ADHERENCE BY HEALTHCARE PROVIDERS TO ETHIOPIA’S NATIONAL TUBERCULOSIS GUIDELINES

by

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SUPERVISOR: PROFESSOR VJ EHLERS

JUNE 2011
DECLARATION

I declare that ADHERENCE BY HEALTHCARE PROVIDERS TO ETHIOPIA'S NATIONAL TUBERCULOSIS GUIDELINES is my own work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references and that this work has not been submitted before for any other degree at any other institution.

Aragaw Getahun Sisay

ST no: 42056802

10th June 2011
DEDICATION

I dedicate this dissertation to my dear wife Emebet Yeshaw and my lovely son Ermias Getahun.
ACKNOWLEDGMENTS

First and foremost, I praise the almighty God for giving me the strength and endurance to complete this study.

I would also like to express my deepest and most sincere gratitude to the following persons for their invaluable support in the completion of my dissertation:

- Prof VJ Ehlers, my supervisor at Unisa, for her continuous, conscientious guidance and support
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ABSTRACT

This study examined healthcare providers’ adherence to the national Tuberculosis guidelines (NTG) during the diagnosis and treatment of TB in Addis Ababa, Ethiopia using a descriptive, cross-sectional study design. Data were collected from 233 medical records using checklists.

Adherence of healthcare providers to the NTG during the diagnosis of TB was 60.9% (n=67) for female and 56.1% (n=69) for male TB patients. However, 91.8% (n=101) female and 90.2% (n=111) male TB patients had been prescribed the correct numbers of anti-TB pills, complying with the NTG recommendations. There was an over-diagnosis of smear negative pulmonary Tuberculosis (PTB) as only 2.6% (n=2) of the 76 smear negative PTB patients were diagnosed correctly.

Healthcare providers’ compliance with the NTG could be enhanced by providing appropriate in-service education, maintaining accurate records of all TB patients and providing supportive supervision to identify and address shortcomings.

Keywords:
Adherence to Tuberculosis (TB) guidelines, diagnosis of TB, quality of TB care, TB treatment
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<td>AFB</td>
<td>Acid-Fast Bacilli</td>
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<tr>
<td>AIDS</td>
<td>Acquired immune deficiency syndrome</td>
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<td>AM</td>
<td>Amikacin</td>
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<td>BCG</td>
<td>Bacillus Calmette Guerin</td>
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<td>Cs</td>
<td>Cycloserin</td>
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<td>DOTS</td>
<td>Directly Observed Therapy Short Course</td>
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<td>E</td>
<td>Ethambutol</td>
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<td>EPTB</td>
<td>Extra-Pulmonary Tuberculosis</td>
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<td>Eto</td>
<td>Ethionamide</td>
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<td>FNA</td>
<td>Fine needle aspiration</td>
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<td>H</td>
<td>Isoniazid</td>
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<td>HEW</td>
<td>Health extension worker</td>
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<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<td>HSDP</td>
<td>Health sector development plan</td>
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<tr>
<td>INH</td>
<td>Isoniazid</td>
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<tr>
<td>IPT</td>
<td>Isoniazid preventive therapy</td>
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<tr>
<td>ISTC</td>
<td>International standard of TB care</td>
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<td>Kg</td>
<td>Kilogram</td>
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<td>KM</td>
<td>Kanamicin</td>
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<td>Lfx</td>
<td>Levofloxacin</td>
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<td>LN</td>
<td>Lymph node</td>
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<td>LTBI</td>
<td>Latent TB infection</td>
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<td>M</td>
<td>Mycobacterium</td>
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<td>MDG</td>
<td>Millennium development goal</td>
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<td>MDR</td>
<td>Multi Drug Resistance</td>
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<td>MoH</td>
<td>Ministry of Health</td>
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<td>NTG</td>
<td>National Tuberculosis Guideline</td>
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<td>PHC</td>
<td>Primary healthcare</td>
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<td>PHCU</td>
<td>Primary healthcare unit</td>
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<td>PTB</td>
<td>Pulmonary Tuberculosis</td>
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<td>R</td>
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<td>S</td>
<td>Streptomycin</td>
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<td>Acronym</td>
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<td>SPSS</td>
<td>Statistical Package for Social Science</td>
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<td>SSA</td>
<td>Sub Sahara Africa</td>
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<td>SSCC</td>
<td>Standardised Short Course Chemotherapy</td>
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<td>TB</td>
<td>Tuberculosis</td>
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<tr>
<td>TBCTA</td>
<td>TB coalition for technical assistance</td>
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<tr>
<td>Unisa</td>
<td>University of South Africa</td>
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<tr>
<td>WHA</td>
<td>World Health Assembly</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>XDR</td>
<td>Extensively Drug Resistant</td>
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<td>Z</td>
<td>Pyrazinamide</td>
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CHAPTER 1

INTRODUCTION

1.1 INTRODUCTION AND BACKGROUND INFORMATION

Tuberculosis (TB) is caused by the bacterium, mycobacterium TB, which was recognised by the German scientist Robert Koch on March 24, 1882. TB caused more than 1.7 million deaths in 2007 throughout the world (Daniel 2005:1181-1182; WHO 2009a:12).

The WHO TB fact sheet (WHO 2007) indicates that every second of every day a person was infected by TB during 2006. Smear positive TB is a highly infectious disease, and it spreads via droplet nuclei when the TB infected person coughs, sneezes, speaks and talks. The person who inhales air contaminated by the tubercle bacilli will be infected. According to the (WHO 2009a:7), one third of the world’s population were infected by the tubercle bacilli and more than 9 million people developed full-blown TB globally during 2007.

TB infection is profound in resource-limited countries with high HIV infection rates co-existing with poverty. Africa is facing the worst TB burden in the world. Despite implementing the internationally recommended Directly Observed Therapy Short course (DOTS) strategy, the African region continues to contribute a high proportion of the global TB burden. Of the 22 high burden countries responsible for 80.0% of the total global burden of TB, nine countries are in the African region. Thirteen of the 15 countries with the highest estimated TB incidence rates in the world are found in Africa (WHO 2009a:9). The lack of infrastructure compounded by the higher HIV prevalence in the African region, contributes to Africa’s high TB burden. Patients’
limited healthcare seeking behaviours and shortages of healthcare professionals in the region contribute to the TB prevalence rates in the region (Richard & Neil 2008).

Global efforts to control TB were strengthened in 1991 when the World Health Assembly (WHA) resolution declared TB as a major global public health problem. The WHA planned to detect 70.0% of smear positive TB cases and to successfully treat 85.0% of smear positive TB cases detected by the year 2000 (WHO 2009a:6). But the targets were not achieved by the year 2000 and later the Stop TB partnership in 2000 re-set the targets of the WHA at 70.0% detection of smear positive TB cases and to successfully treat 85.0% of smear-positive TB cases by the year 2005 through the DOTS programme which had been launched in 1994 (Stop TB strategy 2006). The case detection rate was met in 74 countries and in two regions –the Americas (73.0%) and the Western Pacific region (77.0%). TB case detection and treatment success rates were 47.0% and 75.0% respectively for Africa during 2007 (WHO 2009a:2-3).

According to the 2008 WHO estimation, Ethiopia ranks 7th in the list of high burden countries for TB (WHO 2009a:7). According to Ethiopia’s Ministry of Health (MoH), TB is the major cause of morbidity and the second leading cause of mortality preceded by malaria (MoH 2008a:4). In resource-limited countries the effects of TB are profound where it affects the productive age groups of the society. Despite the efforts made to prevent and control TB, the disease is still a major public health problem, and its incidence continues to increase. According to Ethiopia’s national TB programme Annual Bulletin (MoH 2009a:16), the incidence of all forms and smear positive TB in Ethiopia stood at 379 and 168 per 100 000 of the population respectively in 2008. Only 40 794 smear positive TB cases were detected (MoH 2007/8:33). Unless collaborative measures are taken to identify infectious TB cases, this large number of patients will multiply these infections in the community.

According to the MoH of Ethiopia health and health-related indicators (MoH 2007/8:33), the case detection rate in Ethiopia varies from region to region where the highest case detection rate was documented in the Gambella region, namely 76.7% while the lowest 20.3% was documented in the Somali region during 2008. The case detection rate in Addis Ababa, the capital city of Ethiopia, was 68.3% in the same
year. This is lower than the global target set by the WHO hence it is crucial to identify, and address factors that impact negatively on TB case detection rates in Ethiopia.

Case detection rates need to be increased over time in order to control the burden of TB. According to David and Richard (2009:294), maintaining the TB case detection rate at a constant level may not produce a significant reduction in TB incidence. Therefore, incremental case detection rates beyond the global target are required to reduce the incidence of TB in Ethiopia.

As explained by Cambanis, Ramsay, Wirkom, Tata and Cuevas (2007:40), TB is the number one infectious cause of death and its magnitude is increasing from time to time mainly due to its association with the Human Immunodeficiency Virus (HIV) and the situation is intensified in areas like Sub-Saharan African (SSA) where poverty and high HIV prevalence rates co-exist. The SSA region constitutes 30.0% of the global TB burden while the total population of the region is around 10.0% of the global population (WHO 2009b).

Besides the patients’ healthcare seeking behaviours, healthcare workers’ understanding about the need for three sputum analyses for identification of TB and its public health significance, are affected by the healthcare workers’ educational background, previous experience of management of TB and familiarity with the national tuberculosis control programme (Shimeles, Assefa, Yamuah & Engers 2006:1172). Assessing healthcare providers’ compliance with the national Tuberculosis guidelines (NTG) during the diagnosis and treatment of TB will contribute to TB prevention and control strategies by availing crucial information to TB programme mangers.

Mengiste, Tesfay, Israel, Yohannes, Witten and Madeley (2005a:7) describe that delays in diagnosis and treatment of infectious cases of TB is likely to be associated with worse clinical prognoses and increased risks of death and transmission in the community. One of the goals of a TB control programme is the interruption of TB transmission within the communities through early identification and effective treatment of infectious cases of TB (MoH 2008a:20). Achieving this objective
requires collaborative efforts between the health sector and the communities. Therefore, an effective TB control programme requires early identification of infectious cases and immediate initiation of treatment. Patients' knowledge of TB symptoms and healthcare workers' understanding of TB diagnosis are the key areas for early TB case detection and initiation of effective treatment. TB symptoms, particularly cough with sputum, are prevalent in many communities. Delayed contact with health professionals for these symptoms result in delayed diagnosis and thus also delayed treatment of TB (Storla, Yimer & Bjune 2008:15).

A smear positive pulmonary TB patient (PTB), who is not identified and treated early, can infect between 10-15 people every year (WHO 2007). Delays in diagnosis and treatment of smear positive cases will sustain infectiousness in the community and hamper TB prevention and control. These delays might be due to patients’ delays in seeking healthcare, healthcare providers’ delays in diagnosing and delays (health system delays) in starting TB treatment. A study conducted in Ethiopia revealed that patients’ delays in seeking healthcare were up to 30 days and this was associated with distance from the healthcare provider, age above 45 years and self-treatment (Yimer, Bjune & Alene 2005). This study also indicated that only 9.0% of TB patients had commenced treatment within one month of the onset of TB symptoms while the rest started treatment after 31 days. This indicates the risk of infectivity in the community as TB patients are presenting at health facilities very late. This implies higher rates of TB transmission in the communities before TB patients are diagnosed and treated at health institutions resulting in increased TB patient loads. Identifying the reasons for late presentation and healthcare providers’ adherence to the NTG might enhance the implementation of TB prevention and control strategies in Ethiopia.

A study conducted in Mongolia, revealed that patients’ knowledge of TB, healthcare seeking behaviours, income and educational attainment were significant factors associated with low TB detection rates (Zhang, Liu, Bromley & Tang 2007:155-165). Besides the patient–related factors, the healthcare providers-related factors such as their adherence to the NTG during diagnosis of TB need to be assessed for TB prevention and control strategies to be effective, in Ethiopia and in other developing countries.
A study conducted in Tanzania identified poor knowledge of TB symptoms, being female, having no primary education and higher rates of unemployment as factors contributing to delayed healthcare seeking behaviours (Mfinanga, Mutayoba, Kahwa, Kimaro, Mtandu, Ngadaya, Egwaga & Kitua 2008). Another study, conducted in Cameroon, showed that the use of traditional medicines was the first level treatment option, fuelled by the perception that TB was stigmatised, delaying TB patients’ health seeking from formal healthcare institutions (Cambanis, Ramsay, Yasin & Cuevas 2007a:1309-1314).

A study conducted in the Tigray region of Ethiopia also reported that many patients used traditional medicines before they went to the modern healthcare system. As many as 46.0% of patients sought modern healthcare only after their traditional treatments had failed (Mengiste, Jems, John, Amanuel & Richard 2009a). Many TB patients’ first attempts to get rid of their problems involved using holy water from the Orthodox Church, or consulting private practitioners, visiting traditional healers and private drug vendors or pharmacies. The reason why patients first sought traditional treatments before accessing the modern healthcare sector should become known to provide more effective TB prevention and control strategies in Ethiopia.

The WHO launched DOTS in 1994 as a strategy for TB prevention and control. The components of the DOTS strategy included government commitment, case detection through sputum smear microscopic examinations among symptomatic patients, standardised short course chemotherapy (SSCC), regular uninterrupted drug supplies and standardised recording systems for programme monitoring and evaluation (WHO 2006b:4). Of these components, identification of infectious cases of TB is influenced by individual healthcare seeking behaviour, access to healthcare and health facilities’ capabilities for diagnosing TB (Shargie, Morkev & Lindtjorn 2006:112). Identification of the factors influencing TB patients’ decisions to consult health professionals, health facilities’ TB diagnostic capabilities and health workers’ familiarity with the NTG will affect TB control strategies’ effectiveness in Ethiopia.

In 1992, the Ethiopian government MoH TB prevention and control programme started using DOTS as a pilot project in the Arsi and Bali zones of the Oromia region.
The DOTS programme was subsequently scaled-up and implemented at national level. During 2009 the DOTS geographic coverage reportedly reached 100.0% whereas the health facility coverage was 92.0% in Ethiopia (MoH 2009b:3).

The diagnosis algorithms for smear positive PTB include ordering of spot–morning–spot-sputum analyses for patients who presented with TB symptoms. Spot-morning-spot-sputum analyses means the patient will provide sputum on his/her first encounter with the healthcare worker and will be appointed to come with an early morning sputum during the next day and the third sample will be taken after his/her appearance at the health facility. Those with productive coughs, lasting more than two weeks, and with two or more positive sputum results, should be initiated on TB drugs. If three of the sputum analyses are negative, the patient will start broad-spectrum antibiotics for two consecutive weeks. Then the patient will be re-evaluated and if the symptoms had improved, no TB can be diagnosed. However, if the patient failed to improve, the sputum analyses will be repeated and if positive for one or more of the samples, smear positive PTB will be diagnosed and TB treatment commenced. On the other hand if the result is negative chest x-rays will be ordered and the diagnosis will be made by the physician as being either smear negative PTB or no TB, based on clinical evaluations (MoH 2008a:171).

The Ethiopian MoH (2008a:35-39) recommends treatment of TB patients based on the different diagnostic categories. There are four patient diagnostic categories:

- **Category I** - New smear-positive PTB patients; new smear-negative PTB patients with extensive parenchymal involvement; severe forms of EPTB patients.
- **Category II** - Previously treated sputum smear-positive PTB: relapse; treatment after interruption; treatment failures and sputum smear-negative PTB patient who becomes sputum smear-positive after two months of treatment.
- **Category III** - New smear-negative PTB and new EPTB patients who are not seriously ill.
- **Category IV** - chronic and multi-drug resistant TB (MDR-TB) cases (still sputum positive after supervised re-treatment).
Patients with category I and category III are treated with the same treatment regimen. Treatment of TB has two phases, the intensive and the continuation phases. During the intensive phase, anti-TB drugs must be collected daily by the patient and swallowed under the direct supervision of the health worker while during the continuation phase drugs must be collected monthly by the patient and self-administered. The intensive phase for category I and category III TB patients is for two months while it is three months for category II TB patients.

A study conducted in the northern part of Ethiopia revealed that only 13.9% of smear positive PTB patients were diagnosed based on the national diagnostic criteria among all forms of TB patients (Mengiste, Tesfay & Madeley 2005:16). Accurate identification of smear-positive PTB patients is the cornerstone for TB control. Failure to adhere to the NTG diagnostic criteria may increase missed opportunities for diagnosis of TB and is likely to reduce case detection rates and an increased number of infectious TB cases resulting in an increased prevalence of TB in the community, increasing the risk of spread of TB and MDR-TB throughout the community.

The majority of TB patients who started TB treatment do not complete their treatment that leads to prolonged infectiousness, relapses, drug resistance and death (Munro, Lewin, Smith, Engel, Fretheim & Volminik 2007). Patients who fail to complete the standard course of treatment may develop MDR-TB and extensively drug resistant TB (XDR-TB). This situation jeopardises the prevention and control strategy of TB, especially in developing countries, where there are high rates of HIV and poverty.

TB poses a challenge for Ethiopia’s socio-economic development as it affects 75.0% of the most economically and socially productive group, aged 15-54 years (MoH 2008a:5). This in turn increases the rates of tubercle bacilli transmission in the communities and result in more cases of full-blown TB.
1.2 RESEARCH PROBLEM

The Ethiopian MoH (2007/8:33) reported an under achievement of the national TB case detection rate of 33.9% during 2008. In the era of MDR-TB, the national case detection rate is lower than the global target of 70.0% set by the WHO (MoH 2007/8:32; WHO 2009a:7). A country’s TB control programme is measured by its smear positive PTB case detection and treatment success rates. Ethiopia’s case detection and treatment success rates were 33.9% and 84.0% respectively during 2008 (MoH 2007/8:32). Early case detection and treatment of TB patients are the cornerstones of TB prevention and control strategies. The earlier the infectious cases of TB are identified and treated effectively, the lower the chance of TB transmission in the community. Despite the expansion of Ethiopia’s health service coverage, the case detection rate is very low. This necessitates prompt assessment of healthcare providers’ compliance with the NTG during diagnosis and treatment of TB which may increase TB case detection rates.

1.2.1 Statement of the research problem

Ethiopia has NTG in place. Persons can access TB diagnostic and treatment facilities at public health centres and hospitals. Nevertheless the TB detection rate of Addis Ababa (68.3%) and TB cure rate (72.0%) remain below the WHO’s (2005) global target rates of 70.0% and 85.0% (MoH 2007/8:32; WHO 2006b:6). Despite the availability of the NTG and the accessibility of TB diagnostic and treatment services, the TB case detection rates remain unacceptably low. Consequently the question arose: Are healthcare providers complying with the NTG during the diagnosis and treatment of TB in Addis Ababa, Ethiopia?

