MAGNITUDE AND ASSOCIATED FACTORS WITH UNFAVORABLE TREATMENT OUTCOMES OF TUBERCULOSIS PATIENTS UNDER DIRECTLY OBSERVED TREATMRNT SHORT COURSE IN DEBREBERHAN REFERRAL HOSPITAL, NORTH SHOA ZONE, ETHIOPIA 2014

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Abstract

Background: Tuberculosis is the leading cause of mortality among infectious disease worldwide. Despite many efforts to put TB under control, even now the disease remains to be a major public health problem. For effective prevention and control of tuberculosis it is a pre requisite to detect the cases as early as possible and to ensure that the tuberculosis patients are completes their treatment and get cured. Assessing treatment outcome and associated factors with unfavorable treatment outcomes of tuberculosis patients enrolled in DOTs helps to find the gaps of the service delivered in DOTs program and improve services for better favorable treatment outcome, to reduce recurrence of tuberculosis, development of multi-drug resistance and extensive drug resistance form of tuberculosis

Objective: *To determine magnitude and associated factors with Treatment outcome of Tuberculosis patients under DOTs in Debre Berhan Referral Hospital, North Shoa Zone, Ethiopia*

Methods: *A cross sectional study covering the period of January 2009 to December 2013 was employed. After the completion of data collection; editing, coding and cleaning was carried out. Data were entered using EPi-info version 3.2.2 and was exported into SPSS version 16.0 statistical software and analysis was performed. Bivariate logistic regression analysis was used to see significance of association between unfavorable treatment outcome and independent variables. All explanatory variables that were associated with the outcome variable and those with p-value < 0.25 in binary logistic regression analysis were included in multiple logistic regression analysis. P-value <0.05 was considered as a statistical significant.*

Result: *Records of 1280 registered tuberculosis patients (n=649 males and 631 =females) were included in this study. Of these patients 15.95% were documented as being cured, 63.5 % as treatment completed, 1.8% dead during follow up, 0.3% treatment failure, 8.0% were reported as defaulter, and 10.5% were transferred out to another health facility. Patient's residence, types of TB and follow –up sputum smear microscopic examination at 2nd months of treatment were significantly associated with unfavorable treatment outcomes.*

Conclusion and recommendation: *The unfavorable treatment outcomes of tuberculosis patients were high (20.6%). A high proportion of TB patients were defaulted (8.0%) and transfer out (10.5%) which is a serious public health problem that needs to be addressed urgently. Being rural dwellers were 1.4 times more likely to experience unfavorable treatment outcome than urban dwellers, being pulmonary TB negative and extra-pulmonary type were 70.5% and 72% less risky for unfavorable Treatment outcomes, respectively than Pulmonary TB positive type and having negative sputum smear result at second month of treatment had a 90% reduction in experiencing unfavorable treatment outcome when compared to sputum smear result positive during that follow up period. Continuous strong supportive supervision, defaulter tracing, health education about TB and its treatment and the necessities of follow up sputum examinations are strongly recommended.*

Key words: *TB patients, Treatment out comes: Magnitude and associated factors*

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Acronyms and Abbreviations

AFB Acid Fast Bacilli

AIDS Acquired Immunodeficiency Syndrome

ART Anti retroviral therapy

ARTI Annual Risk of TB infection

BCG Bacille-Calmette-Guerin

BSc Bachelor of Science Curriculum

CWHs Community Health Workers

CDR case detection rate

CPT Co-trimexazole preventive therapy

Dx Diagnosis

DOTs Direct observed Treatment short course

EHNRI Ethiopian Health and Nutrition Research Institute

EPTB Extra pulmonary tuberculosis

EQA External Quality Assessment

EH Ethambutol and Isoniazid combined drug

FEFO First expired first out

FMOH Federal Ministry of Health

FIFO First in first out

HF Health Facility

HO Health officer

HIV Human Immunodeficiency Virus

IPLS Integrated pharmaceutical and logistic system

IUATLD International Union against Tuberculosis and Lung Disease

MD Medical Doctor

MDR TB -Multi Drug Resistance Tuberculosis Control Program

NPLCP National TB and Leprosy

NTP National Tuberculosis Program

OPD Outpatient Department

PITC Provider initiated HIV testing and counseling

PLWHA People living with HIV/AIDS

PTB Pulmonary tuberculosis

PTB^{+} Pulmonary tuberculosis positive

PTB^{-} Pulmonary tuberculosis Negative

RH Rifampicin and Isoniazid combined drug

RNTCP Revised National Tuberculosis Control programme

Rx Treatment

SNNPRS Southern Nations Nationalities and Peoples Regional state

SPSS Statistical Package for Social Sciences

STM Streptomycin

TB Tuberculosis

TSR Treatment success rate

TLCP Tuberculosis and Leprosy Control Programme

UNICEF United Nation International Children Fund

USAID United States Agency for International Development

WHO World Health Organization

XDR TB Extensively drug-resistant tuberculosis

Chapter One

Introduction

1.1 Background

Tuberculosis is a chronic infectious disease caused by mycobacterium tuberculosis, an acid-fast bacillus. Though it affects peoples of all ages and sexes, poverty, malnutrition, overcrowding and more recently HIV/AIDS have been known for decades to make some groups more vulnerable to develop the Disease[1]. The target set within the context of the millennium Development Goal (MDGs) is to halt and reverse the incidence of TB by 2015[2, 3]. Despite the availability of highly efficacious treatment for decades, TB remains a major global health problem. In 1993, the World Health Organization (WHO) declared TB a global public health emergency, at a time when an estimated 7–8 million cases and 1.3–1.6 million deaths occurred each year[4]. According to the WHO Global TB Report 2012, there were an estimated 8.7 million incident cases and 12 million prevalent cases of TB globally, in 2011, of which 1.1 million (13%) were among people living with HIV. About 26% of the incident TB cases occurred in Africa in 2011. The proportion of TB cases co-infected with HIV is highest in countries in the African region; overall, the African region accounted for 79% of TB cases among people living with HIV[5, 6].

Tuberculosis (TB) is still amongst the most important causes of human morbidity and mortality, killing approximately two million people each year. Tuberculosis is a serious obstacle to sustainable national development[7]

Developing countries, where 95% of all new TB cases and 99% of deaths occur, are the hardest hit[8]. The Arising global TB burden is attributed to high transmission rates, inadequate sanitation, poor control of TB infections, widespread malnutrition exacerbated by poverty and a high incidence of TB/HIV co-infection rates in high prevalence settings. Arguably lack of adequate education and knowledge in the community on TB is also a key factor in the rising global TB burden[9].Of the six WHO regions, five have TB incidence that is falling or stable, but Africa has an incidence that keeps increasing at almost 10% per year, offsetting the gains in the rest of the world[10].Nine of the twenty-two high TB disease burden countries in the world are found in Africa. Even though the region contributes only about 24% of the global TB burden, it has the highest TB disease burden per capita[11]

Ethiopia is one of the top sixteen countries in the world, and one of the top three in Africa, with regard to the number of tuberculosis (TB) patients. Over a third of the population has been exposed to TB. TB is the leading cause of morbidity, the third cause of hospital admission and the second cause of death in Ethiopia [12].The Annual Risk of TB Infection (ARTI) is 2.2%. An estimated 377,030 Ethiopians (0.62% of the

population) have active TB of all forms, with more than 120,000 new cases in 2003/04, nearly a third of which having smear-positive TB[13].

DOTS remain one of the most widely-implemented and longest- running global health interventions. Given that DOTS will likely continue to occupy a central place in global tuberculosis control efforts in coming years[14]

The specific targets of DOTs detailed in the updated Global plan (2011-2015) are to achieve a case Detection rate (CDR) of 84 % (of all forms of TB and smear positive TB specifically) and treatment success rates (TSR) of 87% by 2015[15].

The national population based TB prevalence survey conducted in 2010/11 revealed that the prevalence of smear positive TB among adults and all age group was found to be 108 and 63 per 100,000 populations, respectively. The prevalence of bacteriologically confirmed TB was found to be 156/100,000 populations and by extrapolations, the prevalence of all forms of TB in Ethiopia is estimated to be 240/100,000 populations[6]. According to the WHO global TB report 2012 which considered the findings from the national TB prevalence survey, there were an estimated 220,000 (258 per 100,000 populations) incident cases of TB in Ethiopia in 2011. According to the same report the prevalence of TB was estimated to be 200,000 (237 per 100,000 populations). There were an estimated 15,000 deaths (18 per 100,000 populations) due to TB, excluding HIV related deaths, in Ethiopia during the same period.)[6].

