maintained. These routine data can be calibrated by periodic (special) or sentinel surveys.
- Sentinel surveys collect information in a regular and constant way from a predetermined number of people in targeted locations, including particular groups who are of special interest to the surveillance conducted. Some difficulties can arise during sentinel surveillance as a result of a representative mismatch between the sampled group and the general population. Sentinel survey methods are usually developed using unlinked anonymous testing methods. Such methods include the use of blood samples that have been collected for other purposes and stripped of all identifying markers.
- Periodic special surveys are also of use, especially where the prevalence of HIV among TB patients has not been previously estimated. These can
form an important part of initial situation analyses. Periodic surveys, employing representative sampling methods and appropriate sample sizes, can provide accurate estimates of the burden of HIV in TB patients.

According to Talbot et al (2001:710) and the WHO (2004a:3), evidence from descriptive studies have demonstrated that HIV surveillance among TB patients is a critical activity needed in order to understand the epidemic's development, as well as to create sound strategies to address the dual TB/HIV epidemic (Bowen et al 200:1488; Talbot et al 2001:710).

2.2.5.3 Joint TB/HIV planning

Joint planning involving representatives of agencies, clinics, and other institutions involved in all levels with the treatment of both HIV and TB, is fundamental for any TB/HIV collaboration. A joint plan must contain the following components: clear definitions of the roles and responsibilities of the TB and HIV treatment regimes, delineation of the implementation of all 12 collaborative TB/HIV activities, and collaborative development of TB/HIV guidelines for prevention, diagnosis, treatment and care. This last category ought to include activities related to advocacy, communication and social mobilisation tools, joint resource mobilisation for collaborative TB/HIV activities, and joint strategies for human resource departments to ensure adequate staff for the delivery of collaborative TB/HIV activities. Joint training on TB and HIV for all health-care workers should be provided to enhance effective communication and advocacy strategies for TB and HIV control and implementation programmes.

Third party research findings (Floyd 2003:83; WHO 2004a:4; WHO 2009f:13) have shown that effective and efficient implementation of collaborative TB/HIV activities depends on joint planning and implementation conducted by the TB and HIV/AIDS programmes concerned. This process, in turn, requires close
collaboration between community care services and government health institutions.

### 2.2.5.4 Monitoring and evaluation of collaborative TB/HIV activities

The presence of an integrated system for the coordination and evaluation of collaborative HIV activities is a very important element of a broader series of guidelines or recommendations. Routine monitoring includes data collection about TB/HIV indicators and the regular evaluation of all collaborative activities forming the foundation for a TB/HIV collaborative monitoring and evaluation system.

### 2.2.5.5 Intensified TB case-finding among PLWHIV

In 2011, 1.1 million (13%) of the 8.7 million people who developed TB globally during that year were HIV-positive; 79% of these HIV-positive TB cases were in the African region (WHO 2012:1). The percentage of notified TB patients with a documented HIV test result in SSA rose from 60% in 2010 to 69% in 2011. In 2011, 46% of those tested were HIV-positive, ranging from 8% in Ethiopia to 77% in Swaziland. Worldwide, 40% of TB patients notified in 2011 had a documented HIV test result, up from 33% in 2010 and more than ten times the level of 2004. Of those individuals enrolled in HIV care in 2011, a total of more than 3.2 million were reported to have been screened for TB, an increase of 39% from the 2.3 million screened in 2010. Amongst those found to be without active TB, 450 000 were provided with IPT, more than twice the number of people who had been given IPT in 2010 (WHO 2012:83).

Effective TB/HIV collaboration is usually characterised by a system capable of monitoring the notification of TB amongst PLWHIV. In general, HIV care and treatment registers (pre-ART and ART) record TB treatment, which can then be aggregated in quarterly reports that can provide numbers verifying the proportion
of people enrolled in HIV care who had started TB treatment. These figures can also include rates of intensified TB case-finding for those who were found to be HIV-positive during testing. They can also reveal intensified TB case-finding for PLWHIV at all levels of care, and formal referral mechanisms set up between HIV diagnostic and care services and TB diagnostic and treatment services.

Research (WHO 2004a:7; 2008d:4; 2010:11) has pointed to intensified case-finding's importance in any collaborative activities. Intensified case-finding and treatment of TB among HIV-positive patients can interrupt the disease transmission, reduce mortality, decrease the risk of nosocomial TB transmission, and allow the provision of IPT to HIV-positive patients. According to Burgess et al (2001:15) and Nachega et al (2003:17), intensified case-finding is cost effective and feasible. According to the WHO (2012:11), any intensified case-finding mechanism used to promptly detect TB and prevent TB among PLWHIV should also include regular screening for TB and obligatory IPT for those without active TB.

2.2.5.6 Isoniazid preventive therapy (IPT) for PLWHIV

Isoniazid is generally given to patients with latent MTB infections in order to prevent progression to active TB disease. The exclusion of active TB is critically important before this therapy can be started. Isoniazid is given to patients daily as self-administered therapy for six to nine months. Since HIV-infected people can develop TB before ART is indicated, and as there is no evidence arguing against the combined use of these drugs, ART does not preclude the use of IPT. However, IPT has the potential disadvantage of an increased risk of drug toxicity and the possible emergence of drug resistance (WHO 2004:201).

IPT has been found to be more effective and safer in terms of preventing latent TB than regimens based on rifampicin or pyrazinamide (WHO 2004a:7). Randomised trials have demonstrated that IPT is effective in reducing the
incidence of TB and TB mortalities amongst HIV-positive patients with a positive
tuberculin skin test (LoBue & Moser 2003:443; WHO 2004a:7; WHO 2010:5). IPT
has also resulted in cost savings in medical care and in the reduction of social
costs in SSA (Terris-Prestholt, Kumaranayake, Ginwalla, Ayles, Kayawe, Hillery
& Faussett 2008:5). However, this therapy requires several particular steps to be
taken, including the identification of HIV-positive patients, screening to exclude
active TB, and IPT adherence. For these reasons, it might be possible to
question the feasibility of implementing IPT in developing countries. In some
studies, the combined use of ART and IPT was reported without conclusive
evidence about the overall treatment effectiveness (Girardi et al 2000:1985;
assessing the effectiveness of the joint treatment will need to be closely followed
in order to provide proper guidance for on-going policy development (LoBue

2.2.5.7 Control of TB infections in healthcare and congregate settings

Healthcare and congregate settings (such as prisons, police stations, and military
barracks) – places where people with TB and HIV are frequently crowded
together - TB infection rates have been consistently increased (WHO 2004a:8).
Measures to reduce TB transmission in such environments include
administrative, environmental, and personal protection measures, all aimed at
generally reducing the exposure of healthcare workers, prison staff, police and
their clients, as well as any other individuals living in congregate settings.
Administrative measures should include early TB detection, diagnosis, and
treatment of TB suspects, particularly those with PTB, as well as the separation
of PTB suspects from others in the congregate population until diagnosis has
been confirmed or excluded. Environmental protections should include
maximising natural ventilation, and using ultraviolet radiation (if applicable).
Personal protection methods ought to include the protection of HIV-positive
individuals from possible exposure to TB (for example, the transfer of a HIV-infected worker from medical wards) and the provision of IPT.

Overall, there does seem to be an increased risk of TB infection among health workers, medical and nursing students who have contact with patients, prisoners, and soldiers in military barracks, exacerbated by the HIV epidemic (WHO 2003b:281). HIV promotes the progression to active TB in people with recently acquired infections, or with latent TB infections (Miles 2003:174; WHO 2002:296; WHO 2003b:281).

2.2.5.8 Providing HIV testing and counselling for TB patients

HIV testing and counselling for TB patients, using rapid tests, offers an entry point for an ongoing continuum of prevention, care, support, and treatment for HIV/AIDS as well as for TB (WHO 2004a:8). This testing provides benefits that will accrue to the patient, his or her family, and the community in which the patient lives. HIV testing should be readily available, and should include both provider-initiated and voluntary testing. Informed consent should be obtained from all of those undergoing testing and the confidentiality of patients should be maintained.

Increases in HIV testing amongst TB patients have proven to be higher than expected in some areas. For example, a study in rural Malawi has shown an 88% acceptance level of HIV tests amongst TB patients (Godfrey-Faussett et al 2002:939; WHO 2003a: 336; Zachariah et al 2003:1053). In addition, it should be noted that the cost-effectiveness of voluntary HIV counselling and testing improves significantly when this testing is aimed at populations with a high prevalence of HIV (Sweat et al 2000:113).

2.2.5.9 Introducing HIV prevention methods for TB patients
As the WHO has indicated (2004a:9), the reduction of sexual, parenteral, and vertical transmissions of HIV is most effectively built upon broad HIV/AIDS education programmes. Measures used to reduce the sexual transmission of HIV include the promotion of safer and more responsible sexual behaviour and practices, as well as education about the delayed onset of sexual activity, a reduced number of sexual partners, the effective use of condoms (male and female), and the diagnosis and treatment of other sexually transmitted infections (STIs). On the other hand, activities that can be applied to reduce parenteral HIV transmission include ensuring blood supply safety and the use of sterilised injection and surgical equipment in medical settings. Amongst intravenous drug users, harm-reduction strategies such as wider access to sterile needles, drug-dependence treatments, and outreach services aimed at the reduction of drug use are of particular value. Vertical transmission of HIV can also be reduced through the provision of antiretroviral drugs to pregnant women and their children as an element of effective prevention of mother-to-child transmission (PMTCT) programmes (Wilkinson & Rutherford 2001:2).

A review of available evidence (Creese et al 2002:1635) has shown that HIV prevention methods are cost effective compared to other treatment regimes. The provision of HIV prevention methods within TB control programmes, as well as the effective referral of patients to AIDS programmes, is feasible in settings with a high joint prevalence of TB and HIV. The improved treatment of STIs has reduced the HIV incidence in environments characterised by the HIV epidemic’s emergent status (Godfrey-Faussett et al 2002:939; Wilkinson, Rutherford 2001:2).

2.2.5.10 Introducing co-trimoxazole preventive therapy (CPT) for TB/HIV patients

Co-trimoxazole preventive therapy has been promoted by the WHO and UNAIDS (FMoH 2006:1; WHO 2004a:9) as a method of preventing of several secondary
bacterial and parasitic infections in eligible adults and children living with HIV/AIDS in Africa. TB/HIV patients are within this category and are thus eligible for this therapy. According to Godfrey-Faussett (2003:1079) and Zachariah et al (2001:843), evidence from randomised controlled trials of CPT has demonstrated reduced mortality rates among HIV-positive smear-positive TB patients and reduced hospitalisation and morbidity rates among PLWHIV when CPT is applied. In addition, other non-randomised and operational studies have shown that CPT is feasible, safe, and reduces mortality rates among a wide cross-section of TB patients (Godfrey-Faussett 2003:1079; Zachariah et al 2001:843; Zachariah et al 2002:1046).

### 2.2.5.11 Ensuring HIV/AIDS care and support for TB patients

For people living with HIV/AIDS, access to health care is a basic human right and includes the provision of clinical care as part of a continuum of a comprehensive AIDS care (WHO 2004a:10). This approach to AIDS care includes clinical management (prophylaxis, early diagnosis, rational treatment, and follow-up care for opportunistic infections), nursing care (including promoting hygiene and nutritional support), palliative care, home care (including education for home care providers and patients' relatives), counselling, and social support. People living with HIV/AIDS, who are undergoing or who have completed TB treatment, are provided with a full continuum of care and support, as engendered by the client referral system.

Linking HIV/AIDS prevention to care and support regimes generates synergies and strengthens HIV/AIDS programmes (UNAIDS 2003a:30). Farmer et al (2001a:404) have additionally stated that directly observed antiretroviral therapy given to people living with HIV/AIDS, when modelled on successful similar TB control efforts, has been useful as a way of extending moral and social support to people living with HIV/AIDS. According to the WHO (2003a:311), operational research has shown that collaboration between TB and HIV programmes can
effectively scale up the delivery of care and support activities to HIV-infected TB patients (Farmer et al 2001b:408; UNAIDS 2002:29;WHO 2003a:31).