1.3 AIM AND PURPOSE OF THE STUDY

The aim of this study was to assess the healthcare providers’ adherence to the NTG during diagnosis and treatment of TB patients and thereby to contribute to the existing knowledge about feasible effective TB prevention and control strategies.
1.3.1 Research purpose

The purpose of this study was to examine healthcare providers’ adherence to the NTG during diagnosis and treatment of TB in Addis Ababa, Ethiopia.

1.3.2 Research objectives

The specific objectives of the study were to assess:

- healthcare providers’ adherence to the NTG during diagnosis of TB in Addis Ababa, Ethiopia
- healthcare providers’ adherence to the NTG during initial treatment of TB in Addis Ababa, Ethiopia

1.4 SIGNIFICANCE OF THE STUDY

This study attempted to identify the level of healthcare providers’ adherence levels to the NTG during diagnosis and treatment of TB from which recommendations will be made to TB managers for enhancing TB prevention and control strategies, as well as for conducting further research.

1.5 DEFINITIONS OF KEY CONCEPTS

The key terms used in this study are defined and explained as applied throughout the dissertation so that the readers can share the intended meaning with the researcher.

**Anti–TB drugs:** These are combinations of different drugs given to patients diagnosed with TB. The anti-TB drugs used in Ethiopia include: Ethambutol (E), Rifampicin (R), Isoniazid (H), Streptomycin (S) and Pyrazinamid (Z). Adult TB patients under category I and category III are treated with ERHZ during the intensive phase for two months and during the continuation phase with EH for six months. Whereas category II patients are treated with S (ERHZ) for two months plus ERHZ for one month during the intensive phase and E (RH) are taken three times per week for 5 months during the continuation phase (MoH 2008a:36-38).
The MDR-TB treatment regimen consists of two phases and it lasts for a minimum of 18 months beyond culture conversion. The drugs prescribed during the intensive phase include: E, Z, kanamycin (KM) or Amikacin (Am), Levofloxacin (Lfx), Ethionamide (Eto) and Cycloserin (Cs) for a minimum of six months. The drugs prescribed during the continuation phase are E, Z, Lfx, Eto and Cs and this phase lasts for a minimum of 12 months. The intensive phase for MDR-TB treatments further classified as an in-patient (until smear conversion takes place or at least for one month) and out-patient phase where drugs can be received at an outpatient department (MoH 2009b:46-50). Some publications might use TB drugs and anti-TB drugs synonymously. In this dissertation the term ‘anti-TB drugs’ was used in accordance with the terminology used by healthcare workers and by the MoH of Ethiopia.

**Case detection rate:** This indicates the ratio of sputum smear positive pulmonary TB case notifications in a given year to the estimated number of new smear positive PTB cases occurring in that year (United nations 2003:55).

**Cure rate:** The percentage of new smear positive PTB cases who become smear negative at, or one month prior to the completion of treatment and at least on one previous occasion during the follow up sputum analyses (MOH 2008a:53).

**Extensively-drug resistant TB (XDR-TB):** This type of TB is caused by Mycobacterium TB resistant to multiple first-line drugs as well as to any one of the fluoroquinolones and to at least one of the three injectable second-line drugs (WHO 2008:20).

**Extra pulmonary TB (EPTB):** It refers to TB of the organs other than the lungs (MoH 2008a:18). A person may have both smear positive PTB and EPTB simultaneously and in that case the patient is classified as being smear positive PTB (MoH 2008a:30).

**Multidrug-resistant TB (MDR-TB):** This type of TB is caused by Mycobacterium TB resistant in vitro to the effects of the two known anti-TB drugs that is isoniazid
(INH) and rifampicin, with or without resistance to any other anti-TB drugs (WHO 2008: 20).

**New TB case**: A patient who had never been treated for TB or who had anti-TB treatment for less than one month (MoH 2008a:31).

**Provider adherence to the NTG**: Healthcare providers’ compliance with the NTG recommendations during the diagnosis and treatment of TB patients. The Ethiopian NTG expects healthcare providers to order spot-morning-spot sputum analyses for patients presented with productive cough of more than two weeks. Those patients whose acid-fast bacilli (AFB) results are negative three times initially should be put on broad-spectrum antibiotics for two weeks and be re-evaluated for AFB. Whereas patients with two initial positive AFB results, or one initial AFB positive and culture positive or one initial AFB positive and radiologic abnormalities consistent with TB, will be diagnosed as a case of PTB. Hence, healthcare providers who followed the steps and treated their TB patients based on the guideline as explained in the anti-TB drugs definition are considered as being compliant with the NTG.

**Pulmonary TB (PTB)**: It refers to disease involving the lung parenchyma (MoH 2008a:18).

**Smear positive TB patient**: A TB patient who is found to be smear positive on bacteriological microscopic examination of sputum. A PTB suspected patient will be ordered spot-morning-spot sputum analyses. Smear positive TB patient will be diagnosed if at least two initial sputum smear examinations are positive for AFB by direct microscopy. If one initial smear examination is positive by direct microscopy and culture positive, or one initial smear examination positive for AFB by direct microscope and radiologic abnormalities consistent with active TB as determined by a clinician (MoH 2008a:29). The diagnosis of smear positive PTB is confirmed in HIV positive persons when one AFB is positive by direct microscopy.
**TB Diagnosis:** The conclusion or judgment reached by healthcare providers after a thorough enquiry of patients’ symptoms, signs and different diagnostic procedures. TB is diagnosed in Ethiopia after the healthcare provider obtained a thorough history of the patient with his/her presenting complaint and physical examinations. Following the steps the healthcare provider will order a spot-morning-spot sputum analyses and based on the results the patient will be diagnosed to have TB or not.

**TB patient:** any person of any age who has been diagnosed to have TB. However, this study focused only on persons aged 15 and older who had been diagnosed with TB.

**TB Treatment:** The actions taken to get rid of TB by use of a combination of anti-TB drugs which is capable of killing or preventing replication of mycobacterium TB in the patient’s body (WHO 2004:28).

### 1.6 CONCEPTUAL FRAMEWORK

A framework is the structure of the idea or concept and how it is put together. It guides the researcher during the development of the study and enables the researcher to link the findings to the body of knowledge (Burns & Grove 2005:37).

If initially all smears are negative and only one smear appears to be positive after antibiotics, the NTG advises to carry out two additional smears. If one or both are positive, proceed to treat the patient as a TB patient. If both are negative, proceed with chest x-ray and evaluation of the patient for conditions other than TB (MoH 2008a:172).

This framework indicates the different steps to be followed by healthcare providers during the diagnosis of TB and the study focused on assessing providers’ adherence to the NTG during diagnosis and treatment of TB, which may influence TB case detection rates.
Patients with symptoms suggestive of TB

Sputum microscopy for AFB (3 samples)

- 2 or 3 positive
  - Only 1 positive
    - Examine 2 additional sputum samples
      - 1 or 2 positive
        - Repeat sputum microscopy (three samples)
          - Chest X-ray and physician’s judgment
            - Smear-positive Pulmonary TB
            - Smear-negative Pulmonary
            - No Tuberculosis: Treatment based on clinical
            - No Tuberculosis
    - 1-3 positive
      - Repeat sputum microscopy (three samples)
        - Chest X-ray and physician’s judgment
          - Smear-positive Pulmonary TB
          - Smear-negative Pulmonary
          - No Tuberculosis: Treatment based on clinical
          - No Tuberculosis
  - 1 or 2 positive
    - Examine 2 additional sputum samples
      - both negative
        - Treat with non-specific broad-spectrum antibiotics (excluding anti-TB drugs for 7-10 days)
    - Only 1 positive
      - Examine 2 additional sputum samples
        - both negative
          - Treat with non-specific broad-spectrum antibiotics (excluding anti-TB drugs for 7-10 days)
  - 3 negative smears
    - Review after 2-4 weeks
      - No improvement

Improved

Appropriate patient treatment categorisation and anti-TB drugs prescription

Figure 1.1 Conceptual framework for PTB and EPTB diagnosis (MoH 2008a:170)
1.7 RESEARCH DESIGN

1.7.1 Research paradigm

The research paradigm chosen was quantitative research since the purpose of the study was to assess the level of healthcare providers' adherence to the NTG during the diagnoses and treatment of TB. Quantitative research emanated from the principles of positivism, assuming the existence of a single reality ascertainable by objective measurement (Bowling 2002:126). Positivism establishes a reliable and valid knowledge base through analytical empiricism where the actual evidences are gathered through objective measurement rather than through theory and abstraction (Bowling 2002:126).

Some of the characteristics of quantitative research include hypothesis testing (deductive reasoning) and the researcher will remain objective throughout the research process, including the data collection and analysis phases. The results obtained from quantitative research can be generalised, provided that the sample is representative of the population, and the sample is sufficiently large.

1.7.2 Research design

A research design is a plan to study a particular event by maximising the control over the factors that could interfere with the study's desired outcomes. The chosen research design for this study was cross-sectional because it identified events at a single point in time (Stommel & Wills 2004:163-164).

The rationale behind the selection of this research design was that, the study attempted to assess healthcare providers' adherence to the NTG that might impact on TB diagnosis and treatment. Cross-sectional studies are relatively easy, economical, and useful for assessing the healthcare needs of a population.
1.8 RESEARCH METHODS

1.8.1 Research setting

Addis Ababa, the capital city of Ethiopia is divided into ten sub cities or administrative units. It has five regional hospitals and 26 health centres. The study included four public health facilities (two hospitals and two health centres). All 26 health centres and two of the regional hospitals were treating TB patients on the DOTS programme during the data collection phase of this study. The health centres were selected randomly while the two hospitals were selected purposively as only two of the regional hospitals were providing DOTS services. The TB patients who participated in this study were from diverse backgrounds in terms of ethnicity, gender, education and income levels.

1.8.2 Population

A population is the total set of study individuals or elements as defined by Burns and Grove (2005:342). A population is the total group of persons, animals, events, places or things who have something in common (Mitchell 2001:45). Population is a collection of persons or other elements who share a common characteristic, such as having been diagnosed with TB, in the case of this study (Stommel & Wills 2004:297).

Burns & Grove (2005:342) define a target population as “the entire set of individuals or elements who meet the sampling criteria”. In this study the target population comprised all persons diagnosed with TB who lived in Addis Ababa during the time of conducting the survey (March – November 2010 excluding those diagnosed from April 11- July 2, 2010 since during these weekends TB campaigns were held by the Addis Ababa Regional Health Bureau). The accessible population, as defined by Burns and Grove (2005:789), comprises that section of the target population to whom the researcher has reasonable access during the survey. In this study the accessible population comprised all TB patients who received TB treatment, during
the data collection phase from one of the four TB treatment sites that participated in this study in Addis Ababa (Burns & Grove 2005:342; Stommel & Wills 2004:298).

1.8.3 Sample and sampling procedures

A sample denotes the selected group of people that fulfilled the criteria set for inclusion and who were approached to participate in a specific study. Probability sampling was used because a sampling frame existed of all TB patients receiving TB treatment at all four participating sites during the data collection phase. In probability sampling the selection of the sample involves the identification of the accessible population, and then using standardised random selection procedures to select every respondent.

Two health centres were randomly selected for this study while two of the regional hospitals were selected using purposive sampling technique since three of the regional hospitals were not treating TB patients with DOTS programme at the time of the study.

Simple random sampling is a probability sampling technique where samples are selected randomly from a sampling frame using random numbers (Burns & Grove 2005:347; Stommel & Wills 2004:303). The sample was selected using simple random sampling technique, allowing each component of the sample a chance of being selected. The sample selection method will be discussed in detail in chapter 3.

A list of all individuals comprising a specific population is called a sampling frame (Burns & Grove 2005:346). A sampling frame is a prerequisite for being able to select a random sample representative of the population. A sampling frame existed with details of every person receiving TB treatment at all participating sites. A list of patients diagnosed with TB was available at each health facility as TB registers had been kept. These TB registers served as a sampling frame for this study. Therefore, a random sample could be selected, representing the accessible population of TB patients receiving treatment from these sites.
The sample size was calculated using simple size determination for single proportion by the following equation (Gina & Rodney 2007:347):

\[ n = \frac{P (1-P) z^2}{d^2} \]

Where \( n \) = sample size, \( z (\alpha/2) \) the reliability coefficient 95% i.e. 1.96, \( p \) (healthcare providers adherence to the NTG during diagnosis and treatment of TB) is taking 45% from a study done in Tigray (Mengiste et al 2005a:16), and taking 5% (\( d = 0.05 \)) for the precision, resulting in a total of 380.

The total population in the four study sites comprised 476 persons. The sample size was calculated for the finite population using the adjusted sample size formula \( \frac{s}{1+s/population} \) (The Survey System 2007) and results into 212 observations. Considering that there could be loss of medical records 10% contingency was added rendering the final sample size of 233 TB patients’ medical records.

The numbers of medical records from each health facility were allocated using probability proportional size of TB patients diagnosed in each health facility during the data collection period. Then the medical records of new TB patients who were taking anti-TB treatment were retrospectively reviewed for the type of diagnostic procedures followed and patients’ treatment categorisations and their treatment regimens. TB patients who had been diagnosed at other facilities were excluded because their previous medical records were unavailable. This was the case because the referring health facilities in Ethiopia do not refer patients with their previous medical records as these remain the property of the referring health facility.

Facilities which are not treating TB patients, based on the DOTS programme, refer TB patients with referral slips which do not show all the previous diagnostic procedures followed by the healthcare providers. Medical records of TB patients who were diagnosed with TB and HIV/AIDS were also excluded from review as HIV positive persons are routinely screened for TB.
1.8.3.1 Inclusion and exclusion criteria

The inclusion criteria were: new TB patients’ aged 15 and older and who started anti-TB treatment. Whereas the exclusions criteria were: TB patients who were diagnosed with TB in other facilities and referred for anti-TB treatment, TB patients who were under the ages of 15 years, TB patients diagnosed from April 11, 2010 to July 2, 2010 and those TB patients who were HIV positive since they are routinely screened by healthcare providers for TB. TB treatment protocol for children under 15 years of age is different from the adult TB treatment protocol in Ethiopia (MoH 2008a:65).

TB patients’ medical records were selected using random sampling technique through random table numbers, as discussed in more detail in chapter 3.

1.8.4 Data collection instrument

A checklist was developed specifically for this study in order to capture data from the TB patients’ medical records. The checklist was prepared by consulting TB programme managers, literature reviewed and the Ethiopian MoH 2008 NTG. Before the data collection commenced, pre-testing of the research instrument was undertaken on 10 TB patients’ medical records from public facilities not included in the study. The shortcomings identified during the pre-testing of the checklist were corrected. Examples of the shortcomings identified during the pre-testing of the checklist were TB patient’s marital status and ethnicity.

1.8.5 Validity of the research instrument (checklist)

Validity refers to an instrument’s capacity to measure what it intends to measure (Bowling 2002:147). To enhance the instrument’s internal validity, pre-testing was conducted and vague terms from the checklist were modified and updated. The checklist validity was tested based on face and content validity.
1.8.6 Data collection

Data were collected manually from each TB patient’s medical records. The TB patients’ medical records were reviewed for healthcare providers’ adherence to the NTG on diagnostic procedures followed and patient treatment categorisation and anti-TB treatment regimen. The TB patients’ medical records were reviewed for information on symptoms suggesting TB with duration, physical examinations’ findings, laboratory/x-ray results, treatment with broad spectrum antibiotics, previous history of TB, diagnosis and TB treatment category, age, sex, and weight of the patient, the types of drugs prescribed with their strength. Based on the documented clinical, physical, and laboratory evidence, the diagnosis of each patient was compared with the diagnostic criteria set by the NTG of Ethiopia. The diagnostic steps followed, patient treatment categorisation and the anti-TB treatment regimen prescribed /ordered were transcribed manually from the individual TB patient’s medical records by the researcher using the specifically designed checklist.

Healthcare providers’ compliance with the NTG was assessed based on providers’ compliance during diagnosis of TB suspects and the prescription of correct anti-TB drugs using the specifically designed checklist (see annexure F).

1.8.7 Data analysis

Data were entered into the computer and were checked for completeness. Data were analysed using the Statistical Package for Social Science (SPSS) version 16 by the researcher. Demographic data were analysed using descriptive statistics like frequencies, means, median, minimum, maximum and ranges. In order to compare groups’, chi-square tests calculated for categorical variables.

1.9 ETHICAL CONSIDERATIONS

According to Stommel and Wills (2004:373), ethics deals with morality which is related to issues of right and wrong and how human being behaves. The basic four principles of ethics in health studies (Gina & Rodney 2007:32-33) are autonomy,
beneficence, non-malifence and justice. The data in this study were not collected by interviewing TB patients and hence most of ethical principles were not applicable to this study. However, confidentiality and anonymity were maintained.

1.9.1 Anonymity and confidentiality

Since the names of the TB patients were de-identified from their medical records and no data related to the identities of TB patients were recorded. Neither the researcher nor any other person could identify any specific patient from the information recorded on the checklist.

1.9.2 Ethical approval

All health research conducted in public facilities under the mandates of Addis Ababa regional health bureau should request written permission from Addis Ababa Regional Health Bureau. Written permission was obtained from the Research and Ethics Committee of the Department of Health Studies of the University of South Africa (UNISA) and Addis Ababa Regional Health Bureau and before data the collection commenced (see annexures C and E).

1.10 SCOPE AND LIMITATIONS OF THE STUDY

Only records were studied using checklists based on the NTG, at four participating public health facilities (two hospitals and two health centres) providing TB treatment. Possibilities existed that patients who received treatment at other sites might have had different experiences and/or outcomes.

1.11 SUMMARY

In the era of MDR-TB, the national TB case detection rate was lower than the global target set by the WHO in spite of the expansion of health service coverage in Ethiopia. This chapter described the burden of TB in the world, Africa and Ethiopia. In this chapter, the following areas were discussed: introduction and background, research problem, aim and purpose of the study, significance of the study,
objectives, definitions of key concepts, research design, research methodology, design validity, ethical consideration, scope and limitation of the study.

The next chapter will provide a summary of literature reviewed pertaining to TB diagnosis and treatment and to DOTS programmes.
CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

The purpose of the study was to assess healthcare providers’ adherence to the Ethiopian NTG during diagnosis and treatment of TB in Addis Ababa, Ethiopia. This chapter presents literature related to providers’ compliance with the NTG. As pointed out by Stommel and Wills (2004:339) a literature review is a summery and evaluation of information collected from different literature sources. It helps the researcher to obtain adequate knowledge on the topic of interest, what is known and not known about the topic of interest, and it provides key information on the methods used by previous researchers.