1.2 Statement of the problem

The question of what DOTS has or has not accomplished over the past 15 years is a central technical question; it is also critical to global health transparency and accountability. Since 1997 WHO has evaluated the performance of DOTS in the course of specific studies as well as detailed annual reports. These publications make use of two major indicators of program performance: treatment results and percent of tuberculosis cases detected by national[14]

The problem of tuberculosis is increased by the dual epidemic of tuberculosis and HIV and the threat of MDR-TB (Multi drug resistance). Multi drug resistance TB has been documented in nearly every country in the world with nearly half a million cases each year[7].

Poor adherence contributes to development of strains of the bacterium that are resistant to treatment. Drug resistance TB is usually treatable but requires two years of treatment that is far more expensive and potentially toxic to patients[16]. Without proper health education on the risks of stopping treatment early and other motivators to encourage continued treatment, patients may stop taking drugs when they start to feel better. Unreliable drug supply, poor prescribing practices and inadequate patient management can also result inappropriate tuberculosis treatment[16, 17].

According to the anti-TB drug resistance survey conducted nationwide in 2005 (EHNRI/FMOH), among 804 newly diagnosed TB cases 1.6% were found to be infected with MDR TB. The rate of MDR TB among specimens from 76 previously treated TB cases was 11.8%. According to WHO 2012 report, there were an estimated 1700 and 550 MDR TB cases among notified new and re-treatment pulmonary TB cases in 2011, respectively in Ethiopia [6]. Patient-related factors include low economic status and lack of awareness about TB and its treatment; and Health service delivery and control program factors include ineffective communication, poor supervision of health staff and poorly accessible TB care leads to poor treatment success rate[1] .

Even where free medication is available, many patients are not successfully treated for TB[3]. Incomplete treatment may result in an extended period of infection, TB resistance to treatment and lead to increased morbidity and mortality[3].

According to the 2003 EC (2011) health and health related indicators of the FMOH, tuberculosis is the third leading cause of death in Ethiopia. During the year 2010/11 (2003 EC), a total of 159,017 TB cases were notified in Ethiopia. Among these 151,866 (95.5%) were new cases of TB, all forms. The proportion of new smear-positive, smear negative and EPTB among all new cases is 32.7%, 34.8%, and 32.5% respectively. Re-treatment cases represent about 2.9% of all TB cases notified[5].

In 2012/2013, the Annual report of North Shoa Zone, case detection rate of all forms of TB and treatment success rate were 52.7% and 84.5% respectively which was below from the WHO targets of case detection

rate (84%) and from the WHO's target treatment success rate(87%). During the same year there were 50 MDR-TB suspected cases in the Zone among them 15 cases were confirmed MDR TB cases[18].

A study done in Tigray Region Revealed that sex, residence, educational status, HIV status and distance from treatment center of patients did not show any statistically significant association with un successful treatment outcome and the risk of un successful Treatment outcome was 2.5 times higher among pulmonary tuberculosis patients older than 4o years of age compared to those aged 15-40 years[15].

Another similar study done at Gondar teaching referral hospital shows that as the age of tuberculosis patients increased death rate of patients was increased. In addition males had the trend to be more likely to experience death or default than females as an outcome [19].

Another study conducted at FelegeHiwot Hospital shows that the risk associated with unsuccessful treatment outcome for people living in rural areas could be as much as seven times higher than for urban residents[20]

Another study done in china revealed that treatment success was found to be associated with young age, lack of cavitations and compliance with treatment [21]. In most studies conducted in Ethiopia factors associated with unfavorable treatment outcome varies from area to area and contradict each other.

As the recent previous years Health management information system(HMIS) reports from Debreberhan referral hospital indicates, favorable outcomes like treatment cure rate and treatment success rates are below the WHO targets and unfavorable outcomes like death rate, defaulter rate and treatment failures are higher than expected. As a result the number of MDR suspects and MDR cases in the study area are increasing.

Therefore, the aim of current study is focusing on identifying the magnitude of unfavorable Treatment outcome and understanding unclear associated factors with unfavorable Treatment outcome of Tuberculosis patients under DOTs and assessing areas of improvements for better and effective TB control strategies. In addition to this it can have its own role in the prevention of MDR and XDR TB.

Chapter Two

1. Literature review

Effective drugs for tuberculosis have been available since the 1940s, but two million people continue to die each year, mostly in low income countries. People with tuberculosis require treatment for at least six to eight months. Many find it difficult to complete their course of treatment and this serves as a major constraint to eradicating the disease[17].Tuberculosis is a public health emergency in Africa, Eastern Europe, and Central Asia. Of the estimated 1.7 million deaths from TB, 98 percent are in the developing world, the majority being among the poor. In order to reach the MDG and the Stop TB partnership targets for 2015, TB detection rates need to double, treatment success rates must increase to more than 70-75 percent, and strategies to address HIV-associated TB and multi-drug resistant TB must be aggressively expanded. DOTS, the internationally-recommended TB control strategy are the foundation of TB control efforts worldwide. A standard recording and monitoring system built on routine service-based data allows nearly all countries in the world to track progress in case detection and treatment completion through routine monitoring. This provides a good base for measuring the impact of different strategies for improving TB control outcomes[16]

The scale of the global TB epidemic demands urgent and effective action. It is very important in tuberculosis (TB) control to detect the disease as early as possible and to ensure that those diagnosed complete their treatment and get cured. The World Health Organization (WHO) target for treatment success is 85% of all detected smear-positive cases[21]. Even where free medication is available, many patients are not successfully treated. . Main reasons for non-success are death (while on treatment or before start of treatment) and loss to follow-up. Incomplete treatment may result in prolonged excretion of bacteria that may also acquire drug resistance, cause transmission of disease and lead to increased morbidity and mortality[21].

Human immunodeficiency virus (HIV) has had a profound Impact on tuberculosis (TB), particularly in Africa. HIV is the most common risk factor in Africa for reactivation of latent TB infection, and is also strongly associated with rapid progression from infection to disease. As a result of the rising in incidence of TB in countries where both TB and HIV infection are common, TB control programs are being stretched to their limits. The World Health Organization (WHO) has advocated better supervision of therapy for TB to ensure that patients are cured. A target cure rate of 85% has been set, although it is acknowledged that the high mortality rates among Patients with HIV-related TB may make this unattainable [19, 22].

Monitoring the outcome of treatment is essential in order to evaluate the effectiveness of the intervention. Recommendations on how to evaluate treatment outcomes using standardized categories have been issued by

the World Health Organization (WHO) in conjunction with the European Region of the International Union against Tuberculosis and Lung Disease (IUATLD). WHO and IUATLD use an agreed set of six possible and mutually exclusive categories of treatment outcome in high-incidence countries. These categories are cured; treatment completed, failure, death, treatment interrupted, and transfers out. Ideally, treatment outcomes in all patients should be routinely monitored by the epidemiological surveillance system. This would make it possible to recognize and amend system failures before the incidence and proportion of resistant isolates rise[21].

Detection and treatment of all forms of TB should be integrated within national TB control programs. In the past, many public health authorities reasoned that scarce resources should be used for new patients with drug-susceptible TB because the cost of detecting and treating the disease was 10- to 100-fold lower than for MDR-TB. However, it has now proved feasible and cost-effective to treat all forms of TB, even in middle- and low-income countries. Untreated or improperly treated patients with resistant TB are a source of ongoing transmission of resistant strains, resulting in future added costs and mortality [23].

Poor treatment adherence increasing the risk of drug resistance, treatment failures, relapses, deaths and prolonged infectiousness remains a hurdle to the success of tuberculosis programmes. Countries implementing DOTS to ensure treatment adherence have shown impressive results with increasing treatment success and low default rates .The Revised National Tuberculosis Control Programmes (RNTCP) based on the internationally acclaimed DOTS strategy has made rapid strides since its implementation. The DOTS is now accessible to more than a billion people in India. The overall program performance, particularly, with regards to high cure and low default rates has been consistent after RNTCP implementation. Nonetheless, more than 30% of the states still report a cure rate of less than 85% and a default rate of more than 5%[14]. Even where free medication is available, many patients are not successfully treated for TB. Incomplete treatment may result in an extended period of infection, TB resistance to Treatment, and lead to increased morbidity and mortality[24].