2.2.5.12 Providing antiretroviral therapy (ART) for TB/HIV patients

Studies have found that ART improves the quality of life and greatly improves the rate of survival amongst PLWHIV (WHO 2004a:10). The availability of ART can also serve as an incentive for people to be tested for HIV, since it transforms HIV infection from a death sentence into a chronic condition. Of course, it is a lifelong treatment requiring a high adherence rate (of at least 95%), without which long-term benefits are difficult to achieve and the development of drug resistant HIV strains could occur.

Other researchers have found that there is evidence for potent ARVs’ ability to reduce the incidence of TB in HIV-positive persons by more than 80% (Badri, Wilson, Wood 2002:2059; Girardi et al 2000:1985). However, in order for ART to prevent a significant portion of TB cases from developing, ART must be initiated early in the course of a HIV infection, and a high rate of compliance is required. The initiation of ART in HIV-infected TB patients can result in the temporary worsening of TB symptoms in up to 30% of the patients in the developed world (Farmer et al 2001b:404; Williams & Dye 2003:1126). Observational studies (Farmer et al 2001b:1145; Liechty & Bangsberg 2003:1383; Mitty et al 2003) have in some cases proposed that TB DOT programmes be used as a model for ART delivery. At the same time, however, there have been conflicting opinions about this strategy, especially because of a scarcity of evidence (Liechty & Bangsberg 2003:1388).

In conclusion, TB/HIV collaboration programmes’ goals are best achieved through the effective and joint implementation of DOTS, enhanced HIV prevention and care, and the delivery of the 12 standard collaborative TB/HIV activities described above. These collaborative activities address the overlap
between the intersecting TB and HIV epidemics, and should be carried out as parts of a broader health-sector response to the dual TB/HIV epidemic. They will be more successful, when combined with the effective implementation of national HIV and TB control strategies, based on international guidelines.

2.2.6 The relationship of TB and HIV clinical management

According to the Ethiopian TB/HIV Guidelines (FMoH & FHAPCO 2007a:23), an HIV-positive patient is eligible to start IPT after the exclusion of active TB (which would require immediate TB treatment). Regular screening for TB among HIV-positive patients, at every stage of the disease, is also seen as a key TB/HIV collaborative activity (FMoH 2008a:25), which is aimed at reducing the burden of TB in PLWHIV. Screening for TB is conducted at HIV clinics. Based on the results of the screening, patients start TB prophylaxis with INH if the screening result is negative or will be referred to the TB clinic for effective treatment of TB if the HIV patient is diagnosed as suffering from TB.

The Ethiopian ART Guidelines (FMoH 2006: 24) describe eligibility for ART for TB patients as follows:

- ART is recommended for all TB patients at WHO clinical stage III with CD4 counts < 350 cells/mm3, and TB patients with WHO clinical stage IV defining conditions irrespective of their CD4 count

or

- In cases where CD4 count is not possible, all TB patients are eligible for ART

In addition, the Ethiopian TB/HIV Guidelines (FMoH & FHAPCO 2007a:23) dictate that an HIV-positive patient is eligible to start IPT after active TB has been excluded. According to these guidelines (FMoH & FHAPCO 2006: 12), all TB/HIV
co-infected patients are eligible to start CPT, irrespective of their CD4 cell count or stage of their disease.

The WHO, however, has argued that the optimal time to start ART relative to the start of TB therapy is not yet clear. At the same time, however, one randomised controlled trial has provided some evidence for early initiation of ART in terms of reduced all-cause mortality, improved TB outcomes, and a reduced incidence of IRIS (WHO 2009b:70).

It has been additionally found that when TB is diagnosed in patients already receiving ART, TB treatment should be started immediately (WHO 2009b:71). There are two more issues to consider in these cases. First, it must be established whether or not ART will need to be modified as a result of drug to drug interactions, or in order to reduce the potential for overlapping toxicities. Second, it will need to be determined whether or not the existence of active TB in a HIV-positive patient on ART constitutes an ART failure that would require a change in the ART regimen.

This touches upon broader concerns related to the overlap of ART and TB treatment regimes. Outbreaks of drug-resistant TB (MDR TB) amongst HIV-positive patients have been widely documented in nosocomial and other congregate settings, but little information has been made available about the association between HIV and drug-resistant TB on a wider population level (WHO 2009d:11). Two main reasons have been found, however, as to why drug-resistant TB might be associated with HIV. The first is the documented acquisition of isolated rifampicin resistance among HIV-positive patients under treatment for TB, although this fact remains possible to explain as a result of disruptions in therapy. Anti-TB drug malabsorption has also been documented in patient cohorts with a high prevalence of HIV, which suggests that HIV-positive TB patients might be at greater risk of acquiring drug resistance. The second reason that could explain the higher than usual levels of MDR TB amongst HIV-
positive patients is related to their exposure. HIV-positive patients and drug-resistant TB patients might have similar risk factors, such as a history of hospitalisations, which in turn might mean that HIV-positive TB patients are at a higher risk of exposure to resistant forms of TB than HIV-negative patients.

Further research has pointed to the equanimity of joint therapy. In one study 49 HIV-positive patients, most of whom were receiving ART and who also had active TB, were treated with Rifampin 600mg, Isoniazid 400mg and Pirazinamide 2g daily (Dianna et al 2004:1). These patients also received ARVs, consisting of Efavirenz (600mg/day), plus 2 NRTIs. All the patients were followed up for at least 24 months. The non-concomitant ARV regimen was introduced at least three weeks after the beginning of TB treatment. Severe adverse reactions to the joint treatment included skin rashes (2), toxic hepatitis (6), IRIS (7), and four deaths. The study concluded that efavirenz at a daily dose of 600 mg was a sufficient and safe treatment for HIV/TB patients using a regimen that contains rifampicin.

### 2.2.7 Factors affecting TB case detection among PLWHIV and TB/HIV co-management

The impact of TB screening on PLWHIV has proven hard to estimate (WHO 2012:81). While the frequency of TB screenings has been shown to determine how early TB diagnosis can be made, compared to a lack of screening altogether, no global data on the frequency of such screenings has been made available.

The WHO (2007c:36-38) has indicated that HIV/AIDS affects the prevention and control of TB in numerous ways, including through an increase in the number of suspected TB cases, the disease’s impact on human and health infrastructure resources, the provision of diagnostic services and case management, the risks
of nosocomial TB infections and MDR, increased possibilities for low staff morale at healthcare institutions, and increased mortality rates. An individual infected with HIV, can be affected by TB in many ways. TB boosts HIV replication, which leads to an increased viral load. TB also increases the occurrence of other opportunistic infections, because of the increased viral load resulting from TB infections. TB patients who are HIV positive thus have an increased chance of getting AIDS-defining illnesses, as well as infecting other people with ART-resistant HIV strains. The management of TB and HIV co-infected patients is also challenging because of pill burden, increased adverse effects, drug-to-drug interactions and IRIS (WHO 2004:36-39).

When working in populations where HIV/TB is common, health services have been reported to struggle with the large and rising number of TB cases (WHO 2004c:32). HIV/AIDS affects the prevention and control of TB. This includes the simple increase in possible TB carriers and TB patients, which in turn impacts on human and infrastructure resources in the health sector, services for diagnosis and case-holding, the risk of nosocomial TB infections and the risk of MDR TB cases, the possibility for lowered staff morale, and increased mortality rates. On an individual level, infection with HIV and the presence of TB can have various effects. TB increases HIV replication, which leads to an increased viral load. In addition, TB increases the occurrence of other opportunistic infections (WHO 2004c:34), aggravating the patient’s general illness and hastening the development of AIDS-defining illnesses.

It has been recommend by the British HIV Association that if HIV treatment is started in patients who are on anti TB therapy, then HAART might need to be modified. TB treatment should be modified if a patient has developed intolerance to, or has severe toxicity from, HIV drugs, or if there is evidence of genotypic resistance to specific HIV drugs, which would limit HAART therapy to agents that are unlikely to interact with anti TB therapy. In addition, a cohort study in Ethiopia indicated that HIV-infected Ethiopian patients, who had developed TB, already had low CD4 counts and high viral loads prior to their TB diagnoses. The viral
load did not decrease following TB treatment, leading to these patients’ poor overall prognosis (Wolday et al 2003:1).

2.2.8 Measuring effective TB case detection and TB/HIV collaboration

Information about TB screening and IPT has in the past few years been collected through the UNAIDS monitoring system (WHO 2012:79). This system’s data helped to explain why fewer countries reported data on TB screening and the provision of IPT in 2011 than in 2010. Recording and reporting TB screening among people living with HIV, and the provision of IPT to those without active TB, are activities that pose challenges in many countries. Further efforts will be needed to facilitate and improve the tracking information on both national and global levels. From 53 countries that reported data to the UNAIDS system, 3.2 million people were recorded as having enrolled in HIV care and having been screened for TB during 2011, compared to 2.3 million from 71 countries in 2010 (WHO 2012:80).

However, since the publication of the WHO’s first policy guidelines on collaborative TB/HIV activities in 2004, considerable progress has been made in terms of implementing the recommended package of interventions. If analysis is extended through 2011, and a full spectrum of four interventions are considered – ART for TB patients living with HIV, CPT for HIV patients with TB, IPT for early case HIV-positive patients, and systemic TB screening and diagnosis amongst HIV-positive patients – then striking estimates might become apparent about the number of lives saved as a result of the coordinated activities. Based on information from the WHO, more than 1.3 million lives were saved between 2005 and 2011. During 2011 alone, more than 400 000 lives were saved, a significant increase from the 50 000 reportedly saved as a result of the coordinated activities in 2005 (WHO 2012:81).

It has been effectively argued that collaborative TB/HIV activities should be included as part of both TB and HIV control programme reviews. This process
should bring together key staff from both programmes. Reviewers should ensure that review findings are shared with both parties concerned with these programmes.

**Table 2.1: Features of a legitimate monitoring and evaluation system of HIV and TB collaboration**

<table>
<thead>
<tr>
<th>Monitoring &amp; Evaluation (M&amp;E) unit</th>
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<tbody>
<tr>
<td>Dedicated personnel overseeing health service M&amp;E</td>
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<tr>
<td>A budget for M&amp;E (10% of total budget)</td>
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<tr>
<td>Formalised links with partners - research institutions, NGOs, donors, and those in the private sector</td>
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<tr>
<td>Data processing and statistical expertise from the M&amp;E unit or an affiliated unit</td>
</tr>
<tr>
<td>Data dissemination expertise from the M&amp;E unit or an affiliated unit</td>
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<tr>
<td>Development and maintenance of local M&amp;E human resource capacity</td>
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<td>Regular and independent programme reviews</td>
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<tr>
<th>Clear goals</th>
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<tr>
<td>Well-defined national programme aims, objectives, activities, and targets</td>
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<tr>
<td>Regular evaluations of the progress achieved in implementing national M&amp;E plans</td>
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<tr>
<td>Guidance given to districts and regions or provinces on M&amp;E</td>
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<tr>
<td>Guidelines provided for the linking of M&amp;E to the private and other sectors</td>
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<tr>
<td>Coordination between national and donor M&amp;E needs</td>
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<tr>
<th>Indicators</th>
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<tr>
<td>A set of priority core indicators for different levels of M&amp;E</td>
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<tr>
<td>Indicators that are comparable between themselves over time</td>
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<tr>
<td>Indicators that are comparable between geographical areas within a country and between countries</td>
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<table>
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<tr>
<th>Data collection and analysis</th>
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<tr>
<td>A national-level data collection and analysis plan</td>
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<tr>
<td>A logical flow of data from service delivery to national level</td>
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<tr>
<td>A plan to collect data and analyse indicators at different levels of M&amp;E</td>
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<table>
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<th>Data dissemination and use of results</th>
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<tbody>
<tr>
<td>A national-level data dissemination plan with clear guidance on how information can be used for programme improvement at all levels</td>
</tr>
<tr>
<td>A well-disseminated and informative annual M&amp;E report</td>
</tr>
<tr>
<td>Annual meetings that will disseminate and discuss M&amp;E and research findings with policy-makers and planners, including programme implementation reviews</td>
</tr>
<tr>
<td>A centralised database or library for all TB- and HIV-related data collection, including on-going research</td>
</tr>
<tr>
<td>Coordination between national and donor M&amp;E dissemination needs</td>
</tr>
</tbody>
</table>

(WHO 2009f:8)

According to the WHO’s standards (2009f:14), effective TB/HIV collaboration can be measured according to the following indicators:

- The percentage of TB patients who had an HIV test result recorded in the TB register
The number of registered TB patients with documented HIV status in the TB register who are HIV-positive, expressed as a proportion of the total number of all registered TB patients with documented HIV status over the reporting period.