Several sources were consulted, including research books, medical and research journals, policy documents and guidelines. Reviewed documents on TB, provider adherence to guidelines, quality of TB care and healthcare provider were obtained from websites and journals. The major websites browsed were WHO (http://www.who.int/en/), the United States National Institute of Health (http://www.ncbi.nlm.nih.gov/pmc/), Google scholar (www.scholar.google.com) and Google (http://www.google.com.et). The literature review covered the period from 2001 to 2009. The key words used in the literature search were: adherence to TB guidelines, healthcare providers’ adherence, quality of TB care, TB and TB guidelines.
2.2 DEFINITION AND HISTORIC BACKGROUND OF TB

The term TB comes from the French word called “tubercules” which is defined as “small, round lesions scattered over the affected areas of the body”. TB is one of the oldest human diseases in the world since its effects had been seen in Egyptian mummies’ deformed skeletons, supposedly caused by TB. The symptom associated with the ongoing emaciation of the patient as a result of TB was named “phthisis” by Hippocrates (WHO 2001:9).

TB is caused by mycobacterium (M) TB complex. The MTB complex includes M Bovis (which is transmitted through unpasteurised milk and is a cause of a small percentage of cases in some developing countries), M Africanum (which occurs in West, Central, and East Africa), M Microti (a very rare and less virulent organism), and M Canetti (a cause of very rare TB cases in Africa) as described by Raviglione and O’Brien (2005:953).

All these organisms are known as tubercle bacilli or acid fast bacilli (AFB) (Demissie, Omer, Lindjorn & Hombergh 2006:409; WHO 2004:10). TB often spreads through the air when a person inhales air contaminated with the tubercle bacilli and rarely spreads congenitally or through milk contaminated by mycobacterium bovis (WHO 2004:10). TB was identified under the microscope by the German pathologist Dr Robert Koch in 1882 which brought a major breakthrough in combating TB (Daniel 2005:1181-1182).

Generally TB is classified into PTB and EPTB. PTB accounts for 85.0% of global TB cases and it is further classified into smear positive PTB and smear negative PTB. Smear positive PTB accounts for 75.0-80.0% of all PTB cases. EPTB is TB of organs other than the lungs most commonly pleura, lymph nodes, abdomen, genito-urinary tract, nervous system and bones and it accounts for 14.0% of global TB cases in the world (MoH 2008a:17).
2.3 PROVIDERS’ ADHERENCE TO THE NTG

Providers’ adherence to the NTG is defined as providers’ compliance with the NTG recommendations during diagnosis and treatment of TB patients. Marquez (2001:3-4) described service providers’ adherence to evidence based standards with improved health outcomes and failure to adhere to NTG recommendations or standards as resulting in discontented patients and healthcare providers, loss of scarce resources, loss of time of the healthcare providers and patients and missed opportunities of early TB diagnoses.

The international standard of TB care (ISTC), which has been developed by TB coalition for technical assistance (TBCTA), sets standards for TB care to standardise a widely acceptable level of performance in diagnosis of suspected TB cases and in the treatment of patients diagnosed with TB by all healthcare providers. TBCTA recommends that healthcare providers’ should evaluate patients presenting with productive cough lasting more than two to three weeks for TB through bacteriologic microscopic sputum analysis. Failure to order a spot-early morning-spot sputum (collection of sputum samples during the patient’s first encounter with the healthcare provider, early in the morning for the second sample and the third sample is collected when the patient appears at the health facility during the day after the first sample’s collection) analysis may result in missed opportunities for earlier TB detections which could later lead to worsening of the patients’ clinical conditions and result in higher TB transmission rates in their communities (MoH 2008a:24; WHO 2006a:17).

The NTG of Ethiopia recommends diagnosis of smear positive PTB to be based on at least two AFB positive smears and cases with at least one initial and one repeat sputum smear positive result. While the diagnosis of smear negative PTB is based on the four diagnostic steps namely: three initial smear negative results, no response to broad spectrum antibiotics, three repeat smear negative results and chest x-ray findings consistent with TB (MoH 2008a: 171).
2.4 SCOPE OF THE PROBLEM

Early diagnosis and prompt treatment of TB are the cornerstones for TB prevention and control strategies. Inappropriate medical practices for TB diagnosis, treatment, and case management contribute to unnecessary suffering of patients, diagnostic delays, continuous spread of TB, high healthcare costs for patients and society, and development of MDR-TB. The appropriate technologies, such as bacteriologic sputum smear examinations, evidence-based treatment regimens and standardised patient monitoring mechanisms might be underutilised.

A study conducted in Thailand revealed that 70.0% of TB patients were diagnosed based on the NTG diagnostic criteria while 30.0% of TB patients’ diagnoses were inconsistent with the NTG TB diagnostic procedures (Wilawan, Virasakdi & Petchawan 2008:381). The level of non-adherence to diagnostic TB procedures included missing sputum smear examinations (6.8%), the diagnoses of TB based on three sputum smear negative results and chest x-ray abnormalities but without any antibiotics trials (12.5%) and TB diagnoses based on fewer than three negative sputum smear results and chest x-ray findings (8.6%). The same study revealed that the level of non-compliance with anti-TB drugs dosage selections were 42.9 % in which the highest and the lowest doses of drugs prescribed were E and H 33.6% and 6.1% respectively. Failure to adhere to NTG during diagnosis and treatment of TB will increase the burden of TB in the community since there will be higher risks of TB transmissions, worsening of clinical conditions of TB patients and more MDR-TB cases (WHO 2006a:18).

Healthcare providers’ knowledge and previous experience in the management of TB patients are the key elements in the prevention and control of TB. Patients presenting to higher or speciality institutions are more likely to be diagnosed based on the NTG diagnostic criteria. A study conducted in Taiwan indicated that 74.1%, 48.2%, 36.8%, and 50.0% of TB patients had sputum examinations done at a chest specialty hospital, at medical centres, regional hospitals, and district hospitals respectively (Chung, Chang & Guo 2007:4). The same study revealed that the time of diagnosis and treatment of TB patients were shorter in higher level or speciality healthcare institutions. The mean healthcare institutions’ delays were 10.1, 31.0,
31.2, and 25.4 days at a chest specialty hospital, at medical centres, regional hospitals, and district hospitals respectively.

Wilawan, Virasakdi and Petchawan (2008:381) revealed that being female was found to be a factor influencing non-adherence to TB guidelines recommended by healthcare providers’ during diagnosis and treatment of TB. The study also indicated that non-doctors were found to comply better with TB guidelines recommendations during the diagnosis and treatment of TB patients than medical doctors.

A diagnostic audit conducted in the northern part of Ethiopia revealed that 78.6% of smear positive PTB patients were diagnosed properly based on the NTG of all the smear positive PTB patients. Of the smear positive PTB patients, 19.0% were diagnosed as smear positive PTB without any documented evidence while one patient was put on anti-TB treatment after unsuccessful broad-spectrum antibiotic treatment. A smear positive PTB patient diagnosed according to the national diagnostic criteria represented 13.9% of all forms of TB patients diagnosed in the study area (Mengiste et al 2005b:16).

Over diagnosis of smear negative PTB and failure to adhere to the Ethiopian TB diagnostic criteria have been reported. According to Mengiste et al (2005b:15-17), only 3.0% of smear negative PTB patients were diagnosed based on the four diagnostic criteria specified by the NTG, namely: three initial smear negative results, no response to broad spectrum antibiotics, three repeat smear negative results and chest x-ray findings consistent with TB (MoH 2008a:171). Failure to adhere to the NTG diagnostic criteria may result in missed diagnoses and increased transmissions of TB in the family as well as in the community. The same study revealed that 24.2% and 43.4% of patients were treated as smear negative PTB patients without AFB bacteriologic sputum microscopic examinations and antibiotics trials respectively.

The diagnosis of EPTB is made based on one culture–positive specimen from an extra-pulmonary site or histo-pathological evidence from a biopsy or the patient’s signs/symptoms evidence consistent with active EPTB and decision by a clinician to treat with a full course of anti-TB drugs. According to Mengiste et al (2005b:15-16) 53.2% of EPTB were treated with broad-spectrum antibiotics while 44.7% were not.
This study also revealed that 49.2% of lymph node TB patients were put on anti-TB drugs without any antibiotic trials.

A study conducted in the Amhara region North Wollo, revealed that 92.5%, 23.4% and 36.9% of smear positive PTB, smear negative PTB and EPTB diagnosis were made based on the NTG diagnostic recommendations (Aynie 2007:31). It also indicated that diagnoses made at health centres complied better with the national diagnostic criteria than TB diagnosis at hospital levels. Reportedly 42.8% and 60.8% of TB patients’ diagnosis were based on the NTG diagnostic criteria at hospitals and health centres respectively. Complicated cases beyond the level of the health centres are supposed to be referred to hospitals since the healthcare providers working at hospitals are better qualified. If the healthcare providers working at hospitals are failing to comply with the national diagnostic criteria, the consequences might be worsening of the patients’ clinical conditions with increased risks of spreading TB and MDR TB throughout communities.

The majority of smear negative PTB patients’ diagnoses were not based on the NTG recommendations. This was evidenced from studies conducted in the Tigray and Amhara regions where 68.7% and 76.6% of smear negative PTB patients’ diagnoses respectively did not comply with the NTG diagnostic procedures (Aynie 2007:31; Mengiste et al 2005:15-16).

The main strategies used in the prevention of TB transmission in the community are the detection of infectious cases of TB and the provision of effective treatment to ensure prompt and lasting cures of TB. Treatment of TB is not a matter of individual health, rather a matter of public health. Since failing to treat TB patients with effective anti-TB drugs may result in worsening and disability of TB patients as well as sustained infectiousness in the family members and communities (WHO 2006a:29). Hence, healthcare providers treating TB patients must have adequate knowledge to prescribe anti-TB drugs correctly based on the NTG recommendations.

The recommended weight band for the treatment regimen of TB patients in Ethiopia are: 20-29 kilogram (kg), 30-39kg, 40-54kg, 55-70kg and ≥ 70kg, and anti-TB drug medications are given according to placement within a particular weight band for
every TB patient (MoH 2008a:36). A study conducted in Malawi revealed that 7.0% of TB patients were prescribed incorrect numbers of tablets for one or more anti-TB drugs (Harries, Gausi & Salaniponi 2004:726).

Adherence to the NTG should enhance the diagnosis of TB with an increased TB case detection rate. A study conducted in South Africa indicated that diagnosis of TB, using integrated respiratory guidelines by nurses was 90.0% effective (English, Bachmann, Bateman, Zwarenstein, Fairall, Bheekie, Majara, Lombard, Scherpbie & Ottomani 2006:4).

2.5 TB STATISTICS

Despite being treatable, TB continues to be a major public health challenge in many parts of the world and its incidence continues to increase. Based on the WHO estimation, 9.27 million new cases (139 per 100 000 population) of TB were diagnosed globally during 2007. Of these new cases, an estimated 44.0% or 4.1 million cases (61 per 100 000 population) were smear positive cases. Asia (including the South-East Asia and Western Pacific regions) accounted for 55.0% of global TB cases while the Africa regions contributed 31.0% of the global TB cases during 2007 (WHO 2009a:7-9).

The number of new smear positive PTB, smear negative PTB, EPTB, total new TB patients registered during 2007/8 in Addis Ababa were 2 931, 4 820, 5 170 and 13 413 respectively. According to the NTG, PTB accounts for 85.0% of all TB cases whereas the number of EPTB cases diagnosed during 2007/8 showed that the proportion of EPTB were 35.1% in Ethiopia generally and 40.0% in Addis Ababa specifically. Of the total PTB cases, 75.0-80.0% of cases are estimated to be smear positive. But the proportions of smear positive and smear negative PTB cases diagnosed were 22.7% and 37.3% respectively during 2007/8 (MoH 2007/8:31; MoH 2008a:17). This indicates the possibility of the presence of over diagnosis of smear negative PTB and EPTB cases, and under diagnosis of smear positive PTB possibly due to lack of healthcare providers’ adherence to the NTG of Ethiopia.
2.6 THE HEALTHCARE SYSTEM IN ETHIOPIA

The healthcare delivery system in Ethiopia emphasises primary healthcare (PHC), including preventive, promotive and basic curative services. In order to realise this, Ethiopia developed a 20 year strategic health sector development plan (HSDP) which is derived from the millennium development goals (MDGs). The government of Ethiopia has a four-tier health system for health service delivery, characterised by a primary healthcare unit (PHCU), comprising one health centre and five satellite health posts, and then the district hospital, zonal hospital and specialised hospital (MoH 2005:8). The health policy of Ethiopia focuses on the provision of preventive and promotive healthcare to the population under the health post, which involves prevention and control of diseases, including TB.

The health centres are responsible for diagnosis and treatment of TB patients while health posts are responsible for providing promotive and preventive healthcare services. The health extension workers (HEWs) at health posts are expected to visit each household and to provide both promotive and preventive services. Concerning TB, the HEWs are expected to refer household members who cough for two or more weeks and they are the key agents in enhancing the patients’ healthcare seeking behaviours. Failure to adhere to TB diagnostic criteria could frustrate patients and HEWs who are referring household member suspects for TB diagnosis and possible treatment.

A community randomised trial in the southern parts of Ethiopia indicated that involvement of HEWs increased TB case detection and treatment success rates. The mean TB case detection rate was higher in the intervention than the control kebeles (lowest administrative units in Ethiopia) 122.2% and 69.4% respectively. The treatment success rate was also slightly higher in the intervention than the control kebeles 89.3% and 83.1% respectively (Datiko & Lindtjørn 2009:5-6).

The TB control programme in Ethiopia is supported by policy and guidelines adopted at national level. The effort to control TB was started in the early 1960s with the establishment of TB centres and sanatoriums in three major urban areas namely
Addis Ababa, Asmara (currently the capital city of Eritrea) and Harar. In 1976, the central office of the National TB Control Programme was established (MoH 2008a:1; Ethiopian Public Health Association 2006: 74).

2.7 THE COURSE OF TB

2.7.1 Transmission of TB

TB is an infectious disease and transmitted through the air, though in extremely rare cases it could be transmitted congenitally or through milk infected with M Bovis. When an untreated infectious PTB patient coughs, sneezes or laughs, tiny particles containing MTB are released into the air. The particles, about one to five micron in diameter, form droplet nuclei which can remain in the air up to several hours depending on the environment. Transmission occurs when a healthy person inhales air contaminated by MTB. Transmission is facilitated when there is poor ventilation and overcrowding and in areas where there is no direct sunlight since good ventilation removes droplet nuclei and direct sunlight kills MTB (WHO 2004:10).

2.7.2 Risks of TB infections

An individual’s risk of infection depends on the concentration of MTB in the air and the duration of exposure to the droplet nuclei as well as to the individual’s susceptibility to the infection. Not everyone exposed to an infectious smear positive PTB patient becomes infected with TB. The factors which predispose an individual to become infected with TB are longer duration of exposure to infectious TB patients, overcrowded living conditions, lack of ventilation, absence of direct sunlight and the presence of higher concentrations of droplet nuclei in the air generated by infectious TB patients (WHO 2004:11-12).

In general, the risk of acquiring MTB infection is mainly determined by external factors. As a result of delayed heath care seeking behaviour and delayed diagnosis, an estimated 20 contacts will be infected by an infectious TB patient before detection, particularly in high TB burden countries (Raviglione & O’Brien 2005:955).
2.7.3 Risks of progression to TB disease

In 90.0-95.0% of persons infected with MTB the immunologic defence system either kills the inhaled bacilli or keeps them suppressed causing latent MTB infection (MoH 2008a:18). Individuals will develop full blown TB disease when their immune system cannot keep the bacilli under control. The life time risk of developing active TB disease in infected persons with immune competent individuals is about 10.0% whereas the life time risk of developing full blown TB in HIV infected person is 50% (WHO 2004:12). A person’s immune system is the determining factor for a person to develop full blown TB. In areas where there is high HIV prevalence, the prevalence of TB is also high since there is a direct relationship between persons infected with HIV and TB.

The known risk factors for developing full blown TB disease are poverty, malnutrition and over-crowding living conditions which facilitate transmission of MTB bacilli and HIV infection or immune suppression (MoH 2008a:18).

2.7.4 Clinical manifestations of TB

Healthcare providers should record their patients’ clinical manifestations in order to ease their diagnoses and to provide continued care to their patients. The usual presentations of TB patients are cough, chest pain, coughing up of blood and dyspnoea, fever, night sweating, weight loss, tiredness and loss of appetite (WHO 2004:19; MoH 2008a:22). A study conducted in Cameroon reported that the patients’ presenting complaints in descending order were cough (71.0%), fever (12.0%), chest pain (4.0%), abdominal pain (4.0%) and coughing up of blood (3.0%) (Cambanis et al 2007:1310). A study conducted in Norway and six countries of the Eastern Mediterranean region (Egypt, Iraq, Pakistan, Somalia, Syria and Yemen) revealed that cough, fever and weight loss were the most frequent symptoms reported by the TB patients (Farah, Rygh, Steen, Selmer, Heldal & Bjune 2006; WHO 2006c:19). Another study conducted in Taiwan revealed that the patients’ presenting complaints were cough (78.8%), fever (41.7%), and dyspnoea (29.3%) (Chung et al 2007:3).
English et al (2006:5) described productive cough, dyspnoea, loss of weight and night sweat as the predominant symptoms of TB patients. Hence healthcare providers need to be aware of the major symptoms of TB in order to ease its prompt diagnosis. A study conducted in Turkey by Canan, Tanrikulu, Acemoglu, Palanci, Yilmaz, Guler, Sahin, Dagli and Koksal (2009:359) pointed out that only 22.2% of doctors recognised cough as the first symptom of PTB.

### 2.8 DIAGNOSIS OF TB

Early diagnosis and prompt treatment of TB patients are crucial steps for prevention and control of TB. Bacteriologic examination is the gold standard for TB diagnosis, and healthcare providers should order specimens for microscopic examination. But a study conducted in Turkey reported that only 28.8% of doctors regarded bacteriology as a first priority for diagnosis of PTB (Canan et al 2009:359; WHO 2009c:24). Hence healthcare providers need to have adequate knowledge about the most appropriate techniques for PTB diagnosis.

The Ethiopian NTG (MoH 2008a:24-25) recommends that healthcare providers should order spot-early morning-spot sputum analysis for any patient presenting to health facilities with productive cough of two weeks’ duration. The diagnosis of smear positive PTB is confirmed when two AFB smears are positive in HIV negative individuals but one AFB positive for HIV positive individuals. For TB diagnosis algorithm see section 1.6 of this dissertation.

In the PHCU of low and middle income countries, respiratory complaints (including cough) represents on average 18.4% of symptoms which urged patients above five years of age to visit health facilities. Of these patients, 5.0% were suspected of having TB because of unexplained coughs of 2-3 weeks’ duration. Collection of sputum from patients presenting with productive coughs lasting more than two weeks’, the number of suspected TB patients increased by 61.0% and the detection of TB increased by 46.0% compared to the collection of sputum from patients presenting with productive cough of more than 3 weeks’ duration. Active enquiries of the presence of productive cough in all out-patient department attendees might increase the detection of TB patients. About 7.0% of patients, who presented to
health facilities, and who did not complain about productive coughs but admitted to having coughed for more than two weeks on active inquiries, were found to be AFB smear positive. However, many patients presenting with persistent productive coughs were not evaluated for TB. This could result in missed opportunities for earlier diagnosis of TB, worsening of TB patients clinical conditions and higher transmission rates of TB to communities (WHO 2006a:18).