World health organization and the “Stop TB” partnership recommended case detection rate of new smear-positive pulmonary TB to be at least 70% of the estimated incidence, where the case detection rate is primarily passive and should primarily be based on sputum microscopy, which is the most reliable and important one. During sputum microscopy, three sputum specimens must be collected and examined in two consecutive days (spot-early morning-spot): a first spot specimen, when the patient presents him/herself; an early morning specimen- consisting of all the sputum raised in the first 1-2 hours and a second spot specimen

when the patient returns with the early morning specimen. Similarly they recommended treatment success rate of at least 85% for newly detected smear-positive pulmonary, smear-negative and EPTB. And adequate chemotherapy requires an appropriate combination of drugs, which are prescribed in the correct dosage and taken regularly by the patient for sufficient period of time. Treatment of TB has two main phases: intensive phase and continuation phase. The intensive phase consists of treatment with combination of four drugs for the first eight weeks for new cases and with a combination of five drugs for the first eight weeks followed by four drugs for the next four weeks for re-treatment cases. It renders the patient non-infectious by rapidly reducing the load of bacilli in the sputum, usually within 2-3 weeks except in case of drug resistance. Whereas the continuation phase is the phase follows the intensive phase and is important to ensure cure or completion of treatment. It is necessary in order to prevent relapse after completion of treatment. This phase requires treatment with a combination of two drugs, to be taken for 4 months for new cases and treatment with a combination of three drugs for re-treatment cases for 5months [1, 6] . Before the implementation of DOTS, TB treatment in many resource poor settings was chaotic, non- standardized, and poorly monitored and consequently had little epidemiological impact on the incidence of TB worldwide. The introduction of the DOTS strategy has led to improvements in treatment outcomes for many patients. For many years, WHO has reported the success rate of DOTS in cohorts of patients in terms of 'Died', 'Failed', 'Defaulted', 'Transferred', and 'Not evaluated' . As at 2005, the cure rate among cases registered under DOTS worldwide was reported to average 77.6%, and a further 7.1% completed treatment (no laboratory confirmation of cure), giving a reported overall treatment success rate of 84.7%.Of the smear-positive cases estimated to have occurred in 2005, only 49% were treated successfully by DOTS programs [24].

As the study conducted in Addis Ababa patient treated under DOTs programme, socio-demographic and medical information of 6,450 registered TB patients was summarized. The mean, standard deviation and median age of the study participants were 30.13, 13.7 and 28.0 years, respectively. Out of the total study participants 46.8% were males and 77.9% were in the age group of 15-44 years. In total, 25.6% were pulmonary positives, 33.9% were pulmonary negatives and 40.5% were extra pulmonary TB patients. Majority of the study participants (88.9%) were new cases. In this study, the proportion of death from pulmonary positives, pulmonary negatives and extra pulmonary TB patients were 2.7%, 3.6%, and 4.3%, respectively. Patient age, weight at initiation of anti-TB treatment, patient category, year of enrollment and treatment center were significantly associated with time to death ($p < 0.05$). TB patients weighting more than 34 kg at initiation of anti-TB treatment were 11.5% less likely to die [AHR = 0.899 with 95%CI of 0.804 to 0.973] compared with those weighting less than 34 kg [25].

2.1 Conceptual framework

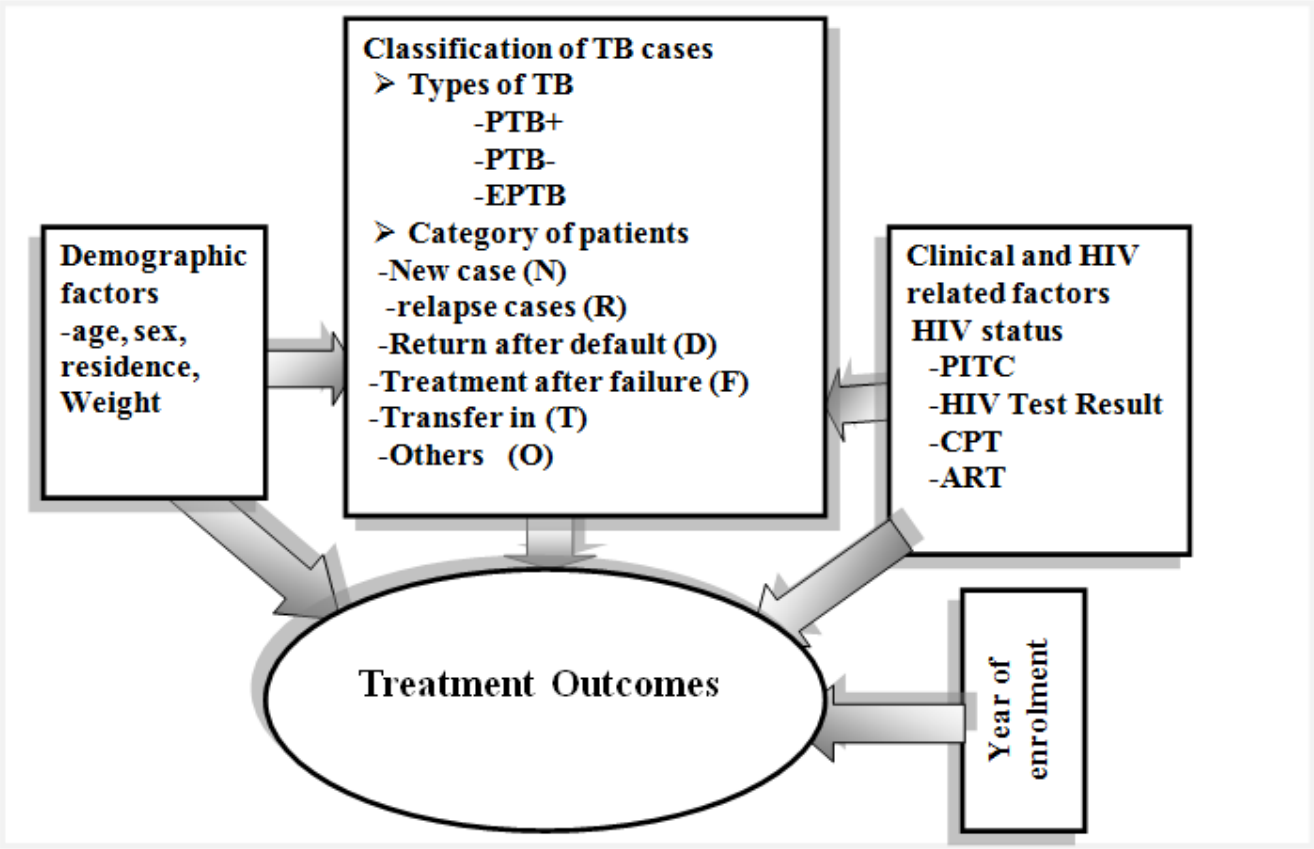

Figure 1: conceptual framework on magnitude and associated factors with treatment outcome of TB patients enrolled in dots in debreberhan hospital.(developed after reviewing literature)

2.2 Significance of the study

TB is among the leading cause of morbidity and mortality in Ethiopia. TB control program is one of the components of MDG and priority public health problem where the Government is committed to support the achievements of global targets. Although DOTs implementation has started as pilot project since 1992 and the WHO recommended DOTs strategy has been adopted in 1995 in Ethiopia, the national targets have not been achieved .Besides, there have been poor performances achieved in TB control activities in Ethiopia in general and in Amhara region, North Shoa Zone in particular..As the recent previous years Health management information system(HMIS) reports of Debreberhan referral hospital indicates, favorable outcomes like treatment cure rate and treatment success rates are below the WHO targets and unfavorable outcomes like death rate, defaulter rate and treatment failures became higher than expected. As a result the number of MDR suspects and MDR cases in the study area are increasing.

Hence, determining the magnitude and associated factors with unfavorable Treatment outcome of Tuberculosis patients and understanding the specific reasons for factors associated with treatment outcome can have significant importance in evaluating TB control and prevention activities and in identifying area of improvements for better and effective TB control strategies. In addition to this it can have its own role in the prevention of MDR and XDR TB.

As far as the investigators' knowledge little research activities on treatment outcome of tuberculosis patients have been conducted in this country but there is no research in this study area.

Therefore, the aim of current study is focusing on identifying the magnitude of unfavorable Treatment outcome and understanding unclear associated factors with unfavorable Treatment outcome of Tuberculosis patients enrolled in DOTs in the hospital and assessing areas of improvements for better and effective TB control strategies. The results may contribute for policy makers and health departments at different level to develop targeted and evidence based strategies to improve services for better favorable treatment outcome, reduce recurrence of tuberculosis, development of multi-drug resistance and extensive drug resistance form of tuberculosis and it is also serving as input for further study on this area.