The number of HIV-positive TB patients who have started and are continuing previously initiated CPT TB treatment, expressed as a proportion of all HIV-positive TB patients registered over the reporting period.

The number of HIV-positive TB patients enrolled in HIV care services during TB treatment, expressed as a proportion of the total number of HIV-positive TB patients.

The number of HIV-positive TB patients who have started or are continuing previously initiated ART that is occurring during TB treatment, expressed as a proportion of all HIV-positive TB patients registered over the reporting period.

The number of adults and children enrolled in HIV care whose TB status was assessed and recorded during their last visit during the reporting period, expressed as a proportion of all adults and children enrolled in HIV care and seen for care in the reporting period.

The number of adults and children enrolled in HIV care who have started treatment, expressed as a proportion of adults and children enrolled in HIV care during the reporting period.

The percentage of estimated HIV-positive patients with TB infections that have received treatment for TB and HIV.

The number of adults and children who are newly enrolled in HIV care, who have started treatment for latent TB infection (IPT), expressed as a proportion of the total number of adults and children newly enrolled in HIV care during the reporting period.

The number of health-care facilities providing services to people living with HIV, with demonstrable infection control practices that include TB control, expressed as a proportion of the total number of health-care facilities evaluated.
• The number of health-care workers employed in facilities providing care for people living with HIV who develop TB in one year, expressed as a proportion of the total number of health-care workers employed in facilities providing care for people living with HIV during that same year.

A national TB and HIV policy should reflect international policy guidance on collaborative TB/HIV activities (WHO 2009f:22). For this to occur, the content of a government’s TB or HIV policies, plans, and guidelines should be analysed and compared with a checklist of key policy components. According to the WHO (2009f:23), a national policy is considered to be complete if it contains the following 14 key components: explicit recognition of the potential impact of TB mortality rates on people living with HIV

• inclusion of representatives from the National TB Program (NTP) in the planning process of the National HIV/AIDS Control Program (NACP), and vice versa
• surveillance of HIV’s prevalence amongst TB patients that is consistent with international recommendations.
• advocacy, communication, and social mobilisation (ACSM) strategy for HIV, including appropriate information about TB, and vice versa.
• training for those working with HIV patients should include appropriate information about TB, and vice versa.
• regular and intensive TB case-finding is recommended for all PLWHIV
• ART is provided for all eligible HIV-positive TB patients in accordance with national protocols
• HIV-positive TB patients have access to a full continuum of care for people living with HIV
• CPT is provided for all HIV-positive TB patients and all people living with HIV in accordance with international guidelines
• Access to diagnosis for and treatment of TB is part of a basic package of care for people living with HIV
• Treatment of latent TB infection is offered to all people living with HIV in accordance with international guidelines
• A national TB and HIV coordinating body, technical advisory committee, or task force should be established
• HIV testing and counselling are routinely offered to all TB patients
• A well-established and functioning infection control policy and monitoring system.

2.3 SUMMARY

This literature review emphasised the importance of TB case detection amongst PLWHIV, as well as the implementation of TB/HIV co-management. Implementation of co-management is essential in a country like Ethiopia in order to ensure high quality TB/HIV management. Quality TB/HIV care is necessary to suppress the HIV virus to undetectable levels and cure TB. Together, these treatments can increase immunological responses and enable patients to achieve a better quality of life. Although the measurement of treatment’s quality is not an easy process, the results of different studies have demonstrated that the implementation of TB/HIV co-management, including enhanced TB case detection among PLWHIV, can significantly improve patients’ quality of life and notably decrease TB/HIV’s joint mortality rates. It is extremely important to attain and maintain high levels of collaboration between HIV and TB programmes for the effective management of these two diseases.

Chapter 3 will address the research methodology used to study TB case detection among PLWHIV in one hospital in Ethiopia.
CHAPTER 3

RESEARCH METHODOLOGY

3.1 INTRODUCTION

This study adopted a quantitative, descriptive, and contextual research design insofar as the researcher was interested in analysing available and quantifiable data. The data employed were collected using a checklist covering 300 HIV-positive patients’ records from one hospital in Ethiopia.

3.2 STUDY DESIGN

A research design is a written plan for a study (Kumar 2008:28). This design expresses a researcher’s intentions, the study’s purpose, and its value. It also includes a step by step plan for the study’s implementation. A research design should be a logical and systematic plan that has been prepared in order that a research study is properly conducted. It is comparable to a blueprint that an architect prepares before construction of a building commences (Kumar 2008:33).

This study adopted attempted to analyse available and quantifiable data. This study is descriptive in nature insofar as the researcher will observe a situation (the referral of HIV-positive patients for TB screening) and then describe what has been observed (Donald et al 2010:27). The description included is related to TB diagnosis amongst HIV-positive patients from one hospital in Ethiopia. This
study represents a formal, objective, systematic, and quantifiable process aimed at describing a specific situation (Burns & Grove 2005:44). The situation in question constitutes a review of the records of registered HIV-positive patients, done in order to identify whether or not TB screening was done in accordance with Ethiopia’s TB/HIV collaborative guidelines. Statistical analysis will be also used to summarise and describe the data collected. The aim of this study is to identify problems in the implementation of TB case detection amongst HIV-positive patients from one hospital in Ethiopia using a structured checklist to analyse the available data records.

3.2.1 Descriptive research

This study was descriptive in nature because the researcher observed a situation and then described what had been observed (Babbie & Mouton 2001:80-81). The description in question is related to rates of TB screening amongst PLWHIV at one hospital in Ethiopia.

3.2.2 Quantitative research

This study was also a formal, objective, systematic, and quantitative process used to describe a particular situation (Burns & Grove 2005:44). The situation under analysis was a review of patients’ files applied in order to study rates of TB case detection among PLWHIV in the participating hospital. Statistics were used to summarise and describe the data.

3.2.3 Contextual research

A context is the complex of factors, conditions, and contradictory elements that either support or limit a historically and culturally related framework that is constantly changing (Eisner & Day 2008:440). For a contextual study, a case can be a person, an institution, a culture or a group. In this study the case was one
hospital where data had been recorded and analysed related to the records of HIV patients.

3.3 RESEARCH METHOD

This section covers the exact steps followed during the process of data collection. These included definitions of the research population and of the research setting.

3.3.1 Research population

A research population is the set of elements on which a study focuses (Bless & Higson 2005:85). The population of research sites for this study comprised all the Ethiopian hospitals and all relevant clinics providing HIV/TB collaborative services to HIV positive patients.

3.3.1.1 Site target population

Only one HIV clinic of a single hospital in Adama, Ethiopia participated in this study. This clinic has been offering TB/HIV collaborative services since 2002, and was purposively selected because it offers services to about 3 000 follow-up and 100 new PLWHIV per month.

3.3.1.2 Accessible site

This study was conducted at one HIV clinic in one public hospital in Ethiopia. The researcher conducted the study at this hospital’s clinic because it was one of the first nine public health facilities where TB/HIV collaborative management was piloted during 2002 (FMoH & FHAPCO 2007c:1). As a result, this site offers an accessible opportunity from which to determine the extent to which TB/HIV
collaborative activities have been implemented over the ten years of this programme’s implementation. The clinic attends to approximately 3 000 follow-up and 100 newly diagnosed HIV patients per month.

3.3.1.3 Target population

The records of all patients who visited the targeted HIV clinic, at the participating hospital in Adama, comprised the accessible population for this study. The records of all 3 000 patients who visited the participating HIV clinic during the month of data collection (December 2012) comprised the target population for this study, provided that they were at least 18 years old (given the focus of the study on TB diagnosis and treatment among adult HIV-positive patients) and had been diagnosed as HIV-positive at least six months previously. HIV patients attending the clinic who had been diagnosed less than six months prior to the data collection procedure were excluded from the study. This limitation was applied because allowing six months since the patient’s HIV-positive diagnosis ensures sufficient time for the patient to have been referred for TB screening and to have collected some records about his or her TB diagnosis, treatment or prophylaxis. Including newly diagnosed HIV positive patients’ files might have produced some amount of contradictory variables because there could have been insufficient time for these patients’ TB treatment to have been properly recommended or implemented.

3.3.1.4 Site sampling technique

The participating hospital contains only one HIV clinic that participated in this study. This clinic was intentionally selected because it offers services to more than 3 000 follow-up and 100 new patients per month and has 10 years’ experience implementing TB/HIV collaborative programme. Questions of site sample size are not applicable since only one clinic participated in this study.

3.3.2 Sampling
Random sampling was used until data from 300 HIV-positive patients (amounting to 10% of the total number of patients treated per month at the participating clinic) had been recorded, and a checklist related to every patient’s file had been completed.

3.3.2.1 Sampling frame

The HIV clinic’s register, which indicated the names and numbers of all patients who visited the HIV clinic during the data collection month in December 2012 comprised the sampling frame for the population for this study.

3.3.2.2 Sampling technique

Random sampling was used to select the records of HIV-positive patients visiting the participating clinic during December 2012, until 300 follow-up patients’ files had been examined. A total of 15 files that met the inclusion criteria were selected on a daily basis. Every day the numbers of all files belonging to patients who visited the clinic on the day in question were written on slips of paper and placed into a container. An independent person was asked to draw 15 numbers blindly from the container. These 15 files were acquired and checked. If any patient was younger than 18, or had been diagnosed as being HIV positive less than six months prior to the date of data collection, these files were excluded from the sample and additional numbers were drawn blindly from the container until 15 files had been selected for the day.

3.3.3 Sample size
A total of 300 patients’ files was used, which amounted to 10% of the total population of follow-up HIV patients who visited the participating HIV clinic on a monthly basis.

3.4 DATA COLLECTION

3.4.1 The research instrument

Checklists are defined by Burns & Grove (2005:791) as “Techniques for indicating whether a behavior occurred”. The major advantage of using a checklist was that the researcher had a structured approach to recording relevant data from a specific patient’s file to his/her checklist, by ticking off the relevant recorded behaviours. A potential disadvantage of using a checklist was that the researcher could miss important information not recorded on the checklist. The researcher attempted to overcome this limitation by noting any information relevant to this study, but not covered in the checklist, as notes on the checklist.

A checklist was designed by the researcher based on findings from an in-depth literature review, and the FMoH’s (2006) guidelines. Health care workers’ expected behaviours to diagnose TB among HIV-positive persons were listed and the researcher could tick the behaviours recorded in the patients’ files. The checklist was pre-tested on 10 HIV patients’ files that were excluded from the data analysis. No amendments were required as a result of the checklist. The checklist was divided into the following three sections:

Section A covered the patient’s biographic data, such as his or her gender, age, education, address, and marital status.
Section B collected information about the patient’s TB screening and diagnosis, such as when TB screening was conducted, method of TB screening used and the outcome of the TB screening.

Section C investigated possible challenges and limitations related to TB/HIV collaborative activities in the hospital such as evidence of stigma, any reasons for late screening, contact tracing and HIV and TB treatment regimens.