Hence the key to the diagnosis of TB is ordering of a spot-early morning-spot sputum analysis for patients who presented themselves to health facilities complaining of cough of more than two weeks.

2.9 TREATMENT OF TB

Before the discovery of antibiotics, TB was the most dreaded enemy of the human race. The discovery of anti-TB drugs in the 1940s proved that this bacillus was beatable because TB cures could be achieved (WHO 2001:11).

The main objectives of Ethiopia’s NTG anti-TB treatment are to cure individual TB patients, to prevent mortality due to TB, to prevent relapses, reduce infectiousness and prevention of MDR-TB. To achieve these objectives healthcare providers are expected to prescribe appropriate combinations of anti-TB drugs and the prescription of the correct dosage. In addition to treating TB patients, healthcare providers must have the strategy to assess these patients’ adherence to the standard treatment regimens and address poor adherence to ensure that the patients completed their treatment (MoH 2008a:32; WHO 2006a:29).

In Ethiopia, TB patients’ treatments are free of charge which should ensure proper control and completion of TB treatment. Currently TB treatment is being given in both public health facilities and in selected private hospitals and clinics. TB patients are treated with multi-drug therapy. TB is a notifiable disease and the local health authority is notified quarterly with the standard reporting format. The TB register has a column to record a patient’s contacts as a tracing mechanism. There are two
treatment phases namely the intensive and continuation phases (MoH 2009b:2; MoH 2008a:33; MoH 2008b:58).

- **Intensive Phase**

During the intensive phase TB patients should collect their drugs every day and should swallow these under the direct observation of the healthcare provider. The intensive phase lasts for two months (56 days) in cases of category I and category III TB patients while it is three months for category II TB patients. The AFB examination will be done at the end of the intensive phase, and if the result is found to be smear positive the treatment will be extended by one month. The anti-TB drugs prescribed during the intensive phase are four drugs namely HERZ in cases of category I and III and it is five drugs that are HERZS for two months followed by HERZ for one month in cases of category II TB patients.

- **Continuation phase**

During the continuation phase TB patients should collect their drugs every month and the drugs are self administered by the patient, except anti-TB drug regimen containing R and re-treatment TB patients where drugs are swallowed under the direct observation of a healthcare provider. The continuation phase lasts for six months with treatment of EH in cases of category I and III TB patients. Whereas the continuation phase lasts five months in cases of category II TB patients and the anti-TB drugs prescribed are RHE to be taken three times weekly (MoH 2008a:33-38). Annexure B presents information on anti-TB drug regimens and dosages.

A study by Mengiste, Newell, Walley, Gessessew, Tesfaye, Lemma and Madeley (2009:461) indicated that only 5.0% of TB patients who completed the intensive phase received the recommended intensive phase treatment for 56 days while 93.0% of all TB patients received the intensive phase treatment for more than 56 days. The study also reported that TB treatment provided by poorly trained healthcare providers leads to more treatment interruptions or defaulters than in cases where the healthcare providers had received adequate training.
• **Side effects of anti-TB drugs**

Most TB patients complete their treatment without any significant side effects. However, a few TB patients do develop side effects. The major side effects experienced by TB patients are arthralgia or joint pain, peripheral neuropathy, visual disturbances, hearing impairments, gastro-intestinal disturbances (like abdominal pain, nausea and vomiting), disturbed balance and pruritus or itching of the skin (MoH 2008a:39; WHO 2004: 32-33). Clinical monitoring for side effects of all TB patients is therefore crucial during treatment. A study conducted in Thailand reported that anti-TB treatment defaulter rates were higher in patients who had severe medication side-effects (Jittimanee, Madigan, Jittimanee & Nontasood 2007:358). The common side effects observed according to this study were yellowish discoloration of the eye, pruritus or itching of the skin, nausea and visual disturbances. Hence healthcare providers should educate their TB patients about the potential side effects of anti-TB drugs. (See Annexure B for the particular side effects caused by each anti-TB drug).

### 2.10 TB AND HIV/AIDS

Immune suppression, as a result of HIV infection, increases the susceptibility of infection with MTB, the risk of progression to full blown TB disease, the reactivation of latent MTB infection and the incidence and prevalence of TB disease. It also enhances the tendency of re-infections and relapses of TB. Latent TB-infection in HIV positive personsreactivates at a rate of 10.0% per year as opposed to the 5-10% life time risk of HIV negative persons. HIV positive persons are liable to re-infections with new strains of TB from the community and they may develop MDR-TB more frequently (MoH 2008a:71).

Of the 9.27 million cases of TB in 2007, 1.37 million or 14.8% were HIV positive. During the same year, the African region accounted for 79.0% of HIV positive TB cases globally. South Africa accounted for 31.0% of HIV positive TB cases in the African region during 2007 (WHO 2009a:9).
Ethiopia is one of the highly affected countries by TB/HIV co-epidemics. Routine data collected in Ethiopia during 2006/7 indicated that 31.0% of TB patients were HIV positive (MoH 2008b:3). According to 2009/10 1st quarter official report of Addis Ababa regional health bureau, 24.3% of 3 081 TB patients were found to be HIV positive.

The proportion of smear negative PTB is higher in persons infected with HIV as opposed to HIV negative persons. The presence of one AFB positive microscopic result in HIV positive persons is sufficient to diagnose smear positive PTB (MoH 2008a:74-76).

2.11 MDR-TB

The causes of MDR-TB may be classified as microbial, clinical and programmatic. From the microbial point of view, a resistant strain is caused by genetic mutation that makes a drug ineffective against the mutant bacilli. From the clinical and programmatic point of view, MDR-TB is caused by inadequate and poorly administered anti-TB drugs to patients diagnosed with TB. One of the causes of poorly administered anti-TB drugs is healthcare providers’ incapability to adhere to NTGs during treatment of TB patients (WHO 2008:3).

MDR-TB is a major public health problem, particularly in developing countries where there is low socio-economic development and failing healthcare infrastructures. In developing countries where patients’ delayed healthcare seeking behaviours, high rates of defaulter and minimal treatment adherence are compounded with longer health system delays in diagnosis and commencement of anti-TB treatment, the likelihood of development of MDR-TB is very high. A study conducted in Abkhazia (Georgia, Eastern Europe), indicated that longer treatment duration, lower cure rates, and higher defaulter rates are the factors which lead to the persistent prevalence of MDR-TB which may result in greater infectiousness to the community, further accelerating the burden of MDR-TB (Manuela, Stefan, Francis, Elisabetta, Francesca, Germano, Hasan, Thierry, Peter, Mike, Francesco, Heinz, Graziella, Sabine, Lanfranco, Marco & Maryline 2009:321).
In developing countries, like Ethiopia, not all TB patients are undergoing culture and drug susceptibility testing hence MDR-TB cases are identified when patients fail to respond to first-line TB treatment (MoH 2009b:21). Prolonged periods of sputum smear positivity might then result in enhanced transmission of MDR strains, further accelerating the increase of MDR-TB incidence.

According to the WHO (2009a: 11) estimation there were a total of 511 000 cases of MDR-TB globally during 2007. Of these, 289 000 were among new cases (3.1% of all new cases) and 221 000 were among cases that had been previously treated for TB (19.0% of all previously treated cases). Of the total cases of MDR-TB, 68.0% were smear positive PTB.

In Ethiopia MDR-TB is estimated to be 1.6% among newly diagnosed TB patients and 11.8% in previously treated TB patients according to the anti-TB drugs survey conducted during 2005 (MoH 2009b:3). The treatment of MDR-TB with second line anti-TB drugs is long, complex and costly with considerably more side effects than the first line anti-TB drugs.

2.12 THE PREVENTION OF TB

Among TB prevention and control strategies, the best way to prevent and control TB is prompt diagnosis of infectious cases and effective treatment of infectious cases.

In addition to early diagnosis and effective treatment of infectious cases of PTB, vaccination of children with Bacillus Calmette Guerin (BCG) and treatment of persons with latent TB infection (LTBI), who are at high risk of developing active disease, are other important strategies to prevent and control TB.

Vaccination of children with BCG can prevent serious forms of TB like TB meningitis and miliary TB. In Ethiopia BCG is given to all infants except those who developed AIDS. Children under 5 years of age, people infected with HIV and people with AIDS who had contact history with infectious cases of PTB should be given Isoniazid preventive therapy (IPT) provided that active or full blown TB disease had been ruled out. Currently IPT is being given to the aforementioned target groups from
whom active TB have been ruled out for six months’ duration and it should be repeated every three years (MoH 2008a: 89-90; MoH 2008b:22). Raviglione and O’Brien (2005:964) revealed that a randomised placebo controlled clinical trial of 6 - 12 months of IPT, reduced the risk of developing active TB in LTBI people in more than 90.0% of TB cases in the United States of America.

From a public health point of view, ventilation of rooms particularly where TB patients are encountered in health facilities and in their dwelling sites are another strategy to prevent and control TB since good ventilation decreases the intensity of tubercle bacilli in the air.

2.13 SUMMARY

In this chapter the historic background and definition of TB, adherence to NTG, scope of the problem, recent TB statistics, diagnosis of TB, TB treatment, health system in Ethiopia, course of TB disease like risk of MTB infection, clinical manifestations, TB HIV/AIDS, MDR-TB and prevention of TB were explored. The research methodology will be discussed in chapter three.
CHAPTER 3
RESEARCH METHODOLOGY

3.1 INTRODUCTION

Research methodology is the approach or the design that is followed by a researcher to answer a particular research question. This research was done using a quantitative descriptive, retrospective, cross-sectional research design. Data were collected using a checklist which was specifically designed by the researcher in order to collect the selected variables using retrospective medical record reviews.

3.2 STUDY DESIGN

A research design is a plan indicating how the study is going to be carried out. It is a plan guide for providing sound answers to a research questions. The study design guides what type of observations, and which measurement instrument will be adopted and when to conduct the data collection (Stommel & Wills 2004:32-34). The research design followed for this study was a descriptive, cross-sectional quantitative study design. The objective of the study was to assess healthcare providers’ adherence to the Ethiopian NTG recommendations during diagnosis and treatment of TB patients. This study intended only to describe whether healthcare providers were complying with the NTG during diagnosis and treatment of TB patients rather than the association of variables.

3.2.1 Descriptive

Descriptive study, as defined by Burns and Grove (2005:232), is a study design which is used to obtain and describe information of particular characteristics in more detail. In this study the characteristics assessed were healthcare providers’
adherence to the Ethiopian NTG recommendations during diagnosis and treatment of TB patients using a specifically designed checklist.

### 3.2.2 Retrospective

A retrospective study design as defined by Stommel and Wills (2004:127) is a study design which focuses on events that have already happened and have been recorded. This study followed a descriptive, retrospective, cross-sectional study design since healthcare providers’ adherence to the Ethiopian NTG recommendations, during the diagnosis and treatment of TB cases, was recorded from the TB patients’ medical records according to the specifically designed checklist.

Data were collected from TB patients’ medical records, if they commenced anti-TB treatment from March till November 2010 (excluding those diagnosed from 11 April till 2 July 2010 since these weekends TB campaigns were held by the Addis Ababa Regional Health Bureau). A specifically designed checklist was used to record information from the TB patients’ medical records.

### 3.2.3 Cross sectional

As described by Stommel and Wills (2004:159) a cross-sectional study is a study which collects information at a single point in time. A cross-sectional study is less costly in terms of time and resource as a large sample can be studied within a relatively short period of time (Bowling 2002:197).

### 3.2.4 Quantitative

Burns and Grove (2005:23) describe quantitative research as a “formal, objective, systematic process to describe variables, examine relationships among variables, and determine cause-and-effect interactions between variables”. This study systematically and objectively reviewed TB patients’ medical records to assess healthcare providers’ adherence to the Ethiopian NTG recommendations during the
diagnosis and treatment of TB. Statistics were used to summarise and describe healthcare providers’ adherence to the Ethiopian NTG recommendations during the diagnosis and treatment of TB patients.

3.3 RESEARCH METHODS

As described by Burns and Grove (2005:211), research methodology is the strategy from the identification of the research problem to the end plan of data collection. This section covers how the sample was selected, the setting where the study was conducted and inclusion and exclusion criteria used during the study.

3.3.1 Sampling

Sampling involves a process of selecting a sub-set of a population which represents the entire population in order to obtain characteristics of a particular phenomenon. A sample is the sub-set of cases or observations drawn from a population, who fulfilled the eligibility criteria participated in the study. There are two methods of sampling; one yields probability sampling in which the probability of selection relies on random selection process and the other is the non-probability sampling where sample selection does not follow random selection procedures (Stommel & Wills 2004:297-300).

This study used simple random sampling to select TB patients’ medical records using the TB register as a sampling frame. The study was conducted in four public health facilities (two health centres and two hospitals). The health centres were selected by using simple random sampling while the hospitals were selected using purposive sampling as only these two regional hospitals provided DOTS services at the time of data collection.

Selection of samples using the probability sampling method enables one to generalise the results to the target population since the study samples were selected randomly in which each study samples has an equal and independent chance of being selected.
3.3.1.1 Study population

Population is the collection of persons, objects or things that fulfil certain criteria set by the researcher for inclusion in the study where the researcher has a reasonable access (Burns & Grove 2005:40). In this study, the study population comprised TB patients' who started anti-TB treatment at any of the four participating public health facilities and met the inclusion criteria.

Inclusion criteria

- New TB patients who had started anti-TB treatment from March-November 2010 excluding those who started anti-TB treatment from April 11- July 2, 2010
- Newly diagnosed TB patients aged 15 years and older

Exclusion criteria

- TB patients who were diagnosed in facilities other than the study facilities and referred for treatment
- TB patients who were younger than 15
- TB patients who were diagnosed from April 11- July 2, 2010 since Addis Ababa regional health bureau undertook weekends' TB campaigns and they might have interfered with the healthcare providers' routine service provision
- Those TB patients with known HIV status since HIV positive patients are usually screened for TB routinely

The numbers of TB patients per facility were determined from each facility's TB register. The proportionate sampling method was used to allocate the study population's medical records among the four public health facilities based on the number of TB patients who fulfilled the inclusion criteria. The medical record of each TB patient who fulfilled the eligibility criteria were then selected randomly using numbers from random tables. The medical record numbers of each TB patient was written on a piece of paper and then the data collector placed a pencil on the table
with the eyes closed. The desired sample size was obtained by moving the pencil up, down, right and left taking the number touched initially as a starting point.

3.3.2 Research setting

The study was conducted in Addis Ababa, the capital city of Ethiopia. It is divided into ten sub cities and 99 kebeles (the lowest administrative units in Ethiopia). It has five regional hospitals and 26 health centres. During the data collection all health centres and two of the regional hospitals were providing DOTS service. The study included four public health facilities (two hospitals and two randomly selected health centres. The TB patients’ who were treated at these four public health facilities were from diverse backgrounds in terms of ethnicity, gender, education and income levels.

3.4 DATA COLLECTION

Data collection is the gathering of all the pertinent information necessary to answer a particular research question or hypothesis (Stommel & Wills 2004:363). Data were transcribed from each TB patient’s medical records using the specifically designed checklist by the researcher. Data were transcribed from TB patients’ medical records if they had commenced anti-TB treatment from March-November 2010 excluding those who were diagnosed and started anti-TB drugs from 11 April till 2 July 2010.

3.4.1 Research instrument

A research instrument is used to measure a variable of interest (Bowling 2002:144). Burns and Grove (2005:395) define a checklist as a technique used to indicate the occurrence of a particular behaviour. In this study a checklist was used as a research instrument since it enabled the researcher to assess whether healthcare providers were complying with the Ethiopia’s NTG during the diagnosis and treatment of TB. The checklist (annexure F) was developed by the researcher based on the Ethiopian MoH 2008 NTG, reviewed literature findings and in consultation with TB programme managers. The checklist was pre-tested on ten TB patients’
medical records in public health facilities that were not included in the study. The checklist comprised the following sections:

**Section I:** General information  
**Section II:** TB patients’ personal and socio-demographic characteristics  
**Section III:** History and physical examinations of TB patients  
**Section IV:** Laboratory investigations  
**Section V:** Classification and treatment of TB patients  
**Section VI:** Evidence for the classification and treatment of TB patients

### 3.4.1.1 Validity

Validity refers to the instrument’s accuracy to measure the characteristics or attributes that it intends to measure (Stommel & Wills 2004:222). The checklist’s validity was tested on face validity and content validity.

**Face validity**

Face validity refers to experts’ subjective assessments as to whether the questions appear to be relevant, practical, and explicit to measure what it intends to measure (Bowling 2002:150-151). The checklist was developed in consultation with TB programme managers and the review of relevant literature, based on Ethiopia’s NTG. The researcher’s colleagues and supervisor agreed that the checklist appeared to address only issues pertaining to the adherence to Ethiopia’s NTG and thus its face validity was deemed to be acceptable.

**Content validity**

According to Burns and Grove (2005:377), content validity refers to the examination of an instruments’ accuracy whether it includes all the major elements pertinent to the construct being measured. Healthcare providers’ adherence to the Ethiopian national TB guideline was measured retrospectively using TB patients’ medical records. Healthcare providers were said to be adhering to the NTG when they complied with the diagnosis and treatment recommendations of the NTG of Ethiopia.
3.4.1.2 Reliability

Mitchell (2001:52) defined reliability as the capacity of an instrument to measure consistently the same phenomenon. Reliability is the reproducibility and consistency of a measurement instrument’s ability to produce results that are consistent across persons and time (Stommel & Wills 2004:209). An instrument’s reliability can be tested if more than one observation revealed similar results. Generally, there is no proof whether documented data are reliable since one cannot justify how much of the recorded data were generated from the observed situation and how much were from the observer.

Burns and Grove (2005:374) defined reliability as the consistency of results obtained using a particular research instrument. This implies that if the same instrument is used by different data collectors, similar results should be obtained. Before using an instrument, researchers should test the reliability of an instrument and the estimate of the reliability is specific to the sample being tested. Estimates of reliability testing are only specific to the particular sample being tested hence high reported reliability values of an instrument do not guarantee that reliability will be satisfactory in another sample or with a different population. It is therefore important that reliability testing needs to be performed on each instrument used in a study prior to performing other statistical analysis. Reliability testing enables the researcher to examine the amount of random error in the measurement instrument. Burns and Grove (2005:374) stated that reliability is related to characteristics such as dependability, precision, consistency and comparability. The consistency of repeated measures of an attribute using the same measuring instrument or scale is referred to as test-retest reliability. This implies that if there is no change in the attribute being measured, repeated measurement of an attribute should produce stable results (Burns & Grove 2005:374; Stommel & Wills 2004:209).