Chapter Three

Objectives

1. General objective

The objective of this study is to determine magnitude and associated factors with unfavorable treatment outcome of TB patients under DOTs in Debre Berhan Referral Hospital, North Showa Zone, Ethiopia 2014

2. Specific objectives

- To assess magnitude of unfavorable treatment outcome of tuberculosis patients in Debre Berhan Referral Hospital ,2014
- To identify factors associated with unfavorable treatment outcomes of tuberculosis patients in Debre Berhan Referral Hospital ,2014

Chapter Four

Methods and materials

4.1 Study setting and study period

North Shoa is one of the eleven zones of the Amhara region with the population of 2,093,354. Debre Berhan, which is the capital city of North Shoa zone, Amhara National Regional State, is found at 130 km in the North direction of Addis Ababa, at 39°30' East longitude and 09°36' North latitude. It is one of the two city administration districts in the zone with a population of 84, 920 of which 41,187and 43,733 male and female, respectively. The town is subdivided into nine Kebeles (public administration units). There are one government referral hospital, one private hospital, two health centers, six private clinics and one clinic in Debre Berhan Prison. Among them one government referral hospital, one private hospital, two health center and one clinic in Debre Berhan Prison perform TB diagnosis, treatment and other related Activities (TB DOTs).The government hospital is Debereberhan Referral Hospital which was established during Italian invasion in 1937. Records of TB patients who have been treated from January 2009 to December 2013 were reviewed from April to May 2014.

4.2 Study design

Cross sectional study was conducted

4.3 Population

4.3.1 Source Population

All TB patients who took their anti TB treatment in DebreBerhan Referral Hospital from January 2009 to December 2013

4.3.2 Study Population

All TB patients who took their anti TB treatment from January 2009 to December 2013 and fulfills inclusion criteria in DebreBerhan Referral Hospital

4.3.3 Inclusion/exclusion criteria

4.3.3.1 Inclusion criteria

TB patients who start DOTs treatment and who have complete medical records for all selected variables in the past five years in DebreBerhan Referral Hospital

4.3.3.2 Exclusion criteria

TB patients with incomplete medical records for selected variables

4.4 Sample size and sampling procedures

4.4.1 Sample Size Determination

All TB patients who received DOTs and have complete medical records in the past five years preceding the study were included

4.4.2 Sampling techniques

The study was conducted at Debreberhan referral hospital since it is the only hospital in the town which implements DOTs programme for nearly two decades in the past. It is selected purposively to get adequate sample for optimal period of the study with better complete medical records relatively. The profiles of all TB patients enrolled in DOTS from January 2009 to December 2013 with complete records were evaluated and included in the final analysis.

4.5 Study variable

Dependent Variable:

Treatment outcome

Favorable outcome

Unfavorable outcome

Independent variables:

- Demographic (age, sex, weight, residence) variables.
- Clinical and HIV related factors

  -Provider initiated testing and counseling (PITC)

  -HIV test result

  -Status of enrollment to CPT

  - Status of enrollment to ART
- Classification of TB cases and category of TB patients

  -Type of tuberculosis (PTB+, PTB-, and EPTB)

  -category of TB patients (New, Relapse, Treatment after failure, Return after Default, Transfer out, others)
- Year of enrolment
- Smear result at diagnosis
- Follow up sputum smear result at second month
- Follow up sputum smear result at fifth month
- Follow up sputum smear result at sixth month
- Follow up sputum smear result at eight month

4.6 Data Collection Process and tool

Based on the unit TB register Checklist was designed by the principal investigator. TB patient's record review for data extraction from the registers of the TB clinic of the hospital using checklist specially designed for this study was accomplished. Data extraction containing variables like demographic, classification of TB cases, HIV related and clinical factors and treatment outcomes was undertaken by nurses working at the TB clinic of other health facility. Before conducting the data collection process, two data collectors (nurses) from other health facility DOTs clinic and one supervisor who is TB Officer in another woreda health office was recruited. Training for one day on how to collect data by using checklist and general information about the contents of the checklist was performed. Data were collected with close supervision by principal investigator and supervisor.

4.7Data processing and Analysis

After the completion of data collection, editing, coding and cleaning was carried out. Data was entered using EPi-info version 3.2.2 and exported into SPSS version 16.0 statistical software for analysis.

Bivariate logistic regression analysis was used to see significance of association between treatment outcome and independent variables. All explanatory variables that were associated with the outcome variable in binary logistic regression analysis and those with p-value < 0.25 were included in multiple logistic regression analysis. Back ward LR variable entering method was used to inter variables in multiple logistic regressions. The model fitness was checked by Hosmer and Lemeshow test and it is fitted as it is > 0.5 i.e. 0.967. P-value <0.05 was considered as a statistical significant. Odds ratios and 95% CI were computed to measure the strength of the association between the outcome and the explanatory variables. The characteristics of study participants were described in terms of mean, and standard deviation value for continuous data and percentage for categorical data.

4.8 Ethical considerations

Ethical clearance and approval was obtained from Ethical clearance board of Public Health and Medical Science College of Jimma University. Support letter was requested and obtained from Jimma University to zonal health department and support letter was also requested from zonal health department and given to Debreberhan Referral Hospital. In order to ensure confidentiality of the information, names of TB patients was not be included in the checklist.

4.9 Data quality assurance

The data was extracted from the registration book by using check list specially prepared for this study and was checked for completeness and consistency by the supervisor and principal investigator. There was a regular supervision of data collectors by the supervisors and principal investigator throughout the study period in a daily basis.

4.10 Plan for data dissemination and utilization of findings

The findings will be presented to the Jima University scientific community and will be submitted to the College of Public health and Medical sciences department of Epidemiology. The result will also be disseminated to Amhara Regional state health bureau, North shoa zone health department, Debereberan referral hospital and other health planners and relevant stakeholders at regional, zonal, and Health facility level in the area to enable them take recommendations in to consideration during their planning process. In addition to this publication in scientific journal will be attempted.

4.11 Operational definitions and definitions of terms

4.11.1 Operational definitions

1. Treatment outcome: the outcome of TB patients under treatment, which can be favorable or unfavorable Outcome

2. **Favorable outcome:** successful Treatment outcome of Tuberculosis patients who have been either completed their treatment or cured as indicated in the unit TB register

3. **Unfavorable outcome**: unsuccessful Treatment outcome of Tuberculosis patients who have been either Died, Treatment Defaulted, Treatment failure, or transfer out during treatment period as found in the unit TB register.

11.4.2 Definitions of terms

1. A Case of Tuberculosis: A patient in whom TB has been bacteriologically confirmed, or has been diagnosed by a clinician according to national guidelines.

2. Case detection rate: the percentage of TB cases detected among the total number of TB cases estimated to occur in a region/country in a year.

3. Continuation phase: the phase that immediately follows the intensive phase consisting of at least two drugs for 4-6 weeks.

4. Cured: A patient whose sputum smear or culture was positive at the beginning of the treatment but who was smear- or culture-negative in the last month of treatment and on at least one previous occasion.

5. Died: A patient who dies for any reason during the course of TB treatment.

6. Directly Observed treatment short-course: a strategy devised to help patients adhere to treatment which means health workers should watch the TB patient swallow each dose of the prescribed drugs.

7.Multi Drug resistant TB (MDR-TB): TB caused by a strain resistant to, at least, Isoniazid (H) and Rifampicin (R) at the same time.

8. ***Extensively drug resistant TB (XDR-TB):*** TB caused by a strain that is resistant to at least Rifampicin and Isoniazid (i.e. MDR-TB), plus resistance to any medicine in the fluroquinolone family (such as Ciprofloxacin, Levofloxacin, Ofloxacin, Moxifloxacin, Gatifloxacin; and also resistance to at least one of the second line inject able anti-TB drugs such as Capreomycin, Kanamycin and Amikacin.

9 **Extra-pulmonary TB (EPTB):** TB in organs other than the lungs, proven by one culture-positive specimen from an extra-pulmonary site or histo-pathological evidence from a biopsy or TB based on strong clinical evidence consistent with active EPTB and the decision by a physician to treat with a full course of anti-TB therapy.

10. Intensive phase- the phase consists of treatment with combination of four drugs for the first 8 weeks for new cases and with combination of five drugs for the first eight weeks followed by four drugs for the next four weeks for re-treatment cases.