3.4.2 Data collection procedures

While pre-testing the checklist, the researcher checked if all items on the checklist were relevant to the information recorded in the HIV patients’ files. No amendments were required as every item on the checklist was relevant to Ethiopia’s TB/HIV collaboration guidelines. The researcher numerically assigned a number to each checklist (ranging from 001 to 300) before data collection began. The researcher kept a list indicating the checklist number and the corresponding patient’s HIV file number. Only the researcher had access to this list, the hard copy of which was kept in a locked-up location and the MS Excel version of which was protected by a secure password on a computer to which only the researcher had access. This enabled the researcher to retrace any specific patient’s HIV file should this have been required for research or oversight and review purposes. This list will be destroyed after the current research report has been accepted.

The following information was transcribed from the HIV registers onto each of the 300 checklists:

- Demographic profiles
- Was the HIV positive patient screened for TB?
- Was the HIV patient referred from the HIV clinic to a TB clinic for effective treatment?
• When was the first TB screening conducted?
• What tests were used for TB screening?
• Which category of healthcare professional performed the TB screening?
• Which category of healthcare professional made a TB or non-TB diagnosis?
• Did the patient receive INH prophylaxis, if not, why not, and if so, what was the outcome?

In addition, any opportunistic infections (OIs) that the patient might have suffered from during the preceding six months were noted.

3.4.3 Data analysis

Data in this study were analysed using SPSS version 19 and Microsoft Excel. The analysis comprised descriptive statistics (frequency tables and graphs, p-values, and correlations (Pearson rho) to summarise and describe data. The researcher entered the data in the SPSS statistical software, and a statistician checked the data entries from the completed checklists and assisted the researcher in calculating and interpreting any relevant statistics. (Please see a letter from the statistician to this effect- Annexure F).

3.5 VALIDITY

Validity refers to the degree to which evidence and theory support the interpretations of test scores or those arguments entailed by proposed users of tests (Donald et al 2010:225).

3.5.1 Internal validity
A study has internal validity to the degree that it concludes that a relationship between variables is causal or that the absence of the relationship implies a lack of cause (Ellen & Robert 2011:4). In this study, the researcher measured independent and dependent variables to identify possible factors impacting on TB case detection among PLWHIV and further analysed the effect of delayed or absent TB screening.

3.5.2 External validity

A study has external validity to the degree that the results can be generalised beyond the current study to situations that use other methods, measures, and populations (Ellen & Robert 2011:5). This study was only conducted at one clinic, and the results cannot be generalised beyond this clinic, unless the study could be repeated at randomly selected HIV clinics across Ethiopia.

The research instrument and checklist’s validity was tested based on face validity, content validity, and construct validity. The instrument was shared with experts working in the field of collaborative TB/HIV services to confirm its face validity. The content validity of the checklist was evaluated by confirming that every item on the checklist was directly relevant to TB/HIV collaborative activities. The checklist’s construct validity was confirmed because the expert reviewers agreed that every item on the checklist related to the FMoH guidelines on TB/HIV collaborative activities.

3.6 RELIABILITY

Reliability refers to the degree to which a measure would produce the same results on different occasions (David 2010:28). In other words, reliability is a matter of consistency of results obtained from using the same instrument on different occasions.
The data collected for this study can be verified by comparing the checklists’ information with that from the specific patient’s files. The research instrument was pre-tested on 10 HIV patients’ files that were subsequently excluded from participation in the actual study. The data for the 10 files were analysed before the data collection commenced to identify potential data entry and analysis problems. No such problems were encountered.

3.7 ETHICAL CONSIDERATIONS

Self-designed checklists were completed by the researcher, reflecting the data recorded in the selected patients’ files. No patient’s name and no healthcare worker’s name have been mentioned. Neither the participating HIV clinic's name, nor the hospital’s name, has been mentioned in any report. No information was gathered from patients.

Ethical clearance was granted by the Higher Degrees Committee of the Department of Health Studies, University of South Africa and by the manager of the hospital that participated in the study (see Annexures B and C).

3.8 SUMMARY

This study adopted a quantitative, descriptive, and contextual research design because the researcher was interested in analysing quantifiable data, available from HIV-positive patients’ files, pertaining to their TB screening, diagnoses, treatment and treatment outcomes.

Data collection was conducted during December 2012 using a checklist to collect information from 300 randomly selected HIV-positive patients' file. The collected data were analysed using the SPSS and MS Excel programs.
Chapter 4 presents an analysis and discussion of the data obtained as a result of the study outlined in this chapter.
CHAPTER 4

ANALYSIS AND DISCUSSION OF RESEARCH RESULTS

4.1 INTRODUCTION

This chapter presents and discusses the results of the study. The overall goal of this study was to identify possible problems encountered during the implementation of TB case detection among HIV-positive patients at one hospital in Ethiopia. Based on this study's findings, recommendations will be suggested for the improvement of existing TB/HIV management guidelines, the improvement of TB diagnosis of HIV-positive patients, and increasing the number of HIV-positive patients referred for effective TB treatment at the participating clinic.

This study's particular objectives were to:

- Identify problems with the implementation of the TB/HIV guidelines at one hospital in Ethiopia
- Assess whether the TB case detection among HIV-positive persons was conducted according to the TB/HIV management guidelines
- Identify which diagnostic procedures were used to detect TB among HIV-positive patients
- Identify how long after a HIV-positive diagnosis a patient was referred for TB diagnostic tests
4.2 DATA MANAGEMENT AND ANALYSES

The data collection instrument was organised into three sections:

Section A: Biographic data
Section B: TB tracing among HIV-positive persons at one participating HIV clinic
Section C: Challenges and limitations related to TB/HIV collaboration activities at the participating hospital

The data recorded on the checklists from the HIV-positive patients’ files, were analysed using SPSS version 17 and MS Excel programs. To see the relationship between two pieces of numerical data, such as a patient’s age and his/her CD4 count, a Pearson correlation coefficient was calculated with its corresponding p-value.

In statistical significance testing the $p$-value is the probability of obtaining test result with statistics at least as extreme as the one that was actually observed, assuming that the null hypothesis is true. This implies no correlation existed between the relevant variables. The decision to “reject the null hypothesis” is taken when the $p$-value is less than the predetermined significance level which is often 0.05, indicating that the observed result would be highly unlikely. The $p$-value ranges between +1 and -1. “Probability statements are tested statistically to determine the extent of probability that B will occur in the event of A” (Burns & Grove 2001:138). Many common statistical tests, such as chi-square tests or the student’s t-test, produce statistics which can be interpreted using $p$-values.

Pearson's correlation coefficient $[r]$ is a measure of the strength and direction of the linear relationship between two variables that is defined in terms of the covariance of the variables divided by their standard deviations, giving a value between +1 and −1. The correlation is strong if $|r| >0.8$, middle if $0.5 < |r| < 0.8$, and weak otherwise.
As a total of 300 patients’ records were reviewed, the total number of respondents will be indicated by \( N=300 \), any subtotals will be indicated by \( n \) and frequencies within subtotals will be indicated by \( f \).

4.3 DEMOGRAPHIC INFORMATION

This section presents demographic data, followed by clinical data with discussions about TB case detection and TB/HIV co-management at the participating clinic. All figures are rounded off to the first decimal place. The demographic section addresses the results pertaining to the participants’ gender, ages, residential types, education levels and marital status.

4.3.1 Gender

A total of 300 HIV-positive patients’ records were analysed. Of the respondents 56.2% (\( n=168 \)) were females. In this study there were more females (56.2%; \( n=168 \)) than males (43.8%; \( n=132 \)) which reflects the higher HIV prevalence among females normally seen in the urban areas of Ethiopia. Reportedly the adult HIV prevalence rate in urban areas of Ethiopia is higher among females, 9.25% compared to males (6.2%) (FMoH and FHAPCO 2007b:07). In a study conducted in Taiwan among 1,622 respondents, females were less likely to use a condom at their last sexual encounter which increased their chances of acquiring HIV infection (Tony et al 2011: 763). Gender and HIV risk have been widely examined in southern Africa, generally with a focus on dynamics within sexual relationships. “Yet the social construction of women’s lives reflects their broader engagement within a gendered social system, which influences both individual-level risks and social and economic vulnerabilities to HIV/AIDS” (Abigail et al 2013:1).
In terms of the respondents’ age groups, 42.3% (n=127) were 31 to 40 years of age, followed by those aged 18 to 30 (26.3%; n=79), then those aged 41 to 50 (23.7%; n=71), and those older than 50 (7.7%; n=23).

The measures of central tendency of the respondents’ ages included a mean of 36.47, median of 35.5 and standard deviation of 9.42. These statistics indicate that the average age of all respondents was 36.37 (mean) and that 50% of the respondents were younger and 50% were older than 35.5 (median) years of age. Besides, the average deviation of each respondent’s age from the mean age is 9.42 which indicates there is variation, implying that 68.0% of all respondents’ ages varied between 45.79 (36.37 + 9.42) and 26.95 (36.37 – 9.42), as explained by Polit & Hungler (1991:416). This finding is consistent with the demographic health survey conducted in Ethiopia in 2012. For women HIV prevalence increases with age to a peak of 3.7% at age 30-34. For men, HIV prevalence increases from 0.0%
at age 15-19 to 3.0% at age 35-39 and drops thereafter. Overall, HIV prevalence is higher for women than men in most age groups ((Abigail et al 2013:1; CSA and Macro International 2012:256).

![Figure 4.2: Respondents' age groups (N=300)](image)

**4.3.3 Urban-rural residential areas**

Most respondents lived in urban environments (76.3%; n=229) and this could be attributable to the study site which was an HIV clinic at an urban hospital. Only 16.0% of Ethiopia’s population lives in urban areas (CSA and Macro International 2012:25). This finding is also supported by the single prevalence estimate conducted in Ethiopia in 2007. According to the FMoH and FHAPCO (2007:4) the rural component of the national HIV prevalence estimate for 2007 was 0.9% as rural prevalence and 7.7% for urban prevalence.
4.3.4 Marital status

The marital status distribution shows that of the respondents 50.7% (n=152) were married, followed by those who were divorced or separated 19.3% (n=58), widowed 16.3% (n=49) and single 13.7% (n=41). This is also more or less similar with previous researchers' reports. According to CSA and Macro International (2012:81) 27% of women aged 15-49 were never married, 58% were married, 4% were living together with a man, and 11% were divorced, separated, or widowed. The low proportion (less than 1%) of women, aged 45-49, who had never been married indicates that marriage is nearly universal in this part of Ethiopia.

A study conducted in Malawi, reported an association between marriage and HIV infection. Although early sexual debuts, not marrying one’s first sexual partner and having a disrupted marriage increased the likelihood of HIV infection, their risk was not cumulative. Women who both delayed sexual debuts and did not marry their first sexual partners were more likely to experience marital disruption and to be HIV-positive than those who did not delay their sexual debuts but who married their first sexual partners (Boileau et al 2009:1).

4.3.5 Education

As far as their level of education was concerned, respondents who had not completed primary school made up 20.7% (n=62) of the total number, while 37.3% (n=112) had completed primary school, 31.3% (n=94) had completed secondary school, and 10.7% (n=32) had completed some (unspecified) post-school education. According to this study there was no evidence that a person’s educational level affected his/her TB case detection status. Whether a person had been educated or not, he/she could go through TB case detection as prescribed by the healthcare provider. This is also supported by a study conducted in Bangladesh (Mohammed et al 2002:1). This anonymous survey was conducted to assess the HIV-AIDS-related knowledge, practices and
behaviours of the respondents. Despite their low educational level, the respondents had a satisfactory level (93.4%) of essential knowledge about HIV/AIDS.