The researcher recorded the TB patients’ medical record numbers from the TB unit register at TB clinic in each participating health facility. Hence the collected data can easily be verified for consistency and correctness by comparing the transcribed data
from the checklist with that of the true source of the data in this case the medical records.

3.4.2 Data collection procedure

The checklist was pre-tested on ten TB patients’ medical records. During the pre-testing of the checklist, the researcher identified that some of the variables were not possible to collect based on the information recorded on TB patient’s medical records. It was impossible to transcribe patients’ ethnicity, marital status and educational levels from the TB patients medical records since all these variables were not recorded on patients’ medical records.

The TB patients’ medical records were reviewed for information on symptoms suggesting TB, physical examinations undertaken and findings, laboratory/x-ray requisitions and their results, treatments with broad spectrum antibiotics, previous history of TB, diagnosis and TB treatment category, age, sex, and weight of the patient, the types and dosages of drugs prescribed. Based on the documented clinical, physical, and laboratory evidence, the diagnosis of each patient was compared with the diagnostic criteria set by the NTG of Ethiopia. The demographic data of the patient, symptoms which made the patient seek healthcare, previous history of TB, physical examination findings, laboratory results, and the types of drugs with their strengths were transcribed manually from each individual TB patient’s medical records by the researcher using the specifically designed checklist.

3.4.3 Data management

Each checklist was coded by the level of the health facility to ease its analysis. The completed checklists did not contain the names of patients and were kept securely locked up by the researcher. Only the researcher had access to the completed checklists. The researcher kept these completed checklists in case queries arose from the research report. Subsequent to the acceptance of the research report, these completed checklists would be destroyed.
3.4.3.1 The use of routine data

Routine data are collected on an ongoing basis to evaluate or monitor the progress of the patient (Stommel & Wills 2004:271). The data used in this study were routinely collected data as part of service provision to the particular TB patient.

Advantages of the use of routine data

This data source can provide ample information particularly about the patients’ visits, chief complaints, main diagnosis, concomitant infections, types of medications prescribed, the patient’s adherence to medication, family and social characteristics of the patient. The researcher could spend less time on data collection and more time on analysing the data (Stommel & Wills 2004:271).

Disadvantages of using routine data

The researcher did not control the data collection process, the researcher only transcribed the recorded data from each patient’s medical record to the checklist. Routinely collected data could be poor in quality because of incomplete recording, incorrect coding and recording and/or unavailability of some patients’ medical records (Stommel & Wills 2004:271-272). The researcher encountered poor recording of the data and some variables could not be transcribed because of missing data on some patients’ medical records.

3.4.4 Ethical considerations related to data collection

This study did not involve direct patient inquiry and the ethical principles of autonomy, beneficence, non-malifence and justice did not apply. However, the ethical principles of anonymity and confidentiality applied. Before the data collection commenced, the names of TB patients’ were de-identified from their medical records in order to protect the TB patients’ identity hence neither the researcher nor any other person could identify the TB patient by name.
3.4.5 Permission to conduct the study

Permission to conduct the study was obtained from the Research and Ethics Committee of the Department of Health Studies of the University of South Africa (Unisa) and Addis Ababa Regional Health Bureau before data collection started. The permission that was obtained from Addis Ababa regional health bureau was communicated to each study facilities before data collection commenced (See Annexure E).

3.4.6 Data analysis

Data analysis is the systematic summarisation and combination of research data and testing of hypothesis. According to Stommel and wills (2004:369), data analysis is the search for meaningful patterns of data. Data analysis involves three steps namely description of the background information, the main analysis which enables the researcher to answer the research question and finally follow-up analysis in cases of unanticipated results or findings (Stommel & Wills 2004:369-370). In this study, the data were analysed using the SPSS version 16.

3.5 SUMMARY

In this chapter the research methodology, design, data collection procedure, the use of routine data with its pros and cons, ethical consideration, data analysis, validity and reliability have been covered. Chapter four will present the results of the study.
CHAPTER 4

ANALYSIS AND DISCUSSION OF RESEARCH FINDINGS

4.1 INTRODUCTION

This chapter presents and discusses the research findings. The purpose of this study was to assess Ethiopian healthcare providers' adherence to the NTG during the diagnosis and treatment of TB patients. This information could contribute to the existing knowledge about feasible and effective TB prevention and control strategies in Ethiopia.

The specific objectives of the study were to:

- assess healthcare providers’ adherence to the NTG during the diagnosis of TB in Addis Ababa, Ethiopia
- assess healthcare providers’ adherence to the NTG during the initial treatment of TB in Addis Ababa, Ethiopia

4.2 POPULATION

A retrospective diagnostic audit was conducted on 233 TB patients' records. These patients were at least 15 years old and received TB treatment from the four participating public health facilities (two hospitals and two health centres) in Addis Ababa.

4.3 DATA ANALYSIS

The data were analysed using the SPSS version 16. Data were transcribed from medical records of TB patients, who had been diagnosed and treated in the four selected public health facilities, onto the specifically designed checklist by the researcher. The data analysis will be discussed in accordance with the sections of the checklist. For the statistical tests, the accepted level of significance (alpha level) was 0.05.
4.3.1 General information

4.3.1.1 Healthcare providers’ compliance with the NTG during the diagnosis of TB patients by type of health facility (n=4)

Out of the 233 TB patients, 65.2% (n=152) were diagnosed in hospitals and 34.8% (n=81) were diagnosed at health centres. The diagnoses were made according to the NTG diagnostic criteria in 51.3% (n=78) of the hospitals’ cases. The percentage of correctly diagnosed TB patients, complying with the NTG diagnostic criteria in hospitals by type of TB were smear positive PTB (93.3%, n=14), smear negative PTB (4.0%, n=2) and EPTB (71.3%, n=62). While in health centres 97.5% (n=39) of smear positive PTB, 0% (n=0) smear negative PTB and 60.0% (n=9) EPTB patients were diagnosed correctly in compliance with the NTG diagnostic criteria (see table 4.1).

<table>
<thead>
<tr>
<th>Type of TB</th>
<th>Number of records reviewed</th>
<th>Correctly diagnosed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hospital</td>
<td>Health centre</td>
</tr>
<tr>
<td>Smear positive PTB</td>
<td>15</td>
<td>40</td>
</tr>
<tr>
<td>Smear negative PTB</td>
<td>50</td>
<td>26</td>
</tr>
<tr>
<td>EPTB</td>
<td>87</td>
<td>15</td>
</tr>
<tr>
<td>Total</td>
<td>152</td>
<td>81</td>
</tr>
</tbody>
</table>

In this study, compliance of healthcare providers with the NTG recommendations during TB diagnosis was assessed by type of health facility to identify any association between healthcare providers’ adherence to the NTG by type of health facility using the variables type of facility and diagnosis of TB as shown in table 4.2.

There were no significant variations in healthcare providers’ levels of adherence to the NTG during the diagnosis of TB patients by type of health facility since there was no statistical significance at 5% level of significance (p=0.307). This indicates that compliance of healthcare providers with the NTG during the diagnosis of TB patients was independent of the type of healthcare facility. Whether a patient went to a health centre or hospital, the
chances of his/her TB diagnosis to be made by healthcare providers in compliance with the NTG were similar.

Table 4.2  Factors that affected compliance with the NTG during the diagnosis of new TB patients (n=233)

<table>
<thead>
<tr>
<th>Type of facility</th>
<th>Correctly diagnosed new TB patients according to the NTG diagnostic criteria</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>Number</td>
<td>%</td>
<td>No</td>
</tr>
<tr>
<td>Hospital</td>
<td>51.3%</td>
<td>78</td>
<td>48.7%</td>
<td>74</td>
</tr>
<tr>
<td>Health Center</td>
<td>59.3%</td>
<td>48</td>
<td>40.7%</td>
<td>33</td>
</tr>
<tr>
<td>Total</td>
<td>54.1%</td>
<td>126</td>
<td>45.9%</td>
<td>107</td>
</tr>
</tbody>
</table>

A study conducted in Taiwan indicated that patients presenting to higher or speciality institutions, were more likely to be diagnosed based on the NTG diagnostic criteria (Chung et al 2007:4). However, the opposite was found in this study and the percentage of correctly diagnosed TB patients at health centres in this study were 59.3% (n=48) which was higher than 51.3% (n=78) of TB patients diagnosed correctly at hospitals. These percentages were higher than 58.4% and 42.8% of a similar study in the Amhara region of Ethiopia at health centres and hospitals respectively (Birara 2007:31). The current study showed better compliance with the NTG diagnostic criteria at health centres than at hospitals. Since more patients were seen at hospitals than at health centres, failure to comply with the NTG at hospitals might have had detrimental effects to individual TB patients as well as to the national TB control programme. The statistics from Birara’s (2007) study, as well as those of the current study, indicate that healthcare workers did not follow the NTG rigorously during the diagnosis of TB patients.

4.3.1.2  Healthcare providers’ compliance with the NTG during the initial treatment of TB patients by type of health facility (n=4)

Of the 152 TB patients treated at hospitals, 88.2% (n=134) had been prescribed the correct number of anti-TB pills. At health centres, 96.3% (n=78) of the 81 patients had been prescribed the correct number of pills during the initial treatment, as shown in table 4.3.
Table 4.3  Prescription of initial anti-TB drugs by type of facility (n=233)

<table>
<thead>
<tr>
<th>Type of facility</th>
<th>Dose too high</th>
<th>Dose too low</th>
<th>Total</th>
<th>Number</th>
<th>%</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health centre</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>78</td>
<td>96.3</td>
<td>81</td>
<td>34.8</td>
</tr>
<tr>
<td>Hospital</td>
<td>4</td>
<td>14</td>
<td>18</td>
<td>134</td>
<td>88.2</td>
<td>152</td>
<td>65.2</td>
</tr>
<tr>
<td>Total</td>
<td>6</td>
<td>15</td>
<td>21</td>
<td>212</td>
<td>91.0</td>
<td>233</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Out of the 21 TB patients who had been prescribed the incorrect number of anti-TB pills, 85.7% (n=18) were from hospitals and of these 77.8% (n=14) had been prescribed doses lower than the NTG’s recommendations. While in health centres, 14.3% (n=3) of TB patients had been prescribed the incorrect number of pills and of these 66.7% (n=2) were prescribed anti-TB pills exceeding the NTG’s recommended dosages.

The level of healthcare providers’ compliance with the NTG during the initial prescribing of anti-TB pills was lower in hospitals than at health centres. This practice could lead to increased risks of MDR TB. This is the case because one of the causes of MDR TB is the inadequate administration of anti-TB drugs (WHO 2008:3).

Non-adherence of healthcare providers to the NTG treatment recommendations might thus contribute to increased numbers of MDR TB cases in the country with serious healthcare and budgetary consequences. MDR TB patients require more sophisticated diagnostic and treatment facilities than TB, which are difficult to afford in developing countries (MoH 2009b:21). TB patients, whose doses of anti-TB drugs exceeded the NTG’s recommendations, might encounter severe side effects which could cause TB patients to default their treatment further increasing the risk of MDR TB (Jittimanee et al 2007:359).
4.3.2 Demographic characteristics

4.3.2.1 Healthcare providers’ compliance with the NTG during the diagnosis of TB patients by gender (n=233)

Of the 233 TB patients, 52.8% (n=123) were males of whom 56.1% (n=69) had been diagnosed correctly according to the NTG diagnostic criteria. Of female TB patients, 60.9% (n=67) were diagnosed according to the NTG diagnostic criteria. Healthcare providers tended to comply slightly better with the NTG during the diagnosis of female TB patients (figure 4.1) than when diagnosing male patients.

![Figure 4.1 Number of correctly diagnosed TB patients by gender (n=233)](image)

A study conducted in Thailand indicated better healthcare providers’ compliance with the NTG during the diagnosis of male TB patients while in this study, healthcare providers tended to comply with the NTG during the diagnosis of female TB patients (Wilawan et al 2008:381). Since MTB attacks both male and female, healthcare providers should comply with the NTG during the diagnosis of both male and female patients.
4.3.2.2 Healthcare providers’ compliance with the NTG during the initial treatment of TB patients by gender (n=233)

Out of the 110 female TB patients 91.8% (n=101), and out of 123 male TB patients 90.2% (n=111) had been prescribed the correct numbers of anti-TB pills in compliance with the NTG treatment recommendations. This indicates that there was no major difference in healthcare providers’ compliance with the NTG treatment recommendations during the initial treatment of TB patients, irrespective of their gender as compared to healthcare providers’ compliance during their diagnosis.

Figure 4.2  Number of male and female TB patients who had been prescribed the correct number of anti-TB pills (n=233)

Table 4.4  Prescription of initial anti-TB drugs by gender (n=233)

<table>
<thead>
<tr>
<th>Gender</th>
<th>Number of TB patients prescribed incorrect number of anti-TB pills</th>
<th>Number and % of TB patients prescribed the correct number of anti-TB pills</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dose too high</td>
<td>Dose too low</td>
<td>Total</td>
</tr>
<tr>
<td>Female</td>
<td>3</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>Male</td>
<td>1</td>
<td>11</td>
<td>12</td>
</tr>
<tr>
<td>Total</td>
<td>4</td>
<td>17</td>
<td>21</td>
</tr>
</tbody>
</table>
Of the 233 TB patients, 9.0% (n=21) had been prescribed the incorrect number of anti-TB pills and of these 57.1% (n=12) were males and 42.9% (n=9) were females. Out of the 21 TB patients who had been prescribed the incorrect numbers of anti-TB pills, 57.1% (n=12) were males and 42.9% (n=9) were females. TB patients, whose doses of anti-TB drugs are too low, run the risk of developing treatment failure and MDR TB. Similar to TB patients’ diagnosis, healthcare providers were inclined to comply better with the NTG during the initial TB treatment with female than with male patients.

4.3.2.3 Healthcare providers’ compliance with the NTG during the diagnosis of TB patients by age (n=233)

The TB patients’ ages ranged from 15 to 74 years, with a mean age of 32.2 years and with a standard deviation of 13.8. Patients aged 15-44 years constituted the majority (79.4%; n=185) while those aged 45-74 years comprised the minority (20.6%, n=48). There were lower levels of healthcare providers’ compliance with the NTG during the diagnosis of TB patients whose ages ranged from 65 to 74 years where only 14.3% (n=1) TB patients had been diagnosed correctly, complying with the NTG. However, there was no statistical difference during diagnosis of TB patients by age group at 5% level of significance (p=0.15) as shown in Table 4.5.

Table 4.5 Relationship between age and diagnosis compliance with NTG (n=233)

<table>
<thead>
<tr>
<th>Age</th>
<th>Correctly diagnosed TB patients based on NTG</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
<td></td>
<td>Total</td>
</tr>
<tr>
<td></td>
<td>Number</td>
<td>%</td>
<td>Number</td>
<td>%</td>
</tr>
<tr>
<td>15-24</td>
<td>48</td>
<td>59.3</td>
<td>33</td>
<td>40.7</td>
</tr>
<tr>
<td>25-34</td>
<td>41</td>
<td>59.4</td>
<td>28</td>
<td>40.6</td>
</tr>
<tr>
<td>35-44</td>
<td>15</td>
<td>42.9</td>
<td>20</td>
<td>57.1</td>
</tr>
<tr>
<td>45-54</td>
<td>12</td>
<td>50.0</td>
<td>12</td>
<td>50.0</td>
</tr>
<tr>
<td>55-64</td>
<td>9</td>
<td>52.9</td>
<td>8</td>
<td>47.1</td>
</tr>
<tr>
<td>65-74</td>
<td>1</td>
<td>14.3</td>
<td>6</td>
<td>65.7</td>
</tr>
<tr>
<td>Total</td>
<td>126</td>
<td>54.1</td>
<td>107</td>
<td>45.9</td>
</tr>
</tbody>
</table>
4.3.2.4 Healthcare providers’ compliance with the NTG during the initial treatment of TB patients by age (n=233)

The NTG recommends the prescription of anti-TB pills based on the TB patients’ body weight and the guideline recommends 1.5, 2, 3, 4, 5 anti-TB pills for those whose body weight is 20-29, 30-39, 40-54, 55-70, and over 70 kg respectively (see Annexure B).

Unlike healthcare providers’ compliance with the NTG during the diagnosis of TB patients, all TB patients (100.0%; n=7) whose ages ranged from 65 to 74 years had been prescribed the correct number of anti-TB pills while 16.7% (n=4) of TB patients in the 45-54 year age group, had been prescribed the incorrect number of anti-TB pills as shown in table 4.6.

Table 4.6 Prescription of initial anti-TB pills by age (n=233)

<table>
<thead>
<tr>
<th>Age</th>
<th>Prescribed correct number of anti-TB pills during initial treatment</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
<td>Total</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Number</td>
<td>%</td>
<td>Number</td>
<td>%</td>
<td>Number</td>
</tr>
<tr>
<td>15-24</td>
<td>77</td>
<td>95.1</td>
<td>4</td>
<td>4.9</td>
<td>81</td>
</tr>
<tr>
<td>25-34</td>
<td>63</td>
<td>91.3</td>
<td>6</td>
<td>8.7</td>
<td>69</td>
</tr>
<tr>
<td>35-44</td>
<td>30</td>
<td>85.7</td>
<td>5</td>
<td>14.3</td>
<td>35</td>
</tr>
<tr>
<td>45-54</td>
<td>20</td>
<td>83.3</td>
<td>4</td>
<td>16.7</td>
<td>24</td>
</tr>
<tr>
<td>55-64</td>
<td>15</td>
<td>88.2</td>
<td>2</td>
<td>11.8</td>
<td>17</td>
</tr>
<tr>
<td>65-74</td>
<td>7</td>
<td>100.0</td>
<td>0</td>
<td>0.0</td>
<td>7</td>
</tr>
<tr>
<td>Total</td>
<td>212</td>
<td>91.0</td>
<td>21</td>
<td>9.0</td>
<td>233</td>
</tr>
</tbody>
</table>

Out of those TB patients whose ages ranged from 15 to 24 years, 95.1% (n=77) had been prescribed the correct number of anti-TB pills. Providers should adhere to the NTG during the initial anti-TB prescriptions’ recommendations in order to minimise the risk of MDR-TB or the risk of developing side effects. Out of 233 TB patients, only 9.0% (n=21) had been prescribed incorrect TB treatments while 91.0% (n=212) had been given the correct prescriptions.
4.3.3 Patients’ complaints and physical examinations

4.3.3.1 TB patients’ presenting complaints

Out of the 233 TB patients, 91.0% (n=212) had their presenting complaints recorded. In 9.0% (n=21) of TB patients, nothing had been recorded on the patients’ charts except the diagnosis. This lack of information might decrease communication among healthcare providers concerning patients’ continued care, treatment and follow-up examinations of the patients’ symptoms. Out of the 212 patients whose presenting complaints had been recorded, coughs (71.2%, n=151), chest pains (30.2%, n=64), night sweats (29.2%, n=62), fever (27.4%, n=58) and loss of appetite (23.1%, n=49) were the top five leading complaints which caused TB patients to seek medical care as shown in figure 4.3.