11. New TB cases (N): patients who have never had treatment for TB or have been on anti-TB treatment for less than four weeks.

12. ***Other (O)*****:** A patient who does not fit in any of the defined categories (e.g. smear-negative PTB case who returns after loss to follow-up, EPTB case returning after loss to follow-up, previously treated TB patients with an unknown outcome of that previous treatment and who have returned to treatment with smear-negative PTB or bacteriologically negative EPTB.).

13. **Pulmonary tuberculosis (PTB): A** case of TB involving the lung parenchyma.

14. **Relapse cases (R):** patients who has been declared cured or treatment completed from any form of TB in the past but found to be AFB smear-positive or culture positive.

15. ***Return after Lost to follow up*****/*****Return after default/:*** A patient previously recorded as Lost to follow up from treatment and returns to the health facility with smear-positive sputum

16. ***Treatment after Failure (F):***
A patient who, while on treatment, is smear or culture positive at the end of the fifth month or later, after commencing.

17. Treatment completed: A patient who completed treatment without evidence of failure but who does not have a negative sputum smear or culture result in the last month of treatment and on at least one previous occasion.

18. **Treatment Defaulter:** A patient who has been on treatment for at least four weeks and whose treatment was interrupted for eight or more consecutive weeks

19. Treatment failure: A patient whose sputum smear or culture is positive at 5 months or later during treatment. Or Patients found to harbor a multidrug-resistant (MDR) strain at any point of time during the treatment, whether they are smear-negative or -positive.

20. ***Treatment success rate***: proportion of TB cases on treatment who are "cured" plus those who have "completed treatment" relative to all those smear and /or culture positive cases that started treatment during a specified time period.

21. ***Tuberculosis (TB) suspect:*** Any person who presents with symptoms and/or signs suggestive of tuberculosis, in particular cough of two weeks or more duration

22. **Transfer in**- A patient who is transferred-in to continue treatment in a given treatment unit after starting treatment in another treatment unit. The receiving treatment unit should register such patients as "*transfer in*"

23. **Transfer out:** A patient who has been transferred to another recording and reporting unit and whose treatment outcome is unknown at the original registering unit.

5.1Demographic and Clinical characteristics of study subjects

During the period considered, a total of 1830 tuberculosis patients were registered in the unit TB register. Of these, 1280 (70%) tuberculosis cases that had complete records were taken for the study in Debreberhan referral hospital between January, 2009 and December 2013. Out of the total 1280 respondents, 379(29.6%) were PTB positive, 724(56.6%) were PTB negative and 177(13.8%) were EPTB patients (Figure2). Of the total registered TB patients with complete record, 649(50.7%) were males. The mean age of the patient was 30.5 years with SD ± 15.2. About 79.9 % of the registered TB patients in this study were between ages 15-54, which are the known reproductive age groups. About seventy two percent (n=930) of the patients were urban residents. Of 1280 total TB cases 1190(93%), 33 (2.6%), 22(1.7%) and 35((2.7%) were new cases, retreatment cases, transfer in and other cases respectively. Among all TB cases 907(70.9%) were tested for HIV and one in every five of the patients (20.5%) were HIV positive of which 114 (56.5%) were females. Regarding patient category 93%, 2%, 0.2%, 0.4%, 1.7% and 2.7% were new, relapse, treatment after failure, return after default, transfer in and other cases, respectively(Table1).

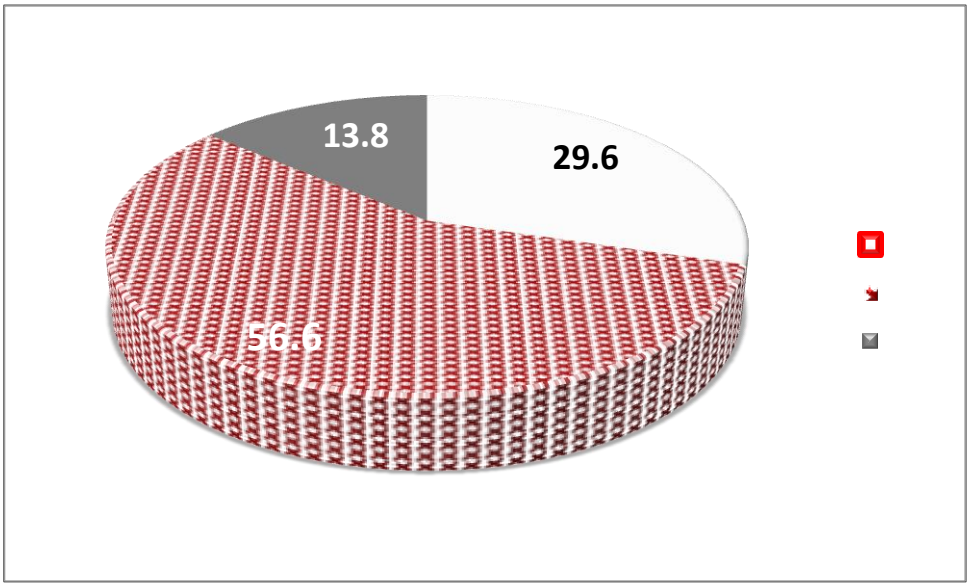

Figure 2 : Proportions of TB patients by type of TB (n=1280) in Debreberhan referral hospital, January 2009 to 2013.

Table 1: Socio-demographic and clinical Characteristics of registered TB patients (n=1280) in Debreberhan referral hospital, January 2009 to December 2013

variables		TB patients, n (%)
sex		
Male		649(50.7)
Female		631(49.3)
0-14		141(11)
15-24		351(27.4)
25-34		341(26.6)
35-44		215(16.8)
45-54		117(9.1)
55-64		68(5.3)
> 65		47(3.7)
Residence		
Urban		930(72.7)
Rural		350(27.3)
Category TB patients		
New TB cases		1190(93)
Relapse cases		26(2)
Treatment after failure		2(0.2)
Return after default		5(0.4)
Transfer in		22(1.7)
Other		35(2.7)
PITC offered		907(70.9)
Not offered		373(29.1)
HIV test result	reactive	262(20.5%)
	Non reactive	645(50.4%)
Total		1280(100)

5.2 Follow up Acid fast staining result of registered TB patients

Of the 379 pulmonary TB positive patients, 310(81.8%) had AFB staining laboratory examination at the 2nd month of treatment. From the total of 310 TB patients who had AFB staining laboratory examination at the 2nd month, 40(10.6%) was AFB positive. A little more than half (54.4%) of pulmonary TB positive patients had AFB staining laboratory examination at the 5th month of treatment and 6 (2.9%) were smear positive. At 6th month 2(1.02%) were AFB staining positive out of 197(52%) pulmonary positive TB patients and none of them were AFB staining positive out of 14 pulmonary positive TB patients at 8th month of treatment according to the recorded data in the unit TB registration in the study area.