### Table 4.1: Respondents’ biographic information (N=300)

<table>
<thead>
<tr>
<th>Biographic Information</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>132</td>
<td>44.0</td>
</tr>
<tr>
<td>Female</td>
<td>168</td>
<td>56.0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>300</td>
<td>100.0</td>
</tr>
<tr>
<td><strong>Age group</strong> (mean=36.37, SD=9.42, md=35.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18 – 30</td>
<td>79</td>
<td>26.3</td>
</tr>
<tr>
<td>31 – 40</td>
<td>127</td>
<td>42.3</td>
</tr>
<tr>
<td>41 – 50</td>
<td>71</td>
<td>23.7</td>
</tr>
<tr>
<td>&gt;50</td>
<td>23</td>
<td>7.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>300</td>
<td>100.0</td>
</tr>
<tr>
<td><strong>Address</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>229</td>
<td>76.3</td>
</tr>
<tr>
<td>Rural</td>
<td>71</td>
<td>23.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>300</td>
<td>100.0</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>41</td>
<td>13.7</td>
</tr>
<tr>
<td>Married</td>
<td>152</td>
<td>50.7</td>
</tr>
<tr>
<td>Divorced/separated</td>
<td>58</td>
<td>19.3</td>
</tr>
<tr>
<td>Widowed</td>
<td>49</td>
<td>16.3</td>
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<tr>
<td><strong>Total</strong></td>
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<td>100.0</td>
</tr>
<tr>
<td><strong>Educational status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Didn’t complete primary</td>
<td>62</td>
<td>20.7</td>
</tr>
<tr>
<td>Completed primary</td>
<td>112</td>
<td>37.3</td>
</tr>
<tr>
<td>Completed secondary</td>
<td>94</td>
<td>31.3</td>
</tr>
<tr>
<td>Post school qualification</td>
<td>32</td>
<td>10.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>300</td>
<td>100.0</td>
</tr>
</tbody>
</table>

### 4.4 TB screening procedures followed by the HIV clinic

Table 4.2 indicates that 99.3% (n=298) of the HIV-patients, had TB screening tests performed on the same day of enrolment at their respective HIV clinics. (“Enrolment” refers to the registration of the patients at the HIV clinic after their HIV diagnosis had been confirmed). According to Ethiopia’s TB/HIV
GUIDELINES (FMoH 2007:23) all HIV-positive patients should be screened by the HIV clinic, which was not fully implemented by the HIV clinic.

This finding is also consistent with other research conducted in Ethiopia. According to Assefa (2011:411), intensified TB case finding is used in PLWHIV to reduce the burden of TB. A retrospective study was conducted among 300 PLWHIVs attending an HIV clinic in Ethiopia to assess TB screening performance during a 12-month period. Between 80% and 95% of patients were screened for TB at enrolment and at each three monthly follow-up visit. Thirty-four (11%) patients were diagnosed with TB.

According to the WHO (2011:65), until 2010 data on intensified tracing for TB among people living with HIV and provision of IPT to those without active TB were requested from NTPs as part of the global TB data collection form. It was noted that monitoring of access to these two interventions at country level is considered weaker than for other interventions such as ART.

According to the Ethiopian TB/HIV GUIDELINES, regular TB screening among HIV-positive patients, at every stage of the disease, is mandatory (FMoH 2008:25), with the aim to reduce the burden of TB among PLWHIV.

4.4.1 Methods used for TB screening

According to the current study's findings only clinical assessments were used for TB screening. These clinical assessments involved only a questionnaire of TB symptoms to be completed by the patient. No laboratory tests were conducted.

The WHO guidelines recommend TB screening using four symptoms (current cough, fever, weight loss and night sweats) and providing IPT if these symptoms are absent. This symptom-based screening questionnaire is effective in
accelerating TB screening in settings where the prevalence of TB among people living with HIV is 5% or higher (WHO 2011:68).

In Ethiopia routine data from 44 sites in the year 2005/6 showed that 41% of TB patients were HIV-positive. Other routine data collected in 2006/7 showed that the co-infection rate was 31% (FMoH 2007:9). Therefore, rigorous TB tracing mechanisms are suggested by the national TB/HIV Guideline. Rates of smear-negative pulmonary and extra pulmonary tuberculosis have been rising in countries experiencing HIV epidemics. The mortality rate among HIV-infected TB patients is higher than that of non-HIV infected TB patients, particularly for those with smear-negative PTB and extra EPTB. Delayed diagnosis might contribute to mortality among people living with HIV who have smear-negative PTB and EPTB (FMoH 2007:5). These statistics necessitated the FMoH to insist on intensified TB case finding, including laboratory tests. For WHO stage 1 and 2 HIV-positive patients, the FMoH suggested clinical screening with sputum examinations. For HIV patients in WHO stage 3 and 4 it is highly recommended to conduct clinical assessments, sputum examinations, chest X-rays and other laboratory tests to increase the TB case detection rate (FMoH 2007:6). The findings of this study did not indicate that the FMoH’s guidelines were fully implemented at the HIV clinic participating in this survey.

There is growing evidence from national Ethiopian TB prevalence surveys and other research of a large pool of undetected TB in the community. Intensified efforts to further break down access barriers and scale up new and rapid diagnostic tools are likely to improve the situation particularly for high risk groups such as patients suffering from TB/HIV co-infection (Lonnroth 2013:289).

TB case detection among HIV patients are categorised according to smear positive PTB, smear negative PTB and EPTB. In resource constraint and HIV highly prevalent settings, the WHO recommends conducting clinical symptom
assessments, AFB for sputum, sputum cultures or chest X-rays individualised according to the type of the TB (WHO 2007:6a).

4.4.2 **Outcomes of TB screening**

The goal of TB case detection among PLWHIV is to detect TB as early as possible and provide treatment or prophylaxis to PLWHIV to reduce morbidity and mortality. Intensified efforts are needed to approach the Global Plan’s targets of providing screening for TB for all those enrolled in HIV care and providing IPT to all those attending HIV care services who are eligible for it by 2015 (WHO 2011:65).

In this research, the outcomes of the TB screening procedures conducted amongst HIV patients included that:

- 84.3% (n=253) had no TB
- 11.7% (n=35) were TB suspect, and
- 4.0% (n=12) were diagnosed as suffering from TB.

Out of the 253 patients who did not have TB, 60.9% (n=154) started IPT. Out of these 154 IPT patients, 98.1% (n=151) completed their treatments, 1.3% (n=2) were on treatment, and 1.3% (n=2) defaulted before completing their IPT. Similar results were reported by a study conducted in Uganda. According to Namuwenge PM, et al (2011:1), a retrospective cohort study was conducted from 2006-2008 and revealed that out of 586 patients who started IPT, 341 (58.2%) were lost to follow-up, 197 (33.6%) completed IPT, 29 (4.9%) discontinued IPT and 19 (3.2%) died.

According to the WHO (2009c:12), IPT is effective among people living with HIV because it reduces the risk of developing active TB. The incidence of TB also decreases in HIV-positive cohorts on ART.
Therefore, increasing TB screening and enrolling eligible patients on IPT is a critical intervention for reducing morbidity and mortality of HIV patients. The finding of this research is also in line with findings from other countries as reported by the WHO. Globally, during 2008, almost 1.4 million TB patients were tested for HIV and accessed HIV prevention, treatment and care services, up from 1.2 million in 2007 (WHO 2009e:1). Of the TB patients who were known to be HIV-positive, two thirds (200 000) received co-trimoxazole treatment (CPT) and one third (100 000) received ART. During 2008, the number of people living with HIV, who were screened for TB, more than doubled from 600 000 in 2007 to 1.4 million in 2008. However, this represents only a fraction of the 33 million people estimated to be living with HIV. In 2008, only 56 000 people living with HIV, commenced IPT but TB infection control measures are not yet implemented in many HIV service settings, particularly in the SSA region. All these figures are powerful indicators for a need of accelerated implementation of TB/HIV collaborative activities, particularly TB case detection among PLWHIV, (WHO 2009e:2) to reduce the mortality and morbidity rates among persons co-infected with TB and HIV.

Furthermore the FMoH insists that strict IPT adherence should be encouraged among all IPT patients. However, TB must be excluded before IPT can be commenced even in areas where diagnostic capacities are limited. In settings where there are no facilities for chest x-rays, it might be better not to start IPT for symptomatic patients as they might indeed be suffering from TB. It would be advisable to do TB evaluations on WHO stage 3 and 4 HIV patients three months after commencing ART, so as to decide whether to implement IPT or not (FMoH 2007:16).

The implementation of IPT intervention has been a challenge at the global level. IPT has been shown to be beneficial for PLWHIV, but uptake has been slow due to resource constraints and reluctance on the part of policy makers and programme implementers. IPT is primarily an HIV intervention, which should be
the responsibility of national AIDS programmes, HIV services, and primary health care (PHC) services where PLWHIV receive treatment. Prevention of TB in this population will contribute to the overall goal of reducing the global TB burden and improving the quality of life of PLWHIV (Getahun 2010:57).

Out of 300 HIV-positive patients, 15.3 % (n=46) were diagnosed with TB. Out of these 46 TB patients, 34.8% (n=16) were diagnosed with smear positive PTB, 34.8% (n=16) with smear negative PTB, and 30.4% (n=14) with EPTB. The TB/HIV GUIDELINES is in line with the global WHO recommendations in terms of diagnosing TB patients at the TB Clinic (WHO 2007:29; FMoH 2007:12). According to the WHO (2007:29) major changes in diagnosing TB patients among PLWHIV have been recommended:

- the diagnosis should be adapted with patients suspected of having TB and living in settings with an HIV prevalence >1% among pregnant women or an HIV-prevalence ≥5% among TB patients
- separate diagnostic guidelines should be followed for patient's aged >15 and for childhood TB (not applicable to this study which focussed only on adult TB patients)
- adhering to the international standards for tuberculosis care
- “trial” antibiotics is not required to diagnose smear-negative PTB
- two sputum specimens, one must be collected in the morning, are sufficient for the initial diagnosis of TB in HIV patients
- a patient is considered to have smear-positive TB if at least one sputum specimen is positive for AFB
- sputum culture for MTB should be performed in patients who are sputum smear-negative to confirm the diagnosis of tuberculosis

Out of the 38 respondents who were treated for TB, 86.8% (n=33) completed their treatment, 7.9% (n=3) were successfully cured, and 5.3% (n=2) were still on treatment.
Table 4.2 TB tracing among HIV-positive persons in the HIV clinic

<table>
<thead>
<tr>
<th>Background characteristics</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TB screening tests performed</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Same day</td>
<td>298</td>
<td>99.3</td>
</tr>
<tr>
<td>Missing</td>
<td>2</td>
<td>0.7</td>
</tr>
<tr>
<td>Total</td>
<td>300</td>
<td>100.0</td>
</tr>
<tr>
<td><strong>TB screening method used</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical assessment</td>
<td>300</td>
<td>100.0</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Total</td>
<td>300</td>
<td>100.0</td>
</tr>
<tr>
<td><strong>Outcome of TB screening</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TB excluded</td>
<td>253</td>
<td>84.3</td>
</tr>
<tr>
<td>TB suspect</td>
<td>35</td>
<td>11.7</td>
</tr>
<tr>
<td>TB diagnosed</td>
<td>12</td>
<td>4.0</td>
</tr>
<tr>
<td>Total</td>
<td>300</td>
<td>100.0</td>
</tr>
<tr>
<td><strong>IPT started for TB excluded</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>154</td>
<td>60.2</td>
</tr>
<tr>
<td>No</td>
<td>102</td>
<td>39.8</td>
</tr>
<tr>
<td>Total</td>
<td>256</td>
<td>100.0</td>
</tr>
<tr>
<td><strong>Outcome of IPT</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Still on treatment</td>
<td>2</td>
<td>1.3</td>
</tr>
<tr>
<td>Completed</td>
<td>151</td>
<td>97.4</td>
</tr>
<tr>
<td>Defaulted</td>
<td>2</td>
<td>1.3</td>
</tr>
<tr>
<td>Total</td>
<td>155</td>
<td>100.0</td>
</tr>
<tr>
<td><strong>Type of TB diagnosed</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smear positive pulmonary TB</td>
<td>16</td>
<td>34.8</td>
</tr>
<tr>
<td>Smear negative pulmonary TB</td>
<td>16</td>
<td>34.8</td>
</tr>
<tr>
<td>Extra pulmonary TB</td>
<td>14</td>
<td>30.4</td>
</tr>
<tr>
<td>Total</td>
<td>46</td>
<td>100.0</td>
</tr>
<tr>
<td><strong>Outcome of TB treatment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Still on treatment</td>
<td>2</td>
<td>5.3</td>
</tr>
<tr>
<td>Successfully treated</td>
<td>33</td>
<td>86.8</td>
</tr>
<tr>
<td>Successfully cured</td>
<td>3</td>
<td>7.9</td>
</tr>
<tr>
<td>Total</td>
<td>38</td>
<td>100.0</td>
</tr>
</tbody>
</table>

According to Hannock (2013:1), out of 2 361 new smear-positive pulmonary TB patients, 86% had successful treatment outcome (were cured or completed treatment), 5% died, 6% were lost to follow-up, 1% failed treatment, and 2% transferred-out. A TB patient is considered to be cured if the patient who was initially smear-positive becomes smear-negative during the last month of treatment and on at least one previous occasion (WHO 2011:41). A patient will be considered as having completed TB treatment when he/she has completed
treatment but did not meet the criteria for cure or treatment failure. This definition applies to pulmonary smear-positive and smear-negative patients and to patients with EPTB.