Out of the 212 TB patients whose presenting complaints had been recorded, cough was the most frequently occurring symptom (71.2%, n=151) and this finding was similar to the results of other studies (Cambanis et al 2007b:1310; Chung et al 2007:3; Farah et al 2006; WHO 2006c:19). Therefore, healthcare providers should be aware of patients’ presenting complaints in order to institute early diagnosis of and treatment for TB.

Figure 4.3  TB patients’ presenting complaints (n=212)
4.3.3.2 Duration of cough

Out of 151 patients who had complained about coughing, the duration of coughing was reported in 80.8% (n=122) of their records. Out of these 122 patients, 85.2% (n=104) had been coughing for more than two weeks as shown in figure 4.4.

![Figure 4.4 Number of TB patients who complained of coughing and the duration of coughing (n=151)]

4.3.3.3 Findings of physical examinations

Out of the 233 TB patients' records, physical examinations' findings were recorded only in 53.2% (n=124) of their medical records (see figure 4.5). However, the physical examinations' findings were recorded for 67.1% (n=102) of TB patients who had been seen at hospitals. Physical examinations' findings were recorded only in 27.1% (n=22) of the 81 TB patients seen at health centres. This might indicate poorer healthcare practices at health centres than hospitals which might jeopardise the quality of service provision at health centres.
A study conducted in the Amhara region revealed that more than half of the TB patients’ physical examinations’ results were not recorded (Birara 2007:47). In this study, 53.2% (n=124) of patients’ physical examinations’ findings had been recorded. The duration of illness was recorded in 80.8% (n=122) out of 151 patients’ files who complained of coughing. Proper recording of patients’ presenting complaints, duration of illness and physical examination findings are important for healthcare providers for diagnosing and treating patients correctly. The NTG and WHO (MoH 2008a:25; WHO 2004:17) recommended 100.0% recording of patients’ presenting complaints and physical examinations’ findings for this information could aid healthcare providers to diagnose patients correctly. Failure to record patients’ presenting complaints, the duration of illness and physical examinations’ findings might interrupt communication among attending healthcare providers relating to the follow-up of patients’ continued care, affecting the quality of services provided to the patient.

Out of 151 TB patients who complained of coughing, physical examinations were recorded only for 55.6% (n=84) of them. In 73.8% (n=62) of these 84 TB patients, chest findings were the most frequently reported results (see figure 4.6).
Figure 4.6 Number of TB patients complaining of coughing and physical examinations (n=151)

4.3.4 Laboratory investigations

This section presents the laboratory investigations undertaken by healthcare providers to diagnose TB and will be discussed in the order of their appearance in the checklist.

4.3.4.1 Sputum analyses

Out of the 151 TB patients who complained of coughing, 68.9% (n=104) had coughed for more than two weeks. Of those 104 who had coughed for more than two weeks, sputum smear examinations were done in 80.8% (n=84) of these cases and 48.8% (n=41) were sputum smear positive for two or more slides (see figure 4.7).

Fewer sputum smear examinations were reportedly done in this study than in a study done in the Amhara region that indicated that 82.4% of TB patients had sputum smear examinations done. However, the results of sputum smear positivity in the Amhara region were reported to be 46.5% positivity for more than two slides (Birara 2007: 31), compared to 48.8% in the current study. The slightly higher sputum positivity in this study (in the
Addis Ababa area) might be due to the potentially better qualified professionals and laboratory facilities in the capital city compared to those in the more rural Amhara region.

![Figure 4.7 Sputum microscopic examinations (n=151)](image)

**Figure 4.7 Sputum microscopic examinations (n=151)**

Early diagnosis and prompt treatment of TB patients are crucial steps for the prevention and control of TB. Bacteriological examinations are the gold standard for TB diagnosis. Therefore, healthcare providers should be familiar with sputum examinations. A study conducted in Turkey reported that only 28.8% of doctors regarded bacteriology as a first priority for diagnosis of PTB (Canan et al 2009:359; WHO 2009c:24).

### 4.3.4.2 Chest x-rays

Chest x-rays were ordered for 62.6% (n=82) of PTB patients, and the results indicated that TB was suspected in 89.0% (n=73) of them (see figure 4.8).

In this study 62.6% of PTB had chest x-rays done and 89.0% were suggestive of TB. In a similar study in the Amhara region, 38.8% of PTB had chest x-rays done and 92.0% of them were suggestive of TB (Aynie 2007:31). Sending patients for x-rays, without following the NTG diagnostic algorithm, might overburden the x-ray facilities, waste patients’ time and incur unnecessary healthcare costs.
4.3.4.3 Fine needle aspirations

Out of the 233 TB patients, 18.9% (n=44) of TB patients complained about enlarged lymph nodes. Most of them (95.5%; n=42) had fine needle aspiration (FNA) tests done and in 88.1% (n=37) of these the results were suggestive of TB (see figure 4.9).
The percentage of patients who underwent FNAs was higher in this study than in a study done in the Amhara region, where reportedly only 21.1% of the TB patients with enlarged lymph nodes underwent this diagnostic test. This could be attributed to the geographical variations since there are more diagnostic facilities in Addis Ababa compared to the Amhara region.

### 4.3.5 Final diagnosis of TB patients

This section presents the type of TB and PTB diagnosed in the study facilities and the initial treatment prescribed for TB patients.

#### 4.3.5.1 Type of TB diagnosed

Of the total 233 TB patients, 56.2% (n=131) were diagnosed as PTB and 43.8% (n=102) were diagnosed as EPTB based on the NTG diagnostic criteria (figure 4.10).

![Figure 4.10 Type of TB diagnosed (n=233)](image)

According to the NTG (MoH 2008a:17), PTB accounts for 85.0% of global TB and EPTB accounts for 14.0% of global TB cases. However, this study identified lower percentages of PTB and higher percentages of EPTB cases. Of all PTB cases diagnosed in the study area, 42.0% (n=55) were smear positive PTB patients while it was expected to be 75-80% (MoH 2008a:17). This indicates a potential over diagnosis of smear negative PTB in this
study, probably attributable to lower levels of healthcare providers’ compliance with the NTG diagnostic criteria. Only 2.6% (n=2) of the smear negative PTB patients were diagnosed correctly based on the NTG diagnostic criteria, also indicating a potential lack of adherence to the NTG.

In 58.0% (n=76) of PTB and 30.4% (n=31) of EPTB patients, the diagnoses were not made based on the NTG diagnostic recommendations. These findings imply that healthcare providers were not complying with the NTG during the diagnosis of PTB as shown in table 4.7.

Table 4.7 Correctly diagnosed TB patients as per the NTG diagnostic criteria (n=233)

<table>
<thead>
<tr>
<th>Type of TB</th>
<th>Correctly diagnosed TB patients as per the NTG diagnostic recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Number</td>
<td>%</td>
</tr>
<tr>
<td>PTB</td>
<td>55</td>
</tr>
<tr>
<td>EPTB</td>
<td>71</td>
</tr>
<tr>
<td>Total</td>
<td>126</td>
</tr>
</tbody>
</table>

This study also found that healthcare providers did not adhere to the NTG diagnostic algorithm during the diagnosis of smear positive and smear negative PTB patients. There were differences in healthcare providers’ levels of compliance with the NTG diagnostic criteria as shown in table 4.8. This could indicate the presence of over diagnosis of smear negative PTB patients in the study area which might result in increased risks of TB transmission due to the suboptimal detection of smear positive PTB patients.
Table 4.8 Correctly diagnosed PTB patients as per the NTG (n=131)

<table>
<thead>
<tr>
<th>Type of TB</th>
<th>Correctly diagnosed PTB patients as per the NTG diagnostic criteria</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
<td></td>
<td>Total</td>
</tr>
<tr>
<td></td>
<td>Number</td>
<td>%</td>
<td>Number</td>
<td>%</td>
</tr>
<tr>
<td>Smear positive</td>
<td>53</td>
<td>96.4</td>
<td>2</td>
<td>3.6</td>
</tr>
<tr>
<td>Smear negative</td>
<td>2</td>
<td>2.6</td>
<td>74</td>
<td>97.4</td>
</tr>
<tr>
<td>Total</td>
<td>55</td>
<td>42.0</td>
<td>76</td>
<td>58.0</td>
</tr>
</tbody>
</table>

As shown in figure 4.8, 58.0% (n=76) of PTB patients were diagnosed as smear negative PTB and of these only 2.6% (n=2) were correctly diagnosed according to the NTG diagnostic criteria.

The percentage of EPTB (43.8%, n=102) was higher than 38.5% of EPTB reported during 2007/2008 in Addis Ababa, possibly indicating lower levels of healthcare providers’ compliance with the NTG diagnostic criteria (MoH 2007/8:31). Smear negative PTB accounted for 58.0% (n=76) of all PTB cases. This indicates that the chance of TB transmission could be high in the study area because of suboptimal detection of smear positive PTB which might be attributed to the lower levels of healthcare providers’ compliance with the NTG and possibly also a poor quality of sputum microscopy.
As shown in figure 4.13, the percentages of patients diagnosed correctly according to the Ethiopian NTG diagnostic recommendations were smear positive PTB (96.4%, n=53), smear negative PTB (2.6%, n=2) and EPTB (69.6%, n=71). Healthcare providers declined to follow the NTG diagnostic recommendations during the diagnosis of smear negative PTB patients which might have contributed to the over diagnosis of smear negative PTB in the study area.

Figure 4.12 Types of diagnosed TB (n=233)

Figure 4.13 Proportions of correctly diagnosed TB patients (n=233)
The percentage of correctly diagnosed smear positive PTB, 96.4%, is higher than 92.6% and 78.6% of those reported in studies done in the Amhara and Tigray regions of Ethiopia (Aynie 2007:31; Mengiste et al 2005b:16) respectively. This might be attributed to different factors: the active participation of urban health extension workers in Addis Ababa who refer TB suspects to health facilities, the TB training of healthcare providers on TB case detection, and frequent follow-up supervisions by Addis Ababa regional health bureau and its TB partners working in the region.

The percentage of correctly diagnosed smear negative PTB of 2.6%, was lower than reported by studies conducted in the Amhara and Tigray regions which reported 23.2% and 3.0% (Aynie 2007:31; Mengiste et al 2005b:16) respectively. This could indicate lower levels of healthcare providers’ compliance with the NTG during the diagnosis of smear negative PTB.

As shown in table 4.1, smear positive PTB patients, diagnosed according to the NTG recommendations, represented 22.7% (n=53) of all forms of TB patients and 40.5% of PTB patients which is higher than 13.9% and 24.6% of the study conducted in the Tigray region (Mengiste et al 2005b:16). Patients with presumed sputum smear negative diagnosis accounted for 32.6% (n=76) of all TB patients and 58.0% (n=76) of PTB patients which is lower than 42.6% and 70.6% of a similar study in the Tigray region (Mengiste et al 2005b:16). The percentage of PTB is expected to be 85% (smear positive 75-80% and smear negative 20-25%) according to the NTG (MoH 2008a:18). In 2007/8, the proportion of smear positive and smear negative PTB constituted 37.8% and 62.2% of all PTB patients in Addis Ababa (MoH 2007/8:31). The increase in smear negative PTB diagnosis in Addis Ababa might be attributed to different factors including non-compliance of healthcare providers with NTG and poor quality of sputum microscopic examinations. Non-adherence of healthcare providers to the NTG when diagnosing smear negative PTB patients might have contributed to the over-diagnosis of smear negative PTB.

The percentages of correctly diagnosed EPTB (see table 4.1) constituted 69.6% (n=71) of all EPTB patients which is higher than 36.9% of a similar study conducted in the Amhara region, while no EPTB patients were diagnosed as per the NTG recommendation in the Tigray region (Aynie 2007:48; Mengiste et al 2005b:16). This difference might be attributed
to the availability of more advanced diagnostic facilities in Addis Ababa as compared to the Amhara and Tigray regions of Ethiopia.

Over diagnosis of smear negative PTB and EPTB in Ethiopia could be attributed to the lower levels of healthcare providers’ adherence to the NTG as indicated in this and other similar studies (Aynie 2007:48; Mengiste et al 2005b:16). Failing to adhere to the NTG diagnostic recommendations might result in the wastage of resources and also compromise the quality of services rendered to patients.

Of the 233 TB patients, only 54.1% (n=126) were diagnosed based on the NTG diagnostic criteria (see table 4.1) which is higher than 48.7% of the healthcare providers’ compliance levels reported for the Amhara region (Aynie 2007:32-33). However, the level of healthcare providers’ adherence in this study was lower than in a similar study conducted in Thailand that reported that 70.0% of TB patients’ diagnoses were made according to the NTG (Wilawan et al 2008:381). Failure to adhere to the NTG during the diagnosis of TB patients will increase the burden of TB in the country since there would be higher risks of TB transmissions, deterioration of TB patients’ clinical conditions and the spread of more MDR-TB cases (WHO 2006a:18).

4.3.5.2 Initial TB treatment

The prescription of anti-TB drug regimens were 100.0% (n=233) in compliance with the NTG treatment recommendations and all 233 TB patients were prescribed the correct regimens of anti-TB drugs. Adhering to the NTG treatment recommendations would minimise the chances of MDR-TB cases from developing (WHO 2008:3).

Of the 233 TB patients, 9.0% (n=21) were prescribed the incorrect number of pills and of these 71.4% (n=15) were prescribed anti-TB drug pills below the recommended dose as shown in table 4.9.

As indicated in table 4.9, the level of healthcare providers’ compliance with the NTG initial anti-TB prescriptions, 91.0% (n=212), was better than 57.1% but lower than 93.0% in studies done in Thailand and Malawi respectively (Harries et al 2004:726; Wilawan 2007:381). Mistakes in prescribing anti-TB pills were frequent in those TB patients whose
pre-treatment weight band ranged from 55 to 70kg where 22.6% (n=14) of these 62 patients had been prescribed incorrect numbers of anti-TB pills.

Table 4.9  Prescription of initial anti-TB pills by weight band (n=233)

<table>
<thead>
<tr>
<th>Weight band in kg</th>
<th>Number of TB patients prescribed incorrect numbers of anti-TB pills</th>
<th>number and % of TB patients prescribed correct numbers of anti-TB pills</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dose too high</td>
<td>Dose too low</td>
<td>Total</td>
</tr>
<tr>
<td>20-29</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>30-39</td>
<td>4</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>40-54</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>55-70</td>
<td>0</td>
<td>14</td>
<td>14</td>
</tr>
<tr>
<td>Over 70</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>6</td>
<td>15</td>
<td>21</td>
</tr>
</tbody>
</table>

Of the 21 TB patients who had been prescribed incorrect numbers of anti-TB pills, 28.6% (n=6) were over-prescribed and 71.4% (n=15) were under-prescribed which might lead to drug toxicity and treatment failure respectively. Healthcare providers should adhere to the NTG during treatment of TB patients in order to prevent and control the spread of MRD TB, and to enhance the TB patients’ chances of getting cured.

4.3.6  Evidence of TB patients’ diagnoses

This section will present and discuss evidence used to diagnose TB patients in the study area.

4.3.6.1  Number of visits required before TB was diagnosed

In this study, TB patients visited the health facility one to five times before they had been diagnosed with TB. Most patients (70.0%; n=163) visited the health facility twice before a final TB diagnosis had been made and 18.5% (n=43) visited the health facility three or more times before their diagnoses were confirmed (see figure 4.10).
Table 4.10  Frequency of health facility visits (n=233)

<table>
<thead>
<tr>
<th>Number of visits</th>
<th>Number of TB patients</th>
<th>Percentages</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>27</td>
<td>11.6</td>
</tr>
<tr>
<td>2</td>
<td>163</td>
<td>70.0</td>
</tr>
<tr>
<td>3</td>
<td>33</td>
<td>14.2</td>
</tr>
<tr>
<td>4</td>
<td>7</td>
<td>3.0</td>
</tr>
<tr>
<td>5</td>
<td>3</td>
<td>1.3</td>
</tr>
<tr>
<td>Total</td>
<td>233</td>
<td>100.1</td>
</tr>
</tbody>
</table>

4.3.6.2 Health services’ delays in diagnosing TB

The mean health service delay was 16.73 days from the date of the first visit till the diagnosis of TB had been made. The median health service delay was four days, but it ranged from 0 to 273 days.

The median health service delay in this study, 4 days, is lower than 9 days of a study done in the Tigray region (Mengiste et al 2005a:11). Delays in the diagnosis and treatment of TB might exacerbate TB-related morbidity and mortality, and also increase TB transmission rates to other members of the TB patients’ families and communities.

Table 4.11  Duration between first visit to a health facility and TB diagnosis (n=131)

<table>
<thead>
<tr>
<th>Number of days</th>
<th>Smear positive</th>
<th>Smear negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>%</td>
<td>Number</td>
</tr>
<tr>
<td>0-30</td>
<td>49</td>
<td>89.1</td>
<td>65</td>
</tr>
<tr>
<td>31-60</td>
<td>4</td>
<td>7.3</td>
<td>8</td>
</tr>
<tr>
<td>60-90</td>
<td>2</td>
<td>3.6</td>
<td>1</td>
</tr>
<tr>
<td>&gt;90</td>
<td>0</td>
<td>0.0</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>55</td>
<td>100.0</td>
<td>76</td>
</tr>
</tbody>
</table>

As indicated in table 4.11, 13.0% (n=17) out of 131 smear positive and smear negative PTB patients waited more than 31 days before their TB diagnoses had been confirmed by healthcare providers. There was a longer health service delay beyond 31 days in 76 smear negative PTB patients’ (14.4%; n=11) diagnosis than for the 55 smear positive PTB patients (10.9%, n=6).
4.3.6.3 Evidence of smear positive PTB diagnoses

Among patients who were diagnosed as smear positive PTB, 65.5% (n=36), 27.3% (n=15), 1.8% (n=1) and 1.8 (n=1) were diagnosed based on at least two initial sputum positive results, one or more repeat sputum positive result, one smear positive and one positive culture (see table 4.12).

Table 4.12 Diagnostic audit of new smear positive PTB cases (n=55)

<table>
<thead>
<tr>
<th>Type of diagnostic criteria</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correct diagnostic criteria:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients with at least 2 or more initial sputum positive</td>
<td>36</td>
<td>65.5</td>
</tr>
<tr>
<td>Patients with one or more repeat sputum positive after antibiotics trial</td>
<td>15</td>
<td>27.3</td>
</tr>
<tr>
<td>Patient with 1 smear and 1 culture positive</td>
<td>1</td>
<td>1.8</td>
</tr>
<tr>
<td>One sputum positive + chest X-ray finding</td>
<td>1</td>
<td>1.8</td>
</tr>
<tr>
<td>Incorrect diagnostic criteria/no evidence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Only one sputum positive</td>
<td>2</td>
<td>3.6</td>
</tr>
<tr>
<td>Total cases reviewed</td>
<td>55</td>
<td>100.0</td>
</tr>
</tbody>
</table>

The NTG of Ethiopia recommends that sputum smear examinations should be repeated if three sputum smear examinations were negative or only one sputum smear was positive before diagnosing PTB (MoH 2008a:170). However, in this study 3.6% (n=2) of the TB patients were classified as being smear positive PTB by only one sputum smear positive result which indicated non-adherence of healthcare providers to the NTG diagnostic criteria.