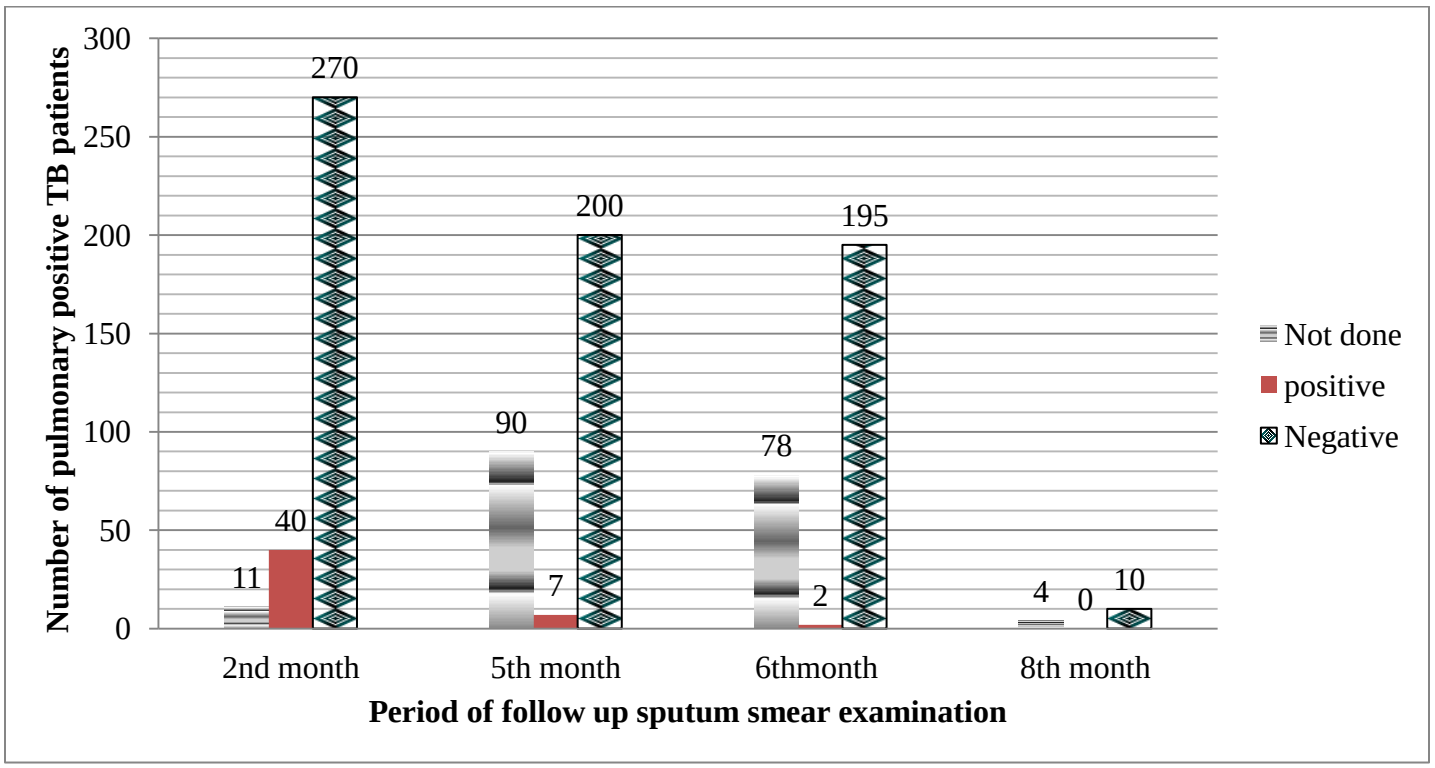

Figure 3:follow-up sputum smear microscopy for PTB+ patients (n=379) at 2nd, 5th, 6th months of treatment in Debreberhan referral hospital, January 2009 to December 2013.

5.3 Treatment Outcomes

From the total 1280 registered tuberculosis patients, 1016(79.4%) had favorable treatment outcome. Of the total favorable treatment outcomes, 203(19.98%) were cured and 813(80.02%) were treatment completed. With regard to unfavorable treatment outcome 23 (1.8%), 4(0.3%), 102(8%), 135(10.5%) were dead, treatment failure, defaulted and transfer out, respectively. Of the total 264 unfavorable treatment outcome, 138(52.3%) were male 126(67.0%) were from urban residences 70(26.5%) were pulmonary positive TB cases, 157 (59.5%) were pulmonary negative TB cases and 37(14.0 %) were extra-pulmonary TB cases. With regard to year of enrolment to anti-TB treatment, out of the total unfavorable treatment outcomes 72(27.3%), 55(20.8 %), 55(20.8%), 43(16.3%) and 39(14.8%) were in year 2009, 2010, 2011, 2012 and 2013, respectively, as obtain from the record of unit TB register of the study area.

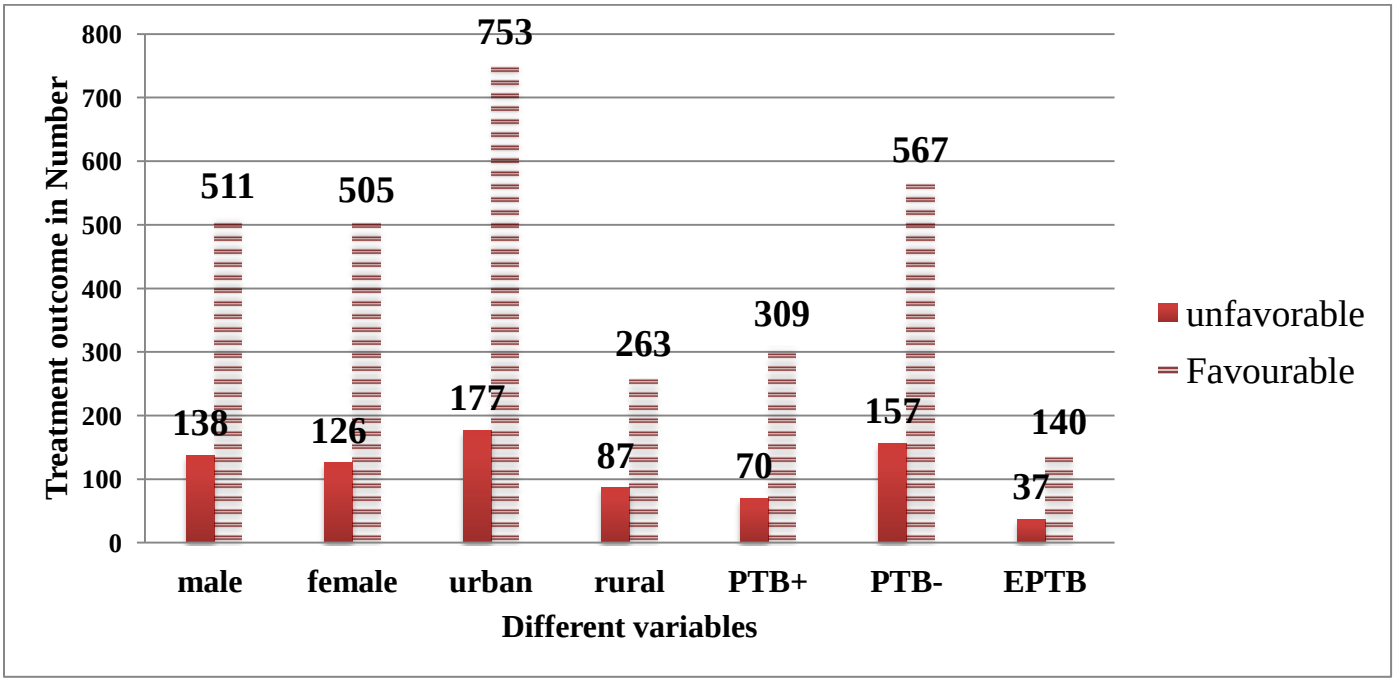

Figure 4: Favorable versus unfavorable treatment outcomes of TB patients (n=1280) in Debreberhan referral hospital January 2009 to December 2013.

Table 2: Treatment outcomes of registered TB patients (n=1280) in Debreberhan referral hospital, January 2009 to December 2013.

	Treatment outcome		
variables	Favorable outcome n (%)	Unfavorable outcome (%)	Total n (%)
sex of patients			
Male	511(39.9)	138(10.8)	649(50.7)
Female	505(39.5)	126(9.8)	631(49.3)
Residence of patients			
Urban	753(58.8)	177(13.8)	930(72.7)
Rural	263(20.5)	87(6.8)	350(27.3)
Age category			
0-14	108(8.4)	33(2.6)	141(11.0)
15-24	278(21.7)	73(5.7)	351(27.4)
25-34	277(21.6)	64(5.0)	341(26.6)
35-44	176(13.8)	39(3.0)	215(16.8)
45-54	91(7.1)	26(2.0)	117(9.1)
55-64	52(4.1)	16(1.2)	68(5.3)
> 65	34(2.7)	13(1.0)	47(3.7)
Category of patients			
New TB cases	950(74.2)	240(18.8)	1190(93.0)
Relapse Cases	22(1.7)	4(0.3)	26(2.0)
Treatment after Failure	0(0.0)	2(0.2)	2(0.2)
Return after default	3(0.2)	2(0.2)	5(0.4)
Transfer in	16(1.2)	6(0.5)	22(1.7)
Other	25(2.0)	10(0.5)	35(2.7)
type of TB			
PTB+	309(24.1)	70(5.5)	379(29.6)
PTB-	567(44.3)	157(12.3)	724(56.6)
EPTB	140(10.9)	37(2.9)	177(13.8)

When we compare the trends of treatment outcome over the years during the study period, the unfavorable treatment outcome from 2009(21.5%) to 2010(24.1%) increased, then a little bit decrement in each year's (23.6%, 18.8%,15.6%) was shown in 2o11,2012,and 2013 consecutively. But when we see the trends of favorable treatment outcome, the opposite of this was shown.