4.5 Challenges and limitations of TB-related activities at the hospital

According to the FMoH (2007:22) TB case finding should be intensified in all HIV testing and counselling services for HIV-positive clients to identify TB suspects early before their condition deteriorates. HIV-positive clients should be informed by the health care providers of HIV counselling and testing services about the advantages of being screened for TB. Once informed about the risk of developing active TB, they should undergo screening for TB and they should be further evaluated, using the WHO algorithm, for improving the diagnosis of smear negative TB in HIV-positive patients.

As shown in table 4.3, for 98.3% (n=295) of the patients, initial TB screening was conducted by a hospital nurse, followed by a hospital doctor (1.0%; n=3), or community health worker (0.7%; n=2). Only one patient’s file indicated that stigma was a challenge that caused the patient to refuse TB screening or IPT. Only one patient’s contacts were traced and found to be suffering from TB. Two patients were restarted on anti-TB category two drugs and their cultures and drug sensitivities were retested. This was done because these two HIV-positive patients had developed TB re-infections although they had already received anti-TB treatment.

However, some studies on TB/HIV conducted in Ethiopia revealed significant double stigma of TB/HIV co-management. A study conducted in the Ormiya region, Ethiopia, had a total of 591 participants of whom 124 (21.0%) were co-infected with TB/HIV. The stigma items were highly reliable (Cronbach’s alpha = 0.93) and had strong inter-dimensional correlations. Respondents who were co-infected with TB and HIV were more likely to have perceived stigma compared to
non-co-infected HIV patients (OR=1.4, 95% CI). Non-literate individuals (OR = 1.9, 95% CI) and females (OR = 1.6, 95% CI) reported more perceived stigma.

Another study conducted in Addis Ababa, Ethiopia, indicated that stigma and knowledge about TB/HIV co-infection was limited. According to Mekdes et al (2011:1) a qualitative study was conducted among 12 TB/HIV patients and 9 health workers. Most patients were aware of an association between TB and HIV. Some reported that TB could transform into HIV, while others said that the body could be weakened by HIV and become more susceptible to illnesses such as TB. Some patients classified TB as either HIV-related or non-HIV-related, and weight loss was a hallmark for HIV-related TB. Most patients believed that people in the community knew that there was an association between TB and HIV, and some feared that this would predispose them to HIV-related stigma.

<table>
<thead>
<tr>
<th>Table 4.3 Challenges and limitations of TB-related activities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Background characteristics</strong></td>
</tr>
<tr>
<td><strong>Health professional who conducted TB screening</strong></td>
</tr>
<tr>
<td>Community health worker</td>
</tr>
<tr>
<td>Hospital nurse</td>
</tr>
<tr>
<td>Hospital Doctor</td>
</tr>
<tr>
<td><strong>Total</strong></td>
</tr>
<tr>
<td><strong>Stigma as a challenge for TB screening and preventive therapies</strong></td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td><strong>Total</strong></td>
</tr>
<tr>
<td><strong>Able to trace TB patient’s contact</strong></td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td><strong>Total</strong></td>
</tr>
<tr>
<td><strong>Contacts tested positive for TB</strong></td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td><strong>Total</strong></td>
</tr>
<tr>
<td><strong>What done for re-infection of TB</strong></td>
</tr>
<tr>
<td>Culture and drug sensitivity test</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td><strong>Total</strong></td>
</tr>
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</table>
### Referral to MDR centre

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>1</td>
<td>299</td>
</tr>
<tr>
<td></td>
<td>0.3</td>
<td>99.7</td>
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</tbody>
</table>

### Restarting the patient on category two of anti TB drugs

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>2</td>
<td>298</td>
</tr>
<tr>
<td></td>
<td>0.7</td>
<td>99.3</td>
</tr>
</tbody>
</table>

|        | 300 | 100   |

### 4.6 Clinical Findings

The clinical findings of this study, discussed in the following sections, include CD4 counts' correlations with HAART and TB/HIV co-management.

### 4.6.1 CD4 counts and relationships with HAART

According to Williams et al. 2013:2798, the concentration of CD4 T-lymphocytes (CD4 count), in a person's plasma is widely used to decide when to start HIV-positive people on ART and to predict the impact of ART on the future course of HIV and TB. However, CD4 cell counts vary widely within and among populations and depend on many factors besides HIV-infection. The way in which CD4 counts decline over the course of HIV infection is neither well understood nor widely agreed upon.

In this study, in terms of patients' CD4 count at the point of the start of their HAART treatment, 72.1% (n=214) were under 200, 23.2% (n=69) within the range of 200-349, and 4.7% (n=14) had CD4 counts greater than or equal to 350.

The measures of central tendency of the respondents' CD4 counts during a time in which HAART had been started included a mean of 172.34, median of 124.5 and standard deviation of 80.86. These statistics indicate that the average CD4 count of all respondents was 172.34 (mean) and that 50% of the respondents had CD4 counts of less than 124.5 while 50% of respondents have
greater than 124.5 CD4 count (median). Besides, the average deviation of each respondent’s CD4 count from the mean CD4 count was 80.86, indicating variations, implying that 46.92% of all respondents’ CD4 count varied between 253.2 (172.34 + 80.86) and 91.48 (172.34 – 80.86).

The Pearson correlation coefficient between patients’ CD4 count for the duration of their HAART and their age was calculated to be r=-0.041 with a p-value of 0.485. This depicts a slightly negative correlation as the age of the patient increased, the CD4 count decreased, and vice versa. This relationship, however, was not statistically significant at the 5% level, since the p-value of 0.43 is greater than 0. This finding of this study is also supported by another study conducted in Nepal in 2012. Bhatta et al (2012:6) conducted a descriptive retrospective cross-sectional study among 258 clients, at registered ART sites in the Doti district from August to October 2011. There was significant improvement in CD4 counts in patients taking ART within the first year of treatment and yet the mortality rate among this group was also high in these six months. This finding indicates that the first six months of ART is crucial for every aspect of management of the HIV-positive patients.

4.6.2 TB/HIV co management

According to the WHO (2008d:1), TB is the most frequent life threatening opportunistic disease for PLWHIV, even in those receiving ARVs. TB remains the leading cause of death. Thus, TB/HIV co-management is a key intervention to improve the quality of life of PLWHIV.

The Ethiopian ART Guidelines (FMoH 2006: 24) indicate that all TB patients at WHO clinical stage III with CD4 counts < 350 cells/mm3 are eligible for ART. TB patients with WHO clinical stage IV defining conditions are also eligible for ART, irrespective of their CD4 count.
Table 4.4 indicates that 95.7% (n=287) of the patients’ CD4 counts were used as indicators to start HAART, while for 60% (n=180) clinical assessments were also employed. For only one patient the viral load was used as an indicator to start HAART.

According to Salim et al (2010:543) an open-label, randomised, controlled trial in Durban, South Africa, was conducted among 642 patients with both TB and HIV infection to start antiretroviral therapy either during anti-TB therapy (in two integrated therapy groups) or after the completion of such treatment (in one sequential therapy group). The initiation of ART during anti-TB therapy significantly improved survival and provided further impetus for the integration of TB and HIV services.

Another study in Ethiopia has revealed the importance of TB/HIV co-management. According to Sileshi et al (203:297), despite the availability of free ART from health institutions in Northwest Ethiopia, mortality was high among TB-HIV co-infected patients, and strongly associated with the absence of ART during TB treatment. In addition prophylactic therapy remained an important factor in the reduction of mortality rates during anti-TB treatment. The study also noted the importance of early commencement of ART even at higher CD4 counts. Another study also indicated simultaneous HAART and TB treatment in dual infected patients to be associated with improved survival rates (Velasco et al 2009:148).

According to the WHO (2009b:71), when TB is diagnosed in patients already receiving ART, TB treatment should be started immediately. There are two issues to consider in such cases. Firstly it must be established whether ART needs to be modified because of drug–drug interactions or to reduce the potential for overlapping toxicities, since both treatments can be hepato-toxic. Secondly it needs to be determined whether the presentation of active TB in a patient on ART constitutes ART failure that requires a change in the ART regimen.
According to the FMoH (2007:17), the first line HAART regimen comprises Stavudine, Lamuvidine, and Nevirapine. But Stavudine is associated with major potential toxicity, neuropathy, pancreatitis and lipo-atrophy while Nevirapine is related with hepatotoxicity and severe rashes. If Nevirapine is used with Rifampicin and INH, severe hepato-toxicity is a potential side effect. Thus for TB/HIV co-infected patients it is suggested to use an Efavirenz-based regimen.

In addition, according to Dianna et al (2004:1), 49 AIDS patients, most of whom were on ART, with active TB, were treated with Rifampin 600mg, Isoniazid 400mg and Pirazinamide 2g daily. They also received ARVs, consisting of Efavirenz (600mg/day) plus 2 NRTIs. All patients were prospectively followed up for at least 24 months. A non-concomitant ARV regimen was introduced at least three weeks after TB treatment initiation. Severe adverse reactions included rashes (two), toxic hepatitis (six), IRIS (seven), and four deaths. The study concluded that Efavirenz at a daily dose of 600 mg was sufficient and safe to treat TB/HIV patients using a rifampicin-containing regimen.

In the current study, the proportions of the total number of treatment regimens used for existing HIV-positive patients on treatment were:-

- Stavudine (d4T) + Lamivudine (3TC) + Nevirapine (NVP), 33.3% (n=82)
- Zidovudine (AZT) + Lamivudine (3TC) + Nevirapine (NVP), 19.9% (n=49),
- Zidovudine (AZT) + Lamivudine (3TC) + Efavirenz(EFV), 2.8%(n=7), and
- Other regimens 43.9% (n=108).

The proportions of the total number of treatment regimens used for the new HIV-positive patients, in the current study, on treatment were:-

- Stavudine (d4T) + Lamivudine (3TC) + Nevirapine (NVP), 5.1% (n=2),
- Zidovudine (AZT) + Lamivudine (3TC) + Nevirapine (NVP), 5.1% (n=2),
- Zidovudine (AZT) + Lamivudine (3TC) + Efavirenz(EFV), 17.9% (n=7), and
- Other regimen, 71.8% (n=28).
These figures indicate that for all of the patients with newly commenced HAART treatment regimes, Nevirapine-based regimens were excluded. This is a good practice for TB/HIV co-infected patients, as they would not be forced to change their HAART regimen when they start their anti-TB treatment.