Out of the diagnoses of 55 smear positive PTB cases, based on at least two sputum smear positive results, were done correctly in 65.5% (n=36) of cases. This is lower than 92.6% and 78.6% of the study findings in the Amhara and Tigray regions respectively (Aynie 2007:48; Mengiste et al 2005b:15).

4.3.6.4 Evidence of smear negative PTB diagnoses

The diagnosis of 76 smear negative PTB patients were considered correct for only 2.6% (n=2) smear negative PTB patients based on the NTG diagnostic criteria (three initial sputum smear negative followed by a trial of broad spectrum antibiotics; and three repeat smear negative and chest x-ray findings consistent with active PTB).
Table 4.13 Criteria used for diagnosing new smear negative PTB patients (n=76)

<table>
<thead>
<tr>
<th>Type of diagnostic criteria</th>
<th>Number</th>
<th>Percentages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correct diagnostic criteria</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>All four diagnostic criteria used:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 initial sputum negative + no response to a trial of broad spectrum antibiotics + repeat sputum smear negative + radiological abnormalities consistent with active PTB</td>
<td>2</td>
<td>2.6</td>
</tr>
<tr>
<td>Incorrect diagnostic criteria/ no evidence</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Three of the four diagnostic criteria used:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 initial sputum negative + no response to a trial of broad spectrum antibiotics + radiological abnormalities consistent with active PTB</td>
<td>10</td>
<td>13.2</td>
</tr>
<tr>
<td>3 initial sputum negative + no response to a trial of broad spectrum antibiotics + repeat sputum negative</td>
<td>2</td>
<td>2.6</td>
</tr>
<tr>
<td><strong>Two of the four diagnostic criteria used:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 initial sputum negative + radiological abnormalities consistent with active PTB</td>
<td>21</td>
<td>27.6</td>
</tr>
<tr>
<td>No response to a trial of broad spectrum antibiotics + radiological abnormalities consistent with active PTB</td>
<td>11</td>
<td>14.5</td>
</tr>
<tr>
<td>3 initial sputum negative + no response to a trial of broad spectrum antibiotics</td>
<td>4</td>
<td>5.3</td>
</tr>
<tr>
<td><strong>One of the four diagnostic criteria used:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiological abnormalities consistent with active PTB only</td>
<td>19</td>
<td>25.0</td>
</tr>
<tr>
<td>3 initial sputum negative examinations</td>
<td>2</td>
<td>2.6</td>
</tr>
<tr>
<td><strong>No documented supportive evidence for the diagnosis</strong></td>
<td>5</td>
<td>6.6</td>
</tr>
<tr>
<td><strong>Total reviewed</strong></td>
<td>76</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Of the smear negative PTB patients, 25.0% (n=19) were diagnosed using only radiological evidence. This percentage was higher than 6.9% of the study done in Tigray region but lower than 41.4% of the study done in the Amhara region (Aynie 2007:32; Mengiste 2005b:15).

In 39.5% (n=30) of the 76 smear negative PTB patients, no sputum smear examinations were done. This might have resulted in miss-diagnoses of PTB patients because of the low specificity of clinical signs and radiological findings, particularly in high HIV burden countries like Ethiopia (MoH 2008a: 26).

4.3.6.5 Evidence of EPTB diagnoses

The NTG recommends the use of FNAs, strong clinical evidence consistent with active and worsening or no clinical response to trial of broad-spectrum antibiotics, as a diagnostic tool for the diagnosis of EPTB patients. Out of the 102 diagnosed EPTB patients, 61.8% (n=63)
were diagnosed based on FNA suggestive results, while 7.8% (n=8) were diagnosed based on strong clinical evidence consistent with active TB, and deterioration or no clinical response to trials of broad spectrum antibiotics.

Table 4.14  Diagnostic criteria used to diagnose new EPTB patients (n=102)

<table>
<thead>
<tr>
<th>Type of diagnostic criteria</th>
<th>Number</th>
<th>Percentages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correct diagnostic criteria used:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FNA suggestive of TB in organs other than the lungs</td>
<td>63</td>
<td>61.8</td>
</tr>
<tr>
<td>Strong clinical evidence consistent with active TB and worsening or no clinical response to</td>
<td>8</td>
<td>7.8</td>
</tr>
<tr>
<td>trial of broad-spectrum antibiotics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incorrect diagnostic criteria/ no evidence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Only strong clinical evidence consistent with active TB</td>
<td>4</td>
<td>3.9</td>
</tr>
<tr>
<td>Only worsening or no clinical response to trial of broad-spectrum antibiotics</td>
<td>5</td>
<td>4.9</td>
</tr>
<tr>
<td>Patient put on anti-TB drugs without trial of antibiotics</td>
<td>11</td>
<td>10.8</td>
</tr>
<tr>
<td>Put on anti-TB treatment without documented evidence of TB diagnosis</td>
<td>11</td>
<td>10.8</td>
</tr>
<tr>
<td>Total reviewed</td>
<td>102</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Out of the 102 EPTB patients, 52.9% (n=54) had glandular TB, 15.7% (n=16) had pleural TB and 9.8% (n=10) had peritoneal TB as shown in table 4.15. In 5.9% (n=6) of the EPTB patients the type of organ involved could not be identified from their medical records, indicating inaccurate record-keeping practices by some healthcare providers. Failure to indicate the organ affected on a patient's medical records, might necessitate further unnecessary tests to confirm the affected organ by any healthcare provider unfamiliar with the specific patients' condition.

Table 4.15  EPTB diagnoses (n=102)

<table>
<thead>
<tr>
<th>Body part involved</th>
<th>Number of TB patients</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glands</td>
<td>54</td>
<td>52.9</td>
</tr>
<tr>
<td>Pleura</td>
<td>16</td>
<td>15.7</td>
</tr>
<tr>
<td>Peritoneum</td>
<td>10</td>
<td>9.8</td>
</tr>
<tr>
<td>Organ unknown</td>
<td>6</td>
<td>5.9</td>
</tr>
<tr>
<td>Spine</td>
<td>5</td>
<td>4.9</td>
</tr>
<tr>
<td>Skin (subcutaneous)</td>
<td>2</td>
<td>2.0</td>
</tr>
<tr>
<td>Kidney</td>
<td>2</td>
<td>2.0</td>
</tr>
<tr>
<td>Breast</td>
<td>2</td>
<td>2.0</td>
</tr>
<tr>
<td>Joints (arthritis)</td>
<td>2</td>
<td>2.0</td>
</tr>
<tr>
<td>Testicles</td>
<td>1</td>
<td>1.0</td>
</tr>
<tr>
<td>Heart (endometrial)</td>
<td>1</td>
<td>1.0</td>
</tr>
<tr>
<td>Disseminated throughout body</td>
<td>1</td>
<td>1.0</td>
</tr>
<tr>
<td>Total</td>
<td>102</td>
<td>100.0</td>
</tr>
</tbody>
</table>
4.4 SUMMARY OF FINDINGS

Table 4.16 Summary of findings (n=233)

<table>
<thead>
<tr>
<th>Objectives</th>
<th>Activity</th>
<th>Indicator</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis of TB suspects compliance</td>
<td>To diagnose TB suspects based on the NTG</td>
<td>Proportion of patients where duration of illness recorded</td>
<td>Number: 212, %: 91.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Proportion of patients where physical examination findings recorded</td>
<td>124, 53.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Proportion of TB suspects with cough of more than 2 weeks’ duration ordered for sputum smear examination</td>
<td>122, 80.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Proportion of TB patients diagnosed correctly based on the NTG diagnostic recommendations</td>
<td>126, 54.1</td>
</tr>
<tr>
<td>Prescription of anti-TB drugs compliance</td>
<td>To prescribe anti-TB drugs based on NTG</td>
<td>Proportion of new TB patients who were prescribed the correct regimens</td>
<td>233, 100.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Proportion of new TB patients on appropriate types of drugs</td>
<td>233, 100.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Proportion of new TB patients on correct dosages of drugs (correct number of pills)</td>
<td>212, 91.0</td>
</tr>
</tbody>
</table>

This study identified lower levels of healthcare providers’ adherence (54.1%, n=126) to the NTG during the diagnosis of TB patients which could contribute to the over-diagnoses of smear negative PTB and EPTB. Healthcare providers complied with the NTG and prescribed the correct regimen and type of anti-TB drugs. However, 9.0% (n=21) of the 233 TB patients were prescribed the incorrect numbers of anti-TB pills which could result in increased transmission of TB and MDR TB which requires expensive and sophisticated treatments that can hardly be afforded by developing countries, like Ethiopia.

Chapter 5 presents the conclusions, limitations and recommendation of this study and will suggest possible areas for further study.
5.1 INTRODUCTION

The purpose of the study was to assess the level of healthcare providers' adherence to the NTG during diagnosis and initial treatment of TB patients. This knowledge could contribute to the existing knowledge about feasible and effective TB prevention and control strategies. Better adherence to the NTG might enable more TB patients to be diagnosed and treated effectively, reducing the risk of infecting other patients, and reducing the risk of spreading MDR TB.

The research question that initiated the undertaking of this study was: Are healthcare providers complying with the NTG during the diagnosis and treatment of TB in Addis Ababa, Ethiopia?

5.2 RESEARCH DESIGN AND METHODOLOGY

Ethiopia’s TB DOTS programme was piloted in the Arsi and Bale zones of Oromia region in 1992, and has subsequently been implemented throughout the country (MoH 2009a:3). Despite the expansion of Ethiopian health service coverage, the TB case detection rate is very low, 33.9%, in 2008 according to the Ethiopia’s MoH report (MoH 2007/8:33). The Ethiopian government has standardised NTG in place and persons could access TB diagnosis and treatment at public health facilities. Nevertheless the TB detection rate of Addis Ababa (68.3%) and TB cure rate (72.0%) remained below the WHO’s (2005) global target rates of 70.0% and 85.0% (MoH 2007/8:32; WHO 2006b:6) respectively.

The study population comprised TB patients who were diagnosed in one of the four participating public health facilities (two hospitals and two health centres). The study population included newly diagnosed TB patients aged 15 years and older, and who had
started anti-TB treatment at the four public health facilities that participated in this study. Based on these inclusion criteria, 233 medical records of TB patients were selected and audited, to identify to what extent healthcare providers adhered to the NTG.

Data were transcribed from each TB patient’s medical records using a specifically designed checklist. The TB patients’ medical records were reviewed for information on symptoms suggesting TB, physical examinations undertaken and findings, laboratory/x-ray requests and their results, treatments with broad spectrum antibiotics, previous history of TB, age, sex, and weight of the patient, the types and dosages of drugs prescribed. Based on the documented clinical, physical, and laboratory evidence, the diagnosis of each patient was compared with the diagnostic criteria specified by the NTG of Ethiopia.

5.3 RESEARCH RESULTS

Out of the 233 TB patients, 65.2% (n=152) were diagnosed at hospitals and 34.8% (n=81) at health centres. The level of healthcare providers adherence to the NTG during the diagnosis of TB was 51.3% (n=78) at hospitals and 59.3% (n=48) at health centres. The overall, healthcare providers compliance with the NTG during the diagnoses of TB was 54.1% (n=126) as indicated in table 4.1.

Of the 233 TB patients, 52.8% (n=123) were males and 47.2% (n=110) were females. Out of the 110 female TB patients, 60.9% (n=67) were diagnosed correctly according to the NTG diagnostic recommendations while 56.1% (n=69) of the 123 male TB patients were diagnosed correctly in compliance with the NTG diagnostic criteria (see figure 4.1).

The percentages of TB patients who had been prescribed the correct numbers of initial anti-TB pills were 91.8% (n=101) for females and 90.2% (n=111) for males. The level of healthcare providers’ adherence to the NTG during the initial anti-TB pills prescription was 91.0% (n=212). Of the 233 TB patients, 9.0% (n=21) were prescribed the incorrect number of anti-TB pills and of these 51.7% (n=12) were males and 42.9% (n=9) were females.

As discussed in section 4.3.3, only 91.0% (n=212) of TB patients’ presenting complaints were recorded. The five most common complaints of TB patients were coughs (71.2%, n=151), chest pains (30.2%, n=64), night sweats (29.2%, n=62), fever (27.4%, n=58) and
loss of appetite (23.1%, n=49). Of those who complained of coughing, the duration of cough was recorded in 80.8% (n=122) of cases. Of the 233 TB patients, the physical examination findings were recorded only in 53.2% (n=124) of the patients.

Out of the 151 TB patients who were complaining of cough, the duration of illness was recorded in 80.8% (n=122) of the cases and of these 122 patients 85.2% (n=104) had coughed for more than two weeks.

Of the 233 TB patients, physical examination findings were recorded only in 53.2% (n=124) of the cases. Out of the 151 TB patients who complained of coughing, physical examination findings were recorded in 55.6% (n=84) of the cases and in 73.8% (n=62) of these 84 patients, chest findings were the most frequently recorded findings in patients medical records as indicated figure 4.6.

Out of the 104 TB patients who coughed for more than two weeks, sputum smear examinations were done in 80.8% (n=84) of these TB patients. The sputum smear positivity was 48.8% (n=41) for two or more slides. Of the 131 PTB patients, 62.6% (n=82) had chest x-rays done and TB was suspected in 89.0% (n=73) of these cases. Out of the 44 TB patients who had complained about enlarged lymph nodes, 95.5% (n=42) underwent FNAs and these examinations’ results suggested TB in 88.1% (n=37) of these cases.

As presented in section 4.3.5, healthcare providers diagnosed smear positive PTB (23.6%, n=55), smear negative PTB (32.6%, n=76) and EPTB (43.8%, n=102) patients in the study facilities. The percentages of correctly diagnosed TB patients complying with the NTG diagnosis criteria, were 96.4% (n=53), 2.6% (n=2) and 69.6% (n=71) of smear positive PTB; smear negative PTB and EPTB respectively. The diagnosis of PTB and EPTB was not made based on the NTG diagnostic recommendations. This study also identified low levels of healthcare providers’ adherence to the NTG during the diagnosis of smear negative PTB patients and only 2.6% (n=2) of the 76 smear negative PTB patients were diagnosed correctly in compliance with the NTG diagnostic recommendations.

All TB patients (100%; n=233) had been prescribed the correct anti-TB regimens. However, only 91.0% (n=212) of these TB patients were prescribed the correct number of
anti-TB pills according to the NTG initial treatment recommendations. Healthcare providers did not adhere to the NTG during their initial anti-TB tablets’ prescriptions for 9.0% (n=21) of the TB patients. Out of these 21 patients, 81.0% (n=17) had been prescribed doses exceeding the NTG and 19.0% (n=4) were under-prescribed doses of anti-TB pills.

As stated in section 4.3.6, 65.5% (n=36) of the smear positive PTB patients were diagnosed based on at least two initial sputum smear positive results and 27.3% (n=15) were diagnosed with one or more repeat sputum smear positive after antibiotics trial. Two PTB patients were incorrectly diagnosed as smear positive PTB by healthcare providers with single sputum smear positive result. Only 2.6% (n=2) smear negative PTB patients were diagnosed correctly with the four NTG diagnostic criteria (3 initial sputum negative + no response to a trial of broad spectrum antibiotics + repeat sputum smear negative + radiological abnormalities consistent with active PTB). As many as 25.0% (n=19) of the TB patients had been diagnosed incorrectly as smear negative PTB by chest x-ray findings only. In addition, 6.6% (n=5) of TB patients were diagnosed as smear negative PTB without documented evidence of diagnosis. Nearly 10.8% (n=11) of TB patients were diagnosed as EPTB patients and were put on anti-TB treatment as EPTB patients without documented evidence of this diagnosis.

The three most commonly affected extra pulmonary sites were glands (52.9%, n=54), pleura (15.7%, n=16) and peritoneum (9.8%, n=10). In 5.9% (n=6) of EPTB patients, the type of organ involved could not be identified from their medical records, indicating inaccurate record-keeping practices by some healthcare providers.

5.4 LIMITATIONS OF THE STUDY

The limitations that were identified during the study included that:

- The study was done in only four public health facilities out of the 28 public health facilities treating TB patients based on the DOTS programme (26 health centres and 2 hospitals) and TB patients seen in other facilities might have had different characteristics
- Only medical records were reviewed, and the assumption was that procedures recorded reflected procedures implemented. No observations were done of
healthcare professionals who were actually treating patients to confirm or refute this assumption.

- Based on the medical records’ information it proved difficult to identify which professional categories of staff members adhered to the NTG diagnostic criteria during the diagnosis and treatment of TB, and which categories failed to do so.
- Some medical records were not found either due to misplacement or loss and might have influenced the outcomes.
- No healthcare providers were interviewed to identify factors that might have influenced their non-adherence to the NTG during TB diagnosis and treatment of TB patients.

5.5 RECOMMENDATIONS

Based on the research findings, some recommendations are suggested for enhancing healthcare practices and for conducting further research.

5.5.1 Practice

Ethiopia’s FMoH and Addis Ababa’s regional health bureau should consider

- Identifying strategies that could enhance healthcare providers’ adherence levels to the NTG in order to improve the quality of TB diagnosis and treatment.
- Improving the information management system so that healthcare providers would record patients’ presenting complaints and their physical examinations’ findings on the patients’ medical records. Such records would aid healthcare providers to decide on the type of TB. These records are also legal documents and sources of health statistics and should reflect accurate information.
- Emphasising the importance of adhering to the NTG during TB diagnosis and treatment in both the basic and refresher in-service training sessions of healthcare providers working in the diagnostic and DOTS units.
- Conducting integrated supportive supervision for healthcare facilities in order to identify and address shortcomings.
Healthcare facilities should

- Establish proper record tracing mechanisms in order to prevent or minimise loss of medical records
- Discuss the importance of compliance with the NTG diagnostic and treatment recommendations during self assessment meetings

5.5.2 Recommendations for further research

The following topics could be addressed by future research projects

- Factors affecting healthcare providers' adherence to the NTG during TB diagnosis and treatment
- Factors influencing the diagnosis and treatment of TB
- Factors contributing to over diagnosis of smear negative PTB and EPTB
- Assess healthcare providers' knowledge of TB diagnosis and treatment

5.6 CONCLUDING REMAKRS

The data, obtained from the completed checklists, were analysed and discussed, with respect to research reports, wherever possible. The results indicated that healthcare providers' overall adherence to the NTG during the diagnosis of TB patients was 54.1% (n=126), as reflected in table 4.1.