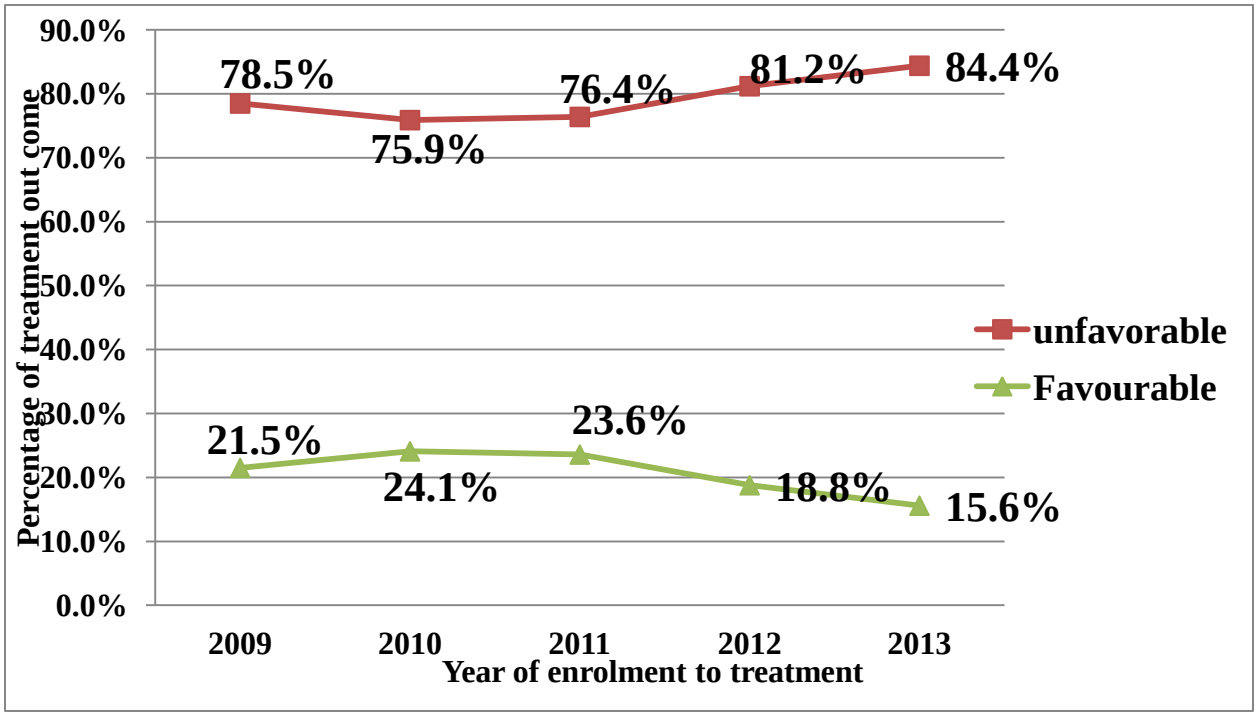

Figure 5: Trends of favorable versus unfavorable treatment outcomes of TB patients (n=1280) attending DOTs in Debreberhan referral hospital January 2009 to December 2013.

5.3.1 Factors associated with TB Treatment outcome

Bivariate logistic regression analysis showed of TB patient being rural residence were 1.4itmes (COR=1.407, 95 CI 1.050.1.885) more likely to experience unfavorable treatment outcome than urban dwellers. TB patients for those follow-up sputum smear examination at 2nd month of treatment has been done and having negative result had a 89% (AOR=0.307, 95% CI 0.195, 0.483) reduction in experiencing unfavorable treatment outcome when compared to sputum smear result positive at second month, enrollment time were associated to TB treatment outcome and TB patients enrolled in 2010 and 2011 were 1.7 times (COR=1.721, 95% CI 1.097,2.701) and 1.6 times(COR=1.676, 95% CI 1.062,2.644) more risky for unfavorable treatment outcome (Table 3)

Table 3: Binary Logistic regression analysis of factors associated with treatment outcome of TB patients in Debreberhan referral hospital, Ethiopia, January 2009 to December 2013.

		Treatment outcome	
Characteristics		unfavorable outcome	COR(95 % CI)
residence of the patient	Urban	177(13.8%)	**1.00**
	Rural	87(20.5%)	**1.407(1.050, 1.885)***
year of enrolment	2009	72(5.6%)	1.482(0.971,2.263)
	2010	55(4.3%)	**1.721(1.097, 2.701)***
	2011	52(4.1%)	**1.676(1.062.2.644)***
	2012	44(3.4%)	1.254(0.786,2.001)
	2013	41(3.2%)	1.00
Follow up sputum Smear examination at 2nd month of treatment	positive	16(1.2%)	1.00
	negative	23(1.8%)	**0.307(0.195,0.483)***
	Not done	1(0.1%)	0.733(0.157 ,3.419)
sex	Male	138(10.8%)	1.00
	Female	126(9.8%)	0.924(0.705, 1.211)
Age Group	0-14	33(2.6%)	1.00
	15-24	73(5.7%)	0.859 (0.539,1.371)
	25-34	64(5%)	0.756 (0.470 ,1.216)
	35-44	39(3%)	0.725(0.430, 1.222)
	45-54	26(2%)	0.935(0.521, 1.678)
	55 -64	16(1.2%)	1.007 (0.509,1.993)
	≥ 65	13(1.0%)	1.251(0.592,2.645)
types of TB	PTB+	70(5.5%)	1.00
	PTB-	157(12.3%)	1.222(0.893,1.673)
	EPTB	37(2.9%)	1.167(0.747, 1.822)
PITC	Offered	179(14.0%)	1.00
	Not offered	85(6.6%)	1.200(0.896,1.607)
CPT	started	41(3.2%)	1.00
	Not stared	14(1.1%)	1.693(0.887, 3.232)
HIV test result	Reactive	55(4.3%)	1.00
	Non reactive	124(9.7%)	0.806(0.591 ,1.101)

* Has significant association

5.3.2 Predictors of TB treatment outcome

Multiple logistic regression analysis for treatment outcome of TB patients revealed residence of TB patients, types of TB and examination of follow -up sputum smear microscopy at 2nd month of treatment were independent predictors of treatment outcome.

The study revealed that for TB patients of rural residence were 1.4 times (AOR =1.413, 95% CI (1.044, 1.911) more likely to experience unfavorable treatment outcome than urban dwellers. TB Patients with pulmonary TB negative and extra-pulmonary type were 70.5 % (AOR=0.295, 95% CI 0.172, 0.506) and 72% (AOR 0.282, 95% CI 0.151, 0.528) less risky for unfavorable Treatment outcomes, respectively than TB patients with Pulmonary TB positive type. TB patients for those follow-up sputum smear examination at 2nd month of treatment has been done and having negative result had a 90% (AOR=0.097 95% CI 0.050, 0.189) reduction in experiencing unfavorable treatment outcome when compared to sputum smear result positive at second month of treatment.

Table 4: Independent predictors of TB treatment outcome (n=1280) in Debreberhan referral hospital, Ethiopia, January 2009 to December 2013