According to the WHO (2007:62), the use of INH, the main anti-TB drug used with a HAART regimen containing Nevirapine, increases heap-totoxicity. Some of the critical decisions in the management of TB/HIV co-infected patients include when to start ART (tarting); when to substitute one therapy for another because of significant side effect (ubstitution); when to switch therapy because of treatment failure (witching); and when to stop therapy and move to end-of life and palliative care due to second-line regimen treatment failure (topping) (FMoH 2007:9)

Table 4.4 Challenges and limitations of HIV-related activities in the hospital

<table>
<thead>
<tr>
<th>Background characteristics</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indicators used to start HAART</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CD4 count</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>287</td>
<td>95.7</td>
</tr>
<tr>
<td>No</td>
<td>13</td>
<td>4.3</td>
</tr>
<tr>
<td>Total</td>
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<td>100.0</td>
</tr>
<tr>
<td><strong>Viral load</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1</td>
<td>0.3</td>
</tr>
<tr>
<td>No</td>
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<td>99.7</td>
</tr>
<tr>
<td>Total</td>
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<td>100.0</td>
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<td><strong>Clinical assessment</strong></td>
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<td></td>
</tr>
<tr>
<td>Yes</td>
<td>180</td>
<td>60.0</td>
</tr>
<tr>
<td>No</td>
<td>120</td>
<td>40.0</td>
</tr>
<tr>
<td>Total</td>
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</tr>
<tr>
<td><strong>CD4 count while HAART started</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(mean=172.34, st.devn.=80.86, median=124.5)</td>
<td>214</td>
<td>72.1</td>
</tr>
<tr>
<td>&lt; 200</td>
<td>69</td>
<td>23.2</td>
</tr>
<tr>
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</tr>
<tr>
<td>&gt;= 350</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
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<td>100.0</td>
</tr>
</tbody>
</table>
### Treatment regimen for new HIV-positive patient

<table>
<thead>
<tr>
<th>Treatment Regimen</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stavudine (d4T) + Lamivudine (3TC) + Nevirapine (NVP)</td>
<td>82</td>
<td>33.3</td>
</tr>
<tr>
<td>Zidovudine (AZT) + Lamivudine (3TC) + Nevirapine (NVP)</td>
<td>49</td>
<td>19.19</td>
</tr>
<tr>
<td>Zidovudine (AZT) + Lamivudine (3TC) + Efavirenz(EFV)</td>
<td>7</td>
<td>2.8</td>
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<tr>
<td>Other regimen</td>
<td>108</td>
<td>43.9</td>
</tr>
<tr>
<td>Total</td>
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<td>100.0</td>
</tr>
</tbody>
</table>

### Treatment regimen for the existing HIV patient on treatment

<table>
<thead>
<tr>
<th>Treatment Regimen</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stavudine (d4T) + Lamivudine (3TC) + Nevirapine (NVP)</td>
<td>2</td>
<td>5.1</td>
</tr>
<tr>
<td>Zidovudine (AZT) + Lamivudine (3TC) + Nevirapine (NVP)</td>
<td>2</td>
<td>5.1</td>
</tr>
<tr>
<td>Zidovudine (AZT) + Lamivudine (3TC) + Efavirenz(EFV)</td>
<td>7</td>
<td>17.9</td>
</tr>
<tr>
<td>Other regimen</td>
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<td>71.8</td>
</tr>
<tr>
<td>Total</td>
<td>39</td>
<td>100.0</td>
</tr>
</tbody>
</table>

### 4.7 CONCLUSION

According to this study individual' gender and age group were found to be statistically significant predictors for starting IPT among TB-excluded HIV-positive patients.

The findings of this study depicted that for the 99.3% of the HIV-positive patients TB screening was performed on the same day of enrolment at their respective HIV clinics. And the percentage of the outcome of TB screening for HIV patients were 84.3% for TB-excluded followed by 11.7% TB-suspects and 4% TB-diagnosed.

The next chapter will present the conclusions, limitations and recommendations of this study as well as propose areas for possible future research.
CHAPTER 5
CONCLUSIONS, LIMITATIONS AND RECOMMENDATIONS

5.1 INTRODUCTION

The purpose of the study was to identify problems encountered during the implementation of TB case detection among HIV-positive persons at one hospital in Ethiopia. The time and type of TB diagnostic procedures were examined. Based on the findings of this study, recommendations are suggested to improve the existing TB/HIV co-management guidelines to improve the TB diagnosis of HIV-positive persons, and to increase the number of HIV-positive patients referred for effective TB treatment at the participating site.

This chapter presents the conclusions of the study which are related to the following research questions stated in section 1.4 of this dissertation:

- What percentage of HIV-positive persons were screened for TB in the HIV clinic based on the reports in the patients’ files?
- How long after the diagnosis of being HIV-positive, was the patient referred for TB screening?
- What treatment was provided to the HIV-positive persons diagnosed with TB?
- What were the TB treatment outcomes of the referred HIV-positive persons?

This chapters also identified the limitations of the study and provides possible recommendations which are relevant for conducting future studies and for enhancing the TB/HIV co-management strategies at the participating hospital in Ethiopia.
5.2 CONCLUSIONS IN RELATION TO THE STUDY’S OBJECTIVES

The purpose of the study was to identify problems encountered during the implementation of TB case detection among HIV-positive persons at one hospital in Ethiopia.

5.2.1 Objective: Identify problems with the implementation of the TB/HIV guidelines at one hospital in Ethiopia

Out of the 256 patients for whom TB had been excluded, 60.2% (n=154) had started IPT. All these 256 patients should have commenced with IPT to prevent the progression of latent TB to active TB, and to help prevent further transmission of TB in the communities. IPT is the one of the key intervention to reduce morbidity and mortality among TB/HIV clients.

5.2.2 Objective: Assess whether the TB case detection among HIV-positive persons are conducted according to the TB/HIV management guidelines.

As shown in table 4.3, most patients’ initial TB screening tests were conducted by hospital nurses (98.3%) compared to the 1.0% done by hospital doctors. The NTG states this screening should be done by qualified health professionals. Quality TB/HIV care is required to suppress the HIV to an undetectable level and cure TB to increase immunological responses and enhance patients’ well-being. Qualified and trained health workers improved the quality of patients’ lives through decreasing morbidity of these two diseases (WHO 2004a:1; WHO 2012:83).
5.2.3 Objective: Identify what diagnostic procedures were used to detect TB among HIV-positive persons

In this study it was revealed that HIV-positive patients’ CD4 counts were not considered when they were screened for TB by completing questionnaires. No laboratory tests were performed. This traditional symptom screening is insufficient for detecting TB disease among HIV infected persons particularly for HIV patients at advanced WHO stages. In addition to the questionnaire, x-rays and sputum examinations could enhance the early diagnosis and timely treatment of TB. It will also prevent giving INH prophylaxis to HIV-positive patients who might be suffering from TB but who remained undetected when the questionnaires were completed.

5.2.4 Objective: Identify how long after being diagnosed HIV-positive, a patient was referred for TB investigations

The results show, for the 99.3% of the respondents, TB screening test was performed on the same day of enrolment at their respective HIV clinics. This is in line with the WHO recommendation which states that TB screening should be done at the time that HIV infection is diagnosed, before the initiation of ART and at regular intervals during follow up.

Implications: All TB screening is conducted on the same day of their visit to HIV clinic which is in line with the national TB/HIV Guideline. However, all possible efforts should be made to screen all 100% of HIV patients visiting the clinic (WHO 2012:83).

5.3 LIMITATIONS OF THE STUDY

The limitations that were identified during the study included that:

- The study was conducted at one of the nine Ethiopian public health facilities where the TB/HIV collaborative management had been piloted
since 2005 which cannot be generalised to the whole country’s TB/HIV collaborative activities.

- A review of the HIV-positive patients’ records was done. No information was collected from health professionals about the actual performance of their HIV/TB collaborative activities in the hospital that participated in this study.
- This research covered only 10% of the estimated population of 3,000 follow-up HIV patients who are visiting this clinic on a monthly basis.
- It is a quantitative study which was not supported by qualitative data.

5.4 RECOMMENDATIONS

The following recommendations could help to improve TB case detections among HIV-positive patients at one hospital in Ethiopia:

- The hospital should be equipped to test HIV-positive patients for TB by using chest x-rays, sputum smears and microscopic cultures and sensitivity examinations.
- If IPT is administered to HIV-positive patients suffering from TB, INH resistance could develop. Therefore it is necessary to design improved ways of delivering IPT especially to those with early HIV infection, for whom TB has definitely been excluded.
- Because of the poor performance of sputum smear microscopy in HIV infected patients, newer diagnostic tests are urgently required that are not only sensitive and specific but also easy to use in remote and resource constrained settings.

The following recommendations pertain to future studies assisting researchers to increase the quality and coverage of TB case identification:

- Similar studies duplicated in other health facilities would enable comparisons of the findings and possible generalisations to more facilities providing HIB/TB collaborative services.
• The association should be investigated between the status of HIV-positive TB-excluded patients who commenced IPT early and completed the prophylactic regimen, and patients who did not do so.

• Reasons should be investigated as to why only patients’ completed questionnaires were accepted as clinical assessments of TB screening. The possibility of using x-rays and laboratory tests should also be investigated as well as the cost-effectiveness of this potential approach. Meticulous records should be kept of all HIV-positive patients who were diagnosed with TB at any stage.

• The effectiveness of TB screening conducted mostly by hospital nurses should be investigated, potential shortcomings identified and addressed by in-service education and sustained audits of patients’ records.

• Problems encountered by the health professionals at public health facilities to apply the country’s guidelines for TB/HIV co-infected patients should be investigated on an ongoing basis and remedial actions should be implemented.

• Conduct qualitative research to determine the knowledge, attitudes and perceptions of people in the community concerning the association between HIV and TB.

• Monitor the quality of TB screening methods used at the participating hospital and other public health facilities where TB/HIV collaborative activities are implemented.

• Identify factors influencing the treatment of TB among HIV patients.

Regular audits should be done to keep management informed about the challenges and the accomplishments experienced by health care workers during the implementation of the TB/HIV collaboration guidelines.

Basic and post basic nursing, medical and related programmes should emphasise the dire necessity for implementing effective TB/HIV collaborative activities. Regular in-service education sessions should also address this issue.
5.6 CONCLUDING REMARKS

Diagnosing TB among HIV-infected individuals is a major public health challenge. This study showed that screening for TB is based almost exclusively on questionnaires completed by patients to assess clinical symptoms. In the hospital chest x-rays, sputum smear and microscopic culture and sensitivity were not used as TB screening methods.

The findings of this study revealed 99.3% of the HIV-positive patients had TB screening tests performed on the same day that they enrolled at their respective HIV clinics. The outcomes of TB screening for HIV-positive patients were: 84.3% for TB-excluded followed by 11.7% TB-suspected and 4% TB-diagnosed.

Out of 300 HIV-positive patients, 46 (15.3%) were diagnosed as suffering from TB: 16 (34.8%) were smear positive PTB, 16 (34.8%) were smear negative PTB and 14(4.7%) were EPTB.

Only one patient refused TB screening due to the fear of stigmatisation of TB in the community.

Van Rie, Westreich and Sanne (2011:354) maintain that “… TB remains a major challenge to the health of people living with HIV in sub-Saharan Africa, even among those receiving ART. Severity of HIV disease is the strongest risk factor for prevalent and early incident TB and response to ART the strongest risk factor for late incident TB. Early initiation of ART will significantly reduce TB incidence among people on ART…” Thus it remains vital that TB should be diagnosed and treated early among HIV-positive patients, and that IPT should be administered early to prevent the development of TB in HIV-positive patients who do not suffer from TB. However, IPT must be avoided in all persons already suffering from TB, explaining why accurate diagnosis of TB remains vital for commencing IPT or anti-treatment before complications arise.
LIST OF REFERENCES


CSA – see Central Statistical Agency (Ethiopia)


FMoH – see Federal Ministry of Health (of Ethiopia)


UNAIDS – see Joint United Nations Programme on HIV/AIDS


WHO - see World Health Organization.