Compliance of healthcare providers with the NTG during the diagnosis of TB was 60.9% (n=67) for female and 56.1% (n=69) for male TB patients. However, 91.8% (n=101) female and 90.2% (n=111) male TB patients had been prescribed the correct numbers of anti-TB pills in compliance with the NTG's treatment recommendations. The percentages of smear positive PTB (96.4%; n=53), smear negative PTB (2.6%; n=2) and EPTB (69.6%; n=71) patients were diagnosed in compliance with the NTG diagnosis recommendations.

This study also revealed the possible over-diagnosis of smear negative PTB in the participating healthcare facilities. Healthcare providers were not adhering to the NTG diagnostic recommendations during the diagnosis of smear negative PTB. Only 4.0% (n=2) of the 50 smear negative PTB patients had been diagnosed correctly based on the NTG diagnostic criteria at hospitals while none (0.0%, n=0) of the 26 smear negative PTB
patients were diagnosed correctly in compliance with the NTG diagnostic recommendations at health centres (see table 4.1).

Correct anti-TB drug regimens were prescribed for all TB patients, 100.0% (n=233), and 91.0% of TB patients were prescribed the correct number of anti-TB drug pills. The study’s findings indicated relatively higher levels of healthcare providers adherence to the NTG during the initial treatment of TB patients (91.0%; n=212) than during TB diagnoses (54.1%; n=216). The study also indicated that 9.0% (n=21) of the TB patients had been prescribed incorrect numbers of anti-TB pills and 81.0% (n=17) had been prescribed fewer anti-TB pills than the NTG recommendations.

This study indicated that non-adherence to the NTG during the diagnosis and initial anti-TB pills prescription is a problem in the study healthcare facilities. This necessitates an action to enhance healthcare providers’ compliance with the NTG during the diagnosis and the initial treatment of TB. Factors affecting healthcare providers’ compliance with the NTG during the diagnosis and the initial treatment of TB need to be identified in order to seek strategies that improve healthcare providers’ adherence to the NTG diagnostic and treatment recommendations which could improve the quality of TB diagnoses and treatment of TB patients.

Unless TB is diagnosed and treated correctly according to the NTG’s recommendations, Ethiopia might not succeed in providing effective TB treatment to its patients. Unless TB is diagnosed and treated early, the TB patient could infect or re-infect many other people. If too many anti-TB pills are prescribed, TB patients might suffer from side-effects and discontinue the treatment. If too few pills are prescribed the treatment will not cure the patient’s TB. In both cases the patient might continue to suffer from TB, develop resistance to TB treatment and infect others with MDR TB. A MDR TB epidemic could result in high mortalities and exorbitant healthcare expenditures. The healthcare providers’ adherence to the NTG recommendations, should be enhanced and sustained to prevent TB patients from developing and spreading MDR TB. Regular audits of TB patients’ medical records and feedback given during in-service education sessions, could contribute towards enhancing the effectiveness of anti-TB treatment in Ethiopia.
LIST OF REFERENCES:


### Annexure A: Matrix of judgment for health care providers' compliance to the Ethiopian NTG during the diagnosis and treatment of TB

<table>
<thead>
<tr>
<th>Objective</th>
<th>Activity</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis of TB suspects compliance</td>
<td>To diagnose TB suspects based on the NTG</td>
<td>Proportion of patients where duration of illness recorded</td>
</tr>
<tr>
<td></td>
<td>To classify TB patients based on the NTG</td>
<td>Proportion of patients where physical examination findings recorded</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Proportion of TB suspects with cough of more than 2 weeks ordered for sputum smear examination</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Proportion of PTB suspects who were sputum smear positive</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Proportion of new smear positive PTB, smear negative PTB, and EPTB patients diagnosed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Proportion of new smear positive PTB, smear negative PTB, and EPTB patients from those who were diagnosed correctly</td>
</tr>
</tbody>
</table>

Prescription of anti-TB drugs compliance

<table>
<thead>
<tr>
<th>Activity</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>To prescribe anti-TB drugs based on NTG</td>
<td>Proportion of new TB patients who were prescribed the correct regimen</td>
</tr>
<tr>
<td></td>
<td>Proportion of new TB patients on appropriate types of drugs</td>
</tr>
<tr>
<td></td>
<td>Proportion of new TB patients on correct dosage of drugs</td>
</tr>
</tbody>
</table>
Annexure B: Anti-TB drug regimen, dose and major side effects

Annexure B.1: Anti-TB drug regimen and dosages for TB patients under category I and III

<table>
<thead>
<tr>
<th>Weight band</th>
<th>Initial phase (two months)</th>
<th>Continuation phase (6 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2 (HREZ)</td>
<td>6 (EH) daily</td>
</tr>
<tr>
<td>Anti-TB drug combinations:</td>
<td></td>
<td>Drug combinations:</td>
</tr>
<tr>
<td>2</td>
<td>75 mg of H + 150 mg of R + 400 mg of Z + 275 mg of E</td>
<td>150 mg of H + 400 mg of E</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of tablets to be taken each day</th>
</tr>
</thead>
<tbody>
<tr>
<td>20-29 kg</td>
</tr>
<tr>
<td>30-39 Kg</td>
</tr>
<tr>
<td>40-54 Kg</td>
</tr>
<tr>
<td>55-70 Kg</td>
</tr>
<tr>
<td>Over 70 Kg</td>
</tr>
</tbody>
</table>

(MoH NTG 2008a:36)

Annexure B.2: Major side effects of anti-TB drugs

<table>
<thead>
<tr>
<th>Anti-TB drugs</th>
<th>Major side effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoniazid (H)</td>
<td>Peripheral neuropathy, psychosis, convolution, pruritus/itching of the skin</td>
</tr>
<tr>
<td>Rifampicin (R)</td>
<td>Hepatitis, pruritus/itching reaction to the skin and gastro-intestinal disturbances like abdominal pain, nausea and vomiting,</td>
</tr>
<tr>
<td>Pyrazinamide (Z)</td>
<td>Arthralgia (joint pain) and hyperuricemia</td>
</tr>
<tr>
<td>Ethambutol (E)</td>
<td>Visual disturbance (visual impairment), Ocular toxicity, peripheral neuritis,</td>
</tr>
<tr>
<td>Streptomycin (S)</td>
<td>Hearing impairment, disturbed balance, numbness, tingling, pruritus/itching of the skin</td>
</tr>
</tbody>
</table>

(MoH NTG 2008a:39; WHO 2004:32-33)
Proposed title: Adherence by health care providers to Ethiopia’s National Tuberculosis Guidelines

Principal investigator: Mr GS Aragaw (student no. 4205-680-2) Degree: Master of Public Health

Reviewed and processed as: Class approval (see paragraph 10.7 of the UNISA Guidelines for Ethics Review)

Approval status recommended by reviewers: Approved

The Ethics Subcommittee of the College of Human Sciences has reviewed your proposal and considers the methodological, technical and ethical aspects of the proposal to be appropriate to the tasks proposed. Approval is hereby granted for the candidate to proceed with the study in strict accordance with the approved proposal and the ethics policy of the University of South Africa.

In addition, the candidate should heed the following guidelines:
- To only start this research study after obtaining informed consent from the research participants.
- To carry out the research according to good research practice and in an ethically sound manner.
- To maintain the confidentiality of all data collected from or about research participants, and maintain security procedures for the protection of privacy.
- To work in close collaboration with your supervisor(s) and to record the way in which the ethical guidelines as suggested in your proposal has been implemented in your research.
- To notify the Ethics Subcommittee in writing immediately if any change to the study is proposed and await approval before proceeding with the proposed change.
- To notify the Ethics Subcommittee in writing immediately if any adverse event occurs.

Approvals are valid for ONE academic year after which a request for a continuation of the approval must be submitted to your supervisor(s).

Kind regards

Prof Li Zungu
Chair: Ethics Subcommittee: College of Human Sciences
To: Addis Ababa regional health bureau  
       P.o. Box 30738  
       Addis Ababa

September 28, 2010

Subject: request for permission to carry out a research for academic purposes

Dear Sir /Madam

I am a fourth year MPH student from University of South Africa (UNISA). As mentioned above I want to carry out a research for academic purposes on "adherence by health care providers to Ethiopia’s national TB guidelines in Addis Ababa" in 4 public health facilities (in two hospitals namely Ras Desta Damtew and Yekatit 12 hospitals, and two health centres namely Shiromeda and Woreda 7).

The objectives of my study are to:

- assess health care providers’ adherence to the NTG during diagnosis of TB in Addis Ababa, Ethiopia
- assess health care providers’ adherence to the NTG during initial treatment of TB in Addis Ababa, Ethiopia

When I completed my study, I will submit the result to the region for subsequent use of the study findings for it may help to improve tuberculosis case detection in the region. I have annexed my research instrument and Amharic institutional consent form along with the proposal for further review. I kindly request your esteemed organization to allow me to conduct this research as part of my academic requirements.

Yours sincerely,

Mr Aragaw G S
To Shiromeda Health Center  
Woreda 7 Health Center  
Yekatit 12 Hospital  
Ras Desata Hospital  
Addis Ababa

Subject: A request to allow research at health facilities

This letter is to support Getahun Sisay to conduct his research, which is titled as "Adherence by health care providers to Ethiopia's National Tuberculosis Guidelines".

Study proposal was duly reviewed and approved by Ethical clearance committee of Addis Ababa Health bureau, the Principal investigator is informed with a copy of this letter to report any changes in the study procedures and submit an activity progress report to the Ethical committee as required.

Therefore we request the Health facilities to provide all related support to the principal investigators.

With Regard

[Signature]

Alemu H/Mariam
Head, Ethical Clearance Committee

Cc:-

To

UNISA
Getahun Sisay
Addis Ababa
Ethical clearance committee
Health Bureau
Annexure F: Checklist on health care providers’ compliance to Ethiopia’s NTG

Objective: to assess health care providers’ compliance to the Ethiopian national tuberculosis guideline during the diagnosis and treatment of TB in Addis Ababa, Ethiopia.

i. General information

- Name of sub city____________________ Name of health facility ______________
- Type of health facility 1. Hospital 2. Health centre
- Patient’s MRN________________   Unit TB number____________
- Date of data collection_______/______/________
- Name of data collector
  1. ___________________________ signature ______________

ii. Personal and socio-demographic characteristics

<table>
<thead>
<tr>
<th>S .n</th>
<th>Variable</th>
<th>Findings</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Sex</td>
<td>1. Male  2. Female</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Age</td>
<td>______year</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Weight</td>
<td>________kg</td>
<td></td>
</tr>
</tbody>
</table>

iii. History and physical examination

<table>
<thead>
<tr>
<th>S.n</th>
<th>History</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Persistent cough of more than 2 weeks</td>
<td>1. Yes 2. No</td>
</tr>
<tr>
<td>6</td>
<td>Fever</td>
<td>1. Yes 2. No</td>
</tr>
<tr>
<td>7</td>
<td>Night sweats</td>
<td>1. Yes 2. No</td>
</tr>
<tr>
<td>8</td>
<td>Shortness of breath</td>
<td>1. Yes 2. No</td>
</tr>
<tr>
<td>9</td>
<td>Chest pain</td>
<td>1. Yes 2. No</td>
</tr>
<tr>
<td>10</td>
<td>Weight loss</td>
<td>1. Yes 2. No</td>
</tr>
<tr>
<td>11</td>
<td>Tiredness</td>
<td>1. Yes 2. No</td>
</tr>
<tr>
<td>12</td>
<td>Haemoptysis</td>
<td>1. Yes 2. No</td>
</tr>
<tr>
<td>S.No</td>
<td>Variable</td>
<td>Response</td>
</tr>
<tr>
<td>------</td>
<td>--------------------------------------------------------------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>13</td>
<td>Enlargement of lymph node/s</td>
<td>1. Yes   2. No</td>
</tr>
<tr>
<td>14</td>
<td>Previous history of tuberculosis</td>
<td>1. Yes   2. No</td>
</tr>
<tr>
<td>15</td>
<td>Duration of illness for at least cough recorded</td>
<td>1. Yes   2. No</td>
</tr>
<tr>
<td>16</td>
<td>Write the date when the patient presented for the 1st time to the health facility</td>
<td>1. Yes   2. No</td>
</tr>
<tr>
<td>17</td>
<td>Physical examination done</td>
<td>1. Yes   2. No</td>
</tr>
<tr>
<td>18</td>
<td>If yes to question 13, - matted</td>
<td>1. Yes   2. No</td>
</tr>
<tr>
<td>19</td>
<td>- Discharging pus</td>
<td>1. Yes   2. No</td>
</tr>
<tr>
<td>20</td>
<td>Chest finding present</td>
<td>1. Yes   2. No</td>
</tr>
<tr>
<td>21</td>
<td>Mass or fluid in the abdominal cavity</td>
<td>1. Yes   2. No</td>
</tr>
<tr>
<td>22</td>
<td>Localised bone swelling without discharge of pus</td>
<td>1. Yes   2. No</td>
</tr>
<tr>
<td>23</td>
<td>Localised bone swelling with discharge of pus</td>
<td>1. Yes   2. No</td>
</tr>
<tr>
<td>24</td>
<td>Paralysis of extremities</td>
<td>1. Yes   2. No</td>
</tr>
</tbody>
</table>

iv. Laboratory investigation

<table>
<thead>
<tr>
<th>S.no</th>
<th>Variable</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>Sputum smear examination ordered</td>
<td>1. Yes   2. No</td>
</tr>
<tr>
<td>26</td>
<td>If yes to question 25, is the result registered</td>
<td>1. Yes   2. No</td>
</tr>
<tr>
<td>27</td>
<td>If yes to question 26, what is the result</td>
<td>1. Positive 2. Negative</td>
</tr>
<tr>
<td>28</td>
<td>If positive to question 27, how many slides</td>
<td>1. 1            2. ≥2</td>
</tr>
<tr>
<td>29</td>
<td>Culture ordered</td>
<td>1. Yes   2. No</td>
</tr>
<tr>
<td>30</td>
<td>If yes to question 29, is result registered</td>
<td>1. Yes   2. No</td>
</tr>
<tr>
<td>31</td>
<td>If yes to question 30, what is the result</td>
<td>1. Positive 2. Negative</td>
</tr>
<tr>
<td>32</td>
<td>Chest examination ordered</td>
<td>1. Yes   2. No</td>
</tr>
<tr>
<td>33</td>
<td>If yes to question 32, is the result registered</td>
<td>1. Yes   2. No</td>
</tr>
<tr>
<td>34</td>
<td>Chest x-ray result reading suggestive of tuberculosis</td>
<td>1. Yes   2. No</td>
</tr>
<tr>
<td>35</td>
<td>Fine-needle aspiration (FNA) ordered</td>
<td>1. Yes   2. No</td>
</tr>
<tr>
<td>36</td>
<td>If yes to question 35, is the result registered</td>
<td>1. Yes   2. No</td>
</tr>
<tr>
<td>37</td>
<td>If yes to question 36, is FNA suggestive of tuberculosis</td>
<td>1. Yes   2. No</td>
</tr>
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</table>
v. Final classification and treatment of patients

<table>
<thead>
<tr>
<th>S.no</th>
<th>Variable</th>
<th>Source of data</th>
</tr>
</thead>
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<tr>
<td></td>
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<td>Patient chart</td>
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<td>Register</td>
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<tr>
<td>38</td>
<td>Disease classification</td>
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</tr>
<tr>
<td></td>
<td>Pulmonary tuberculosis</td>
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</tr>
<tr>
<td></td>
<td>Extra pulmonary tuberculosis</td>
<td></td>
</tr>
<tr>
<td>39</td>
<td>Type of patient if pulmonary tuberculosis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>New smear positive</td>
<td></td>
</tr>
<tr>
<td></td>
<td>New Smear negative</td>
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</tr>
<tr>
<td></td>
<td>Failure</td>
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</tr>
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<td>Return after default</td>
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<tr>
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<td>Relapse</td>
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<td>Category II</td>
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<td>Category III</td>
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</tr>
<tr>
<td></td>
<td>Category IV</td>
<td></td>
</tr>
<tr>
<td>41</td>
<td>Anti-TB drugs prescribed</td>
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<tr>
<td></td>
<td>Drugs ordered with duration – intensive phase</td>
<td></td>
</tr>
<tr>
<td></td>
<td>drugs ___________________ duration _____ months</td>
<td></td>
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<td>- Continuation phase</td>
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<td>Drugs ___________________ duration _____ months</td>
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<td></td>
<td>Correct drug types (to be filled by the researcher)</td>
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<tr>
<td></td>
<td>Appropriate dosage (to be filled by the researcher)</td>
<td></td>
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<tr>
<td></td>
<td>Appropriate duration (to be filled by the researcher)</td>
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</tbody>
</table>

vi. Evidence for classification and treatment of TB patients

A. How many times did the patient present to the health facility before he got diagnosed for TB? ___________ times
B. Write the date when the patient was finally diagnosed to suffer from TB

\[
\text{_______/_______/___________}
\]

C. If the answer to question 39 is smear positive PTB, What were the investigations and procedures undertaken to reach smear positive PTB diagnosis?

1. Patients with at least 2 initial sputum positive
2. Patient with at least 1 initial and 1 repeat sputum smear positive
3. Patient with a trial of antibiotics treatment only
4. Patient with no documented sputum smears result
5. Patient treated with chest x-ray findings only
6. Patient with 1 smear and 1 culture positive

D. If the answer to question 39 is smear negative PTB, What were the investigations and procedures used to reach smear negative PTB diagnosis?

1. Patient with 3 initial sputum negative examinations
2. No response to a trial of broad spectrum antibiotics
3. Repeat examination of sputum for AFB negative
4. Radiological abnormalities consistent with active PTB only
5. Clinicians’ decision to treat with a full course of anti-TB
6. Culture positive

E. If the answer to question 38 is EPTB, What were the investigations and procedures undertaken to reach EPTB diagnosis?

1. Strong clinical evidence consistent with active TB
2. TB in organs other than the lungs proved by one positive culture
   2.1 List the organ affected __________________________________________
3. TB in organs other than the lungs proved by biopsy
   3.1 List the organ affected _________________________________________
4. Worsening or no clinical response to trial of antibiotics
5. Patient put on anti-TB drugs without trial of antibiotics
Subject: Statistician support letter

This is to notify that I have provided statistical analysis assistance to Mr. Getahun Sisay Aragaw for his dissertation of limited scope titled adherence by healthcare providers to Ethiopia’s national tuberculosis guidelines as part of the fulfillment of his MPH degree. I am a statistician with an extensive experience of undertaking both descriptive and inferential statistical analysis.

Name: Gadissa Lemecha, BSC, MSc

Date: March 31, 2011

Signature: [Signature]