variables		Treatment outcomes: Total TB patients evaluated	Unfavorable outcome	Favorable outcome	COR(95% CI)	AOR(95% CI)
patients residence	urban	930	177(13.8%)	753(58.8%)	1	1
	rural	350	87(6.8%)	263(20.5%)	1.407(1.050, 1.885)	**1.413(1.044 ,1.911)***
Types of TB	PTB+	379	70(5.5%)	309(24.1%)	1	1
	PTB-	724	157(12.3%)	567(44.3%)	1.222(0.893,1.673)	**0.295(0.172 ,0.506)***
	EPTB	177	37(2.9%)	140(10.9%)	1.167(0.747, 1.822)	**0.282 (0.151 ,0.528)***
Follow-up sputum smear exam at 2nd	Positive	40	16(1.2%)	24(1.9%)	1	1
	Negative	270	23(1.8%)	247(19.3%)	0.307(0.195,0.483)	**0.097(0.050,0.189)***
	Not done	10	1(0.1%)	9(0.7%)	0.733(0.157,3.419)	0.266(0.053,1.339)
Year of enrolment to treatment	2009	335	72(5.6%)	263(20.5%)	1.482(0.971,2.263)	0.803(0.353,1.825)
	2010	228	55(4.3%)	173(13.5%)	1.721(1.097, 2.701)	1.452(0.900,2.345)
	2011	220	52(4.1%)	168(13.1%)	1.676(1.062.2.644)	1.631(1.006,2.644)
	2012	234	44(3.4%)	190(14.8%)	1.254(0.786,2.001)	1.277(0.789,2.069)
	2013	263	41(3.2%)	222(17.3%)	1	1
PITC	offered	177	37(2.9%)	140(10.9%)	1.167(0.747, 1.822)	2.069(1.012,4.229)
	Not offered	907	179(14.0%)	728(56.9%)	1	1
HIV Test Result	Reactive	262	55(4.3%)	207(16.2%)	1	1
	Non reactive	645	124(9.7%)	521(40.7%)	0.806(0.591 ,1.101)	1.754(0.899,3.422)
CPT	Started	216	41(3.2%)	175(13.7%)	1	1
	Not started	46	14(1.1%)	32(2.5%)	1.693(0.887, 3.232)	0.903(0.614,1.329)
Age Group	0-14	141	33(2.6%)	108(8.4%)	1	1
	15-24	351	73(5.7%)	278(21.7%)	0.859(0.539,1.371)	0.905(0.552,1.485)
	25-34	341	64(5%)	277(21.6%)	0.756 (0.470 ,1.216)	0.762(0.459,1.264)
	35-44	215	39(3%)	176(13.8%)	0.725(0.430, 1.222)	0.757(0.436,1.313)
	45-54	117	26(2%)	91(7.1%)	0.935(0.521, 1.678)	1.061(0.578,1.948)
	55-64	68	16(1.2%)	52(4.1%)	1.007 (0.509,1.993)	1.047(0.515,2.130)
	≥65	47	13(1.0%)	34(2.7%)	1.251(0.592,2.645)	1.444(0.663,3.144)

*Significantly associated

Chapter six

Discussion

In this study treatment success of tuberculosis patients was 79.4%, lower than the WHO international target of 87% and similar research conducted in Addis Ababa and Tigray region, (82.7%, and 89.0%) respectively[3, 15]. But higher than previous studies conducted in some parts of Ethiopia including Southern Ethiopia (74.8 %), Gondar university teaching hospital, (29.5%) ,in Felegehiwot referral hospital (49%) [19, 20, 28]. The low treatment Success rate might be due to high transfer out (10.5%) and Defaulted (8.0%) cases. The defaulter rate in this study (8.0%) was higher than the study done in china Guangzhou (5.9%) and the average (6.2%) among the 22 high burden countries[21,29]and markedly higher than study conducted in North west Ethiopia (2.5%) [20].The reason for high defaulter rate could be low awareness of the patient about the danger of defaulting their treatment , long distance between their home and DOTs providing health facility and weak defaulter tracing mechanism. Thus, the findings of this study indicating the necessity of defaulter tracing interventions to reduce defaulter rate of tuberculosis patients in the study area. The treatment failure rate in this study was 0.4% which is varied from 0.1% in Zimbabuwe to 9.1% in the Russian Federation, with an average of 1.5% in high burden countries[28]. The study shows that prevalence rate of HIV among TB patients in the area is 20.5% which is in line with the previous study conducted in North West Ethiopia (25%) but much lower than the previous report from Gondar (52.1%)
[19,20]. In this study the number of smear negative pulmonary tuberculosis cases (50.1%-67.3%) remained highest compared to smear positive and extra- pulmonary tuberculosis cases over the years. Similarly the study done at Gondar university teaching hospital has shown continuous increase in the proportion of smear negative pulmonary tuberculosis cases from 53.9% in 2003 to 56.5% in 2008[19].This study revealed that patients of rural residence were 1.4 times (AOR =1.413, 95% CI (1.044, 1.911) more likely to experience unfavorable treatment outcome than urban dwellers which is in line with some study conducted in North west Ethiopia and Southern Ethiopia[20 , 27] , but another study in North Ethiopia showed that there was no statistical association with residence[15]. Lower favorable treatment outcome in rural patients is probably due to low awareness of the patient about TB treatment, and long distance between their home and DOTs providing health facilities and additional costs for transportation and for their living there. In agreement with the previous studies done in South Ethiopia and Addis Ababa about 79.9 % of the registered TB patients in this study were from the reproductive age groups.[3, 29].This may indicate negative impact of TB on the socio-economic condition of the society.

This study revealed that TB Patients with pulmonary TB negative and extra-pulmonary type were 70.5 % (AOR=0.295, 95% CI 0.172, 0.506) and 72% (AOR 0.282, 95% CI 0.151, 0.528) less risky for unfavorable Treatment outcomes, respectively than TB patients with Pulmonary TB positive type. This is in different with some studies done in Addis Ababa and Gondar University teaching hospital which showed no significant association with types of TB and had shown PTB- patients had significantly low treatment success rate compared to PTB+ and EPTB patients respectively [3,19].

With regard to examination of follow –up sputum smear microscopy at the second month of treatment, TB patients for those follow-up sputum smear examination at 2nd month of treatment has been done and having negative result were about 90% (AOR=0.097 95% CI 0.050, 0.189) less risky for unfavorable treatment outcome when compared to sputum smear result positive at second month of treatment. Having positive sputum smear result at second month of treatment or later is an indication of being risk for multi drug résistance TB in addition to being more risky for experiencing unfavorable treatment outcome [23]. It indicates the necessity of adequate supervision of DOTS Provision and patient follow-up.

Chapter seven

Conclusion and Recommendation

7.1 Conclusion

The treatment outcome of tuberculosis patients in Debreberhan referral hospital was assessed. As the result indicates there were high proportion of unfavorable treatment out cone (20.6%).Among these the proportion of defaulted , transfer out and died were (8.0%), (10.5%), (1.8%) respectively, which is a serious public health problem that needs to be addressed urgently. This study has identified significant predictor of tuberculosis treatment outcomes among TB patients attending DOTS services. These factors were being rural dwellers; pulmonary negative and extra-pulmonary types of TB and follow-up sputum smear microscopic examination at the second month of treatment being negative were independent predictors of treatment out come.

7.2 Recommendations

Based on the above findings the following recommendations are given to:

Zonal health department and wereda health office

- Strong supportive supervision should be strengthened
- Emphasis should be given to community TB care in order to address rural community with DOTs program and to reduce the high proportion of defaulter and transfer out rate.
- Establish a mechanism for defaulter tracing.

Hospital

- Continuous Health education should be given
- DOTs program including follow-up sputum smear microscopic examination should be run with strict follow-up and monitoring.
- Attention should be given for culture and drug sensitivity test for those TB patients with follow- up sputum smear positive result at the second month of treatment or later.

Researchers

- Further prospective study should be done to assess other factors which were not considered in this study.

Strength

- Using adequate sample size
- Use of Epi-info for data entering into SPSS to minimize error

Limitation

- Collecting data from the registration might have incomplete data
- Unable to assess some variable like educational status, marital status, income of the respondents

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Annexes

Annex 1 Check list for data collection

INTRODUCTION AND CONSENT:

Good morning/afternoon, my name is ---------- I am working as a data collector temporarily for postgraduate student of Jimma University College of Medical Science. The objective of the present study is to assess the last five years' TB Treatment outcomes and associated factors with unfavorable Treatment outcomes like Treatment failure, Treatment defaulter and transfer out of TB patients of this Hospital from the unit TB register. Patients name will not be recorded in the checklist, so confidentiality will be kept strict.

Are there any questions about what I have just explained? If questions are raised give appropriate answer ,if no ask to get the unit TB register which contain the last five years TB patents' document and continue to fill the data

Checklist prepared to assess TB treatment outcomes of TB patients and associated factors from the unit TB register

Date of Data collection from April 01 to 30/ 2013.

ID No	Unit TB No	Sex 1= M 2=F	Age in years	Residence 1= U 2=R	Weight at Diagnosis In Kg	Smear Result at diagnosis 1= Pos 2=Neg 3=not done	Category of patients 1=N 2=R 3=F 4=D 5=T 6=O	Type of TB 1=PTB+ 2=PTB- 3=EPTB	Year of enrolment	PICT 1=offered 2=not offered	HIV test result 1=R 2=NR 3=I	CPT 1=started 2=not started	ART 1=started 2=not started	smear result at 2month 1=pos. 2=Neg 3= not done	smear result at 5month 1=pos. 2=Neg 3= not done	smear result at 6month 1=pos. 2=Neg 3= not done	smear result at 8month 1=pos. 2=Neg 3= not done	Treatment outcomes 1=cured 2=completed 3=died 4=failure 5=defaulted 6=transfer out
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