World Health Organization. 2008d. Intensified Case Finding (ICF), Isoniazid Preventive Therapy (IPT) and TB Infection Control (IC) for people living with HIV. Geneva.


Date: 08/14/ 2012

To: Manager, Adama Hospital
   Ethiopia, Adama

   Re: Support Letter

I am called Dr Tedla Mezemir Damte who has worked as a clinician, medical director, health department head, university lecturer/health faculty dean, and public health implementer with international organizations and UN agencies at different level in health development field. In regard with my professional development, I am doing my MPH degree with University of South Africa.

As part of completion of my MPH degree, I am currently doing my thesis titled as ‘Tuberculosis case detection among HIV positive persons in a hospital in Ethiopia’. As you might be aware I have worked in the same hospital for long time as a deputy director and director of this hospital. In addition, I led the establishment of the HIV clinic in the hospital. This would have given me a better understanding of the situation and therefore I would like to conduct my research in Adama Hospital.

The aim of this study is to assess the implementation of TB case detection among HIV positive persons in Adama hospital.

Specific objectives include;

- Assess whether the TB case detection among HIV positive persons are conducted according to the TB/HIV management guidelines
- Identify how TB case detection among HIV positive persons was conducted (what diagnostic TB procedures were conducted)
- Identify how long after the diagnosis of being HIV positive, a patient was referred for TB investigations.

The finding of this study will be used as an input to strengthen the quality of the TB/HIV co management in Adama Hospital, Ethiopia. The research will also be used to enrich the body of knowledge and baseline references for TB/HIV in the country, which will support the scale up of the service in the country. The main finding of this study will be presented to relevant MoH structure such as Ethiopian Public Health Association.
Thus, I am kindly asking your support to conduct the assessment in your Hospital, which is the referral hospital for this specific region of the country.

Thank you in advance for the support,

With many regards,

Tedla Mezemir Damte
Final Year UNISA Student
Std No: 36670650
UNIVERSITY OF SOUTH AFRICA
Health Studies Higher Degrees Committee
College of Human Sciences
ETHICAL CLEARANCE CERTIFICATE

HSHDC/84/2012

Date: 3 October 2012  Student No: 3667-065-0

Project Title: Tuberculosis case detection among HIV positive persons in a hospital in Ethiopia

Researcher: TM Damte
Degree: Masters in Public Health
Code: DIS4986
Supervisor: Prof VJ Ehlers
Qualification: D Litt et Phil
Joint Supervisor: -

DECISION OF COMMITTEE

Approved [✓]  Conditionally Approved [ ]

Prof L Roets
CHAIRPERSON: HEALTH STUDIES HIGHER DEGREES COMMITTEE

Dr MM Moleki
ACTING ACADEMIC CHAIRPERSON: DEPARTMENT OF HEALTH STUDIES

PLEASE QUOTE THE PROJECT NUMBER IN ALL ENQUIRES
ANNEXURE A: Map of Ethiopia
Annexure B: Checklist (research instrument)

TUBERCULOSIS CASE DETECTION AMONG HIV POSITIVE PERSONS IN A HOSPITAL IN ETHIOPIA

INSTRUMENT:

The researcher will complete a checklist from each patient’s file. The researcher will keep a list indicating the checklist number and the corresponding patient’s HIV register number in an excel sheet format, but no patient’s file number will be entered onto any checklist. The researcher will also keep the file under lock and correlate every completed checklist’s number with the patient’s file number, in case future audits of the entered data might be required.

CHECKLIST

SECTION I: Biographic data

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<th>Questions</th>
<th>Coding categories</th>
<th>Remark</th>
</tr>
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<td>...................</td>
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<tr>
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<td>2. Female</td>
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<tr>
<td>003</td>
<td>Age of the patient</td>
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<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. 30 – 39</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>3. 40 – 49</td>
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</tr>
<tr>
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<td>4. 50 and older</td>
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<td>-----------</td>
<td>-------------------</td>
<td>--------</td>
</tr>
</tbody>
</table>
| 005 | Marital status of the patient | 1. Single  
2. Co-habiting  
3. Married  
4. Divorced/Separated  
5. Widowed  
6. Not recorded | |
| 006 | Educational status of the patient | 1. Did not complete primary school  
2. Completed primary school (7 years)  
3. Completed secondary school (12 years)  
4. Post school qualifications, please specify | |
| 007 | After how many days of enrolment in the HIV clinic, was TB screening tests performed? | 1- Same day  
2- 2-29 days  
3- 30 – 89 days  
4- 90 days or more | |
| 008 | How many times did the patient visit the HIV clinic before the first TB screening test was done? | .......times | |
| 009 | What TB screening method was used? (mark every test done) | 1. Clinical assessment  
2. Chest x-rays  
3. Sputum smear  
4. Microscopic culture and sensitivity |
| 010 | What was the outcome of the screening for the patient? | 1. TB excluded  
2. TB suspect  
3. TB diagnosed (please specify date of TB diagnosis)  
4. Not recorded |
| 011 | If TB was excluded, did the patient start with IPT? | 1. Yes  
2. No |
| 012 | If the patient was on IPT what was the outcome? | 1. Still on treatment  
2. Completed  
3. Defaulted |
| 013 | If the patient defaulted on the IPT, what was the reason? (Please record all relevant reasons). | 1. Patient refused treatment  
2. Side effects (please specify)  
3. Family influence (please specify)  
4. Physician’s decision (give a reason)  
5. Patient referred to other facility (give a reason)  
6. Patient discontinued clinic visits (since what date?)  
7. Not recorded |
<p>| 014 | On what date was the patient (diagnosed with TB) referred to the TB clinic? |</p>
<table>
<thead>
<tr>
<th>No</th>
<th>Questions</th>
<th>Coding categories</th>
</tr>
</thead>
</table>
| 015| Which type of TB was diagnosed?                                           | 1. Smear Positive Pulmonary TB  
2. Smear Negative Pulmonary TB  
3. Extra Pulmonary TB (please specify organs affected by TB)  
4. Others, please specify |
| 016| If the patient was treated for TB what was the outcome?                   | 1. Still on treatment  
2. Successfully treated (specify reason)  
3. Successfully cured (based on what clinical results?)  
4. Defaulted (after how many weeks on TB treatment?)  
5. Not recorded |
| 017| During the period when the patient was on anti TB & ART, what consequences were reported? | 1. Anti TB discontinued because of side effects  
2. ART discontinued because of side effects  
3. ART regimen changed due to side effect  
4. CD4 count deteriorated due to anti TB treatment  
5. Patient discontinued follow up  
6. Others, please specify |

SECTION C: Challenges and limitations about TB/HIV collaborative activities in the hospital

<table>
<thead>
<tr>
<th>No</th>
<th>Questions</th>
<th>Coding categories</th>
</tr>
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</table>
| 018| Which health professional category conducted the first TB screening?      | 1. Community Health Worker  
2. Hospital Nurse  
3. Hospital Doctor  
4. Doctor at TB clinic |
<table>
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<tr>
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</table>
| 019 Is stigma recorded in the patient’s file as a challenge for refusing TB screening or for taking TB preventive therapies? | 1. Yes  
2. No                                                                 |
| 020 If the HIV positive patient was screened for TB after 6 months after enrolment at the HIV clinic, what was/were the reason(s) for late screening? (more than one reason can be indicated) | 1. Lack of lab supplies  
2. Shortage of health personnel  
3. Lack of other diagnostic equipments  
4. Lack of drugs and commodities  
5. Fear of stigma and discrimination  
6. Omission by the health workers contacted the patient  
7. Patient refusal  
8. Other, please specify                                                                 |
| 21 Were the TB patient’s contacts traced?                                | 1. Yes  
2. No                                                                 |
| 22 If the answer to q21 is “yes” please specify what tests were done on these contacts | TB tests done on contacts:  
………………………………………….  
………………………………………….                                                                 |
| 23 If contact tracing was done please indicate how many contacts of the patient were traced for each listed category | 1. Only partner/s (no….)
2. Children (no…)
3. Other family members (no…)
4. All close contacts who visited the patient during the previous month (no…..)
 |
| 24 If contacts were traced, how many contacts tested positive for TB?    | 1. Yes  
2. No                                                                 |
| 25 Please indicate which indications were used to start HAART? (More than answer can be recorded) | 1. CD4 count  
2. Viral load  
3. Clinical assessment                                                                 |
<p>| | | |</p>
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</table>
| 26 | Please indicate the CD4 count when HAART was started? **Please provide the exact CD4 count in every case and then circle the relevant category.** | 1. Up to 199  
2. Between 200-349  
3. 350 or more  
4. Not recorded  
5. Exact CD 4 count when HAART was started……… |
| 27 | If the HIV patient was on anti TB treatment and developed re-infection of TB, what has been done for the patient? | 1. Culture and drug sensitivity test  
2. Referral to MDR centre  
3. Restarting the patient on category two of anti TB drugs  
4. Others, please specify  
…………………………………… |
| 28 | Which treatment regimen was used for the new HIV positive patient on treatment during August 2012? | 1. Stavudine (d4T) + Lamivudine (3TC) + Nevirapine (NVP)  
2. Zidovudine (AZT) + Lamivudine (3TC) + Nevirapine (NVP)  
3. Zidovudine (AZT) + Lamivudine (3TC) + Efavirenz(EFV)  
4. Other regimen please specify  
…………………………………… |
| 29 | Which treatment regimen was used for the existing HIV patient on treatment during August 2012? | 1. Stavudine (d4T) + Lamivudine (3TC) + Nevirapine (NVP)  
2. Zidovudine (AZT) + Lamivudine (3TC) + Nevirapine (NVP)  
3. Zidovudine (AZT) + Lamivudine (3TC) + Efavirenz(EFV)  
4. Other regimen, please specify  
…………………………………… |
<p>| 30 | For how long did the patient take his/her TB treatment? | -----months |
| 31 | If the anti TB treatment was discontinued how many days after initiation of the TB |   |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>treatment was it discontinued?</td>
<td>1. During intensive phase (first two month)</td>
</tr>
<tr>
<td></td>
<td>2. During continuation phase</td>
</tr>
<tr>
<td></td>
<td>3. During full course of the anti TB treatment</td>
</tr>
<tr>
<td></td>
<td>4. Not applicable</td>
</tr>
<tr>
<td>For patients on TB/HIV co-treatment, when was the side effect intolerable and prominent?</td>
<td>1. During intensive phase (first two month)</td>
</tr>
<tr>
<td></td>
<td>2. During continuation phase</td>
</tr>
<tr>
<td></td>
<td>3. During full course of the anti TB treatment</td>
</tr>
<tr>
<td></td>
<td>4. Not applicable</td>
</tr>
<tr>
<td>If the patient received INH, what was the outcome of this treatment?</td>
<td></td>
</tr>
<tr>
<td>If the patient received CPT, what was the outcome of this treatment?</td>
<td></td>
</tr>
<tr>
<td>List all infections which the patient had during the preceding six months</td>
<td></td>
</tr>
<tr>
<td>For each infections listed in 35, please add the treatment provided and the outcome</td>
<td></td>
</tr>
</tbody>
</table>
Subject: Letter from Statistician

My name is Girum Taye Zeleke, BSc. in Statistics and MSc. in the field of Epidemiology and Biostatistics, currently serving as a lecturer of statistics at Kigali Institute of Science and Technology (KIST), Rwanda.

I have a tremendous experience in health related data analysis, presentation and interpretation.

This is to notify that I have provided statistical analysis assistance to Dr. Tedla Mezemir Damte for his interesting M.Sc. dissertation entitled “Tuberculosis case detection among HIV-positive persons in a hospital in Ethiopia”

With Best Regards

Girum